DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 418

[CMS–3844–P]

RIN 0938–AH27

Medicare and Medicaid Programs: Hospice Conditions of Participation

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the existing conditions of participation that hospices must meet to participate in the Medicare and Medicaid programs. The proposed requirements focus on the care delivered to patients and their families by hospices and the outcomes of that care. The proposed requirements continue to reflect an 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 furnished through the Medicare and Medicaid programs.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on July 26, 2005.

ADDRESSES: In commenting, please refer to file code CMS–3844–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. Electronically. You may submit electronic comments to *http://www.cms.hhs.gov/regulations/ecomments* (attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).

2. By mail. You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3844–P, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Mary Rossi-Coajou, (410) 786–6051. Danielle Shearer, (410) 786–6617. Steve Miller, (410) 786–6656.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–3844–P and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Introduction

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.

Eliciting quality health care for Federal beneficiaries from CMS-certified providers and suppliers requires taking advantage of continuing advances in the health care delivery field. As a result, we are revising the Medicare hospice requirements, which are also used by Medicaid, to focus on a patient-centered, outcome-oriented process that promotes patient care foremost, rather than penalizing unproductive providers. We have developed a set of core requirements for hospice services that encompass the following: Patient rights, comprehensive assessment, and 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.

To achieve this objective, we are working to revise not only the hospice requirements but the requirements for several other major health care provider types, such as hospitals, home health agencies, and end-stage renal disease facilities, through separate rules. All of the revised requirements are directed towards improving patient outcomes of care and satisfaction.

II. Background

A. The Medicare Hospice Benefit

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 treatment for the relief of pain and other

uncomfortable symptoms through the appropriate coordination of all aspects of care needed to maximize personal comfort and relieve distress. Hospice care allows the patient to remain at home as long as possible by providing support to the patient and family, and 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), Public Law 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 are currently 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 and to promote the effective and efficient use of Medicare funds. To implement this requirement, State survey agencies conduct surveys of hospices to assess their compliance with the CoPs.

B. Why Revise the Conditions of Participation?

The hospice CoPs were originally promulgated 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.

We are proposing changes to the current CoPs based on four main considerations. First, we considered the suggestions that emerged 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 two largest changes that resulted from the Committee's recommendations are the clarification of the relationship between nursing facilities and hospices at proposed § 418.112, and the changes to the nursing services standard at proposed § 418.110(b).

Our second consideration was the Balanced Budget Act of 1997 (Pub. L. 105–33) because it made changes to the hospice statute that need to be incorporated into the CoPs.

Our third consideration was prompted by sections 408 and 946 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173). Section 408 amended the Social Security Act to permit a nurse practitioner to be deemed a patient's attending physician when the patient elects hospice care. Section 946 amended section 1861(dd), Hospice Care: Hospice Program, of the Act to permit a hospice to enter into an arrangement with another hospice to provide core hospice services, or to provide highly specialized services of a registered professional nurse, in certain circumstances.

Finally, this revision is part of a larger effort to bring about improvements in the quality of care furnished to Medicare and Medicaid beneficiaries through an outcome-oriented approach to quality of care responsibilities. The existing hospice CoPs do not contain patient-centered, outcome-oriented standards, nor do they provide for the operation of a quality assessment and performance improvement program.

Historically, we have established requirements for participation in the Medicare program that address the structure and process of health care. These early requirements are the result of professional consensus. Enforcing structure and process requirements by identifying deficient providers has not been adequate to meet the growing challenges associated with the changing hospice care environment. For example, rather than focusing on the relationship between the needs of patients and the staff available in an inpatient facility, the current regulations require that a registered nurse be present on every shift. Hospices often contract with local nursing facilities to provide inpatient respite care, and these facilities are only required to have a registered nurse on duty for a single eight hour shift each day. A hospice would have to supplement the nursing facility's staff with its own, at a significant cost to the hospice, even if the needs and acuity of the patient do not require a registered nurse. A hospice that did not supplement the facility's staff could be cited for not meeting the requirements, even though the requirements had no relevance to the needs of the patient. Thus, revisions to the hospice CoPs are essential.

C. Transforming the Hospice Conditions of Participation

Before developing these proposed CoPs for hospices, we 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 these suggestions, we have 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.
- Use performance measurement systems to evaluate and improve care.

Based on these principles, we are proposing to set forth four core conditions of participation: Patient Rights, Patient/Family Assessment, Interdisciplinary Care Planning and Coordination of Services, and Quality Assessment and Performance Improvement.

- The Patient Rights CoP emphasizes a hospice's responsibility to respect and promote the rights of each hospice patient.
- The comprehensive Patient/Family Assessment CoP reflects the critical nature of a comprehensive assessment in determining appropriate treatments and accomplishing desired health outcomes.
- The Care Planning and Coordination of Services CoP incorporates the interdisciplinary team approach to providing hospice care.
- The Quality Assessment and Performance Improvement CoP charges each hospice with the responsibility for carrying out a performance effort to effect continuing improvement in the

quality of care it furnishes to its patients and their families.

The last three requirements establish a cycle of individual care and hospice-wide performance improvement. First, the patient's needs are comprehensively assessed and outcome measure data are collected. Second, the interdisciplinary group, in consultation with the patient's attending physician, establishes a plan of care to address those needs. Third, the plan of care is implemented and the results of the care are evaluated through updates of the comprehensive assessment and plan of care. Fourth, the outcome measure data collected during the initial and updated comprehensive assessments are analyzed to identify practices that lead to positive outcomes as well as opportunities for improvement. Finally, the hospice uses the results of such analyses to implement performance improvement activities. These activities will influence the establishment of plans of care and their implementation, thus creating a continuous cycle of individual care and an ongoing effort to improve the hospice's performance related to identified outcomes of care for all patients.

This cycle of care adapts to changing standards of practice while addressing issues that surveyors have identified. Below is a list of the most cited deficiencies found by surveyors (year ending September 3, 2002):

1. Plan of care was not complete.
2. No written plan was established.
3. Plan was not reviewed at specific intervals.
4. Plan did not include an assessment of needs.
5. Plan was not established before providing care.
6. RN supervisory visits were not made for home health aide services.
7. No plan of care was included for bereavement services.
8. Hospice did not conduct a self-assessment of quality and care provided.
9. Clinical record was not maintained for every patient.
10. Interdisciplinary group did not review and update the plan of care for each patient.

We note that 8 of the 10 top deficiencies are related to plan of care, assessment, and quality assurance. Based on industry comments and our own surveys, we believe that the current plan of care condition contained in § 418.58 must be strengthened. We did this by creating a separate condition for the assessment of individual needs and for the time frames related to that assessment. We also revised the quality assurance requirement and strengthened the plan of care requirement.

These requirements would focus provider and surveyor efforts on the actual care delivered to the patient, the performance of the hospice as an organization, and the impact of the medical, physical, social, emotional, and spiritual care delivered to the patient.

We are proposing to retain some of the current process-oriented requirements when they are likely to produce desirable outcomes and/or prevent harmful outcomes. These proposed CoPs invest in hospices the responsibility for improving patient care performance, rather than relying on an externally based approach where prescriptive requirements are enforced through the punitive aspects of the survey process.

This change signals an opportunity for CMS, hospices, and States to join in a partnership for improvement. When implemented, hospice programming will reflect a patient-centered, outcome-oriented approach that will likely alter the manner in which CMS and States manage the survey process. We believe that this approach will provide opportunities for improvement in patient care that have been lacking in the past. The addition of a strong quality assessment and performance improvement requirement will stimulate the hospice to continuously monitor its performance and find opportunities for improvement.

D. Development of Outcome-Based Performance Measures for Hospices

[If you choose to comment on issues in this section, please include the caption ''OUTCOME-BASED PERFORMANCE MEASURES'' at the beginning of your comments.]

We are proposing to require that hospices implement an outcome-based internal performance improvement program that can be used to measure individual patient outcomes. The information a hospice gleans from its own data analysis will serve as a baseline for hospice quality improvement. Measures quantify quality and are tools for the hospice to use in assessing and improving patient care, outcomes, and satisfaction. An outcome based performance program can help hospices improve the effectiveness and efficiency of their services, improve the outcomes of care they provide, and increase patient satisfaction with their services.

Hospice outcome measures, data elements, tools, and instructions for using them have already been developed by the industry. A Task Force initiative was sponsored and convened by the National Hospice Work Group (NHWG) and the National Hospice and Palliative Care Organization (NHPCO) in 1999. We participated in the development of the measures and provided technical assistance for pilot testing of the measures. The Task Force was invited to present the results of the measurement development work and results of the pilot studies to us in November 2000.

The work of the Task Force resulted in four measures for the outcome domains of self-determination, comfort, safety, and effective grieving. The hospice industry rapidly moved to include these four measures in the data set that they encourage member hospices to use and report. The data elements and instructions for using the measures are publicly available on the NHPCO Web site at *http://www.nhpco.org.*

These outcome-based measures are part of a national reporting process created by the hospice industry. If a hospice chooses to participate in the NHCPO process, it submits its data to the NHPCO (or its contractor). Reports are then generated for a hospice to compare its performance with other hospices. The hospice may also choose to send additional information for the NHPCO reporting process in the areas of pertinent utilization data, appropriateness and effectiveness of services, and patient/family satisfaction. All hospices that participate in the NHPCO reporting process must comply with regulations mandated by the Health Insurance Portability and Accountability Act of 1996 (Pub.L. 104–191, ''HIPAA''). Regulations implementing HIPAA were published on December 28, 2000 (65 FR 82462) and were amended on August 14, 2002 (67 FR 53182).

We are not proposing to require that hospices participate in the NHPCO process described above, but hospices may choose to use some of the measures the NHPCO is already using as part of its comprehensive assessment of the patient, and as part of the organization's quality assessment and performance improvement program. Hospices may also develop their own data elements and measurement processes. Participating in the NHPCO outcome measurement and reporting process would assist hospices in meeting the requirements of proposed § 418.54(e). At this time, we are neither proposing that hospices use any particular measures of outcomes, nor that they report data to us. However, we may consider doing so in the future.

We invite comments from the public on this aspect of the proposed rule.

III. Provisions of the Proposed Regulations

A. Overview

Under our proposal, the hospice conditions of participation would continue to be set forth in regulations under 42 CFR part 418. However, since many of the existing requirements in part 418 would be revised, consolidated with other requirements, or eliminated, we are proposing changes to the existing organizational scheme. A significant change would be to group all CoPs directly related to patient care and place them together in a separate subpart. CoPs concerning hospice organization and administration would be contained in another subpart. We believe that this proposed organization better reflects a patient/family-centered orientation and helps illustrate that patient assessment, care planning, and quality assessment and improvement efforts are central to the delivery of high quality care.

B. Subpart A, General Provisions

The revised conditions would begin with existing § 418.2 that specifies the statutory authority and scope of the part for the ensuing regulations. Section 418.1 would remain unchanged.

1. Scope of the Part (Proposed § 418.2)

Section 418.2 would be revised to reflect the reorganization of the part and to include an introductory statement describing the purpose of the part.

2. Definitions (Proposed § 418.3)

Existing § 418.3 sets forth definitions for terms used in the hospice CoPs. This section is being revised in order to provide further clarification. We are proposing to move existing definitions of ''physician'' and ''social worker'' to proposed § 418.114, personnel requirements. We believe these definitions better fit in this new condition. We propose to include the following definitions:

- Attending physician (revised)
- Bereavement counseling (revised)
- Cap Period (same)
- Clinical note (new)
- Drug restraint (new)
- Employee (revised)
- Hospice (revised)
- Hospice care (new)
- Licensed professional (new)
- Palliative care (new)
- Physical restraint (new)
- Progress note (new)
- Representative (revised)
- Restraint (new)
- Satellite location (new)
- Seclusion (new)
- Terminally ill (revised)

These definitions would be revised to read as follows:

Attending physician means a—

(a)(1) Doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs that function or action; or (2) Nurse practitioner who meets the training, education and experience requirements as the Secretary may prescribe; and

(b) Is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care.

Here after, except as indicated, the term ''attending physician'' includes nurse practitioners.

We modified this definition to address changes made to the Act by Congress in section 408 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) (''MMA''). Nurse practitioners are often the primary medical health care professionals for some patients, particularly those residing in rural areas. For example, a nurse practitioner that works in conjunction with a doctor may be the health care professional a patient sees most often. The patient would develop a relationship with the nurse practitioner, and would like the nurse practitioner to continue to be involved in his or her care once he or she elects the hospice benefit. Under the current regulations, this is not allowed. Under the proposed regulations, we would permit a nurse practitioner to continue serving his or her patient as that patient's attending physician once that patient elects to receive hospice care. We believe that this would ensure the continuity of care and improve the quality of care because the health care professional most familiar with the patient, his or her conditions, and his or her personal situation would be involved in developing the plan of care and in making other important decisions.

Within the provisions of section 408 of the MMA nurse practitioners are prohibited from certifying or recertifying a patient's terminal illness. CMS will publish additional information regarding section 408 in a forthcoming **Federal Register** document.

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

Cap period means the 12-month period ending October 31 used in the application of the cap on overall hospice reimbursement as specified in § 418.309.

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

Drug restraint means a medication used to control behavior or to restrict the patient's freedom of movement which is not a standard treatment for a patient's medical or psychiatric condition.

Employee means a person who works for the hospice and for whom the hospice is required to issue a W–2 form on his or her behalf, or if the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is appropriately trained and assigned to the hospice or is a volunteer under the jurisdiction of the hospice.

Hospice means a public agency or private organization or subdivision of either of these that is primarily engaged in providing hospice care as defined in this section.

Hospice care means a comprehensive set of services described in 1861(dd)(1) of the Act, identified and coordinated by an interdisciplinary team to provide for the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care.

Licensed professional means a licensed person sanctioned by the State in which services are delivered, furnishing services such as skilled nursing care, physical therapy, speech-language pathology, occupational therapy, and medical social services.

Palliative care means patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice.

Physical restraint means any manual method or physical or mechanical device, material, or equipment attached to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.

Progress note means a written notation, dated and signed by any person providing services, that summarizes facts about the care furnished and the patient's response during a given period of time.

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

Restraint means either a physical restraint or a drug used as a restraint.

Satellite location means a Medicare-approved location from which the hospice provides hospice care and services within a portion of the total geographic area served by the hospice provider issued the provider agreement number. The satellite location is part of the hospice and shares administration, supervision, and services in a manner that renders it unnecessary for the satellite location to independently meet the conditions of participation as a hospice.

We are proposing to add this definition to recognize long-standing Medicare survey and certification policies, which allow for the operation of multiple locations by a single hospice provider. We are proposing that a hospice satellite location be approved by CMS before it begins to furnish service to patients. In the past, some hospices were found to be furnishing services from locations that had not been shown to be in compliance with applicable regulations. We envision the approval process to be consistent with determining that patients receive safe services from the satellite location in question. As is done for other appropriate providers and suppliers, we are accepting comment on applying the Medicare Appeals Procedures that affect participation in the Medicare program (42 CFR 498.3). If a hospice, including any or all satellite locations, is accredited by an accrediting organization such as JCAHO or CHAP, the hospice and each satellite location must still receive Medicare approval.

Seclusion means the confinement of a person in a room or an area where a person is isolated and physically prevented from leaving.

Terminally ill means that a patient has a medical prognosis that his or her life expectancy is six months or less if the illness runs its normal course.

C. Subpart B, Eligibility, Election and Duration of Benefits

Subpart B concerns eligibility, election, and duration of hospice benefits. We are not proposing changes to this subpart at this time.

D. Subpart C, Conditions of Participation—Patient Care

1. Patient's Rights, Condition of Participation (Proposed § 418.52)

[If you choose to comment on issues in this section, please include the caption ''PATIENTS RIGHTS'' at the beginning of your comments.]

This section would replace the current condition of participation, Informed consent, laid out at § 418.62. This condition would set forth certain rights to which hospice patients would be entitled, and would require that hospices inform each patient of these rights and that hospice personnel ensure and support these rights. Among these rights would be the following, laid out at proposed § 418.52: Being informed in advance regarding the care to be provided; having an opportunity to participate in care planning; voicing grievances; being assured of confidentiality of records; having personal property respected; being informed whether services are covered or not covered, and having information provided in writing. We are proposing to specify that the patient must also be informed about factors that affect palliation and comfort. We believe that these revisions would act as an additional safeguard of patient health and safety. Open communication between hospice staff and the patient, and patient access to palliative information is vital to enhancing the patient's participation in his or her coordinated care planning. All hospices must also comply 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 contained in 45 CFR parts 160 and 164.

We are specifically soliciting public comment on this proposed condition of participation.

2. The Cycle of Care: Assessment, Planning, and Delivery (Proposed § 418.54 Through § 418.62)

The patient care assessment, planning, and palliative care process represented by the next four CoPs (§ 418.54 through § 418.62) can be seen as a cycle. Through the use of a comprehensive assessment, accurate and timely patient information is made available for use in the patient care process. The palliative care process consists of all hospice care and services furnished to the patient and family. The patient palliative care process results in an effect on the patient's condition, whether it is positive or negative. The assessment of the effectiveness of palliative care then results in subsequent care decisions, and the cycle begins anew. Through this cycle, accurate patient and family information obtained from each comprehensive assessment should yield effective and appropriate palliative care decisions, thus generating a positive effect on patient care and desired outcomes.

Condition of Participation: Comprehensive Assessment of the Patient (Proposed § 418.54)

The proposed comprehensive assessment requirement reflects our view that a patient-centered, interdisciplinary, and systematic patient assessment is essential to improving patient quality of care and patient outcomes.

In hospice care, the comprehensive assessment of the patient contributes to quality of care improvements in closely linked stages. First, the information generated from an interdisciplinary comprehensive assessment is a vital tool for developing a hospice patient's plan of care that will guide decisions on how best to determine the individual care and support needs of the patient. Second, based on updates of the comprehensive assessment, a hospice is able to track the patient's progress towards achieving the desired care outcomes, and where this does not occur, make appropriate changes to the patient's plan of care. Finally, the hospice is able to evaluate the results of its care decisions, thus yielding information to help form the hospice's future care planning process. We believe this approach reflects contemporary standard practice for many hospices, and we are proposing to revise the CoPs to support this outcome-oriented approach.

The centerpiece of this outcome-oriented approach is that each patient receives a patient-specific comprehensive assessment that identifies the patient's need for medical, nursing, psychosocial, emotional and spiritual care. The care needs identified in the assessment would include, but not be limited to, those necessary for palliation and management of the terminal illness and related medical conditions. The comprehensive assessment would be completed by the interdisciplinary group in consultation with the individual's attending physician to ensure that each member of the interdisciplinary group provided input within the scope of that individual's practice. We believe that the patient-specific comprehensive assessment requirement we are proposing is already recognized and practiced by the hospice industry in general.

The existing CoPs contain few requirements that address the need for patient assessment; therefore, we are emphasizing the importance of the comprehensive assessment by establishing it as a separate CoP. In hospice surveys nationwide, we have identified a pattern of healthcare related deficiencies that indicate that the current assessment requirements are not sufficient. The fourth most frequently cited deficiency is that the plan of care did not include an assessment of the patient's needs. The frequency with which this area is cited indicates that there are a significant number of hospices that are not doing enough to properly assess their patients.

The expanded assessment condition would guide these deficient hospices in thoroughly assessing their patients by identifying the general areas that should be included in each assessment and by identifying time frames for the completion of assessments. We believe that this proposed CoP would enable hospices to specifically identify patient care needs. Once a hospice has completed a timely and thorough assessment of the patient, it can develop an accurate plan of care that reflects the needs identified during the assessment. The accuracy and timeliness of the plan of care may lead to an improvement in the quality of the hospice experience for the patient and his or her family.

In addition, we believe that the broad assessment outline we are proposing will encourage hospices to exercise flexibility in determining how best to achieve positive outcomes. We believe that this approach is consistent with currently accepted practices in hospices.

In § 418.54(a), Initial assessment, we are proposing that a registered nurse make the initial assessment visit to determine the patient's immediate care and support needs within 24 hours after the hospice receives a physician's admission order for care (unless another date is specified by the physician). We realize that some hospices meet with patients and their families, at their request, before the actual admission for care orders are received, and this regulation would not prevent this practice. However, meeting with a patient and his or her family before the patient's physician orders hospice care would not satisfy the initial assessment requirement.

In § 418.54(b), Time frame for completion of the comprehensive assessment, we are proposing that the hospice interdisciplinary group, in consultation with the hospice medical director or physician designee and/or the individual's attending physician, complete the comprehensive assessment in a timely manner consistent with the patient's immediate needs, but no later than 4 calendar days after the patient elects the hospice benefit. We believe that most hospices already complete the assessment within this time frame and, due to the decreased length of stay, as explained in the discussion of § 418.54(d), Update of the comprehensive assessment, and the potential severity of the patient's condition, we believe it is essential to ensure that patients are assessed in a timely manner.

Section § 418.54(c), Content of the comprehensive assessment, would describe the requirements for the content of the comprehensive assessment that we believe are critical to quality hospice care. These content requirements are at the core of hospice care and are needed to evaluate the patient's need for physical, social, emotional, medical, and spiritual care.

Under proposed § 418.54(c)(3)(ii), Drug therapy, the patient's comprehensive assessment would have to'include a review of the patient's current medication. The review and accompanying documentation would include identification of the following items:

- Ineffective drug therapy;
- Unwanted side and toxic effects; and
- Drug interactions.

This review must be repeated as necessary to ensure that the patient continues to receive drug therapy that is effective and appropriate for his or her needs. A review of a patient's drugs would be included in the initial assessment and in the development of the plan of care. This review could occur at any time, but specifically when a patient is prescribed or begins to take any new drug and/or when use of a drug is discontinued.

In § 418.54(d), Update of the comprehensive assessment, we are proposing that the comprehensive assessment be updated by the interdisciplinary group as frequently as the patient's condition requires, but no less frequently than every 14 days. We believe that these frequent reviews are necessary and predictive of quality outcomes for two reasons:

(1) In the terminal stages of care, patient status needs, circumstances, and family expectations can change greatly, affecting the type and frequency of services that should be furnished. Reassessments assist the hospice in developing a more responsive care plan. The interdisciplinary group would use assessment information to guide necessary reviews and/or changes to the patient's plan of care.

(2) We are proposing that a hospice medical director or physician designee be required to recertify a patient for hospice care at specific intervals as stated in § 418.21. We believe recertification, which occurs at the end of the initial and subsequent 90-day benefit periods (and at the end of the remaining benefit periods as described in § 418.21), serves as a logical point for updating an assessment in addition to the minimum 14 days and when the patient's condition changes.

We believe that to ensure quality and timely care for our hospice beneficiaries, timely completion of the initial assessment requirement and the comprehensive assessment update requirement is necessary. In 2001 the average length of enrollment in hospice care was 51 days (2002 Nov. Medicare National Summary for HHA, Hospice, SNF, and outpatient CY 1999–2001, *http://www.cms.hhs.gov/statistics/feeforservice/National Summary.pdf).* According to research by the NHPCO, in 2000 the average length of enrollment in hospice care was 48 days (2000 NHPCO National Data Set Summary Report, 2001 Nov.). There has been some concern regarding short lengths of stay. Hospices have been admitting patients late in their terminal illness and those patients need extensive hospice services and resources initially, and right before death. In order to ensure that patients receive the necessary services and thus begin to benefit from hospice care at the earliest time possible, we believe that it is important that the comprehensive patient assessment be completed within the time frame that we have proposed. A delay in completing the initial comprehensive assessment and the updated assessments is ultimately not as beneficial to the patient and family as if the patient had entered hospice care and received timely assessments to determine the proper care to be provided.

These requirements, though process-oriented in part, are predictive of good patient care and safety. Our rationale for requiring the completion of the initial comprehensive assessment is that a new patient being referred to a hospice for initiation of services is at a point of immediate need and often in crisis. Likewise, maintaining an ineffective plan of care could jeopardize patient health and safety. Regular assessment updates would minimize this possibility.

We believe that the comprehensive assessment requirements pose little or no burden for hospices because it is a current standard of practice to

comprehensively assess hospice patients. However, we recognize that the proposed 4-day timeframe for completing the initial comprehensive assessment as proposed in § 418.54(b) and 14-day timeframe for updating the comprehensive assessment as proposed in § 418.54(d) may set higher performance expectations for some hospices then the self-imposed standards they currently utilize. We believe that if a hospice recognizes that it is not capable of furnishing services within these timeframes, new patients should not be accepted for care.

We welcome public comments on the review of our proposed timeframes for the initial comprehensive assessment and updated comprehensive assessment. We believe the timeframes are reasonable and consistent with current hospice practice.

[If you choose to comment on issues in this section, please include the caption ''ASSESSMENT TIME FRAMES'' at the beginning of your comments.]

Under the proposed § 418.54(e), Patient outcome measures, we are proposing that a patient's comprehensive assessment include measurement and documentation of aspects of care that are essential outcomes of optimal hospice care. Documentation is carried out in the same way for all patients through what we refer to as data elements. The hospice may develop its own data elements or use existing, externally developed data elements. However, some of the data elements should be related to the domains of self-determination, comfort, safety, and effective grieving related to bereavement services. If a hospice chooses to collect information for the data elements developed by the NHPCO, it may also choose to submit this information to the NHCPO. However, submission must be in accordance with the HIPAA privacy rule (45 CFR Parts 160 and 164). The hospice may also choose to send additional information for the NHPCO reporting process in the areas of pertinent utilization data, appropriateness and effectiveness of services, and patient/family satisfaction.

The data elements used by the hospice must be an integral part of both the initial comprehensive and updated assessments. The application of these data elements to the identified domains must be documented in a systematic and retrievable way for each patient, as the outcome measurements will be used in patient care planning and coordinating services. Measurements will also be used (in the aggregate) for the hospice quality assessment and performance improvement program.

