

State Operations Manual

Appendix M - Guidance to Surveyors: Hospice - (Rev. 1, 05-21-04)

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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 and 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 certain avenues for investigation in preparation for the survey, in conducting the survey, and in evaluation of 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 also 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 the 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 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.

Types of Hospice Surveys

A - Initial Certification Surveys

At the time of the survey, the hospice must be operational, have accepted patients (who are not required to be Medicare patients), be providing all services needed by the patients actually being served, and have demonstrated the operational capability of all facets of its operations. In the event that the hospice patients presently being served 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 Conditions of Participation.

It is not necessary to schedule another survey to inspect the arranged-for inpatient services **if** the contracts have been reviewed and there is no doubt that the hospice is providing the service or is fully prepared to provide the service when needed. However, 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 the hospice Conditions of Participation. In no case can the effective date be earlier than the date of the survey.

All initial and recertification hospice surveys must verify compliance with **all** the regulatory requirements contained in [42 CFR 418.50-418.100](#).

B - Recertification Survey of Participating Hospices

Follow the procedures for initial surveys.

C - Follow-Up Surveys

The nature of the deficiencies dictates the necessity for and scope of the follow-up visit. The purpose of the follow-up survey is to reevaluate the specific care and services that were cited during the survey that cannot be adequately assessed by mail or telephone contact. Assess the status of the corrective actions being taken on all deficiencies cited on the Form CMS-2567. In those circumstances where an onsite follow-up visit is necessary, examine as many conditions as needed to determine compliance status.

D - Complaint Investigations

Investigation and resolution of complaints is a critical certification activity. Each complaint against a hospice must be investigated and resolved. (See §3281.)

II – The Survey Focus

The outcome-oriented survey process for hospices places emphasis on the effects of the hospice's performance on the patients receiving hospice services and directs the focus of the surveyor, at least initially, to the services the hospice is providing to its patients. The surveyor then examines the structures and processes contributing to the quality of these services.

The principal focus of the survey is on the outcome of the hospice's practices in implementing hospice requirements and providing hospice services, i.e., the effect of the hospice's services on the patients. The intent of the survey process is to evaluate each of the conditions in the most efficient manner possible. Instead of proceeding condition by condition through the requirements, consider the interrelatedness of the regulations. Assess each condition concurrently through observation, interviews, record reviews, and home visits, if appropriate. Direct your principal attention to how skillfully and effectively the staff interacts with the patient/caregiver, how effective the plan of care is

in meeting the needs of the patient/caregiver, and how responsive the patient/caregiver is to the hospice's interactions and interventions.

III - The Survey Tasks

A survey of a hospice consists of the following tasks and 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. Also, review the information in the State files relating to the disclosure of information statement made by the hospice. Check this information for accuracy with the information obtained during the course of the survey.

Task 2 - Entrance Interview

The entrance interview sets the tone for the entire survey. Upon arrival, the surveyor or team leader should present identification, introduce any team members, inform the hospice administrator, director, or supervisor of the purpose of the survey, explain the survey process, and estimate the time schedule for completion. Surveyor(s) should be organized and courteous and aware of the fact that the unannounced survey may be disruptive to the normal daily activities of the hospice. Information should be requested and not demanded from the hospice personnel. Be sure to inform the hospice that you may conduct visits to patients as part of the certification process, and request a current list of all hospice patients receiving care.

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 each of the regulatory requirements reviewed during the survey.

A - Clinical Record Review

Select a representative sample of clinical records according to the following guidelines:

Number of Hospice Patients Admitted During Recent 12 Month Period	Minimum Number of Record Reviews of Patients Admitted During Recent 12 Month Period
Less than 150	3
150 – 750	4
751 - 1250	6
1,251 or more	8

The sample selected is 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 is to include patients with different types of terminal diagnoses. In addition to the clinical records (active and closed), request the policies and procedures, personnel files, documentation of home health aide training and/or competency evaluations, and other relevant documents, as necessary.

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 you with additional information in considering any alternative explanations before you make compliance decisions. Pay particular attention to the following areas:

1. Assessment of the Plan of Care

- Care is furnished according to the plan of care.
- Care is directed at managing pain and other uncomfortable symptoms and is revised and updated as necessary to reflect both the patient's current status and the family/caregiver's needs.
- All covered services are available as necessary to meet the needs of the patient.
- Substantially all core services are routinely provided by hospice employees.

- Drugs and medical supplies are provided as needed for the palliation and management of the terminal illness and related conditions. Drugs are furnished in accordance with accepted professional standards of practice.
- The plan of care reflects the participation of the patient to the extent possible. The hospice communicates the plan of care to the patient/caregiver in a comprehensible way.

2. Coordination of Service/Continuity of Care

- The hospice plan of care and clinical record reflect the activities of all disciplines providing care to the patient/caregiver.
- The hospice assumes overall professional management responsibility for all contracted services.
- The hospice makes arrangements for the provision of all necessary covered hospice services.
- The hospice makes arrangements for any necessary inpatient care according to [42 CFR 418.98](#), and retains professional management responsibility for services furnished by inpatient facility staff.

3. Home Health Aide Services

- Home health aides who are employees of the hospice, as well as aides used by the hospice under an arrangement or contract, meet the personnel qualifications specified in [42 CFR 484.4](#) for “home health aide.”
- Home health aide services are adequate in frequency to meet the needs of the patient.
- A hospice registered nurse provides written patient care instructions and monitors the services provided by the home health aide.
- A hospice registered nurse makes an onsite visit to the patient’s residence no less frequently than every 2 weeks if aide services are provided, to assess aide services and relationships and determine whether goals are being met. The onsite visit need not be made while the aide is furnishing services.

B - Hospice Home Visit Procedures

Home visits **must** be made to a sample of Medicare/Medicaid hospice patients during a hospice survey if one or more of the following conditions exist:

- The hospice has been in operation less than 6 months;
- The hospice provides routine home care to a resident(s) of a SNF, NF, or other inpatient facility;
- The hospice had one or more conditions out of compliance during its last survey;
- The hospice provides 3 or more services under arrangement;
- The hospice is found to have deficiencies in the area of quality and/or delivery of services based on the onsite portion of the current survey; or
- The surveyor determines that home visits are required to verify that the hospice is in compliance with all conditions and standards.

Even if the above conditions do not exist, home visits are to be made, if possible, since these visits yield valuable information about patient satisfaction, plan of care implementation, continuity of care, the role of volunteers, and the availability of both routine and emergency services.

1 - Patient Selection for Home Visits

When you determine that home visits are feasible or necessary, work with the hospice staff to help you identify patients who meet one or more of the following criteria:

- Reside in a SNF/NF, or other residential facility;
- Receive four or more different hospice services;
- Receive infrequent visits from the hospice;
- Have frequent contacts with the hospice;
- Have been at home for 2 or more months;
- Have made a complaint against the hospice; or
- Receive two or more hospice services under arrangements made by the hospice.

Select a random sample of at least three or four of these patients to visit. In addition, the random sample selected is to capture the different types of settings in which the hospice provides routine home care (i.e., private residence, nursing facility) and include patients with different types of terminal diagnoses (i.e., cancer, AIDS.)

2 - Patient's Consent

You may visit patients from all payment sources who have given consent for the visit. Patients must understand that a home visit is voluntary and that refusal to consent to a home visit will in no way affect Medicare/Medicaid benefits. Be certain that the patient (or representative) has signed 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.

The hospice representative who provides the care or services should contact the patient/family/caretaker to request permission and make arrangements for the home visit. However, if you have concerns about this arrangement, you may contact the patient/family/caretaker directly and request permission to make the home visit. 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 his/her 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 are able to 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 most 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 hospice 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 by patients.
- Determine the dates and times of the next visits, the types of personnel making the visits (i.e., skilled nurse, home health aide, social worker), and the names of the individuals providing the services;
- 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.

There may be circumstances, however, that should be reviewed during a home visit without the hospice representative being present.

In certain instances (i.e. to investigate the effectiveness of the hospice's bereavement program) it may be necessary to contact the family of a deceased hospice patient. In this situation, you may conduct an interview by telephone in lieu of a home visit. Wait at least six months after the patient's death to allow the caregiver time to adjust to his/her loss.

4 - Home Visit

At the patient's home you may talk with the patient, his/her 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. Do not conduct the visit as an interrogation with a display of survey forms and long lists of questions to be answered. The following probes may be helpful to use during your interview to measure patient satisfaction with the care he/she is receiving and to assess the scope and quality of the plan of care.

- 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?
- Has there ever been any time that the hospice did not do everything they could to help control your pain?
- Have you ever had to wait long to get pain medication? 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?
- Since you have been receiving care from the hospice, have you had any out-of-pocket expenses for your health care? If yes, what kinds?
- How satisfied are you with the services provided? Do you have any suggestions for improvement?

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 of the home.

Observe, but do not interfere with, the delivery of care or the interactions between the hospice representative and the patient/family and/or caretaker.

Discontinue the interview if:

- The patient shows signs of being uncomfortable or seems reluctant to talk, and if after asking the patient, he or she says 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.

5 - Follow-Up Procedures

Check any specific patient's 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, cite these deficiencies on the Form CMS-2567. These deficiencies could include, but are not limited to:

- Failure to follow the patient's plan of care;
- Failure to complete clinical records;
- Failure to use volunteers if required in the plan of care;
- Failure of the hospice to routinely provide substantially all core services directly to hospice patients, including those patients who are residents of nursing facilities;
- Failure to provide all covered services, as necessary, including home health aide and counseling;
- Failure to provide nursing and physician services on a 24-hour basis; or
- Failure to retain professional management responsibility for all services provided under arrangement.

Task 4 - Information Analysis

A - General

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. Review all your findings and use your professional judgment to decide whether further information is necessary.

