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Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-09-19

DATE: **January 2, 2009**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Advance Copy – Hospice Program Interpretive Guidance Version 1.1

Memorandum Summary

Hospice Interpretive Guidance Update: Attached is an advance copy of the Hospice Interpretive Guidance. This Interpretive Guidance will also be published in an updated Appendix M of the State Operations Manual (SOM).

The attached Hospice Program Interpretive Guidance represents the most recent guidance related to the 42 CFR Part 418 Conditions of Participation for Hospice. This Interpretive Guidance should replace all previously-released versions.

Attachment A is an advance copy of the interim final Hospice Interpretive Guidance. This guidance will ultimately be published in Appendix M of the SOM. Appendix M in the SOM may differ slightly from this advance copy as the document is still in the internal clearance process.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: The information contained in this letter should be shared with all survey and certification staff, their managers, and the State/RO training coordinators. If you have additional questions or concerns, please contact Kim Roche through email at Kim.roche@cms.hhs.gov.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

Attachment

Interim Version 1.1 *Advance Copy*

State Operations Manual

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Part I – Investigative Procedures

I – Introduction

Survey protocols and Interpretive Guidelines are established to provide guidance to personnel conducting surveys of hospices. They serve to clarify and/or explain the intent of the regulations. All surveyors are required to use them in assessing compliance with Federal requirements. The purpose of the protocols and guidelines is to direct the surveyor's attention to avenues of investigation in preparation for the survey, conducting the survey, and evaluating the survey findings.

These protocols represent the view of the Centers for Medicare & Medicaid Services (CMS) on relevant areas and items that must be inspected/reviewed under each regulation. The use of these protocols promotes consistency in the survey process. The protocols assure that a facility's compliance with the regulations is reviewed in a thorough, efficient, and consistent manner so that at the completion of the survey, surveyors have sufficient information to make compliance decisions.

Although surveyors use the information contained in the Interpretive Guidelines in the process of making a determination about a hospice's compliance with the regulations, these guidelines are not binding. Interpretive Guidelines do not establish requirements that must be met by hospices, do not replace or supersede the law or regulations, and may not be used alone as the sole basis for a citation. All mandatory requirements for hospices are set forth in relevant provisions of the Social Security Act and in regulations.

The Interpretive Guidelines do however, contain authoritative interpretations and clarification of statutory and regulatory requirements and are used to assist surveyors in making determinations about a hospice's compliance.

Survey Team

The State survey agency (SA), or the CMS Regional Office (RO) for Federal teams, decides the size of the team. Each hospice survey team should include at least one RN with hospice survey experience. Other surveyors who have the expertise to determine whether the hospice is in compliance may be used as needed.

Training for Hospice Surveyors

Hospice surveyors should have the necessary training and experience to conduct a hospice survey. All hospice surveyors must attend a CMS sponsored Basic Hospice Surveyor Training Course. New surveyors may accompany the team as part of their training prior to completing the CMS Basic Hospice Surveyor Training Course.

Types of Hospice Surveys

A - Initial Certification

Prior to the initial Medicare certification survey, a prospective hospice should notify the RO and/or the SA that it wants to apply for Medicare certification. The prospective hospice must complete a Medicare enrollment application (Form CMS 855A). This form can be found at: http://www.cms.hhs.gov/MedicareProviderSupEnroll/02_EnrollmentApplications.asp#TopOfPage. The assigned Medicare Administrative Contractor (MAC) will review the application, verify the information and notify the RO and SA of their enrollment recommendation. Additional information on this process is available in §2005A.

Initial Medicare Certification Survey

Before the SA or the National Accrediting Organization (AO) with deeming authority conducts the initial Medicare certification survey, the SA must have received written documentation submitted by the prospective hospice requesting an initial certification survey. At the time of the survey, the prospective hospice must:

- Be operational.
- Have completed the Medicare Enrollment Application Form CMS-855A and had this form verified by the assigned MAC.
- Have provided care to a minimum of 5 hospice patients (not required to be Medicare patients). At least 3 hospice patients should be receiving care at the time of the initial Medicare certification survey. If the hospice is located in a medically underserved area, as determined by the CMS RO, the CMS RO may reduce the minimum number of patients from 5 to 2. At least 1 of the 2 required patients should be receiving care from the hospice at the time of the initial Medicare survey.
- Be providing all services needed by the patients actually being served.
- Be capable of demonstrating the operational capability of all facets of its operations.

In the event that the hospice patients being served at the time of the survey do not require the full scope of hospice services, verify that the hospice is fully prepared to provide all services necessary to meet the hospice CoPs.

It is not necessary to inspect the facility where the inpatient services will be provided under arrangement or in space share with a Medicare certified facility. The contract for the inpatient services must be reviewed to ensure that it is valid and there is no doubt that the hospice will be able to provide the service when needed.

The effective date of Medicare participation can be no earlier than the date the hospice is prepared to provide all of the required services and meets all hospice CoPs. In no case can the effective date be earlier than the date the hospice meets all the Federal requirements (42 CFR 489.13).

All initial hospice surveys are unannounced and must verify compliance with all the regulatory requirements contained in §418.52-§418.116. (See §2700A)

B - Recertification Survey of Participating Hospices

All recertification hospice surveys are unannounced and must verify compliance with all the regulatory requirements contained in §418.52-§418.116. If an existing certified hospice has a new inpatient unit or an inpatient unit that it wishes to relocate, verify compliance with the regulations at §418.110.

Routinely conduct the recertification survey at a multiple location of the hospice, if applicable, when that location serves more patients than the initial location issued the CMS certification number. Whenever possible, visit all locations of the hospice during the survey. Deficiencies found at any multiple location(s) are applicable to the entire hospice.

C - Post-Survey Revisit

In some cases, the SA may verify correction of deficiencies through mail, telephone or electronic contact in lieu of an on-site visit. However, an on-site visit is required for any condition level deficiency. Through the on-site visit or other contact, assess the hospice's correction of the deficiencies previously cited on the Statement of Deficiencies and Plan of Correction, Form CMS-2567.

The purpose of the post-survey onsite revisit is to reevaluate the specific care and services that were cited during the survey that cannot be adequately assessed by mail, telephone, or electronic contact. The nature of the deficiencies dictates the necessity for and scope of the post-survey revisit. If deficiencies were originally identified during home visits, home visits may be necessary on the revisit. Conduct as many home visits as necessary to assess compliance. Assess the compliance of the hospice on all deficiencies cited on the Form CMS-2567. If a deficiency is subsequently corrected, the SA completes the Post-Certification Revisit Report, Form CMS-2567B, as appropriate. (Refer to §2732B for additional information). If at the time of the post-survey revisit, some deficiencies have not been corrected, or additional deficiencies are identified, the SA completes another Form CMS-2567 summarizing the deficiencies by data prefix tag. The SA may examine all conditions, as needed, to determine compliance status. The hospice must provide a plan of correction including completion dates for deficiencies identified during a post-survey revisit.

D - Complaint Investigations

Investigation and resolution of complaints is a critical certification activity. Each complaint against a hospice must be documented, investigated and resolved. Follow the guidance in Chapter 5 for investigations of complaints.

If the hospice is found to have one or more condition-level deficiencies during the complaint investigation, all conditions must be reviewed. Follow the Interpretive Guidelines contained in Part II of this Appendix.

II – The Survey Focus

The hospice outcome-oriented survey process emphasizes the hospice's performance and its effect on patients. The process first directs the surveyor to focus on the services being provided, and then to examine the structures and processes that contribute to the quality of the services. The primary focus of the survey is on patient outcomes, the hospice's practices in implementing the requirements, and provision of hospice services. The intent of the survey is to evaluate each of the CoPs in the most efficient manner possible. The surveyor considers the interrelatedness of the regulations while evaluating compliance through observations, interviews, home visits, and record reviews.

III - The Survey Tasks

The hospice survey process consists of completing the following tasks with an assessment of the principal components listed below.

- Task 1 Pre-Survey Preparation
- Task 2 Entrance Interview
- Task 3 Information Gathering
- Task 4 Information Analysis
- Task 5 Exit Conference
- Task 6 Formation of the Statement of Deficiencies

Task 1 - Pre Survey Preparation

Prior to each survey, review the hospice's file in accordance with §2704. In addition, review the Interpretive Guidelines, which contain critical questions to ask during the entrance conference and throughout the survey.

Task 2 - Entrance Interview

The entrance interview sets the tone for the entire survey. The surveyor must establish rapport with the hospice staff. During this interview, gather information to understand how the hospice organizes itself, and provides hospice care and services to patients.

1. Upon arrival at the hospice, complete the following primary activities:

- Present identification and introduce any survey team members.
- Request a meeting with appropriate staff based on the organizational characteristics of the hospice. Request a copy of the organizational chart.
- Inform the administrator or designee of the purpose of the survey.
- Ask the administrator or designee to explain the organization, services provided (directly and under arrangement) and the relationship to any corporate structure.
- Explain the survey process, and estimate the number of days onsite.
- Be aware that the unannounced survey may be disruptive to the normal daily activities of the hospice.
- Discuss the extent to which hospice staff may be involved during the survey.
- Set up the schedule for any necessary interviews with key staff (e.g., medical director, spiritual or pastoral counselor, bereavement counselor, volunteer supervisor, social worker, RN coordinator, etc.)
- Request that the hospice complete the Form CMS-417, Hospice Request for Certification in the Medicare Program (Exhibit 72) and return it to you as soon as possible, but no later than within 24 hours of the entrance conference.
- Request space to work.

Investigate any discrepancies in information obtained during the entrance interview through observation, interviews with key staff, and a review of source documents, as needed, during the survey.

2. Request the following information during the entrance interview:

- Verification of addresses of all locations and/or short term inpatient facilities used by the hospice (either directly or under arrangements).
- Access to clinical records and the equipment necessary to read any clinical records maintained electronically. The hospice must also produce a paper copy of the record, if requested by the surveyor.
- Information given to the patient on admission to hospice.
- Documentation of hospice aide training and/or competency evaluations and in-service training.
- Information concerning services not provided directly.

- Number of unduplicated admissions for the entire hospice during the recent 12 month period, including Medicare/Medicaid and private pay patients.
- Number of current patients who are receiving hospice care at home, in an inpatient facility, SNF/NF, ICF/MR or other facility.
- List or access to names of patients scheduled for a home visit during the survey.
- Access to all active patient names (Medicare/Medicaid/private pay) receiving hospice services that identifies the election date, diagnosis, and date the initial and comprehensive assessment was completed. This will aid in selecting the sample for home visits and record reviews.
- Access to bereavement records for expired patients who received services during the last 12 months.
- List of current employees and volunteers (including name, title).
- List of contracts as applicable (e.g., SNF/NF, DME, Pharmacy, Inpatient facilities.
- Names of key staff (e.g., RN coordinator(s) for IDG(s), and persons most knowledgeable about the hospice aides, homemakers, volunteers, infection control, quality assessment and performance improvement (QAPI), in-service training, clinical supervision, bereavement).
- Clinical staff person who will be the primary resource responding to the surveyor's questions.
- Documentation of grievances/complaints that the hospice received during the past 12 months.
- Personnel files, policies and procedures, and CLIA certificate (if applicable).
- Date(s) and time(s) of IDG reviews and plan of care updates.

Task 3 - Information Gathering

This task includes an organized, systematic, and consistent gathering of information necessary to make decisions concerning the hospice's compliance with the CoPs. Review each condition using the Interpretive Guidelines to assist you. Throughout your survey maintain an open and ongoing dialogue with hospice personnel. Discuss your observations, as appropriate, with team members and hospice personnel. Give the hospice the opportunity to provide additional information. Fully investigate the issues of concern through further observation, interviews and document reviews before making compliance decisions. Pay particular attention to the following areas related to patient care and organizational environment:

A – Patient Care

Is there evidence during the survey that:

- The hospice promotes and protects the rights of its patients.
- The hospice IDG gathers the appropriate patient/family information needed to perform accurate comprehensive assessments and necessary updates to the assessment.

- The IDG works together to develop and update the individualized plan of care for each patient, based on the assessments, to meet the identified patient/family needs and goals (During the survey, it is helpful to attend at least a part of the scheduled IDG reviews of the patients' plans of care, if possible.)
- The hospice involves the patient and/or family in developing the plan of care. (Interviews with staff, patients and family can be helpful in determining how the hospice involves patient/families in developing the plan of care.)
- All members of the IDG and all relevant patient care providers (e.g., hospice aide, volunteer etc.,) share current relevant information regarding each patient/family's status.
- The hospice provides education to the patient/family about the patient's disease process, the palliation and management of the patient's symptoms, the safe and effective use of medication and medical equipment used by the patient, and the physical, psychosocial and spiritual aspects of the dying process.
- All personnel are qualified and furnish services to the patient in accordance with accepted professional standards of practice.
- The hospice assures that hospice aides are competent to provide care to their patients and supervised by a registered nurse.
- The hospice's infection control program protects patients, families, visitors, and hospice personnel by preventing and controlling infections and communicable diseases.
- The hospice develops, implements, and maintains an effective, ongoing, hospice-wide data-driven QAPI program.

B – Organizational Environment

Is there evidence during the survey that:

- The governing body ensures the hospice has an ongoing program to promote quality assessment and performance improvement.
- The hospice administrator assumes full responsibility for the day-to-day operations of the hospice.
- The hospice understands the principles surrounding quality assessment and implements effective ongoing performance improvement projects utilizing data collected.
- When the hospice identifies trends that indicate potential or actual problems, it takes follow up actions to resolve the issue(s).
- The hospice provides care that optimizes the patient's comfort and dignity and is consistent with the patient and family needs and goals.
- The hospice assumes overall professional management responsibility for all services provided directly and under arrangement.
- Nursing services, physician services, drugs and biologicals are routinely available on a 24-hour basis, 7 days a week. Other covered services are available on a 24-hour basis when reasonable and necessary to meet the needs of the patient and family.

- The on call system is operational on a 24 hour basis so that patients can contact the hospice as necessary.
- Drugs, treatments and medical supplies are provided as needed for the palliation and management of the terminal illness and related conditions.
- The hospice makes arrangements for any necessary inpatient care according to §418.108, and retains professional management responsibility for services furnished by inpatient facility staff.

C – Clinical Records

The minimum number of clinical records to be reviewed during the hospice survey will be the sum of the number of clinical records without home visits and the number of clinical records with home visits. See chart below.

Unduplicated Admissions	Min # Of Record Reviews Without Home Visit	Min # Of Record Reviews With Home Visit	Total Record Reviews
< 150	8	3	11
150-750	10	3	13
751-1250	12	4	16
1251 or more	15	5	20

1. Selection of Clinical Records

The number of record reviews without home visits, based on the total number of unduplicated admissions during a recent 12-month period, is as follows:

Number of Unduplicated Hospice Patients Admitted During Recent 12 Month Period	**Minimum Number of Record Reviews Without Home Visits of Patients Admitted During Recent 12 Month Period**
Less than 150	8
150 – 750	10
751 – 1250	12
1,251 or more	15 or more

The sample is selected to capture the different types of settings in which the hospice provides care (i.e., routine home care in a private residence or nursing facility, as well as inpatient care provided directly or under arrangement), and to include patients with different terminal diagnoses.

In addition to the sample of records selected, review a record of a hospice patient who has been discharged from a nursing home and a patient who has revoked the hospice benefit if there are concerns about discharge or revocation. In addition, review a sample of 2-3 bereavement plans of care from a list of patients who have died within the past 12 months to determine if the bereavement services provided reflected the needs of the bereaved.

2. Clinical Record Review

The arrangement and format of clinical records vary among hospices. To minimize time spent in reviewing a clinical record and to maximize the substantive information that can be obtained, use the following approach:

- Review the arrangement and format of one or two clinical records with the hospice staff person designated to answer your questions about how services are organized, delivered, and evaluated. Ask him/her where you are likely to find the information in the clinical record. If the record is maintained electronically, the hospice must provide all equipment necessary to read the record in its entirety. The hospice must also produce a paper copy of the record, if requested by the surveyor.
- Determine if the patient's comprehensive assessment and updates to the assessment were timely and accurately reflect the patient/family's status.
- Review the plan of care to identify whether the IDG used the comprehensive assessment and assessment updates to make sound care planning decisions appropriate to the patient/family needs.
- Determine if the plan of care is current and reflects the participation of all members of the IDG.
- Evaluate the hospice's ability to coordinate care and services that optimize patient comfort and dignity.
- Review a sample of clinical notations by all personnel providing services. Determine if the plan of care and frequency of visits by hospice personnel support the findings of the comprehensive assessment and updates to the assessment. Did the agency's interventions follow the plan of care? Was the documentation specific to changes in the patient/family's status?
- Determine how the hospice ensures coordination of services among and between the IDG members and other personnel providing services. What evidence is found in the clinical record(s) that this is occurring?
- Determine if hospice aide clinical notes document the status of the patient. Do the hospice aides report changes in the patient's condition to a registered nurse?

- If you cannot find information or you have questions about the content of the clinical record, ask the hospice staff to either find the information or help you understand its content.

D - Hospice Home Visit Procedures

Home visits must be made to a sample of hospice patients during a hospice survey. In the event that the hospice is part of another provider type (e.g., HHA) be sure that the patients selected for the home visit during the hospice survey are receiving hospice services from the hospice, not palliative care or home health services from the HHA. Terminally ill patients who do not wish to elect the Medicare hospice benefit and are admitted to a Medicare HHA for services under a dually-certified HHA/Hospice are considered HHA patients. These patients may **not** be selected for clinical record reviews or home visits during the Medicare hospice certification survey.

Home visits yield valuable information about how the hospice:

- Promotes and protects the rights of patients.
- Conducts the initial and comprehensive assessments.
- Updates the assessment.
- Implements the plan of care.
- Promotes patient/family satisfaction.
- Provides drugs, treatments, services and durable medical equipment (DME).
- Uses volunteers.
- Provides the required level of care related to the needs of the patient.

1 - Patient selection for home visit.

The number of record reviews with home visits, based on the total number of unduplicated admissions during a recent 12-month period, is as follows:

Number of Unduplicated Hospice Patients Admitted During Recent 12 Month Period	Minimum Number of Record Reviews With Home Visits of Patients Admitted During Recent 12 Month Period
Less than 750	3
751-1250	4
1251 or more	5

The surveyor identifies and selects patients who will receive hospice services during the remaining days of the survey. Additional home visits may be made as desired or indicated to determine the scope of any concerns initially identified by home visits or record reviews. Conduct a record review of each patient selected for a home visit either before or after the visit. The sample is selected to capture the different types of settings in which the hospice provides

routine home care[1] (i.e., private residence, nursing facility, etc.,) and include patients with different types of terminal diagnoses.

2 - Patient's Consent

You may visit patients from all payment sources that have given permission for the visit. Patients must understand that a home visit is voluntary and refusal to consent to a home visit will not affect Medicare/Medicaid benefits to which the beneficiaries are entitled. Have the patient (or representative) sign the hospice consent form before beginning the visit. You may obtain this signature upon arrival at the patient's residence if prior verbal consent has been obtained. (See model consent for hospice home visit form (Exhibit 128).

It is important to contact the patient before you arrive at the home or place of residence, if possible, because the first onsite contact may be intimidating to the patient/family or may generate some fear that would interfere with access to the patient's home or the quality of the interview. In most situations, the hospice representative who provides care or services should contact the patient/family to request permission and make the arrangements for the home visit. However, you may choose to contact the patient/family directly. The contact requesting the visit should be made in a neutral, non-alarming manner, without suggesting that there is a problem.

3 - Visit Procedure

Work with the hospice administrator or designee to develop a visit schedule that is the least disruptive to the usual scheduling of visits. If a patient refuses to have the surveyor accompany the hospice representative, select an alternate patient.

A home visit is more effective in assessing the scope and quality of care being provided if you observe how hospice personnel implement one or more parts of the patient's plan of care. In order to observe the delivery of care, attempt to schedule home visits at a time when the hospice is actually providing services. Use the following procedures to select patients for home/residence visits:

- Identify and select patients who will be visited by the hospice during the days of the scheduled survey, and who meet the criteria for patient selection. The sample size should include a few more patients than the number of proposed visits to accommodate possible refusals and include different individuals providing the services (e.g., nurse, social worker, hospice aide).
- Request a copy of the most recent plan of care for each patient selected for a home visit.
- If the hospice does not have any visits scheduled, invite the hospice to have one of its employees accompany you on home visits to patients that you have selected. However,

[1] Home visits are not required to be limited to patients receiving routine home care. If in reviewing contracts or other documentation (e.g., clinical records, plans of care), questions arise concerning the hospice's provision of inpatient care, either directly or under arrangements, conduct an onsite visit to the institution providing the inpatient services to review the care provided. See §2084.2

there may be circumstances (i.e., complaints) that should be reviewed during a home visit without the hospice representative being present.

4 - Home Visit

At the patient's home you may talk with the patient, family/caregiver or both. Indicate that the primary purpose of the home visit is to evaluate the effectiveness of the hospice's services. Conduct the visit with sensitivity and understanding of the life crises that the patient and caregiver are experiencing. Refer to the Interpretive Guidelines for questions to use during the home visit to help you understand the patient/family satisfaction with the hospice care/services and to assess the scope, quality and effectiveness of the plan of care and services delivered.

The following additional questions may be useful during the home visit:

- Who comes to see you from the hospice?
- How frequently do you receive care and services?
- Has the nurse talked with you about treating your pain and/or other uncomfortable symptoms?
- Have there been any instances where the hospice failed to respond to the patient's request for pain medication or symptom management?
- Have you ever had to wait long to get medication for discomfort? If yes, how long was the wait?
- Has someone from the hospice given you a chance to talk about your religious or spiritual beliefs or concerns?
- Have you ever needed to call the hospice on weekends, evenings, nights, or holidays? What was your experience with this?
- Have you received care in any other setting while under hospice care? If so, what was your experience?
- Since you have been receiving care from the hospice, have you had any out-of-pocket expenses for your health care? If yes, what kind?
- How satisfied are you with the services provided? Do you have any suggestions for improvement?
- Would you recommend this hospice?

Observe, but do not interfere with, the delivery of care or the interactions between the hospice representative and the patient/family and/or caregiver. Be continuously aware that as a guest in a patient's home/residence, courtesy, common sense, and sensitivity to the importance of an individual's own environment is absolutely essential, regardless of the condition.

Additional general information about facility personnel accompanying surveyors and physical contact of patients by surveyors is included in §2713A and §2713B of this manual.

Discontinue the interview if:

- The patient shows signs of being uncomfortable or seems reluctant to talk, and if after asking the patient, they would rather discontinue the discussion; or
- The patient appears tired, overly concerned, agitated, etc., and would like to end the interview; or
- In your judgment, it appears to be in the patient's best interest to end the interview.

E - Follow-Up Procedures

Check any specific patient/family complaints concerning the hospice's delivery of items and services with the hospice to be sure that there are no misunderstandings and that the patient's plan of care is being followed.

If hospice deficiencies are identified as a result of a home visit and/or clinical record review, cite these deficiencies on the Form CMS-2567. These deficiencies could include, but are not limited to:

- Failure to promote and protect the patient's rights.
- Failure to accurately conduct a patient-specific comprehensive assessment that identifies the patient/family's need for hospice care and services, and the patient/family's need for physical, psychosocial, emotional, and spiritual care.
- Failure to develop and implement a plan of care that meets the needs identified in the initial or comprehensive assessment.
- Failure of the IDG to meet the physical, medical, psychosocial, emotional, and spiritual needs of the hospice patient/family.
- Failure to provide all covered services, as necessary, including the continuous home care level of care, respite care and short-term inpatient care.
- Failure to provide nursing and physician services, drugs and treatments on a 24-hour basis.
- Failure to retain professional management responsibility for all hospice services provided under contract to patients.
- Failure to develop, implement, and maintain an effective, ongoing, hospice-wide data-driven QAPI program.

Task 4 - Information Analysis

A – General

The information analysis process requires surveyors to review the information gathered during the survey and make judgments about the compliance of the hospice. Do not make an evaluation of whether a finding constitutes a deficiency or whether a condition level deficiency exists until

all necessary information has been collected. Additional activities and investigation through record review, home visit observations and interviews should substantiate and support any findings of non-compliance with the CoPs. Review all your findings and use your professional judgment to decide whether further information gathering is necessary.

B – Analysis

Analyze your findings relative to each requirement for the:

- Effect or potential effect on the patient(s).
- Degree of severity.
- Frequency of occurrence.
- Impact on the delivery of services.

An isolated incident that has little or no effect on the delivery of patient services may not warrant a deficiency citation. Conversely, a condition may be considered out of compliance for one or more deficiencies if, in your judgment, the deficiency constitutes a significant or serious problem that adversely affects, or has the potential to adversely affect the patient(s). A deficiency must be based on the statute or the regulations. Citation of a deficiency must not be based on a violation of a guideline alone. In each case you must determine, based on the facts and circumstances existing at the time and any further investigation as may be warranted, whether a deficiency exists based on the applicable statutory or regulatory provision.