We want to emphasize that we are not proposing that hospices use any specific data elements to measure domain outcomes. We are simply proposing that hospices collect the data necessary to evaluate the quality of care they are providing and use this information in a systematic and retrievable way. Hospices may develop their own data elements related to the aspects of care related to hospice and palliation, such as self-determination, comfort, safety, and effective grieving, or may use the data elements related to the seven outcome measures in the NHPCO data set *(http://www.nhpco.org)*.

Currently, there is insufficient evidence for a valid and reliable common set of measures (that is, data elements) for use in hospice care. We are aware that the industry is studying this area. We also know that there are many measures that are currently used to help gauge the processes of care for hospice patients and to make adjustments to care on their basis. For example, there are multiple scales for use in pain management, anxiety, and depression, and there are several quality-of-life scales appearing in the relevant literature *(http://www.nhpco.org* and *http://www.chcr.brown.edu/pcoc/toolkit.htm)*. Some measurable outcomes can be captured in single items while others require multiple items to capture the full range of measurement issues.

We welcome comments on our ''outcome measures'' approach to this proposed regulation. We are particularly interested in comments as to whether this approach is necessary in assessment, care planning, service delivery, and most importantly, to the hospice's quality assessment and performance improvement program.

[If you choose to comment on issues in this section, please include the caption ''OUTCOME MEASURES'' at the beginning of your comments.]

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

[If you choose to comment on issues in this section, please include the caption ''PLAN OF CARE'' or ''COORDINATION OF SERVICES'' where appropriate, at the beginning of your comments.]

The existing condition of participation concerning the plan of care is set forth at § 418.58. We are proposing to revise the contents of this section and place them in a new condition, ''Interdisciplinary group care planning and coordination of services'' (proposed § 418.56). The proposed condition would contain five standards that reflect the interdisciplinary approach to hospice care delivery.

As proposed, each patient and family would have a written plan of care developed by the hospice interdisciplinary group in consultation with the patient's attending physician that specifies the hospice care and services necessary to meet the patient/family-specific needs identified in the comprehensive and updated assessments. All hospice services furnished to patients and their families must follow this written plan of care.

Under proposed § 418.56(a), Approach to service delivery, we are proposing that the hospice 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. We believe that the role of the interdisciplinary group is paramount in directing and monitoring the patient care and is one of the factors that makes the hospice benefit unique. The hospice would designate a qualified health care professional who is a member of the interdisciplinary group to provide program coordination, ensure the continuous assessment of each patient's and family's needs, and ensure the implementation and revision of the plan of care.

The proposed standard at § 418.56(b), Plan of care, is the same as the existing standard at § 418.58(a), with one addition. We are including a reference to the patient's family when establishing the plan of care. We would require that all hospice services furnished to patients and their families follow a written plan of care established by the hospice interdisciplinary group in collaboration with the attending physician. Family plays an important role in the care of a hospice patient, and this change reflects that role.

Under the proposed standard at § 418.56(c), Content of the plan of care, we would require that each patient's plan of care reflect interventions for problems identified in the comprehensive and updated assessments. This requirement ensures that care and services are appropriate to the level of each patient's and family's specific needs. The plan of care must include the following:

- Interventions to facilitate the management of pain and symptoms;
- A detailed statement of the scope and frequency of services required to meet the patient's and family's specific needs;

- Measurable outcomes anticipated from implementing and coordinating the plan of care;
- Drugs and treatment necessary to meet the needs of the patient;
- Medical supplies and appliances required to meet the needs of the patient; and
- The interdisciplinary group's documentation in the clinical record indicating the patient's and family's understanding, involvement, and agreement with the plan.

As we noted in the description of the previous standard, we are proposing to add a requirement that the plan address the patient's and family's expectations, understanding, agreement, and ability to participate in the care as the patient and family desire. Since family members need to understand the importance of their role in care of the hospice patient, their input and agreement regarding care is essential in developing a productive relationship with the hospice. We would expect a hospice to document the patient's and family's understanding of and agreement to the plan of care in accordance with its own policies. This could include an attestation signed by the patient and family, a note in the clinical record, and/or another form of documentation decided upon by the hospice governing body.

Proposed standard § 418.56(d), Review of the plan of care, would require that a revised plan of care include current information from the patient's updated comprehensive assessment and information concerning the patient's progress toward achieving outcomes specified in the plan of care. The plan of care must be reviewed at intervals specified in the plan but no less frequently than every 14 calendar days. We believe that it is essential to include the requirement that actual care provided also be changed as needed, thus establishing the essential linkage between assessment information, evaluation of treatment results, and plan of care modification.

We also propose to require that the hospice take steps to involve the patient's attending physician in the review of the patient's plan of care. The attending physician often has had a lengthy relationship with the patient; and his or her input into the review of the plan of care can be invaluable. We do not have the authority in the Conditions of Participation governing hospices to require that an attending physician, an individual who is not an employee of the hospice and thus not governed by these hospice regulations, participate in this process. However, we can and are proposing that the hospice collaborate with the patient's attending physician to the extent possible when reviewing the plan of care. We believe that requiring hospices to involve interested attending physicians will benefit patients by helping to ensure that the care described in the plan of care reflects the needs and desires of patients and their families.

We are proposing to add a new standard, Coordination of services, at § 418.56(e). This standard would require that the hospice maintain a system of communication and integration to enable the interdisciplinary group to ensure the overall provision of care and the efficient implementation of the day-to-day policies. These new standards would also make it easier for the hospice to ensure that the care and services are provided in accordance with the plan of care, and that all care and services provided are based on the comprehensive and updated assessments of the patient's and family's needs. An effective communication system would also enable the hospice to ensure 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.

We believe that this standard is appropriate for two reasons. First, a hospice patient typically encounters many services delivered at different times by a variety of individuals with different skills. An efficient method of communication and integration of observations among members of the interdisciplinary group and others providing care is essential to meet and respond to the patient's and family's needs in a timely manner. Second, effective communication and coordination of services will assist a hospice in avoiding a duplication of effort or a furnishing of conflicting services.

We recognize the value of an interdisciplinary approach to the delivery of hospice services. This approach to care reflects actual industry practice, and as a result, we believe the proposed requirement is in step with the hospice industry.

We are specifically soliciting public comment on the proposed requirements for the content of the plan of care, the time frames for review of the plan of care, and the new coordination of services standard.

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

[If you choose to comments on issues in this section, please include the caption ''QAPI'' at the beginning of your comments.]

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 surveyors nationwide. According to the hospice industry associations, hospices are no longer using the quality assurance model. 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 pre-emptive plan that continuously addresses quality assessment and performance improvement (QAPI). Hospice industry associations have indicated that their upgraded QAPI systems are incompatible with the existing quality assurance condition. Therefore, the providers who have moved beyond quality assurance in order to make meaningful and sustained quality improvements in their own programs are actually in violation of the outdated quality assurance condition.

On the other end of the spectrum are providers who are truly deficient because they do not have any quality program. These providers would find more guidance in the proposed regulation. In the following section of this preamble we will discuss two publicly available resources for data measures, an integral part of the proposed QAPI requirement. In the proposed regulation we have outlined when those should be collected and what role they play in the proposed QAPI condition. In addition, we have described the scope of the proposed QAPI program requirement, the guidelines for identifying performance improvement activities, and the individuals responsible for ensuring that a hospice has a QAPI program. The proposed regulations provide hospices that are unsure of what is expected of them with the guidelines to begin tailoring a QAPI program that meets their needs and circumstances.

Therefore, we believe that this proposed condition will reduce the number of deficient providers by recognizing those who are practicing QAPI and guiding reluctant providers to meet current standards of practice. The proposed QAPI requirement would raise the performance expectations for hospices seeking entrance into the Medicare program, as well the expectations of those currently participating in Medicare. We are proposing that each hospice 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 is that the hospice will 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, the 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.

This proposed condition requires the hospice to develop, implement, and maintain an effective data driven quality assessment and performance improvement program (QAPI). The program establishes a planned approach to quality improvement and takes into account the complexity of the hospice's organization and services, including those provided directly or under arrangement. The hospice must take whatever actions are necessary to implement improvements in its performance as identified by its quality assessment and performance improvement program. The hospice is also responsible for ensuring that the professional services it offers are carried out within current clinical practice guidelines as well as professional practice standards applicable to hospice care.

In the first proposed standard under this condition at § 418.58(a), Standard: Program scope, we are proposing that the hospice's quality assessment and performance improvement program must include, but not be limited to, an ongoing program that is able to show measurable improvement in indicators that are linked to improving palliative outcomes and end-of-life support services. We expect that a hospice will use standards of care and the findings made available in current literature to select indicators to monitor its program. The hospice must 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, are occurrences that are harmful or contrary to the targeted patient outcomes.

The second proposed standard under § 418.58(b) Program data, would require the hospice program to incorporate quality indicator data, including patient care data and other relevant data, into its QAPI program. This would include data that are received from or submitted to hospice professional organizations. A fundamental barrier in identifying quality care at the end of life is the lack of measurement tools. Measurement tools can identify opportunities for improving medical care and examining the impact of interventions.

CMS does not currently require the submission of data from hospices to calculate quality measures but is interested in the development of a set of measures. Hospice measures were submitted and discussed as part of the recent National Quality Forum process identifying home health measures but were withdrawn and added to the more focused end of life discussions. CMS would be interested in comments regarding clinical measures, patient experience of care measures, and systems measures (use of information technology, staffing, follow up mechanisms) specific to hospice care. These comments should include existing measures in use, measures to be developed, data collection methods and issues, and how measures are currently being used. We are especially interested in the feasibility, usability, if the measures presented are proprietary or publicly available, and burden of collecting and reporting the measures.

An example of available measurement tools would be the hospice outcome measures, data elements, tools, and instructions developed by a hospice industry task force in which the CMS participated as a stakeholder. A Task Force initiative was sponsored and convened by the National Hospice Work Group (NHWG) and the National Hospice and Palliative Care Organization (NHPCO) in 1999. We participated in developing the measures and provided technical assistance for pilot testing the measures. In addition to the work that has already been done in this area, we are committed to working with all relevant interest groups and associations as they develop and provide hospices with model quality assessment and performance improvement programs and other services.

The work of the Task Force resulted in measures addressing the outcome domains of self-determined life closure, comfortable dying, safe dying, and effective grieving. The hospice industry moved to include these measures in the data set that they encourage member hospices to use and report. The data elements, tools, and instructions for using the measures are publicly available on the NHPCO website *http://www.nhpco.org.*

If a hospice chooses to participate in this voluntary process as described in the NHPCO web site, it would collect the specified data elements, analyze the data to assess its performance, and implement performance improvement projects to address weaknesses while reinforcing strengths. A hospice may also choose to submit its data to the NHPCO or its contractor. The national reporting process includes pertinent utilization data, appropriateness and effectiveness of services, and patient and family satisfaction. Reports are then generated by the NHPCO for hospices to compare their performance with other hospices.

All hospices that choose to utilize the NHPCO reporting process will need to follow the HIPAA Privacy Rule. We believe that participating in the NHPCO reporting process in order to improve the quality of care delivered to patients would probably be deemed to be part of the hospice's health care operations under the HIPAA Privacy Rule. The NHPCO would be doing work on behalf of the hospice. Therefore, it appears that the hospice and the NHPCO would be required to have a business associate agreement, ensuring that the NHPCO would protect the health information submitted by the hospice. Sample business associate language is available at *http://www.hhs.gov/ocr/hipaa/contractprov.html.* Hospices should confer with their legal counsel to ensure that their disclosures are in compliance with the Department's rules. Once the business associate agreement was in place and the hospice began to submit its data, it would not need individual authorization to disclose protected health information to the NHPCO. In addition, the hospice would not need to account for the disclosures to the NHPCO.

We are not proposing to require that hospices use any particular process or outcome measures. However, a hospice that uses the available quality measures may be able to expect an enhanced degree of insight into the quality of its services and patient satisfaction than if it began the outcome-measure development process anew. In addition to the NHPCO measures, there are many other resources available. One of these resources, for example, is the ''TIME: Toolkit of Instruments to Measure End of life care,'' developed by Brown University. It can be found at *http://www.chcr.brown.edu/pcoc/toolkit.htm.* This Toolkit takes steps toward crossing the measurement barrier by creating patient-focused, family-centered survey instruments that address the needs and

concerns of patients and their families, as defined by them.

The hospice could also develop its own data elements and measurement process as part of its quality assessment and performance improvement program. A hospice is free to develop a program that meets its needs. We recognize the diversity of provider needs and concerns with respect to QAPI programs. As such, a provider's QAPI program will not be judged against a specific model.

Under the proposed standard, Program data, found at § 418.58(b), the hospice is expected to monitor the effectiveness of services and be able to target areas for improvement. The main goal of the quality assessment and performance improvement standard is to identify and correct ineffective and/or unsafe care. We expect hospices to assess their patient load and identify circumstances that could lead to significant patient care issues and concentrate quality assessment and performance improvement energies in these areas. For example, patients with minimal support care, those experiencing frequent exacerbations of symptoms, and those whose diagnosis and care may be unique to the hospice, may be the subject of more intense quality assessment and performance improvement activity. We expect a hospice to be able to demonstrate consistent performance progress in successful quality assessment and performance improvement interventions.

The third standard under the quality assessment and performance improvement program at proposed § 418.58(c), Program activities, states that the hospice must set priorities for its performance improvement activities that: focus on high risk, high volume and problem-prone areas; consider the prevalence and severity of identified problems; and give priority to improvement activities that affect palliative, patient safety, and quality of care outcomes. We expect that a hospice would take immediate action to correct any identified problems that directly or potentially threatened the care and safety of patients. Prioritizing areas of improvement is essential for the hospice to gain a strategic view of its operating environment and to ensure the consistent quality of care provided over time.

In § 418.58(c) we are also proposing to require the hospice to track adverse patient events, analyze their causes, and implement preventive actions that include feedback and learning throughout the hospice. The hospice's quality assessment and performance improvement program is expected to view staff as full partners in quality improvement. Because staff members are in a unique position to provide the hospice with structured feedback on its performance and suggestions on how performance can be improved, we expect the hospice to demonstrate how staff contribute to its quality improvement program.

We are proposing at § 418.58(d), Performance improvement projects, to require that the number and scope of improvement projects conducted annually must reflect the scope, complexity, and past performance of the hospice's services and operations. The hospice must document what improvement projects are being conducted, the reasons for conducting them, and the measurable progress achieved on these projects. We believe that giving hospices the flexibility to review their own organization and quality performance and improvement program may improve the effectiveness and efficiency of their services, improve the outcomes of care they provide, and potentially improve beneficiary satisfaction with their services.

We are proposing at § 418.58(e), Executive responsibilities, to require the hospice's governing body to be responsible and accountable for ensuring that the ongoing quality improvement program is defined, implemented, and maintained. The governing body must ensure that the program addresses priorities for improved quality of care and patient safety. The governing body must also specify the frequency and detail of the data collection and ensure that all quality improvement actions are evaluated for effectiveness. The governing body's most important role is to ensure that staff are furnishing and patients are receiving the most appropriate level of care. Therefore, it is incumbent on the governing body to lend its full support to agency quality improvement and performance improvement efforts.

We are specifically soliciting public comments on this proposed condition of participation.

Condition of Participation: Infection Control (Proposed § 418.60)

[If you choose to comments on issues in this section, please include the caption ''INFECTION CONTROL'' at the beginning of your comments.]

There is no current requirement for infection control other than the requirement at § 418.100(a) that ''* * * each patient is to be kept comfortable, clean, well groomed, and protected from accident, injury, and infection.'' We are now proposing a new CoP due to the seriousness and hazards of infectious and communicable diseases. There is a substantial amount of research from government agencies and private organizations regarding the effect of infections and communicable diseases in the inpatient environment. This research documents their widespread prevalence. While there is less research that examines infections and communicable diseases in the home, the effect of both on the health and safety of patients and the cost of patient care cannot be dismissed. In response, the health care industry has developed guidelines and recommendations for managing preventative programs. For example, the Association for Professionals in Infection Control and Epidemiology, Inc. have published ''Requirements for infrastructure and essential activities of infection control and epidemiology in out-of-hospital settings: A Consensus Panel report'' (*http://www.apic.org/pdf/cpinfra2.pdf*). The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) responded to the issue by designing new infection control standards for, among others, home care providers. These standards will become effective in 2005. Due to the negative effects on patient health and safety that are posed by infections and communicable diseases, and due to the significant amount of public, industry, and government attention that this issue has generated, we believe that hospices need to address infection control in a more complete manner.

In this proposed CoP, we are requiring hospices to take specific actions to address the prevention and control of infections and disease, and to educate patients, staff, and caregivers on their hazards, prevention, and control. It is essential that agencies consider the devastating effects of rampant communicable disease as they carry out their quality assessment and performance improvement programs. As a result, we expect the hospice to maintain an effective and up-to-date infection control program that may be part of its overall quality assessment and performance improvement program.

We recognize that a hospice cannot be directly responsible for the maintenance of an infection-free environment in an individual's home or inpatient setting. We are proposing 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 staff understanding.

In § 418.60(b),Control, we are proposing that the hospice engage in an ongoing system-wide program that focuses on the surveillance, identification, prevention, control, and investigation of infections and communicable disease. We expect the hospice to use best control practices in this endeavor. We are also expecting that each hospice 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 givers' interactions. Where infection and/or communicable disease is identified, we expect that this information is made part of the hospice's quality assessment and performance improvement program.

In § 418.60(c), Education, we are proposing a standard allowing the hospice flexibility in meeting its infection control, prevention and education objectives. For example, the amount of training in infection control necessary for the hospice's personnel would depend on the patient mix and experience of the staff. While we would expect that established best practices be adhered to, we are not proposing any specific approaches to meeting this requirement. However, all staff and family will be educated on the use of standard precautions for the safety of the patient, family and caregivers. We will expect to see clear evidence that the hospice aggressively seeks to minimize the spread of disease and infection through the use of effective techniques by its staff and through its efforts to help families and care givers understand what can and should be done to minimize infection.

We are specifically soliciting public comments on this proposed condition of participation.

Condition of Participation: Licensed Professional Services (Proposed § 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 are proposing to delete § 418.82, § 418.84, and § 418.92, and replace them with a more simplified condition, licensed professional services. Instead of identifying detailed tasks, we are broadly describing the expected contributions of the licensed professionals who are furnishing hospice services.

We are proposing that licensed professionals who provide services to hospice patients either directly or under arrangement must 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. The expected outcome is the coordinated, comprehensive, interdisciplinary delivery of appropriate and effective licensed professional services delivered and supervised by health care professionals who practice under State licensure requirements and the hospice's policies and procedures. Licensed professional services, for purposes of this section, include skilled nursing care, physical therapy, speech-language pathology, occupational therapy, and medical social services. The services of these licensed professionals are described in more detail under the core services condition proposed at § 418.64 and the non-core services condition at § 418.70.

Medicare makes a distinction between providing services directly, as opposed to providing services under arrangement. The most common way services are provided directly is through the use of employees. The common law definition of ''employee'' fundamentally relates to whether a person is under control by the entity or individual providing the services. The ''physician referral provisions'' at section 1877(h)(2) of the Act references the Internal Revenue Service (IRS) ''employee'' definition. Section 1877(h)(2) provides that an individual is considered to be ''employed by'' or an ''employee'' of an entity if the individual would be considered to be an employee of the entity under the usual common law rules applicable in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986).

Condition of Participation: Core Services (Proposed § 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 are proposing to combine these into a single condition. We are also proposing to incorporate the requirement at existing § 418.50(b)(3) that core services be provided in a manner consistent with accepted standards of practice.

This section has been revised to reflect changes to the Act made by section 946 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (''MMA''). In accordance with that provision, we are proposing to allow a hospice (the primary hospice) to enter into arrangements with another Medicare certified hospice to obtain core hospice services. This could be done under extraordinary or other non-routine circumstances. Pursuant to Section 1861(dd)(5)(D) of the Act, as added by section 946(a) of the MMA, those circumstances are: Unanticipated periods of high patient loads; staffing shortages due to illness or other short-term temporary situations that interrupt patient care such as natural disasters; and temporary travel of a patient outside the hospice's service area. We believe that the new MMA provision authorizes us to propose that hospices may not routinely contract for a specific level of care (*e.g.*, continuous care) or for specific hours of care (*e.g.*, evenings and week-ends), as these are regularly occurring situations that hospices are able to plan staffing for.

We propose to require that contractual arrangements under the provision be set forth in a legally binding written agreement between the hospices. The written agreement would ensure that contracted staff meet all hospice personnel qualifications and receive necessary training. The primary hospice would be responsible for enforcing the contractual provisions. This would ensure that the primary hospice maintains professional management responsibility for the service(s) being provided and the individual(s) providing such service(s), as described in sections 418.62, Skilled professional services and 418.100, Organization and administration of services. These sections require contracted services to be provided according to professional standards and practices. Finally, contracted individuals would be required to actively participate in the coordination of care, including patient assessment and care planning, and in the primary hospice's in-service training and quality assessment and performance improvement programs.

The physician services requirement would be changed to allow the use of contracted physicians, including the medical director (see proposed 418.102).

In proposed § 418.64(b), Nursing services, we would 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 many other hospice functions that are in the scope of their practice and license, as well as within the laws of the State in which they practice.

In this standard we have also proposed to allow hospices to provide certain types of nursing services under a legally binding written contract. This change also results from section 946 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which added new 1861(dd)(5)(E) to the Act. 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 will be able to better implement an efficient staffing plan and ensure proficiency in the skilled service being provided. Highly specialized services, as described, would not include continuous care because, while time intensive, such care does not require highly specialized nursing skills.

As with all other contracting arrangements, the hospice would be required to maintain professional management responsibility for the service(s) being provided under arrangement as well as the individual(s) providing them. The responsibilities of both the primary hospice and the ''lending'' nursing provider would need to be outlined in the written agreement, and there would have to be a mechanism in place to ensure that the terms of the agreement were met. To that end, the contracted individual(s) would have to provide care in accordance with professional standards of practice; actively participate in the coordination of care, including the comprehensive patient assessment and the formulation of the plan of care; and actively participate in the hospice's inservice training and quality assessment and performance improvement programs.

In proposed § 418.64(c), we are proposing to maintain the current medical social services requirement found 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 § 418.64(d), we address the counseling services that would be available to hospice patients. Those services would be bereavement, nutritional, and spiritual counseling. In the bereavement counseling section, we propose 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 propose to alter the standard to allow qualified individuals such as dietitians and nurses to furnish this service, provided that it is within their scope of practice and expertise according to State law. We believe that allowing other qualified individuals to participate in nutritional counseling will give hospices greater flexibility and will help ensure that all hospice patients have access to this service when needed. This proposal for increased flexibility is a result of recommendations made by the Secretary's Advisory Committee on Regulatory Reform.

In the spiritual counseling section we propose 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 do not desire spiritual counseling, then they would not have to be provided this service. If a patient and family do 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. We have examined the relevant jurisprudence regarding the provision of spiritual counseling by Medicare certified hospices (Kong v. Scully *et al.* 341 F.3d 1132 (9th Cir. 2003) reh. den. as amended, 357 F.3d 895 (9th Cir. 2004). We do not see any impediment to requiring hospices to offer spiritual services if a patient and family so desire.

Condition of Participation: Nursing Services Waiver of Requirement That Substantially All Nursing Services Be Routinely Provided Directly by a Hospice (Proposed § 418.66)

[If you choose to comment on issues in this section, please include the caption ''STATUTORY NURSING WAIVER'' at the beginning of your comments.]

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 remains virtually unchanged in this proposal. This condition provides hospices the opportunity to obtain a waiver from the requirement that substantially all nursing services be routinely provided directly by the hospice. 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 specifies that if a waiver is requested by an organization that meets the statutory requirements, and if it is submitted in the form and contains the information required by the Secretary, the waiver will be deemed granted unless the request is denied in 60 days after the request is received by the Secretary.

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

Condition of Participation: Furnishing of Non-Core Services (Proposed § 418.70)

The current CoP governing the provision of other services is contained in § 418.90. The hospice must ensure that the services described in § 418.72 through § 418.78 are provided directly by employees of the hospice or by others under an arrangement with the hospice. This is discussed further in proposed § 418.100. As with core services, non-core services should be provided in a manner consistent with current standards of practice.

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

Currently, the CoP concerning physical therapy, occupational therapy, and speech language pathology is laid out at § 418.92. We are proposing to recodify this CoP at § 418.72 without changes.

Condition of Participation: Waiver of Requirement—Physical Therapy, Occupational Therapy, Speech-Language Pathology, and Dietary Counseling (Proposed § 418.74)

We are proposing a new CoP that provides for a waiver of the requirement that physical therapy (PT), occupational therapy (OT), speech-language pathology (SLP) and dietary counseling services be provided as needed on a 24-hour basis. In addition, the waiver allows the hospice to provide the above services directly or under arrangements made by the hospice, as specified in current § 418.56.

We may approve a hospice's request for a waiver of the requirement that it furnish PT, OT, SLP and/or dietary counseling services if it is located in a nonurbanized area and can demonstrate that it has been unable, despite diligent efforts, to recruit appropriate personnel. Hospices will be required to submit evidence of their efforts to hire. We will apply similar requirements as are used for the nursing services waiver requests found in proposed § 418.66. As in the case for a waiver of nursing services, eligibility for a waiver is based on the primary location of a hospice. For a hospice that operates in several areas, its primary location is considered to be the location of its central office. The hospice must provide evidence that it made a good faith effort to hire a sufficient number of PTs, SLPs, OTs, and dietary counselors to provide services directly through hospice employees or under arrangement.