B - Analysis

Analyze your findings relative to each requirement for the effect or potential effect on the patient(s), the degree of severity, frequency of occurrence, and the impact on the delivery of services. An isolated incident that has little or no effect on the delivery of patient services does not warrant a deficiency citation. On the other hand, a condition may be considered out of compliance for one or more deficiencies if, in your judgment, the deficiency constitutes a significant or a serious problem that adversely affects, or has the potential to adversely affect patients. 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.

Task 5 - Exit Conference

General Objective

The exit conference is held at the end of the survey to inform the hospice of observations and preliminary findings of the survey. Because of ongoing dialogue between surveyors 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, director, supervisor and other staff invited by the hospice;
- Provide instructions and time frame necessary for submitting a plan of correction. (See §2724.);
- Describe the regulatory requirements that the hospice does not meet and the findings that substantiate these deficiencies; and

- Present the Form CMS-2567 onsite, or in accordance with the State agency's policy, but no later than 10 calendar days after the exit conference.

Refer to §2724 for additional information on the 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

§418.3 Definitions

For purposes of this part--

“Attending physician” means a physician who--

- (a) Is a doctor of medicine or osteopathy; and**
- (b) Is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual’s medical care.**

“Bereavement counseling” means counseling services provided to the individual’s family after the individual’s death.

“Employee” means an employee (defined by section [210\(j\)](#) of the Act) of the hospice or, if the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is appropriately trained and assigned to the hospice unit. “Employee” also refers to 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 care to terminally ill individuals.

“Physician” means physician as defined in [§410.20](#) of this chapter.

“Representative” means an individual who has been authorized under State law to terminate medical care or to elect or revoke the election of hospice care on behalf of a terminally ill individual who is mentally or physically incapacitated.

“Social worker” means a person who has at least a bachelor’s degree from a school accredited or approved by the Council on Social Work Education.

“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.

L100**§418.50 Condition of Participation: General Provisions**

L101**§418.50(a) Standard: Compliance**

A hospice must maintain compliance with the conditions of this subpart and subparts D and E of this part.

Guidelines §418.50(a)

The hospice Conditions of Participation apply to all patients of the hospice (Medicare and non-Medicare) with the exception of the following regulations (which apply only to Medicare beneficiaries):

- | | |
|------------|---|
| §418.60 | The continuation of care requirement; and |
| §418.98(c) | The 80-20 inpatient care limitation. |

L102**§418.50(b) Standard: Required Services**

A hospice must be primarily engaged in providing the care and services described in [§418.202](#), must provide bereavement counseling and must--

Guidelines §418.50(b)

The hospice must be primarily engaged in providing services to hospice patients as specified below. A hospice cannot serve as a brokerage agent by contracting or administratively arranging for all hospice services.

As required by [§418.202](#), hospice services include, but are not limited to, the following:

- Nursing services;
- Physical therapy, occupational therapy, speech-language pathology services;
- Medical social services;
- Home health aide and homemaker services;

- Physician services;
- Counseling services (dietary, pastoral and other);
- Short-term inpatient care; and
- Medical appliances and supplies, including drugs and biologicals.

In addition, the hospice must provide bereavement counseling to the patient's family/caregiver after the patient's death.

L103

(1) Make nursing services, physician services, and drugs and biologicals routinely available on a 24-hour basis;

Probes §418.50(b)(1)

How does the hospice arrange staffing to meet the varied and changing needs of its patients 24 hours a day?

What evidence is there that the on-call system of the hospice is in place and operational?

L104

(2) Make all other covered services available on a 24-hour basis to the extent necessary to meet the needs of individuals for care that is reasonable and necessary for the palliation and management of terminal illness and related conditions; and

L105

(3) Provide these services in a manner consistent with accepted standards of practice.

Guidelines §418.50(b)(3)

Accepted standards of practice are typically developed by professional associations such as nurses, therapists, and social workers, to establish the standards of practice for competent persons serving in a particular professional role. The accepted professional standards and principles that the hospice and its staff must comply with include, but are not limited to, the hospice Federal regulations, State practice acts, and commonly accepted health standards established by national organizations, boards, and councils

(i.e., American Nurses' Association, Centers for Disease Control and Prevention (CDC)) and the hospice's own policies and procedures.

Any deficiency cited as a violation of accepted standards and principles must have a copy of the applicable standard 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.

If a hospice has developed or adopted professional practice standards and principles for its staff, there should be information available which demonstrates that the hospice monitors its staff for compliance with these standards and principles, and takes corrective action as needed.

The regulations do not impose specific standards of practice. Do not impose your own preferred standards of practice.

Probes §418.50(b)(3)

How does the hospice ensure that its employees and personnel serving the hospice under arrangement or contract provide services to patients that are within the context of accepted professional standards of practice and that, in fact, meet patient needs?

L106

§418.50(c) Standard: Disclosure of Information

The hospice must meet the disclosure of information requirements at [§420.206](#) of this chapter.

Guidelines §418.50(c)

This requirement refers to the disclosure of financial interest and business ownership. The State agency should have the necessary information in its files to determine compliance with this requirement. Review this information in the State files prior to the survey and compare it with the data obtained during the onsite visit.

L107

§418.52 Condition of Participation: Governing Body

L108

A hospice must have a governing body that assumes full legal responsibility for determining, implementing and monitoring policies governing the hospice's total operation.

L109

The governing body must designate an individual who is responsible for the day to day management of the hospice program.

L110

The governing body must also ensure that all services provided are consistent with accepted standards of practice.

Guidelines §418.52

The designated governing body, individual, group, or corporation must have the ultimate responsibility and authority specified in writing for setting and monitoring hospice policies.

Probe §418.52

What evidence is there that the governing body's records reflect direct involvement in hospice policy development and oversight?

L111

§418.54 Condition of Participation: Medical Director

L112

The medical director must be a hospice employee

L113

who is a doctor of medicine or osteopathy

L114

who assumes overall responsibility for the medical component of the hospice's patient care program.

Guidelines §418.54

The BBA 1997 amended section [1861\(dd\)\(2\)\(B\)\(I\)](#) of the Social Security Act to allow a hospice to contract for a physician to be the medical director of the hospice. Although the hospice CoP have not been revised to reflect the changes, a hospice should not be cited for a deficiency at 42 CFR 418.54 for surveys performed August 5, 1997, or later, solely because the hospice's medical director is under contract to the hospice rather than an employee of the hospice.

The medical director may be employed full-time or part-time by the hospice, although he/she need not be a paid employee. If the medical director is not a paid employee, he/she is considered a volunteer under the control of the hospice. Volunteers are defined at [42 CFR 418.3](#) as hospice employees to facilitate compliance with the hospice core services requirement.

For Medicare certification purposes, an individual is considered a hospice employee only in the following circumstances:

- The individual is a volunteer under the jurisdiction of the hospice;
- The individual is an employee of the hospice, as the term employee is defined by [§210\(j\)](#) of the Act. In such a case, the hospice is responsible for paying the individual directly for services performed either through a salary or on an hourly or per visit basis, **and** the hospice is required to issue a form W-2 on his/her behalf; or
- The individual is an appropriately trained employee of the agency or organization of which the hospice is a sub-division and the individual is assigned to the hospice unit. If the individual divides work time between the parent organization and the hospice, the hospice must maintain a record of the individual's assigned time to the hospice which is distinctly identifiable as hospice time.

Volunteers are defined at [42 CFR 418.3](#) as hospice employees to facilitate compliance with the hospice core services requirement.

The medical director may also be the physician representative of the interdisciplinary group (IDG) and/or an attending physician. Responsibilities of the medical director or physician member of the hospice IDG include, but are not limited to:

- Certifying (in conjunction with the attending physician if applicable) that the patient is terminally ill. Terminally ill is defined by the statute to mean that the medical prognosis of life expectancy is 6 months or less if the terminal illness runs its normal course; and
- Recertifying eligibility for hospice care for subsequent election periods. All certifications of terminal illness must be written, even if a single election continues in effect for two or three periods.

L115

§418.56 Condition of Participation: Professional Management

Subject to the conditions of participation pertaining to services in [§§418.80](#) and [418.90](#), a hospice may arrange for another individual or entity to furnish services to the hospice's patients. If services are provided under arrangement, the hospice must meet the following standards:

Guidelines §418.56

When an individual elects to receive services under the hospice benefit, the hospice assumes full responsibility for the professional management of the hospice patient's care related to the terminal illness. It is the responsibility of the hospice to ensure that all services are provided in accordance with the plan of care at all times and in all settings.

L116

§418.56(a) Standard: Continuity of Care

The hospice program assures the continuity of patient/family care in home, outpatient, and inpatient settings.

Probes §418.56(a)

What evidence exists in the clinical record or other documentation that indicates that there is adequate ongoing communication between the hospice and a contract provider?

How does the hospice ensure that the plan of care is being followed in all settings?

§418.56(b) Standard: Written Agreement

L117

The hospice has a legally binding written agreement for the provision of arranged services.

L118

The agreement includes at least the following:

(1) Identification of the services to be provided.

Probes §418.56(b)

How does the hospice monitor and exercise control over services provided by personnel under arrangements or contracts?

How and when does communication occur between the hospice and contracted facilities?

What evidence is there that all services provided by the contract facility are authorized by the hospice?

L119

(2) A stipulation that services may be provided only with the express authorization of the hospice.

L120

(3) The manner in which the contracted services are coordinated, supervised, and evaluated by the hospice.

L121

(4) The delineation of the role(s) of the hospice and the contractor in the admission process, patient/family assessment, and the interdisciplinary group care conferences.

L122

(5) Requirements for documenting that services are furnished in accordance with the agreement.