The surveyor's role is to assess the quality of care and services the hospice provides and relate those findings to the statutory and regulatory requirements. When deficiencies are found during a survey, the surveyor should explain to the provider what the deficiency is so the provider understands why the requirement is not met. It is not the surveyor's job to provide consultation on how to fix the deficiencies. See §4018 for further information on the regulatory role of the surveyor.

Task 5 - Exit Conference

The exit conference is held at the end of the survey in accordance with §2724. The purpose of the exit conference is to inform the hospice of observations and preliminary findings of the survey. Because of ongoing dialogue between the surveyor(s) and hospice staff during the survey, there should be few instances where the hospice is not aware of the surveyor concerns prior to the exit conference. Implement the following guidelines during the conference:

- Conduct the exit conference with the hospice administrator, clinical supervisors and other staff invited by the hospice.
- Describe the regulatory requirements that the hospice does not meet and the findings that substantiate these deficiencies. Avoid using data tag numbers when referring to your findings.

- Present the Form CMS-2567 onsite, or in accordance with the State agency's policy, but no later than 10 **working** days after the exit conference.
- Provide instructions and time frame for submitting a plan of correction. The plan of correction must be submitted to the SA within 10 **calendar** days after receipt of the Form CMS-2567. (Refer to §2724 and §2728 for additional information).

Refer to §2724 for additional information on the exit conference, presence of counsel, taping of the conference, and situations that would justify refusal to conduct or continue an exit conference.

Task 6 - Formation of the Statement of Deficiencies

Follow §2728 for preparation of the Statement of Deficiencies and Plan of Correction. Refer to the document "Principles of Documentation for the Statement of Deficiencies" for detailed instructions on completing the Form CMS-2567.

Part II – Interpretive Guidelines

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§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 described in Sec. 410.75 (b) of this chapter. (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 before and after the death of the patient to assist with issues related to grief, loss, and adjustment.

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

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

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

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

Employee means a person who: (1) works for the hospice and for whom the hospice is required to issue a W-2 form on his or her behalf; or (2) if the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is assigned to the hospice; or (3) is a volunteer under the jurisdiction of the hospice.

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

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

delineated in a specific patient plan of care.

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

Licensed professional means a person licensed to provide patient care services by the State in which services are delivered.

Multiple location means a Medicare-approved location from which the hospice provides the same full range of hospice care and services that is required of the hospice issued the certification number. A multiple location must meet all of the conditions of participation applicable to hospices.

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

Physician means an individual who meets the qualifications and conditions as defined in section 1861(r) of the Act and implemented at §410.20 of this chapter.

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

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

Restraint means (1) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely, not including devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort); or (2) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

Seclusion means the involuntary confinement of a patient alone in a room or an area from which the patient is physically prevented from leaving.

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

L500

§418.52 Condition of participation: Patient's rights

L501

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.

§418.52(a) Standard: Notice of rights and responsibilities

L502

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

Interpretive Guidelines §418.52(a)(1)

When reference is made to "patient" in the Guidelines, it also refers to any person who may, under State law, act on the patient's behalf when the patient is unable to act for him or herself. That person is referred to as the patient's surrogate or representative. If a court has formally declared the patient incompetent, the surrogate or representative is whomever the court guardian, conservator, or committee) appointed. The hospice should verify that the representative has the necessary authority. For example, a court-appointed conservator might have the power to make financial decisions, but not health care decisions.

All hospice patients should be aware of their rights and responsibilities before the hospice begins to provide care. The hospice must verbally explain the patient rights and responsibilities to all patients accepted for care (or explain the rights to the patient's representative if the patient is physically or mentally incapacitated).

There must be evidence that the hospice conscientiously tried, within the constraints of the individual situation, to inform the patient/family both verbally (spoken) and in writing of patient rights and responsibilities. If a patient is able to read and understand written materials without assistance, an oral summary, along with the complete written documentation is acceptable.

For the patient who does not speak or understand English, hospices should make all reasonable efforts to secure a professional, objective translator for hospice-patient communications, including those involving the notice of patient rights and responsibilities. The hospice may only

use family and friends as translators for the patient when an objective translator cannot be secured by the hospice or if the patient specifically requests this approach. Hospices should make all reasonable efforts to have written copies of the notice of rights and responsibilities

available in the language(s) that are commonly spoken in the hospice's service area. For those patients who speak languages in areas where professional translators for those languages are not readily available, using family and friends of the patient is an acceptable option if the patient agrees.

Further information on this topic is available from the Department of Health and Human Services, Office for Civil Rights Policy Guidance: Title VI Prohibition Against National Origin Discrimination As It Affects Persons With Limited English Proficiency.

Procedures and Probes: §418.52(a)(1)

Ask the hospice for a copy of the material they provide to patients or their representative on admission. During home visits, ask the patient/family if the hospice informed them of their rights and responsibilities, and, if so, how and when. They should be able to give, in their own words, examples of how the rights apply to the care being received and any concerns they have about financial implications of the items or services they receive. They should also be able to explain how to access the hospice staff. If the patient or representative is vague in answering questions, ask for the written patient rights and responsibilities information that the hospice provided him or her as resource material, prior to furnishing care.

L503

(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.

Interpretive Guidelines §418.52(a)(2)

Advance directives generally refer to written statements or instructions, completed in advance of a serious illness, about how an individual wants medical decisions made. The two most common forms of advance directives are a living will and a durable medical power of attorney for health care. It is the patient's right to formulate an advance directive should he/she wish to do so. The patient's admission to hospice should not be affected by his/her desire not to formulate an advance directive or by the contents of an advance directive. There may be State specific requirements for advance directives that must be followed.

The hospices' obligations under 42 CFR 489.102 include the following requirements:
Hospices must maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care by or through the provider and are required to:

(1) Provide written information to such individuals concerning—
   (i) An individual's rights under State law (whether statutory or recognized by the courts of the State) to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual's

option, advance directives. Providers are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met. Providers are to update and disseminate amended information as soon as possible, but no later than 90 days from the effective date of the changes to State law; and

(ii) The written policies of the provider or organization respecting the implementation of such rights, including a clear and precise statement of limitation if the provider cannot implement an advance directive on the basis of conscience. At a minimum, a provider's statement of limitation should:
   (A) Clarify any differences between institution-wide conscience objections and those that may be raised by individual physicians;
   (B) Identify the state legal authority permitting such objection;
   (C) Describe the range of medical conditions or procedures affected by the conscience objection.

(2) Document in a prominent part of the individual's current medical record, or patient care record in the case of an individual in a religious nonmedical health care institution, whether or not the individual has executed an advance directive;
(3) Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;
(4) Ensure compliance with requirements of State law (whether statutory or recognized by the courts of the State) regarding advance directives. The provider must inform individuals that complaints concerning the advance directive requirements may be filed with the State survey and certification agency;
(5) Provide for education of staff concerning its policies and procedures on advance directives; and
(6) Provide for community education regarding issues concerning advance directives that may include material required in paragraph (a)(1) of this section, either directly or in concert with other providers and organizations. Separate community education materials may be developed and used, at the discretion of providers. The same written materials do not have to be provided in all settings, but the material should define what constitutes an advance directive, emphasizing that an advance directive is designed to enhance an incapacitated individual's control over medical treatment, and describe applicable State law concerning advance directives. A provider must be able to document its community education efforts.

Hospices must furnish this information to the patient at the time of initial receipt of hospice care by the individual from the hospice. Hospices:

1. Are not required to provide care that conflicts with an advance directive.
2. Are not required to implement an advance directive if, as a matter of conscience, it cannot implement an advance directive and State law allows the hospice to conscientiously object.

If an adult individual is incapacitated at the time of admission or at the start of care and is unable to receive information (due to the incapacitating conditions or a mental disorder) or articulate whether or not he or she has executed an advance directive, then the hospice may give advance

directive information to the individual's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law. The hospice is not relieved of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.

Compliance with the advance directives requirements is necessary for continued participation in the Medicare and Medicaid programs.

L504

(3) The hospice must obtain the patient's or representative's signature confirming that he or she has received a copy of the notice of rights and responsibilities.

Procedure §418.54(a)(3)

Review the clinical record for evidence of the patient's or representative's signature confirming receipt of the notice of rights and responsibilities.

§418.52(b) Standard: Exercise of rights and respect for property and person

L505

(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;**
- **(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.**

Interpretive Guidelines §418.52(b)(1)(i)-(iv)

Patients must be free to exercise their rights without fear of reprisal from the hospice. The hospice must not hamper, compel, treat differentially, or retaliate against a patient or family for exercising the patient's rights. The hospice must assure that its staff will protect patients' rights and will involve patients in decisions about their care, treatment and services.

A grievance is a formal or informal written or verbal complaint that is made to any hospice employee, including volunteers and individuals furnishing hospice services under arrangement, by a patient or the patient's representative regarding the patient's care, abuse, neglect, or misappropriation of property.

Procedures and Probes §418.52(b)(1)(i)-(iv)

Review patient admission information for instructions on making a complaint. Note any patient-described problems recorded either in the hospice's documentation of complaints received or in the clinical record reviews, and note if they were addressed and resolved. If resolution of the problem was not possible, the hospice should document both the actions attempted and the outcomes achieved.

Ask to see documentation of complaints made by patients or patients' families for the previous 12 months and review how the hospice received, recorded, investigated, and resolved these complaints. Is there evidence that the hospice staff is aware of and follows the hospice's policy for complaint investigation when a patient/family makes a complaint to a staff member? Pay close attention to staff remarks and staff behavior that may represent deliberate actions to promote or to limit a patient's autonomy or choice. Who in the hospice is ultimately accountable for receiving, investigating and resolving any patient concerns or problems that cannot be resolved at the staff level?

During home visits, ask the patient/family if they know how and whom to contact if they have a complaint. Ask the patient, the patient's family, guardian or other legal representative, if they have any comments or concerns, or have registered any grievances or complaints about the hospice or its services. If this has already occurred, ask how it was handled and what the results or outcomes were.

L506

(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.

Procedures and Probes §418.52(b)(2):

Determine if the rights of a patient adjudged incompetent or who has a representative acting on his/her behalf are exercised by the legally appointed individual. If the hospice is currently caring for a patient who has been adjudged incompetent, and you have questions concerning the exercise of the patient's rights, you may contact the patient's legal representative about their involvement in planning care, treatment and services decisions. If the patient is selected for a home visit, obtain the legal representative's approval for the visit.

L507

(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.

L508

(4) The hospice must:

(i) Ensure that all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by anyone furnishing services on behalf of the hospice, are reported immediately by hospice employees and contracted staff to the hospice administrator;

Interpretive Guidelines §418.52(b)(4)(i)

All patient complaints and alleged or real violations included in this standard must be reported immediately to the hospice administrator and should be investigated, resolved and documented**.**

- **"Abuse"** means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish.

- **"Verbal abuse**" includes the use of oral, written or gestured language that willfully includes disparaging and derogatory terms to patients or their families, or within their hearing distance, regardless of their age, ability to comprehend, or disability.

- **"Mental abuse"** includes, but is not limited to, humiliation, harassment, and threats of punishment or deprivation.

- **"Sexual abuse"** includes, but is not limited to, sexual harassment, sexual coercion, or sexual assault.

- **"Physical abuse"** includes, but is not limited to, hitting, slapping, pinching and kicking. It also includes controlling behavior through corporal punishment.

- **"Neglect"** means failure to provide goods and services necessary to avoid physical harm or mental anguish.

- "**Misappropriation of patient property"** means the deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a patient's belongings or money without the patient's consent.

- **"Injuries of unknown source"** – An injury should be classified as an "injury of unknown source" when both of the following conditions are met:

    1. The source of the injury was not observed by any person or the source of the injury could not be explained by the patient; and
    2. The injury is suspicious because of the extent of the injury or the location of the injury (e.g., the injury is located in an area not generally vulnerable to trauma) or the number of injuries observed at one particular point in time or the incidence of injuries over time.

- **"Immediately"** means as soon as possible, but not to exceed 24 hours after discovery of the incident, in the absence of a shorter State time frame requirement.

Procedures and Probes §418.52(b)(4)(i)

- Ask the hospice administrator if he/she has received any reports of the violations listed in the standard and how it was resolved. Is there evidence that all allegations are thoroughly investigated?
- Are staff members able to identify various forms of abuse or neglect? Do staff members know what to do if they witness any violations of mistreatment, abuse, neglect, and injuries of unknown source or misappropriation of patient property?
- During home visits, ask patients and families if they have any concerns about how they or their property have been treated by the hospice staff.

L509

(ii) Immediately investigate all alleged violations involving anyone furnishing services on behalf of the hospice and immediately take action to prevent further potential violations while the alleged violation is being verified. Investigations and/or documentation of all alleged violations must be conducted in accordance with established procedures;

Procedures and Probes §418.52(b)(4)(ii)

Determine what procedures are in place to address how the hospice will protect patients from real or perceived abuse, neglect or exploitation from staff, volunteers, or family members. How does the hospice utilize these procedures when necessary?

L510

(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

L511

(iv) Ensure that verified violations are reported to State and local bodies having jurisdiction (including to the State survey and certification agency) within 5 working days of becoming aware of the violation.

Interpretive Guidelines §418.52(b)(4)(iv)

The hospice has 5 working days from becoming aware of the violation to investigate any alleged violations and, if the alleged violation is verified, it must report the verified violation to the State and local bodies having jurisdiction within those 5 days. If State requirements for reporting verified violations are more stringent than Federal requirements, the more stringent State requirements take precedence. The stringent State requirements may be those that require violations to be reported regardless of whether they are verified or not, or requirements that verified violations be reported in less than 5 days. However, if State requirements are less stringent than Federal requirements, the Federal requirements take precedence.

§418.52(c) Standard: Rights of the patient

L512

The patient has a right to the following:
(1) Receive effective pain management and symptom control from the hospice for conditions related to the terminal illness;

Interpretive Guidelines §418.52(c)(1)

Hospices are responsible for managing the patient's pain and symptoms related to the terminal illness and related conditions in a timely fashion. Patients should not have to experience long waits for pain and symptom management, medications, or interventions to address the patient's condition. Hospices should have methods in place to assure that the patient's pain, and all other distressing symptoms, are controlled effectively 24 hours a day/7days per week, in all settings and wherever the patient resides.

Procedures and Probes §418.52 (c)(1)

- Ask the hospice to describe its policy for assessing, managing and reassessing pain and other symptoms and how it defines effective pain management and symptom control.
- Determine how the hospice assures that the patient receives the needed medications in a timely fashion.
- During the home visit, ask patient/family how quickly the hospice satisfies the patient's request for pain medication or symptom control, during the daytime hours, nights and weekends.

- Observe the patient for any signs of discomfort. Ask the patient or family, as appropriate, if the patient has been experiencing pain or other symptoms. If so, was this reported to the hospice? If reported, what was the hospice's response?
- Have there been any instances where the hospice failed to respond promptly to the patient's request for pain medication or symptom management?

L513

(2) Be involved in developing his or her hospice plan of care;

Probes §418.52 (c)(2)

- Ask staff how they facilitate patient/family participation in planning care.
- Ask the patient/family how they are involved in planning care.

L514

(3) Refuse care or treatment;
Interpretive Guidelines §418.52(c)(3)

While patients have the right to refuse services, probe further if you find a particular trend where a majority or all patients are refusing a particular service (e.g., social work, spiritual counseling, volunteers, etc.,) to assure that patients are fully informed of the service they are refusing and that the hospice is fully prepared to provide the service with qualified personnel.

L515

(4) Choose his or her attending physician;

Interpretive Guidelines §418.52(c)(4)

Patients have the right to choose their attending physician and to have this person involved in their medical care in all hospice settings as long as the attending physician, in turn, undertakes to provide care for the patient.

Probe §418.52(c)(4)

- Is there any evidence that the hospice does not allow patients to choose their attending physician, or pressures the patient to choose the hospice physician as their attending physician?

L516

(5) Have a confidential clinical record. Access to or release of patient information and clinical records is permitted in accordance with 45 CFR parts 160 and 164.

Interpretive Guidelines §418.52(c)(5)

The right to confidential clinical records means safeguarding the content, including paper records and/or electronically stored information from unauthorized disclosure without the specific informed consent of the patient or legal representative. There should be evidence that the hospice ensures the confidentiality of the patient's clinical record.

During the survey, observe whether clinical staff shows evidence of protecting the confidentiality of clinical records. Is patient information posted where visitors or other non-hospice staff can view it? Are clinical records accessible to unauthorized persons who could read or remove the clinical record, thereby violating the patient's privacy?

L517

(6) Be free from mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property;

Interpretive Guidelines §418.52(c)(6)

If, during the course of the survey, you identify the possibility of mistreatment, neglect, abuse(s), or injuries of unknown source and misappropriation of patient property, investigate through interviews, observations, and record reviews. Follow all applicable Federal and State survey guidelines and policies when reporting and documenting any instances where you observe violations listed in this standard. Documentation should include who committed the act, the nature of the act and where and when it occurred. Ensure that the hospice addresses the incident(s) immediately.

L518

(7) Receive information about the services covered under the hospice benefit;

Interpretive Guidelines §418.52(c)(7)

Medicare covered hospice services are set forth at 42 CFR 418.200-204. The hospice should fully inform Medicare patients about all Medicare covered hospice services and fully inform non-Medicare patients about any other hospice services that apply to the patient (e.g., Medicaid, private insurance).

Procedures and Probes §418.52(c)(7)

- Is the patient/family aware of all covered hospice services including the provision of medications related to the terminal condition, continuous care and short-term inpatient care? Discuss whether the hospice has described any services for which the patient might have to pay. Consider the patient's ability to understand and retain coverage information.
- If the patient cannot locate the information, documentation in the clinical record that the hospice has provided this information to the patient/family will suffice.
- Do NOT try to advise the patient about financial, coverage or payment issues.

L519

(8) Receive information about the scope of services that the hospice will provide and specific limitations on those services.

Procedures and Probes §418.52 (c)(8)

- Ask the patient/family what services they are receiving from the hospice and if they are aware of any limitations to those services. Hospices are required to provide all hospice services necessary for the palliation and management of the terminal illness and related conditions and should not accept patients if they cannot provide these hospice services. See §418.56(c) For example, a hospice may not accept a patient if, due to staffing problems, it is not able to provide hospice aide services in the amount needed to meet the patient's needs.

L520

§418.54 Condition of participation: Initial and Comprehensive assessment of the patient

L521

The hospice must conduct and document in writing a patient-specific comprehensive assessment that identifies the patient's need for hospice care and services, and the patient's need for physical, psychosocial, emotional, and spiritual care. This assessment includes all areas of hospice care related to the palliation and management of the terminal illness and related conditions.

Interpretive Guidelines §418.54

The comprehensive patient assessment must accurately reflect the patient's current health status and include information to establish and monitor a plan of care. Hospices are not required to use specific forms or formats to document their initial or comprehensive assessments. They may choose to document patient specific comprehensive assessments in either written or electronic

format provided the assessments are complete, readily identifiable and available in the patient's clinical record.

L522

§418.54(a) Standard: Initial assessment

The hospice registered nurse must complete an initial assessment within 48 hours after the election of hospice care in accordance with §418.24 is complete (unless the physician, patient, or representative requests that the initial assessment be completed in less than 48 hours.)

Interpretive Guidelines §418.54(a)

The purpose of the initial assessment is to gather the critical information necessary to treat the patient/family's immediate care needs. The assessment needs to take place in the location where hospice services are being delivered. The initial assessment is not a "meet and greet" visit whereby the hospice introduces itself to the patient/family and begins to evaluate the patient's interest in and appropriateness for hospice care. It must assess the patient's immediate physical, psychosocial, emotional and spiritual status related to the terminal illness and related conditions. The initial assessment is necessary to gather the essential information necessary to begin the plan of care and provide the immediate necessary care and services.

The registered nurse (RN) must conduct this initial assessment. Hospices may choose to send a social worker or other discipline along with the RN to complete the initial assessment.

Hospices are free to choose their own method for documenting the initial assessment.
Procedures and Probes §418.54(a)

- Determine through interview, observation and record review if the hospice identified the patient/family's immediate needs.
- Did the RN complete the initial assessment within the required timeframes? Clinical record documentation should confirm/support that timeframes are met. Pay particular attention to the effective date/time of the election and the date/time of the completion of the initial assessment.

L523

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

The hospice interdisciplinary group, in consultation with the individual's attending physician (if any), must complete the comprehensive assessment no later than 5 calendar days after the election of hospice care in accordance with §418.24.

Interpretive Guidelines §418.54(b)

All members of the IDG must be involved with completing the comprehensive assessment in order to identify the patient/family's physical, psychosocial, emotional and spiritual needs and contribute to the development of the plan of care to address those needs. The individuals/disciplines that complete the assessment should be consistent with the hospice's own policies and procedures and the discipline's scope of practice. The RN, in consultation with the other members of the IDG, considers the information gathered from the initial assessment as they develop the plan of care and the group determines who should visit the patient/family during the first 5 days of hospice care in accordance with patient/family needs and desires and the hospice's own policies and procedures.

The patient may or may not have an attending physician. If the attending physician is unavailable or unresponsive, the hospice physician must assume this role. If the patient does have an attending physician, one or more members of the IDG should consult with this physician in completing the comprehensive assessment. This consultation can occur through phone calls or other means of communication (Fax, e-mails, text messages, etc.,) and will help to acquire a better understanding of the patient and family. Attending physicians can often provide a history of the patient's disease process and family dynamics that can help the hospice make better care planning decisions that address all areas of need related to the terminal illness and related conditions, resulting in improved patient outcomes.

The "election of hospice care" is the effective date of the election statement. The patient may sign the hospice election statement with a later (not earlier) effective date. Hospices may choose to complete the comprehensive assessment earlier than 5 days after the effective date of the election (e.g., it may complete the comprehensive assessment at the same time the initial assessment is completed.)

L524

§418.54(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.

Interpretive Guidelines §418.54(c)

The assessment would include, but not be limited to, screening for the following: pain, dyspnea, nausea, vomiting, constipation, restlessness, anxiety, sleep disorders, skin integrity, confusion, emotional distress, spiritual needs, support systems, and family need for counseling and

education. The hospice would then gather additional information, as necessary, to be able to meet the patient/family needs. For example, in addition to screening the patient for the presence of pain, a comprehensive assessment of the patient's pain based on accepted clinical standards of practice may necessitate gathering the following information, as applicable to the patient:

- History of pain and its treatment (including non-pharmacological and pharmacological treatment);
- Characteristics of pain, such as:
  - Intensity of pain (e.g., as measured on a standardized pain scale);
  - Descriptors of pain (e.g., burning, stabbing, tingling, aching);
  - Pattern of pain (e.g., constant or intermittent);
  - Location and radiation of pain;
  - Frequency, timing and duration of pain;
  - Impact of pain on quality of life (e.g., sleeping, functioning, appetite, and mood);
  - Factors such as activities, care, or treatment that precipitate or exacerbate pain;
  - Strategies and factors that reduce pain;
  - Additional symptoms associated with pain (e.g., nausea, anxiety).
- Physical examination (may include the pain site, the nervous system, mobility and function, and physical, psychological and cognitive status);
- Current medical conditions and medications;
- The patient/family's goals for pain management and their satisfaction with the current level of pain control.

L525

The comprehensive assessment must take into consideration the following factors:

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

L526

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

L527

(3) Functional status, including the patient's ability to understand and participate in his or her own care.

L528

(4) Imminence of death.

L529

(5) Severity of symptoms.

Procedures and Probes §418.54(c)(1) - (5)

Ask clinical staff to describe how they obtain all relevant information necessary to complete the comprehensive assessment. Is there evidence in the clinical record and during home visits that the reasons for admission, complications and risk factors that could affect care planning, functional status, imminence of death and symptom severity have been identified and are being addressed?

L530

(6) Drug profile. A review of all of the patient's prescription and over-the-counter drugs, herbal remedies and other alternative treatments that could affect drug therapy. This includes, but is not limited to, identification of the following:

- **(i) Effectiveness of drug therapy**
- **(ii) Drug side effects**
- **(iii) Actual or potential drug interactions**
- **(iv) Duplicate drug therapy**
- **(v) Drug therapy currently associated with laboratory monitoring.**

Interpretive Guidelines §418.54(c)(6)

In reviewing the patient's prescribed and over-the-counter medications and any additional substance that could affect drug therapy, the hospice must consider drug effectiveness, side effects, interactions of drugs, duplicate drugs and drugs associated with laboratory testing which could affect the patient. In addition, the hospice should consider both the use of pharmacological and non-pharmacological interventions to promote the patient's comfort level and sense of well being based on the assessment of patient needs and desires.

