National Hospice and Palliative Care Organization

# Regulatory Alerts



# Release of Revised State Operations Manual – Appendix M - Guidance for Surveyors: Hospice

TO: NHPCO Provider and State Members

FROM: NHPCO Regulatory Team

DATE: January 30, 2023

# Summary at a Glance

On January 27, 2023, CMS posted <u>QSO-23-08</u>, Revisions to the State Operations Manual, Appendix M – Hospice. Appendix M contains the LTags and Interpretive Guidelines for each Medicare Hospice Condition of Participation. They provide valuable insights on what surveyors will be reviewing, as well as details on the hospice survey process.

These revisions incorporate changes that were a part of the HOSPICE Act, passed by the Congress and signed into law by President Trump on December 27, 2020. Appendix M now includes guidance for surveyor training, the inclusion of accrediting organizations in surveyor training, protocols for surveyor conflict of interest and adds a sample selection protocol for choosing patient visits in the list of survey tasks. CMS announced that the survey protocols have now been "revised to place an increased focus on quality of care concerns.

Providers should pay special attention to the changes in the survey protocols and the survey focus on quality of care. **Phase 1** includes three core Conditions of Participation and 6 associated CoPs:

- §418.52 Patient Rights
- §418.54 Initial and comprehensive assessment of the patient
- §418.56 Interdisciplinary Group, care planning, and coordination of services

**Phase 2** includes one core Condition of Participation, with 13 associated CoPs:

• §418.58 Condition of participation: Quality assessment and performance improvement. For staff responsible for survey preparation, a thorough review of the revised Appendix M will help prepare a hospice team for the changes in the survey process and a successful survey.

The changes outlined in the revised Appendix M are effective immediately.

The following provides details for the revisions to Appendix M – Hospice: Guidance for Surveyors

# A. Tasks in the Survey Protocol:

#### 1. Task 1: Pre-survey Preparation

Enhanced with additional external and internal resources to assess the current characteristics and services of the hospices. NOTE that the pre-survey preparation includes a "public media search for information or concerns about the hospice, access to the hospice's website, CMS Hospice Care Compare, and survey reports in the past for standard and complaint investigations."

# 2. Task 2: Entrance Conference

Details from CMS on surveyor tasks in Entrance Conference:

- Hold a discussion (not interview) with the hospice administrator or designee.
  - o Discussion items have been more clearly identified, including, but not limited to:
    - Informing the administrator or designee of the survey's purpose.
    - Explaining the survey process and the estimated duration.
    - Requesting patient and agency information and short-term inpatient care documentation.
    - Requesting assistance with a private space to work and access to an assigned staff person from the hospice who will assist with questions and obtaining information.

# 3. Task 3: Sample Selection - NEW

CMS states that this task is "dedicated to sampling strategy for record reviews and home visits. The sampling strategy increases the number of records and ensures that a broader range of hospice activities are investigated (*NOTE: live discharges, bereavement follow-through, care for patients needing higher levels of care*) from all of the locations where the hospice operates ('multiple locations'), and the variety of home settings where patients live."

# **CMS Survey Sample Table**

Number of Admissions (Past 12 months)	Closed Records (Live Discharges)	Closed Records (Bereavement Records)	Record Review – No Home Visit (RR- NHV)	Record Review with Home Visit (RR- HV)	Total Minimum Sample	Inclusion of Records from Multiple Location(s)
< 150	2	2	7	3	14	The number
150-750	2	3	10	4	19	of records
751-1250	2	3	12	6	23	from each
1251 or more	3	4	14	6	27	multiple location should be proportionate. Include at least one RR- NHV or RR-HV

			from each
			location1

Source: State Operations Manual - Appendix M, pg. 41

#### 4. Task 4: Information Gathering

CMS states that for Phase 1 and Phase 2 components of the survey, the information gathering will include:

- "Provide a more specific investigative protocol based on the core requirements/quality of care concept;
- Specify inpatient hospice survey procedures;
- Provide more survey guidance on evaluating hospice patients who reside in SNF/NF and ICF/IID.
- Provide guidance on how to evaluate continuous home care as well as general inpatient care for pain and symptom management.
- Provide more guidance on how to evaluate bereavement counseling Enhanced assessment for patient abuse and neglect and conflict of interest."