L123

§418.56(b)(6) The qualifications of the personnel providing the services.

L124

§418.56(c) Standard: Professional Management Responsibility

The hospice retains professional management responsibility for those services and ensures that they are furnished in a safe and effective manner by persons meeting the qualifications of this part, and in accordance with the patient's plan of care and the other requirements of this part.

Guidelines §418.56(c)

It is the responsibility of the IDG to provide information concerning the care of the hospice patient, to monitor this care, and to ensure that all care rendered follows the hospice plan of care.

Probe §418.56(c)

What evidence is there that the hospice maintains professional management responsibility for all care, including inpatient care, rendered to the patient?

What evidence is there that the hospice maintains and documents communication between the contract provider and hospice staff?

L125

§418.56(d) Standard: Financial Responsibility

The hospice retains responsibility for payment for services.

Guidelines §418.56(d)

The condition of participation at 42 CFR 418.56 requires the hospice to maintain professional management responsibility for the services it provides under arrangement.

The standard at 42 CFR 418.56(d), requires the hospice to retain responsibility for payment for those services. 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 which another insurer is obligated to pay.

§418.56(e) Standard: Inpatient Care

L126

The hospice ensures that inpatient care is furnished only in a facility which meets the requirements in [§418.98](#) and its arrangement for inpatient care is described in a legally binding written agreement that meets the requirements of paragraph (b) and that also specifies at a minimum--

L127

(1) That the hospice furnishes to the inpatient provider a copy of the patient's plan of care and specifies the inpatient services to be furnished;

L128

(2) That the inpatient provider has established policies consistent with those of the hospice and agrees to abide by the patient care protocols established by the hospice for its patients;

L129

(3) That the medical record includes a record of all inpatient services and events and that a copy of the discharge summary and, if requested, a copy of the medical record are provided to the hospice;

L130

**(4) The party responsible for the implementation of the provisions of the agreement;
and**

L131

(5) That the hospice retains responsibility for appropriate hospice care training of the personnel who provide the care under the agreement.

Guidelines §418.56(e)

Short-term inpatient care may be provided in a Medicare participating hospice inpatient unit, or in a Medicare participating hospital, SNF, or NF that meets the special hospice standards regarding staffing and patient areas. (See [§418.100\(a\)](#) and [\(e\)](#).) The Medicare conditions for each of these providers of service apply, as conditions always do, to all patients regardless of payment source, unless a specific exception is provided in the regulations. It is the responsibility of the hospice to establish a cooperative arrangement with the provider of inpatient care to assure that the patient's plan of care can be developed, with the consent of the patient, in a manner that is consistent with the requirements governing both the hospice and the inpatient provider.

There is no limit on the number of hospitals or facilities that a hospice may have agreements with to provide inpatient care. Services provided in an inpatient setting must conform to the hospice patient's written plan of care and must be reasonable and necessary for the palliation of symptoms or management of the terminal illness. General inpatient care may be required to adjust and monitor the patient's pain control or manage acute or chronic symptoms which cannot be provided in another setting. Inpatient admission may also be furnished to provide respite for the individual's family or other persons caring for the individual at home. Respite care is the only type of inpatient care that may be furnished in a NF. However, in order to provide respite care, the NF must meet the standards specified in [§§418.100\(a\)](#) and [\(e\)](#) regarding 24 hour nursing service and patient areas. The hospice is accountable for all hospice services provided under arrangement at the above facilities.

If a hospice is hospital-based, it is not necessary for the hospice to develop a formal contract with the parent hospital for the provision of inpatient care. However, a hospital-based hospice should document, either in its bylaws or in other official documents, that the hospital will be used to furnish inpatient services to hospice patients.

The adequacy of the hospice care training of personnel who provide care under arrangement is measured by the demonstrated competencies of the staff in implementing the plan of care.

Although Medicare regulations do not require a hospice to maintain documentation in the clinical record of the inpatient facility with which it has a contract, the hospice must ensure that the care provided in the inpatient setting is in accordance with the hospice philosophy.

Probes §418.56(e)

How does the hospice monitor the inpatient provider for conformance with the established plan of care?

How does the hospice ensure that a member of the IDG is available to the inpatient staff for consultation concerning implementation of the patient's plan of care?

L132

§418.58 Condition of Participation: Plan of Care

L133

A written plan of care must be established and maintained for each individual admitted to a hospice program, and the care provided to an individual must be in accordance with the plan.

Guidelines §418.58

Standardized plans of care are not acceptable unless each plan is individualized to meet the specific needs of the patient and caregiver. Plans of care must be established according to §418.58(a).

L134

§418.58(a) Standard: Establishment of Plan

The plan must be established by the attending physician, the medical director or physician designee and interdisciplinary group prior to providing care.

Guideline §418.58(a)

The physician designee must be a physician and may be the physician member of the IDG.

Probe §418.58(a)

How does coordination of care occur among staff providing services to the patient?

L135**§418.58 (b) Standard: Review of Plan**

The plan must be reviewed and updated, at intervals specified in the plan, by the attending physician, the medical director or physician designee and interdisciplinary group. These reviews must be documented.

Probes §418.58(b)

How does the hospice ensure that the plan of care is revised and updated, as needed, when the patient's condition changes?

§418.58(c) Standard: Content of Plan

L136

The plan must include an assessment of the individual's needs and identification of services including the management of discomfort and symptom relief.

L137

It must state in detail the scope and frequency of services needed to meet the patient's and family's needs.

Guidelines §418.58(c)

Hospice care focuses on palliative care rather than curative care. The goal of the plan of care is to help the patient live as comfortably as possible, with emphasis on eliminating or decreasing pain and/or other uncomfortable symptoms.

Probes §418.58(c)

What criteria does the hospice use to assess the needs of the patient and caregiver?

Who is involved in this process?

How does the IDG decide what services the patient will receive?

How does the hospice evaluate if the services provided are continuing to meet the patients' and caregivers' needs?

Is there any indication that the patient needs hospice services that he/she is not receiving?

How does the hospice monitor the delivery of services, including those provided under arrangement or contract, to ensure compliance with the hospice philosophy?

L138

§418.60 Condition of Participation: Continuation of Care

A hospice may not discontinue or diminish care provided to a Medicare beneficiary because of the beneficiary's inability to pay for that care.

Guidelines §418.60

This condition applies to Medicare beneficiaries only

L139

§418.62 Condition of Participation: Informed Consent

A hospice must demonstrate respect for an individual's rights by ensuring that an informed consent form that specifies the type of care and services that may be provided as hospice care during the course of the illness has been obtained for every individual, either from the individual or representative as defined in [§418.3](#).

Guidelines §418.62

Informed consent implies that the consenting individual is competent to evaluate the decision requiring consent (i.e., is able to evaluate the implications of choosing to receive hospice care.) The patient, or representative, must sign or mark the consent form. The representative must be permitted by State law to elect or revoke hospice care or terminate medical care on behalf of a terminally ill individual. With respect to an individual granted the power of attorney for the patient, State law determines the extent to which the individual may act on the patient's behalf.

Hospice admission criteria should clearly define primary caregiver requirements or decision-making policies related to patients without caregivers. If the hospice requires a primary caregiver for each patient, the policy must be specified in writing in the admission criteria and discussed with the patient and family/caregiver during the initial assessment.

Probes §418.62

How does the hospice communicate to the family/caregiver the role that it expects them to play in providing care to the patient?

What evidence of informed consent related to care and services is documented in the patient's chart?

What documentation indicates that the hospice advised the patient of all the services available to the patient?

L140

§418.64 Condition of Participation: Inservice Training

A hospice must provide an ongoing program for the training of its employees.

Guidelines §418.64

The adequacy of the inservice training program is measured in the demonstrated competencies of the hospice staff in consistently applying the interventions necessary to meet the needs of the patient/caregiver.

The training may be done directly by the hospice or by other relevant outside organizations.

Probes §418.64

What evidence demonstrates that the hospice has developed a system to disseminate its policies, procedures, and training materials to all its staff?

What evidence is there that all employees have been properly oriented to the tasks they are expected to perform, that they are kept informed of the latest changes in techniques, philosophies, pharmaceuticals, etc., and that they demonstrate these skills, when needed, in practice?

How does the hospice ensure that staff can demonstrate the skills and techniques needed to do their jobs?

L141**§418.66 Condition of Participation: Quality Assurance**

L142

A hospice must conduct an ongoing, comprehensive, integrated, self-assessment of the quality and appropriateness of care provided, including inpatient care, home care and care provided under arrangements. The findings are used by the hospice to correct identified problems and to revise hospice policies if necessary.

Guidelines §418.66

This self-assessment should include all services that were provided, and the patients' and caregivers' response to those services. It should also include those services that might have been provided but were omitted. Special attention should be given to the ability of the hospice to deal with symptom management, pain control, stress management, continuity of care, and inpatient care. Suggestions for improving care and any problems identified in providing hospice care should receive the appropriate consideration from the hospice management or governing body.

Probes §418.66

What type of system does the hospice use to monitor and evaluate the care and services it provides to its patients and their caregivers/families?

How does the hospice receive, record, investigate and resolve patient grievances or complaints?

Who has the overall responsibility for the development and implementation of the quality assurance program?

How do the medical director and IDG implement procedures to monitor quality which include at least the following:

- Problem identification, assessment, correction, monitoring and documentation;
- Policy implementation evaluations and monitoring of staff performance;
- Recommendations to the administrator and governing body for improving patient care; and
- Implementation of recommendations resulting from evaluations and studies?

L143

§418.66 Those responsible for the quality assurance program must--

- (a) **Implement and report on activities and mechanisms for monitoring the quality of patient care;**

L144

- (b) **Identify and resolve problems; and**

L145

- (c) **Make suggestions for improving patient care.**

L146

§418.68 Condition of Participation: Interdisciplinary Group

L147

The hospice must designate an interdisciplinary group or groups composed of individuals who provide or supervise the care and services offered by the hospice.