"Medication Interaction" is the impact of another substance (such as another medication, nutritional supplement (including herbal products), food, or substances used in diagnostic studies) upon a medication's action. The interactions may alter absorption, distribution, metabolism, or elimination. These interactions may decrease the effectiveness of the medication or increase the potential for adverse consequences.

"Duplicate therapy" refers to multiple medications of the same pharmacological class/category or any medication therapy that substantially duplicates a particular effect of another medication that the individual is taking.

"Non-pharmacological interventions" refers to approaches to care that do not involve medications, generally directed towards stabilizing or improving a person's mental, physical or psychosocial well being.

There should be evidence in the clinical record that common side effects of medications are anticipated and preventive measures are implemented. The hospice should review each patient's medications and monitor for medication effectiveness, actual or potential medication-related effects, duplicate drug therapy and untoward interactions during each update to the comprehensive assessment, and as needed as new medications are added or changed, or the patient's condition changes.

Procedures and Probes §418.54(c)(6)

Ask clinical staff to describe their process/policy of drug regimen/medication review including:

- How potential adverse effects and drug reactions are identified?
- What process is followed when a patient/family is found to be noncompliant?
- What non-pharmacological methods are considered to relieve pain and other symptoms?
- How patients and families are educated about effective pain and symptom management.
- What process the hospice utilizes to assess and measure pain and other uncomfortable symptoms.
- What procedures or protocols the hospice uses to reassess pain and symptom management.
- How the hospice monitors a patient when they begin a new medication, increase/ decrease a dosage or discontinue a medication.

During the home visit, ask the patient/caregiver what medications (prescription and over-the-counter drugs, herbal remedies, etc.) the patient is currently taking and compare this information with the medications documented within the plan of care. Are the patient's preferences/goals for pain management and symptom control followed and achieved?

L531

(7) Bereavement. An initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the plan of care and considered in the bereavement plan of care.

Interpretive Guidelines §418.54(c)(7)

Although a bereavement plan is initiated after the death of the patient, prior to the death, the hospice must assess any grief/loss issues of the patient's family through an initial bereavement risk assessment that is incorporated in the plan of care. Bereavement issues continue to be part of the ongoing assessments, and the bereavement plan of care after death is based on all these assessments. Bereavement services may be offered prior to the death when the initial assessment, comprehensive assessment, or updates to the assessment identifies the need for the patient/family.

Social, spiritual and cultural factors that may impact a family member or other individual's ability to cope with the patient's death would include, but not be limited to:

- History of previous losses.
- Family problems.
- Financial concerns.
- Communication issues.
- Drug and alcohol abuse.
- Health concerns.
- Legal and financial concerns.
- Mental health issues.
- Presence or absence of a support system.
- Feelings of despair, anger, guilt or abandonment.

These issues may not be readily apparent during the initial bereavement risk assessment, but should be incorporated into the hospice plan of care if they become evident, and must be considered in the bereavement plan of care.

Procedures and Probes §418.54(c)(7)

What evidence is present which shows that the hospice conducted an initial bereavement risk assessment? Does the plan of care reflect/address the bereavement issues identified in the assessment?

L532

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

Procedures and Probes §418.54(c)(8)

Ask the hospice how they determine the need to refer a patient or family member(s) to appropriate health professionals for further evaluation.

L533

§418.54(d) Standard: Update of the comprehensive assessment

The update of the comprehensive assessment must be accomplished by the hospice interdisciplinary group (in collaboration with the individual's attending physician, if any) and must consider changes that have taken place since the initial assessment. It must include information on the patient's progress toward desired outcomes, as well as a reassessment of the patient's response to care. The assessment update must be

accomplished as frequently as the condition of the patient requires, but no less frequently than every 15 days.

Interpretive Guidelines §418.54(d)

Hospices are free to choose their own method for documenting updates to the assessment. The hospice should evaluate and document the patient's response to the care, treatment and services provided, and progress toward desired outcomes. The purpose of updating the assessment is to ensure that the hospice IDG has the most recent accurate information about the patient/family in order to make accurate care planning decisions. Assessment updates should be easily identified in the clinical record.

Hospices are required to update the comprehensive assessment as frequently as the condition of the patient requires, which may be more frequently than every 15 days. The hospice must ensure that each update is completed no later than 15 days from the previous one. Hospices are not required to complete, in full, those documents that they identified as comprising their comprehensive assessment every 15 days, although hospices are free to do so if they so choose. They are required to identify and document if there were no changes in the patient/family condition or needs.

There should be evidence that the IDG identifies through its ongoing assessments when a change is needed to the plan of care and evidence that the patient/family receives the care and services necessitated by the change.

Procedures and Probes §418.54(d)

Determine through interview, observation and record review if there is evidence that all members of the IDG are actively involved in evaluating the patient's care, so that the patient receives the benefit of the full IDG's assessment.

§418.54(e) Standard: Patient outcome measures

L534

(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.

Interpretive Guidelines §418.54(e)(1)

Examples of data elements that would allow for the measurement of outcomes include, but are not limited to, patient reported data on outcomes of treatment for pain, dyspnea, nausea, vomiting, constipation, emotional distress, and spiritual needs. For example, a hospice may

choose to measure patients whose pain is controlled within 48 hours of admission. Incorporating a data element into the initial assessment and comprehensive assessment will identify the patients that had pain upon admission and identify the patients that had their pain controlled within 48 hours.

L535

(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.

Procedures §418.54(e)(2)

Interview key staff and have them explain the hospice's system of documentation and retrieval of patient specific data elements. Ask to see a copy of the data elements that comprise the hospice's comprehensive assessment. Have the hospice explain how they use these data elements in care planning, coordination of services and in their quality assessment and performance improvement (QAPI) program.

L536

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

L537

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.

Interpretive Guidelines §418.56

The physician member of the IDG may be the hospice medical director or another hospice physician who is employed by or under contract with the hospice. The nurse, social worker and counselor members of the IDG must be hospice employees or employees of the agency or organization of which the hospice is a sub-division (e.g., a hospital) who are appropriately trained and assigned to the hospice.

Probes §418.56

Ask the hospice how it assures that a written plan of care is developed for each patient with full participation of the IDG members in consultation with the patient's attending physician, if any.

Request documentation that verifies the participation of all IDG members in each patient-specific written plan of care.

L538

The plan of care must specify the hospice care and services necessary to meet the patient and family-specific needs identified in the comprehensive assessment as such needs relate to the terminal illness and related conditions.

Interpretive Guidelines §418.56

There should be a direct link between the needs identified in the patient/family assessment and the plan of care developed by the hospice. Hospices may identify needs in the comprehensive assessment that are not related to the terminal illness and related conditions, and should document that they are aware of these needs and note who is addressing them. Hospices are not required to provide direct services to meet needs unrelated to the terminal illness. Hospices are responsible for including services and treatments in the plan of care that address how they will meet the patient and family-specific needs related to the terminal illness and related conditions.

The medical director and/or other hospice physician is responsible for meeting the medical needs of the patient according to §418.64(a)(3) per the patient's attending physician's request or when the hospice is unable to contact the attending physician to address the patient's medical needs.

§418.56(a) Standard: Approach to service delivery

L539

(1) The hospice must designate an interdisciplinary group or groups composed of individuals who work together to meet the physical, medical, psychosocial, emotional, and spiritual needs of the hospice patients and families facing terminal illness and bereavement. Interdisciplinary group members must provide the care and services offered by the hospice, and the group, in its entirety, must supervise the care and services.

Interpretive Guidelines §418.56(a)(1)

Members of the IDG must be appropriately trained in the hospice philosophy and competent to perform in their assigned area(s). The hospice may involve other members of the care team in the IDG's activities.

"Supervision" of care by the IDG members may be accomplished by face-to- face or telephonic conferences, evaluations, discussions and general oversight, as well as by direct observations.

Procedures §418.56(a)(1)

Ask the RN coordinator to describe the hospice's system related to:

- Developing and revising patient care goals/objectives.
- Facilitating exchange of information among staff and patient/caregiver.
- Developing a mechanism whereby a continual flow of information regarding patient/family needs are made available to the IDG staff.

L540

The hospice must designate a registered nurse that is a member of the interdisciplinary group to provide coordination of care and to ensure continuous assessment of each patient's and family's needs and implementation of the interdisciplinary plan of care.

Procedures and Probes §418.56(a)(1)

- Ask the administrator to identify the individual(s) designated as the RN coordinator(s).
- How does this person assure that coordination of care and continuous assessment of needs occur among staff providing services to the patient/family so that all members of the IDG are kept informed of the patient/family's status?

L541

The interdisciplinary group must include, but is not limited to, individuals who are qualified and competent to practice in the following professional roles:

(i) A doctor of medicine or osteopathy (who is an employee or under contract with the hospice).
(ii) A registered nurse.
(iii) A social worker.
(iv) A pastoral or other counselor.

Interpretive Guidelines §418.56(a)(1)(i)-(iv)

The number of individuals on the IDG is not as important as their qualifications and abilities. For example, if a group member meets the hospice criteria and is licensed as a registered nurse and also meets the Medicare criteria to be considered a social worker under the hospice benefit, he/she would be qualified to serve on the IDG as both a nurse and a social worker.

Procedures §418.56(a)(1)(i)-(iv)

Determine through interview, observation and record review that all disciplines comprising the IDG contribute to the patient's comprehensive and ongoing assessments and care planning process.

L542

(2) If the hospice has more than one interdisciplinary group, it must identify a specifically designated interdisciplinary group to establish policies governing the day-to-day provision of hospice care and services.

Interpretive Guidelines §418.56(a)(2)

If the hospice has more than one IDG, it may select members from different IDGs to serve on the IDG that establishes the hospice's policies, as long as all required disciplines are represented (e.g., physician, RN, social worker, counselor).

§418.56(b) Standard: Plan of care

L543

All hospice care and services furnished to patients and their families must follow an individualized written plan of care established by the hospice interdisciplinary group in collaboration with the attending physician (if any), the patient or representative, and the primary caregiver in accordance with the patient's needs if any of them so desire.

L544

The hospice must ensure that each patient and the primary care giver(s) receive education and training provided by the hospice as appropriate to their responsibilities for the care and services identified in the plan of care.

§418.56(c) Standard: Content of the plan of care

L545

The hospice must develop an individualized written plan of care for each patient. The plan of care must reflect patient and family goals and interventions based on the problems identified in the initial, comprehensive, and updated comprehensive assessments. The plan of care must include all services necessary for the palliation and management of the terminal illness and related conditions, including the following:

Procedures and Probes §418.56(c)

- Determine through interview/observation and record review if the plan of care identifies all the services needed to address problems identified in the initial, comprehensive and updated assessments.
- Is there evidence of patients receiving the medication/treatments ordered?
- Are plans of care individualized and patient-specific?

- Does the plan of care integrate changes based on assessment findings?
- Is there documentation to support that the development of the plan of care was a collaborative effort involving all members of the IDG and the attending physician, if any? The attending physician and the IDG members do not have to sign the plan of care but there must be documentation of their involvement.

L546

(1) Interventions to manage pain and symptoms.

Interpretive Guidelines §418.56(c)(1)

The goal of effective pain and symptom management is quality of life. When the pain and symptoms that cause distress to the patient are effectively managed, the patient and family are better able to focus on their vision of a "good death." Effective pain and symptom management include the ongoing assessment of the patient's physical, psychosocial, emotional and spiritual needs and re-evaluating the effectiveness of the current plan of care in order to address those needs.

There should be evidence in the clinical record and on home visits that the hospice treats patient's symptoms such as pain, nausea, vomiting, dehydration, constipation, dyspnea, emotional distress, insomnia, neuropsychiatric symptoms, and spiritual needs using accepted professional standards of practice.

The hospice may also include the use of alternative therapies in the plan of care, to benefit hospice patients/families (e.g., art, yoga, massage, music and light therapy).

Procedures and Probes §418.56(c)(1)

- Ask clinical managers and hospice staff about specific patients, including information about the patient's condition and what interventions are being used to manage pain and ease symptoms. Is there evidence the hospice proactively anticipates potential medication side-effects and implements preventive measures to address them?
- During home visits, observe the patient's comfort level. Is the patient satisfied with his/her level of comfort? Ask the patient or family if they have ever had to call the hospice because the patient's pain or symptoms were out of control. If so, what was the hospice's response?

If the interventions or care provided do not appear to be consistent with current standards of practice and/or the patient's pain appears to persist or recur, interview one or more health care professionals as necessary (e.g., hospice nurse, physician member of the IDG) who, by virtue of training and knowledge of the patient, should be able to provide information about the evaluation and management of the patient's pain/symptoms. Depending on the issue, ask about:

- How chosen interventions were determined to be appropriate.

- How they guide and oversee the selection of pain management interventions.
- The rationale for not intervening, if pain was identified for which no intervention was implemented.
- Changes in pain characteristics that may warrant review or revision of interventions.
- When and with whom the professional discussed the effectiveness, ineffectiveness and possible adverse consequences of pain management interventions.

L547

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

Interpretive Guidelines §418.56(c)(2)

The use of visit ranges in the patient plan of care should follow these parameters:

- The plan of care may include a range of visits and PRN orders for visit frequencies to ensure the most appropriate level of service is provided to the patient.
- A range of visits is acceptable as long as it continues to meet the identified needs of the patient/family.
- Visit ranges with small intervals are acceptable (i.e. 1-3 visits/week; 2-4 visits/week) but ranges that include "0" as a frequency are not allowed.
- The IDG may exceed the number of visits in the range to address patient/family's needs. There should be documentation in the record to support the need for the extra visit(s).

If the patient requires frequent use of PRN visits, the plan of care should be updated to include the need for additional visits.

Standing orders or routine orders must be individualized to address the specific patient's needs and signed by the patient's physician.

The IDG should be proactive in developing each patient's plan of care by planning ahead for anticipated patient changes and needs. Decisions should reflect the patient/family preferences rather than be solely a response to a crisis.

Procedures and Probes §418.56(c)(2)

Ask the clinical manager and other IDG members to describe:

- What criteria are used to assess the needs of the patient and family?
- Who is involved in this process?
- How the IDG decides what services the patient will receive?

- How the hospice evaluates if the services provided are continuing to meet the patients' and families' needs?
- How the hospice monitors the delivery of services, including those provided under arrangement or contract, to ensure compliance with the hospice philosophy?

During the home visit, ask the patient/family if they are aware of all the services included in the hospice benefit. If they are not able to describe them, ask to see any information/documentation the hospice may have left with them describing these services. Ask the patient/family who comes to see them from the hospice, how often they come, what services they provide and if they are provided in a timely manner. Are they satisfied with the level of services they are receiving?

During your clinical record review and home visit, determine if there is any indication the patient needs hospice services that he/she is not receiving.

L548

(3) Measurable outcomes anticipated from implementing and coordinating the plan of care.
Interpretive Guidelines §418.56(c)(3)

The outcomes should be a measurable result of the implementation of the plan of care. The hospice should be using data elements as a part of the plan of care to see if they are meeting the goals of care.

Probes §418.56(c)(3)

Are the outcomes documented and measurable? Look for movement towards the expected outcome(s) and revisions to the plan of care that have been made to achieve the outcomes.

L549

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

Interpretive Guidelines §418.56(c)(4)

See guideline at §418.52(c)(1).

L550

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

L551

(6) The interdisciplinary group's documentation of the patient's or representative's level of understanding, involvement, and agreement with the plan of care, in accordance with the hospice's own policies, in the clinical record.

Interpretive Guidelines §418.56(c)(6)

While the patient/family must be included in developing/updating the plan of care, they do not need to be present during IDG meetings.

§418.56(d) Standard: Review of the plan of care

L552

The hospice interdisciplinary group (in collaboration with the individual's attending physician, if any) must review, revise and document the individualized plan as frequently as the patient's condition requires, but no less frequently than every 15 calendar days.

Interpretive Guidelines §418.56(d)

Communication with the attending physician may be through phone calls, electronic methods, orders received, or other means according to hospice policy and patient needs.

L553

A revised plan of care must include information from the patient's updated comprehensive assessment and must note the patient's progress toward outcomes and goals specified in the plan of care.

Procedures and Probes §418.56(d)

Ask the hospice to describe the plan of care review process. How does the hospice IDG (in collaboration with the individual's attending physician, if any) ensure that each patient's individualized plan of care is reviewed, and revised if warranted, no later than 15 days from the previous review?

§418.56(e) Standard: Coordination of services

L554

The hospice must develop and maintain a system of communication and integration, in accordance with the hospice's own policies and procedures, to-

(1) Ensure that the interdisciplinary group maintains responsibility for directing, coordinating, and supervising the care and services provided.

L555

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

L556

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

L557

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

L558

(5) Provide for an ongoing sharing of information with other non-hospice healthcare providers furnishing services unrelated to the terminal illness and related conditions.

Probes §418.56(e)

- What systems are in place to facilitate the exchange of information and coordination of services among staff and with other non-hospice healthcare providers?
- How does the hospice ensure that coordination of care occurs between services provided directly and those under arrangement?
- Is there documentation in the clinical record of the sharing of information between all disciplines providing care and with other healthcare providers furnishing services to the patient?

L559

§418.58 Condition of participation: Quality assessment and performance improvement

L560

The hospice must develop, implement, and maintain an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement program. The hospice's governing body must ensure that the program: reflects the complexity of its organization

and services; involves all hospice services (including those services furnished under contract or arrangement); focuses on indicators related to improved palliative outcomes; and takes actions to demonstrate improvement in hospice performance. The hospice must maintain documentary evidence of its quality assessment and performance improvement program and be able to demonstrate its operation to CMS.

Interpretive Guidelines §418.58

The condition requires each hospice to develop its own QAPI program to meet its needs. Hospice outcome measures, data elements, tools, and instructions for using them have been developed by the hospice industry and quality improvement organizations. Quality improvement in hospice is a developing field. The methods used by the hospice for self-assessment are flexible and may include a review of current documentation (e.g., review of clinical records, incident reports, complaints, patient satisfaction surveys, etc.); patient care, direct observation of clinical performance, operating systems and interviews with patients and/or staff. The information gathered by the hospice should be based on criteria and/or measures generated by the medical and professional/technical staffs and reflect hospice best practice patterns, staff performance, and patient outcomes.

Ongoing means that there is a continuous and periodic collection and assessment of data. Assessment of such data enables areas of potential problems to be identified and indicates additional data that should be collected and assessed in order to identify whether a problem exists.

The following elements should be considered within the QAPI plan however it is structured:

- Program objectives.
- All patient care disciplines.
- Description of how the program will be administered and coordinated.
- Methodology for monitoring and evaluating the quality of care.
- Priorities for resolution of problems.
- Monitoring to determine effectiveness of action.
- Oversight responsibility reports to governing body.
- Documentation of the review of its own QAPI program.

The fundamental purpose of the QAPI CoP is to set a clear expectation that hospices must take a proactive approach to improve their performance, and focus on improved patient/family care and activities that impact patient health and safety. CMS stresses the improvement in systems in order to improve processes and patient outcomes.

Hospices must have all of the components of a QAPI program in place hospice wide. CMS expects hospices to demonstrate, with objective data, that improvements have taken place in actual care outcomes, processes of care, patient/family satisfaction levels, hospice operations, or other performance indicators.

The QAPI program will be evaluated for its hospice-wide effectiveness on the quality of care provided and activities that impact upon patient health and safety. The impact of the program can be assessed by looking at data gathered at different points in time, compared, and actions taken based on that comparison. The hospice should be analyzing data and evaluating the effectiveness of their own program continually.

The organized hospice-wide QAPI program must be ongoing and have a written plan of implementation. Opportunities to improve care should be applied on a hospice-wide basis, when appropriate. The hospice takes and documents remedial action when problems are identified and evaluates the outcome of these actions. The results must be transmitted to the governing body to fulfill its responsibility to ensure an effective QAPI program.

Quality assessment and performance improvement is a process of continual assessment of a hospice's performance with implementation of solutions, assessment of the effectiveness of the solutions, and evaluations to determine how it can do even better. The QAPI program fosters the continual striving of improvement of the delivery of care and services provided by a hospice. Performance improvement fosters a "blame-free" environment and encourages hospices to evaluate the operating systems and processes in the agency instead of fixing one problem at a time.

Procedures and Probes §418.58

Hospices are required to collect and analyze patient care and administrative quality data and to use that data to identify, prioritize, implement, and evaluate performance improvement projects to improve the quality of services furnished to hospice patients.

In order to assess compliance with the QAPI requirements and to assess the adequacy and appropriateness of a hospice's QAPI program, request the following:

- The hospice's aggregated data and its analysis of that data.
- The hospice's QAPI plan.
- The individuals responsible for the QAPI program.
- Evidence that the QAPI system has been implemented and is functioning effectively, including evidence of:

    - Regular meetings
    - Investigation and analysis of sentinel and adverse events
    - Recommendations or options for systemic change to prevent recurrence of sentinel or adverse events
    - Identified performance measures that are tracked and analyzed
    - Regular review and use of the QAPI analyses by hospice management and the governing body to make systemic improvements.

- Any other necessary resources needed to assess a hospice's compliance.

This information will allow you to match the data provided by the hospice with the actual experiences of hospice employees and patients to ensure that the QAPI program is prevalent throughout the hospice's operations and services, and that it is positively influencing patient care.

Focus on areas such as how and why the hospice chose its quality measures, how it ensures consistent data collection, how it uses data in patient care planning, and how it aggregates and analyzes data. Ask the hospice how it uses the data analysis to select performance improvement projects, how it implements such projects, and how it uses the data to evaluate the effectiveness of those projects.

While a copy of QAPI meeting minutes may be an acceptable method of demonstrating that regular meetings were held, alternate evidence may be acceptable. Surveyors may not require copies of meeting minutes unless the meeting minutes are judged to be essential to an assessment of whether the QAPI actually analyzed an adverse or sentinel event that is the subject of a complaint investigation or standard survey. Essential in this context means that there is not alternate evidence that suffices to address the central question of whether an assessment that meets CMS requirements was conducted. Alternate evidence, for example, may be a recommendation for systemic change that was sufficiently detailed that a reasonable person would conclude the recommendation was based on competent analysis.

§418.58(a) Standard: Program scope

L561

(1) The program must at least be capable of showing measurable improvement in indicators related to improved palliative outcomes and hospice services.

L562

(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.

Interpretive Guidelines §418.58(a)(2)

Hospices are required to assess quality in all areas of operations that might be adversely affecting patient care or core hospice services. There is a specific requirement to track adverse events (as they are defined in hospice policy) and reduce their occurrence where possible. They must be able to show (using quantitative data or other means) that they can improve quality, as measured by their own indicators or measures.

Procedures and Probes §418.58(a)(2)

- Does the hospice adhere to its definition of 'adverse event' when tracking and monitoring and implementing preventive actions for these events?
- Does the hospice's QAPI program measure, analyze and track quality indicators related to processes of care, hospice services and operations?

§418.58(b) Standard: Program data

L563

(1) The program must use quality indicator data, including patient care, and other relevant data, in the design of its program.

Interpretive Guidelines §418.58(b)(1)

Hospices must not limit their QAPI data collection efforts to the data collected during patient assessments. Data collection must look beyond patient assessment data to examine all facets of a hospice's operation. All patient services and all activities that may impact patient/family care should be evaluated as part of the QAPI program. This would include but not be limited to: physician services, nursing services, medical social services, counseling services, clinical records, infection control, pharmaceutical services, durable medical equipment (DME), patient rights, administrative services, contract services, volunteers, hospice aide and adverse events. Whatever measures the hospice chooses to assess quality should be monitored regularly so that opportunities for improvement can be identified and prioritized. Data should be collected in a timely manner so that measures can be reported on the schedule set up by the hospice.

Procedures and Probes §418.58(b)(1)

- Is the hospice's QAPI program data-driven?
- Is there evidence that the hospice uses the data collected to identify opportunities for improvement?

L564

(2) The hospice must use the data collected to do the following:
(i) Monitor the effectiveness and safety of services and quality of care.
(ii) Identify opportunities and priorities for improvement.

L565

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

Interpretive Guidelines §418.58(b)(3)

The governing body may assume hands-on control of the QAPI program to ensure that the program is in compliance with this rule, or it may choose to appoint one or more individuals to handle the structure and administration of the QAPI program. The governing body retains ultimate responsibility for the actions of the designated individual(s).

§418.58(c) Standard: Program activities

L566

(1) The hospice's performance improvement activities must:

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

L567

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

L568

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

Interpretive Guidelines §418.58(c)(1)(iii)

Outcomes are the results of care provided; palliative outcomes are the results of palliative care provided.

L569

(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.