Condition of Participation: Home Health Aide and Homemaker Services (Proposed § 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. We are proposing in § 418.76 that a home health aide completes a State-established or other training program, and in § 418.76(b) we outline requirements that this training must meet. Except for minor reorganization, these training requirements are consistent with existing home health aide requirements in § 484.36.

For example, we would continue to permit a home health aide to meet the proposed § 418.76(a), Home health aide qualifications, requirement in one of three ways: by completing a training and competency evaluation program that meets the proposed training requirements, by completing a competency evaluation program, or by completing a State licensure program that meets the proposed training requirements. We propose to include three separate ways to meet the proposed requirement because we understand that home health aides come to hospices with various levels of experience and qualifications. We would expect that, if a State licenses home health aides, then an aide would meet those licensure requirements and would, in fact, be licensed by that State. If a State does not have licensure requirements, then we would expect that a home health aide who had not previously participated in a training program that meets the proposed requirements would be trained in a program that meets the proposed requirements. In addition, we would expect that, following such training, that aide would be evaluated in a systematic way to assess his or her skills and competencies before performing patient care. If, however, a home health aide has already completed a training program that meets the proposed requirements while employed at another provider, then we would only expect the aide to complete a competency evaluation program at his or her new employer. We believe that this would make it easier for aides to change employers and faster for hospices to get qualified new employees out in the field. One of the skills a home health aide would be required to master is the ability to observe, report, and document patient status and the care or service furnished. We believe that clear and effective communication between the many providers of hospice care is an important part of ensuring high quality patient care. We believe that a home health aide should be able to both verbally report and document in writing what he or she observes and does at a patient's home.

Three standards have been particularly adapted for the hospice conditions of participation. First, § 418.76(j), homemaker qualifications, has been adapted from the existing § 418.94. The proposed standard clarifies that a qualified homemaker is a home health aide as described in § 418.76 or an individual who has 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 may include assistance in maintenance of a safe and healthy environment to enable the patient to benefit from care that is furnished.

Second, § 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 every 28 days while the home health aide is providing care. 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 present and performing his or her duties is the only way to provide such thorough supervision. On-site 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 are having their needs met by such services.

Finally, § 418.76(k) would require a member of the interdisciplinary group 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.

Condition of Participation: Volunteers (Proposed § 418.78)

The current CoP for volunteers is located at § 418.70. We are proposing to recodify this CoP at § 418.78 with minor changes. We are removing the existing § 418.70(f), regarding the availability of clergy, because the role of the pastoral, clergy, or other spiritual counselor is described in proposed § 418.56(a)(1)(iv), Interdisciplinary group, care planning and coordination of services. This change does not preclude the hospice from continuing to use or starting to use clergy as volunteers.

Subpart D, Conditions of Participation, Organizational Environment

Condition of Participation: Organization and Administration of Services (Proposed § 418.100)

[If you choose to comment on issues in this section, please include the caption ''ORGANIZATION AND

ADMINISTRATION'' at the beginning of your comments.]

We are proposing to revise existing regulations at § 418.50, General provisions, § 418.52, Governing body, and § 418.56, Professional management, by creating a new condition. This new condition would simplify the structure of these current requirements and clarify new performance expectations for the governing body. We believe the structure of the current requirements does not establish clear performance expectations for the operation of all services. The overall goal of the revised requirement would be to ensure a management structure that is organized and accountable. We believe that a well-managed hospice will be more likely to allocate resources so that patients maintain their highest functional capacity.

In the proposed organization and administration of services condition (that is, § 418.100), we have taken the current CoPs and proposed changing them to standards:

- Governing body and administrator (existing § 418.52).
- Continuation of care (existing § 418.60).
- Professional management responsibility (existing § 418.56).
- In-service training (existing § 418.64).

We would also include a standard clearly listing the services that the statute requires hospices to furnish. We are also proposing to add a new standard for in-service training that would require a hospice to provide in-service training to all individuals, including volunteers, to address identified skill and competency gaps. The hospice would be required to have written policies and procedures describing its methods for assessing skills and competency. It would also be required to maintain a written description of in-service trainings offered during the previous 12 months.

Currently, § 418.50(b)(3), Required services; § 418.52, Governing body; § 418.82(c), Acceptable standards of practice; § 418.92(a), PT, OT and SLP; and § 418.96(a), Administration of drugs and biologics, all exist as separate standards. To emphasize the importance of continuity of care and the focus on quality, regardless of the site of service, we are proposing to move these existing provisions and incorporate their performance expectation into the quality assessment and performance improvement program that is proposed at § 418.58.

We have long used the term ''in accordance with accepted standards of practice,'' in various provider and supplier requirements, (such as in the existing § 418.82(c)) to set a performance expectation and to be able to employ regulatory authority to shed light on inappropriate and/or dangerous practices. We are proposing to retain this authority and move the existing § 418.82(c) into § 418.64, Core services and § 418.70, Furnishing of non-core services.

In the proposed governing body and administrator standard at § 418.100(b) we emphasize the responsibility of the hospice governing body (or designated persons so functioning) for the management and provision of all hospice services including fiscal operations, quality assessment, performance improvement, and the appointment of the administrator. The actual approach to the administration of the hospice is left to the discretion of the governing body, thereby affording the hospice management flexibility. The proposed governing body standard reflects our goal of promoting the effective management and administration of the hospice as an organizational entity without dictating prescriptive requirements for how a hospice must meet that goal.

Section 418.100(c), Services, includes nursing, medical social services, physician services, counseling services, home health aide and homemaker services, therapy services, short-term inpatient care and medical supplies. The nursing services, physician services, and drugs/biologicals as specified in § 418.100(c)(2) must be routinely available on a 24-hour basis. All other covered services must be available on a 24-hour basis when reasonable and necessary to meet the needs of the patient and family.

In § 418.100(d), Continuation of care, the current standard is at § 418.60. We are proposing to recodify this section at § 418.100(d) without change.

In § 418.100(e), Professional management responsibility, we are proposing to revise some of the current requirements found at § 418.56(b) and (c). This standard would require written agreements for services furnished under arrangement, and would require that the hospice retain professional management and supervisory and financial responsibility for all services that are provided to the patient and family. The hospice would be required to ensure that all services provided are authorized by the hospice, 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.

In § 418.100(f)(1), we are proposing a new standard to address the issue of multiple service locations. Our goal is to establish clear requirements in order to ensure patient comfort, patient safety, and the provision of a consistent level of care throughout the hospice organization. This provision is 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 are adding the definition of a hospice satellite location. The way in which hospices are organized has changed since the original regulations were promulgated. Today, unlike small community based hospices that were operating when the Medicare hospice benefit first began, it is common to find large hospice organizations serving a patient population widely dispersed throughout a sizeable geographic area. Some existing hospices operate from multiple locations. We believe it is appropriate to develop a basis in regulation to better clarify this organizational structure and we have been asked by hospices to more fully consider the nature of the relationship between a hospice and a satellite location.

We expect that any hospice that requests to establish a satellite 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 satellite location. Patients who receive care and services from a hospice satellite location must receive the full range of services that are documented in the plan of care. We will consider the following factors in our review of a hospice's request to establish a satellite location:

- The hospice's ability to supervise the satellite location to ensure the timely provision of quality care for patients and families receiving care.
- The hospice's past compliance history.
- Relevant State issues and recommendations including a reciprocal agreement between the States to assure that at least one of the State agencies assumes responsibility for any necessary surveys of the satellite location in situations in which a hospice provides services in satellite locations across state lines.
- The hospice's assurance that each patient receives care from an assigned interdisciplinary group that works effectively together to identify and meet the physical, social, emotional, and spiritual needs of the hospice patients and families receiving care.

Before operating a satellite location, a hospice must enroll with the fiscal intermediary and notify the State agency

and CMS of all currently approved satellite locations at the time it requests approval for any additional satellite locations. If a hospice provides care and services to Medicare beneficiaries at an unapproved or disapproved satellite location, such services may be determined to be non-covered. At the time of any satellite location closure the hospice is expected to notify the fiscal intermediary, State agency and CMS.

Hospice satellite locations are also subject to survey by the State survey agency or CMS regional office. Deficiencies that are identified at any satellite location will apply to the entire hospice issued the provider agreement number. Satellite locations must comply with the hospice conditions of participation at § 418.52 through § 418.116.

Proposed § 418.100(g), Inservice training, applies to volunteers and employees, including those employed under arrangement or contract. We are expecting a hospice to take steps to develop appropriate inservice programs or to arrange to acquire training from others.

We are not dictating a specific inservice training program, but rather we expect each hospice to determine the scope of its own program, including the manner in which it chooses to assess competence levels, determine training content, and determine the duration and frequency of training.

We are specifically soliciting public comment on this proposed condition of participation.

Condition of Participation: Medical Director (Proposed § 418.102)

[If you choose to comment on issues in this section, please include the caption ''MEDICAL DIRECTOR'' at the beginning of your comments.]

We would revise the existing medical director CoP at § 418.54 by incorporating current requirements and expanding it to illustrate the importance of having a medical director or physician designee coordinate the activities of physicians and other health care professionals to ensure that care is appropriate and reflects the hospice philosophy. To maintain patient care and coordination of services, the medical director or physician designee appointed by the medical director, must either be a hospice employee or under contract with the hospice. A contractual arrangement with another agency or organization is not permitted.

Section 418.102(a), Initial certification of terminal illness, would incorporate the provisions of current § 418.22, and require that the medical director or physician designee review the patient's clinical information and provide written certification that the individual has a medical prognosis that his/her life expectancy is 6 months or less if the illness runs its normal course. The certification would have to be based on the medical director's or physician designee's clinical judgment regarding the normal course of the individual's illness.

In the second standard, § 418.102(b), Recertification of the terminal illness, we would require that the medical director or physician designee review the clinical information and the patient and family's expectations and wishes for hospice care on an ongoing basis and before each updated assessment. Assessments would be required to be updated at least every 14 calendar days according to § 418.54(d). In addition, this standard would also require that the assessment be updated at the time of each recertification. The timeframes for recertification are described in § 418.21.

Within § 418.102(c), Coordination of medical care, we are proposing that the medical director or physician designee and the hospice interdisciplinary group maintain responsibility for coordinating a patient's medical care in all settings, even when multiple physicians are participating in the care. This level of coordination ensures that the patient receives continuous medical care and services that are consistent with the hospice philosophy.

We are also proposing to require that the medical director or physician designee be responsible for the hospice's quality assessment and performance improvement program. This program and implementation of its findings are critical to ensuring that patients receive effective and meaningful care.

We are specifically soliciting public comment on this proposed condition.

Condition of Participation: Clinical Records (Proposed § 418.104)

[If you choose to comment on issues in this section, please include the caption ''CLINICAL RECORDS'' at the beginning of your comments.]

The proposed condition of participation, Clinical records, would incorporate several of the existing requirements in § 418.74 of the current regulation, Central clinical records. We are proposing to add a new requirement that the clinical record contain accurate clinical information that is available to the physician and hospice staff.

The proposed condition continues to require that all clinical records contain past and current findings and that they are maintained for each patient who is admitted by the hospice.

We are also providing an opportunity for the hospice to choose to maintain clinical records electronically if it desires and recognize that some hospices are beginning to maintain electronic records. The use of electronic health records (EHRs) has the potential to improve patient care and improve efficiency. We anticipate that the use of electronic health records will become widespread, and will be required in future hospice conditions of participation.

We also recognize that there may be significant barriers for hospices that are interested in maintaining electronic health records (EHRs) for their patients. We are interested in learning how the final hospice CoPs and/or other future regulations can reduce or eliminate those barriers.

We are interested in public comments on the following areas:

1. What are the components of an electronic health record (EHR)? What are the advantages and disadvantages of using an EHR in a hospice setting?

2. Should an EHR include a personal health record which is accessible to the patient? What are the positive and negative consequences (*e.g.* caregivers less likely to record certain procedures or observations) of personal health records?

3. What are the barriers (*e.g.* technical, clinical) to implementing an EHR system in a hospice?

It is obvious that there are many different issues regarding the institutionalization of EHRs. We are aware that some hospices have already chosen to pursue this option to one degree or another. We are interested in knowing what their experience has been thus far. How have electronic health records impacted the way they allocate and deliver patient care, and how has this, in turn, impacted patient outcomes?

At § 418.104(a), Content, we would retain the requirement that the record include all assessments (including the initial assessment and all updated assessments), plan of care, consent and election forms, and clinical and progress notes. We are proposing the following requirements for the content of the clinical record—

- Advance directive information as described in proposed § 418.52(a)(3);
- Informed consent, authorization and election 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).

We recognize that there has been some confusion between the meaning of clinical note and progress note. To eliminate this confusion, we have defined ''clinical note'' and ''progress note'' in the definitions section. The key differences between clinical and progress notes are that:

1. Clinical notes summarize an actual patient encounter (as this term is used in the field) while progress notes do not necessarily have to; and

2. Clinical notes comprehensively describe the care provided during that encounter while progress notes briefly summarize care furnished (which could cover a span of time) and the patient's response. We believe that these definitions, adopted from the current conditions of participation for home health agencies (42 CFR part 484) will provide needed clarity and will ensure that the records contain information necessary to provide high quality patient care.

We are proposing to add a new standard at § 418.104(b), Authentication, that requires authentication of clinical records. All entries must 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 addresses technological changes in information management such as the computerization of records as well as electronic signatures. A similar requirement is in the conditions of participation for hospitals.

We are proposing to re-codify the existing requirement found in § 418.74(b) as § 418.104(c), Protection of information. This re-codified provision would require that all patient information, including the clinical record and its contents, be safeguarded against loss or unauthorized use. The text would also be revised to reflect that all hospices must also comply 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 contained in 45 CFR parts 160 and 164.

Under § 418.104(d), Retention of records, we propose to ensure protection of the patients information by adding a new requirement that patient records be retained for 5 years after the death or discharge of the patient, unless State law stipulates a longer period of time. If the hospice discontinues operation, hospice policies would be required to provide for the retention and storage of clinical records. The hospice would be required to notify the State agency and its CMS regional office where the clinical records would be stored.

Under proposed § 418.104(e)(1), Discharge or transfer of care, we have 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 to which the patient is being transferred. This would help to ensure that the information flow between the hospice and the transfer facility is smooth, so that the level of care will continue without being compromised.

Under § 418.104(e)(2), we would add a new requirement that the hospice provide a copy of the patient's clinical record and hospice discharge summary to the attending physician if the patient revoked the election of hospice care or was discharged from hospice because eligibility criteria were no longer met. This requirement was added to ensure that the patient's attending physician would be aware of the most current clinical information.

The hospice discharge summary requirement proposed at § 418.104(e)(3) would be a new requirement and would detail what would be required to be contained in the discharge summary. The purpose of the discharge summary is to provide important clinical information to those medical and other health professionals who will be assuming the care of the patient upon discharge from the hospice. At a minimum, the discharge summary would contain information that accurately describes 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.

Under § 418.104(f), Retrieval of clinical records, we would require that clinical records, whether in hard copy or electronic form, be made readily available to, and retrievable by, an appropriate authority.

We are specifically soliciting public comment on this proposed condition of participation.

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

[If you choose to comment on issues in this section, please include the caption ''DRUGS, SUPPLIES, and DME'' at the beginning of your comments.]

This condition of participation revises the current requirement, found at § 418.96, and would clarify 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 plan of care, must be provided by the hospice while the patient is under hospice care.

In addition, restrictions regarding the use of controlled substances in the patient's home would be conveyed more clearly. We believe that the hospice, as well as the patient and family, need to share in the responsibility and accountability for maintaining controlled substances in the home. Primary responsibility rests with the hospice, and the hospice must assume responsibility to educate the family about the proper use and disposal of drugs and biologicals and the consequences of misuse.

Section 418.106(a)(1), Administration of drugs and biologicals, would require 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 are proposing to add a new requirement that the interdisciplinary group be responsible for periodically reviewing the plan of care to determine whether the patient and/or family continues to have the ability to safely administer drugs and biologicals.

Under proposed § 418.106(b), Controlled drugs in the patient's home, the hospice would ensure the safe delivery and accountability of controlled drugs in the patient's home. The hospice would have to have a policy for the tracking, collecting, and disposing of controlled drugs maintained in the patient's home. During the initial assessment, the hospice policy regarding the use and disposal of controlled drugs would be required to be discussed with the patient and family, and the hospice nurse would be required to document that the policy had been discussed with the patient and family. Because controlled drugs can pose significant danger to patients if improperly ingested or abused, educating patients and families may prevent unwanted complications.

In § 418.106(c), Use and maintenance of equipment and supplies, a hospice would be responsible for overseeing the use of durable medical equipment and supplies in the patient's home. Through the Medicare survey process and beneficiary complaints, we have found

that equipment that is not properly maintained does not perform properly and may harm the patient. Under this proposal, the hospice would be responsible for making certain that equipment being furnished under the plan of care is operating safely. The hospice may carry out this responsibility through a contractual arrangement with others, but would continue to maintain primary responsibility.

Stressing the importance of providing families with information and levels of comfort relative to the care being furnished to family members, we are proposing a new medical equipment and supplies requirement. The hospice would be required to take action to ensure that the family received instruction in the safe use of equipment and supplies. In order for the family to participate in providing quality care to the patient, the family members would need to understand how and when to use equipment and supplies.

We are specifically soliciting public comment on this proposed condition of participation.

Condition of Participation: Short-Term Inpatient Care (Proposed § 418.108)

[If you choose to comment on issues in this section, please include the caption ''SHORT TERM INPATIENT CARE'' at the beginning of your comments.]

Under proposed § 418.108, we would 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 would recodify the current requirement found at § 418.98(a), Short-term inpatient care, as § 418.108(a), Inpatient care for symptom management and pain control.

The references to the condition at § 418.108(b), Inpatient care for respite purposes, would no longer focus on process as in the existing § 418.98. Rather, the updated standards reflect expected outcomes of care.

We would eliminate the existing requirement found at § 418.100(a)(2), requiring a registered nurse to provide direct patient care on each shift. We believe 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 to provide requisite care. If the patient does not need care by a registered nurse, imposing a requirement on a hospice that mandates a registered nurse to be in attendance on a particular shift to serve the patient will have no effect on the patient's care.

Under proposed § 418.108(c), Inpatient care provided under arrangement, we would incorporate many of the existing requirements in existing § 418.56(e). In particular, we would require that a hospice train the personnel who would be providing patient care in an inpatient facility. The hospice model of patient care is very different from the curative model of patient care that medical personnel are trained in. Therefore, in order to ensure that patients in inpatient facilities continue to receive care that is consistent with the hospice philosophy (*i.e.*, proactive pain management, interdisciplinary care), it is important that inpatient facility personnel be trained to understand the hospice philosophy and model of care.

Under proposed § 418.108(d), Inpatient care limitation, and § 418.108(e), Exemption from limitation, we are proposing to re-codify the existing requirements at § 418.98(c) and (d), respectively, without changes.

Condition of Participation: Hospices That Provide Inpatient Care Directly (Proposed § 418.110)

[If you choose to comment on issues in this section, please include the caption ''INPATIENT CARE'' at the beginning of your comments.]

Under proposed § 418.110, we are proposing to revise the existing requirements, currently located at § 418.100, as follows:

Under § 418.110(a), Staffing, we would include the expectation that staffing for all services provided by the hospice reflect the volume of patients, patient acuity, and the level of intensity of the services as reflected in the plan of care to ensure that expected outcomes of care are achieved and negative outcomes are avoided. We also would eliminate our requirement that a registered nurse provide direct patient care each shift when the condition of the patient does not require the care of a registered nurse on each shift. This change would reduce the staffing burden for hospices and is a result of recommendations made by the Secretary's Advisory Committee on Regulatory Reform.We are proposing to remove the requirement in the existing § 418.100(a)(2) that each shift include a registered nurse that provides direct patient care for those patients who are receiving short-term inpatient care for symptom management. We are proposing in § 418.110(b), 24-hour nursing services, that the hospice facility 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, as well as the skill level of the staff that provides care, in accordance with State licensing requirements. We would require that each patient be kept comfortable, clean, well-groomed and protected from accident, injury, and infection.

When assessing a facility's compliance with this proposed regulation, we would expect to see that the staffing level met the needs of the patients. For example, if a patient experiences unexpected break-through pain and needs additional pain management, we would expect that a staff member with the appropriate skills be available to care for that patient. If a staff member with the appropriate skills, and knowledge is not available to care for that patient and assure that his or her pain is effectively managed, then the hospice would be considered to be out of compliance with this proposed regulation.

In § 418.110(c), Physical environment, we are proposing that the hospice maintain a safe physical environment that is free of hazards for patients, staff, and visitors. In § 418.110(c)(1), Safety management, in paragraphs (c)(1)(i) and (c)(1)(ii), we are proposing that the hospice prevent situations that pose a threat to the health and safety of the patients, others, or property whenever possible. The hospice would be required to promptly report and investigate all incidents that involve injury to patients, staff or visitors, or that involve damage to property. The hospice would be required to report such incidents to the appropriate State and local bodies having regulatory jurisdiction. The hospice would also be required to take action to correct the problems promptly. The hospice would be required to take steps to prevent equipment failures and correct and report any equipment failures promptly. In § 418.110(c)(1)(iii) we have retained 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. We believe that special emphasis should be placed on carrying out the procedures necessary to protect the patients and others.

In § 418.110(c)(2), Physical plant and equipment, paragraphs (c)(2)(i) through (c)(2)(iv), we are proposing that there be procedures for the management of light, temperature, and ventilation controls throughout the hospice (including air exchange) for patient care. The hospice

would be required to make battery lamps and flashlights available in all areas not served by an emergency electrical supply source. The hospice would be required to make available an emergency gas and water supply. All equipment would be required to be properly maintained.

In § 418.110(d), Fire protection, we are proposing to recodify, without change, the existing provisions in § 418.100(d). These provisions were amended on January 10, 2003 (68 FR 1374) to adopt the year 2000 version of the Life Safety Code. They were also amended on August 11, 2004 to clarify the effective date of the roller latch prohibition (69 FR 49266). In addition, they were amended on March 25, 2005 (70 FR 15229) to address the use and placement of alcohol-based hand rubs.

Proposed § 418.110(e), Patient areas, would be recodified from § 418.100(e) without change.

Proposed § 418.110(f), Patient rooms, would be revised. We are proposing in § 418.110(f)(3)(iv) that each room accommodate no more than two patients. We are proposing the two patients per room requirement in recognition of the fact that hospice patients in the inpatient setting are critically ill and may be actively dying. These patients and their 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.

Due to the potentially high cost of retrofitting older buildings, the proposed rule would 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 or not the hospice was already providing direct inpatient care when this regulation would become effective. That is, if a hospice is providing direct inpatient care in a building on the day before the effective date of a final rule, and they had more than two patients in each room, then the hospice would qualify for a waiver of the proposed requirement. If a hospice chose to begin operating its own inpatient unit after the effective date of a final rule, then it would not qualify for the proposed waiver, and would thus 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 (§ 418.100(f), with only minor language changes that would not change the substantive requirements of the regulation.

Proposed § 418.110(g), Toilet/bathing facilities, is linked with patient rooms in the current requirement found at § 418.100(f). We are proposing to revise this requirement as a stand-alone standard. As such, it would highlight our concern for the adequacy of toilet and bathing facilities, and would provide more flexibility for State agency surveyors in evaluating the appropriateness of these facilities. We believe it is important for the privacy and comfort of the patient and family to have toilet and bathing facilities in each patient room, or conveniently located near the patient's room.

We are proposing no changes to existing § 418.100(g) bathroom facilities, except to recodify it at § 418.110(h) and rename it, Plumbing facilities.

In § 418.110(i), Infection control, we are proposing to revise infection control standards to conform to those required of other provider types, such as home health agencies and hospitals. We would require a hospice to establish an infection control program that protects 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 national infection control standards and be part of the hospice's overall quality assurance and performance improvement and education program. We also propose to retain the requirement that hospices provide a sanitary environment by following accepted standards of practice.

We are not proposing any specific approaches to meeting the infection control requirement, but we would expect to see clear evidence that the hospice aggressively sought to minimize the spread of infection through the use of infection control techniques, such as standard precautions by its staff, and through the efforts made by the hospice to help families and caregivers minimize the spread of infection.

We are proposing to re-codify the current requirement § 418.100(h), Linen, as § 418.110(k) without substantive change.

In proposed § 418.110(l), Meal service and menu planning, we are proposing to revise the existing § 418.100(j). We would make this standard less restrictive, and would emphasize the need for a hospice to focus more on outcomes rather than process. Specifically, we believe that a hospice should focus on meeting the patient's nutritional and plan of care needs. We would eliminate 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 § 418.110(m), Pharmaceutical services, we are proposing to re-codify the existing requirement found at § 418.100(k) without substantive change.

In § 418.110(n), Pharmacist, we would assign this requirement a higher level of importance by making it a standard. However, we would retain the essential elements of the current requirement.

[If you choose to comment on the issues contained in paragraph (o) of this section, please include the caption ''SECLUSION AND RESTRAINT'' at the beginning of your comments.]

Section 418.110(o), Seclusion and restraint, would be a new standard. A number of accidental injuries and deaths across inpatient providers due to the use of seclusion and restraints have been documented. Therefore, we discourage the use of seclusion and restraints, but are aware that their application may be warranted for brief periods or in rare instances. In response to the accidental deaths and injuries, we published (in 1999) a new condition in the hospital CoPs that included a new standard at § 482.13(f), Standard: Seclusion and restraint for behavior management.