Guidelines §418.68

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 unit. All IDG members have the same responsibilities regardless of whether they are employed directly, assigned, or volunteer employees of the hospice. An employee is one who meets the common law definition of employee as found in title II of the Social Security Act, or one who is a volunteer under the control of the hospice. (See [§418.3](#), Definitions.)

The hospice may involve other members of the care team in the IDG's activities. A hospice with more than one IDG group must designate a specific group to establish policies governing care and services.

The IDG should conduct an ongoing assessment of each patient's and caregiver's or family's needs.

“Supervision” of care may be accomplished by conferences, evaluations, discussions and general oversight, as well as by direct over-the-shoulder observations.

Probe §418.68

How does the hospice ensure that all individuals on the IDG have been trained and are competent to perform in the area(s) assigned?

§418.68(a) Standard: Composition of Group

L148

The hospice must have an interdisciplinary group or groups that include at least the following individuals who are employees of the hospice:

L149

(1) A doctor of medicine or osteopathy.

L150

(2) A registered nurse

L151

(3) A social worker.

L152

(4) A pastoral or other counselor.

Guidelines §418.68(a)

The number of individuals on the IDG is not as important as their qualifications and abilities. For example, if a group member 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.

Probes §418.68(a)

Who are the members of the IDG?

How are their responsibilities to provide or supervise patient care and services implemented?

How do the members of the IDG document the supervision of staff providing services under the plan of care?

§418.68(b) Standard: Role of Group

L153

The interdisciplinary group is responsible for--

(1) Participation in the establishment of the plan of care;

L154

(2) Provision or supervision of hospice care and services;

L155

(3) Periodic review and updating of the plan of care for each individual receiving hospice care; and

Guidelines §418.68(b)

As required by [§418.58\(a\)](#), the IDG participates in establishing the plan of care for each patient prior to providing care. This plan is reviewed regularly and revised as needed. The plan should note each contributor as well as those persons assigned to provide the care.

Probes §418.68(b)

What is the IDG's policy related to:

- Developing and revising patient care objectives;
- Facilitating exchange of information among staff and patient/caregiver; and
- Developing a mechanism whereby a continual flow of information regarding patients' and their caregivers'/families' needs is made available to the IDG staff?

L156

(4) Establishment of policies governing the day-to-day provision of hospice care and services.

L157

§418.68(c) If a hospice has more than one interdisciplinary group, it must designate in advance the group it chooses to execute the functions described in paragraph (b)(4) of this section.

L158

§418.68(d) Standard: Coordinator

The hospice must designate a registered nurse to coordinate the implementation of the plan of care for each patient.

Guidelines §418.68(d)

What evidence exists in the clinical record that a designated registered nurse coordinates the implementation of the patient's plan of care?

L159

§418.70 Condition of Participation: Volunteers

L160

§418.70 The hospice in accordance with the numerical standards specified in paragraph (e) of this section, uses volunteers, in defined roles, under the supervision of a designed hospice employee.

Guidelines §418.70

Volunteers are defined at [§418.3](#) as hospice employees to facilitate compliance with the core services requirement.

L161

§418.70(a) Standard: Training

The hospice must provide appropriate orientation and training that is consistent with acceptable standards of hospice practice.

Guidelines §418.70 (a)

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

Probes §418.70(a)

What evidence is there that the volunteers are aware of:

- Their duties and responsibilities;
- The persons to whom they report;
- The person(s) to contact if they need assistance and instructions regarding the performance of their 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; and
- Guidance related specifically to individual responsibilities?

How does the hospice supervise the volunteers?

Is there evidence that all the volunteers have received training or orientation before being assigned to a patient/family?

L162**§418.70(b) Standard: Role**

Volunteers must be used in administrative or direct patient care roles.

Guidelines §418.70(b)

Volunteers who are qualified to provide professional services should meet all standards 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.

Probes §418.70(b)

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

What evidence is there documenting the roles assigned to that hospices' volunteers?

L163**§418.70(c) Standard: Recruiting and Retaining**

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

Guidelines §418.70(c)

This documentation could include evidence such as advertisements in local newspapers, bulletins, flyers, or medic announcements.

§418.70(d) Standard: Cost Saving

L164

The hospice must document the cost savings achieved through the use of volunteers.

L165

Documentation must include--

(1) The identification of necessary positions which are occupied by volunteers;

L166

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

L167

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

Guidelines §418.70(d)

It is anticipated that the hospice will use volunteers to supplement the care being provided by the paid staff who work directly with patients and their family members, both in the patients' home and the inpatient setting.

The cost savings achieved through the use of hospice volunteers is computed from the time that the hospice's volunteers spend in administrative support or direct patient care activities. Administrative support means support of the patient care activities of the hospice (e.g., clerical duties in the offices of the hospice) and not more general support activities (e.g., participation in hospice fund raising activities.) The time volunteers spend attending education/support meetings would not be included in computing the cost savings.

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

§418.70(e) Standard: Level of Activity

L168

A hospice must document and maintain a volunteer staff sufficient to provide administrative or direct patient care in an amount that, at a minimum, equals 5 percent of the total patient care hours of all paid hospice employees and contract staff.

Guidelines §418.70(e)

In computing the level of activity that the hospice spends in administrative or direct patient care, the hospice may include the time spent orienting volunteers to a specific patient's care in the home, e.g., teaching infection control procedures during an introductory visit or demonstrating comfort measures for the patient in his/her home. They can also count the time that they are training a volunteer to do a particular administrative task (clerical duties in the office.) But in computing the level of activity, the hospice should not count the hours that they spend in the general orientation and training about hospice philosophy, employee issues, or education support meetings.

L169

The hospice must document a continuing level of volunteer activity.

L170

Expansion of care and services achieved through the use of volunteers including the types of services and the time worked, must be recorded.

Guidelines §418.70(e)

Administrative support in this context means support of the patient care activities of the hospice (i.e., clerical duties in the office) rather than general support activities (i.e., fund raising).

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

L171

§418.70(f) Standard: Availability of Clergy

The hospice must make reasonable efforts to arrange for visits of clergy and other members of religious organizations in the community to patients who request such visits and must advise patients of this opportunity.

Probes §418.70(f)

What relationship does the hospice have with the clergy in the community?

How does the hospice ensure that all patients are at least offered the services of clergy?

L172**§418.72 Condition of Participation: Licensure**

The hospice and all hospice employees must be licensed in accordance with applicable Federal, State and local laws and regulations

Guidelines §418.72

All professional and State licenses must be available upon request. Notify the regional office (RO) if you observe non-compliance with the laws of other Federal agencies relating to the hospice program. The RO will notify the Federal agency of the observations.

Probe §418.72

How does the hospice assure that all professional employees and personnel have current licenses and/or registration?

L173**§418.72(a) Standard: Licensure of Program**

If State or local law provides for licensing of hospices, the hospice must be licensed.

Guidelines §418.72(a)

Be aware of all State and local laws covering the licensure of hospices. In order for §418.72 to be determined NOT MET, the State or local agency must have completed action to revoke the hospice's license or the hospice must have failed to apply for a license. If a State or local agency has a licensure law, but does not revoke the hospice's license when the requirements are not met, the hospice will be considered to be in conformance with State and local laws until such time as the State license is revoked

L174**§418.72(b) Standard: Licensure of Employees**

Employees who provide services must be licensed, certified or registered in accordance with applicable Federal or State laws.

Guidelines §418.72(b)

The hospice must have a procedure for verifying the validity of a hospice employee's license or registration. Professional and paraprofessional volunteers must meet all necessary standards, registration and licensure requirements associated with their specialty area(s) the same as if they were salaried employees.

L175

§418.74 Condition of Participation: Central Clinical Records

L176

In accordance with accepted principles of practice, the hospice must establish and maintain a clinical record for every individual receiving care and services. The record must be complete, promptly and accurately documented, readily accessible and systematically organized to facilitate retrieval.

Guidelines §418.74

The clinical record must contain sufficient information to show that the hospice is aware of the current status of the patient/caregiver, accurate documentation of the care/services provided to the patient/caregiver and the results of the care provided.

A hospice which has created the option for an individual's record to be maintained electronically, rather than in hard copy, may use electronic signatures as long as there is a process for reconstruction of the information, and there are safeguards to prevent unauthorized access to the records. The following guidelines must be in place and operational before such a system would be acceptable:

- The hospice has a written policy describing the authentication policy(ies) in force at the facility;
- The computer has built-in safeguards to minimize the possibility of fraud;
- Each person responsible for an entry has an individualized identifier;
- The hospice has the responsibility to demonstrate that the identifier is used under safeguards to assure that no one but the person assigned the code uses the code.
- A secret password known only to the user is to be employed to maintain confidentiality.

- The date and time is recorded from the computer's internal clock at the time of entry;
- An entry is not to be changed after it has been recorded;
- The computer program controls what sections/areas any individual can access or enter data, based on the individual's personal identifier (and, therefore, his/her level of professional qualifications).

A hospice is not precluded by the statute or regulations from providing services at locations other than the site to which a provider number has been assigned. However, all hospice patients' clinical records must be available to the surveyor at the time of the survey. If you have concerns about the provision of services at any outlying hospice location, home visits should be made to beneficiaries receiving services from those locations.

Probe §418.74

How does the hospice ensure that the records of all patients, including those who live in outlying areas, are accurately documented, readily accessible, and systematically organized?

§418.74(a) Standard: Content

L177

Each clinical record is a comprehensive compilation of information.

L178

Entries are made for all services provided.