Interpretive Guidelines §418.58(c)(2)

Hospices may choose to develop their own definition for the term "adverse event" or use a definition developed by a national accrediting organization or industry organization. Once a hospice has identified the definition of an adverse event, it is responsible for adhering to the definition when tracking and analyzing these events and when implementing preventive actions. In general, an adverse event would be any action or inaction by a hospice that caused harm to a hospice patient. However, hospices are not bound to use this generic description.

L570

(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.

Interpretive Guidelines §418.58(c)(3)

Hospices must consider how often certain quality issues arise and the severity of potential harm when prioritizing opportunities for improvement. When adverse event monitoring reveals a problem area, the hospice must implement changes designed to decrease occurrence of the adverse event. The hospice must assure that the new process is implemented hospice wide and that it is effective in reducing the adverse event. For performance improvement in all areas of operations, the hospice must monitor the level of improvement over time to be sure that is it sustained.

Procedures and Probes §418.58(c)(3)

- Determine if the hospice has taken appropriate action to correct problems identified by the QAPI program. Examine reports and minutes of QAPI meetings to determine if the hospice has documented the remedial action and its outcome. Examples of appropriate remedial action may include, but are not limited to changes in policies and procedures.
- Is there evidence that the hospice continues to monitor performance to ensure that improvements are sustained?

L571

§418.58(d) Standard: Performance improvement projects

Beginning February 2, 2009, hospices must develop, implement and evaluate performance improvement projects.

L572

(1) The number and scope of distinct performance improvement projects conducted annually, based on the needs of the hospice's population and internal organizational needs, must reflect the scope, complexity, and past performance of the hospice's services and operations.

L573

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

Interpretive Guidelines §418.58(d)(2)

There is no requirement for hospices to conduct a specific number of performance improvement projects. They must select the number and topics of projects based on the results of their quality monitoring and other quality information such as the results of State or accreditation surveys. Performance improvement projects must be documented in written form and include the elements outlined in the standard.

Procedures and Probes §418.58(d)(2)

Do the number and scope of performance improvement projects conducted by the hospice accurately reflect the scope, complexity and past performance of the hospice? Are all performance improvement projects appropriately documented?

§418.58(e) Standard: Executive responsibilities

L574

The hospice's governing body is responsible for ensuring the following:
(1) That an ongoing program for quality improvement and patient safety is defined, implemented, and maintained, and is evaluated annually.

L575

(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.

L576

(3) That one or more individual(s) who are responsible for operating the quality assessment and performance improvement program are designated.

Interpretive Guidelines §418.58(e)(3)

The governing body is responsible for assuring that the QAPI program is working to address any problem areas in patient care and hospice operations, and to improve performance in these areas. The governing body must also appoint individuals who will operate the QAPI program for the hospice.

Probes §418.58(e)(3)

- Do hospice records indicate that the hospice's governing body is involved in oversight of the QAPI program?

- Is there an individual appointed by the governing body who is responsible for operating the QAPI program?

L577

§418.60 Condition of participation: Infection control

L578

The hospice must maintain and document an effective infection control program that protects patients, families, visitors, and hospice personnel by preventing and controlling infections and communicable diseases.
Interpretive Guidelines §418.60

The hospice infection control program must identify risks for the acquisition and transmission of infectious agents in all settings where patients reside. There needs to be a system to communicate with all hospice personnel, patients, families and visitors about infection prevention and control issues including their role in preventing the spread of infections and communicable diseases through daily activities.

The hospice's infection control program may include, but not be limited to the following:

- Educating staff on the science of infectious disease transmission.
- Protocols for addressing patient care issues and prevention of infection related to infusion therapy, urinary tract care, respiratory tract care, and wound care.
- Guidelines on caring for patients with multi-drug resistant organisms.
- Policies on protecting patients, staff and families from blood borne or airborne pathogens.
- Monitoring staff for compliance with hospice policies and procedures related to infection control.
- Protocols for educating staff and families in standard precautions and the prevention and control of infection.

Procedures and Probes §418.60

- Ask the hospice what steps it takes to assure that staff take appropriate infection and communicable disease prevention and control precautions, including educating the patient and families about their role in communicating the information to others who may have contact with the patient.

- How does the hospice ensure that patients/families receive timely instruction regarding standard precautions to follow in preventing and controlling infections and communicable diseases?
- If the hospice provides inpatient care directly, observe for appropriate infection prevention and control precautions including signage or other posted information or materials in patient rooms or staff areas.

L579

§418.60(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.

Interpretive Guidelines §418.60(a)

Accepted standards of practice for health care providers are typically developed by government agencies, professional organizations and associations. Examples would include, but not be limited to, the Centers for Disease Control and Prevention (CDC), the Agency for Healthcare Research and Quality, State Practice Acts, and commonly accepted health standards established by national organizations, boards, and councils (e.g., Association for Professionals in Infection Control and Epidemiology (APIC), American Nurses' Association.)

Standard Precautions are based on the principle that all blood, body fluids, secretions, excretions (except sweat), non-intact skin, and mucous membranes may contain transmissible infectious agents. Standard Precautions include a group of infection prevention practices that apply to all patients, regardless of suspected or confirmed infection status, in any setting in which healthcare is delivered. These include: hand hygiene; use of gloves, gown, mask, eye protection, or face shield, depending on the anticipated exposure; and safe injection practices. Also, equipment or items in the patient environment likely to have been contaminated with infectious body fluids must be handled in a manner to prevent transmission of infectious agents (e.g., wearing gloves for direct contact, contain heavily soiled equipment, properly clean and disinfect or sterilize reusable equipment before use on another patient). (Excerpt from CDC Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007.)

Any deficiency cited as a violation of accepted standards of practice must have a copy of the applicable standard of practice provided to the hospice along with the statement of deficiencies. A hospice may also be surveyed for compliance with State practice acts for each relevant discipline. Any deficiency cited as a violation of a State practice act must reference the applicable section of the State practice act allegedly violated, and a copy of that section of the act must be provided to the hospice along with the statement of deficiencies.

Procedures §418.60(a)

During home visits, observe the hospice's practices related to prevention and transmission of infections and communicable diseases and use of standard precautions.

§418.60(b) Standard: Control

L580

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

Interpretive Guidelines §418.60(b)(1)

Examples of infection control practices that the hospice may use include monitoring work related employee illness and infections, analyzing them in relation to patient infections, and taking appropriate actions when an infection or communicable disease is present to prevent its spread among staff, patients, family and visitors.

Surveillance data should be routinely reviewed and monitored. Appropriate corrective actions need to be taken based on the data analysis. The hospice must use this information as a part of its QAPI program.

L581

(2) Includes the following:
(i) A method of identifying infectious and communicable disease problems; and
(ii) A plan for implementing the appropriate actions that are expected to result in improvement and disease prevention.

Procedures and Probes §418.60(b)(2)

- Ask the hospice to explain the method(s) it uses to identify infectious and communicable disease problems.
- Does the hospice redesign its strategies to improve its infection prevention and control policies when it identifies problems?
- If you have concerns, ask to review the hospice's policies related to infection control and communicable diseases.

L582

§418.60(c) Standard: Education

The hospice must provide infection control education to employees, contracted providers, patients, and family members and other caregivers.

Probes §418.60(c)

- Is hospice staff (direct employees and contacted staff) aware of infection control principles and procedures?
- Do they demonstrate this knowledge during home visits?
- During home visits ask the patient/family or other caregivers to describe infection control education they have received.

L583

§418.62 Condition of participation: Licensed professional services.

L584

(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.

Interpretive Guidelines §418.62(a)

Licensed professional services, for purposes of this section, would include, but not be limited to, skilled nursing care, physical therapy, speech language pathology, occupational therapy, and medical social services.

L585

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

L586

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

Procedures and Probes §418.62(c)

- Interview key staff to determine how the hospice ensures that licensed professionals participate in their QAPI and in-service training programs.
- What evidence is there that all employees (direct and contracted) have been properly oriented to the tasks they are expected to perform, participate in the appropriate hospice in-service training programs, and demonstrate the appropriate skills, when needed, in practice?

L587

§418.64 Condition of participation: Core services

L588

A hospice must routinely provide substantially all core services directly by hospice employees. These services must be provided in a manner consistent with acceptable standards of practice. These services include nursing services, medical social services, and counseling. The hospice may contract for physician services as specified in paragraph (a) of this section.

L589

A hospice may use contracted staff, if necessary, to supplement hospice employees in order to meet the needs of patients under extraordinary or other non-routine circumstances. A hospice may also enter into a written arrangement with another Medicare certified hospice program for the provision of core services to supplement

hospice employee/staff to meet the needs of patients. Circumstances under which a hospice may enter into a written arrangement for the provision of core services include: unanticipated periods of high patient loads, staffing shortages due to illness or other short-term temporary situations that interrupt patient care; and temporary travel of a patient outside of the hospice's service area.

Interpretive Guidelines §418.64

Employee means a person who: (1) works for the hospice and for whom the hospice is required to issue a W-2 form on his or her behalf; or (2) if the hospice is a subdivision of an agency or

organization, an employee of the agency or organization who is assigned to the hospice; or (3) is a volunteer under the jurisdiction of the hospice.

If a contracting service or agency pays the individual, and is required to issue a form W-2 on the individual's behalf, or if the individual is self-employed, the individual is not considered a hospice employee.

Extraordinary circumstances generally would be a short-term temporary event that was unanticipated. Examples of such circumstances might include, but are not limited to, unanticipated periods of high patient loads (such as an unexpectedly large number of patients requiring continuous care simultaneously), staffing shortages due to illness, receiving patients evacuated from a disaster such as a hurricane or a wildfire, or temporary travel of a patient outside the hospice's service area. If a hospice chooses to contract with another Medicare-certified hospice or a non-hospice entity, the contracting hospice must maintain professional management responsibility for the services provided, in accordance with §418.100(e).

Probes §418.64

How does the hospice assure that all contract providers receive training in the hospice's philosophy and care before providing services to patients?

§418.64(a) Standard: Physician services

L590

The hospice medical director, physician employees, and contracted physician(s) of the hospice, in conjunction with the patient's attending physician, are responsible for the palliation and management of the terminal illness and conditions related to the terminal illness.

> **(1) All physician employees and those under contract, must function under the supervision of the hospice medical director.**
>
> **(2) All physician employees and those under contract shall meet this requirement by either providing the services directly or through coordinating patient care with the attending physician.**
>
> **(3) If the attending physician is unavailable, the medical director, contracted physician, and/or hospice physician employee is responsible for meeting the medical needs of the patient.**

Interpretive Guidelines §418.64(a)

The medical director may also serve as the physician member of the IDG.

Probe §418.64(a)

Is there evidence that the medical needs of the patients are being met by the hospice physician for patients who do not have an attending physician or when the attending physician is unresponsive or unavailable?

§418.64(b) Standard: Nursing services

L591

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

L592

(2) If State law permits registered nurses to see, treat and write orders for patients, then registered nurses may provide services to beneficiaries receiving hospice care.

Interpretive Guidelines §418.64(b)(2)

If an R.N., including a nurse practitioner, advanced practice nurse, etc., is permitted by State law and regulation to see, treat, and write orders, then the R.N. may perform this function while providing nursing services for hospice patients. Hospices are free to use the services of all types of advanced practice nurses within their respective scopes of practice to enhance the nursing care furnished to its patients. Services provided by a nurse practitioner (NP) who is not the patient's attending physician, are included under nursing care.

L593

(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.

Interpretive Guidelines §418.64(b)(3)

Highly specialized services, such as complex wound care and infusion specialties, are determined by the nature of the service and the nursing skill level required to be proficient in the service. For example, a hospice may need to contract with a pediatric nurse because of the very infrequent pediatric patients the hospice cares for and that to employee a pediatric nurse would be impracticable and expensive. Continuous care is not a highly specialized service, because while time intensive, it does not require highly specialized nursing skills.

§418.64(c) Standard: Medical social services

L594

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.

Interpretive Guidelines §418.64(c)

The social worker's services are provided in accordance with the plan of care. Because social work services must be provided under the direction of a physician, physician approval of the plan of care will satisfy the intent of this requirement.
The psychosocial assessment is an evolving document that is revised as new information is acquired and as progress toward goals is made. The psychosocial assessment may also include the bereavement risk assessment. The purpose of the psychosocial assessment is to help the IDG identify issues that either impede or facilitate the patient's treatment and to assist the patient/family in reaching the maximum benefit from hospice care and services. The assessment should include a wide variety of factors, including but not limited to, the patient and family's adjustment to the terminal illness, the social and emotional factors related to the terminal illness, the presence or absence of adequate coping mechanisms, the family dynamics and communication patterns, financial resources or constraints, the caregiver's ability to function effectively, identifying obstacles and risk factors which may effect compliance with the plan of care, and identifying family support systems to help facilitate coping with end of life issues.

Procedures and Probes §418.64(c)

- How does the hospice introduce and offer medical social work services to the patient/family?
- Ask the social worker or clinical manager to describe the factors that are included in the psychosocial assessment and how this information is used in the care planning process to benefit the patient/family.
- Is there evidence that each patient receives social work services (unless specifically refused by the patient) that reflect the needs identified in the psychosocial assessment?

§418.64(d) Standard: Counseling services

L595

Counseling services must be available to the patient and family to assist the patient and family in minimizing the stress and problems that arise from the terminal illness, related conditions, and the dying process.

L596

Counseling services must include, but are not limited to, the following:

(1) <u>Bereavement counseling</u>. The hospice must:

- **(i) Have an organized program for the provision of bereavement services furnished under the supervision of a qualified professional with experience or education in grief or loss counseling.**
- **(ii) Make bereavement services available to the family and other individuals in the bereavement plan of care up to 1 year following the death of the patient. Bereavement counseling also extends to residents of a SNF/NF or ICF/MR when appropriate and identified in the bereavement plan of care.**
- **(iii) Ensure that bereavement services reflect the needs of the bereaved.**
- **(iv) Develop a bereavement plan of care that notes the kind of bereavement services to be offered and the frequency of service delivery. A special coverage provision for bereavement counseling is specified in §418.204(c).**

Interpretive Guidelines §418.64(d)(1)

The supervisor of bereavement services may be the IDG social worker or other professional with documented evidence of experience or education in grief or loss counseling.

Procedures and Probes §418.64(d)(1)

- Ask the hospice to explain how and when they incorporate the bereavement assessment into the comprehensive assessment.
- What services does the hospice provide to reflect the needs of the family and other individuals in the bereavement plan of care?
- How does the hospice evaluate the outcomes and effectiveness of the bereavement services they provide?
- Select and review a sample of 2-3 bereavement plans of care from a list of the patients who have died within the past 12 months. Determine if the bereavement follow up was appropriate and provided within identified time frames? Did the bereavement services provided reflect the needs of the bereaved?

L597

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

Interpretive Guidelines §418.64(d)(2)

Hospices are required to assure the dietary needs of the patient are met by a qualified individual. If an RN is capable of meeting the patient's needs, then the dietary counseling can be provided by the RN. If the needs of the patient exceed the expertise of the nurse, then the hospice must have available an appropriately trained and qualified individual such as a registered dietitian or nutritionist to meet the patient's dietary needs.

Procedures and Probes §418.64(d)(2)

- Ask the clinical manager how the hospice meets the needs of patients and families who experience challenges and conflict with end of life care dietary issues. This may include providing education about how the dying process naturally results in lack of appetite and intake and how this may relate to the patient's decreasing appetite and food intolerances during the end of life.
- Ask the clinical manager how the hospice meets the needs of patients who experience dysphasia, problematic enteral feedings, or unresolved nutritional issues secondary to nausea, vomiting, or the dying process.

L598

(1) <u>Spiritual counseling</u> The hospice must:

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

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

(iii) Make all reasonable efforts to facilitate visits by local clergy, pastoral counselors, or other individuals who can support the patient's spiritual needs to the best of its ability.

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

Interpretive Guidelines §418.64(d)(3)

There should be evidence in the clinical record that the hospice has offered and/or provided spiritual counseling in accordance with the patient/family's desires. If a patient and family desires spiritual counseling, then a hospice should facilitate visits by local clergy, pastoral counselors, or others to the best of its ability.

Procedures and Probes §418.64(d)(3)

- Determine through clinical record review, interview and home visits how the hospice addresses the spiritual needs/concerns of the patients and families.
- How does the hospice introduce the availability of spiritual counseling?
- What mechanisms are in place to meet the patient/family spiritual needs?

L599

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

L600

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

1) The location of the hospice's central office is in a non-urbanized area as determined by the Bureau of the Census.
2) There is evidence that a hospice was operational on or before January 1, 1983 including the following:

(i) Proof that the organization was established to provide hospice services on or before January 1, 1983.
(ii) Evidence that hospice-type services were furnished to patients on or before January 1, 1983.
(iii) Evidence that hospice care was a discrete activity rather than an aspect of another type of provider's patient care program on or before January 1, 1983.

1) By virtue of the following evidence that a hospice made a good faith effort to hire nurses:
(i) Copies of advertisements in local newspapers that demonstrate recruitment efforts.
(ii) Job descriptions for nurse employees.
(iii) Evidence that salary and benefits are competitive for the area.
(iv) Evidence of any other recruiting activities (for example, recruiting efforts at health fairs and contacts with nurses at other providers in the area).

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

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

(d) If a hospice wishes to receive a 1-year extension, it must submit a request to CMS before the expiration of the waiver period, and certify that the conditions under which

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

Interpretive Guidelines §418.66

Section 8161(dd)(5)(a)(i) of the Social Security Act specifically references urbanized areas as defined by the Bureau of the Census. Further information on this topic is available at http://www.census/gov. Hospices may also contact their assigned Medicare administrative contractor or check the hospice wage index, which is updated and published yearly.

If there is any question concerning a waiver, contact the CMS RO.

L601

§418.70 Condition of participation: Furnishing of non-core services

L602

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.

Interpretive Guidelines §418.70

The hospice must ensure that all clinical staff members (direct and contractual) are aware of and follow professional practice standards, laws, hospice policies and procedures. If questions arise during home visits or record reviews, ask clinical managers and staff what the hospice's policies are regarding the issue in question.

Procedure §418.70

Ask how the hospice monitors the professional skills of its staff to determine if those skills are appropriate and adequate for its patients.

L603

§418.72 Condition of participation: Physical therapy, occupational therapy, and speech-language pathology.

L604

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.

Interpretive Guidelines §418.72

Rehabilitative services such as training in the use of adaptive equipment, home safety assessment, and caregiver instruction in use of good body mechanics for turning and lifting patients, may be appropriate/beneficial for the hospice patient/family.

L605

§418.74 Waiver of requirement-Physical therapy, occupational therapy, speech-language pathology, and dietary counseling.

L606

(a) A hospice located in a non-urbanized area may submit a written request for a waiver of the requirement for providing physical therapy, occupational therapy, speech-language pathology, and dietary counseling services. The hospice may seek a waiver of the requirement that it make physical therapy, occupational therapy, speech-language pathology, and dietary counseling services (as needed) available on a 24-hour basis. The hospice may also seek a waiver of the requirement that it provide dietary counseling directly. The hospice must provide evidence that it has made a good faith effort to meet the requirements for these services before it seeks a waiver. CMS may approve a waiver application on the basis of the following criteria:

1) **The hospice is located in a non-urbanized area as determined by the Bureau of the Census.**
2) **The hospice provides evidence that it had made a good faith effort to make available physical therapy, occupational therapy, speech-language pathology, and dietary counseling services on a 24-hour basis and/or to hire a dietary counselor to furnish services directly. This evidence must include the following:**

    - **(i) Copies of advertisements in local newspapers that demonstrate recruitment efforts.**
    - **(ii) Physical therapy, occupational therapy, speech-language pathology, and dietary counselor job descriptions.**
    - **(iii) Evidence that salary and benefits are competitive for the area.**
    - **(iv) Evidence of any other recruiting activities (for example, recruiting efforts at health fairs and contact discussions with physical therapy, occupational therapy, speech-language pathology, and dietary counseling service providers in the area).**

(b) Any waiver request is deemed to be granted unless it is denied within 60 days after it is received.
(c) An initial waiver will remain effective for 1 year at a time from the date of the request.
(d) If a hospice wishes to receive a 1-year extension, it must submit a request to CMS before the expiration of the waiver period and certify that conditions under which it originally requested the waiver have not changed since the initial waiver was granted.

Interpretive Guidelines §418.74

Eligibility for this waiver, as with the nursing waiver, is based on the primary location of the hospice. If the hospice operates in multiple locations, the primary location is considered to be location of the central office. This office must be located in a non-urbanized area as determined by the Bureau of Census.

This waiver does not waive the hospice's responsibility to provide PT, OT, SLP, and dietary counseling; only to provide them (as needed) on a 24-hour basis.

There are no limit restrictions to the number of extensions a hospice may request to the original waiver request.

L607

§418.76 Condition of participation: Hospice aide and homemaker services

L608

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

§418.76(a) Standard: Hospice aide qualifications

L609

(1) A qualified hospice aide is a person who has successfully completed one of the following:
- **(i) A training program and competency evaluation as specified in paragraphs (b) and (c) of this section respectively.**
- **(ii) A competency evaluation program that meets the requirements of paragraph (c) of this section.**
- **(iii) A nurse aide training and competency evaluation program approved by the State as meeting the requirements of §483.151 through §483.154 of this chapter, and is currently listed in good standing on the State nurse aide registry.**

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

L610

(2) A hospice aide is not considered to have completed a program, as specified in paragraph (a)(1) of this section, if, since the individual's most recent completion of the program(s), there has been a continuous period of 24 consecutive months during which none of the services furnished by the individual as described in § 409.40 of this chapter were for compensation. If there has been a 24-month lapse in furnishing services, the individual must complete another program, as specified in paragraph (a)(1) of this section, before providing services.

§418.76(b) Standard: Content and duration of hospice aide classroom and supervised practical training

L611

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

L612

(2) A minimum of 16 hours of classroom training must precede a minimum of l6 hours of supervised practical training as part of the 75 hours.

L613

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

- **(i) Communication skills, including the ability to read, write, and verbally report clinical information to patients, care givers, and other hospice staff.**
- **(ii) Observation, reporting, and documentation of patient status and the care or service furnished.**
- **(iii) Reading and recording temperature, pulse, and respiration.**
- **(iv) Basic infection control procedures.**
- **(v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.**
- **(vi) Maintenance of a clean, safe, and healthy environment.**
- **(vii) Recognizing emergencies and the knowledge of emergency procedures and their application.**

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

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

(A) Bed bath.
(B) Sponge, tub, and shower bath.
(C) Hair shampoo (sink, tub, and bed).
(D) Nail and skin care.
(E) Oral hygiene.
(F) Toileting and elimination.

(x) Safe transfer techniques and ambulation.

(xi) Normal range of motion and positioning.

(xii) Adequate nutrition and fluid intake.

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

L614

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

Interpretive Guidelines §418.76(b)(4)

A hospice aide may receive training from different organizations if the amount of training totals 75 hours, the content of training addresses all subjects listed at §418.76(b)(3) and the organization, training, instructors, and documentation meet the requirements of the regulation.

Documentation of training should include:

- A description of the training/competency evaluation program, including the qualifications of the instructors;
- A record that distinguishes between skills taught at a patient's bedside with supervision, and those taught in a laboratory using a real person (not a mannequin) and indicators of which skills each aide was judged to be competent; and
- How additional skills (beyond the basic skills listed in the regulation) are taught and tested if the hospice's admission policies and case-mix of hospice patients require aides to perform more complex procedures.

§418.76(c) Standard: Competency evaluation

L615

An individual may furnish hospice aide services on behalf of a hospice only after that individual has successfully completed a competency evaluation program as described in this section.

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

L616

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

Interpretive Guidelines §418.76 (c)(1) – (2)

The hospice must ensure that the skills learned or tested elsewhere can be transferred successfully to care of the hospice patient in all settings. The hospice should give careful attention to evaluating both employed aides and those aides who provide services under arrangement or contract. This review of skills could be done when the nurse installs an aide into a new patient care situation or during a supervisory visit. A mannequin may not be used for this evaluation.

If the hospice's admission policies and the case-mix of patients demand that the aide care for individuals whose needs require additional competency beyond the minimum required in the regulation, the hospice must document how these additional skills are taught and tested.

L617

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

L618

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

completes a subsequent evaluation. A hospice aide is not considered to have successfully completed a competency evaluation if the aide has an "unsatisfactory" rating in more than one of the required areas.

Interpretive Guidelines §418.76 (c)(4)

A hospice aide who is evaluated as satisfactory in all subject areas except one would be considered competent. However, this aide would not be allowed to perform the task in which he or she was evaluated as unsatisfactory except under direct supervision. If a hospice aide receives an unsatisfactory evaluation in more than one subject area, the aide would not be considered to have successfully passed a competency evaluation program and would be precluded from functioning as a hospice aide in any subject area. The regulations place no restrictions on the number of times or the timeframe in which an aide can be tested in a deficient area.