The hospital seclusion and restraint CoP was the basis for the proposed hospice seclusion and restraint CoP. We also considered the seclusion and restraint language in section 3207 of the Children's Health Act (CHA), Public Law 106–310, codified at section 591 of the Public Health Service Act (42 U.S.C. 290ii). The CHA provision requires that any health care facility that receives Federal funds, including Medicare approved hospices, protect and promote every patient's right to be free from ''any restraints or involuntary seclusions imposed for purposes of discipline or convenience.'' The CHA clearly described the circumstances in which restraints or seclusion may be appropriate. The proposed seclusion and restraint requirement for hospices would codify the changes made to the Act by the CHA. We believe that adding this new requirement to the hospice CoPs may promote safe use of seclusion and restraints and may prevent accidental injury or death while a patient is receiving care as an inpatient in a hospice.

We have focused this standard on the proper use of seclusion and restraints, the need for hospice personnel to receive training and education in the proper use of seclusion and restraint application and techniques, and the

need for hospice personnel to receive training and education in alternative methods for handling situations that arise. We emphasize that seclusion and restraint may only be used if needed to improve the resident's well-being or protect him or her or others from harm, and only when less restrictive interventions have been determined ineffective. We encourage the public to comment on this standard, especially with respect to instances where seclusion and restraint are appropriate and inappropriate.

Condition of Participation: Hospices That Provide Hospice Care to Residents of a SNF/NF, ICF/MR, or Other Facilities (Proposed § 418.112)

[If you choose to comment on issues in this section, please include the caption ''RESIDENTS RESIDING IN A FACILITY'' at the beginning of your comments.]

Hospice care is an approach to treatment that recognizes that the impending death of an individual warrants a change in the focus from curative care to palliative care (relief of pain and other uncomfortable symptoms). The goal of hospice care is to help terminally ill individuals to continue life with minimal disruption to normal activities while remaining primarily in the home environment.

A participating hospice may provide care to an eligible patient in an environment that the patient chooses to be his or her home. This includes hospice care provided to residents who choose to live in skilled nursing facilities, nursing facilities, intermediate care facilities, mental retardation facilities, and other facilities.

The provision of hospice care to residents of those facilities has come under scrutiny as a result of Operation Restore Trust (ORT) activities and Inspector General (OIG) reports from 1996, 1997, and 1998. An OIG report released in 1997 found that ''contractual arrangements between hospices and nursing homes present vulnerabilities for inappropriate use of excessive Medicare and Medicaid payments being made to hospices or to nursing homes'' (U.S. D.H.H.S. OIG, *Hospice and Nursing Home Contractual Relationships,* Nov. 1997, OEI–05–95–00251. See also, OIG Special Fraud Alert, *Fraud and Abuse, Nursing Home Arrangements with Hospices,* Mar. 1998). In addition, in 2000 the Assistant Secretary for Planning and Evaluation (ASPE) Office of Disability, Aging and Long-Term Care Policy and the Urban Institute published a report entitled ''Synthesis and Analysis of Medicare Hospice Benefit Executive Summary and Recommendations'' (Harvell, Jennie; Jackson, Beth; Gage, Barbara; Miller, Susan; and Mor, Vincent, 2000 March). This report made several recommendations, some of which related to training and hospice care outcome measurement.

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 the patients accessing the hospice benefit while they are facility residents. Based on the recommendations of the committee, as well as the reports from Operation Restore Trust, the Office of Inspector General, and the Assistant Secretary for Planning and Evaluation, we would add this new condition of participation. We are preparing a separate regulatory document to address long-term care facility obligations regarding residents receiving hospice services.

To ensure that quality hospice care is provided to eligible patients, we are proposing a new condition at § 418.112, Hospices that provide care to residents of a SNF/NF, ICF/MR or other facility. Regardless of where the hospice patient resides, the responsibility for developing and implementing an appropriate plan of care rests with the hospice.

Under proposed § 418.112(a), Resident eligibility, election and duration of benefits, we would specify that it is incumbent upon the hospice to ensure that the resident meets 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 proposed § 418.112(b), Professional management, the hospice would be expected to assume full responsibility for all of the hospice care provided to the resident. This would include making arrangements for any inpatient care that the patient would require in accordance with § 418.100. This standard reinforces our belief that continuity of care is crucial for hospice care in any setting.

In proposed § 418.112(c), Core services, (and in accordance with sections 1861(dd)(1) and (2)(A) of the Act), the hospice would be required to provide all necessary core services to its patients in the same manner that it would provide core services to a patient residing in a home in the community. The plan of care would have to identify the care and services that were needed and specify which provider would be responsible for providing that care. It is not reasonable to expect the hospice to delegate any of its standard hospice core services to the nursing or residential facility staff.

In proposed § 418.112(d), Medical director, a hospice medical director would be expected to play an integral role in providing medical supervision to the hospice interdisciplinary group and in providing overall coordination of the patient's plan of care. The medical director's expertise in managing pain and symptoms associated with the patient's terminal disease is necessary, regardless of the setting in which the patient is receiving hospice services to ensure that the hospice patient has access to quality hospice care. Therefore, the medical director must communicate with all facility physicians and the attending physician and other professionals involved in developing and/or implementing the patient's plan of care.

Under proposed § 418.112(e), Written agreement, we are proposing that a comprehensive and legally binding written agreement be developed between the hospice and facility and that it be in effect before any hospice care is 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 are clearly articulated and executed in a manner that ensures that the resident will receive quality hospice care. The written agreement would be required to include the following:

(1) Written consent and documentation of the patient or the patient's representative that hospice services were desired;

(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; and

(4) A requirement that the facility immediately notify the hospice when—

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

(ii) Clinical complications appeared that suggested a need to alter the plan of care;

(iii) A life threatening condition(s) appeared;

(iv) A need to transfer the patient from the facility arose; and

(v) The patient died.

As the primary entity responsible for the patient's care, the hospice should assume responsibility for determining the appropriate course of care and the decision to change the level of services provided. The hospice would make arrangements for, and remain

responsible for, any necessary continuous care or necessary inpatient care related to the terminal illness.

We would require that the agreement delineate the facility's responsibilities, including room and board and other services and treatment, support or otherwise. We would also require a delineation of the hospice's responsibilities including medical direction and management of the patient, as well as nursing, counseling (including spiritual and dietary counseling), social work, bereavement counseling for family members, the provision of medical supplies and durable medical equipment, and the provision of drugs necessary for the palliation of pain and symptoms associated with the terminal illness. The hospice would be required to provide directly substantially all of the services necessary for the care of the patient's terminal illness.

The hospice would be able to utilize the facility's nursing personnel (where permitted by the facility and by law), for 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 limit the scope of the relationship between the hospice and the facility. Additional provisions could be added subject to mutual agreement.

Under proposed § 418.112(f), Hospice plan of care, just as required for hospice services furnished to patients not residing in an inpatient facility, we are proposing that a written plan of care would be required to be established and maintained for each facility patient. The plan of care would be required to be coordinated with and developed by the hospice interdisciplinary group and SNF/NF, ICF/MR, or other facility in collaboration with the attending physician. The care provided would have to be in accordance with the plan. The plan would have to reflect the hospice philosophy in all aspects and be based on an assessment of the patient's needs and unique living situation in the facility. The plan would have to address the patient's current medical, physical, social, emotional, and spiritual needs based on the problems identified in the initial comprehensive and updated comprehensive assessments, and other assessments. Directives for the management of pain would have to be addressed and updated as necessary to reflect the patient's status.

We are proposing that the plan of care identify the care and services that would be needed and specifically identify which provider would be responsible for performing the respective functions that were agreed upon and included in the plan of care. The performance of the functions should reflect the participation of the hospice, SNF/NF, ICF/MR, or other facility, and the patient and family to the extent possible. The plan of care would need to be reviewed at least every 14 days and as needed to reflect changes in the patient's condition. In conjunction with members of the facility's team, the hospice and the attending physician would have to discuss any changes in the plan of care, and these changes would have to be approved by the hospice before implementation.

At proposed § 418.112(g), Coordination of services, we are proposing that the hospice designate a member of the interdisciplinary group to coordinate the implementation of the plan. The hospice would provide the 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 proposed § 418.112(h), Transfer, revocation, or discharge from hospice care, we would specify that the proposed requirement for discharge or revocation found at § 418.104(e) applies. In addition, we would specify 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 proposed § 418.112(i), Orientation and training of staff, we would specify that the hospice staff would be required to train facility staff who provide 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.

We are specifically soliciting public comment on this proposed condition of participation.

Condition of Participation: Personnel Qualifications for Licensed Professionals (Proposed § 418.114)

[If you choose to comment on issues in this section, please include the caption ''PERSONNEL QUALIFICATIONS'' at the beginning of your comments.]

We are proposing significant revisions to the personnel qualifications for hospice employees. Specifically, we would provide that in cases where personnel requirements are not statutory, or do not relate to a specific payment provision, we would require personnel to meet State certification or licensure requirements. Under our proposal, the personnel qualifications would fall into three basic categories that include: (1) General qualifications, (2) personnel qualifications for physicians, speech-language pathologists, and home health aides, and (3) personnel qualifications when no State licensing laws or State certification or registration requirements exist. Under our proposed reorganization of part 418, the personnel qualifications would be located at § 418.114. We discuss the personnel qualifications in detail below.

(1) General qualifications (proposed § 418.114(a)).

This category would encompass licensed professionals who provide hospice services directly, either as employees or under individual contract, or under arrangement with a hospice. These professionals must be licensed, or 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. Examples of personnel who fall into this category are registered nurses, licensed practical nurses, physical therapists, and physical therapist assistants; all States currently have licensing or certification requirements for these caregivers.

(2) Personnel qualifications for physicians, speech-language pathologists, and home health aides (proposed § 418.114(b)).

Section 1861(r) of the Act defines a physician as a doctor of medicine, osteopathy, or podiatry legally authorized to practice medicine and/or surgery by the State in which that function or action is performed. We would refer to this definition at § 418.114(b)(1). Sections 1861(ll)(1) and (3)(A) of the Act define a qualified speech-language pathologist as an individual with a master's or doctoral degree in speech-language pathology who is licensed as a speech-language pathologist by the State in which the individual furnishes those services. In the case of an individual who furnishes services in a State that does not license speech-language pathologists, the

individual must have successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating the supervised clinical experience), performed not less than 9 months of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field, and successfully completed a national examination in speech-language pathology approved by the Secretary.

Section 1891(a) of the Act also defines the qualifications for home health aides. However, we believe that the description of qualifications for home health aides would be more appropriately located under the home health aide services CoP. Thus, the requirement would be cross-referenced at proposed § 418.76(a).

(3) Personnel qualifications when no State licensing laws or State certification or registration requirements exist.

When a State does not have a licensure, certification, or registration requirement, the hospice would apply the qualifications in § 418.114(c). This category would consist of all current personnel qualifications specified in proposed § 418.3, Definitions. We understand that portion of these qualifications may seem outdated. However, we believe that there may still be individuals who met the requirements of the 1960s and 1970s and who are still practicing in their chosen field today. Therefore, we propose to include these personnel qualifications. We welcome comments on these revisions.

[If you choose to comment on issues related to the qualification standards for social workers, please include the caption ''SOCIAL WORK'' at the beginning of your comments.]

We are specifically requesting comment on the qualifications for a social worker. Hospice care marks the passage from life to death. The services furnished by a hospice takes on a higher level of importance that greatly affects a patient's physical and emotional comfort, and which will be remembered by family members forever. The social worker plays an important role in providing these services to patients and their families. Patients often enter hospice care in a time of crisis and they along with their families sometimes require intense interventions that are handled by a social worker. Patients and their families rely on social workers for emotional support and guidance during the patient's care.

Later, the social worker's goal is to help family members during the bereavement process through in-depth counseling. Bereavement counseling can take many forms, depending on the individuals who will be receiving it. For example, one patient's family may require intimate counseling sessions for the patient's children while a large group session may be more appropriate for nursing facility staff and residents. Determining the exact needs of these individuals and meeting those needs through counseling sessions and other support mechanisms requires the expertise of a qualified social worker.

At present, a social worker is required to possess a bachelor's degree in social work from an accredited school. There is no consensus regarding the optimum qualifications that a social worker must possess when furnishing services to a hospice patient. However, there is strong anecdotal evidence that a social worker who possess a Master's of Social Work (MSW) degree from an accredited institution and who has at least one year of health care experience would provide a higher level patient care. Anecdotal evidence also exists that suggests that patients and families that receive services from a Master's of social work are more satisfied with the care they receive.

In addition to the patient care advantages that MSWs offer, a hospice may anticipate a reduction in overall and per patient costs when utilizing MSWs who have at least one year of experience. A study conducted by the National Hospice and Palliative Care Organization (NHPCO) found that an increase in social work experience after academic training resulted in decreased overall care costs, including nights of continuous care. The study concludes that, ''[h]ospice programs will benefit by hiring the best qualified and most experienced social workers available.'' (Reese, Dana J.; Raymer, Mary; and Richardson, Joan, National Hospice Social Work Survey, 2000 March).

Two issues may contribute to limiting any change in the social work qualification requirement— the availability of personnel to work full time, and the availability of personnel to serve rural areas. Some hospices may not be able to employ an MSW on a full-time basis. Even if CMS were to increase the education requirement to an MSW level, hospices would still be allowed to employ individuals with a bachelor's degree in some circumstances. These individuals would be able to work under the supervision of an MSW and would be identified as social work assistants. A social work assistant would be defined as an individual who has a bachelor's degree from a school accredited by the Council on Social Work Education, or a bachelor's degree in psychology, sociology or another field related to social work.

In 2001, 4,087 MSWs were employed by the nation's 2,316 hospices (National Association for Homecare, 2002 Hospice Industry Report, *http://www.nahc.org/Consumer/hpcstats.html).* We recognize that MSWs may not be available in all areas. If a hospice chooses to also utilize the services of a social work assistant, then the MSW would only have to be employed part-time to supervise the services. According to the NHPCO study, ''[a]ppropriate clinical supervision is essential for social workers. Like any other profession, social workers require supervision by seasoned social work practitioners to continue to grow into high quality skilled professionals.''

We are specifically soliciting comments about whether the care furnished by an MSW should be considered the standard of care for hospice patients. Would an MSW provide a higher level of care than a social worker with a bachelor's degree? Should CMS require that any social worker, regardless of the degree, have at least one year of experience in a health care setting? Should CMS allow social work assistants with bachelor's degrees to function under the supervision of an MSW? Would increasing the qualifications for social workers to an MSW while retaining social work assistants with bachelor's degrees impact patient access to social work services? Would employing both social workers and social work assistants ensure that hospices have the flexibility to meet the needs of patients and their families?

Please note that the policy regarding credentialing would not apply under Medicare Part B, when a specific level or education or training is specified as a precondition for reimbursement. For example, Part B payment may be made for the services of clinical social workers, and the law specifically defines a clinical social worker in section 1861(hh) of the Act. Thus, the definitions contained in this section generally would apply for hospice certification purposes only in States where there were no State licensure requirements.

In § 418.114(d), we are proposing a new requirement that a hospice be required to 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 are soliciting public comment on this proposed standard.

Condition of Participation: Compliance With Federal State and Local Laws and Regulations Related to Health and Safety of Patients (Proposed § 418.116)

The provisions concerning licensure requirements for hospices are currently located at § 418.72, Condition of participation: Licensure. We are proposing to expand this condition in the following manner:

We would make a minor revision to the language at existing § 418.72(a), which would require 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 health and safety of patients. The State agency and CMS would exercise discretion in determining whether a violation of an applicable Federal, State, or local law or regulation related to health and safety would be cited as a violation under the Medicare CoPs. We would not cite a hospice whose problem was remedied. We will cite hospices when violations of Federal, State, and local laws and regulations affect the health and safety of patients; the ability of hospices to deliver quality services; the rights and well-being of patients; and/or the management of the hospice and its ability to recruit qualified staff.

Under § 418.116(b), Multiple locations, we would continue to require that the hospice comply with the requirements of § 420.206 regarding disclosure of ownership and control information. We would also provide 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 provision seeks to ensure that hospice patients receive the same level of quality care from the appropriate personnel at all sites of service. The requirement that hospices comply with State licensure laws before providing services to Medicare beneficiaries would apply to the hospice as an entity as well as to any personnel furnishing services to hospice patients.

We are proposing to recodify the current requirements at § 418.92(b), regarding laboratory services, at § 418.116(c).

IV. Hospice Crosswalk (Cross Refers Existing Requirements to Proposed Requirements)

The following table shows the relationship of the former sections to the current ones.

DERIVATION TABLE

Current conditions (Part 418, subpart C, D, E)	Citation existing section	Proposed condition	Citation
Scope of Subpart			
Definitions	418.3	Definitions	418.3
General provisions	418.50		
(a) Compliance		Organization and Administration of Services.	418.100(c)(2)
(b) Required services		Organization and Administration of Services.	418.100(c)(2)
(c)(1) 24 hour nursing, physician services, and drugs and biologics.		Organization and Administration of Services.	418.100(c)(1)
(2) Other 24 hour services.			
(3) Utilize accepted standards of practice		Core Services and Furnishing of Non-core Services.	418.64 and 418.72
(d) Disclosure of information		Deleted.	
Medical director: The medical director is: A hospice employee, a doctor of medicine or osteopathy, responsible for the medical component of the hospice's patient care program.	418.54	Medical Director	418.102
Professional management	418.56		
(a) Continuity of care		Deleted.	
(b) Written agreement:			
(1) Identification of services to be provided		Interdisciplinary Group Care Planning and Coordination of services.	418.56(c)
(2) Express authorization of the hospice required for all services.		Organization and Administration of Services.	418.100(e)(1)
(3) Coordination, supervision, and evaluation of contracted services.		Organization and Administration of Services.	418.100(e)
(4) Roles of hospice and contractor in admission, assessment, and interdisciplinary group.		Deleted	
(5) Documentation of services furnished by contractor		Organization and administration of services.	418.100(e)
(6) Personnel qualifications		Organization and administration of services.	418.100(e)(2)
(c) Professional management		Organization and administration of services.	418.100(e)
(d) Financial responsibility.			
(e) Inpatient care:			
(1) Copy of the patient plan of care specifying the services to be provided is given to inpatient provider.		Short term inpatient care	418.108(c)(1)
(2) Inpatient provider abides by hospice patient care protocols and maintains compatible policies.		Short term inpatient care	418.108(c)(2)
(3) Medical record provided to hospice upon request. Must include all inpatient services and events and a copy of the discharge summary.		Short term inpatient care	418.108(c)(3)
(4) Responsibility for implementing agreement provisions		Short term inpatient care	418.108(c)(4)

DERIVATION TABLE—Continued

Current conditions (Part 418, subpart C, D, E)	Citation existing section	Proposed condition	Citation
(5) Hospice responsible for training all care providers	.....	Short term inpatient care	418.108(c)(5)
	NEW	Comprehensive Assessment of the Patient Initial assessment.	418.54
	.....	(a) Time frame for the completion of the comprehensive assessment	
	.....	(b) Content of the comprehensive assessment	
	.....	(c) Update of the comprehensive assessment	
	.....	(d) Outcome measures on the patient	
Plan of Care	418.58		
A written plan of care must be established and maintained for each individual admitted to a hospice program and the care provided to an individual must be in accordance with the plan.	.....	Interdisciplinary Group Care Planning and Coordination of Services.	418.56
(a) Plan established by attending physician, medical director or physician designee and interdisciplinary group prior to providing care.	.....	Interdisciplinary Group Care planning and Coordination of Service.	418.56(b)
(b) Plan reviewed, updated, and documented at specified intervals by attending physician, medical director or physician designee and the interdisciplinary group.	.....	Interdisciplinary Group Care Planning and Coordination of Services.	418.56(d)
(c) Plan includes assessment of needs and identification of services. It state in the scope and frequency of services needed.	.....	Interdisciplinary Group Care Planning and Coordination of Services.	418.56(c)
Continuation of care: No discontinuation or diminishment of care due to the Medicare beneficiary's inability to pay for that care.	418.60	Organization and Administration of Services.	418.100(d)
Informed Consent: The Informed consent form specifies the type of care and services that may be provided during the course of the illness, and it must be completed for every individual, either from the individual or representative as defined in 418.3.	418.62	Patient Rights	418.52(a)
Inservice training: A hospice must provide an ongoing program for the training of its employees.	418.64	Organization and Administration of services.	418.100(g)
Quality assurance: A hospice must conduct an ongoing, comprehensive, intetrated, self-assessment of the quality and appropriateness of all care provided. The findings are used to correct problems and revise hospice policies. Those responsible for the quality assurance program must.	418.66	Quality Assessment and performance Improvement.	418.60
(a) Implement and report on activities and mechanisms for monitoring the quality of patient care.	.....	Quality Assessment and performance Improvement.	418.60(d)
(b) Identify and resolve problems	.....	Deleted.	
(c) Make suggesitons for improving patient care	.....	Quality Assessment performance Improvement.	418.60(c)(3)
Interdisciplinary group: The hospice must designate an interdisciplinary group(s) composed of individuals who provide or supervise care and services offered by the hospice.	418.68	IDG Group Care Planning and Coordination of Services.	418.56(a)
(a) The interdisciplinary group(s) must include certain specialists.	.....	IDG Care Planning and Coordination of Services	418.56(a)
(b) The interdisciplinary group is responsible for—			
(1) Participation in the establishment of the plan of care ..	.....	IDG Care Planning and Coordination of Services.	418.56(b)
(2) Provision of supervision of hospice care and services	.....	IDG Care Planning and Coordination of Services.	418.56(a)(1)(3)
(3) Periodic review and updating of the plan of care for each individual receiving hospice care; and.	.....	IDG Care Planning and Coordination of Services.	418.56(d)
(4) Establishment of policies governing the day-to-day provision of hospice care and services.	.....	IDG Care Planning and Coordination of Services.	418.56(a)(2)
Only one interdisciplinary group chosen in advance may execute the functions described in the paragraph (b)(4) of this section.	.....	Deleted.	
(d) Designating a registered nurse to coordinate the implementation of the plan of care for each patient.	.....	IDG Care Planning and Coordination of Services.	418.56(a)(1)
Volunteers: The hospice in accordance with the numerical standards, specified in paragraph (e) of this section, uses volunteers, in defined roles, under the supervision of a designated hospice employee.	418.70	Volunteers	418.78
(a) The hospice must provide appropriate orientation and training.	.....	Volunteers	418.78(a)
(b) Volunteers must be used in direct patient care or administrative roles.	.....	Volunteers	418.78(b)

DERIVATION TABLE—Continued

Current conditions (Part 418, subpart C, D, E)	Citation existing section	Proposed condition	Citation
(c) The hospice must document active and ongoing efforts to recruit and retain volunteers.	.....	Volunteers	418.78(c)
(d) The hospice must document the cost savings achieved through volunteer use. Documentation must include— (1) Necessary positions which are occupied by volunteers. (2) The work time spent by volunteers occupying those positions; and (3) Estimates of the dollar costs of paying employees to occupy the positions identified in (d)(1) for the time specified in (d)(2).	.....	Volunteers	418.78(d)
(e) Volunteer staff providing direct patient care and administrative support must equal at least 5 percent of the total patient care hours of all paid hospice employees and contract staff. Any expansion of care and services achieved by using volunteers, including the type of services and time worked, must be recorded.	.....	Volunteers	418.78(e)
(f) Reasonable efforts made to arrange for visits of members of religious organizations to patients who request such visits and must advise patients of this opportunity.	.....	Deleted.	
Licensure: The hospice and all its employees must be licensed in accordance with applicable Federal, State, and local laws and regulations.	418.72	Compliance with Federal, State & local laws & regulations related to health & safety of patients.	418.116
(a) The hospice must be licensed if State or local law provides for licensure.	.....	Personnel Qualifications for Skilled Professionals; and Compliance with Federal, State & local laws & regulations related to health & safety of patients.	418.114 and 418.116(a)
(b) Employees who provide services must be licensed, certified or registered in accordance with applicable Federal or State laws.			
Central Clinical Records: Establishment and maintenance of a clinical record for every patient. The record must be complete, promptly and accurately documented, readily accessible and systematically organized to facilitate retrieval.	418.74	Clinical Records	418.104
(a) Clinical record is comprehensive. Entries are made and signed for all services provided whether furnished directly or under arrangements made by the hospice. Each individual's record contains—.	.....	Clinical Records	418.104(a)
(1) Initial and subsequent assessments	.....	Clinical Records	418.104(a)(1)
(2) Plan of care	.....	Clinical Records	418.104(a)(1)
(3) Identification data	.....	Deleted.	
(4) Consent and authorization and election forms	.....	Clinical Records	418.104(a)(2)
(5) Pertinent medical history	.....	Deleted.	
(6) Complete documentation of all services and events	.....	Clinical Records	418.104(a)(1)
(b) Protection of information. The hospice must safeguard the clinical record against loss, destruction, and unauthorized use.	.....	Clinical Records	418.104(c)
Subpart D—Condition of Participation: Core Services:			
Furnishing of Core Services: Hospice employees must routinely provide all core services. Contracted staff may supplement hospice employees to meet patient needs during peak periods or under extraordinary circumstances. The hospice must maintain professional, financial, and administrative responsibility for contracted services and must assure that the qualifications of staff and services provided meet specified requirements. See exception in 418.83.	418.80	Core services	418.64
Nursing services: Nursing care and services provided by or under the supervision of a registered nurse.	418.82	Core services	418.64(b)
(a) The nursing needs of the patients must be met	.....	Core services	418.64(b)
(b) Patient care responsibility of nursing personnel must be specified.	.....	Deleted.	
(c) Services are provided in accordance with recognized standards of practice.	.....	Core services	418.66
Waiver of all requirements that substantially all nursing services be routinely services be routinely provided directly by a hospice.	418.83	Nursing service waver (re-codified).	418.66
(a) Waiver if located in non-urbanized area, operational on or before January 1, 1983, and good faith effort made to fulfill staffing needs.			

