STANDARDS OF PRACTICE FOR HOSPICE PROGRAMS

PROFESSIONAL DEVELOPMENT AND RESOURCE SERIES

9 / Compliance with Laws and Regulations (CLR)

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PRINCIPLE

Ensuring compliance with applicable laws, regulations, and professional standards of practice and implementing systems and processes that prevent fraud, waste, and abuse.

Standard:

CLR 1: The organization maintains full compliance with legal and regulatory requirements.

Requirements include but are not limited to:

Medicare Hospice Regulations: The Medicare hospice regulations include the Conditions of Participation (CoPs – Subparts C and D), but also include Subpart A – General Provisions and Definitions, Subpart B – Election and Duration of Benefits, Subpart C – Patient Care, Subpart D – Organizational Environment, Subpart F – Covered Services, Subpart G - Payment for Hospice Services and Subpart H – Coinsurance. The CoPs are the health and safety requirements that all Medicare certified hospices are required to meet. They are the framework for patient care delivery, administrative and organizational processes, and quality improvement that hospices must comply with in order to receive payment for services under Medicare. Subpart B contains the regulations related to election of the hospice benefit, certifying and recertifying eligibility, and discharge, revocation and transfer regulations. Subpart F specifies the requirements for coverage, which specifies what must be done for Medicare reimbursement. The Medicare Hospice regulations can be accessed at: **https://www.ecfr.gov/cgi-bin/text-idx?SID=45c00a9dd3d5dc55b66290b274c76054&mc=true&node=pt42.3.418&rgn=div5**

Medicare Hospice Interpretive Guidelines: The Interpretive Guidelines provide additional guidance, questions, and probes established by CMS to assist state survey agency and accrediting organization staff who are reviewing hospices for compliance with the Medicare Hospice Conditions of Participation. The guidelines offer explanation and amplification on the intent of the Medicare hospice regulations. The Interpretive Guidelines are a component of Appendix M of the State Operations Manual, which provides guidance for the entire survey process. They can be accessed at: **https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_m_hospice.pdf** The hospice emergency preparedness interpretive guidelines appear in Appendix Z and can be accessed at **https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/Advanced-Copy-SOM-Appendix-Z-EP-IGs.pdf**

State Hospice Licensure Regulations: Most states have requirements that a hospice must meet in order to be licensed to provide hospice care and maintain hospice provider licensure in their respective state. State laws differ in regard to the licensure and certification process. The hospice must be in compliance with state laws and regulations regarding hospice licensure.

Health Insurance Portability and Accountability Act (HIPAA): Addresses the use and disclosure of "protected health information" (PHI including electronic protected health information (e-PHI). The complete document can be accessed at: **www.hhs.gov/hipaa/for-professionals/index.html**

The Health Information Technology for Economic and Clinical Health (HITECH) Act: Subtitle D of the HITECH Act addresses the privacy and security concerns associated with the electronic transmission of health information, in part, through several provisions that strengthen the civil and criminal enforcement of the HIPAA rules. HITECH information can be access at: **http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/hitechblurb.html**

HIPAA Omnibus Final Rule: Clarifies the definition of a Business Associate (BA) and delineates what constitutes breaches of regulations and consumer rights including protections for decedents. Information can be accessed at: **www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/combined-regulation-text/omnibus-hipaa-rulemaking/index.html**

Clinical Laboratory Improvement Amendments (CLIA): CMS Conditions of Participation 418.116(b) require a hospice that performs clinical tests to have a certificate for the level of testing being performed. Details can be found at: **https://www.ecfr.gov/cgi-bin/text-idx?SID=45c00a9dd3d5dc55b66290b274c76054&mc=true&node=pt42.3.418&rgn=div5**

The Federal Occupational Safety & Health Administration (OSHA): Requires employers to provide their employees with working conditions that are free from known dangers and enforces protective workplace safety and health standards. More information about OSHA can be found at: **www.osha.gov/**