L179

Entries are made and signed by the person providing the services. The record includes all services whether furnished directly or under arrangements made by the hospice.

L180

§418.74(a) Each individual's record contains--

(1) The initial and subsequent assessments;

L181

(2) The plan of care;

L182

(3) Identification data;

L183

(4) Consent and authorization and election forms;

L184

(5) Pertinent medical history; and

L185

(6) Complete documentation of all services and events (including evaluations, treatments, progress notes, etc.).

Guidelines §418.74(a)

The use of initials is acceptable provided the record identifies the initials with the signer's signature and title. Entries are made for care, services, observations, and assessments, and are signed by the person who provided the care, service, observations, and assessment. Signed physician orders which have been sent to the hospice by facsimile (FAX) machines are acceptable. However, the hospice is responsible for obtaining original signatures if an issue surfaces that would require verification of an original signature.

A hospice may store clinical and health insurance records on microfilm or optical disk imaging systems. All material must be available for review by CMS, the intermediary, DHHS audit, or other specially designated components for bill review, audit, or other examination during the retention period.

All clinical records, along with any necessary equipment to read them, must be made available during the survey.

Probes §418.74(a)

How does coordination of services among the various staff members occur?

What documentation is there that indicates that the physician's orders in the plan of care are being implemented both in the home and the inpatient setting?

L186

§418.74(b) Standard: Protection of Information

The hospice must safeguard the clinical record against loss, destruction and unauthorized use.

Probes §418.74(b)

How are the clinical records stored to protect them from physical destruction and unauthorized use?

What written policies and procedures govern the use, removal and release of clinical records?

What measures does the hospice use to protect the patient's confidentiality?

L187

§418.80 Condition of Participation: Furnishing of Core Services

L188

Except as permitted in [§418.83](#), a hospice must ensure that substantially all the core services described in this subpart are routinely provided directly by hospice employees.

L189

A hospice may use contracted staff if necessary to supplement hospice employees in order to meet the needs of patients during periods of peak patient loads or under extraordinary circumstances. If contracting is used, the hospice must maintain professional, financial, and administrative responsibility for the services and must assure

that the qualifications of staff and services provided meet the requirements specified in this subpart. (§§418.80 - 418.88)

Guidelines §418.80

For certification purposes, an individual is considered an employee of the hospice if the hospice pays the individual directly for services performed on an hourly or per visit basis and the hospice is required to issue a form W-2 on his/her behalf. 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.

A hospice employee may also be an appropriately trained employee of the agency of which the hospice is a sub-division if the individual divides work time between the parent organization and the hospice. However, the hospice must maintain a record of the individual's assigned time which is distinctly identifiable as hospice time.

An individual is also considered a hospice employee if the individual is a volunteer under the jurisdiction of the hospice. See [§418.3](#).

The hospice must maintain coordination of all staff to ensure continuity of care.

Probes §418.80

What evidence is there that the core staff employed by the hospice is able to provide all needed services to hospice patients, including continuous home care, on an ongoing, routine basis?

How does the hospice ensure that the services provided are consistent with the established plan of care?

What evidence is there that the hospice provides training in hospice philosophy and care to contract providers?

L190

§418.82 Condition of Participation: Nursing Services

L191

The hospice must provide nursing care and services by or under the supervision of a registered nurse.

L192

(a) Nursing services must be directed and staffed to assure that the nursing needs of patients are met.

L193

(b) Patient care responsibilities of nursing personnel must be specified.

L194

(c) Services must be provided in accordance with recognized standards of practice.

Guidelines §418.82

This individual may also be a member of the IDG and may be a coordinator. Supervision should include clinical record review, written and/or verbal instructions, plan of care review, and observations in the clinical area.

For guidelines on services provided in accordance with recognized standards of practice, see [§418.50\(b\)\(3\)](#).

Probe §418.82

What evidence is there that nursing services are provided based on a nursing assessment and in accordance with the plan of care?

§418.83 Nursing Services-Waiver of Requirement That Substantially All Nursing Services Be Routinely Provided Directly by a Hospice

§418.83(a) CMS may approve a waiver of the requirement in [§418.80](#) for nursing services provided by a hospice which 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 that it was operational on or before January 1, 1983, and that it made a good faith effort to hire a sufficient number of nurses to provide services directly. CMS bases its decision as to whether to approve a waiver application on the following:

(1) The current Bureau of the Census designations for determining non-urbanized areas.

Guidelines §418.83

If a hospice claims to have a waiver, there must be written evidence from CMS to that effect. If there is any question concerning a waiver, contact the RO.

(2) Evidence that a hospice was operational on or before January 1, 1983 including:

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

(3) Evidence that a hospice made a good faith effort to hire nurses, including:

- (i) Copies of advertisements in local newspapers that demonstrate recruitment efforts;**
- (ii) Job descriptions for nurse employees;**
- (iii) Evidence that salary and benefits are competitive for the area; and**
- (iv) Evidence of any other recruiting activities (e.g., recruiting efforts at health fairs and contacts with nurses at other providers in the area);**

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

§418.83(c) Waivers will remain effective for one year at a time.

§418.83(d) CMS may approve a maximum of two one-year extensions for each initial waiver. If a hospice wishes to receive a one-year extension, the hospice must submit a certification to CMS, prior to the expiration of the waiver period, that the employment market for nurses has not changed significantly since the time the initial waiver was granted.

L195

§418.84 Condition of Participation: Medical Social Services

Medical social services must be provided by a qualified social worker, under the direction of a physician.

Guidelines §418.84

A social worker is defined at [§418.3](#) as a person who has at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education.

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.

Probe §418.84

What evidence is there that each patient/family has received an assessment of their psychosocial needs and that the plan of care has identified ways to meet the needs identified in this assessment as required by [§418.58\(c\)](#)?

L196

§418.86 Condition of Participation: Physician Services

In addition to palliation and management of terminal illness and related conditions, physician employees of the hospice, including the physician member(s) of the interdisciplinary group, must also meet the general medical needs of the patients to the extent that these needs are not met by the attending physician.

Guidelines §418.86

The attending physician is the physician identified by the patient, at the time he/she elects to receive hospice care, as the one who is primarily responsible for the individual's medical care. (See [§418.3](#).)

Oversight of physician services in the hospice is generally considered to be the responsibility of the medical director. The medical director should complement the attending physician's care, act as a medical resource to IDG members, and assure overall continuity of the hospice program's medical services. These services, to meet general medical needs, must be provided by the hospice to the extent that they are not met by

others. The most important aspect of physician services is that the individual receives appropriate measures to control uncomfortable symptoms.

The BBA amended section [1861\(dd\)\(2\)\(B\)\(I\)](#) of the Social Security Act to allow a hospice to contract for a physician to be a member of the hospice's interdisciplinary group effective August 5, 1997. Although the hospice CoP have not been revised to reflect the changes, a hospice should not be cited for a deficiency at 42 CFR 418.86 for surveys performed August 5, 1997, or later, solely because the physician member of the IDG is under contract to the hospice rather than an employee of the hospice .

Probes §418.86

How does the hospice assure that each physician maintains a current license in the State in which the physician is practicing?

What evidence is there in the clinical record of physician involvement with the patient and the IDG?

What system is in place to ensure that any necessary medical orders are signed by a physician? Signed physician's orders that are faxed are acceptable. See guidelines at [§418.74\(a\)](#).

L197

§418.88 Condition of Participation: Counseling Services

L198

Counseling services must be available to both the individual and the family. Counseling includes bereavement counseling, provided after the patient's death, as well as dietary, spiritual and any other counseling services for the individual and family provided while the individual is enrolled in the hospice.

Guidelines §418.88

Counseling services are core services and must routinely be provided directly by hospice employees. (See [§418.80](#).) A hospice may use contracted staff for core services only under extraordinary circumstances, similar to when nursing services are provided to supplement hospice employees in order to meet patients' needs during periods of peak patient loads. If contracting is used, the hospice must continue to maintain professional, financial, and administrative responsibility for the services. If the hospice provides all of its overall counseling services directly through hospice employees, it could, in a specific situation, provide a particular counseling service entirely through a contract with an individual who is not a hospice employee or a separate entity such as a hospital. In this

situation, the hospice must document in detail the extraordinary circumstances which warrant the use of contracted staff to provide core services.

L199

§418.88(a) Standard: Bereavement Counseling

There must be an organized program for the provision of bereavement services under the supervision of a qualified professional.

L200

The plan of care for these services should reflect family needs, as well as a clear delineation of services to be provided and the frequency of service delivery (up to one year following the death of the patient). A special coverage provision for bereavement counseling is specified [§418.204\(c\)](#).

Guidelines §418.88(a)

Bereavement counseling is provided based on an assessment of the family/caregiver's needs, the presence of any risk factors associated with the patient's death, and the ability of the family/caregiver to cope with grief. (See [§418.3](#).)

The supervisor of bereavement services may be the IDG social worker or other professional with documented evidence of training and experience in dealing with grief.

Documentation for bereavement counseling does not necessarily have to be contained in the clinical record, but must be maintained by the hospice in some form in an organized, easily retrievable manner.

Probes §418.88(a)

How does the hospice ensure that each patient/caregiver is assessed for the need for bereavement counseling?

How does the hospice counsel those individuals who are at risk for pathological grief?

L201

§418.88(b) Standard: Dietary Counseling

Dietary counseling, when required, must be provided by a qualified individual.

Guidelines §418.88(b)

Dietary counseling must be available to the caregiver/family and patient, but must relate to the patient's needs rather than the personal needs of the caregiver/family. Dietary counseling may be provided to family members to enable them to prepare food for the patient.

Hospices should provide dietary counseling to hospice patients who experience unmet nutritional needs. This could include patients with dysphagia or other swallowing problems, problematic enteral feedings, unresolved nutritional issues secondary to nausea, vomiting, or the dying process.