DERIVATION TABLE—Continued

Current conditions (Part 418, subpart C, D, E)	Citation existing section	Proposed condition	Citation
(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 one year at a time. (d) HCFAa may approve a maximum of two one-year extensions for each initial waiver.			
Medical social services: Medical social services must be provided by a qualified social worker, under the direction of a physician.	418.84	Core services	418.64(c)
Physician services: In addition to palliation and management of terminal illness and related conditions, physician employees of the hospice must also meet the general medical needs of the patient.	418.86	Core services	418.64(a)
Counseling services: Counseling services, including bereavement, dietary, and spiritual counseling, must be available to both the individual and the family.	418.88	Core services	418.64(d)
(a) Organized program for the provision of bereavement services under the supervision of a qualified professional. A special coverage is specified in 418.204(c).	.....	Core services	418.64(d)(1)
(b) Provision of dietary counseling	.....	Core services	418.64(d)(2)
(c) Spiritual counseling must include notice to patients as to the availability of the clergy as provided in 418.70(f).	.....	Core services	418.64(d)(3)
(d) Counseling may be provided by others	.....	Deleted.	
Subpart E—Condition of Participation: Other services:			
Furnishing other services: The services described in this subpart must be provided directly by hospice employees or under arrangements made by the hospice as specified in 418.56.	418.90	Furnishing of non core services ..	418.70
Physical therapy, occupational therapy and speech language pathology.	418.92(a)		418.70, 418.72
(a) Physical therapy, occupational therapy, and speech-language pathology services must be available and provided under acceptable standards of practice.	.....	Physical therapy, occupational therapy and speech language pathology and dietary counseling, Non-core services.	418.70, 418.72
(b)(1) Laboratory testing services must be in compliance with all applicable requirements of part 493 of this chapter.	.....	Compliance with Federal, State & local laws & regulations related to the health & safety of patients.	418.116(c)(1)
(2) All referral laboratories must be certified in the appropriate specialties and subspecialties of services. See part 493 of this chapter.	.....	Compliance with Federal, State & local laws & regulations & related to the health & safety of patients.	418.116(c)(2)
Home health aide and homemaker service: Home health aide and homemaker must be services available and adequate in frequency to meet the needs of the patients. A home health aide is a person who meets the training, attitude and skill requirements specified in 484.36 of this chapter.	418.94	Home Health Aide and homemaker services.	418.76
(a) Standard: A registered nurse visits the home site at least every two weeks when aide services arebeing provided, and conducts an assessment of the aide services.	.....	Home health aide and homemaker services (revised).	418.76(h)(1)
(b) Standard: A registered nurse prepares written instructions for patient care. Duties include, but may not be limited to, the duties specified in 484.36(c) of this chapter.	.....	Home health aide and homemaker services.	418.76(g)(1)
Medical supplies: Medical supplies, appliances, drugs and biologicals must be provided for the palliation and management of the terminal illness and related conditions.	418.96	Drugs, controlled drugs, and biologicals, medical supplies and durable medical equipment.	418.106
(a) All drugs and biologicals must be administered in accordance with accepted standards of practice.	.....	Drugs, controlled drugs, and biologicals, medical supplies and durable medical equipment.	418.106(a)
(b) The hospice must have a policy for the disposal of extraneous controlled drugs maintained in the patient's home.	.....	Drugs, controlled drugs, and biologicals, medical supplies and durable medical equipment.	418.106(b)
(c) Only certain individuals may administer drugs and biologicals.	.....	Deleted.	
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.	.....	Short term inpatient care	418.108
(a) Inpatient care for pain control and symptom management must be provided in one of the following:	.....	Short term inpatient care	418.108(a)

DERIVATION TABLE—Continued

Current conditions (Part 418, subpart C, D, E)	Citation existing section	Proposed condition	Citation
(1) A hospice that meets the standards for providing inpatient care directly specified in 418.100.	.....	Short term inpatient care	418.108(a)(1)
(2) A hospice or skilled nursing facility that also meets the standards of 418.100(a) and (e).	.....	Short term inpatient care	418.108(a)(2)
(b) Inpatient care for respite purposes must be provided by: ...	.....	Short term inpatient care	418.108(b)
(1) A provider specified in paragraph (a) of this section	.....	Short term inpatient care	418.108(b)(1)
(2) An intermediate care facility (ICF) meeting the standards in 418.100 (a) and (e).	.....	Short term inpatient care (delete ICF and replace with nursing facility (NF)).	418.108(b)(2)
(c) Inpatient care for Medicare beneficiaries may not exceed 20 percent of the total number of days for this beneficiary group.	.....	Short term inpatient care	418.108(d)
(d) Exemption from limitation in paragraph (c)	.....	Short term inpatient care	418.108(e)
Hospices that provide inpatient care directly: A hospice that provides inpatient care directly must comply with all of the following standards.	418.100	Hospices that provide inpatient care directly.	418.110
(a) Twenty-four hour nursing services:			
(1) The facility provides 24-hour nursing services in accordance with patient plan of care sufficient to meet total nursing needs.	.....	Hospices that provide inpatient care directly.	418.110(b)
(2) Each shift includes a direct care registered nurse	.....	Deleted.	
(b) The hospice has an acceptable written plan, periodically rehearsed with staff, with internal and external disaster procedures.	.....	Hospices that provide inpatient care directly.	418.110(c)(1)(iii)
(c) The hospice must meet all Federal, State and local laws, regulations, and codes pertaining to health and safety.	.....	Compliance with Federal, State & local laws and regulations related to health and safety of patients.	418.116
(d) Fire protection	.....	Hospices that provide inpatient care directly.	418.110(d)(1)
(1) Hospices must comply with the 1985 edition of the Life Safety Code of the NFPA. See exceptions in (d)(2) and (3).			
(2) Waiver for specific provisions of Life Safety Code.			
(3) 1981 edition compliance by May 9, 1988 will be considered as meeting this standard.			
(4) Restrictions on facilities of two or more stories not of fire resistive construction.			
(e) Patient areas.	.....	Hospices that provide inpatient care directly.	418.110(e)
(1) Design and equipment of patient/family areas.			
(2) Specifications for patient/family accommodations			
(3) Visitor specifications.			
(f) Patient rooms and toilet facilities.	.....	Hospices that provide inpatient care directly.	418.110(f)
(1) Specifications for equipment, size, and location of patient rooms and toilet.			
(2) Waiver of space and occupancy requirements for unreasonable hardships.			
(g) Requirements for bathroom facilities	.....	Hospices that provide inpatient care directly.	418.110(g), 418.110(h)
(h) Requirements for linens	.....	Hospices that provide inpatient care directly.	418.110(k)
(i) Isolating areas for patients with infectious diseases	.....	Hospices that provide inpatient care directly.	418.110(j), 418.110(i)
(j) Meal service and menu planning	.....	Hospices that provide inpatient care directly.	418.110(l)
(1) Three meals a day served at regular times; no more than 14 hours between substantial evening meal and breakfast.	418.100	Deleted.	
(2) Procure, store, prepare, distribute, and serve all food under sanitary conditions.	.....	Deleted.	
(3) Have a staff member trained or experienced in food management or nutrition.			
(4) A professionally qualified dietitian must plan and supervise a menu for patients requiring special diets.			
(k) Pharmaceutical services. The hospice provides appropriate methods and procedures for the dispensing and administering of drugs and biologicals.	.....	Hospices that provide inpatient care directly.	418.110(m)

DERIVATION TABLE—Continued

Current conditions (Part 418, subpart C, D, E)	Citation existing section	Proposed condition	Citation
(1) Licensed pharmacist The hospice must—	.....	Hospices that provide inpatient care.	418.110(n)
(i) employ a licensed pharmacist; or			
(ii) have a formal agreement with a licensed pharmacist to advise the hospice on ordering, storage, administration, disposal and record keeping of drugs and biologicals.			
(2) Orders for medications.	.....	Hospices that provide inpatient care directly.	418.110(n)
(i) Physician orders all patient medications.			
(ii) Verbal medication order:			
(A) Only given to a registered nurse, pharmacist, or physician.			
(B) the individual receiving the order must record and sign it immediately and have the prescribing physician sign it in a manner consistent with good medical practice.			
(3) Medications are administered only by one of the individuals specified.			
(4) The pharmaceutical service has procedures for control and accountability of all drugs and biological throughout the facility, including record keeping and reconciliation procedures.			
(5) The labeling of drugs and biologicals is based on currently accepted professional principles, and includes the appropriate accessory and cautionary instructions, as well as the expiration date when applicable.			
(6) All drugs and biologicals are stored and locked in compartments under proper temperature controls and only authorized personnel have access to the keys. Separately locked compartments are provided for schedule II and other drugs subject to abuse, except under single unit package drug distribution systems. An emergency medication kit is kept readily available.			
(7) Extraneous controlled drugs are disposed of in compliance with State requirements. When none apply, the pharmacist and a registered nurse must dispose of the drugs and prepare a record of the disposal.			
	NEW	Hospices that provide inpatient care directly: Seclusion and Restraint.	418.110(o)
	NEW	Waiver of Physical therapy, occupational therapy and speech language pathology and dietary counseling.	418.74
	NEW	*Hospices that provide hospices care to residents of a SNF/NF, ICF/MR or other facility* 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 abide by the following additional standards.	418.112
		(a) Standard: Resident eligibility, election, and duration of benefits.	418.112(a)
		(b) Standard: Professional management.	418.112(b)
		(c) Standard: Core services	418.112(c)
		(d) Standard: Medical director	418.112(d)
		(e) Standard: Written agreement	418.112(e)
		(f) Standard: Hospice plan of care.	418.112(f)
		(g) Standard: Coordination of services.	418.112(g)
		(h) Standard: Transfer, revocation, or discharge from hospice.	418.112(h)

DERIVATION TABLE—Continued

Current conditions (Part 418, subpart C, D, E)	Citation existing section	Proposed condition	Citation
		(i) Standard: Orientation and training of staff.	418.112(i)
	NEW	*Personnel qualifications*	418.114
		(a) General qualification requirements.	418.114(a)
		(b) Federally defined qualifications.	418.114(b)
		(c) Personnel qualifications when no States licensing laws, certification or registration requirements exist.	418.114(c)
		Criminal background checks	418.114(d)
	NEW	*Compliance with Federal, State, & local laws and regulations related to health and safety of patients* The hospice and its staff must operate and furnish services in compliance with all applicable Federal, State, & local laws & regulations related to the health & safety of patients. If State and local law provides for licensing of hospices, the hospice must be licensed.	418.116
		(a) Standard: Licensure of staff ..	418.116(a)
		(b) Standard: Multiple locations ..	418.116(b)
		(c) Standard: Laboratory services	418.116(c)

V. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information 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 PRA 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.

We are soliciting public comment on each of these issues for the information collection requirements discussed below. The following information collection requirements in this proposed rule and the associated burdens are subject to PRA.

Section 418.52 Condition of Participation: Patient's Rights

Paragraph (a) of this section would require that the hospice provide each patient with: a verbal and written notice of the patient's rights and responsibilities during the initial evaluation visit, in advance of furnishing care; written information concerning its policies on advance directives, including a description of applicable State law; and written or verbal information regarding the hospice's drug policies and procedures, including the tracking and disposing of controlled substances. The hospice would also be required to maintain documentation showing that it complied with the requirements of this section and that the patient or representative demonstrated an understanding of these rights.

The burden associated with these requirements would be the time associated with disclosing the information and documenting that the hospice did disclose the information. We estimate that this would take approximately 5 minutes per patient or 24.58 hours per hospice, for an annual total of 59,417 hours.

Paragraph (b) of this section would require a hospice to document a patient/representative complaint, and the steps taken by the hospice to resolve it.

The burden associated with this requirement would be the time it took to document the necessary aspects of the issues. We anticipate 15 complaints per year per hospice and 15 minutes to document the complaint and resolution activities, for a total of 9,045 hours annually.

Paragraph (e) of this section would require the patient to be informed of the extent to which payment may be expected from the patient, Medicare or Medicaid, third-party payers, or other resources of funding known to the hospice, verbally and in writing, and in a language that he or she can understand, before care is initiated. The burden associated with this requirement would be the time it would take to notify patients. We estimate that it would take no more than 5 minutes per patient, for a total of 24.58 hours per hospice and 59,417 hours nationally.

Section 418.54 Condition of Participation: Comprehensive Assessment of the Patient

This section would require each hospice to conduct and document in writing a comprehensive patient-specific assessment, and maintain documentation of the assessment and any updates.

The burden associated with this requirement would be the time it would

take to record the assessment and any changes/updates to it. We believe that documenting a patient assessment is a usual and customary business practice and as such the burden is not subject to the PRA.

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

This section would require all hospice care and services furnished to patients and their families to follow a written plan of care established by the hospice interdisciplinary group in collaboration with the attending physician. The hospice would be required to ensure that each patient/family and primary caregiver(s) receive education and training provided by the hospice as appropriate to the care and services identified in the plan of care. The section would specify the minimum elements the plan of care must include.

In addition, the medical director or physician designee and the hospice interdisciplinary team, in collaboration with the individual's attending physician, would be required to 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 would have to include information from the patient's updated comprehensive assessment, and would have to document the patient's progress toward the outcomes specified in the plan of care.

These requirements are subject to the PRA; however, they are currently approved under OMB control number 0938–0302 with a current expiration date of September 30, 2006.

The burden associated with these requirements would be the time it would take to document the plan of care (10 minutes) and any revisions to it (15 minutes) in the clinical record. We estimate that it would take 25 minutes to comply with these requirements per patient, for a total of 123 hours on average per hospice, and 297,083 hours nationally.

Section 418.58 Condition of Participation: Quality Assessment and Performance Improvement

This section would require a hospice to develop, implement, and maintain an effective ongoing hospice-wide data-driven quality assessment and performance improvement (QAPI) program. The hospice's governing body would have to ensure that the program reflected the complexity of its organization and services; involved all hospice services, including those services furnished under contract or arrangement; focused on indicators related to improved palliative outcomes and end-of-life support services provided; and took actions to demonstrate improvement in hospice performance. The hospice would be required to maintain and demonstrate evidence of its quality assessment and performance improvement program and be able to demonstrate its operation to the CMS.

The hospice would be required to take actions aimed at performance improvement and, after implementing those actions, the hospice must measure its success and track its performance to ensure that improvements were sustained.

The hospice would be required to document what quality improvement projects were being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

The burden associated with this requirement would be the time it would take to document the development of the quality assessment and performance improvement and associated activities. We estimate that it would take each hospice an average of 24 hours per year to comply with these requirements for a total of 57,888 hours annually.

Section 418.60 Condition of Participation: Infection Control

The hospice would be required to maintain and document a coordinated infection control program that protected patients, families and hospice personnel by preventing and controlling infections and communicable diseases.

The burden associated with this requirement would be the time it would take to document the program. We believe that this proposed requirement reflects usual and customary medical and business practice; thus the burden is not subject to the PRA.

Section 418.64 Condition of Participation: Core Services

We are proposing that a hospice could choose to enter into an arrangement with another hospice to obtain personnel to furnish core hospice services under certain circumstances. Such an arrangement would have to be supported by a legally binding written agreement. The burden associated with this requirement would be the time required to negotiate, draft and sign an agreement. We believe that this requirement is a customary and usual business practice. Thus, the burden would not be subject to the PRA.

Under the nursing services standard for this condition, the hospice could enter into a written agreement for the provision of certain nursing services by an outside body. The burden associated with this requirement would be the time required to negotiate, draft and sign an agreement. We believe that this requirement is a customary and usual business practice. Thus, the burden would not be subject to the PRA.

Under the counseling standard for this condition, the hospice would be required to advise the patient/family that the hospice would facilitate visits by local clergy, pastoral counselor, or other individuals who could support the patient's spiritual needs. We believe that this requirement is a customary and usual hospice practice, and is therefore not subject to the PRA.

Section 418.66 Condition of Participation: Nursing Services Waiver of Requirement That Substantially all Nursing Services Be Routinely Provided Directly by a Hospice

Under this section, if a hospice wanted a waiver from the requirement that substantially all nursing services be routinely provided by the hospice, it would be required to provide evidence that it made a good faith effort to hire a sufficient number of nurses to provide services. To extend the waiver, the hospice would be required to submit a request to CMS attesting that the conditions under which it originally requested the initial waiver had not changed since the initial waiver was granted.

The burden associated with this requirement would be the time it would take to provide the necessary documentation, and the time it would take to request an extension. We estimate that there will be no more than 5 hospices providing the information and requesting extensions. Under section 1320.3, this requirement would not be subject to the PRA as it would affect fewer than 10 entities.

Section 418.74 Condition of Participation: Waiver of Requirement-Physical Therapy, Occupational Therapy, Speech-Language Pathology, and Dietary Counseling

A hospice located in a non-urbanized area would be able to submit a written request for a waiver of the requirement that the hospice directly provide physical therapy, occupational therapy, speech-language pathology, and dietary counseling services. The hospice would be able to 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 would also be able to seek a waiver of the requirement that it provide dietary counseling directly. The hospice would have to provide evidence that it had made a good faith effort to meet the requirements for these services before it sought such a waiver. To extend the waiver, the hospice would be required to submit a request to CMS recertifying that the conditions under which it originally requested the initial waiver had not changed since the initial waiver was granted.

The burden associated with this requirement would be the time it would take to provide the necessary documentation and the time it would take to request an extension. We estimate that there would be no more than 5 hospices providing the information and requesting extensions. Under section 1320.3, this requirement would not be subject to the PRA, since it would affect fewer than 10 entities.

Section 418.76 Condition of Participation: Home Health Aide and Homemaker Services

Under this section, the hospice would be required to maintain documentation that it met the requirements of the standard concerning the content and duration of home health aide classroom and supervised practical training, competency evaluation, and in-service training.

We estimate that it would take approximately 5 minutes per home health aide to document meeting this standard and that 2,412 home health aides would be trained each year nationally, for a total of 201 hours annually.

Under this section, written patient care instructions would have to be prepared by a registered nurse or other licensed professional.

We believe that this requirement reflects a usual and customary business practice and the burden would not be subject to the PRA.

Home health aides would be required to report changes in the patient's medical, nursing, rehabilitative, and social needs to a registered nurse or other appropriate licensed professional, and complete appropriate records in compliance with the hospice's policies and procedures. In addition, as members of the interdisciplinary team, home health aides would be required to report any change in a patient's condition as the change related to the plan of care and quality assessment and performance improvement activities.

Under this section as well, homemakers would be required to report all concerns about the patient or family to the member of the interdisciplinary group who was coordinating homemaker services.

We believe that reporting and documenting this is a usual and customary business practice and, as such, the burden would not be subject to the PRA.

Section 418.78 Conditions of Participation—Volunteers

Under this section, the hospice would be required to maintain, document and provide volunteer orientation and training that was consistent with hospice industry standards.

We estimate that on average a hospice would provide orientation and training 6 times per year and that it would take no more than five minutes to document each orientation session, for a total of 30 minutes per year, and a national total of 1,206 hours.

Under this section, the hospice would be required to document savings achieved through the use of volunteers.

We estimate that this activity would take approximately 3 hours per hospice per year, or 7,236 hours nationally.

The hospice would also be required to record examples of patient care tasks and administrative services performed by volunteers, including the type of services and time worked.

We estimate that recording these examples would take approximately 600 hours per year per hospice, or 1,447,200 hours nationally.

Section 418.100 Condition of Participation: Organization and Administration of Services

Under paragraph (e) of this section, arranged services would be required to be supported by written agreements that would have to require specified activities.

Written agreements are a necessary part of usual and customary business practice; thus, the burden would be exempt from the PRA under section 1320.3(b)(2).

Under paragraph (g), the hospice would be required to have written policies and procedures describing its method(s) of assessing competency and would be required to maintain a written description of the in-service training provided during the previous 12 months.

Written policies and procedures are a necessary part of usual and customary business practice; thus, we believe that the burden would be exempt from the PRA under section 1320.3(b)(2).

Section 418.102 Condition of Participation: Medical Director

This section would require the medical director or physician designee to review the clinical information for each hospice patient and provide written certification that it was anticipated that the patient's life expectancy was 6 months or less if the illness were to run its normal course.

The burden associated with this would be the review time and the written certification. We estimate that it would take approximately 10 minutes per patient, for a total of 49 hours per hospice annually and 118,833 nationally.

Section 418.104 Condition of Participation: Clinical Records

Under this section the hospice would be required to maintain on each patient a clinical record that contained accurate clinical information and was available to the patient's attending physician and hospice staff.

The burden associated with this requirement would be the time it would take to maintain a record on each patient. We believe that the requirement reflects usual and customary medical practices and, as such, the burden would not be subject to the PRA.

Paragraph (e) of this section would require that, if the care of a patient were transferred to another Medicare/Medicaid-approved facility, the hospice would be required to forward a copy of the patient's clinical record and the hospice discharge summary to that facility. If a patient revoked the election of hospice care, or was discharged from hospice because eligibility criteria were no longer met, the hospice would have to provide a copy of the clinical record and the hospice discharge summary of this section to the patient's attending physician.

The burden associated with this requirement would be the time it took to forward the clinical record and discharge summary. This is a usual and customary business practice, and as such the burden would not be subject to the PRA.

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

Under paragraph (b), the hospice would be required to have a written policy for tracking, collecting, and disposing of controlled drugs maintained in the patient's home.

The burden associated with this requirement would be the time it would require to put the policy in writing. Written policies are a necessary part of usual and customary business practice; thus, we believe that the burden would be exempt from the PRA under section 1320.3(b)(2).

Under paragraph (b) of this section, during the initial hospice assessment, the use and disposal of controlled substances would be required to be discussed with the patient and family to ensure the patient and family were educated regarding the use and potential danger of controlled substances. The hospice nurse would be required to document that the policy was discussed with the patient and family.

We anticipate that the discussion and documentation of the discussion would take approximately 5 minutes per patient, and 24.58 hours per hospice, for a total of 59,417 hours annually for all patients.

Under paragraph (c) of this section, if, for a piece of equipment, there were no manufacturer recommendations for repair and routine maintenance, the hospice would be required to develop in writing its own repair and routine maintenance policy.

The burden associated with this requirement would be the time required to put the policy in writing. Written policies are a necessary part of usual and customary business practice; thus, we believe that the burden would be exempt from the PRA under section 1320.3(b)(2).

Section 418.108 Condition of Participation—Short-Term Inpatient Care

If the hospice had an arrangement with a facility to provide for short-term inpatient care, the arrangement would have to be described in a legally binding written agreement that at a minimum contained specified elements.

The burden associated with this requirement would be the time it took to negotiate, draft, and sign the agreement. Having written agreements is a usual and customary business practice and, as such, we believe that the burden would not be subject to the PRA.

Section 418.110 Condition of Participation: Hospices That Provide Inpatient Care Directly

Under paragraph (c)(1)(i) of this section, we would require a hospice to report breaches of safety and equipment failures to the appropriate State and local bodies having regulatory jurisdiction.

The reporting burden associated with this requirement would be the time required to report such safety and equipment breaches. We estimate that there would be approximately 110 safety and equipment breaches annually nationwide. Filing a report regarding these events would take approximately 30 minutes per event for a total of 55 hours annually nationwide.

Under paragraph (c)(1)(iii) of this section, the hospice would be required to have a written disaster preparedness plan in effect for managing the consequences of power failures, natural disasters, and other emergencies that might affect the hospice's ability to provide care.

The burden associated with this requirement would be the time it took to write the disaster preparedness plan. We believe that hospices will each spend 1 hour developing a disaster plan for a total of 2,412 hours on a one time basis.

Under paragraph (m) of this section, under the direction of a qualified pharmacist, the hospice would be required to provide pharmaceutical services such as drugs and biologicals and have a written protocol in place that would ensure dispensing accuracy.

The burden associated with this requirement would be the time it took to devise and write down the protocol. We believe that having such a protocol in writing is a usual and customary business practice, and, as such, we believe that the burden would be exempt from the PRA.

Paragraph (n) of this section would require a physician to order all medications for a patient; all drugs and biologicals to be labeled in accordance with accepted professional practice, containing specified information; and would require the hospice to keep current and accurate records of the receipt and disposition of all controlled drugs. Any discrepancies in the acquisition, storage, use, disposal, or return of controlled drugs would have to be investigated immediately by the pharmacist and hospice administrator and, where required, reported to the appropriate State agency; a written account of the investigation would be required to be made available to State and Federal officials.

The burden associated with these requirements would be the time required to (1) document orders, label drugs, and maintain current and accurate records of the receipt and disposition of all controlled drugs; and (2) document, investigate, and report drug discrepancies. We believe that the first requirement, concerning ongoing documentation, reflects customary and usual medical and business practices and the burden would therefore be exempt under the PRA. For the documentation, investigation and reporting of drug discrepancies, we estimate that there are 55 events annually that would require such documentation, and that each event would require one hour of labor to meet the proposed requirements for a total of 55 hours nationally annually.

Paragraph (o) of this section would require orders for a physical restraint or seclusion to be written, and that physical restraint or seclusion be supported by a documented order and the patient's response or outcome and documented in the patient's clinical record. In addition, the hospice must report any death that occurs while the patient is restrained or in seclusion.

We estimate that there would be approximately 7,130 incidents of physical restraint or seclusion and that it would take approximately 4 minutes to write the orders and to document the incident, for an annual national total of 475 hours. Additionally, it would take six hours for a hospice to develop a customized pre-printed seclusion and restraint order, totaling 14,472 hours nationwide on a one-time basis.