#### 5. Task 5: Preliminary Decision Making and Analysis of Findings

• Additional guidance on standard versus condition-level noncompliance.

#### 6. Task 6: Exit Conference

- CMS has added surveyor guidance to clarify:
  - o "Avoid using data tag numbers only when referring to survey findings.
  - Surveyors may give specific regulatory citation references.
  - Surveyors do not need to provide instructions or a timeframe for the hospice to submit a Plan of Correction."

#### 7. Task 7: Post Survey Activities

- No updates
- **B.** Hospice Survey Protocol Focuses on Quality of Care: CMS reports that "a significant change in the hospice survey protocol is an enhanced approach to investigating the quality of care provided to hospice patients. While each of the 23 CoPs continues to have equal weight in the final certification decision, in the final certification decision, special attention is directed to those Phase I CoPs directly impacting patient care."

# Focused Hospice Survey Process with 2 sequential "Phases"

#### Phase 1

3 Core Requirements
6 Associated CoPs
Direct care of the patient and family
Uses home visits, observations and interviews

# Phase 2 1 Core Requirement

13 Associated CoPs
Uses review of development and execution of administrative
and structural factors, e.g. QAPI plan, review of waivers,
furnishing core and special services, etc.

# Phase 1 CoPs

# Core Requirements - Phase 1

- §418.52 Patient Rights
- §418.54 Initial and comprehensive assessment of the patient
- §418.56 Interdisciplinary Group, care planning, and coordination of services

# Associated Quality of Care CoPs - Phase 1

- §418.60 Condition of participation: Infection control.
- §418.76 Condition of participation: Hospice aide and homemaker services.
- §418.102 Condition of participation: Medical director.

CMS has included a table with the roles and responsibilities of the hospice medical director, hospice physician, nurse practitioner and physician assistant.

Table 1: Medical Director Responsibilities Compared to All Hospice Physicians, Nurse Practitioners and Physician Assistants

Medical Director Only	Nurse Practitioner (NP)	Physician Assistant (PA)
	Only	Only
The hospice must designate a physician to	NPs may function as the	Functioning as the
serve as medical director. The medical	"Attending Physician"	"Attending Physician," PAs
director must be a doctor of medicine or	and may write orders	may write orders that are
osteopathy who is an employee or is under	within the scope of their	unrelated to the terminal
contract with the hospice. (§418.102). When	state practice act. As a	illness, within the scope of
the medical director is not available, a	hospice employee, NPs	their state practice act.
physician designated by the hospice assumes	may do face-to-face	PAs who are hospice
the same responsibilities and obligations as	examination required	employees or providing
the medical director.	for the 3rd or later	care under arrangement
	hospice benefit period.	may not write orders
Supervision of all physician employees. All		pertaining to the terminal
physician employees and those under		illness or the face-to-face

contract, must function under the supervision		assessment for certifying
of the hospice medical director.		the terminal illness.
Admission to hospice care. The hospice		
admits a patient on the recommendation of		
the medical director in consultation with		
patient's attending physician (if any).		
(§418.25(a)). Discharge from hospice care.		
Prior to discharging a patient, the hospice		
must obtain a written physician's discharge		
order from the hospice medical director.		
(§418.26(b)).		
Medical Director/Physician Designee	NP/PA	
Medical component of patient care	Neither NPs or PAs can fu	nction as the physician on
<b>program</b> . The medical director or physician	the interdisciplinary team	or certify terminal illness.
designee, in the absence of the medical		
director, has responsibility for the medical		
component of the hospice's patient care		
program.		
program.		
Certification and Recertification of Terminal		
Certification and Recertification of Terminal		
Certification and Recertification of Terminal Illness. Medical director or physician		
Certification and Recertification of Terminal Illness. Medical director or physician designee, in the absence of the medical		
Certification and Recertification of Terminal Illness. Medical director or physician designee, in the absence of the medical director, reviews the clinical information for		
Certification and Recertification of Terminal Illness. Medical director or physician designee, in the absence of the medical director, reviews the clinical information for each hospice patient and provides written		
Certification and Recertification of Terminal Illness. Medical director or physician designee, in the absence of the medical director, reviews the clinical information for each hospice patient and provides written certification that the patient's life expectancy		