Dietary counseling should be planned by a person who has relevant education or training and may include a registered nurse.

CMS is also allowed to waive the requirement that hospices provide dietary counseling directly if certain conditions are present. See guideline at [§418.92](#).

L202

§418.88(c) Standard: Spiritual Counseling

Spiritual counseling must include notice to patients as to the availability of clergy as provided in [§418.70\(f\)](#).

Guidelines §418.88(c)

At a minimum, the hospice should discuss the patient's religious preference, if any, and assist the patient in evaluating his/her spiritual needs.

Probes §418.88(c)

How does the hospice address the spiritual needs/concerns of the patients?

What evidence is there in the clinical record that indicates that assistance has been offered to provide the patient an opportunity for counseling with his/her choice of available clergy?

L203

§418.88(d) Standard: Additional Counseling

Counseling may be provided by other members of the interdisciplinary group as well as by other qualified professionals as determined by the hospice.

Probe §418.88(d)

What evidence is there that the counseling services are provided by persons whose skills and training are appropriate for the counseling provided?

L204

§418.90 Condition of Participation: Furnishing of Other Services

A hospice must ensure that the services described in this subpart are provided directly by hospice employees or under arrangements made by the hospice as specified in [§418.56](#).

Probes §418.90

How does the hospice decide what services at §§418.92-418.98 it will provide under contract and what services it will provide directly?

Is there evidence that the hospice is able to provide patients with all the services described in §§418.92 - 418.98?

L205

§418.92 Condition of Participation: Physical Therapy, Occupational Therapy, and Speech-Language Pathology

Guidelines §418.92

Section [1861\(dd\)\(5\)](#) of the Act was amended by the BBA to allow CMS to permit certain waivers of the requirements that the hospice make physical therapy, occupational therapy, speech language pathology services (42 CFR 418.92) and dietary counseling ([42 CFR 418.88 \(b\)](#)) available (as needed) on a 24-hour basis. CMS is also allowed to waive the requirement that hospices provide dietary counseling directly. The Act stipulates that these waivers are only available to an agency or organization that is located in an area which is not in an urbanized area (as defined by the Bureau of the Census), and

demonstrates to the satisfaction of the Secretary that the agency or organization has been unable, despite diligent efforts, to recruit appropriate personnel. CMS will apply the requirements for the nursing services waiver at [42 CFR 418.83\(a\)\(3\)](#) in determining whether a hospice has made diligent efforts. This includes the requirement that a waiver request will be deemed to be granted unless it is denied by CMS within 60 days after it is received. This change became effective August 5, 1997. Waiver applications should be sent to the CMS regional office.

L206

(a) 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

Probe §418.92

What evidence is there that these services are provided when needed, as determined in the plan of care?

How does the hospice verify that the professionals providing these services are appropriately trained and supervised?

L207

(b)(1) If the hospice engages in laboratory testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the FDA, such testing must be in compliance with all applicable requirements of part 493 of this chapter.

(b)(2) If the hospice chooses to refer specimens for laboratory testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.

Guideline §418.92(b)(1)

Determine if the hospice is providing laboratory testing as set forth at [42 CFR 493](#). If the hospice is performing testing, request to see the 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/>.

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/>.

If the hospice performs any other testing procedures, (i.e., moderate or high complexity testing), it would require a registration certificate, a certificate of accreditation, or a certificate of compliance. 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/>.

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 facility does not possess the appropriate CLIA certificate, inform the facility that it is in violation of CLIA law and that it must apply immediately to the State agency for the appropriate certificate. Also, refer this facility's noncompliance to the department within the State agency responsible for CLIA surveys.

If the hospice refers specimens for laboratory testing to an outside laboratory, the referral laboratory must be CLIA-certified. The hospice should have a copy of the referral laboratory's CLIA certificate in its administrative records.

L208

§418.94 Condition of Participation: Home Health Aide and Homemaker Services

L209

Home health aide and homemaker services must be available and adequate in frequency to meet the needs of the patients. A home health aide is a person who meets the training, attitude and skill requirements specified in [§484.36](#) of this chapter.

Guidelines §418.94

In accordance with [§484.4](#), a home health aide must successfully complete a training and competency evaluation program or a competency evaluation program.

In accordance with [§484.36](#), the aide training program must address each of the following subject areas through classroom and supervised practical training totaling at least 75 hours, with at least 16 hours devoted to supervised practical training. The individual being trained must complete at least 16 hours of classroom training before beginning the supervised practical training. "Supervised practical training" means training in a laboratory or other setting in which the trainee demonstrates knowledge while performing tasks on an individual under the direct supervision of a registered nurse or licensed practical nurse. A "pseudo-patient," not a mannequin may be used for training.

The aide training program and competency evaluation program must address each of the following subject areas. Subject areas preceded by an asterisk (*) must be evaluated after observation of the aide's performance of the tasks with a patient.

- Communication skills.
- Observation, reporting and documentation of patient status, and the care or service furnished;
- Basic infection control procedures;
- Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor;
- Maintenance of a clean, safe, and healthy environment;
- Recognizing emergencies and knowledge of emergency procedures;
- 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;
- Adequate nutrition and fluid intake;
- * Reading and recording temperature, pulse, and respiration;
- * Appropriate and safe techniques in personal hygiene and grooming (including bed bath, sponge, tub, or shower bath, shampoo, sink, tub, or bed, nail and skin care, oral hygiene, toileting and elimination);
- * Safe transfer techniques and ambulation;
- * Normal range of motion and positioning; and
- Any other task that the hospice may choose to have the home health aide perform.

The hospice is responsible for ensuring that home health aides used by the hospice meet the personnel qualifications specified in [§484.4](#) for "home health aide" and maintaining adequate documentation of compliance with the regulation. This includes home health aides trained and evaluated by other organizations, and those hired by the hospice directly, as well as under an arrangement. It is the responsibility of the hospice to ensure that its aides are proficient to carry out their patient care assignments in a safe, effective, and efficient manner.

In accordance with [§484.36](#), home health aides are selected on the basis of such factors as a sympathetic attitude toward the care of the sick, ability to read, write, and carry out directions, and maturity and ability to deal effectively with the demands of the job. They are closely supervised to ensure their competence in providing care.

If aides are providing services under arrangement or contract, how does the hospice ensure that the aides providing patient care have the appropriate competency skills?

Probes §418.94

How does the hospice ensure that home health aides and homemakers are proficient to carry out their assignments in a safe, efficient and effective manner?

How does the hospice monitor the assignments of aides to match the skills needed for individual patients?

L210

§418.94(a) Standard: Supervision

A registered nurse must visit the home site at least every two weeks when aide services are being provided, and the visit must include an assessment of the aide services.

Guidelines §418.94(a)

The supervisory visit to the patient's residence at least every 2 weeks to assess relationships and determine whether goals are being met may occur either when the aide is present so that the RN can observe and assist the aide, or when the aide is absent. Supervisory visits may be made in conjunction with a professional visit to provide services. These visits must be documented and recorded in the patient's clinical record.

Probe §418.94(a)

How does the hospice schedule supervisory visits so that aide services can be evaluated?

L211

§418.94(b) Standard: Duties

Written instructions for patient care are prepared by a registered nurse. Duties include, but may not be limited to, the duties specified in [§484.36\(c\)](#) of this chapter.

Guidelines §418.94(b)

Aide assignments must consider the skills of the aide, the amount and kind of supervision needed, specific nursing or therapy needs of the patient, and the capability of the patient's caregiver/family.

Notes by the aide should be dated and signed.

Probes §418.94(b)

What evidence is there in the clinical record that the aide reports significant patient information to the appropriate person designed to receive this information?

How does the hospice communicate with the aides and make them aware of the specific duties that they are expected to perform?

How does the hospice ensure that the aide adheres to the plan of care?

L212

§418.96 Condition of Participation: Medical Supplies

Probes §418.96

How does the hospice ensure that medical supplies are available on a 24 hour basis when needed?

Is there any indication in the records that a patient has been unable to obtain relief from uncomfortable symptoms due to non-compliance with this regulation?

L213

Medical supplies and appliances including drugs and biologicals, must be provided as needed for the palliation and management of the terminal illness and related conditions.

L214

§418.96(a) Standard: Administration

All drugs and biologicals must be administered in accordance with accepted standards of practice.

L215**§418.96(b) Standard: Controlled Drugs in the Patient's Home**

The hospice must have a policy for the disposal of controlled drugs maintained in the patient's home when those drugs are no longer needed by the patient.

Guidelines §418.96(b)

Controlled drugs are those subject to the Controlled Substance Act of 1970. The hospice need only have a written policy for disposal of controlled drugs maintained **in the patient's home** when they are no longer needed.

The term "drugs that are no longer needed" means those drugs that have been discontinued by the physician or are remaining at the time of death.

Probe §418.96(b)

What evidence is there to indicate that the staff follows the policy of the hospice in this matter?

§418.96(c) Standard: Administration of Drugs and Biologicals

L216

Drugs and biologicals are administered only by the following individuals:

(1) A licensed nurse or physician.

L217

(2) An employee who has completed a State-approved training program in medication administration.

L218

(3) The patient if his or her attending physician has approved.

L219

(4) Any other individual in accordance with applicable State and local laws. The persons, and each drug and biological they are authorized to administer, must be specified in the patient's plan of care.