We have no concrete estimate of the number of deaths that would occur per year that occurred while the patient was restrained or secluded. We believe that the number of deaths is less than 10 per year, and we would expect that number to decrease as hospices implement the proposed new seclusion and restraint requirements. Therefore, under section 1320.3, this requirement is not subject to the PRA, as it would affect fewer than 10 entities.

Section 418.112 Condition of Participation: Hospices That Provide Hospice Care to Residents of a SNF/NF, ICF/MR, or Other Facility

Paragraph (e) of this section would require the hospice and the other facility to have a written agreement that would specify the terms under which the hospice would provide hospice services in the facility, and would require the agreement to be signed by authorized representatives of the hospice and the facility, before the hospice could provide such hospice services. The written agreement would have to include specified information and documents.

The burden associated with this requirement would be the time required to draft and sign an agreement and to gather the information to be sent on each patient. Both of these requirements can be considered customary and usual medical and business practices. Thus, the burden would not be subject to the PRA.

Paragraph (f) of this section would require a written plan of care to be established and maintained for each facility patient, developed by and coordinated with the hospice interdisciplinary group in consultation

with facility representatives, and in collaboration with the individual's attending physician. The plan of care would be required to include specified information.

This proposed burden is included with the burden discussed under section 418.56.

Under paragraph (g) of this section we would require a hospice to provide the facility with the following information specified in this paragraph.

The burden associated with this requirement would be the time required by staff to compile the information. However, we believe that such information compilation is a usual and customary medical and business practice. Thus, the burden would not be subject to the PRA.

Section 418.114 Condition of Participation: Personnel Qualifications for Skilled Professionals

Paragraph (d) of this section would require each hospice to obtain a criminal background check on each employee, including but not limited to those employees who have hands-on patient contact, those who are employed in an administrative or maintenance capacity, those who are volunteers, and those who provide services under contract. The background check would be required to be obtained before the hospice would employ that person.

In 2002, 39 states required criminal background checks for hospice employees. In these states approximately 70,395 hospice employees have already received a criminal background check, thus greatly reducing the overall burden. We estimate that hospices that have not previously performed background checks, accounting for 19,876 hospice employees, would each obtain 39 criminal background checks initially. Each background check request form would take 6 minutes to prepare and send, for a total of 4 hours per hospice the first year. For each year thereafter all hospices would complete background checks on approximately 8 new employees per year for a total of 48 minutes per hospice per year and 1,852 hours nationally per year.

The total burden of these requirements would be 2,117,529 hours annually and 16,888 hours on a one-time basis.

To comment on these information collection and record keeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn: William Parham, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Christopher Martin, CMS Desk Officer, (CMS–3844–P), *Christopher_Martin@omb.eop.gov.* Fax: (202) 395–6974.

VI. 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 $13.7 million annually.

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 government agencies. Individuals and States are not included in the definition of a small entity. For purposes of the RFA, most hospices (approximately 73% of Medicare certified facilities) are considered to be small entities, either by virtue of their nonprofit or government status or by having revenues of $6 million to $29 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 2,412 hospices with average admissions of approximately 295 patients per hospice (based on the number of patients in 2003 divided by the number of hospices in 2003). The National Hospice and Palliative Care Organization estimates that 79 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 2003 national expenditure data, Medicare paid $5.7 billion to providers for hospice care in 2003. We estimate this rule will cost hospices approximately $16.9 million or approximately $7,389 per statistically average hospice annually.

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 three 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; group 2 hospices providing 1,755 to 4,373 routine home care days; and group 3 hospices providing 4,374 to 9,681 routine home care days. Group 1 hospices, averaging 23 patients per year, would spend approximately $1,845 to comply with the proposed regulations. The average hospice in this group received $101,181 from Medicare for routine home care days under the 2002 hospice payment rates. Group 2 hospices, averaging 77 patients per year would spend approximately $2,936 to comply with the proposed regulations. The average hospice in this group received $325,533 from Medicare for routine home care days under the 2002 rates. Group 3 hospices, averaging 173 patients per year, will spend approximately $4,889 to comply with the proposed regulations. The average hospice in this group received $767,550 from Medicare for routine home care days under the 2002 rates.

The time and cost burden for these providers is significantly less than that of the statistically average hospice used in part B of this section because the majority of the burden imposed by the proposed regulations is directly tied to patient care and the staff necessary to provide care. Therefore, a reduced patient census leads to reduced burden. These figures do not, however, adjust the estimated quality assessment and performance improvement burden

described in part B of this section. We estimate that the financial burden for group 1 hospices would be 1.75 percent of the payment received for routine home care days. For group 2 hospices the financial burden would be less than 1 percent, and for group 3 hospices the financial burden would be less than 0.75 percent of Medicare payments for routine home care days. 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 21 percent of hospice revenue.

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. 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 proposed rule that may result in an expenditure of $110 million or more in any one year by a State, local, or tribal government, in the aggregate, or by the private sector. This rule has no impact on the expenditures of State, local, or tribal governments, and the impact on the private sector is estimated to be far less than $110 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent 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 proposed regulation 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 the new provisions. The provisions contained in the existing regulations are simply being re-codified and therefore do not present a new burden to hospices.

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.

TABLE 1.—ASSUMPTIONS AND ESTIMATES USED THROUGHOUT THE IMPACT ANALYSIS SECTION

Number of Medicare hospices nationwide	2,412
Number of hospice patients nationwide	713,000
Number of patients per average hospice	295
Hourly rate of registered nurse	$27
Hourly rate of office employee	$19
Hourly rate of administrator	$42
Hourly rate of home health aide	$14
Hourly rate of pharmacist	$45
Hourly rate of medical director	$84

Patient Rights (§ 418.52)

The proposed rule would expand 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 would be required to provide patients or their representatives with written and verbal notice of the patient's rights and responsibilities during the initial evaluation and would have to document this notification as well as document that the patient/representative understands their rights.

A hospice would also be required to inform and distribute written information regarding its policies on advance directives, and it would have to inform the patient, representative, and family of its drug policies and procedures. We estimate that it would take eight hours on a one-time basis for a hospice to develop a patient rights form, at a cost of $336, based on the assumption that an administrator will develop the form. We estimate that it would 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 would cost $2.25 per patient to fulfill the requirement.

- 8 hours × $42 an hour = $336
- $27 hour/60 minutes = $0.45 minute × 5 minutes = $2.25

(b) Standard: Exercise of rights and respect for property and person. A hospice would be required to investigate and document all allegations, unexplained injuries, and misappropriations. It would be required to report such incidents to the hospice administrator and appropriate State and local bodies having jurisdiction, and take action to correct problems once they were identified.

We expect that a hospice administrator would handle the investigations. 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. We estimate that hospices will spend, on average, three minutes per patient, at a cost of $2.10 per patient per year to comply with this provision. The cost for the entire hospice industry would be $1,497,300 a year, while the cost for an average hospice would be $619.50 a year.

- 15 hours × 60 minutes = 900 minutes, 900 minutes/295 patients = 3 minutes per patient
- $42 hour/60 minutes = $0.70 per minute x 3 minutes per patient = $2.10 per patient
- $2.10 per patient × 713,000 patients = 1,497,300,
- $2.10 per patient × 295 patients = $619.50

(c) Standard: Pain management and symptom control. There is no burden associated with this standard.

(d) Standard: Confidentiality of clinical records. There is no burden associated with this standard.

(e) Standard: Patient liability. A hospice would be required to inform a patient verbally and in writing about his or her payment liability. Developing a form to notify patients is not a burden because CMS has already developed this form, CMS–R131, Advanced Beneficiary Notice (ABN). Informing the patient verbally and in writing would take five minutes per patient to fulfill, or 24.58 hours per average hospice and 59,417 hours nationwide. The estimated cost would be $2.25 per patient, $663.75 per hospice, and $1,604,250 nationwide.

- 5 minutes per patient × 295 patients = 24.58 hours
- 5 minutes per patient × 713,000 patients = 59,417 hours
- $27 hour/60 minutes = $0.45 minute × 5 minutes = $2.25
- $2.25 per patient × 295 patients = $663.75
- $2.25 per patient × 713,000 patients = $1,604,250

TABLE 2.—PATIENT RIGHTS BURDEN ASSESSMENT

Standard	Time per patient (minutes)	Time per hospice (hours)	Total time (hours)	Cost per patient	Cost per average hospice	Total cost
Notice of rights	5	24.58	59,417	$2.25	$663.75	$1,604,250
Exercise of rights	3	15	34,740	2.10	630	1,408,325
Notice of liability	5	24.58	59,417	2.25	663.75	1,604,250
Totals	13	64.16	153,574	6.60	1,947	4,705,800

Comprehensive Patient Assessment (§ 418.54)

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 proposed rule would go 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.

Standard: Content of the comprehensive assessment. The assessment would be required to identify the physical, psychosocial, emotional, and spiritual needs related to the terminal illness. Every assessment would likely include factors such as the patient's physical and nutritional needs, pain status, and psychological state. This differs from the current rule in that it describes what would be included in the plan of care. The factors that are described were identified by the industry and reflect standard industry practice.

Standard: Update of the comprehensive assessment. Updates of the patient's comprehensive assessment would have to be conducted at least every 14 days and at the time of each recertification. 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 hospices to update patient assessments at least every 14 days, and often more frequently; therefore, this proposed new standard is simply codifying current industry practice and should not present a burden.

Standard: Patient outcome measures. The comprehensive assessment would have to include consistent pre-determined data elements that allowed for the measurement of outcomes. (Note: There is no data reporting element.)

We believe this standard would 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. If a hospice currently collects data and calculates values for measures that are reported to the NHPCO, it will meet the requirement in the proposed rule.

Interdisciplinary Group, Care Planning and Coordination of Services (§ 418.56)

The proposed rule makes several changes to the existing rule to improve patient care and lessen burden.

(a) Standard: Approach to service and delivery. Unlike the existing requirement that a registered nurse must implement a patient's plan of care, this new rule would allow any qualified member of the interdisciplinary group to implement a patient's plan of care, lessening the burden on hospices and the demand on registered nurses.

(c) Standard: Content of the plan of care. This section goes into further detail about the content of each patient's plan of care than the existing regulation does. The burden of including these items is accounted for in the development of the plan of care, as described in part 2 of this section. The items that would be required under the proposed 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 should be reviewed at intervals specified in the initial plan of care. The proposed rule would require that it be reviewed at least every two weeks. We estimate that documenting the update of a patient's plan of care would take five minutes per patient and that each patient's plan of care would be updated 3 times, based on a an average 51 day length of stay (2002 nov., Medicare National Summary for HHA, Hospice, SNF, and outpatient CY 1999–2001). This amounts to 15 minutes per patient, or 73.75 hours per hospice, at a cost of $6.75 per patient for a registered nurse to complete the updates.

- $27 hour/60 minutes = $0.45 minute × 15 minutes = $6.75
- $6.75 per patient × 295 patients = $1,991.25
- $6.75 per patient × 713,000 patients = $4,812,750

TABLE 3.—INTERDISCIPLINARY GROUP, CARE, PLANNING, AND COORDINATION OF SERVICES BURDEN ASSESSMENT

Standard	Time per patient (minutes)	Time per hospice (hours)	Total time (hours)	Cost per patient	Cost per average hospice	Total cost
Update plan of care	15	73.75	178,250	$6.75	$1,991.25	$4,812,750
Totals	15	73.75	178,250	6.75	1,991.25	4,812,750

Quality Assessment and Performance Improvement (§ 418.58)

The current rule requires a hospice to maintain a quality assurance program that involves an ongoing, comprehensive, integrated self-assessment by the hospice of the quality and appropriateness of care (§ 418.66). The proposed rule would provide more guidance to providers and would require approximately 24 hours a year to implement. Many providers are already using comprehensive quality assessment and performance improvement programs for accreditation or

independent improvement purposes, including one designed by the NHPCO. For those providers who choose to develop their own quality assessment and performance improvement program, we estimate that it would take 12 hours to create a program. We also estimate that hospices would spend 4 hours a year collecting and analyzing data. In addition, we estimate that hospices would spend 3 hours a year training their staff and 5 hours a year implementing performance improvement activities. Both the program development and implementation would most likely be managed by that hospice's administration. Based on an administrator's hourly rate, the total cost of the quality assessment and performance improvement condition of participation would be $1,008 per hospice.

- $42 per hour × 24 hours = $1,008

Our hourly burden estimates are based on the proportion of patients to hours that is found in the CMS final rule, Hospital Conditions of Participation: Quality Assessment and Performance Improvement at 68 FR 3435 (January 24, 2003). CMS estimated that a hospital would spend 80 hours collecting and analyzing data on 12 identified measures. According to 2002 CMS statistics, in 2000, 5,985 hospitals discharged 11.8 million patients. This means that the statistically average hospital discharged approximately 2,000 patients that year. Therefore, collecting and analyzing data for 2,000 patients would take 80 hours, for a ratio of 80 hours/2,000 patients (or 4 hours/100 patients). Based on this estimate, for the average 295 patient hospice, we believe that this ratio would be 12 hours/295 patients. However, we do not expect hospices to collect information on 12 measures, as hospitals are required to do. Hospices that collect information in the four suggested areas (self-determination, comfort, safety, and effective grieving) would have one third the burden required to collect the 12 hospital measures, or 4 hours. This ratio methodology is also used to assess the burden in all other quality assessment and performance improvement areas.

(a) Standard: Program scope. Under the existing regulation, hospices must assess the quality and appropriateness of the care they provide. This new standard would expand on the rule by requiring that the existing assessment become a formal quality assessment and performance improvement program that is capable of showing measurable improvement through the use of quality indicator data.

(b) Standard: Program data. The proposed rule would require the use of quality indicator data in a quality assessment and performance improvement program, but would not require any specific data collection or utilization, nor would it require hospices to report the collected data. This would give hospices flexibility and minimize burden.

(c) Standard: Program activities. This new standard would identify certain areas that would be required to be covered in a hospice's customized quality assessment and performance improvement program. The categories would be sufficiently broad to allow for a vast range of acceptable compliance methods. This would minimize burden.

TABLE 4.—QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT BURDEN ASSESSMENT

Standard	Time per hospice (hours)	Total time (hours)	Cost per hospice	Total cost
QAPI development	12	28,944	$504	$1,215,648
QAPI implementation	12	28,944	504	1,215,648
Total annually	24	57,888	1,008	2,431,296

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 proposed regulation would reinforce those positive infection control practices and would address the serious nature and potential hazards of infectious and communicable diseases. Infection control and standard precautions are long-standing clinical practices that are standard throughout the medical industry. This proposed CoP would require hospices to continue to take specific and appropriate actions to address the prevention and control of infections, and to educate the patients, staff and caregivers on the hazards, prevention and control of infections. We acknowledge that this is a new focus; however, we do not believe this would add any regulatory burden, since this section of the proposed rule reflects contemporary standard practice in hospice programs.

Core Services (§ 418.64)

The proposed rule would allow core services to be provided under contract with another Medicare certified hospice in certain extraordinary or other non-routine circumstances as described, allowing hospices more flexibility. In addition, it would allow hospices to contract for highly specialized nursing services, allowing for even more flexibility. The option to contract out for highly specialized nursing services would allow hospices to provide such highly specialized services at a lower cost than if the hospice directly employed individuals to perform such services. We are proposing that hospices that choose to contract for core services or highly specialized nursing services must have a contract with the entity providing the contracted services. Negotiating, documenting and signing a business contract is a standard business practice and does not impose a burden.

The proposed rule also would require that a psychosocial assessment of the patient be undertaken by the social worker providing medical social services. There is no substantive change to this regulatory burden.

Waiver of Requirement—Physical Therapy, Occupational Therapy, Speech-Language Pathology, and Dietary Counseling (§ 418.74)

This proposed waiver, currently implemented through a memorandum from CMS's Center for Medicaid and State Operations, would reduce the compliance burden on hospices located in non-urbanized areas. If the hospice program could demonstrate that recruitment efforts were unsuccessful, it

could request certain waivers with respect to PT, OT, speech-language pathology, and dietary counseling. Thus far there have been less than five applications for this waiver in the last four years; therefore we believe that the burden is negligible.

Home Health Aide and Homemaker Services (§ 418.76)

Home health 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 proposed regulation, with some minor alterations. The proposed regulation also would add several new requirements.

(b) Standard: Content and duration of home health aide classroom and supervised practical training; (c) Standard: Competency evaluation; (d) Standard: In-service training. These three standards would describe the ways in which a home health aide could meet the proposed qualification requirements. All of these standards would require the hospice to maintain documentation that each home health aide met these qualifications. The burden associated with these standards is the time it would take to complete the required documentation. We estimate that it would take five minutes to document the information and that an office employee would complete this task. In addition, we have calculated the burden based on an assumed employee turnover rate of 20%, meaning that we expect that the average hospice would replace 20% of its home health aides in a given year, or roughly one home health aide a year based on the employment of 5 home health aides. We believe that this is a reasonable assumption. Based on the above-mentioned estimates and assumptions, we estimate that will cost an average hospice $1.60 to document that its home health aides meet the proposed qualification requirements, for a total cost of $3,859.20 nationwide.

- 19 an hour/60 minutes = $0.32 minute × 5 minutes to document that requirements are met per home health aide = $1.60 × 1 document per year = $1.60 per hospice
- $1.60 per hospice × 2,412 hospices = $3,859.20

(g) Standard: Home health aide assignments and duties. The home health aide would be 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 home health aides. This standard would retain the current rule's requirement that a registered nurse or qualified therapist visit the patient's home to assess home health aide services every 14 days. It also would add a requirement that a registered nurse or qualified therapist visit the patient's home every 28 days 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 proposed regulation would require 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 would not impose any additional regulatory burden because hospices train all their employees, including homemakers, to deal with the realities of hospice care; this is already accepted standard practice in the industry.

(k) Standard: Homemaker supervision and duties. The interdisciplinary group would be required to develop written instructions for the homemaker. We believe that providing patient care instructions is a usual and customary medical practice; therefore, this requirement would not impose any additional regulatory burden.

TABLE 5.—HOME HEALTH AIDE AND HOMEMAKER SERVICES BURDEN ASSESSMENT

Standard	Time per aid (minutes)	Time per hospice (minutes)	Total time (hours)	Cost per aid	Cost per average hospice	Total cost
Documentation (based on 1 new HHA per year) *	5	5	201	$1.60	$1.60	$3,859.20
Totals	5	5	201	1.60	1.60	3,859.20

Organization and Administration of Services (§ 418.100)

The proposed requirement is essentially the same as the current regarding the organization and administration of services. However, the proposed rule would add a specification that a hospice's satellite locations be approved by CMS, a practice that is currently mandated through a June 1997 memorandum from CMS' Center for Medicaid and State Operations. A specification for the maintenance of in-service training records and a requirement that education/training be given to the patient, family and primary caregiver would also be new regulations. However, we believe all of these additions reflect standard practice in the industry and present no additional burden.

Medical Director (§ 418.102)

The existing rule requires that the medical director be an employee of the hospice. The proposed rule would permit the medical director to work under a contractual arrangement; this would reduce the program and hiring burden on the hospice, particularly if the hospice is in a rural area.

We believe that the proposed rule would merely codify the current standards of practice to which medical directors adhere. For example, coordinating with other physicians and health care professionals, considering broad criteria when making the determination that hospice care is appropriate, and reviewing relevant information prior to the date that re-certification is necessary are all standard procedures.

Clinical Records (§ 418.104)

The proposed rule would permit hospices to maintain records electronically. This would provide flexibility and reduce burden. While the proposed rule also would add specificity in regard to content, authentication, retrievability, retention, and transfer of records, we believe that these additions reflect standard industry practice and would therefore add no burden.

Drugs, Medical Supplies and Durable Medical Equipment (§ 418.106)

(a) Standard: Administration of drugs and biologicals. The proposed rule would require the interdisciplinary group to periodically review the plan of care to determine whether the patient and/or family continued to have the ability to safely administer drugs and biologicals. This review, however, would not burden hospices because it would be part of the standard 14 day review of the patient's plan of care that already would be performed by the interdisciplinary group. The current rule details persons permitted to administer drugs. The proposed rule would eliminate this level of specificity, thus giving the hospice greater flexibility. The proposed rule would require only that drugs be administered in accordance with standards of practice and the patient's plan of care.

(b) Standard: Controlled drugs in the patient's home. The current rule requires that the hospice have a policy for the disposal of controlled drugs maintained in the patient's home. The proposed rule would add to the existing rule a requirement that the hospice have a policy for tracking and collecting these drugs. The proposed rule would require the use and disposal of controlled substances to be discussed with the family, and would require the hospice nurse to document this discussion. Developing written policies is part of usual and customary medical and business practices. Thus, this standard would create no additional burden.

The second requirement, a documented education session regarding hospice drug policies would require approximately five minutes during the initial evaluation conducted 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 × 5 minutes = $2.25
- $2.25 per patient × 295 patients = $663.75
- $2.25 per patient × 713,000 patients = $1,604,250

(c) Standard: Use and maintenance of equipment and supplies. The existing rule does not address the use of durable medical equipment, but the proposed regulation would do so. The proposed rule would add a requirement that the hospice ensure that there is a process for routine and preventive maintenance of equipment, that the family receives instruction in regard to the use of equipment and supplies, and that the safe use of equipment and supplies be demonstrated and monitored. This requirement would be fulfilled by the individual most frequently at the home, usually a home health aide. Performing these duties would take approximately 15 minutes per patient.

- $14 hour/60 minutes = $0.23 minute × 15 minutes per patient= $3.45 per patient
- $3.45 per patient × 295 patients = $1,017.75
- $3.45 per patient × 713,000 patients = $2,459,850

TABLE 6.—DRUGS, MEDICAL SUPPLIES AND DURABLE MEDICAL EQUIPMENT BURDEN ASSESSMENT

Standard	Time per patient (minutes)	Time per average hospice (minutes)	Total industry time (hours)	Cost per patient	Cost per average hospice	Total industry cost
Drug Education	5	24.58	59,417	$2.25	$663.75	$1,604,250
Equipment	15	73.75	178,250	3.45	1,017.75	2,459,850
Totals	20	98.33	237,667	5.70	1,681.50	4,064,100≤

Short Term Inpatient Care (§ 418.108)

The proposed rule would be more specific than the current rule with respect to the substance of the written agreement, which we believe is a usual and customary business practice. This provision therefore would not increase regulatory burden.

Hospices That Provide Inpatient Care Directly (§ 418.110)

(a) Standard: Staffing. The existing rule is highly prescriptive in requiring a registered nurse to provide direct patient care on each shift. We would eliminate this requirement, to reflect the proposed regulation's focus on expected outcomes of care. We believe that the patient plan of care drives the amount and skill level of the nursing care that would be required and therefore would help the hospice determine staffing levels that would reflect the volume of patients, patient acuity, and the level of intensity of the nursing care required. This approach would give the hospice greater flexibility in staffing and therefore reduce the hospice's regulatory burden.

(c) Standard: Physical Environment. In addition to the existing requirement of having and practicing a disaster plan, under the proposed regulations a hospice would be required to report safety breaches and equipment failures to the appropriate State and local bodies having jurisdiction. The entities to which a hospice would report a breach or failure would depend on the nature of the breach or failure. Additional guidance on this standard would be included in another CMS document, such as the State Operations Manual.

Complying with this standard would require additional staff time. In 2001, 1,375 deficiencies were issued by State surveyors for violations of the Medicare hospice Conditions of Participation. At least some of these deficiencies were related to the physical environment of inpatient hospices. We estimate that 110 of those deficiencies were related to the safety of the physical environment and equipment. Therefore, we believe that approximately 110 safety breaches and equipment failures would need to be reported annually by the hospice industry.

We estimate that reporting safety breaches and equipment failures would take 30 minutes per episode to complete. This task would be completed by a hospice administrator. Each report, therefore, would cost $21, for an industry total of $2,310 annually.

- 110 reports × 30 minutes per report = 55 hours nationwide
- $42 hour/60 minutes = $0.70 minute × 30 minutes = $21 per report
- $21 per report × 110 reports = $2,310

(i) Standard: Infection Control, contains a cross-reference to standards contained in § 418.60. A discussion of the burden of those requirements is discussed in that section.

(l) Standard: Meal service and menu planning. The existing rule is highly prescriptive in terms of specifying the number of meals, meal spacing, meal planning, and menu planning. The proposed rule would give these hospices far greater flexibility by requiring only that the food be sanitary,

nutritious (including therapeutic diets that are in the plan of care), fulfilling, palatable and attractive. We believe that this would reduce the hospice's burden.

(n) Standard: Pharmacist. The proposed rule would provide greater flexibility in regard to administering medication by permitting any health care professional to carry out this function, if it were in accordance with his/her scope of practice. We believe that this would reduce the hospice's regulatory burden.

The proposed rule also would require hospices to investigate discrepancies involving controlled drugs and to document an account of the investigation. Of the 1,375 deficiencies issued by State surveyors in 2001, we estimate that 55 were related to controlled drug violations. We do not expect a significant increase in violations, and estimate that 55 investigations would be conducted and documented throughout the hospice industry.

The proposed rule would require 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 additional hour per incident. The entire industry would thus spend 55 hours annually at a cost of $4,785 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.

- $42 hour + $45 hour = $87 hour × 1 hour investigation = $87 per investigation
- $87 per investigation × 55 investigations = $4,785

(o) Standard: Seclusion and restraint. The proposed rule would add considerable detail in regard to seclusion and restraint. This section would be adapted from the language of the Patient's Rights Condition of Participation for hospitals published as an Interim Final Rule in the **Federal Register** in July 1999, currently codified at 42 CFR 482.13. The burden associated with this standard would be the time it would take to document the need for seclusion and/or restraint, and the time to write the order. We estimate that a hospice would spend 6 hours to develop this form, for a nationwide total of 14,472 hours. After this one-time expenditure, it would take four minutes per patient to meet this documentation requirement for a total of 475 hours nationwide, based on an estimate of the use of seclusion and/or restraint on 1% of the entire patient population. The annual cost of this standard would therefore be $39,928 nationwide.