# **Physicians**

The hospice medical director, physician employees, and contracted physicians, in conjunction with the patient's attending physician, are responsible for the palliation and management of the terminal illness and conditions related to the terminal illness. (§418.64(a)). If the attending physician is unavailable, the hospice physician, is responsible for meeting the medical needs of the patient.

Source: <u>State Operations Manual, Revised – Appendix M – Hospice</u>, pg. 63

- §418.108 Condition of participation: Short-term inpatient care.
- §418.110 Condition of participation: Hospices that provide inpatient care directly.
- §418.112 Condition of participation: Hospices that provide hospice care to residents of a SNF/NF or ICF/IID.

Source: State Operations Manual, Appendix M - Hospice, Revised pg. 48

# Phase 2 CoPs

Identified by CMS as the 4<sup>th</sup> Core CoP, Quality Assessment and Performance Improvement (QAPI) determines if the hospice is "actively engaged in monitoring the effectiveness and safety of services and quality of care and includes the remaining 13 CoPs.

CMS states that "Protocol Phase 1 CoPs quality of care findings informs the Protocol Phase 2 CoPs investigation." They also note that "all CoPs continue to have the same weight, be they Phase 1 or Phase 2, in terms of finding noncompliance and citing deficiencies."

# **Protocol Phase 2 Core Requirement CoP**

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

#### **Protocol Phase 2 Associated Quality of Care CoPs**

- §418.62 Condition of participation: Licensed professional services.
- §418.64 Condition of participation: Core services.
- §418.66 Condition of participation: Nursing services—Waiver of requirement that substantially all nursing services be routinely provided directly by a hospice.
- §418.70 Condition of participation: Furnishing of non-core services.
- §418.72 Condition of participation: Physical therapy, occupational therapy, and speech-language pathology.
- §418.74 Waiver of requirement—Physical therapy, occupational therapy, speech-language pathology, and dietary counseling.
- §418.78 Conditions of participation—Volunteers.
- §418.100 Condition of Participation: Organization and administration of services.
- §418.104 Condition of participation: Clinical records.
- §418.106 Condition of participation: Drugs and biologicals, medical supplies, and durable medical equipment.
- §418.113 Condition of participation: Emergency preparedness.
- §418.114 Condition of participation: Personnel qualifications.
- §418.116 Condition of participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.

Source: State Operations Manual – Appendix M, Revised – Hospice, pg. 73

# C. CMS Training for State Agency (SA) and Accrediting Organization (AO) Surveyors:

- The CMS Hospice Basic Surveyor Training has been revised to complement changes in Appendix M.
- Both state surveyors and accrediting organization (AO) surveyors who have not previously taken
  the CMS Hospice Basic Training are required to take the revised training.

- Those surveyors who have taken earlier versions of the basic surveyor training will be required to take the shorter Hospice Basic Surveyor Update 2023 Training, which includes the changes in Appendix M.
- The trainings will be available in the Quality, Safety and Education Portal (QSEP) within 30 days of the issuance of this memorandum.