L220**§418.98 Condition of Participation-Short Term Inpatient Care**

L221

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

Guidelines §418.98

The key to surveying the adequacy of inpatient care services for hospice patients is to examine the actual care provided to the hospice patient in the inpatient facility and see how it relates to the assessment and plan of care developed by the hospice in conjunction with the facility's documented agreement with the hospice with respect to its patients

§418.98(a) Standard: Inpatient Care for Symptom Control

L222

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

- (1) A hospice that meets the condition of participation for providing inpatient care directly as specified in §418.100.**

L223

- (2) A hospital or a SNF that also meets the standards specified in [§418.100\(a\)](#) and [\(e\)](#) regarding 24-hour nursing service and patient areas.**

§418.98(b) Standard: Inpatient Care for Respite Purposes

L224

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

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

L225

(2) An ICF that also meets the standards specified in §418.100(a) and (e) regarding 24-hour nursing service and patient areas.

Guidelines §418.98(b)(2)

The Omnibus Budget Reconciliation Act of 1987 eliminated the SNF/ICF distinction, based on levels of care, and included a SNF/NF distinction, based on source of certification (i.e., Medicare/Medicaid).

L226**§418.98(c) Standard: Inpatient Care Limitation**

The total number of inpatient days used by Medicare beneficiaries who elected hospice coverage in any 12-month period preceding a certification survey in a particular hospice may not exceed 20 percent of the total number of hospice days for this group of beneficiaries.

Guidelines §418.98(c)

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 not on a case-by-case determination.

L227**§418.98(d) Standard: Exemption From Limitation**

Until October 1, 1986, any hospice that began operation before January 1, 1975 is not subject to the limitation specified in paragraph (c).

L301**§418.100 Condition of Participation: Hospices That Provide Inpatient Care Directly**

A hospice that provides inpatient care directly must comply with all of the following standards.

§418.100(a) Standard: Twenty-Four Hour Nursing Services

L302

(1) The facility provides 24-hour nursing services which are sufficient to meet total nursing needs and which are in accordance with the patient plan of care. Each patient receives treatments, medication, and diet as prescribed, and is kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.

L303

(2) Each shift must include a registered nurse who provides direct patient care.

Guidelines §418.100(a)

Twenty-four hour nursing care requires that the hospice have the number and type of personnel sufficient to meet the total needs of the patient. A registered nurse must be on duty in the facility during each shift.

Probes §418.100(a)

How does the hospice determine that there are enough personnel present to assure 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?

How does the hospice ensure that its personnel respond promptly to patient calls?

L304

§418.100(b) Standard: Disaster Preparedness

The hospice has an acceptable written plan, periodically rehearsed with staff, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from such disasters.

Guidelines §418.100(b)

The hospice should tailor its disaster plan to its geographic location and facility residents. The purpose of the periodic rehearsal is to test the efficiency, knowledge, and response of staff personnel in the event of an emergency. Changes in physical plan or changes external to the facility can also cause a review of the disaster plan. The disaster plan should include, but not be limited to the following:

- Assignment of personnel for specific responsibilities;
- Procedures for prompt identification and transfer of patients and records to an appropriate facility;
- Fire and/or other emergency drills, in accordance with the Life Safety Code;
- Procedures covering persons in the facility and in the community in case of external disasters, i.e., hurricanes, tornadoes, earthquakes; and
- Arrangements with community resources in the event of a disaster.

Probes §418.100(b)

Where does the hospice keep its dated, written report and evaluation of each drill?

Are staff able to answer questions about what to do in an emergency i.e., fire in a patient's room?

Is there evidence that drills were held on all shifts as required by the Life Safety Code?

How does the hospice ensure that each staff member is aware of what to do in an emergency?

What does the written emergency procedure plan contain?

What procedure does the hospice follow for notifying people in an emergency, including the physician, if the attending physician is unavailable?

§418.100(c) Standard: Health and Safety Laws

Guidelines §418.100(c)

Compliance with State law does not include a requirement that the freestanding inpatient unit of the hospice be licensed by the State. However, the unit must meet other applicable State laws relevant to health and safety.

L305

The hospice must meet all Federal, State, and local laws, regulations, and codes pertaining to health and safety, such as provisions regulating--

L306

(1) Construction, maintenance, and equipment for the hospice;

L307

(2) Sanitation;

L308

(3) Communicable and reportable diseases; and

L309

(4) Post mortem procedures.

§418.100(d) Standard: Fire Protection

(1) Except as provided in paragraphs (d)(2) and (3) of this section, the hospice must meet the provisions of the 1985 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference) that are applicable 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 the patients.

- (3) Any hospice that, on May 9, 1988, complies with the requirements of the 1981 edition of the Life Safety Code, with or without waivers, will be considered to be in compliance with this standard, as long as the hospice continues to remain in compliance with that edition of the Life Safety Code.**
- (4) Any facility of two or more stores that is not of fire resistive construction and is participating on the basis of a waiver of construction type or height, may not house blind, nonambulatory, or physically handicapped patients above the street-level floor unless the facility-**
 - (i) Is one of the following construction types (as defined in the Life Safety Code):**
 - (A) Type II (1, 1, 1)-protected non-combustible.**
 - (B) Fully Sprinklered Type II (0, 0, 0)-non-combustible.**
 - (C) Fully Sprinklered Type III (2, 1, 1)-protected ordinary.**
 - (D) Fully Sprinklered Type V (1, 1, 1)-protected wood frame; or**
 - (ii) Achieves a passing score on the Fire Safety Evaluation System (FSES).**

Guidelines §418.100(d)

This aspect of the survey should be conducted by a qualified Life Safety Code surveyor using the appropriate fire safety survey report form. Since an inpatient hospice unit must meet the Health Care Occupancy Chapter of the Life Safety Code, it is surveyed the same as hospitals and SNFs. See §§2470 - 2480. Also, see Appendix I.

If you observe fire hazards or possible deficiencies in life safety from fire, notify the designated State fire authority or the RO

§418.100(e) Standard: Patient Areas

L310

- (1) The hospice must design and equip areas for the comfort and privacy of each patient and family members.**

L311

(2) The hospice must have-

(i) Physical space for private patient/family visiting;

L312

(ii) Accommodations for family members to remain with the patient throughout the night;

L313

(iii) Accommodations for family privacy after a patient's death; and

L314

(iv) Decor which is homelike in design and function

L315

(3) Patients must be permitted to receive visitors at any hour, including small children.

Guidelines 410.100(e)(iv)

A homelike decor is one that de-emphasizes the institutional character of the setting to the extent possible, and allows the patient to use those personal belongings that support a homelike environment.

§418.100(f) Standard: Patient Rooms and Toilet Facilities

L316

Patient rooms are designed and equipped for adequate nursing care and the comfort and privacy of patients.

Guidelines §418.100(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 (e.g., a chair), and adequate lighting suitable to the tasks the patient chooses to perform, or the hospice staff must perform.

To ensure privacy in multi-patient rooms, each bed should have flame retardant cubicle curtains, moveable screens, or other acceptable means of providing full privacy.

L317

(1) Each patient's room must--

(i) Be equipped with or conveniently located near toilet and bathing facilities;

Guidelines §418.100(f)(1)(i)

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

L318

(ii) Be at or above grade level;

Guidelines §418.100(f)(1)(ii)

“At or above grade level” means a room in which the floor is at or above ground level.

L320

(iv) Have closet space that provides security and privacy for clothing and personal belongings;

Guidelines §418.100(f)(1)(iv)

Storage space for personal belongings should be accessible to the patient and protected from casual access by others.

L321

(v) Contain no more than four beds;

L322

- (vi) Measure at least 100 square feet for a single patient room or 80 square feet for each patient for a multipatient room; and**

L323

- (vii) Be equipped with a device for calling the staff member on duty.**

Guidelines §418.100(f)(1)(vii):

Call bells or other communication mechanisms must be placed within easy reach of the patient and must be functioning properly.

(2) For an existing building, CMS may waive the space and occupancy requirements of paragraphs (f)(1)(v) and (vi) of this section for as long as it is considered appropriate if it finds that--

- (i) The requirements would result in unreasonable hardship on the hospice if strictly enforced; and**
- (ii) The waiver serves the particular needs of the patients and does not adversely affect their health and safety.**

L324**§418.100(g) Standard: Bathroom Facilities**

The hospice must--

- (1) Provide an adequate supply of hot water at all times for patient use; and**

L325

- (2) Have plumbing fixtures with control valves that automatically regulate the temperature of the hot water used by patients.**

L326**§418.100(h) Standard: Linen**

The hospice has available at all times a quantity of linen essential for proper care and comfort of patients. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

Guidelines §418.100(h)

The linen supply must be adequate to accommodate the number of beds and the number of incontinent patients on a daily basis, including week-ends and holidays. Soiled linen and clothing should be collected and enclosed in suitable bags or containers in well ventilated areas, separate from clean linen and not permitted to accumulate in the facility.

Probes §418.100(h)

What is the hospice's policy on the frequency of linen change?

How does the hospice store the clean linen to keep it clean, dry, and dust-free?

How does the hospice keep soiled linen separate from the ironing, folding, and storage of clean linen?

L327**§418.100(i) Standard: Isolation Areas**

The hospice must make provision for isolating patients with infectious diseases.