- 6 hours per hospice × 2,412 hospices = 14,472 hours to develop form
- 6 hours per hospice × $42 hour = $252 to develop form
- $252 to develop form × 2,412 hospices = $607,824
- 713,000 patients × 0.01 percent = 7,130 patients nationwide requiring seclusion or restraint × 4 minutes per patient to complete form = 475 hours nationwide to complete form
- 7,130 patients nationwide requiring seclusion or restraint/2,412 hospices = 3 patients per hospice requiring seclusion or restraint
- $84 hour/60 minutes = $1.40 minute × 4 minutes per patient to complete form = $5.60 per patient to complete form
- $5.60 per patient × 3 patients per hospice requiring seclusion or restraint = $16.80 per hospice
- $5.60 per patient × 7,130 patients = $39,928

There would also be costs associated with developing training programs for staff regarding restraint and seclusion use and alternative interventions; however, we are not dictating how a hospice meets this requirement. Therefore, hospices would have the flexibility to decide how to meet this requirement. We believe that the benefits associated with training staff would far outweigh the costs involved, since proper training would protect the hospice from situations of inappropriate restraint and seclusion use and situations that could lead to patient injuries and/or deaths.

Finally, hospices would have to report to CMS, through the appropriate CMS regional office, all deaths that occur while a patient is restrained or in seclusion. We have no concrete estimate of the number of deaths that occur per year. There could be a nominal cost involved in making a telephone call to the appropriate CMS regional office; however, because we expect that this regulation would reduce the number of deaths from restraint and seclusion use, we estimate that the number of reports would average less than one call per hospice per year. Therefore, we think the cost will be negligible.

TABLE 7.—HOSPICES THAT PROVIDE INPATIENT CARE DIRECTLY BURDEN ASSESSMENT

Standard	Time per patient	Time per hospice	Total time (hours)	Cost per patient	Cost per average hospice	Total cost
Physical environment	1 second	5 minutes	55	$0.01	$1.00	$2,310
Pharmacist	1 second	5 minutes	55	0.01	2.06	4,785
Seclusion form development	1 minute	6 hours	14,472	0.84	252	607,824
Seclusion form completion	4 minutes	12 minutes	475	5.60	16.80	39,928
Totals	5 minutes	6.25 hours	15,057	6.46	271.86	$654,847

Hospices That Provide Hospice Care to Residents of a SNF/NF, ICF/MR or Other Facility (§ 418.112)

The proposed rule would specify the minimum content of the written agreement hospice providers and facilities would be required to have and would recodify existing regulations concerning information sharing practices. These requirements reflect usual and customary business practices and would not increase a hospice's regulatory burden.

Personnel Qualifications (§ 418.114)

The proposed rule's personnel qualification section would specify that the current qualifications would apply only where there were no State licensing laws, or State certification or registration requirements for the profession. Additionally, the proposed rule would require a background check for each employee involved in direct patient care. In 2002, 39 states required criminal background checks for hospice employees. In these states, approximately 70,411 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 19,876 hospice employees, would each

obtain 39 criminal background checks initially. Each background check request form would 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 all hospices would complete background checks on approximately 8 new employees per year for a total of 48 minutes per hospice per year and 408 hours nationally per year.

- 90,271 employees in 2001 according to National Association for Home Care 2002 Hospice Industry Report/50 states = 1,805 average number of employees per state × 39 states already requiring background checks = 70,395 already required to have background checks
- 90,271 total employees × 70,395 already required to have background checks = 19,876 employees not already required to have background checks
- 90,271 employees/2,316 hospices in 2001 = 39 employees per average hospice
- 39 employees × 6 minutes per check = 4 hours per hospice
- 19,876 employees × 6 minutes per check = 1,988 hours nationwide

We estimate that the average cost for an individual background check is $12.50. We understand that some 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 proposing to require that hospices conduct a specific type of background check or obtain such a check from a specific source. The flexibility of the proposed requirement would allow hospices to identify the most cost efficient method of meeting the requirement.

- $12.50 per check × 39 employees requiring checks = $487.50
- $12.50 per check × 19,876 employees requiring checks = $248,250

TABLE 8.—PERSONNEL QUALIFICATIONS BURDEN ASSESSMENT

Time per check (minutes)	Time per average hospice (minutes)	Total industry time (hours)	Cost per check	Total cost per average hospice	Total industry cost
6	1st year—4 hours annually—48.	1st year—1,988 hours annually—408.	$12.50	1st year—$487.50 annually—$100.	1st year—$248,250 annually—51,000.

TABLE 9.—TOTAL BURDEN ASSESSMENT PROPOSED REQUIREMENTS

[Total time and cost for all altered or new CoPs:]

Total time per patient (minutes)	Total time per hospice (hours)	Total industry time (hours)	Total cost per patient	Total cost per hospice	Total industry cost
53	275	644,625	$25.51	$7,389	$16,920,902

2. Effects on other providers:

Effects on other providers: We do not expect this regulation to affect any other provider.

3. Effects on the Medicare and Medicaid programs:

The costs to the Medicare and Medicaid programs resulting from this rule will be negligible.

C. Alternatives Considered

One alternative was to keep the existing CoPs. We concluded this was not a reasonable option because our existing CoPs are problem-focused. As discussed in the preamble, the problem-focused approach has inherent limits. Trying to ensure quality through the enforcement of prescriptive health and safety standards, rather than trying to improve quality of care for all patients, would not contribute to hospice improvement or stimulate broad-based quality of care initiatives.

Revising the existing CoPs would take advantage of continuing advances in the health care delivery field. We believe it is necessary to keep pace with growing demands for services.

In addition, listed below are other alternatives.

Patient's Rights (§ 418.52)

We considered including more prescriptive rights regarding privacy of a hospice patient's medical information. However, 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 contained in 45 CFR parts 160 and 164, protects patient privacy adequately.

Comprehensive Assessment of the Patient (§ 418.54)

We considered not proposing the Comprehensive Assessment CoP. However, because the third most cited deficiency noted during hospice surveys is the absence of the assessment of needs, we believe it is essential to address this area. We also heard from hospice industry representatives, who recommended that we include a provision dealing with comprehensive assessment. Our decision to propose a general assessment requirement is based on the knowledge that individual hospices understand patient assessments and why an assessment is important to overall quality of care.

Interdisciplinary Group Care Planning and Coordination of Services (§ 418.56)

We considered leaving the current CoPs as written. However, it was logical to have the coordination of services, the interdisciplinary group requirements, and the care planning requirements in one CoP. Since the interdisciplinary approach to the delivery of hospice services reflects actual practice for hospices, we believe that this new proposed regulation would support current industry practice.

Quality Assessment and Performance Improvement § 418.58

We discussed eliminating any reference to the use of quality indicator data, including patient care data, for regulatory purposes. But, in light of the existing hospital and home health quality assessment and performance improvement activities requirements, we believe hospices must begin to build a foundation where quality indicators can be used to gather patient-related information. The use of quality indicator data would help in creating an effective quality assessment and performance improvement program. As a result, the hospices would be able to

better identify activities that lead to poor patient outcomes, and would be able to take corrective action to improve performance.

Infection Control (§ 418.60)

We considered leaving the existing CoP, which has very little reference to infection control. We also considered making infection control a standard under proposed § 418.58, Quality assessment and performance improvement. However, we believe that the serious nature and potential hazards of infectious and communicable diseases warrants a separate and identifiable CoP. This new condition would work in concert with the hospice's responsibility to carry out a quality assessment and performance improvement program that is geared to patient health and safety.

Licensed Professionals (§ 418.62)

We considered rewriting each existing CoP instead of combining all of them into the proposed CoP, § 418.62. However, we decided that the current CoPs were outdated and too prescriptive, and that a new condition would offer hospices more flexibility.

Medical Director (§ 418.102)

We changed part of this CoP because section 4445 of the Balanced Budget Act of 1997 mandated that CMS give hospices the option to utilize contractual relationships between hospices and physicians. Previously, physicians could only furnish services as direct hospice employees.

Clinical Records (§ 418.104)

We considered keeping the current CoP as written, but opted to clarify some of its standards to reflect current hospice practice. For example, we included the provision that hospices may use electronic records.

Drugs, Controlled Drugs, Biologicals, Medical Supplies, and Durable Medical Equipment (§ 418.106)

We considered a wide range of changes for this CoP. We enhanced the requirement for controlled substances in the home. We considered requiring the hospice, patient, and family to account for the controlled substance including disposal of the substance. We also considered requiring a pharmacist to conduct drug reviews on each patient record. However, we decided to discard these suggestions because they could place too much burden on hospices. We believe that the current CoPs needed to be strengthened and therefore, we opted to require the hospice, patient, and family to share in the accountability of controlled substances in the home.

Inpatient Care (Short-Term, Long-Term, and ICFs/MR) (§ 418.108, § 418.112)

Consideration was given to maintaining this CoP and revising the Long Term Care CoPs. However, we decided against relying on a future change in the Long Term Care CoPs and revised the hospice CoPs to the extent possible, to clarify the roles of SNF/NFs and hospices.

We also decided to separate out hospice care provided to hospice patients in SNF/NF, ICF/MR and other facilities. Thus, instead of a single CoP that addresses hospice care provided in all inpatient facilities, we created a CoP entitled Short Term Inpatient Care and then a second CoP entitled Hospices that Provide Care to Residents in a SNF/NF, ICF/MR or Non certified facility. We chose this alternative because the concerns were related to coordination of care issues expressed by hospice and inpatient facility providers.

Personnel Qualifications (§ 418.114)

More prescriptive requirements addressing personnel qualifications were considered. As an example, we considered utilizing only Federal definitions for personnel qualifications instead of deferring to State law.

However, we decided to defer to State law for two reasons. First, we wanted to be consistent with other health care providers, and second, we believe a State can best determine what qualifications are needed to fit its population's needs. Each hospice has the option to require more stringent qualifications of its practitioners.

D. Conclusion

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this proposed rule would not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

VII. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

List of Subjects in 42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 418 as follows:

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).

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 revised to read as follows:

§ 418.3 Definitions

For the purposes of this part—

Attending physician means a—

(1)(i) Doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs that function or action; or

(ii) Nurse practitioner who meets the training, education and experience requirements as the Secretary may prescribe; and

(2) Is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care.

Bereavement counseling means emotional, psychosocial, and spiritual support and services provided after the

death of the patient to assist with issues related to grief, loss, and adjusting.

Cap period means the 12-month period ending October 31 used in the application of the cap on overall hospice reimbursement specified in § 418.309.

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

Drug restraint means a medication used to control behavior or to restrict the patient's freedom of movement which is not a standard treatment for a patient's medical or psychiatric condition.

Employee means a person who works for the hospice and for whom the hospice is required to issue a W–2 form on his or her behalf, or if the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is appropriately trained and assigned to the hospice or is a volunteer under the jurisdiction of the hospice.

Hospice means a public agency or private organization or subdivision of either of these that is primarily engaged in providing hospice care as defined in this section.

Hospice care means a comprehensive set of services described in 1861(dd)(1) of the Act, identified and coordinated by an interdisciplinary team to provide for the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care.

Licensed professional means a licensed person sanctioned by the State in which services are delivered, furnishing services such as skilled nursing care, physical therapy, speech-language pathology, occupational therapy, and medical social services.

Palliative care means patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice.

Physical restraint means any manual method or physical or mechanical device, material, or equipment attached to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.

Progress note means a written notation, dated and signed by any person providing services, that summarizes facts about the care furnished and the patient's response during a given period of time.

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

Restraint means either a physical restraint or a drug used as a restraint.

Satellite location means a Medicare-approved location from which the hospice provides hospice care and services within a portion of the total geographic area served by the hospice location issued the provider agreement number. The satellite location is part of the hospice and shares administration, supervision, and services in a manner that renders it unnecessary for the satellite location to independently meet the conditions of participation as a hospice.

Seclusion means the confinement of a person in a room or an area where a person is isolated and physically prevented from leaving.

Terminally ill means that the patient has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course.

Subpart E—[Removed and Reserved]

4. Subpart E is removed and reserved.

5. Subparts C and D are revised to read as follows:

Subpart C—Conditions of Participation: Patient Care

Sec.

Core Services

Noncore Services

Subpart D—Conditions of Participation: Organizational Environment

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

(2) The hospice must comply with the requirements of subpart I of part 489 of this chapter regarding advance directives. The hospice must inform and distribute written information to the patient concerning its policies on advance directives, including a description of applicable State law.

(3) The hospice must inform the patient and family of the hospice's drug

policies and procedures, including the policies and procedures regarding the tracking and disposing of controlled substances.

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

(b) *Standard: Exercise of rights and respect for property and person.* (1) The patient has the right—

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

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

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

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

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

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

(4) The hospice must—

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

(ii) Immediately investigate all alleged violations and immediately take action to prevent further potential abuse while the alleged violation is being verified;

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

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

(c) *Standard: Pain management and symptom control.* The patient has a right to receive effective pain management and symptom control from the hospice.

(d) *Standard: Confidentiality of clinical records.* The hospice must maintain the confidentiality of clinical records. Access to or release of patient information and clinical records is permitted in accordance with 45 CFR parts 160 and 164.

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

§ 418.54 Condition of participation: Comprehensive assessment of the patient.

The hospice must conduct and document in writing a patient-specific comprehensive assessment that identifies the patient's need for hospice care and services, and the patient's need for medical, nursing, psychosocial, emotional, and spiritual care. This care includes, but is not limited to, the palliation and management of the terminal illness and related medical conditions.

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

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

(c) *Standard: Content of the comprehensive assessment.* The comprehensive assessment must identify the physical, psychosocial, emotional, and spiritual needs related to the terminal illness that must be addressed in order to promote the hospice patient's well-being, comfort, and dignity throughout the dying process. The comprehensive assessment describes—

(1) The nature and condition causing admission (including the presence or lack of objective data and subjective complaints);

(2) Complications and risk factors that affect care planning;

(3) Factors that must be considered in developing individualized care plan interventions, including—

(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.

(ii) *Drug therapy.* A review of the patient's prescription and over-the-counter drug profile, including but not limited to identification of the following—

(A) Ineffective drug therapy;

(B) Unwanted drug side and toxic effects; and

(C) Drug interactions.

(4) The need for referrals and further evaluation by appropriate health professionals.

(d) *Standard: Update of the comprehensive assessment.* The update of the comprehensive assessment must be accomplished by the hospice interdisciplinary group and must consider changes that have taken place since the initial assessment. It must include information on the patient's progress toward desired outcomes, as well as a reassessment of the patient's response to care. The assessment update must be accomplished—

(1) As frequently as the condition of the patient requires, but no less frequently than every 14 days; and

(2) At the time of each recertification.

(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 and as it relates to the terminal illness and related conditions.

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

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

(ii) A registered nurse.

(iii) A social worker.

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

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

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

(c) *Standard: Content of the plan of care.* The hospice must develop a written plan of care for each patient that reflects prescribed interventions based on the problems identified in the initial comprehensive and updated comprehensive assessments, and other assessments. The plan of care must include but not be limited to—

(1) Interventions to facilitate the management of pain and symptoms;

(2) A detailed statement of the scope and frequency of services necessary to meet the specific patient and family needs;

(3) Measurable targeted outcomes anticipated from implementing and coordinating the plan of care;

(4) Drugs and treatment necessary to meet the needs of the patient;

(5) Medical supplies and appliances necessary to meet the needs of the patient; and

(6) The interdisciplinary group's documentation of patient and family 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 medical director or physician designee, and the hospice interdisciplinary team (in collaboration with the individual's attending physician to the extent possible) must review, revise and document the plan as necessary at intervals specified in the plan but no less than every 14 calendar days. A revised plan of care must include information from the patient's updated comprehensive assessment and the patient's progress toward outcomes specified in the plan of care.

(e) *Standard: Coordination of services.* The hospice must develop and maintain a system of communication and integration, in accordance with the hospice's own policies and procedures, to—

(1) Ensure the interdisciplinary group, through its designated professionals, maintains responsibility for directing, coordinating, and supervising the care and services provided;

(2) Ensure that care and services are provided in accordance with the plan of care;

(3) Ensure that the care and services provided are based on all assessments of the patient and family needs; and

(4) Provide for and ensure the ongoing sharing of information between all disciplines providing care and services in the home, in outpatient settings, and in inpatient settings, irrespective whether the care and services are provided directly or under arrangement.

§ 418.58 Condition of participation: Quality assessment and performance improvement.

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

(a) *Standard: Program scope.* (1) The program must at least be capable of showing measurable improvement in indicators for which there is evidence that improvement in those indicators will improve palliative outcomes and end-of-life support services.

(2) The hospice must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that enable the hospice to assess processes of care, hospice services, and operations.

(b) *Standard: Program data.* (1) The program must utilize quality indicator data, including patient care, and other relevant data, in the design of its program.

(2) The hospice must use the data collected to—

(i) Monitor the effectiveness and safety of services and quality of care; and

(ii) Identify opportunities for improvement.

(3) The frequency and detail of the data collection must be specified by the hospice's governing body.

(c) *Standard: Program activities.* (1) The hospice's performance improvement activities must—

(i) Focus on high risk, high volume, or problem-prone areas;

(ii) Consider incidence, prevalence, and severity of problems in those areas; and

(iii) Affect palliative outcomes, patient safety, and quality of care.

(2) Performance improvement activities must track adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospice.

(3) The hospice must take actions aimed at performance improvement and, after implementing those actions, the hospice must measure its success and track performance to ensure that improvements are sustained.

(d) *Standard: Performance improvement projects.* (1) The number and scope of distinct improvement

projects conducted annually must reflect the scope, complexity, and past performance of the hospice's services and operations.

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

(e) *Standard: Executive responsibilities.* The hospice's governing body is responsible for ensuring the following:

(1) That an ongoing program for quality improvement and patient safety is defined, implemented and maintained;

(2) That the hospice-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated for effectiveness; and

(3) That clear expectations for patient safety are established.

§ 418.60 Condition of participation: Infection control.

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

(a) *Standard: Prevention.* The hospice must follow accepted standards of practice to prevent the transmission of infections and communicable diseases, including the use of standard precautions.

(b) *Standard: Control.* The hospice must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that—

(1) Is an integral part of the hospice's quality assessment and performance improvement program; and

(2) Includes:

(i) A method of identifying infectious; and communicable disease problems; and

(ii) A plan for the appropriate actions that are expected to result in improvement and disease prevention.

(c) *Standard: Education.* The hospice must provide infection control education to staff, patients, and family members or other caregivers.

§ 418.62 Condition of participation: Licensed professional services.

(a) Licensed professional services provided directly or under arrangement must be authorized, delivered, and supervised only by health care professionals who meet the appropriate qualifications specified under 418.114 and who practice under the hospice's policies and procedures.

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

(c) Licensed professionals must participate in the hospice's quality assessment and performance improvement program and hospice sponsored in-service training.

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 § 418.64(a). A hospice may, under extraordinary or other non-routine circumstances, enter into a written arrangement with another Medicare certified hospice program for the provision of core services to supplement hospice employee/staff to meet the needs of patients. Circumstances under which a hospice may enter into a written arrangement for the provision of core services include: Unanticipated periods of high patient loads, staffing shortages due to illness or other short-term temporary situations that interrupt patient care; and temporary travel of a patient outside of the hospice's service area.

(a) *Standard: Physician services.* The hospice medical director, physician employees, and contracted physician(s) of the hospice, in conjunction with the patient's attending physician, are responsible for the palliation and management of the terminal illness, conditions related to the terminal illness, and the general medical needs of the patient.

(1) All physician employees and those under contract, must function under the supervision of the hospice medical director.

(2) All physician employees and those under contract shall meet this requirement by either providing the services directly or through coordinating patient care with the attending physician.

(3) If the attending physician is unavailable, the medical director, contracted physician, and/or hospice physician employee is responsible for meeting the medical needs of the patient.

(b) *Standard: Nursing services.* (1) The hospice must provide nursing care and services by or under the supervision of a registered nurse. Nursing services must ensure that the nursing needs of the patient are met as identified in the patient's initial comprehensive assessment and updated assessments.

(2) If State law permits nurse practitioners (NPs) to see, treat and write orders for patients, then NPs may provide services to beneficiaries receiving hospice care. The role and scope of the services provided by a NP that is not the individual's attending physician must be specified in the individual's plan of care.

(3) Highly specialized nursing services that are provided so infrequently that the provision of such services by direct hospice employees would be impracticable and prohibitively expensive, may be provided under contract.

(c) *Standard: Medical social services.* Medical social services must be provided by a qualified social worker, under the direction of a physician. Social work services must be based on the patient's psychosocial assessment and the patient's and family's needs and acceptance of these services.

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

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

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

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

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

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

(2) *Nutritional counseling.* Nutritional counseling, when identified in the plan of care, must be performed by a qualified individual, which include dietitians as well as nurses and other individuals who are able to address and assure that the dietary needs of the patient are met.

(3) *Spiritual counseling.* The hospice must:

(i) Provide an assessment of the patient's and family's spiritual needs;

(ii) Provide spiritual counseling to meet these needs in accordance with the patient's and family's acceptance of this service, and in a manner consistent with patient and family beliefs and desires;

(iii) Facilitate visits by local clergy, pastoral counselors, or other individuals who can support the patient's spiritual needs to the best of its ability. The hospice is not required to go to extraordinary lengths to do so; and

(iv) Advise the patient and family of this service.

§ 418.66 Condition of participation: Nursing services—Waiver of requirement that substantially all nursing services be routinely provided directly by a hospice.

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

(1) The location of the hospice's central office is in a nonurbanized area as determined by the Bureau of the Census.

(2) There is evidence that a hospice was operational on or before January 1, 1983 including—

(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).

(b) Any waiver request is deemed to be granted unless it is denied within 60 days after it is received.

(c) Waivers will remain effective for 1 year at a time from the date of the request.

(d) CMS may approve a maximum of two 1-year extensions for each initial waiver. If a hospice wishes to receive a 1-year extension, it must submit a request to CMS before the expiration of the waiver period, and certify that the conditions under which it originally requested the initial 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—

(i) Copies of advertisements in local newspapers that demonstrate recruitment efforts;

(ii) Physical therapy, occupational therapy, speech-language pathology, and dietary counselor job descriptions;

(iii) Evidence that salary and benefits are competitive for the area; and

(iv) Evidence of any other recruiting activities (for example, recruiting efforts at health fairs and contact discussions with physical therapy, occupational therapy, speech-language pathology, and dietary counseling service providers in the area).

(b) Any waiver request is deemed to be granted unless it is denied within 60 days after it is received.

(c) An initial waiver will remain effective for 1 year at a time from the date of the request.

(d) CMS may approve a maximum of two 1-year extensions for each initial waiver. If a hospice wishes to receive a 1-year extension, it must submit a request to CMS prior to the expiration of the waiver period and certify that conditions under which it originally requested the waiver have not changed since the initial waiver was granted.

§ 418.76 Condition of participation: Home health aide and homemaker services.

All home health aide services must be provided by individuals who meet the personnel requirements specified in paragraph (a) of this section. Homemaker services must be provided by individuals who meet the personnel requirements specified in paragraph (j) of this section.

(a) *Standard: Home health aide qualifications.* (1) A qualified home health aide is a person who has successfully completed—

(i) A training program and competency evaluation as specified in paragraphs (b) and (c) of this section respectively; or

(ii) A competency evaluation program; or

(iii) A State licensure program that meets the requirements of paragraphs (b) and (c) of this section.

(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 period of 24 consecutive months during which none of the services furnished by the individual as described in § 409.40 of this chapter were for compensation. If there has been a 24-month lapse in furnishing services, the individual must complete another training and/or competency evaluation program before providing services, as specified in paragraph (a)(1) of this section.

(b) *Standard: Content and duration of home health aide classroom and supervised practical training.* (1) Home health aide training must include classroom and supervised practical classroom training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while performing tasks on an individual under the direct supervision of a registered nurse or licensed practical nurse, who is under the supervision of a registered nurse. Classroom and supervised practical training combined must total at least 75 hours.

(2) A minimum of 16 hours of classroom training must precede a minimum of 16 hours of supervised practical training as part of the 75 hours.

(3) A home health aide training program must address each of the following subject areas:

(i) Communication skills, including the ability to read, write, and verbally report clinical information to patients, care givers, and other hospice staff;

(ii) Observation, reporting, and documentation of patient status and the care or service furnished;

(iii) Reading and recording temperature, pulse, and respiration;

(iv) Basic infection control procedures;

(v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor;

(vi) Maintenance of a clean, safe, and healthy environment;

(vii) Recognizing emergencies and the knowledge of emergency procedures and their application;

(viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the hospice, including the need for respect for the patient, his or her privacy, and his or her property;

(ix) Appropriate and safe techniques in performing personal hygiene and grooming tasks, including items on the following basic checklist—

(A) Bed bath;

(B) Sponge, tub, and shower bath;

(C) Hair shampoo (sink, tub, and bed);

(D) Nail and skin care;

(E) Oral hygiene; and

(F) Toileting and elimination;

(x) Safe transfer techniques and ambulation.

(xi) Normal range of motion and positioning.

(xii) Adequate nutrition and fluid intake.

(xiii) Any other task that the hospice may choose to have an aide perform. The hospice is responsible for training home health aides, as needed, for skills not covered in the basic checklist, as described in paragraph (b)(3)(ix) of this section.

(4) The hospice must maintain documentation that demonstrates that the requirements of this standard are met.

