Interim Final Interpretive Guidelines
Version 1.1

Big Changes from November 2008 to January 2009

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

L522

§418.54(a) Standard: Initial assessment

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

Interpretive Guidelines §418.54(a)

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

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

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

- Determine through interview, observation and record review if the hospice identified the patient’s immediate needs.
- Did the RN complete the initial assessment within the required timeframes? Clinical record documentation should confirm/support that timeframes are met. Pay particular attention to the effective date/time of the election and the date/time of the completion of the initial assessment.
§418.54(c) Standard: Content of the comprehensive assessment

The comprehensive assessment must identify the physical, psychosocial, emotional, and spiritual needs related to the terminal illness that must be addressed in order to promote the hospice patient’s well-being, comfort, and dignity throughout the dying process.

Interpretive Guidelines §418.54(c)

The assessment would include, but not be limited to, screening for the following: pain, dyspnea, nausea, vomiting, constipation, restlessness, anxiety, sleep disorders, skin integrity, confusion, emotional distress, spiritual needs, support systems, and family need for counseling and education. The hospice would then gather additional information, as necessary, to be able to meet the patient/family needs. For example, in addition to screening the patient for the presence of pain, a comprehensive assessment of the patient’s pain based on accepted clinical standards of practice may necessitate gathering the following information, as applicable to the patient:

§418.58 Condition of participation: Quality assessment and performance improvement

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

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

- The hospice’s aggregated data and its analysis of that data.
- The hospice’s QAPI plan.
- The hospice’s meeting minutes or notes for meetings concerning the development and implementation of the hospice’s QAPI program.
- The individuals responsible for the QAPI program.
- Evidence that the QAPI system has been implemented and is functioning effectively, including evidence of:
Focus on areas such as how and why the hospice chose its quality measures, how it ensures consistent data collection, how it uses data in patient care planning, and how it aggregates and analyzes data. Ask the hospice how it uses the data analysis to select performance improvement projects, how it implements such projects, and how it uses the data to evaluate the effectiveness of those projects.

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

§418.60 Condition of participation: Infection control

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

Interpretive Guidelines §418.60

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

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

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

§418.64 Condition of participation: Core services

§418.64(c) Standard: Medical social services

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Medical social services must be provided by a qualified social worker, under the direction of a physician. Social work services must be based on the patient’s psychosocial assessment and the patient’s and family’s needs and acceptance of these services.

Interpretive Guidelines §418.64(c)

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

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

§418.100(b) Standard: Governing body and administrator

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

Interpretive Guidelines §418.100(b)

If the hospice is part of a larger organization (e.g., HHA, hospital) and the governing body is the same,
there must be documented evidence that the governing body is assuming full authority and responsibility for the management of the hospice and reviews and addresses the functioning of specific hospice operations, services and QAPI program.

If the administrator is not available to fulfill his or her assigned duties and responsibilities, the hospice must identify another individual to assume those assigned duties and responsibilities in accordance with the hospice’s established policies and procedures. The governing body must assume responsibility for ensuring that the hospice is managed by the administrator and any managers that the administrator appoints.

§418.104 Condition of participation: Clinical records

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§418.104(b) Standard: Authentication

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

Interpretive Guidelines§418.104(b)

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

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

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

With regards to maintaining hardcopies of signatures in the patient's clinical record, the hospice would be in compliance with that requirement, so long as the hospice can produce a legible signature for which the authenticity of that signature can be attested to. That is to say that if the hospice has, as part of the patient's clinical record, an electronic copy of a facsimile or hard copy signature, as long as the hospice can produce a hard copy of that signature and the signature is legible and can be authenticated, the hospice has fulfilled the requirement of maintaining facsimile and hardcopies of physician signatures. Similarly, if the hospice has as part of the patient's clinical record, a facsimile, hard copy, copy of a facsimile, or copy of a hard copy signature, as long as the signature is legible and can be authenticated, the hospice has fulfilled the requirement of maintaining facsimile and hardcopies of physician signatures.
Hospices may not accept stamped physician signatures on orders, treatments, or other documents that are a part of the patient's clinical record.

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

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

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

Interpretive Guidelines §418.106(f)(3)

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

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

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

§418.110(o) Standard: Death reporting requirements

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

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

(i) Each unexpected death that occurs while a patient is in restraint or seclusion.
Each unexpected death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

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

(2) Each death referenced in this paragraph must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death.

(3) Staff must document in the patient's clinical record the date and time the death was reported to CMS.

Interpretive Guidelines §418.110(o)

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

Restraint means (1)—(4) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely, not including devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort); or (2) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

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

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• (ii) Communicating with SNF/NFSNFINF or ICF/MRICFIMR representatives and other health care providers participating in the provision of care for the terminal illness and related conditions and other conditions to ensure quality of care for the patient and family.

Procedures and Probes §418.112(e)(1)(ii)-(e)(1)(ii)

If there are problems identified regarding failure to communicate with facility staff, interview the hospice designated IDGIDO member, and the facility care plan coordinator for the patient, in order to determine:

• The system the hospice has in place to ensure continuity of communication and easy access to ongoing information (e.g., documentation in both respective entities).
clinical records.

• How the information from each provider's team conferences get communicated to the individuals participating in caring for the patient.

Determine if there have been any concerns related to the need to change or alter the plan of care; or if a significant change in condition occurred requiring a transfer to an acute care setting, and how and when the facility notified the hospice of the concerns.

In the event that there are concerns related to the coordination and implementation of the patient’s plan of care for pain control and symptom management, interview the facility’s nurse aides who provide direct care to the patient to determine:

• If they are aware of any complaints of pain from the patient or signs and symptoms that could indicate the presence of pain or discomfort.
• To whom they report the patient’s complaints, signs, or symptoms.

• If they are aware of, and implement, interventions for pain/discomfort management for the patient consistent with the patient’s plan of care, (for example, allowing a period of time for a pain medication to take effect before bathing and/or dressing).

Review the plan of care to determine if the plan was coordinated between the hospice and the facility. Determine if symptom management, including pain management interventions, are included, if needed, and addressed as appropriate:

• Measurable pain management goals, reflecting patient needs and preferences.
• Pertinent non-pharmacological and/or pharmacological interventions.
• Time frames and approaches for monitoring the status of the patient’s pain, including the effectiveness of the interventions.
• Identification of clinically significant medication-related adverse consequences such as falling, constipation, anorexia, or drowsiness, and a plan to minimize those adverse consequences.
• Whether the pain has been reassessed and the plan of care revised as necessary if the current interventions are not effective or the patient has experienced a change of condition or status.

If the plan of care refers to a specific protocol, determine whether interventions are consistent with that protocol. If a patient’s plan of care deviates from the protocol, determine through staff interview or record review the reason for the deviation.

Interview a facility staff person who is knowledgeable about the needs and care of the patient to determine:

• How and when staff communicate with the hospice when/if the patient is experiencing pain.
• If the patient receives pain medication (including PRN and adjuvant medications), how, when, and by whom the results of medications are evaluated (including the dose, frequency of PRN use, schedule of routine medications, and effectiveness).

• How staff monitor for the emergence or presence of adverse consequences of interventions.

• What is done if pain or other symptoms persist or recur despite treatment, and the basis for decisions to maintain or modify approaches.

• How the hospice and the facility coordinate their approaches, communicate about the patient’s needs, and monitor the outcomes (both effectiveness and adverse consequences).

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