Guidelines §418.100(i)

The purpose of the isolation areas is to prevent the spread of infection and protect the patients, staff and visitors from infection. Infection control is a mechanism by which the adherence, colonization, or invasion of an infectious organism is prevented. The hospice should institute the most current recommendations of The Centers for Disease Control and Prevention (CDC) relative to the specific infection(s) and communicable disease(s). The current references on infection control published by the CDC are "Guidelines for Prevention and Control of Nosocomial Infections" and "Guidelines for Preventing the Transmission of Tuberculosis in Health Care Facilities." The hospice provisions for isolating patients with infectious diseases should include:

- Definition of nosocomial infections and communicable diseases;
- Measures for assessing and identifying patients and health care workers (HCWs) at risk for infections and communicable diseases;
- Measures for prevention of infections, especially those associated with immunosuppressed patients and other factors which compromise a patient's resistance to infection;
- Measures for prevention of communicable disease outbreaks, especially tuberculosis;
- Provision of a safe environment consistent with 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 universal precautions;
- Methods for monitoring and evaluating practices of asepsis;
- Care of contaminated laundry, i.e., clearly marked bags and separate handling procedures;
- Care of dishes and utensils, i.e., clearly marked and handled separately;
- Use of any necessary gowns, gloves or masks posted and observed by staff, visitors, and anyone else in contact with the patient; and
- Techniques for handwashing, respiratory protection, asepsis sterilization, disinfection, needle disposal, solid waste disposal, as well as any other means for limiting the spread of contagion;
- Orientation of all new hospice personnel to infections, to communicable diseases and to the infection control program; and
- Employee health policies regarding infectious diseases, and when infected or ill employees must not render direct patient care.

The facility should isolate infected patients **only to the degree needed to isolate the infecting organism**. The method should be the least restrictive possible while maintaining the integrity of the process and the dignity of the patient.

Probes §418.100(i)

What evidence is there that staff members are aware of infection control and measures to prevent cross-contamination, as evidenced by washing their hands and/or changing gloves after performing personal care, when they leave an isolation area, when performing tasks among individuals, and any other time that would provide the opportunity for cross-contamination to occur?

What infection control policies does the hospice use for persons with AIDS or hepatitis B?

How does the hospice define and dispose of infected waste?

How does the hospice control the spread of infection by persons who visit an infected patient?

What system is in place to prevent staff personnel who have been diagnosed with a communicable disease from transmitting this disease to patients/caregivers or other staff?

Is there evidence that universal precautions are being followed?

§418.100(j) Standard: Meal Service, Menu Planning, and Supervision.

L328

The hospice must--

(1) Serve at least three meals or their equivalent each day at regular times, with not more than 14 hours between a substantial evening meal and breakfast

Guidelines §418.100(j)(1)

Professional judgment may dictate that meal service is adjusted to meet variations in individual patients' conditions. This may include offering smaller, more frequent meals, or postponing breakfast or other meals to honor a patient's request (i.e., to sleep).

L329

(2) Procure, store, prepare, distribute, and serve all food under sanitary conditions;

Guidelines §418.100(j)(2)

“Sanitary conditions” means storing, preparing, distributing, and serving food to properly prevent food-borne illness.

Food should be stored at appropriate temperatures. Prevention of food-borne illness focuses on potentially hazardous foods; those subject to continuous time/temperature controls in order to prevent either the rapid and progressive growth of infections or toxigenic microorganisms. Perishable foods which consist of milk or milk products, meat, poultry, fish, or shellfish are maintained at safe temperatures: 45 degrees Fahrenheit or below, or 140 degrees Fahrenheit or above from time of preparation until served to the patient.

Food is covered to prevent contamination during transportation.

Handwashing facilities, including hot and cold water, soap, individual towels (preferably disposable) are provided in the food preparation areas.

Waste, which is not disposed of by mechanical means, is kept in leak-proof, non-absorbent containers with close fitting lids, and is disposed of daily. Nondisposable containers are maintained in sanitary condition. Outside storage of filled disposable bags is not acceptable. Liquid wastes resulting from compacting must be disposed of as sewage.

All sewage, including liquid waste, is properly disposed of by a public sewerage system or by a sewerage disposal system constructed and operated in accordance with State or local law.

L330

- (3) Have a staff member trained or experienced in food management or nutrition who is responsible for--**
- (i) Planning menus that meet the nutritional needs of each patient, following the orders of the patient’s physician and, to the extent medically possible, the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences (Recommended Dietary Allowances (9th ed., 1981) is available from the Printing and Publications Office, National Academy of Sciences, Washington, D.C. 20418); and**

L331

- (ii) Supervising the meal preparation and service to ensure that the menu plan is followed; and**

Guidelines §418.100(j)(3)

If the staff member responsible for dietary services is not a dietitian, it is recommended, but not required, that this person:

- Be a graduate of a dietetic technician or dietetic assistant training program, correspondence or classroom, approved by the American Dietetic Association;
- Be a graduate of a State approved course that provides 90 or more hours of classroom instruction in food service supervision and has experience as a supervisor in a health care institution with consultation from a dietitian; or
- Have training and experience in food service supervision and management in the military service equivalent in content to a dietetic technician or dietetic assistant training program, correspondence or classroom, approved by the American Dietetic Association.

The hospice concept demands more leniency than a 3-meal-a-day schedule. Patients who could benefit from frequent, small, or mechanically-altered meals should be offered them. Meals are palatable and attractively served at the appropriate temperature.

Probes §418.100(j)(3)

How does the hospice plan menus to meet the patients' symptomatic and nutritional needs, or to support the palliative treatment for which patients are there?

What arrangements does the hospice make to serve meals at the proper temperature and in a form to meet the patients' needs?

Who is responsible for recording the patient's response to the diet in the clinical record?

What evidence exists that the dietitian reviews the patient's response to the diet and advises modification if necessary?

L332

- (4) If the hospice has patients who require medically prescribed special diets, have the menus for those patients planned by a professionally qualified dietitian and**

supervise the preparation and serving of meals to ensure that the patient accepts the special diet.

Guidelines §418.100(j)(4)

It is recommended that a professionally qualified dietitian be a person who:

1. Is registered or eligible for registration by the American Dietetic Association; or
2. Has a baccalaureate degree with major studies in food and nutrition, dietetics, or food service management.

§418.100(k) Standard: Pharmaceutical Services

L333

The hospice provides appropriate methods and procedures for the dispensing and administering of drugs and biologicals. Whether drugs and biologicals are obtained from community or institutional pharmacists or stocked by the facility, the facility is responsible for drugs and biologicals for its patients, insofar as they are covered under the program and for ensuring that pharmaceutical services are provided in accordance with accepted professional principles and appropriate Federal, State, and local laws

Guideline §418.100(k)

Drugs and biological ordered by a physician must be made available to the patient insofar as they are covered by the Medicare or Medicaid programs. All drugs and biologicals must be available to meet patients' needs on a 24-hour basis.

L334**(1) Licensed pharmacist.**

The hospice must--

- (i) Employ a licensed pharmacist; or**

L335

- (ii) Have a formal agreement with a licensed pharmacist to advise the hospice on ordering, storage, administration, disposal, and recordkeeping of drugs and biologicals.**

L336**(2) Orders for medications.**

- (i) A physician must order all medication for the patient.**

L337

- (ii) If the medication order is verbal--**

- (A) The physician must give it only to a licensed nurse, pharmacist, or another physician; and**

L338

- (B) The individual receiving the order must record and sign it immediately and have the prescribing physician sign it in a manner consistent with good medical practice.**

Probe §418.100(k)(2)

How does the hospice ensure that there is a valid order for all medications given to the patient?

L339**(3) Administering medications.**

Medications are administered only by one of the following individuals:

(i) A licensed nurse or physician.

L340

(ii) An employee who has completed a State-approved training program in medication administration.

L341

(iii) The patient if his or her attending physician has approved.

Guideline §418.100(k)(3)

To evaluate the accuracy of the drug distribution system, refer to Appendix P. See the Interpretive Guideline for medication error at [§483.25\(m\)](#). If you observe errors, note their frequency and nature, any corrective action taken, and the people notified.

Probe §418.100(k)(3)

What monitoring systems does the hospice use to assure that each patient receives drugs, without medication errors, in a timely manner?

L342**(4) Control and accountability.**

The pharmaceutical services has procedures for control and accountability of all drugs and biologicals throughout the facility. Drugs are dispensed in compliance with Federal and State laws. Records of receipt and disposition of all controlled drugs are maintained in sufficient detail to enable an accurate reconciliation. The pharmacist determines that drug records are in order and that an account of all controlled drugs is maintained and reconciled.

Guideline §418.100(k)(4)

The individual medication record may serve as the record of receipt and disposition of all controlled drugs when the unit dose and individual prescription drug disposition systems

are used. However, if a floor stock system is used, a separate record system will have to be maintained for receipt and disposition of these drugs.

L343

(5) Labeling of drugs and biologicals.

The labeling of drugs and biologicals is based on currently accepted professional principles, and includes the appropriate accessory and cautionary instructions, as well as the expiration date when applicable.

Guideline §418.100(k)(5)

Each patient's individual drug container also contains his/her full name, the prescribing physician's name, and the name, strength and quantity of the drug dispensed. Each floor stock drug container should also bear the name and strength of the drug and the lot and control number.

Each single unit package should bear the name and strength of the drug and the lot and control number, and be clearly identified with the patient's full name and the prescribing physician's name.

Drug containers with illegible, damaged, incomplete or missing labels should be returned to the pharmacist for proper labeling.

L344

(6) Storage.

In accordance with State and Federal laws, all drugs and biologicals are stored in locked compartments under proper temperature controls and only authorized personnel have access to the keys. Separately locked compartments are provided for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention & Control Act of 1970 and other drugs subject to abuse, except under single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected. An emergency medication kit is kept readily available.

Guidelines §418.100(k)(6)

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. No discontinued or outdated or deteriorated drugs and/or biologicals are available for use in the hospice.

“Separately locked” means that the key to the separately locked Schedule II drugs is not the same key that is used to gain access to the non-Schedule II drugs. Drugs brought to the facility by the patient are used only if they have been positively identified with the correct name and strength. They are used only with written orders from the physician.

Probe §418.100(k)(6)

How are all drugs and biologicals stored?

L345

(7) Drug disposal.

Controlled drugs no longer needed by the patient are disposed of in compliance with State requirements. In the absence of State requirements, the pharmacist and a registered nurse dispose of the drugs and prepare a record of the disposal.