# D. Survey Team Size and Composition

- All surveyors must successfully complete the CMS Basic Hospice Surveyor Training Course and any additional, specified training before serving on a hospice survey team.
- Surveyor trainees may accompany the survey team, supervised by an experienced surveyor.
- Each team should include at least one RN with hospice surveyor experience.
- Each team should be multi-disciplinary, "incorporating other areas of professional practice..."
- CMS describes that the SA or CMS Location (for Federal teams) will determine the size of the team, depending on size and characteristics of the hospice, including the following factors listed in Appendix M:
  - 1. The hospice patient census, number of unduplicated admissions, and number of multiple locations at the time of the last survey;
  - 2. The settings the hospice serves (each of which requires visits whenever possible), including:
    - a. home
    - b. inpatient hospice
    - c. nursing home
    - d. respite settings
    - e. intermediate care facilities and assisted living facilities;
  - 3. The pattern of past deficiencies or complaints;
  - 4. Whether new surveyors are to accompany the surveyor as part of their training.

# E. Prohibition of Conflicts of Interest

As the survey team is finalized, CMS requires that SAs, federal teams, and AOs must ensure that no conflicts of interest are present between the team and the hospice being surveyed. Section 488.1115(b) sets out the circumstances that would disqualify a surveyor from surveying a particular hospice. It also notes that surveyor(s) must disclose actual or perceived conflicts of interest prior to participating in a hospice program survey and be provided the opportunity to recuse themselves, as necessary.

Additionally, any of the following circumstances disqualifies a surveyor from surveying a particular hospice program.

• The surveyor currently serves, or, within the previous 2 years has served, with the hospice program to be surveyed as a direct employee; an employment agency staff at the hospice program; or an officer, consultant, or agent for the hospice program to be surveyed.

- The surveyor has a financial interest or an ownership interest in the hospice program to be surveyed.
- The surveyor has an immediate family member, as defined at 42 CFR 411.35, who has a financial interest or an ownership interest with the hospice program to be surveyed

#### F. Changes to Interpretive Guidelines – revisions and adds to language added in red per CMS

L505

§418.52(b) Standard: Exercise of rights and respect for property and person Interpretive Guidelines §418.52(b)(1)(i)-(iv)

A grievance is a formal or informal written or verbal complaint that is made to any hospice employee, including volunteers and individuals furnishing hospice services under arrangement, by a patient or the patient's representative regarding the patient's care, abuse, neglect, or misappropriation of property. Hospices should inform patients and family/caregivers of accurate information for filing a complaint.

L508

§418.52(b)(4) The hospice must: Interpretive Guidelines §418.52(b)(4)(i)

All patient complaints and alleged or real violations included in this standard must be reported immediately to the hospice administrator and should be investigated, resolved and documented. The hospice must ensure that all hospice employees and contracted staff are trained on how and when to report allegations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse by anyone furnishing services on behalf of the hospice. This includes reporting injuries of unknown origin, as well as misappropriation of patient property.

# L515

§418.52(c)(4) Choose his or her attending physician; Interpretive Guidelines §418.52(c)(4)

Patients have the right to choose their attending physician (generally a provider for whom the beneficiary has a relationship with and is not part of the current hospice staff) and to have this person involved in their medical care in collaboration with the hospice medical staff. An attending physician (if any) can also manage those aspects of his/her health care unrelated to the hospice services being provided.

#### L517

§418.52(c)(6) Be free from mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property; Interpretive Guidelines §418.52(c)(6)

States commonly have mandatory reporting requirements for providers, suppliers, and individuals making them legally responsible to report suspicions of abuse and neglect to appropriate State authorities. These facilities and individuals should follow existing mandatory reporting requirements in their State, in addition to any Federal requirements. Action or inaction on the part of a provider or supplier to follow mandatory reporting requirements does not preclude an employee from fulfilling their individual reporting obligations.

Hospices should maintain documentation of any reports filed with law enforcement or State, local, or Federal authorities related to abuse and neglect. The hospice should document the following information:

- Who submitted the report, including name and contact information;
- Who did the reporter contact, including the appropriate authority or law enforcement entity, name, and contact information;
- Date/Time that the report was filed;
- Any copies of the report made to the appropriate authority or law enforcement, if available;
- What information was conveyed to the appropriate authority or law enforcement; and
- The police report number provided by the appropriate authority or law enforcement.