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

(1) The competency evaluation must address each of the subjects listed in paragraphs (b)(1) through (b)(3) of this section. Subject areas specified under paragraphs (b)(3)(i), (b)(3)(iii), (b)(3)(ix), (b)(3)(x) and (b)(3)(xi) of this section must be evaluated by observing an aide's performance of the task with a patient. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient.

(2) A home health aide competency evaluation program may be offered by any organization, except as specified in paragraph (f) of this section.

(3) The competency evaluation must be performed by a registered nurse in consultation with other skilled professionals, as appropriate.

(4) A home health aide is not considered competent in any task for which he or she is evaluated as unsatisfactory. An aide must not perform that task without direct supervision by a registered nurse until after he or she has received training in the task for which he or she was evaluated as ''unsatisfactory,'' and successfully completes a subsequent evaluation.

(5) The hospice must maintain documentation that demonstrates the requirements of this standard are being met.

(d) *Standard: In-service training.* A home health aide must receive at least 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 registered nurse.

(2) The hospice must maintain documentation that demonstrates the requirements of this standard are met.

(e) *Standard: Qualifications for instructors conducting classroom supervised practical training, competency evaluations and in-service training.* Classroom supervised practical training must be performed by or under the supervision of a registered nurse who possesses a minimum of two years nursing experience, at least one year of which must be in home health care. Other individuals may provide instruction under the general supervision of a registered nurse.

(f) *Standard: Eligible training organizations.* A home health aide training program may be offered by any organization except by a home health agency that, within the previous 2 years—

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

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

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

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

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

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

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

(i) Had its participation in the Medicare program terminated;

(ii) Been assessed a penalty of $5,000 or more for deficiencies in Federal or State standards for home health agencies;

(iii) Been subjected to a suspension of Medicare payments to which it otherwise would have been entitled;

(iv) Operated under temporary management that was appointed by a governmental authority to oversee the operation of the home health agency and to ensure the health and safety of the home health agency's patients; or

(v) Been closed by CMS or the State, or had its patients transferred by the State.

(g) *Standard: Home health aide assignments and duties.* A registered nurse or the appropriate qualified therapist that is a member of the interdisciplinary team makes home health aide assignments.

(l) Home health aides are assigned to a specific patient by a registered nurse or the appropriate qualified therapist. Written patient care instructions for a home health aide must be prepared by a registered nurse or other appropriate skilled professional (*i.e.*, a physical therapist, speech-language pathologist, or occupational therapist) who is responsible for the supervision of a home health aide as specified under paragraph (h) of this section.

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

(i) Ordered by the physician or nurse practitioner;

(ii) Included in the plan of care;

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

(iv) Consistent with the home health aide training.

(3) The duties of a home health aide include:

(i) The provision of hands-on personal care;

(ii) The performance of simple procedures as an extension of therapy or nursing services;

(iii) Assistance in ambulation or exercises; and

(iv) Assistance in administering medications that are ordinarily self-administered.

(4) Home health aides must report changes in the patient's medical, nursing, rehabilitative, and social needs to a registered nurse or other appropriate licensed professional, as the changes relate to the plan of care and quality assessment and improvement activities. Home health aides must also complete appropriate records in compliance with the hospice's policies and procedures.

(h) *Standard: Supervision of home health aides.* (1) A registered nurse or qualified therapist must make an onsite visit to the patient's home no less frequently than every 14 days to assess the home health aide's services. The home health aide does not have to be present during this visit. A registered nurse or qualified therapist must make an onsite 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.

(2) The supervising nurse or therapist must assess an aide's ability to demonstrate initial and continued satisfactory performance in meeting outcome criteria that include, but is not limited to—

(i) Following the patient's plan of care for completion of tasks assigned to the home health aide by the registered nurse or qualified therapist;

(ii) Creating successful interpersonal relationships with the patient and family;

(iii) Demonstrating competency with assigned tasks;

(iv) Complying with infection control policies and procedures; and

(v) Reporting changes in the patient's condition.

(3) If the hospice chooses to provide home health aide services under contract with another organization, the hospice's responsibilities include, but are not limited to—

(i) Ensuring the overall quality of care provided by an aide;

(ii) Supervising an aide's services as described in paragraphs (h)(1) and (h)(2) of this section; and

(iii) Ensuring that home health aides who provide services under arrangement have met the training and/or competency evaluation requirements of this condition.

(i) *Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit.* An individual may furnish personal care services, as defined in § 440.167 of the Code of Federal Regulations, on behalf of a hospice or home health agency. Before the individual may furnish personal care services, the individual must be found competent by the State to furnish those services. The individual only needs to demonstrate competency in the services the individual is required to furnish.

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

(k) *Standard: Homemaker supervision and duties.* (1) Homemaker services must be coordinated by a member of the interdisciplinary group.

(2) Instructions for homemaker duties must be prepared by a member of the interdisciplinary group.

(3) Homemakers must report all concerns about the patient or family to the member of the interdisciplinary group who is coordinating homemaker services.

§ 418.78 Conditions of participation: Volunteers.

The hospice must use volunteers to the extent specified in paragraph (e) of this section. These volunteers must be used in defined roles and under the supervision of a designated hospice employee.

(a) *Standard: Training.* The hospice must maintain, document and provide volunteer orientation and training that is consistent with hospice industry standards.

(b) *Standard: Role.* Volunteers must be used in day-to-day administrative and/or direct patient care roles.

(c) *Standard: Recruiting and retaining.* The hospice must document and demonstrate viable and ongoing efforts to recruit and retain volunteers.

(d) *Standard: Cost saving.* The hospice must document the cost savings achieved through the use of volunteers. Documentation must include—

(1) The identification of each position that is occupied by a volunteer;

(2) The work time spent by volunteers occupying those positions; and

(3) Estimates of the dollar costs that the hospice would have incurred if paid employees occupied the positions identified in paragraph (d)(1) of this section for the amount of time specified in paragraph (d)(2) of this section.

(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 terminal illness.

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

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

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

(b) *Standard: Governing body and administrator.* A governing body (or

designated persons so functioning) assumes full legal authority and responsibility for the management of the hospice, the provision of all hospice services, its fiscal operations, and continuous quality assessment and performance improvement. A qualified administrator reports to the governing body and is responsible for the day-to-day operation of the hospice. The administrator must be a hospice employee and possess education and experience required by the hospice's governing body.

(c) *Standard: Services.* (1) A hospice must be primarily engaged in providing the following care and services and must do so in a manner that is consistent within accepted standards of practice:

(i) Nursing services.

(ii) Medical social services.

(iii) Physician services.

(iv) Counseling services, including spiritual counseling, dietary counseling, and bereavement counseling.

(v) Home health aide, volunteer, and homemaker services.

(vi) Physical therapy, occupational therapy and speech-language pathology therapy services.

(vii) Short-term inpatient care.

(viii) Medical supplies (including drugs and biologicals) and medical appliances.

(2) Nursing services, physician services, and drugs and biologicals (as specified in § 418.106) must be made routinely available on a 24-hour basis 7 days a week. Other covered services must be available on a 24-hour basis when reasonable and necessary to meet the needs of the patient and family.

(d) *Standard: Continuation of care.* A hospice may not discontinue or reduce care provided to a Medicare or Medicaid beneficiary because of the beneficiary's inability to pay for that care.

(e) *Standard: Professional management responsibility.* A hospice that has a written agreement with another agency, individual, or organization to furnish any services under arrangement, must retain administrative and financial management, and supervision of staff and services for all arranged services, to ensure the provision of quality care. Arranged services must be supported by written agreements that require that all services be—

(1) Authorized by the hospice;

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

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

(f) *Standard: Hospice satellite locations.* (1) All hospice satellite locations must be approved by CMS before providing hospice care and services to Medicare patients. The determination that a satellite location does or does not meet the definition of a satellite location, as set forth in this part, is an initial determination, as set forth in § 498.3.

(2) The hospice must continually monitor and manage all services provided at all of its locations to ensure that services are delivered in a safe and effective manner and to ensure that each patient and family receives the necessary care and services outlined in the plan of care.

(g) *Standard: In-service training.* A hospice must assess the skills and competence of all individuals furnishing care, including volunteers furnishing services, and, as necessary, provide in-service training and education programs where required. The hospice must have written policies and procedures describing its method(s) of assessment of competency and maintain a written description of the in-service training provided during the previous 12 months.

§ 418.102 Condition of participation: Medical director.

The hospice must designate a physician to serve as medical director. The medical director must be a doctor of medicine or osteopathy who is either employed by, or under contract with, the hospice. When the medical director is not available, a physician designated by the medical director assumes the same responsibilities and obligations as the medical director. The medical director and physician designee coordinate with other physicians and health care professionals to ensure that each patient experiences medical care that reflects hospice policy.

(a) *Standard: Initial certification of terminal illness.* The medical director or physician designee reviews the clinical information for each hospice patient and provides written certification that it is anticipated that the patient's life expectancy is 6 months or less if the illness runs its normal course. The physician must consider the following criteria when making this determination:

(1) The primary terminal condition.

(2) Related diagnosis(es), if any.

(3) Current subjective and objective medical findings.

(4) Current medication and treatment orders.

(5) Information about the medical management of any of the patient's conditions unrelated to the terminal illness.

(b) *Standard: Recertification of the terminal illness.* Before the recertification period for each patient, as described in § 418.21(a), the medical director or physician designee must review:

(1) The patient's clinical information; and

(2) The patient's and family's expectations and wishes for the continuation of hospice care.

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

§ 418.104 Condition of participation: Clinical records.

A clinical record containing past and current findings is maintained for each hospice patient. The clinical record must contain accurate clinical information that is available to the patient's attending physician and hospice staff. The clinical record may be maintained electronically.

(a) *Standard: Content.* Each patient's record must include the following:

(1) The plan of care, initial assessment, comprehensive assessment, and updated comprehensive assessments, clinical notes, and progress notes.

(2) Informed consent, authorization, and election forms.

(3) Responses to medications, symptom management, treatments, and services.

(4) Outcome measure data elements, as described in § 418.54(e) of this subpart.

(5) Physician certification and recertification of terminal illness as required in § 418.22 and described in § 418.102(a) and § 418.102(b) respectively.

(6) Any advance directives as described in § 418.52(a)(3).

(b) *Standard: Authentication.* All entries must be legible, clear, complete, and appropriately authenticated and dated. All entries must be signed, and the hospice must be able to authenticate each handwritten and electronic signature of a primary author who has reviewed and approved the entry.

(c) *Standard: Protection of information.* The clinical record, its contents and the information contained therein must be safeguarded against loss or unauthorized use. The hospice must be in compliance with the Department's rules regarding personal health

information set out at 45 CFR parts 160 and 164.

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

(e) *Standard: Discharge or transfer of care.* (1) If the care of a patient is transferred to another Medicare/Medicaid-approved facility, the hospice must forward a copy of the patient's clinical record and the hospice discharge summary to that facility.

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

(3) The hospice discharge summary must include—

(i) A summary of the patient's stay including treatments, symptoms and pain management;

(ii) The patient's current plan of care;

(iii) The patient's latest physician orders; and

(iv) Any other documentation that will assist in post-discharge continuity of care.

(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, controlled drugs and biologicals, medical supplies, and durable medical equipment.

Medical supplies and appliances, as described in § 410.36 of this chapter; durable medical equipment, as described in § 410.38 of this chapter; and drugs and biologicals related to the palliation and management of the terminal illness and related conditions, as identified in the hospice plan of care, must be provided by the hospice while the patient is under hospice care.

(a) *Standard: Administration of drugs and biologicals.* (1) All drugs and biologicals must be administered in accordance with accepted hospice and palliative care standards of practice and according to the patient's plan of care.

(2) The interdisciplinary group, as part of the review of the plan of care, must determine the ability of the patient and/or family to safely self-administer drugs and biologicals.

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

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

(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.

§ 418.108 Condition of participation: Short-term inpatient care.

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

(a) *Standard: Inpatient care for symptom management and pain control.* Inpatient care for pain control and symptom management must be provided in one of the following:

(1) A Medicare-approved hospice that meets the conditions of participation for providing inpatient care directly as specified in § 418.110.

(2) A Medicare-participating hospital or a skilled nursing facility that also meets the standards specified in § 418.110(b) and (f) regarding 24-hour nursing services and patient areas.

(b) *Standard: Inpatient care for respite purposes.* Inpatient care for respite purposes must be provided by one of the following:

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

(2) A Medicare/Medicaid approved nursing facility that also meets the standards specified in § 418.110(b) and (f).

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

(1) That the hospice supplies the inpatient provider a copy of the patient's plan of care and specifies the inpatient services to be furnished;

(2) That the inpatient provider has established patient care policies consistent with those of the hospice and agrees to abide by the palliative care protocols and plan of care established by the hospice for its patients;

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

(4) That the inpatient facility has identified a individual within the facility who is responsible for the implementation of the provisions of the agreement;

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

(6) That a way to verify that requirements in paragraphs (c)(1) through (c)(5) of this section have been met is established.

(d) *Standard: Inpatient care limitation.* The total number of inpatient days used by Medicare beneficiaries who elected hospice coverage in a 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 must demonstrate compliance with all of the following standards:

(a) *Standard: Staffing.* The hospice is responsible for ensuring that staffing for

all services reflects its volume of patients, their acuity, and the level of intensity of services needed to ensure that plan of care outcomes are achieved and negative outcomes are avoided.

(b) *Standard: Twenty-four hour nursing services.* The hospice facility must provide 24-hour nursing services that meet the nursing needs of all patients and are furnished in accordance with each patient's plan of care. Each patient must receive all nursing services as prescribed and must be kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.

(c) *Standard: Physical environment.* The hospice must maintain a safe physical environment free of hazards for patients, staff, and visitors.

(1) *Safety management.* (i) The hospice must address real or potential threats to the health and safety of the patients, others, and property. The hospice must report a breach of safety to appropriate State and local bodies having regulatory jurisdiction and correct it promptly.

(ii) The hospice must take steps to prevent equipment failure and when a failure occurs, report it appropriate State and local bodies having regulatory jurisdiction and correct it promptly.

(iii) The hospice must have a written disaster preparedness plan in effect for managing the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care. The plan must be periodically reviewed and rehearsed with staff (including non-employee staff) with special emphasis placed on carrying out the procedures necessary to protect patients and others.

(2) *Physical plant and equipment.* The hospice must develop procedures for managing the control, reliability, and quality of—

(i) The routine storage and prompt disposal of trash and medical waste;

(ii) Light, temperature, and ventilation/air exchanges throughout the hospice;

(iii) Emergency gas and water supply; and

(iv) The scheduled and emergency maintenance and repair of all equipment.

(d) *Standard: Fire protection.* (1) Except as otherwise provided in this section—

(i) The hospice must meet the provisions applicable to nursing homes of the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association The Director of the Office of the Federal Register has approved the NFPA 101 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal register/code of federal regulations/ibr locations.html.* Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in the edition of the Code are incorporated by reference, CMS will publish a notice in the **Federal Register** to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to hospice.

(2) In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied would result in unreasonable hardship for the hospice, but only if the waiver would not adversely affect the health and safety of patients.

(3) The provisions of the adopted edition of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in hospices.

(4) Beginning March 13, 2006, a hospice must be in compliance with Chapter 9.2.9, Emergency lighting.

(5) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to hospices.

(6) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a hospice may place alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(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 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the **Federal Register** to announce the changes.

(e) *Standard: Patient areas.* The hospice must provide a home-like atmosphere and ensure that patient areas are designed to preserve the dignity, comfort, and privacy of patients.

(1) The hospice must provide—

(i) Physical space for private patient and family visiting;

(ii) Accommodations for family members to remain with the patient throughout the night; and

(iii) Physical space for family privacy after a patient's death.

(2) The hospice must provide the opportunity for patients to receive visitors at any hour, including infants and small children.

(f) *Standard: Patient rooms.* (1) The hospice must ensure that patient rooms are designed and equipped for nursing care, as well as the dignity, comfort, and privacy of patients.

(2) The hospice must accommodate a patient and family request for a single room whenever possible.

(3) Each patient's room must—

(i) Be at or above grade level;

(ii) Contain a suitable bed and other appropriate furniture for each patient;

(iii) Have closet space that provides security and privacy for clothing and personal belongings;

(iv) Accommodate no more than two patients;

(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 an existing building, CMS may waive the space and occupancy requirements of paragraphs (f)(2)(iv) and (f)(2)(v) of this section for a period of time if it determines that—

(i) Imposition of the requirements would result in unreasonable hardship on the hospice if strictly enforced; or

jeopardize its ability to continue to participate in the Medicare program; and

(ii) The waiver serves the needs of the patient and does not adversely affect their health and safety.

(g) *Standard: Toilet/bathing facilities.* Each patient room must be equipped with, or conveniently located near, toilet and bathing facilities.

(h) *Standard: Plumbing facilities.* The hospice must—

(1) Have an adequate supply of hot water at all times; and

(2) Have plumbing fixtures with control valves that automatically regulate the temperature of the hot water used by patients.

(i) *Standard: Infection control.* The hospice must maintain an infection control program that protects patients, staff and others by preventing and controlling infections and communicable disease as stipulated in § 418.60.

(j) *Standard: Sanitary environment.* The hospice must provide a sanitary environment by following current standards of practice, including nationally recognized infection control precautions, and avoid sources and transmission of infections and communicable diseases.

(k) *Standard: Linen.* The hospice must have available at all times a quantity of clean linen in sufficient amounts for all patient uses. Linens must be handled, stored, processed, and transported in such a manner as to prevent the spread of contaminants.

(l) *Standard: Meal service and menu planning.* The hospice must furnish meals to each patient that are—

(1) Consistent with the patient's plan of care, nutritional needs, and therapeutic diet;

(2) Palatable, attractive, and served at the proper temperature; and

(3) Obtained, stored, prepared, distributed, and served under sanitary conditions.

(m) *Standard: Pharmaceutical services.* Under the direction of a qualified pharmacist, the hospice must provide pharmaceutical services such as drugs and biologicals and have a written process in place that ensures dispensing accuracy. The hospice will evaluate a patient's response to the medication therapy, identify adverse drug reactions, and take appropriate corrective action. Drugs and biologicals must be obtained from community or institutional pharmacists or stocked by the hospice. The hospice must furnish the drugs and biologicals for each patient, as specified in each patient's plan care. The use of drugs and biologicals must be provided in accordance with accepted professional principles and appropriate Federal, State, and local laws.

(n) *Pharmacist.* A licensed pharmacist must provide consultation on all aspects of the provision of pharmaceutical care in the facility, including ordering, storage, administration, disposal, and record keeping of drugs and biologicals.

(1) *Orders for medications.* (i) A physician as defined by section 1861(r)(1) of the Act, or a nurse practitioner in accordance with the plan of care and State law, must order all medications for the patient.

(ii) If the medication order is verbal or given by or through electronic transmission—

(A) The physician must give it only to a licensed nurse, nurse practitioner (where appropriate), pharmacist, or another physician; and

(B) The individual receiving the order must record and sign it immediately and have the prescribing physician sign it in accordance with State and Federal regulations.

(2) *Administration of medications.* Medications must be administered by only the following individuals:

(i) A licensed nurse, physician, or other health care professional in accordance with their scope of practice.

(ii) An employee who has completed a State-approved training program in medication administration.

(iii) The patient, upon approval by the attending physician.

(3) *Labeling of drugs and biologicals.* Drugs and biologicals must be labeled in accordance with currently accepted professional practice and must include appropriate accessory and cautionary instructions, as well as an expiration date (if applicable).

(4) *Drug management procedures.* (i) All drugs and biologicals must be stored in secure areas. All drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1976 must be stored in locked compartments within such secure storage areas. Only personnel authorized to administer controlled medications may have access to the locked compartments.

(ii) The hospice must keep current and accurate records of the receipt and disposition of all controlled drugs.

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

(5) *Drug disposal.* Controlled drugs no longer needed by a patient must be disposed of in compliance with the hospice policy and in accordance with State and Federal requirements.

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

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

(3) The use of restraint and seclusion must be—

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

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

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

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

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

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

issuing another seclusion and restraint order.

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

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

(v) In accordance with safe, appropriate restraining techniques;

(vi) Ended at the earliest possible time; and

(vii) Supported by medical necessity and the patient's response or outcome, and documented in the patient's clinical record.

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

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

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

(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.

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

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

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

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

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

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

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

(d) *Standard: Medical director.* The medical director and physician designee of the hospice must provide overall coordination of the medical care of the hospice resident that resides in an SNF, NF, or other facility. The medical director and physician designee must communicate with the medical director of the SNF/NF, the patient's attending physician, and other physicians participating in the provision of care for the terminal and related conditions to ensure quality care for the patient and family.

(e) *Standard: Written agreement.* The hospice and the facility must have a written agreement that specifies the provision of hospice services in the facility. The agreement must be signed by authorized representatives of the hospice and the facility before the provision of hospice services. The written agreement must include at least the following:

(1) The written consent of the patient or the patient's representative that hospice services are desired.

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

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

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

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

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

(iii) A life threatening condition appears;

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

(v) The patient dies.

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

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

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

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

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

(1) The plan of care must identify the care and services that are needed and specifically identify which provider is responsible for performing the respective functions that have been agreed upon and included in the plan of care.

(2) The plan of care reflects the participation of the hospice, the facility, and the patient and family to the extent possible.

(3) In conjunction with representatives of the facility, the plan of care must be reviewed at intervals specified in the plan but no less often than every 14 calendar days.

(4) Any changes in the plan of care must be discussed among all caregivers and must be approved by the hospice before implementation.

(g) *Standard: Coordination of services.* The hospice must designate a member of its interdisciplinary group to coordinate the implementation of the plan of care with the representatives of the facility. The hospice must provide the facility with the following information:

(1) Plan of care.

(2) Patient or patient's representative hospice consent form and advance directives.

(3) Names and contact information for hospice personnel involved in hospice care of the patient.

(4) Instructions on how to access the hospice's 24-hour on-call system.

(5) Medication information specific to the patient

(6) Physician orders.

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

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

§ 418.114 Condition of participation: Personnel qualifications for licensed professionals.

(a) *General qualification requirements.* Except as specified in paragraph (c) of this section, all professionals who furnish services directly, under an individual contract, or under arrangements with a hospice, must be legally authorized (licensed, certified or registered) to practice by the State in which he or she performs such functions or actions, and must act only within the scope of his or her State license, or State certification, or registration. All personnel qualifications must be kept current at all times.

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

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

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

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

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

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

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

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

(c) *Personnel qualifications when no State licensing, certification or registration requirements exist.* If no State licensing laws, certification or registration requirements exist for the profession, the following requirements must be met:

(1) *Occupational therapist.* An occupational therapist must—

(i) Be a graduate of an occupational therapy curriculum accredited by the American Occupational Therapy Association, and be eligible for the National Registration Examination of the American Occupational Therapy Association; or

(ii) Have 2 years of appropriate experience as an occupational therapist, and have achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapist after December 31, 1977.

(2) *Occupational therapy assistant.* An occupational therapy assistant must—

(i) Meet the requirements for certification as an occupational therapy assistant established by the American Occupational Therapy Association; or

(ii) Have 2 years of appropriate experience as an occupational therapy assistant, and have achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapy assistant after December 31, 1977.

(3) *Physical therapist.* A person who—

(i) Has graduated from a physical therapy curriculum approved by—

(A) The American Physical Therapy Association;

(B) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association; or

(ii) Prior to January 1, 1966—

(A) Was admitted to membership by the American Physical Therapy Association;

(B) Was admitted to registration by the American Registry of Physical Therapists; or

(C) Has graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education; or

(iii) Has 2 years of appropriate experience as a physical therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking qualification as a physical therapist after December 31, 1977; or

(iv) Was licensed or registered prior to January 1, 1966, and prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy; or

(v) If trained outside the United States—

(A) Has graduated, since 1928, from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy;

(B) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

(4) *Physical therapist assistant.* A person who—

(i) Has graduated from a 2-year college-level program approved by the American Physical Therapy Association; or

(ii) Has 2 years of appropriate experience as a physical therapy assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a physical therapy assistant after December 31, 1977.

(5) *Registered nurse.* A graduate of a school of professional nursing.

(6) *Licensed practical nurse.* A person who has completed a practical nursing program.

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

(d) *Standard: Criminal background checks.* The hospice must obtain a criminal background check on each hospice employee and contracted employee before employment at the hospice.

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

The hospice and its staff must operate and furnish services in compliance with all applicable Federal, State, and local laws and regulations related to the health and safety of patients. If State or local law provides for licensing of hospices, the hospice must be licensed.

(a) *Standard: Licensure of staff.* Any persons who provide hospice services must be licensed, certified, or registered in accordance with applicable Federal, State and local laws.

(b) *Standard: Multiple locations.* Every hospice must comply with the requirements of § 420.206 of this chapter regarding disclosure of ownership and control information. All hospice satellite locations must be approved by CMS and licensed in accordance with State licensure laws, if applicable, before providing Medicare reimbursed services.

(c) *Standard: Laboratory services.* (1) If the hospice engages in laboratory testing other than assisting a patient in self-administering a test with an appliance that has been approved for that purpose by the FDA, the hospice must be in compliance with all applicable requirements of part 493 of this chapter.

(2) If the hospice chooses to refer specimens for laboratory testing to a reference laboratory, the reference laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.

§ 418.200 [Amended]

6. Section 418.200 is amended by revising the reference ''§ 418.58'' to read ''§ 418.56''.

§ 418.202 [Amended]

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

(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: February 7, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: February 7, 2005.

Michael O. Leavitt,

Secretary.

[FR Doc. 05–9935 Filed 5–26–05; 8:45 am]

BILLING CODE 4120–01–P