L619

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

§418.76(d) Standard: In-service training

L620

A hospice aide must receive at least l2 hours of in-service training during each 12-month period. In-service training may occur while an aide is furnishing care to a patient.

Interpretive Guidelines §418.76 (d)

Hospices may fulfill the annual 12-hour in-service training requirement on a calendar year basis, an employment anniversary basis, or a rolling 12 month basis as long as each aide meets this in-service training requirement.

Hospice aide in-service training, that occurs with a patient in a place of residence, supervised by an RN, can occur as part of the every 14 day supervisory visit, but the exact new skill or theory taught must be documented. In-service training taught in the patient's environment should not be a repetition of a basic skill.

Procedures and Probes §418.76(d)

Ask how the hospice schedules training to assure that every aide receives at least 12 hours of in-service training within each 12 month period.

L621

(1) In-service training may be offered by any organization, and must be supervised by a registered nurse.

L622

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

Procedures and Probes §418.76(d)(2)

Review a sample of 3-4 hospice aide training files to validate that aides are receiving the required number of training hours. If concerns arise, interview the aides regarding in-service trainings received.

§418.76(e) Standard: Qualifications for instructors conducting classroom and supervised practical training

L623

Classroom and supervised practical training must be performed by a registered nurse who possesses a minimum of 2 years nursing experience, at least 1 year of which must be in home care, or by other individuals under the general supervision of a registered nurse.

Interpretive Guidelines §418.76(e)

The required 2 years of nursing experience for the instructor should be "hands on" clinical experience such as providing care and/or supervising nursing services or teaching nursing skills in an organized curriculum or in-service program. The required 2 years of nursing experience may be in home care or in hospice care.

"Other individuals" who may help with hospice aide training would include health care professionals such as physicians, physical therapists, occupational therapists, medical social workers, and speech-language pathologists. Nutritionists, pharmacists, lawyers and consumers might also be teaching resources.

L624

§418.76(f) Standard: Eligible competency evaluation organizations

A hospice aide competency evaluation program as specified in paragraph (c) of this section may be offered by any organization except by a home health agency that, within the previous 2 years:

(1) Had been out of compliance with the requirements of §484.36(a) and (b) of this chapter.

(2) Permitted an individual that does not meet the definition of a "qualified home health aide" as specified in §484.36(a) of this chapter to furnish home health aide services (with the exception of licensed health professionals and volunteers).
(3) Had been subjected to an extended (or partial extended) survey as a result of having been found to have furnished substandard care (or for other reasons at the discretion of CMS or the State).
(4) Had been assessed a civil monetary penalty of $5,000 or more as an intermediate sanction.
(5) Had been found by CMS to have compliance deficiencies that endangered the health and safety of the home health agency's patients and had temporary management appointed to oversee the management of the home health agency.
(6) Had all or part of its Medicare payments suspended.
(7) Had been found by CMS or the State under any Federal or state law to have:
- **(i) Had its participation in the Medicare program terminated.**
- **(ii) Been assessed a penalty of $5,000 or more for deficiencies in Federal or State standards for home health agencies.**
- **(iii) Been subjected to a suspension of Medicare payments to which it otherwise would have been entitled.**
- **(iv) Operated under temporary management that was appointed by a governmental authority to oversee the operation of the home health agency and to ensure the health and safety of the home health agency's patients.**
- **(v) Been closed by CMS or the State, or had its patients transferred by the State.**

§418.76(g) Standard: Hospice aide assignments and duties

L625

(1) Hospice aides are assigned to a specific patient by a registered nurse that is a member of the interdisciplinary group. Written patient care instructions for a hospice aide must be prepared by a registered nurse who is responsible for the supervision of a hospice aide as specified under paragraph (h) of this section.

Interpretive Guidelines §418.76(g)(1)

Hospice aide written instructions for patient care prepared by the R.N. responsible for the supervision of the aide must be patient specific and not generic.

Procedures and Probes §418.76(g)(1)

Interview key staff to determine the following:

- Are aides direct employees of the hospice or provided by arrangement?
- If services are provided under arrangement, how does the hospice ensure that the aides providing patient care have the appropriate competency skills?

- How the hospice ensures that aides are proficient to carry out their assignments in a safe, efficient and effective manner.
- How the hospice monitors the assignments of aides to match the skills needed for individual patients.

If you have questions that arise as a result of home visits or record reviews, ask the clinical managers to respond to specific issues.

L626

(2) A hospice aide provides services that are:
(i) Ordered by the interdisciplinary group.
(ii) Included in the plan of care.
(iii) Permitted to be performed under State law by such hospice aide.
(iv) Consistent with the hospice aide training.

L627

(3) The duties of a hospice aide include the following:
(i) The provision of hands-on personal care.
(ii) The performance of simple procedures as an extension of therapy or nursing services.
(iii) Assistance in ambulation or exercises.
(iv) Assistance in administering medications that are ordinarily self-administered.

Interpretive Guidelines §418.76(g)(3)(iv)

The IDG determines if there are medications that are appropriate for aides to help administer based on the needs of the patient and family, training and competency of the aide, policies of the hospice, and any applicable State and local laws and rules. If State or local laws and rules prohibit hospice aides from administering medications, they are precluded from doing this activity. However, if medication administration is within the bounds of State and local laws and rules, and if hospices choose to have aides perform this task, the hospice is required to provide aide training in medication administration and assure that the aide is competent to perform this task before he/she is assigned to the patient. See also §418.76(b)(3)(xiii).

L628

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

Procedures §418.76(g)(4)

When conducting home visits to patients receiving hospice aide services be observant for changes in the patient's medical, nursing, rehabilitative and social needs that the aide should be reporting to the RN.

Through clinical record reviews, look for documentation by the aide describing changes in the patient's medical, nursing, rehabilitative and social needs and to whom he or she reported the information. Clinical notations should be dated and signed.

§418.76(h) Standard: Supervision of hospice aides

L629

(1) A registered nurse must make an on-site visit to the patient's home:

(i) No less frequently than every 14 days to assess the quality of care and services provided by the hospice aide and to ensure that services ordered by the hospice interdisciplinary group meet the patient's needs. The hospice aide does not have to be present during this visit.

Interpretive Guidelines §418.76(h)(1)(i)

If the RN makes a supervisory visit on a Tuesday, the next supervisory visit is due by the Tuesday which occurs 14 days later.

In addition to ensuring that hospice aides furnish the care identified in the plan of care, RN supervisors must assess the adequacy of the aide services in relationship to the needs of the patient and family. In-person visits by the supervising nurse to the patient's home allow the nurse to directly observe the patient and the results of the aide's care. The supervisory visits must be documented in the patient's clinical record.

L630

(ii) If an area of concern is noted by the supervising nurse, then the hospice must make an on-site visit to the location where the patient is receiving care in order to observe and assess the aide while he or she is performing care.

Interpretive Guidelines §418.76(h)(1)(ii)

The supervising RN must conduct an in-person supervisory visit with the aide to observe and assess aide skills if a potential deficiency in care furnished by the aide is noted in the regular 14-day supervisory visit (during which the aide is not required to be present).

L631

(iii) If an area of concern is verified by the hospice during the on-site visit, then the hospice must conduct, and the hospice aide must complete, a competency evaluation in accordance with §418.76(c).

L632

(2) A registered nurse must make an annual on-site visit to the location where a patient is receiving care in order to observe and assess each aide while he or she is performing care.

Interpretive Guidelines §418.76(h)(2)

The annual on site supervision visit is to assess and observe each aide providing care to one of the patients. There is no requirement for the observation visit to be conducted on each patient the aide is caring for.

Hospices may determine the appropriate location to document the annual aide on-site evaluation in accordance with their own policies and procedures.

Procedures and Probes §418.76(h)(2)

Interview key staff to determine how the hospice assures that all aides are supervised on-site annually.

L633

(3) The supervising nurse must assess an aide's ability to demonstrate initial and continued satisfactory performance in meeting outcome criteria that include, but is not limited to–
- **(i) Following the patient's plan of care for completion of tasks assigned to the hospice aide by the registered nurse.**
- **(ii) Creating successful interpersonal relationships with the patient and family.**
- **(iii) Demonstrating competency with assigned tasks.**
- **(iv) Complying with infection control policies and procedures.**
- **(v) Reporting changes in the patient's condition.**

Interpretive Guidelines §418.76(h)(3)

Supervisory visits may be made in conjunction with a professional visit to provide services. Documentation of RN supervision should include, but not be limited to, if the aide is following the plan of care, is competent in performing required tasks and is satisfactory to the patient/family.

§418.76(i) Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit

L634

An individual may furnish personal care services, as defined in §440.167 of this chapter, on behalf of a hospice agency.

(1) Before the individual may furnish personal care services, the individual must be found competent by the State (if regulated by the State) to furnish those services. The individual only needs to demonstrate competency in the services the individual is required to furnish.

L635

(2) Services under the Medicaid personal care benefit may be used to the extent that the hospice would routinely use the services of a hospice patient's family in implementing a patient's plan of care.

L636

(3) The hospice must coordinate its hospice aide and homemaker services with the Medicaid personal care benefit to ensure the patient receives the hospice aide and homemaker services he or she needs.

Interpretive Guidelines §418.76(i)(3)

It is up to the State to define the optional Medicaid State Plan personal care services benefit and to determine if the benefit is more extensive than the homemaker/hospice aide benefit provided under the Medicare hospice benefit. If the Medicaid personal care services benefit is more extensive than what is offered under the Medicare hospice benefit, proper coordination of services must occur. In this instance, the State must pay for covered Medicaid personal care services that exceed the scope of the Medicare hospice benefit when a need for those personal care services is indicated in the patient's hospice plan of care.

L637

§418.76(j) Standard: Homemaker qualifications

A qualified homemaker is—
(1) An individual who meets the standards in §418.202(g) and has successfully completed hospice orientation addressing the needs and concerns of patients and families coping with a terminal illness; or

(2) A hospice aide as described in §418.76.

Interpretive Guidelines §418.76(j)

Homemaker services may include assistance in maintaining a safe and healthy environment for the patient/family and services to help the patient/family carry out the treatment plan. See §418.202(g).

§418.76(k) Standard: Homemaker supervision and duties

L638

(1) Homemaker services must be coordinated and supervised by a member of the interdisciplinary group.

L639

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

L640

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

Procedures and Probes §418.76(k)

- Interview key administrative staff regarding which member(s) of the IDG is responsible for the coordination and supervision of homemaker services.
- Through interview, home visits and record reviews assure that there are written instructions for duties to be performed and that any patient and family concerns are being reported to the homemaker services coordinator.
- The duties of the homemaker and the services performed must be documented in the clinical record.

L641

§418.78 Conditions of participation --Volunteers

L642

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.

Interpretive Guidelines §418.78

Volunteers are considered hospice employees to facilitate compliance with the core services requirement.

Procedures and Probes §418.78

Conduct an interview with the individual designated to supervise the volunteers regarding the use, training and supervision of volunteers.

L643

§418.78(a) Standard: Training

The hospice must maintain, document and provide volunteer orientation and training that is consistent with hospice industry standards.

Interpretive Guidelines §418.78(a)

All required volunteer training should be consistent with the specific tasks that volunteers perform.

Probes §418.78(a)

- How does the hospice supervise the volunteers? Is there evidence that all volunteers receive the supervision necessary to perform their assignments?
- Is there documentation supporting that all the volunteers have received training or orientation before being assigned to a patient/family?
- What evidence is there that the volunteers are aware of:
  - Their duties and responsibilities;
  - The person(s) to whom they report;

- The person(s) to contact if they need assistance and instructions regarding the performance of their duties and responsibilities;
- Hospice goals, services and philosophy;
- Confidentiality and protection of the patient's and family's rights;
- Family dynamics, coping mechanisms and psychological issues surrounding terminal illness, death and bereavement;
- Procedures to be followed in an emergency, or following the death of the patient;
- Guidance related specifically to individual responsibilities.

L644

§418.78(b) Standard: Role

Volunteers must be used in day-to-day administrative and/or direct patient care roles.

Interpretive Guidelines §418.78(b)

Qualified volunteers who provide professional services for the hospice must meet all requirements associated with their specialty area. If licensure or registration is required by the State, the volunteer must be licensed or registered.

The hospice may use volunteers to provide assistance in the hospice's ancillary and office activities as well as in direct patient care services, and/or help patients and families with household chores, shopping, transportation, and companionship. Hospices are also permitted to use volunteers in non-administrative and non-direct patient care activities, although these services are not considered when calculating the level of activity descibed in standard (e).

The duties of volunteers used in direct patient care services or helping patients and families must be evident in the patient's plan of care. There should be documentation of time spent and the services provided by volunteers.

Probes §418.78(b)

What evidence exists that the IDG conducts an assessment of the patient/family's need for a volunteer?

L645

§418.78(c) Standard: Recruiting and retaining.

The hospice must document and demonstrate viable and ongoing efforts to recruit and retain volunteers.

L646

§418.78(d) Standard: Cost saving

The hospice must document the cost savings achieved through the use of volunteers. Documentation must include the following:

(1) The identification of each position that is occupied by a volunteer.
(2) The work time spent by volunteers occupying those positions.
(3) Estimates of the dollar costs that the hospice would have incurred if paid employees occupied the positions identified in paragraph (d)(1) of this section for the amount of time specified in paragraph (d)(2) of this section.

Interpretive Guidelines §418.78(d)

There is no requirement for what the cost savings must be, only on how it is computed.

L647

§418.78(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.

Interpretive Guidelines §418.78(e)
In computing this level of activity, the hospice divides the number of hours that hospice volunteers spent providing administrative and/or direct patient care services by the total number of patient care hours of all paid hospice employees and contract staff. For example, if the hospice provides 10,000 hours of paid direct patient care during a one-year period the hospice must provide 500 volunteer hours in direct patient care or administrative activities to meet the required 5 percent total.

A hospice may fluctuate the volume of care provided by volunteers after the hospice meets the required 5 percent minimum.

L648

§418.100 Condition of Participation: Organization and administration of services.

L649

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

L650

§418.100(a) Standard: Serving the hospice patient and family

The hospice must provide hospice care that-

(1) Optimizes comfort and dignity; and
(2) Is consistent with patient and family needs and goals, with patient needs and goals as priority.

L651

§418.100(b) Standard: Governing body and administrator

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

Interpretive Guidelines §418.100(b)

If the hospice is part of a larger organization (e.g., HHA, hospital) and the governing body is the same, there must be documented evidence that the governing body is assuming full authority and responsibility for the management of the hospice and reviews and addresses the functioning of specific hospice operations, services and QAPI program.
If the administrator is not available to fulfill his or her assigned duties and responsibilities, the hospice must identify another individual to assume those assigned duties and responsibilities in accordance with the hospice's established policies and procedures. The governing body must assume responsibility for ensuring that the hospice is managed by the administrator and any managers that the administrator appoints.

Procedures and Probes §418.100(b)

- How is the governing body informed of the hospice's ongoing operations, including patient care delivery issues and quality assessment and performance improvement activities?

- Ask the administrator or clinical supervisor to describe the relationship between the governing body, hospice management and staff.

L652

§418.100(c) Standard: Services

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

(i) Nursing services.
(ii) Medical social services.
(iii) Physician services.
(iv) Counseling services, including spiritual counseling, dietary counseling, and bereavement counseling.
(v) Hospice aide, volunteer, and homemaker services.
(vi) Physical therapy, occupational therapy, and speech-language pathology services.
(vii) Short-term inpatient care.
(viii) Medical supplies (including drugs and biologicals) and medical appliances.

L653

(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.

L654

§418.100(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.

Interpretive Guidelines §418.100(d)

This condition applies to Medicare and Medicaid beneficiaries only.

L655

§418.100(e) Standard: Professional management responsibility

A hospice that has a written agreement with another agency, individual, or organization to furnish any services under arrangement must retain administrative and financial management, and oversight of staff and services for all arranged services, to ensure the

provision of quality care. Arranged services must be supported by written agreements that require that all services be--

(1) Authorized by the hospice;
(2) Furnished in a safe and effective manner by qualified personnel; and
(3) Delivered in accordance with the patient's plan of care.

Interpretive Guidelines §418.100(e)

The hospice must retain administrative and financial management responsibility, and oversight of staff and services provided under arrangement. For Medicare purposes, the hospice is reimbursed for all covered services it provides, whether directly or under arrangement. It is the responsibility of the hospice to pay for those services provided to Medicare beneficiaries under arrangement. When a hospice provides services under arrangements to non-Medicare beneficiaries, the hospice is responsible for establishing how payment for those services will occur, but the standard does not require the hospice to pay for those services directly or to pay for services for which there is no reimbursement or for services that another insurer is obligated to pay.

Procedures and Probes §418.100(e)

- Ask how the hospice assures that all contracted personnel (agency, individual or organization) provide care that is in accordance with the patient's plan of care?
- How does the hospice assure that all services provided under arrangement are authorized by the hospice?
- How does the hospice monitor and exercise control over services provided by personnel under arrangements or contracts?
- How does the hospice assure professional management of patients that are receiving inpatient care under arrangement?
- How and when does communication occur between the hospice and contracted individuals, agencies or organizations?
- How does the hospice assure that services are furnished by qualified staff?

§418.100(f) Standard: Hospice multiple locations

L656

If a hospice operates multiple locations, it must meet the following requirements:

(1) Medicare approval.

(i) All hospice multiple locations must be approved by Medicare before providing hospice care and services to Medicare patients.

Interpretive Guidelines §418.100(f)(1)(i)

It is inherent in the provider certification process for a hospice to notify CMS of its proposal to add a location from which it provides services. Absent such notification, CMS has no way of carrying out the statutorily mandated obligation of determining whether the hospice is complying with all applicable participation requirements at the new location. It is a longstanding CMS policy that there is no basis for a provider to bill Medicare for services provided from a location that has not been determined to meet applicable requirements of participation. This guidance is contained in sections 2086 and 3224 of this manual.

When an existing hospice intends to add a multiple location, it must notify CMS, the state survey agency (SA,) and, if deemed, it should notify its approved national accreditation organization (AO), in writing of the proposed location if it expects this location to participate in Medicare or Medicaid. The hospice must also submit a CMS Form-855A change of information request (including all supporting documentation) to its Medicare Administrative Contractor (MAC) before CMS approval can be granted. The provider must obtain CMS' approval of the new location before it is permitted to bill Medicare for services provided from the new location.

Upon receipt of a hospice's notice and request for approval of a multiple location, the CMS RO will carefully evaluate the information, together with any supporting documentation from the hospice and any other relevant information known to the RO in making its decision. If a decision can be made based on the written application and supporting documentation, CMS will grant or deny an approval without requiring a survey. If, however, the RO concludes that circumstances warrant a survey to establish whether the new location complies with all applicable requirements, CMS will advise the provider and will make no further findings until a Medicare certification survey has been completed and submitted to CMS for its review. In either event, CMS will notify the provider of its decision in writing, as appropriate.

NOTE: CMS will not approve a hospice's inpatient facility or a change of location for a hospice's own inpatient facility without a survey to assure that the facility meets all requirements specified at 42 CFR §418.110.

A hospice may not bill Medicare for services provided from a multiple location until the new site or location has been approved by CMS. The fact that a national accreditation organization with deeming authority has approved a new site or location will not affect CMS' decision. CMS' determination will be based on its independent application of its regulations to the facts in the case. Services provided before the effective date of approval should not be billed to Medicare.

If the hospice does operate at multiple locations, a deficiency found at any location will result in a compliance issue for the entire hospice.

L657

(ii) The multiple location must be part of the hospice and must share administration, supervision, and services with the hospice issued the certification number.

Procedures §418.100(f)(1)(ii)

- Ask the hospice how it assures that any multiple locations operating as a part of the hospice share administration, supervision and services, and participate in the hospice's QAPI activities.
- How does the hospice communicate with the multiple location(s) to assure that it is responsible to the same governing body and central administration that governs the hospice issued the provider agreement, and that the governing body and central administration are able to adequately manage the location, resolve any problems that occur and assure quality of care for all patients.

L658

(iii) The lines of authority and professional and administrative control must be clearly delineated in the hospice's organizational structure and in practice, and must be traced to the location issued the certification number.

L659

(iv) The determination that a multiple location does or does not meet the definition of a multiple location, as set forth in this part, is an initial determination, as set forth in §498.3.

Interpretive Guidelines §418.100(f)(1)(iv)

Initial determinations under 42 CFR §498.3 are subject to administrative review.

L660

(2) The hospice must continually monitor and manage all services provided at all of its locations to ensure that services are delivered in a safe and effective manner and to ensure that each patient and family receives the necessary care and services outlined in the plan of care, in accordance with the requirements of this subpart and subparts A and C of this section.

Interpretive Guidelines §418.100(f)(2)

Surveyors may conduct the entire survey or part of the survey at the multiple location(s). When conducting a survey at a multiple location, the surveyor may request that all necessary documentation for review be transported to that location at the hospice's expense. This may

include, but not be limited to, a sample of clinical records from all other locations, QAPI reports, administrative records, personnel files, and policies and procedures.

There should be evidence that:

- The hospice exerts the supervision and control necessary at each location to assure that all hospice care and services continue to be responsive to the needs of the patient/family at all times and in all settings;
- Each location provides the same full range of services that is required of the hospice issued the certification number;
- Each patient is assigned to a specific IDG responsible for ongoing assessment, planning, monitoring, coordination and provision of care;
- Each location is responsible to the same governing body and central administration that governs the hospice issued the certification number, and the governing body and central administration must be able to adequately manage the location and assure quality of care.

§418.100(g) Standard: Training

L661

(1) A hospice must provide orientation about the hospice philosophy to all employees and contracted staff who have patient and family contact.

L662

(2) A hospice must provide an initial orientation for each employee that addresses the employee's specific job duties.

L663

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

Procedures and Probes §418.100(g)

- Review a sample of personnel records to verify that initial orientation, assessment of skills and competency, and in-service training was provided to all employees, contracted staff and volunteers furnishing care/services to hospice patients and families.

- Review hospice written agreements and training programs provided for contracted personnel.
- If concerns are identified, interview the administrator or his/her designee, and staff regarding the specific issue.

L664

§418.102 Condition of Participation: Medical director

L665

The hospice must designate a physician to serve as medical director. The medical director must be a doctor of medicine or osteopathy who is an employee, or is under contract with, the hospice. When the medical director is not available, a physician designated by the hospice assumes the same responsibilities and obligations as the medical director.

Interpretive Guidelines §418.102

There is only one medical director for the hospice, including all multiple locations, if it has them. That individual may work full time or part time. If the medical director is not a paid employee or a contracted medical director, he/she is considered a volunteer under the control of the hospice. All other hospice physicians function under the supervision of the medical director.

Procedures and Probes §418.102

Identify through interview and documentation who the medical director is and who is designated to serve in this capacity in his/her absence.

L666

§418.102(a) Standard: Medical director contract

(1) A hospice may contract with either of the following—

> **(i) A self-employed physician; or**
> **(ii) A physician employed by a professional entity or physicians group.**

When contracting for medical director services, the contract must specify the physician who assumes the medical director responsibilities and obligations.

Interpretive Guidelines §418.102(a)

The medical director may also be a volunteer physician under the control of the hospice, as long as this person meets all Federal and State requirements for a hospice physician.

L667

§418.102(b) Standard: Initial certification of terminal illness

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

(1) The primary terminal condition;
(2) Related diagnosis(es), if any;
(3) Current subjective and objective medical findings;
(4) Current medication and treatment orders; and
(5) Information about the medical management of any of the patient's conditions unrelated to the terminal illness.

Interpretive Guidelines §418.102(b)

- The medical director or physician designee (who is a hospice employee or under contract with the hospice) has the responsibility for the medical component of the hospice's patient care program, including initial certifications and recertifications of terminal illness.
- During the clinical record review, verify that the clinical information necessary for certification is present in the record.

L668

§418.102(c) Standard: Recertification of the terminal illness

Before the recertification period for each patient, as described in §418.21(a), the medical director or physician designee must review the patient's clinical information.

L669

§418.102(d) Standard: Medical director responsibility

The medical director or physician designee has responsibility for the medical component of the hospice's patient care program.

Interpretive Guidelines §418.102(d)

The single individual who fills the role of the medical director assumes overall responsibility for the medical component of the hospice's patient care program. This responsibility, which extends to all hospice multiple locations, includes overseeing the implementation of the entire physician,

nursing, social work, therapy, and counseling areas within the hospice to ensure that these areas consistently meet patient and family needs.

L670

§418.104 Condition of participation: Clinical records

L671

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

§418.104(a) Standard: Content

L672

Each patient's record must include the following:
(1) The initial plan of care, updated plans of care, initial assessment, comprehensive assessment, updated comprehensive assessments, and clinical notes.

L673

(2) Signed copies of the notice of patient rights in accordance with §418.52 and election statement in accordance with §418.24.