#### L577

(Rev.)

§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.

#### L614

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

Interpretive Guidelines §418.76(b)(4)

A hospice aide may receive training from different organizations if the amount of training totals 75

hours, the content of training addresses all subjects listed at §418.76(b)(3) and the organization, training, instructors, and documentation meet the requirements of the regulation.

Documentation of training should include:

- A description of the training/competency evaluation program, including the qualifications of the instructors;
- A record that indicates which skills each aide was judged to be competent and that distinguishes between skills taught at a patient's bedside with supervision, and those taught in a laboratory or simulated setting using a pseudo-patient as defined at §418.3. A pseudo-patient may be a real person trained to participate in a role-play situation, or a computer-based mannequin device; and
- How additional skills (beyond the basic skills listed in the regulation) are taught and tested if the
  hospice's admission policies and case-mix of hospice patients require aides to perform more
  complex procedures.

#### L615

#### §418.76(c) Standard: Competency evaluation.

- An individual may furnish hospice aide services on behalf of a hospice only after that
  individual has successfully completed a competency evaluation program as described in this
  section.
- §418.76(c)(1) The competency evaluation must address each of the subjects listed in paragraph (b)(3) of this section. Subject areas specified under paragraphs (b)(3)(i), (iii), (ix), (x), and (xi) of this section must be evaluated by observing an aide's performance of the task with a patient *or pseudo-patient*. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a hospice aide with a patient *or a pseudo-patient during a simulation*.

#### L631

§418.76(h)(1)(iii) If an area of concern is verified by the hospice during the on-site visit, then the hospice must conduct, and the hospice aide must complete, a competency evaluation of the deficient skill and all related skill(s) in accordance with §418.76(c).

#### L690

§418.106(b) Standard: Ordering of drugs.

- (1) Drugs may be ordered by any of the following practitioners:
  - (i) A physician as defined by Section 1861(r)(1) of the Act,
  - (ii) A nurse practitioner in accordance with state scope of practice requirements.
  - (iii) A physician assistant in accordance with the state scope of practice requirements and hospice policy who is:
    - (A) The patient's attending physician; and
    - (B) Not an employee of or under arrangement with the hospice.

The LTags for the Hospice Condition of Participation at §418.110 has been re-designated from L719-L758 to L820- L862. See separate document entitled "Crosswalk of LTags for §418.110, Hospices that provide inpatient care directly"

L762 – NOTE specific references to nursing facilities. §418.112(b) Standard: Professional management.

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

# Interpretive Guidelines §418.112(b)

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

Hospices must routinely provide substantially all core services directly by the hospice employee, and cannot delegate these services to the facility. Hospices should specify that facility staff should immediately notify the hospice when facility staff must perform hospice core services in place of hospice

staff. The contract between the hospice and the facility should address potential crisis-situations and temporary emergency measures and how facility staff should handle them.

§418.113 Condition of participation: Emergency preparedness.

Interpretive Guidelines: § 418.113

Hospice programs must comply with the applicable emergency preparedness requirements referenced in Appendix Z of the State Operations Manual. For all applicable requirements, guidance, and survey protocol related to Emergency Preparedness in hospice programs, please refer to Appendix Z.

NOTE: Providers will be expected to prepare for a survey which includes Appendix Z.

The NHPCO Regulatory Team will be updating the <u>NHPCO Survey Readiness and Response Toolkit</u> to reflect the Appendix M, including <u>a crosswalk of the LTags</u> (PDF). It is an important resource for survey preparation.

For questions about this alert or how the State Operations Manual – Appendix M – Hospice fits with the hospice Conditions of Participation, please email <a href="mailto:regulatory@nhpco.org">regulatory@nhpco.org</a> and put Appendix M in the subject line.