L674

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

L675

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

L676

(5) Physician certification and recertification of terminal illness as required in §418.22 and §418.25 and described in §418.102(b) and §418.102(c) respectively, if appropriate.

L677

(6) Any advance directives as described in §418.52(a)(2).

L678

(7) Physician orders.

L679

§418.104(b) Standard: Authentication

All entries must be legible, clear, complete, and appropriately authenticated and dated in accordance with hospice policy and currently accepted standards of practice.

Interpretive Guidelines§418.104(b)

A hospice may create its own policy on authentication of clinical records based on accepted standards of practice. Hospices must follow State laws regarding authentication of clinical records, and, within this context, alter their policies as often as necessary to adapt to changing technologies and practices.

Medicare requires a legible identifier for services provided/ordered. This method must be handwritten (not stamped) or an electronic signature to sign an order or other clinical record documentation. The noted exception is that facsimiles of original written or electronic signatures are acceptable for the certifications of terminal illness for hospice.
Stamped signatures are not acceptable.

Providers and physicians using electronic signatures should recognize that there is a potential for misuse or abuse with alternate signature methods. For example, providers need a system and software products that are protected against modification, etc., and should apply administrative procedures that are adequate and correspond to recognized standards and laws. The individual whose name is on the alternate signature method as well as the provider bear the responsibility for the authenticity of the information to which they have attested. Physicians should check with their attorneys and malpractice insurers in regard to the use of alternative signature methods.

Hospices may not accept stamped physician signatures on orders, treatments, or other documents that are a part of the patient's clinical record.
Surveyors must have access to clinical records. If the record is maintained electronically, the hospice must provide all equipment necessary to read the record in its entirety. The hospice must also produce a paper copy of the record, if requested by the surveyor.

All State licensure and State practice regulations continue to apply to Medicare-approved hospices. Where State law is more restrictive than Medicare, the hospice needs to apply the State law standard.

Procedures and Probes §418.104(b)

Ask the hospice to explain their system of authentication. Verify that at a minimum it includes the following safeguards:

- The hospice has a method to identify the author of each entry. This would include verification of the author of faxed orders/entries or computer entries.
- If the hospice is using electronic medical records, electronic authentication must have a user ID and password protections in place.
- Every entry, both written and electronic, must be signed and dated by the person performing the service.

L680

§418.104(c) Standard: Protection of information

The clinical record, its contents and the information contained therein must be safeguarded against loss or unauthorized use. The hospice must be in compliance with the Department's rules regarding personal health information as set out at 45 CFR parts 160 and 164.

Interpretive Guidelines§418.104(c)

The hospice must ensure that unauthorized individuals cannot gain access to patient records, and that individuals cannot alter patient records.

Procedures and Probes §418.104(c)

- How does the hospice protect the confidentiality of clinical records.
- What is the hospice's policy on leaving and protecting clinical record information in the patient's home?
- If the hospice uses electronic patient records, what security safeguards are in place to protect the electronic system against loss, theft, damage, disruption of operations or unauthorized use?
- Is access to clinical records controlled?
- Are there measures in place to protect the patient from identity theft?
- Observe the hospice's security practices for patient records. Are patient records (hard copy or electronic) left unsecured or unattended?
- Verify that adequate precautions are taken to prevent physical or electronic altering.

L681

§418.104(d) Standard: Retention of records

Patient clinical records must be retained for 6 years after the death or discharge of the patient, unless State law stipulates a longer period of time. If the hospice discontinues operation, hospice policies must provide for retention and storage of clinical records. The hospice must inform its State agency and its CMS Regional office where such clinical records will be stored and how they may be accessed.

L682

§418.104(e) Standard: Discharge or transfer of care

(1) If the care of a patient is transferred to another Medicare/Medicaid-certified facility, the hospice must forward, to the receiving facility, a copy of-

(i) The hospice discharge summary; and
(ii) The patient's clinical record, if requested.

L683

(2) If a patient revokes the election of hospice care, or is discharged from hospice in accordance with §418.26, the hospice must forward to the patient's attending physician, a copy of-

(i) The hospice discharge summary; and
(ii) The patient's clinical record, if requested.

L684

(3) The hospice discharge summary as required by (e)(1) and (e)(2) of this section must include—

- **(i) A summary of the patient's stay including treatments, symptoms and pain management;**
- **(ii) The patient's current plan of care;**
- **(iii) The patient's latest physician orders; and**
- **(iv) Any other documentation that will assist in post-discharge continuity of care or that is requested by the attending physician or receiving facility.**

Interpretive Guidelines §418.104(e)

For further information regarding revocation or termination of hospice services see §2081 and §2082 of the SOM.

L685

§418.104(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.

Interpretive Guidelines §418.104(f)

An appropriate authority includes representatives from the SA or other authorized entity, who visits the hospice for the purpose of determining in accordance with section 1864(a) of the Act whether the hospice is meeting all conditions of participation.

If the clinical record is maintained electronically, the hospice must provide all equipment necessary to read the record in its entirety. The hospice must also produce a paper copy of the record, if requested by the surveyor. In addition, ascertain how the hospice ensures that the record is up-to-date including documentation of recent services/visits or handwritten notes held by staff that were not included in the record when the paper copy was produced.

L686

§418.106 Condition of participation: Drugs and biologicals, medical supplies, and durable medical equipment

L687

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.

§418.106(a) Standard: Managing drugs and biologicals

L688

(1) The hospice must ensure that the interdisciplinary group confers with an individual with education and training in drug management as defined in hospice policies and procedures and State law, who is an employee of or under contract with the hospice to ensure that drugs and biologicals meet each patient's needs.

Interpretive Guidelines §418.106(a)

Hospices must confer with an individual with education and training in drug management, and use acceptable standards of practice for hospice patients to select the most appropriate drugs to meet a particular patient's need. Conferences may take place in person or through other means of communication (e.g., teleconference, FAX, electronically etc.). The hospice should also be

able to explain drug choices to those providing patient care, the patient or representative, the family and any authority having jurisdiction, as necessary.

Individuals with education and training in drug management may include: licensed pharmacists; physicians who are board certified in palliative medicine; RNs who are certified in palliative care; and physicians, RNs and nurse practitioners who complete a specific hospice or palliative care drug management course, and other individuals as allowed by State law. The hospice must be able to demonstrate that the individual has specific education and training in drug management.

L689

(2) A hospice that provides inpatient care directly in its own facility must provide pharmacy services under the direction of a qualified licensed pharmacist who is an employee of or under contract with the hospice. The provided pharmacist services must include evaluation of a patient's response to medication therapy, identification of potential adverse drug reactions, and recommended appropriate corrective action.

L690

§418.106(b) Standard: Ordering of drugs

(1) Only a physician as defined by section 1861(r)(1) of the Act, or a nurse practitioner in accordance with the plan of care and State law, may order drugs for the patient.

(2) If the drug order is verbal or given by or through electronic transmission—

- **(i) It must be given only to a licensed nurse, nurse practitioner (where appropriate), pharmacist, or physician; and**
- **(ii) The individual receiving the order must record and sign it immediately and have the prescribing person sign it in accordance with State and Federal regulations.**

L691

§418.106(c) Standard: Dispensing of drugs and biologicals

The hospice must—

(1) Obtain drugs and biologicals from community or institutional pharmacists or stock drugs and biologicals itself.

(2) The hospice that provides inpatient care directly in its own facility must:
- **(i) Have a written policy in place that promotes dispensing accuracy; and**

(ii) Maintain current and accurate records of the receipt and disposition of all controlled drugs.

Interpretive Guidelines §418.106(c)

A biological is any medicinal preparation made from living organisms and their products including, but not limited to, serums, vaccines, antigens, and antitoxins.

L692

§418.106(d) Standard: Administration of drugs and biologicals

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

(2) Patients receiving care in a hospice that provides inpatient care directly in its own facility may only be administered medications by the following individuals:

- **(i) A licensed nurse, physician, or other health care professional in accordance with their scope of practice and State law;**
- **(ii) An employee who has completed a State-approved training program in medication administration; and**
- **(iii) The patient, upon approval by the interdisciplinary group.**

Interpretive Guidelines §418.106(d)

The patient's individualized written plan of care should identify if the patient and/or family are self-administering drugs and biologicals. If the patient and/or family are not capable of safely administering drugs and biologicals in the home, the hospice must address this issue in the patient's plan of care.

§418.106(e) Standard: Labeling, disposing, and storing of drugs and biologicals

L693

(1) Labeling. Drugs and biologicals must be labeled in accordance with currently accepted professional practice and must include appropriate usage and cautionary instructions, as well as an expiration date (if applicable).

Interpretive Guidelines §418.106(e)(1)

The hospice must have a system to ensure that they do not provide to their patients (either directly or under arrangement) outdated, mislabeled, or otherwise unusable drugs and biologicals.

L694

(2) Disposing. (i) Safe use and disposal of controlled drugs in the patient's home. The hospice must have written policies and procedures for the management and disposal of controlled drugs in the patient's home. At the time when controlled drugs are first ordered the hospice must:

L695

(A) Provide a copy of the hospice written policies and procedures on the management and disposal of controlled drugs to the patient or patient representative and family;

L696

(B) Discuss the hospice policies and procedures for managing the safe use and disposal of controlled drugs with the patient or representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe use and disposal of controlled drugs; and

Interpretive Guidelines §418.106(e)(2)(B)

The hospice's policies and procedures may also address the safe use and disposal of controlled drugs at other times, such as when a drug is discontinued, a new controlled drug is ordered, or when the patient dies.

L697

(C) Document in the patient's clinical record that the written policies and procedures for managing controlled drugs was provided and discussed.

L698

(ii) Disposal of controlled drugs in hospices that provide inpatient care directly. The hospice that provides inpatient care directly in its own facility must dispose of controlled drugs in compliance with the hospice policy and in accordance with State and Federal requirements. The hospice must maintain current and accurate records of the receipt and disposition of all controlled drugs.

L699

(3) Storing. The hospice that provides inpatient care directly in its own facility must comply with the following additional requirements-

(i) All drugs and biologicals must be stored in secure areas. All controlled drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1976 must be stored in locked compartments within such secure storage areas. Only personnel authorized to administer controlled drugs as noted in paragraph (d)(2) of this section may have access to the locked compartments; and

Interpretive Guidelines §418.106(e)(3)(1)

Compartments in the context of these regulations include, but are not limited to, drawers, cabinets, rooms, refrigerators, and carts. The provisions for "authorized personnel" to have access to keys must be determined by the hospice management in accordance with Federal, State, and local laws and facility practice.

L700

(ii) Discrepancies in the acquisition, storage, dispensing, administration, disposal, or return of controlled drugs must be investigated immediately by the pharmacist and hospice administrator and where required reported to the appropriate State authority. A written account of the investigation must be made available to State and Federal officials if required by law or regulation.

§418.106(f) Standard: Use and maintenance of equipment and supplies

L701

(1) The hospice must ensure that manufacturer recommendations for performing routine and preventive maintenance on durable medical equipment are followed. The equipment must be safe and work as intended for use in the patient's environment. Where a manufacturer recommendation for a piece of equipment does not exist, the hospice must ensure that repair and routine maintenance policies are developed. The hospice may use persons under contract to ensure the maintenance and repair of durable medical equipment.

L702

(2) The hospice must ensure that the patient, where appropriate, as well as the family and/or other caregiver(s), receive instruction in the safe use of durable medical equipment and supplies. The hospice may use persons under contract to ensure patient and family

instruction. The patient, family, and/or caregiver must be able to demonstrate the appropriate use of durable medical equipment to the satisfaction of the hospice staff.

Interpretive Guidelines §418.106(f)(2)

The instruction given to the patient/family on the use of the DME and supplies must be documented in the patient's clinical record, as well as the patient/family's understanding of the safe use of the DME and supplies.

Procedures and Probes §418.106(f)(2)

During home visits ask the patient, where appropriate, family and/or other caregiver(s), to describe any instructions received regarding the use of durable medical equipment and supplies. Has the patient/family had any problems with the equipment received? Does the DME function as required and intended? Clinical record documentation should verify/support their responses.

L703

(3) Hospices may only contract for durable medical equipment services with a durable medical equipment supplier that meets the Medicare DMEPOS Supplier Quality and Accreditation Standards at 42 CFR §424.57.

Interpretive Guidelines §418.106(f)(3)

DMEPOS is the acronym for Durable Medical Equipment Prosthetics, Orthotics and Supplies. All DMEPOS suppliers are required under separate rulemaking to be accredited by September 30, 2009, in order to receive Medicare payment. If a hospice has a contract with a DME supplier (that has a Medicare supplier billing number), the hospice should have a letter in its file from the DME supplier stating that the DME supplier is accredited.

If the hospice contracts with a DME supplier that only serves hospices, (therefore no Medicare supplier number), the hospice will still need to have a letter in its file from the DME supplier stating that the DME is accredited.

If the hospice owns its own DME, no accreditation is needed.

L704

§418.108 Condition of participation: Short-term inpatient care

L705

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

§418.108(a) Standard: Inpatient care for symptom management and pain control

L706

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

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

L707

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

§418.108(b) Standard: Inpatient care for respite purposes

L708

(1) Inpatient care for respite purposes must be provided by one of the following:

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

L709

(ii) A Medicare or Medicaid-certified nursing facility that also meets the standards specified in §418.110 (f).

L710

(2) The facility providing respite care must provide 24-hour nursing services that meet the nursing needs of all patients and are furnished in accordance with each patient's plan of care. Each patient must receive all nursing services as prescribed and must be kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.

Interpretive Guidelines §418.108(b)(2)

The hospice must assure that the inpatient facility has enough nursing personnel present on all shifts to guarantee that adequate safety measures are in place for the patients, and that the routine, special, and emergency needs of all patients are met at all times.

§418.108(c) Standard: Inpatient care provided under arrangements

L711

If the hospice has an arrangement with a facility to provide for short-term inpatient care, the arrangement is described in a written agreement, coordinated by the hospice and at a minimum specifies—
(1) That the hospice supplies the inpatient provider a copy of the patient's plan of care and specifies the inpatient services to be furnished;

L712

(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;

L713

(3) That the hospice patient's inpatient clinical record includes a record of all inpatient services furnished and events regarding care that occurred at the facility; that a copy of the discharge summary be provided to the hospice at the time of discharge; and that a copy of the inpatient clinical record is available to the hospice at the time of discharge;

L714

(4) That the inpatient facility has identified an individual within the facility who is responsible for the implementation of the provisions of the agreement;

L715

(5) That the hospice retains responsibility for ensuring that the training of personnel who will be providing the patient's care in the inpatient facility has been provided and that a description of the training and the names of those giving the training are documented; and

L716

(6) A method for verifying that the requirements in paragraphs(c)(1) through (c)(5) of this section are met.

Interpretive Guidelines §418.108(c):

Hospices may have arrangements with more than one facility for the provision of inpatient care.

Procedures and Probes §418.108(c)

- Ask the hospice clinical manager what facilities they use and how they monitor the care their patients receive at each facility. If you have questions concerning the provision of care or the hospice's explanation of how they monitor care at the facility(ies), ask to review a copy of their written agreement.

- Ask how the hospice assures that all staff caring for hospice patients at the inpatient facility(ies) have been trained in the hospice philosophy of care and are able to provide patient care according to the hospice plan of care. If necessary, contact or visit the facility(ies) as needed to verify compliance.

L717

§418.108(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.

Interpretive Guidelines §418.108(d)

This standard applies to **Medicare** beneficiaries only. Compliance with this regulation is based on the total number of **Medicare** beneficiaries enrolled in the hospice program, and does not include patients from other payor sources.

L718

§418.108(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.

L719

§418.110 Condition of participation: Hospices that provide inpatient care directly

L720

A hospice that provides inpatient care directly in its own facility must demonstrate compliance with all of the following standards:

L721

§418.110(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.

Interpretive Guidelines 418.110(a)

The intent of this regulation is to ensure that the hospice provides staffing that is adequate to meet patient needs. Adequate staff means that the numbers and types of qualified, trained, and experienced staff on the inpatient unit meet the care needs of every patient.

Procedures and Probes 418.110(a)

- How does the hospice assure that there is adequate staff on duty, especially during the evening, nighttime, weekends and holiday shifts, to take care of the individual needs of all patients?
- Interview patients/family to determine if they were satisfied with the care and services they received.
- If an on-site visit is conducted, observe if the staff is responsive to patient needs and if call bells are answered promptly.
- Do patients frequently call for assistance?
- Are patients checked frequently for safety, comfort and positioning?
- Ask hospice management for the inpatient staffing schedules and patient census for the past month to determine if staffing was adequate to meet patient needs.
- How does the hospice determine the staff-to-patient ratios on each shift?
- Review at least one clinical record to evaluate if staff provided the treatments, medications, personal care, and diet in compliance with the patient's plan of care.
- If questions arise regarding staffing patterns (staff illness, staff not reporting to work, etc.,) review the facility's staffing schedule and/or timecards as necessary.

L722

§418.110(b) Standard: Twenty-four hour nursing services

(1) The hospice facility must provide 24-hour nursing services that meet the nursing needs of all patients and are furnished in accordance with each patient's plan of care. Each patient must receive all nursing services as prescribed and must be kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.

L723

(2) If at least one patient in the hospice facility is receiving general inpatient care, then each shift must include a registered nurse who provides direct patient care.

Interpretive Guidelines §418.110(b)(2)

The general inpatient care provided in a facility for pain control or acute or chronic symptom management, which cannot be managed in other settings, is a different level of care than respite care. It is not automatically necessary to have an RN assigned to every shift to provide direct patient care if the only hospice patients in a facility are receiving the respite or routine levels of care. Staffing for a facility solely providing the respite or routine home care levels of care to hospice patients should be based on each patient's care needs. The requirements for nursing services for respite care are located at §418.108(b)(2).

Procedures and Probes §418.110(b)(2)

Ask the hospice for a schedule of RN personnel for the past month and inquire about the mechanism to ensure an RN provides direct patient care on each shift.

§418.110(c) Standard: Physical environment

L724

The hospice must maintain a safe physical environment free of hazards for patients, staff, and visitors.

L725

(1) <u>Safety management</u>.

(i)The hospice must address real or potential threats to the health and safety of the patients, others, and property.

Procedures and Probes §418.110(c)(1)(i)

- Ask the hospice what security mechanisms are in place and being followed to protect patients, staff and visitors.
- Review and analyze documentation related to patient and staff incidents and accidents to identify any incidents/accidents or patterns of incidents/accidents concerning a safe environment. Expand your review if you suspect a problem with a safe environment in the hospice.
- If the hospice has identified problems, did it evaluate those problems and take steps to ensure a safe patient environment?

- How does the hospice assure that staff follows current standards of practice for patient environmental safety, infection control, and security?

L726

(ii) The hospice must have a written disaster preparedness plan in effect for managing the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care. The plan must be periodically reviewed and rehearsed with staff (including non-employee staff) with special emphasis placed on carrying out the procedures necessary to protect patients and others.

Interpretive Guidelines§418.110(c)(1)(ii)

There should be documentation of LSC fire drills at varied times on all shifts. For example, fire drills on the day shift should not always occur at 10:00 A.M.

Further information on disaster preparedness guidance is available at http://www.nfpa.org/assets/files/PDF/NFPA1600.pdf

Procedures and Probes §418.110(c)(1)(ii)

- Request a copy of the hospice disaster preparedness plan and determine if the content addresses the management of power failures, natural disasters, and other potential emergencies, specific to the hospice's location.
- Request a copy of staff (both employed and volunteer staff) orientation/periodic education of the components of the disaster plan.
- What is the hospice's procedure for notification of staff, patients, physicians, and others in an emergency?
- Where does the hospice document and maintain its dated, written report and evaluation of each drill? Request and review this information.
- Interview random staff to assess their knowledge of specific responsibilities during a disaster or drill and what to do in a specific emergency i.e. fire in a patient's room.
- Are evacuation diagrams posted and visible to all staff, patient, and family members?
- Review evidence of specific planning for internal and external disasters, patient/record transfers, and arrangements with community resources.

L727

(2) <u>Physical plant and equipment</u>. The hospice must develop procedures for controlling the reliability and quality of--

(i) The routine storage and prompt disposal of trash and medical waste;
(ii) Light, temperature, and ventilation/air exchanges throughout the hospice;

(iii) Emergency gas and water supply; and
(iv) The scheduled and emergency maintenance and repair of all equipment.

Interpretative Guidelines §418.110(c)(2)

The term trash refers to common garbage as well as biohazardous waste. The storage and disposal of trash and medical waste should be in accordance with Federal, State and local laws and regulations (i.e., the Environmental Protection Agency, Occupational Health and Safety Administration (OSHA) CDC, State environmental, health and safety regulations).

The hospice must have a system to provide emergency gas and water as needed to provide care to inpatients. This includes making arrangements with local utility companies and others for the provision of emergency sources of water and gas. The hospice should consider nationally accepted references or calculations made by qualified staff when determining the need for at least water and gas. For example, one source for information on water is the Federal Emergency Management Agency (FEMA).

Procedures and Probes §418.110(c)(2)

- Ask the hospice to explain its system for providing emergency gas and water and routine and preventive maintenance schedules for equipment. Determine that ongoing maintenance inspections are performed, and that necessary repairs are completed.
- How does the hospice assure the reliability and quality of light, temperature, and ventilation/air exchanges throughout the hospice

L728

§418.110 (d) Standard: Fire protection

(1) Except as otherwise provided in this section--

(i) The hospice must meet the provisions applicable to nursing homes of the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association (NFPA). The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal register/code of federal regulations/ibr locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in the edition of the Code are incorporated by reference, CMS will publish a notice in the Federal Register to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to hospices.

(2) In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied would result in unreasonable hardship for the hospice, but only if the waiver would not adversely affect the health and safety of patients.

(3) The provisions of the adopted edition of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in hospices.

(4) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a hospice may place alcohol-based hand rub dispensers in its facility if--

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00-1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00-1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 C.F.R. part 51. A copy of the code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal register/code of federal regulations/ibr locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in the edition of the Code are incorporated by reference, CMS will publish a notice in the Federal Register to announce the changes.

Procedures and Probes §418.110(d)

- Is there documentation of compliance with any State and/or Federal building regulations codes, such as the 2000 edition of the Life Safety Code (LSC). NOTE: The LSC is not applicable where CMS finds that a State has in effect a fire and safety code imposed by State law that adequately protects patients in health care facilities.
- Request to see evidence that fire/safety drills have been held on all shifts at varied times as required by the Life Safety Code.
- Where does the hospice document and store its dated, written report and evaluation of each drill?
- Request evidence of the latest checks of fire extinguishers, sprinkler systems, and smoke alarms.
- Does a preventive maintenance program exist for electrical, HVAC (heat, ventilation and air conditioner), sprinkler, and security systems?
- Observe the location of fire extinguishers.
- Are there functional smoke alarms in each patient room?

L729

§418.110(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.

Interpretive Guidelines §418.110(e)

A homelike atmosphere de-emphasizes the institutional character of the setting to the extent possible.

Procedures §418.110(e)

- Interview patients/family members to validate that visiting hours are not restricted and accommodations are provided for family members to stay with the patient during the night.
- Observe the patient areas for the above requirements.
- Are window treatments and floor coverings residential/homelike in appearance and design?

L730

§418.110(f) Standard: Patient rooms

(1) The hospice must ensure that patient rooms are designed and equipped for nursing care, as well as the dignity, comfort, and privacy of patients.
(2) The hospice must accommodate a patient and family request for a single room whenever possible.
(3) Each patient's room must—

(i) Be at or above grade level;
(ii) Contain a suitable bed and other appropriate furniture for each patient;
(iii) Have closet space that provides security and privacy for clothing and personal belongings;
(iv) Accommodate no more than two patients and their family members;
(v) Provide at least 80 square feet for each residing patient in a double room and at least 100 square feet for each patient residing in a single room; and
(vi) Be equipped with an easily-activated, functioning device accessible to the patient, that is used for calling for assistance.

(4) For a facility occupied by a Medicare-participating hospice on December 2, 2008, CMS may waive the space and occupancy requirements of paragraphs (f)(2)(iv) and (f)(2)(v) of this section if it determines that—

(i) Imposition of the requirements would result in unreasonable hardship on the hospice if strictly enforced; or jeopardize its ability to continue to participate in the Medicare program; and
(ii) The waiver serves the needs of the patient and does not adversely affect their health and safety.

Interpretive Guidelines §418.110(f)

In addition to a clean, comfortable bed, each patient should have at least a place to put personal effects, such as pictures and a clock, furniture suitable for the comfort of the patient and visitors (i.e. a chair) and adequate lighting suitable to the tasks the patient chooses to perform, or the inpatient staff needs to perform.
Waiver requests mentioned in this requirement must be submitted in writing to the CMS RO.

Procedures §418.110(f)

- Does each bed have a flame retardant cubicle curtains, movable screens, or other acceptable means of providing full visual privacy?

L731

§418.110(g) Standard: Toilet and bathing facilities

Each patient room must be equipped with, or conveniently located near, toilet and bathing facilities.

Interpretive Guidelines 418.110(g)

"Toilet facilities" means a space that contains a lavatory and a toilet. Assure that each floor has at least one toilet facility and shower stall large enough to accommodate a wheelchair and patient transfer.

L732

§418.110(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.

Interpretive Guidelines §418.110(h)

The intent of this regulation is that the temperature of water at fixtures and in showers and tubs used by patients shall be automatically regulated by control valves and delivered for use at the appropriate temperature.

There is a risk that patients or staff may be scalded by excessively hot water discharged by plumbing fixtures. Water that is too hot may scald individuals who are exposed to it. This danger is particularly significant for patients who may have circulatory or other neurological deficits that prevent the instantaneous recoil from water that is too hot.

The chart below shows the estimated time for persons to receive second and third degree burns at various temperatures.

Water Temperature	Time to Receive Second Degree Burn	Time to Receive Third Degree Burn
120 degrees	8 minutes	10 minutes
124 degrees	2 minutes	4 minutes
131 degrees	17 seconds	30 seconds
140 degrees	3 seconds	5 seconds
150 degrees	<1 second	1 second

The recommended water temperatures at the plumbing fixtures should be maintained at or below 110 degrees.

Procedures and Probes §418.110(h)

- Interview staff and patients to assure there is always an adequate supply of hot water on the unit.
- Request incident reports for the past 12 months. Has there been any documentation of an incident(s) related to patient scalding with water?
- Ask the hospice to provide the maintenance logs for the automatic control valves used to regulate the temperature of the hot water. Review the water temperatures recorded.
- Check the hot water temperatures at patient's sinks, showers and tubs to verify that the water temperature does not exceed safe bathing temperature.

How to test water temperatures:

1. Follow the thermometer manufacturers recommended instructions for use.
2. Measure the hot water temperature prior to heavy use, or at least one hour after, so the hot water heater has time to recover and heat to its set temperature.
3. To ensure accuracy, do not hold the thermometer under the running water to measure the temperature.
4. Allow the hot water to run for a sufficient amount of time to ensure the water is at its hottest temperature.
5. Fill a bowl or cup with hot water.
6. Immediately immerse the silver end of the thermometer completely into the contained water.
7. Keep the thermometer in the water until the measurement has stabilized (30 to 60 seconds), then read the temperature.

L733

§418.110(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.

Interpretive Guidelines §418.110(i)

The hospice inpatient facility must have an active surveillance program that includes specific measures for prevention, early detection, control, education, and investigation of infections and communicable diseases in the hospice. There must be a mechanism to evaluate the effectiveness of the program(s) and take corrective action when necessary. The program must include implementation of nationally recognized systems of infection control guidelines to avoid sources and transmission of infections and communicable diseases (e.g., the CDC Guidelines for Prevention and Control of Nosocomial Infections, the CDC Guidelines for Preventing the Transmission of Tuberculosis in Health Care Facilities, OSHA regulations, and APIC guidelines on infection control, etc.).

Review disease reporting procedures and evidence of systematic tracking of communicable and reportable diseases. Is this program part of the hospice's overall quality assessment and performance improvement and education program?

Interview management and staff to determine if they are aware of the procedure to be followed if a patient or staff contracts an infectious or communicable disease.

Determine if there have been a high number of infections unrelated to the patients' diagnosis. If identified, what were the hospice's response and actions to prevent these and future occurrences?

The active infection control program should have policies that address the following:

- Definition of nosocomial infections and communicable diseases;
- Measures for identifying, investigating, and reporting nosocomial infections and communicable diseases;
- Measures for assessing and identifying patients and health care workers, including hospice personnel, contract staff (e.g., agency nurses, housekeeping staff) and volunteers, at risk for infections and communicable diseases;
- Measures for the prevention of infections;
- Measures for prevention of communicable disease outbreaks, such as airborne diseases (TB, SARS, etc.), food borne diseases (Hepatitis A, Salmonella, etc.), blood borne diseases (HIV, Hepatitis B, etc.), and others (VRE, MRSA, pseudomonas, etc.);
- Provision of a safe environment consistent with nationally recognized infection control precautions, such as the current CDC recommendations for the identified infection and/or communicable disease;
- Isolation procedures and requirements for infected or immunosuppressed patients
- Use and techniques for standard precautions;

- Education of patients, family members and caregivers about infections and communicable diseases;
- Techniques for hand washing, respiratory protections, asepsis as well as other means for limiting the spread of contagion;
- Orientation of all new hospice personnel to infections, communicable diseases, and to the infection control program;
- Measures for the screening and evaluation of health care workers, including all hospice staff, contract workers (e.g., agency nurses, housekeeping staff, etc), and volunteers, for communicable diseases, and for the evaluation of staff and volunteers exposed to patients with non-treated communicable diseases;
- Employee health policies regarding infectious diseases and when infected or ill employees, including contract workers and volunteers, must not render patient care and/or must not report to work.

L734

§418.110(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.

Interpretive Guidelines §418.110(j)

"Sanitary" includes, but is not limited to, preventing the spread of disease-causing organisms by keeping patient care equipment clean and properly stored. Patient care equipment includes, but is not limited to, toothbrushes, dentures, denture cups, glasses, water pitchers, emesis basins, hair brushes, combs, bed pans, urinals, and positioning or assistive devices.

Procedures and Probes §418.110(j)

- Ask the hospice to describe how they keep the facility clean and sanitary.
- Observe staff providing care. Do staff follow acceptable infection control guidelines?
- Observe the inpatient units – do they appear clean?

L735

§418.110(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.

Procedures and Probes §418.110(k)

- Interview patients/families to determine if linens are promptly changed when soiled throughout all 24-hour periods, including weekends and holidays.
- Ask management what the hospice's policy is on the frequency of linen change and replacement?
- During a tour of the inpatient hospice unit, observe patient bedding to assure cleanliness.
- Request to see the linen storage area to determine if there is an adequate supply to meet ongoing patient needs.
- How does the hospice store the clean linen to keep it clean, dry, and dust free?
- Is soiled linen and clothing collected and enclosed in suitable bags or containers in well-ventilated areas, separate from clean linen and not permitted to accumulate in the facility?

L736

§418.110(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.

Interpretive Guidelines §418.110(l)

The intent of this regulation is to assure that the nutritive value of food is not compromised and destroyed because of prolonged food storage, light, and air exposure.

Food should be palatable, attractive, and served at the proper temperature as determined by the type of food.

- Food-palatability refers to the taste and/or flavor of the food.
- Food attractiveness refers to the appearance of the food when served.
- Food temperature is food served at preferable temperature (hot foods are served hot and cold foods are served cold) as discerned by the patient and customary practice.

Procedures and Probes §418.110(l)

- Evidence for palatability and attractiveness of food, from day to day and meal to meal, may be strengthened through sources such as: observation, patient, family and staff interviews.
- Attempt to visit the inpatient unit while meals are delivered and observe if volunteers or staff are available to assist patients who need help.
- How does the hospice meet the individual patient's nutritional needs as identified in the plan of care?
- What arrangements does the hospice have to serve meals at the proper temperature and in a form that meets the patients' needs and desires?
- Is food served at preferable temperature (hot foods are served hot and cold foods are served cold) as discerned by the patient and customary practice?
- How is the IDG kept informed of the patient's response to the prescribed diet?
- Are meals individually scheduled, if needed, to allow for frequent, small meals if so desired by the patient?
- Is food available 24 hours a day, seven days a week, to respond to the patient's requests and needs?

L737

§418.110(m) Standard: Restraint or seclusion

All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

Interpretive Guidelines §418.110(m)

The hospice is responsible for creating a culture that supports a patient's right to be free from restraint or seclusion. The hospice must also ensure that systems and processes are developed, implemented, and evaluated that support the patients' rights addressed in this standard, and that eliminate the inappropriate use of restraint or seclusion.
If restraints or seclusion is necessary within the parameters of this regulation, it must be discontinued as soon as possible based on an individualized patient assessment and re-evaluation. A violation of any of these patients' rights constitutes an inappropriate use of restraint or seclusion and would be subject to a condition level deficiency.

The use of restraints for the prevention of falls must not be considered a routine part of a falls prevention program. Although restraints have been traditionally used as a falls prevention approach, they have major, serious drawbacks and can contribute to serious injuries. There is no

evidence that the use of physical restraint, (including, but not limited to, raised side rails) will prevent or reduce falls. Additionally, falls that occur while a person is physically restrained often result in more severe injuries and/or death.

L738

(1) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member, or others from harm.

L739

(2) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.

L740

(3) The use of restraint or seclusion must be--

- **(i) In accordance with a written modification to the patient's plan of care; and**
- **(ii) Implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospice policy in accordance with State law.**

L741

(4) The use of restraint or seclusion must be in accordance with the order of a physician authorized to order restraint or seclusion by hospice policy in accordance with State law.

L742

(5) Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).

Interpretive Guidelines §418.110(m)(5)

This regulation prohibits the use of standing or PRN (Latin abbreviation for pro re nata - as needed; as circumstances require) orders for the use of restraint or seclusion. The ongoing authorization of restraint or seclusion is not permitted. Each episode of restraint or seclusion must be initiated in accordance with the order of a physician. If a patient was recently released from restraint or seclusion, and exhibits behavior that can only be handled through the reapplication of restraint or seclusion, a new order would be required. Staff cannot discontinue a restraint or seclusion intervention, and then re-start it under the same order. This would constitute a PRN order.

L743

(6) The medical director or physician designee must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.

L744

(7) Unless superseded by State law that is more restrictive--

(i) Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours:

(A) 4 hours for adults 18 years of age or older;
(B) 2 hours for children and adolescents 9 to 17 years of age; or
(C) 1 hour for children under 9 years of age; and

After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician authorized to order restraint or seclusion by hospice policy in accordance with State law must see and assess the patient.

(ii) Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospice policy.

L745

(8) Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

L746

(9) The condition of the patient who is restrained or secluded must be monitored by a physician or trained staff that have completed the training criteria specified in paragraph (n) of this section at an interval determined by hospice policy.

L747

(10) Physician, including attending physician, training requirements must be specified in hospice policy. At a minimum, physicians and attending physicians authorized to order restraint or seclusion by hospice policy in accordance with State law must have a working knowledge of hospice policy regarding the use of restraint or seclusion.

L748

(11) When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention --

- **(i) By a—**
  - **(A) Physician; or**
  - **(B) Registered nurse who has been trained in accordance with the requirements specified in paragraph (n) of this section.**
- **(ii) To evaluate—**
  - **(a) The patient's immediate situation;**
  - **(b) The patient's reaction to the intervention;**
  - **(c) The patient's medical and behavioral condition; and**
  - **(d) The need to continue or terminate the restraint or seclusion.**

L749

(12) States are free to have requirements by statute or regulation that are more restrictive than those contained in paragraph (m)(11)(i) of this section.

L750

(13) If the face-to-face evaluation specified in §418.110(m)(11) is conducted by a trained registered nurse, the trained registered nurse must consult the medical director or physician designee as soon as possible after the completion of the 1-hour face-to-face evaluation.

L751

(14) All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored--

- **(i) Face-to-face by an assigned, trained staff member; or**
- **(ii) By trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient.**

L752

(15) When restraint or seclusion is used, there must be documentation in the patient's clinical record of the following:

(i) The 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior;
(ii) A description of the patient's behavior and the intervention used;
(iii) Alternatives or other less restrictive interventions attempted (as applicable);
(iv) The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and the patient's response to the intervention(s) used, including the rationale for continued use of the intervention.

L753

§418.110(n) Standard: Restraint or seclusion staff training requirements

The patient has the right to safe implementation of restraint or seclusion by trained staff.

L754

(1) Training intervals. All patient care staff working in the hospice inpatient facility must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion—

(i) Before performing any of the actions specified in this paragraph;
(ii) As part of orientation; and
(iii) Subsequently on a periodic basis consistent with hospice policy.

Interpretive Guidelines§418.110(n)(1)

All staff designated by the hospice as having direct patient care responsibilities, including contract or agency personnel, must demonstrate the competencies specified in standard (n) prior to participating in the application of restraints, implementation of seclusion, monitoring, assessment, or care of a patient in restraint or seclusion. These competencies must be demonstrated initially as part of hospice orientation and subsequently on a periodic basis consistent with hospice policy. Hospices have the flexibility to identify a timeframe for ongoing training based on the level of staff competency, and the needs of the patient population(s) served.

All staff working in a hospice that precludes the use of restraints or seclusion would not have to be trained or demonstrate competencies specified in this standard since no staff in a restraint free facility would be applying restraints or placing patients in seclusion. In this situation, the hospice should ensure that all staff are aware of its restraint and seclusion free philosophy and provide ongoing training in this philosophy. The hospice should also closely monitor patients to be sure that the use of any restraint or seclusion technique is not used.

L755

(2) <u>Training content</u>. The hospice must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

- **(i) Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.**
- **(ii) The use of nonphysical intervention skills.**
- **(iii) Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition.**
- **(iv) The safe application and use of all types of restraint or seclusion used in the hospice, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia).**
- **(v) Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.**
- **(vi) Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospice policy associated with the 1-hour face-to-face evaluation.**
- **(vii) The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.**

Interpretive Guidelines §418.110(n)(2)

The term "appropriate staff" includes all staff that apply restraint or seclusion, monitor, assess, or otherwise provide care for patients in restraint or seclusion.

Staff needs to be able to employ a broad range of clinical interventions to maintain the safety of the patient and others. The hospice is expected to provide education and training at the appropriate level, to the appropriate staff, based upon the specific needs of the patient population(s) being served.

L756

(3) <u>Trainer requirements</u>. Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.

Interpretive Guidelines §418.110(n)(3)

Hospices may develop and implement their own training programs or use an outside training program.

Interview management and review documentation to assure the course trainer has the appropriate qualifications.

L757

(4) Training documentation. The hospice must document in the staff personnel records that the training and demonstration of competency were successfully completed.

Procedures and Probes §418.110(n)(4)

- Request a copy of the training curriculum for the use of restraints or seclusion. Does it contain all the required content items as prescribed in this Standard?
- Request a copy of new employee orientation content to assure that information on use of restraints or seclusion is included.
- Review attendance sheets for initial and periodic training sessions.
- Review 3 new employee (hired within the past 12 months) personnel files to assure there is evidence of appropriate training in restraint and seclusion use.
- Conduct an interview with the actual trainer if additional validation is needed.

L758

§418.110(o) Standard: Death reporting requirements

Hospices must report deaths associated with the use of seclusion or restraint.

(1) The hospice must report the following information to CMS:

(i) Each unexpected death that occurs while a patient is in restraint or seclusion.
(ii) Each unexpected death that occurs within 24 hours after the patient has been removed from restraint or seclusion.
(iii) Each death known to the hospice that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.

(2) Each death referenced in this paragraph must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death.
(3) Staff must document in the patient's clinical record the date and time the death was reported to CMS.

Interpretive Guidelines §418.110(o)

If a patient has an unexpected death that occurs while in restraint or seclusion, or an unexpected death occurs within 24 hours after restraint or seclusion has been discontinued, the death must be reported to CMS RO. Additionally, if a death occurs within one week after the use of restraint or seclusion and it is reasonable to assume the death was associated with restraint and/or seclusion, the death should be reported to CMS RO.

Restraint means (1) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely, not including devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort); or (2) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

Seclusion means the involuntary confinement of a patient alone in a room or an area from which the patient is physically prevented from leaving. Patients who request private rooms would not be considered in seclusion.

Procedures and Probes §418.110(o)

- Does the inpatient hospice policy related to the use of restraints or seclusion include information on reporting to CMS in the event of a death connected to the use of restraints or seclusion?
- Interview management and staff to assess if any deaths have occurred related to the use of seclusion or restraint.
- Review any documentation/clinical records if such a death has occurred. Was this information reported appropriately to CMS within the timeframe required by this Standard?

L759

§418.112 Condition of participation: Hospices that provide hospice care to residents of a SNF/NF or ICF/MR.

L760

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

Interpretive Guidelines §418.112

For the purposes of this guidance under this condition, "facility" will be used in place of SNF/NF or ICF/MR.

All references to a "patient" in the guidance under this condition mean a person who is a resident of a facility and is receiving hospice services from the Medicare certified hospice.

L761

§418.112(a) Standard: Resident eligibility, election, and duration of benefits

Medicare patients receiving hospice services and residing in a SNF, NF, or ICF/MR are subject to the Medicare hospice eligibility criteria set out at §418.20 through §418.30.

L762

§418.112(b) Standard: Professional management

The hospice must assume responsibility for professional management of the resident's hospice services provided, in accordance with the hospice plan of care and the hospice conditions of participation, and make any arrangements necessary for hospice-related inpatient care in a participating Medicare/Medicaid facility according to §418.100 and §418.108.

Interpretive Guidelines §418.112(b)

The term "professional management" for a hospice patient who resides in a SNF/NF or ICF/MR has the same meaning that it has if the hospice patient were living in his/her own home. Professional management involves assessing, planning, monitoring, directing and evaluating the patient's/resident's hospice care across all settings.

The professional services provided by the hospice to the patient in his/her home should continue to be provided by the hospice to the patient in a facility, or other place of residence. Hospice core services must be routinely provided by the hospice, and cannot be delegated to the facility. Hospices should specify that facility staff should immediately notify the hospice of these unplanned interventions. In the contract between the hospice and the facility, potential crisis situations and temporary emergency measures should be addressed and determined how they will be handled by facility staff.

Hospice is responsible for providing all hospice services including:

- Ongoing assessment, care planning, monitoring, coordination and provision of care by the Hospice IDG.

- Assessment, coordination and provision of any needed general inpatient or continuous care.
- Consultation about the patient's care with facility staff.
- Coordination by the hospice RN for the implementation of the plan of care for the patient.
- Provision of hospice aide services, if these services are determined necessary by the IDG to supplement the nurse aide services provided by the facility.
- Provision, in a timely manner, of all supplies, medications, and DME needed for the palliation and management of the terminal illness and related conditions.
- Financial management responsibility for all medical supplies, appliances, medications and biologicals related to the terminal illness and related conditions.
- Determination of the appropriate level of care to be given to the patient (routine homecare, inpatient, or continuous care).
- Arranging any necessary transfers from the facility, in consultation with the facility staff.

L763

§418.112(c) Standard: Written agreement

The hospice and SNF/NF or ICF/MR must have a written agreement that specifies the provision of hospice services in the facility. The agreement must be signed by authorized representatives of the hospice and the SNF/NF or ICF/MR before the provision of hospice services.

Interpretive Guidelines §418.112(c)

The written agreement is for the provision of hospice services between the two entities. As the written agreement is not patient specific, it does not need to be rewritten for each patient. If there are concerns regarding the provision of services, the hospice and the facility may review and revise this agreement as appropriate for needed changes and/or improvement in the working relationship between the two entities.

L764

The written agreement must include at least the following:
(1) The manner in which the SNF/NF or ICF/MR and the hospice are to communicate with each other and document such communications to ensure that the needs of patients are addressed and met 24 hours a day.

Interpretive Guidelines §418.112(c)(1)

There should be evidence that the hospice and the facility have reached an agreement on how to communicate concerns and responses 24 hours a day in order to work together to meet the needs

of the patient identified in the patient's plan of care. The hospice must document that this communication has occurred.

Procedures and Probes §418.112(c)(1)

- What system is in place to assure that the facility knows how to notify the hospice when necessary on a 24/7 basis?
- Is there any evidence that the communication is not occurring as needed during various times of the day or week or specific shifts?
- How does the hospice ensure that facility staff are able to recognize the individuals who are receiving hospice services and know that the services provided to this patient should be in accordance with the coordinated plan of care?
- What evidence is there that the hospice and the facility communicate with each other during and between patient visits, as appropriate, to share information about the patient's needs and response to the plan of care?
- Does the hospice staff have access to and the ability to communicate with facility staff about the patient's care as often as needed?

L765

(2) A provision that the SNF/NF or ICF/MR immediately notifies the hospice if—

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

(ii) Clinical complications appear that suggest a need to alter the plan of care;

(iii) A need to transfer a patient from the SNF/NF or ICF/MR arises, and the hospice makes arrangements for, and remains responsible for, any necessary continuous care or inpatient care necessary related to the terminal illness and related conditions; or

(iv) A patient dies.

Procedures and Probes §418.112(c)(2)

- Have there been instances when the facility transferred a patient to the hospital without notifying the hospice?
- Have there have been instances when the hospice has been unaware of a significant change in the patient's status or death of a hospice patient?
- How does the hospice ensure that facility staff will contact the hospice immediately regarding the required provisions, including but not limited to:
  - Any changes in condition such as changes in cognition or sudden unexpected decline in condition.
  - A condition unrelated to the terminal condition or related conditions, such as a fall with a suspected fracture.
  - Complications, such as adverse consequences to a medication or therapy, requiring a revision to the plan of care.

– A patient's death.

L766

(3) A provision stating that the hospice assumes responsibility for determining the appropriate course of hospice care, including the determination to change the level of services provided.

Procedures and Probes §418.112(c)(3):

- Is there evidence that the patients are receiving the appropriate level of hospice services to meet their needs?
- Does each patient receive updates to the comprehensive assessment at the required time points according to §418.54(d) and plan of care reviews according to §418.56(d)?

L767

(4) An agreement that it is the SNF/NF or ICF/MR responsibility to continue to furnish 24 hour room and board care, meeting the personal care and nursing needs that would have been provided by the primary caregiver at home at the same level of care provided before hospice care was elected.

Interpretive Guidelines §418.112(c)(4):

In entering into an agreement with each other, each provider retains responsibility for the quality and appropriateness of the care it provides in accordance with their respective laws and regulations. Both providers must comply with their applicable conditions/requirements for participation in Medicare/Medicaid. The facility's services must be consistent with the plan of care developed in coordination with the hospice, (the hospice patient residing in a facility should not experience any lack of services or personal care because of his/her status as a hospice patient); and the facility must offer the same services to its residents who have elected the hospice benefit as it furnishes to its residents who have not elected the hospice benefit. If a patient is receiving services from a Medicare/Medicaid certified nursing facility or ICF/MR, and the facility was advised of concerns by the hospice and failed to address and/or resolve issues related to coordination of care or implementation of appropriate services, the hospice surveyor will refer the concerns as a complaint to the State Agency responsible for oversight of the facility identifying the specific patient(s) involved and the concerns identified.

L768

(5) An agreement that it is the hospice's responsibility to provide services at the same level and to the same extent as those services would be provided if the SNF/NF or ICF/MR resident were in his or her own home.

Interpretive Guidelines §418.112(c)(5)

Regardless of where a patient resides, a hospice is continually responsible for furnishing core services, and may not delegate these services to the facility staff.

L769

(6) A delineation of the hospice's responsibilities, which include, but are not limited to the following: providing medical direction and management of the patient; nursing; counseling (including spiritual, dietary and bereavement); social work; provision of medical supplies, durable medical equipment and drugs necessary for the palliation of pain and symptoms associated with the terminal illness and related conditions; and all other hospice services that are necessary for the care of the resident's terminal illness and related conditions.

Interpretive Guidelines §418.112(c)(6)

The agreement should identify how the facility and the hospice determine how all needed services, professionals, medical supplies, DME and drugs and biologicals necessary for the palliation and management of pain and symptoms associated with the terminal illness and related conditions are available to the patient 24 hours a day, 7 days a week, including who may receive and/or write orders for care, in accordance with State/Federal requirements.

Probe §418.112(c)(6)

Is there evidence that the hospice provides the services as needed, as well as medications, equipment and supplies necessary for pain control and symptom management on a 24 hour basis?

L770

(7) A provision that the hospice may use the SNF/NF or ICF/MR nursing personnel where permitted by State law and as specified by the SNF/NF or ICF/MR to assist in the administration of prescribed therapies included in the plan of care only to the extent that the hospice would routinely use the services of a hospice patient's family in implementing the plan of care.

Probes §418.112(c)(7)

- Is there evidence that facility personnel assist in the administration of prescribed therapies included in the plan of care that exceed what a hospice family member might implement?
- How do the hospice and the facility identify the therapies that facility staff will be allowed to perform?

L771

(8) A provision stating that the hospice must report all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by anyone unrelated to the hospice to the SNF/NF or ICF/MR administrator within 24 hours of the hospice becoming aware of the alleged violation.

L772

(9) A delineation of the responsibilities of the hospice and the SNF/NF or ICF/MR to provide bereavement services to SNF/NF or ICF/MR staff.

Interpretive Guidelines §418.112(c)(9)

There are times when facility staff and residents fulfill the role of a patient's family, providing caregiver services, being companions, and generally supporting the patient. A hospice may offer bereavement services to facility staff or residents that fulfill the role of a hospice patient's family as identified in the patient's plan of care.

L773

§418.112(d) Standard: Hospice plan of care

In accordance with §418.56, a written hospice plan of care must be established and maintained in consultation with SNF/NF or ICF/MR representatives. All hospice care provided must be in accordance with this hospice plan of care.

L774

(1) The hospice plan of care must identify the care and services that are needed and specifically identify which provider is responsible for performing the respective functions that have been agreed upon and included in the hospice plan of care.

L775

(2) The hospice plan of care reflects the participation of the hospice, the SNF/NF or ICF/MR, and the patient and family to the extent possible.

Interpretive Guidelines §418.112(d)(2)

The hospice and the facility must develop a coordinated plan of care for each patient that guides both providers. When a hospice patient is a resident of a facility, that patient's hospice plan of care must be established and maintained in consultation with representatives of the facility and the patient/family (to the extent possible). The hospice portion of the plan of care governs the

actions of the hospice and describes the services that are needed to care for the patient. In addition, the coordinated plan of care must identify which provider (hospice or facility) is responsible for performing a specific service. The coordinated plan of care may be divided into two portions, one of which is maintained by the facility and the other, which is maintained by the hospice. The facility is required to update its plan of care in accordance with any Federal, State or local laws and regulations governing the particular facility, just as hospices need to update their plans of care according to §418.56(d) of these CoPs. The hospice plan of care must specifically identify/delineate the provider responsible for each function/service/intervention included in the plan of care.

NOTE: The providers must have a procedure that clearly outlines the chain of communication between the hospice and facility in the event a crisis or emergency develops, a change of condition occurs, and/or changes to the hospice portion of the plan of care are indicated.

Based on the shared communication between providers, both providers' portion of the plan of care should reflect the identification of:

- A common problem list
- Palliative interventions
- Palliative outcomes
- Responsible discipline
- Responsible provider
- Patient goals.

Procedures and Probes §418.112 (d)(2)

- Interview the patient, family or representative if possible to determine their involvement in the development of the plan of care, defining the approaches and goals, and to determine if interventions reflect choices and preferences. Also, determine how they are involved in developing and revising pain management strategies (if any) and any necessary revisions if the interventions do not work.
- Determine whether medications or other interventions for symptom control, medical supplies or DME related to the terminal illness have been arranged and provided by the hospice, and are available for patient use. Determine whether there have been delays in the provision of medications and/or supplies/equipment, and how this has been addressed by the hospice and the facility.

L776

(3) Any changes in the hospice plan of care must be discussed with the patient or representative, and SNF/NF or ICF/MR representatives, and must be approved by the hospice before implementation.

Interpretive Guidelines §418.112(d)(3)

The hospice and facility must have a process by which information from the hospice IDG plan of care reviews, assessment updates, and the facility team, and the patient and family (to the extent possible) conferences will be exchanged when updating the plan of care and evaluating outcomes of care to assure that the patient receives the necessary care and services. The hospice must authorize all changes to the hospice portion of the plan of care prior to the change being made.

Procedures and Probes §418.112(d)(3)

Based on observations, if concerns are identified that the plan of care does not identify the interventions observed, or if the patient and/or representative have indicated that the interventions are not meeting his/her needs, interview hospice and facility staff. Determine how the hospice and facility monitor for the outcome of the interventions and what process they have in place to revise the plan of care to meet the needs of the patient.

Determine how the hospice is providing coordination of the plan of care interventions, assuring that the interventions are being implemented by the facility, and assuring that interventions are not changed without hospice approval.

§418.112(e) Standard: Coordination of services

L777

The hospice must:
(1) Designate a member of each interdisciplinary group that is responsible for a patient who is a resident of a SNF/NF or ICF/MR. The designated interdisciplinary group member is responsible for:

L778

(i) Providing overall coordination of the hospice care of the SNF/NF or ICF/MR resident with SNF/NF or ICF/MR representatives; and

Interpretive Guidelines §418.112(e)(1)(i)

The intent of this regulation is for the hospice IDG to designate a member responsible for overseeing and coordinating the provision of care between the hospice and the facility. This person may or may not be the hospice RN responsible for the coordination of patient's hospice care in the facility. It may also be the physician, social worker or counselor member of the IDG. In order to facilitate the coordination and provision of hospice care to the patient, the hospice and the facility should address how the hospice staff access and communicate with facility staff. This includes, but is not limited to:

- Development of each provider's portion of the plan of care to assure that the plans are complimentary and reflect common goals and the patient's expressed desire for hospice care.
- Documentation in both respective entities' clinical records or other means to ensure continuity of communication and easy access to ongoing information.
- Role of any hospice vendor in delivering supplies or medications.
- Ordering, renewal, delivery and administration of medications.
- Role of the attending physician, and process for obtaining and implementing physician orders.

Procedures and Probes §418.112(e)(1)(i)

- Does the hospice's system for ordering, renewal, delivery and administration of medications work effectively in the facility?
- What procedures are in place to ensure that the patient receives timely medication and treatments for optimal palliation, pain and symptom relief?
- Is there evidence that the hospice provides education to the facility on the hospice resident's pain and symptom management plan?
- Does the hospice work with the facility to monitor the effectiveness of treatments related to pain and symptom control?

L779

(ii) Communicating with SNF/NF or ICF/MR representatives and other health care providers participating in the provision of care for the terminal illness and related conditions and other conditions to ensure quality of care for the patient and family.

Procedures and Probes §418.112(e)(1)(ii)

If there are problems identified regarding failure to communicate with facility staff, interview the hospice designated IDG member, and the facility care plan coordinator for the patient, in order to determine:

- The system the hospice has in place to ensure continuity of communication and easy access to ongoing information (e.g., documentation in both respective entities' clinical records).
- How the information from each provider's team conferences get communicated to the individuals participating in caring for the patient.

Determine if there have been any concerns related to the need to change or alter the plan of care; or if a significant change in condition occurred requiring a transfer to an acute care setting, and how and when the facility notified the hospice of the concerns.

In the event that there are concerns related to the coordination and implementation of the patient's plan of care for pain control and symptom management, interview the facility's nurse aides who provide direct care to the patient to determine:

- If they are aware of any complaints of pain from the patient or signs and symptoms that could indicate the presence of pain or discomfort.
- To whom they report the patient's complaints, signs, or symptoms.
- If they are aware of, and implement, interventions for pain/discomfort management for the patient consistent with the patient's plan of care, (for example, allowing a period of time for a pain medication to take effect before bathing and/or dressing).

Review the plan of care to determine if the plan was coordinated between the hospice and the facility. Determine if symptom management, including pain management interventions, are included, if needed, and addressed as appropriate:

- Measurable pain management goals, reflecting patient needs and preferences.
- Pertinent non-pharmacological and/or pharmacological interventions.
- Time frames and approaches for monitoring the status of the patient's pain, including the effectiveness of the interventions.
- Identification of clinically significant medication-related adverse consequences such as falling, constipation, anorexia, or drowsiness, and a plan to minimize those adverse consequences.
- Whether the pain has been reassessed and the plan of care revised as necessary if the current interventions are not effective or the patient has experienced a change of condition or status.

If the plan of care refers to a specific protocol, determine whether interventions are consistent with that protocol. If a patient's plan of care deviates from the protocol, determine through staff interview or record review the reason for the deviation.

Interview a facility staff person who is knowledgeable about the needs and care of the patient to determine:

- How and when staff communicate with the hospice when/if the patient is experiencing pain.
- If the patient receives pain medication (including PRN and adjuvant medications), how, when, and by whom the results of medications are evaluated (including the dose, frequency of PRN use, schedule of routine medications, and effectiveness).
- How staff monitor for the emergence or presence of adverse consequences of interventions.
- What is done if pain or other symptoms persist or recur despite treatment, and the basis for decisions to maintain or modify approaches.
- How the hospice and the facility coordinate their approaches, communicate about the patient's needs, and monitor the outcomes (both effectiveness and adverse consequences).

L780

(2) Ensure that the hospice IDG communicates with the SNF/NF or ICF/MR medical director, the patient's attending physician, and other physicians participating in the provision of care to the patient as needed to coordinate the hospice care of the hospice patient with the medical care provided by other physicians.

Interpretive Guidelines §418.112(e)(2)

Both providers may document physician orders. Orders are to be dated and signed in accordance with State laws. Implementation of the plan of care changes resulting from physician orders received by the facility must have **prior** hospice approval.

Procedures and Probes §418.112(e)(2)

If concerns were identified that changes to the plan of care, without prior hospice approval, occurred as a result of physician orders received by the facility, determine:

- How the IDG communicates with physicians involved with the patient.
- If there is evidence that the IDG communicates effectively with all physicians involved in the patient's care to ensure that duplicative and/or conflicting physician orders related to the terminal illness and related conditions are not issued.

L781

(3) Provide the SNF/NF or ICF/MR with the following information:

(i) The most recent hospice plan of care specific to each patient;
(ii) Hospice election form and any advance directives specific to each patient;
(iii) Physician certification and recertification of the terminal illness specific to each patient;

(iv) Names and contact information for hospice personnel involved in hospice care of each patient;
(v) Instructions on how to access the hospice's 24-hour on-call system;
(vi) Hospice medication information specific to each patient; and
(vii) Hospice physician and attending physician (if any) orders specific to each patient.

Interpretive Guidelines §418.112(e)(3)

The hospice and facility must have a process by which information from the hospice IDG plan of care reviews, updated assessments, and the facility team and the patient and family (to the extent possible) will be exchanged when developing and updating the plan of care and evaluating outcomes of care to assure that the patient receives the necessary care and services.

Probes §418.112(e)(3)

Interview facility staff involved in the care of the patient on their knowledge of how to contact hospice staff 24 hours a day.

L782

§418.112(f) Standard: Orientation and training of staff

Hospice staff must assure orientation of SNF/NF or ICF/MR staff furnishing care to hospice patients in the hospice philosophy, including hospice policies and procedures regarding methods of comfort, pain control, symptom management, as well as principles about death and dying, individual responses to death, patient rights, appropriate forms, and record keeping requirements.

Interpretive Guidelines §418.112(f)

It is the hospice's responsibility to assess the need for staff training and coordinate the staff training with representatives of the facility. It is also the hospice's responsibility to determine how frequently training needs to be offered in order to ensure that the facility staff furnishing care to hospice patients are oriented to the philosophy of hospice care. Facility staff turnover rates should be a consideration in determining training frequency.

Procedures and Probes §418.112(f)

If during observations and interviews with the patient/representative and staff, concerns are identified that staff are not following the hospice philosophy, 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, interview hospice staff on how they have provided education to the facility staff.

How does the hospice assure that the facility staff furnishing care to hospice patients are trained in the hospice philosophy of care?

L783

§418.114 Condition of participation: Personnel qualifications

L784

§418.114(a): General qualification requirements

Except as specified in paragraph (c) of this section, all professionals who furnish services directly, under an individual contract, or under arrangements with a hospice, must be legally authorized (licensed, certified or registered) in accordance with applicable Federal, State and local laws, and must act only within the scope of his or her State license, or State certification, or registration. All personnel qualifications must be kept current at all times.

L785

(b) Personnel qualifications for certain disciplines. The following qualifications must be met:

(1) Physician. Physicians must meet the qualifications and conditions as defined in section 1861(r) of the Act and implemented at §410.20 of this chapter.

L786

(2) Hospice aide. Hospice aides must meet the qualifications required by section 1891(a)(3) of the Act and implemented at §418.76.

L787

(3) Social worker. A person who—

(i) (A) Has a Master of Social Work (MSW) degree from a school of social work accredited by the Council on Social Work Education; or

(B) Has a baccalaureate degree in social work from an institution accredited by the Council on Social Work Education; or a baccalaureate degree in psychology, sociology, or other field related to social work and is supervised by an MSW as described in paragraph (b)(3)(i)(A) of this section; and

(ii) Has one year of social work experience in a health care setting; or

(iii) Has a baccalaureate degree from a school of social work accredited by the Council on Social Work Education, is employed by the hospice before December 2, 2008, and is not required to be supervised by an MSW.

Interpretive Guidelines §418.112(b)(3)

A hospice social worker must at least meet one of the following options:

1. Have an MSW degree from a school of social work accredited by the Council on Social Work Education (CSWE), and one year of experience in a health care setting.
2. Have a baccalaureate degree in social work (BSW) from a school of social work accredited by the CSWE, and one year of experience in a health care setting and be supervised by a MSW from a school of social work accredited by the CSWE and who has one year of experience in a health care setting. If the BSW is employed by the hospice before December 2, 2008, he/she is exempted from the MSW supervision requirement.
3. Have a baccalaureate degree in psychology, sociology, or other field related to social work, and at least one year of social work experience in a health care setting and be supervised by a MSW from a school of social work accredited by the CSWE and who has one year of experience in a health care setting.

The hospice must also defer to State law regarding social work requirements. If State requirements are more stringent, the hospice must comply with the State requirements. For example, if the State requires a social worker to have a BSW or an MSW, the hospice may not employ a person with a baccalaureate degree in psychology, sociology, or other field related to social work to work as a hospice social worker.

Each hospice must employ or contract with at least one MSW to serve in the supervisor role as an active advisor, consulting with the BSW on assessing the needs of patients and families, developing and updating the social work portion of the plan of care, and delivering care to patients and families. This supervision may occur in person, over the telephone, through electronic communication, or any combination thereof. The hospice must allow time for this supervision to happen on a regular basis and provide documentation as to the nature and scope of supervision. The hospice must also ensure that non-social work trained bachelor's prepared employees filling the role of social worker are supervised by a MSW who graduated from a school of social work accredited by the CSWE and who has at least one year of experience in a health care setting.

Social workers with a baccalaureate degree from a school of social work accredited by the CSWE and who are employed by the hospice before December 2, 2008, are exempted from the MSW supervision requirement. If a hospice hires a new social worker with a baccalaureate degree and one year of experience in a health care setting after December 2, 2008, then the baccalaureate social worker must be supervised by an MSW who has one year of experience in a health care setting.

L788

(4) <u>Speech language pathologist</u>. A person who meets either of the following requirements:

(i) The education and experience requirements for a Certificate of Clinical Competence in speech-language pathology granted by the American Speech-Language-Hearing Association.

(ii) The educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

L789

(5) <u>Occupational therapist</u>. A person who—

(i)---

(A) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing, unless licensure does not apply;

(B) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA), or successor organizations of ACOTE; and

(C) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(ii) On or before December 31, 2009—

(A) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing; or

(B) When licensure or other regulation does not apply—

(1) Graduated after successful completion of an occupational therapist education program accredited by the accreditation Council for Occupational therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or successor organizations of ACOTE; and

(2) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc., (NBCOT).

(iii) On or before January 1, 2008—

(A) Graduated after successful completion of an occupational therapy program accredited jointly by the committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or

(B) Is eligible for the National Registration Examination of the American Occupational Therapy Association or the National Board for Certification in Occupational Therapy.

(iv) On or before December 31, 1977—

(A) Had 2 years of appropriate experience as an occupational therapist; and

(B) Had achieved a satisfactory grade on an occupational therapist proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(v) If educated outside the United States—

(A) Must meet both of the following:

(1) Graduated after successful completion of an occupational therapist education program accredited as substantially equivalent to occupational therapist assistant entry level education in the United States by one of the following:

(i) The Accreditation Council for Occupational Therapy Education (ACOTE).

(ii) Successor organizations of ACOTE.

(iii) The World Federation of Occupational Therapists.

(iv) A credentialing body approved by the American Occupational Therapy Association.

(v) Successfully completed the entry level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

On or before December 31, 2009, is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing.

L790

(6) <u>Occupational therapy assistant</u>. A person who—

(i) Meets all of the following:

(A) Is licensed or otherwise regulated, if applicable, as an occupational therapy assistant by the State in which practicing, unless licensure does apply.

(B) Graduated after successful completion of an occupational therapy assistant education program accredited by the Accreditation Council for Occupational Therapy Education, (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or its successor organizations.

(C) Is eligible to take or successfully completed the entry-level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(ii) On or before December 31, 2009—

(A) Is licensed or otherwise regulated as an occupational therapy assistant, if applicable, by the State in which practicing; or any qualifications defined by the State in which practicing, unless licensure does not apply; or

(B) Must meet both of the following:

(1) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association.

(2) After January 1, 2010, meets the requirements in paragraph (b)(6)(i) of this section.

(iii) After December 31, 1977 and on or before December 31, 2007—

(A) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association; or

(B) Completed the requirements to practice as an occupational therapy assistant applicable in the State in which practicing.

(iv) On or before December 31, 1977—

(A) Had 2 years of appropriate experience as an occupational therapy assistant; and

(B) Had achieved a satisfactory grade on an occupational therapy assistant proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(v) If educated outside the United States, on or after January 1, 2008—

(A) Graduated after successful completion of an occupational therapy assistant education program that is accredited as substantially equivalent to occupational therapist assistant entry level education in the United States by—

(1) The Accreditation Council for Occupational Therapy Education (ACOTE).

(2) Its successor organizations.

(3) The World Federation of Occupational Therapists.

(4) By a credentialing body approved by the American Occupational Therapy Association; and

(5) Successfully completed the entry level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

L791

(7) <u>Physical therapist</u>. A person who is licensed, if applicable, by the State in which practicing, unless licensure does not apply and meets one of the following requirements:

(i) Graduated after successful completion of a physical therapist education program approved by one of the following:

(A) The Commission on Accreditation in Physical Therapy Education (CAPTE).
(B) Successor organizations of CAPTE.
(C) An education program outside the United States determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or an organization identified in 8 CFR 212.15(e) as it relates to physical therapists.
(D) Passed an examination for physical therapists approved by the State in which physical therapy services are provided.

(ii) On or before December 31, 2009—
(A) Graduated after successful completion of a physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE); or
(B) Meets both of the following:
(1) Graduated after successful completion of an education program determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified in 8 CFR 212.15(e) as it relates to physical therapists.
(2) Passed an examination for physical therapists approved by the State in which physical therapy services are provided.

(iii) Before January 1, 2008—
(A) Graduated from a physical therapy curriculum approved by one of the following:
(1) The American Physical Therapy Association.
(2) The Committee on Allied Health Education and Accreditation of the American Medical Association.
(3) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association.

(iv) On or before December 31, 1977 was licensed or qualified as a physical therapist and meets both of the following:
(A) Has 2 years of appropriate experience as a physical therapist.
(B) Has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(v) Before January 1, 1966—
(A) Was admitted to membership by the American Physical Therapy Association;
(B) Was admitted to registration by the American Registry of Physical Therapists; and
(C) Graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education.

(vi) Before January 1, 1966 was licensed or registered, and before January 1, 1970, had 15 years of fulltime experience in the treatment of illness or injury through the practice of

physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy.

(vii) If trained outside the United States before January 1, 2008, meets the following requirements:

- **(A) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.**
- **(B) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.**

L792

(8) Physical therapist assistant. A person who is licensed, registered or certified as a physical therapist assistant, if applicable, by the State in which practicing, unless licensure does not apply and meets one of the following requirements:

- **(i) Graduated from a physical therapist assistant curriculum approved by the Commission on Accreditation in Physical Therapy Education of the American Physical Therapy Association; or if educated outside the United States or trained in the United States military, graduated from an education program determined to be substantially equivalent to physical therapist assistant entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified at 8 CFR 212.15(e); and**
- **(ii) Passed a national examination for physical therapist assistants.**
  - **(A) On or before December 31, 2009, meets one of the following:**
    - **(1) Is licensed, or otherwise regulated in the State in which practicing.**
    - **(2) In States where licensure or other regulations do not apply, graduated before December 31, 2009, from a 2-year college-level program approved by the American Physical Therapy Association and after January 1, 2010, meets the requirements of paragraph (b)(8) of this section.**
    - **(3) Before January 1, 2008, where licensure or other regulation does not apply, graduated from a 2-year college level program approved by the American Physical Therapy Association.**
    - **(4) On or before December 31, 1977, was licensed or qualified as a physical therapist assistant and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.**

L793

(c) Personnel qualifications when no State licensing, certification or registration requirements exist. If no State licensing laws, certification or registration requirements exist for the profession, the following requirements must be met:

(1) Registered nurse. A graduate of a school of professional nursing.

L794

(2) Licensed practical nurse. A person who has completed a practical nursing program.

L795

(d) Standard: Criminal background checks

(1) The hospice must obtain a criminal background check on all hospice employees who have direct patient contact or access to patient records. Hospice contracts must require that all contracted entities obtain criminal background checks on contracted employees who have direct patient contact or access to patient records.

L796

(2) Criminal background checks must be obtained in accordance with State requirements. In the absence of State requirements, criminal background checks must be obtained within three months of the date of employment for all states that the individual has lived or worked in the past 3 years.

L797

§418.116 Condition of participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.

L798

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.

L799

§418.116(a) Standard: Multiple locations

Every hospice must comply with the requirements of §420.206 of this chapter regarding disclosure of ownership and control information. All hospice multiple locations must be approved by Medicare and licensed in accordance with State licensure laws, if applicable, before providing Medicare reimbursed services.

L800

§418.116(b) Standard: Laboratory services

(1) If the hospice engages in laboratory testing other than assisting a patient in self-administering a test with an appliance that has been approved for that purpose by the FDA, the hospice must be in compliance with all applicable requirements of part 493 of this chapter.

Interpretive Guidelines §418.116(b)

Determine if the hospice is providing laboratory testing as set forth at 42 CFR Part 493. If the hospice is performing testing, request to see the Clinical Laboratory Improvement Amendments (CLIA) certificate for the level of testing being performed, i.e., a certificate of waiver, certificate for provider-performed microscopy procedures, certificate of accreditation, certificate of registration, or certificate of compliance (issued upon the determination of compliance after an on-site survey.)

Hospices holding a certificate of waiver are limited to performing only those tests determined to be in the waived category. Some tests that a hospice may perform that fall into the waived category include:

- Dipstick/tablet reagent urinalysis;
- Blood glucose by glucose monitoring devices cleared by the Food and Drug Administration (FDA) specifically for home use;
- Some prothrombin time tests; and
- Some glycosolated hemoglobin tests.

For a complete listing of waived tests, refer to CMS' website at http://www.cms.hhs.gov/CLIA/10_Categorization_of_Tests.asp#TopOfPage

Hospices holding a certificate for provider-performed microscopy procedures are limited to performing only those tests determined to be in the provider-performed microscopy procedure category or in combination with waived tests.

The tests in the provider-performed microscopy procedures category (e.g., wet mounts, urine sediment examinations, and nasal smears for granulocytes) are not typical of those performed in a hospice; however, if they are conducted by hospice staff under a certificate for provider-performed microscopy procedures, they must be performed by a practitioner as specified at §493.19 (i.e., a physician, nurse midwife, nurse practitioner, physician assistant, or dentist). If not performed by these personnel, the hospice would require a registration certificate (which allows the performance of such testing until a determination of compliance is made), certificate of accreditation, or certificate of compliance.

For a complete listing of provider-performed microscopy procedures, refer to CMS' website at http://www.cms.hhs.gov/CLIA/10_Categorization_of_Tests.asp#TopOfPage

A registration certificate, a certificate of accreditation, or a certificate of compliance is required if the hospice performs any other testing procedures, (i.e., moderate or high complexity testing). While some prothrombin testing is in the waived category, as mentioned above, other prothrombin testing is considered moderate complexity testing depending on the skill level required to operate the instrument.

For a complete listing of moderate and high complexity tests, refer to CMS' website at http://www.cms.hhs.gov/CLIA/10_Categorization_of_Tests.asp#TopOfPage

Assisting individuals in administering their own tests, such as fingerstick blood glucose or prothrombin testing, is not considered testing subject to the CLIA regulations. However, if the hospice staff is actually responsible for measuring the blood glucose level or prothrombin times of patients with an FDA approved blood glucose or prothrombin time monitor, and no other tests are being performed, request to see the facility's certificate of waiver, since glucose testing with a blood glucose meter (approved by the FDA specifically for home use) and some prothrombin time tests are waived tests under the provisions at 42 CFR 493.15.

If the hospice does not possess the appropriate CLIA certificate, inform the hospice that it is in violation of CLIA law and that it must apply immediately to the State agency for the appropriate certificate. The hospice is out of compliance with 42 CFR 418.116(b). Also, refer this hospice's noncompliance to the department within the State agency responsible for CLIA surveys.

L801

(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.

Interpretive Guidelines §418.116(b)(2)

The hospice is required to comply with applicable State law and secure a CLIA certificate of waiver for any waived testing performed by staff. Lab specimens obtained in the patient's home must be taken to laboratories that meet CLIA and state law requirements.

The hospice should have a copy of the reference laboratory's CLIA certificate in its administrative records.