Benefit Policy Manual, Chapter 9 – Hospice Services: The Centers for Medicare and Medicaid Services (CMS) provides details on CMS policies for the Medicare Hospice Benefit. The hospice chapter can be accessed at: **www.cms.gov/manuals/Downloads/bp102c09.pdf**

The Centers for Medicare and Medicaid Services (CMS): CMS often issues "sub-regulatory guidance" through the issuance of Change Requests to communicate new or changed policies or procedures that they will incorporate into the CMS Online Manual System. **https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/index.html**

Hospice Quality Reporting Program (HQRP) Regulations: CMS requires hospice providers to report Hospice Item Set (HIS) and CAHPS (Hospice Consumer Assessment of Healthcare Providers and Systems) data per designated timeframes. Failure to report data results shall result in a 2 percentage-point reduction to the market basket percentage increase for that fiscal year. More information about the HQRP programs can be found at: **www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/** Information on the CAHPS can be accessed at: **http://www.hospicecahpssurvey.org/en/**

Brief Physician Narrative: CMS requires the physician writes a brief narrative as a component of the certification and recertification process. The regulation can be found in Section 20.1 "Timing and Content of Certification" in the Hospice Benefit Policy Manual, Chapter 9 at: **www.cms.gov/manuals/Downloads/bp102c09.pdf**

Face-to-Face Encounters: CMS requires that a hospice physician or nurse practitioner conduct a face-to-face encounter for every Medicare patient prior to the beginning of the third benefit period and for each subsequent period. The regulation can be found in Section 20.1 "Timing and Content of Certification in the Hospice Benefit Policy Manual, Chapter 9 at: **https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c09.pdf**

Physician Certification and Recertification of Services: CMS provides details on CMS policies on physician certification and recertification of terminal illness. The regulation can be found in Section 60 – Certification and Recertification by Physicians for Hospice Care. The chapter can be accessed at: **https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ge101c04.pdf**

Processing Hospice Claims: CMS provides details on CMS policies on billing for the hospice benefit in Medicare Claims Processing Manual Chapter 11. The chapter can be accessed at: **www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c11.pdf**

The Certification Process: CMS provides information on the certification process in the State Operations Manual (SOM) Chapter 2.The chapter can be found at: **https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107c02.pdf**

Financial Liability Protections: The CMS State Operations Manual (SOM) Chapter 2 provides instructions regarding issuance of the Advance Beneficiary Notice (ABN) and the Notice of Medicare Non-coverage (NOMNC) to the Medicare beneficiary in advance of initiating, reducing, or terminating what they believe to be non-covered items or services. The CMS Beneficiaries Notifications Initiative page can be accessed at: **https://www.cms.gov/Medicare/Medicare-General-Information/BNI/index.html**

Hospice Cost Report: CMS provides forms and completion instructions for the hospice cost report. Hospice costs must be reported by level of care and submitted to the MAC within 5 months after the end of the fiscal year. The cost report forms and instructions are in Chapter 38 and can be accessed at: **https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935.html**

The Office of the Inspector General's (OIG): Is charged with protecting the integrity of Department of Health and Human Services (HHS) programs, including hospice. Both OIG work plans and reports provide information on OIG areas of focus related to hospice compliance. These can be accessed at: **https://www.oig.hhs.gov/**

CLR 1.1 The governing body adopts bylaws in accordance with the mission of the organization.

CLR 1.2 Mechanisms are in place to address the recommendations made in the reports received from authorized regulatory and accrediting bodies.

CLR 1.3 The hospice has a comprehensive compliance program that includes:

1. The development and distribution of written standards of conduct, as well as written policies and procedures, which promote the hospice's commitment to compliance and address specific areas of potential fraud such as Medicare hospice eligibility and admission, improper financial relationships with nursing facilities and other healthcare professionals and entities, and improper billing practices;
2. The designation of a Compliance Officer and other appropriate bodies (e.g., a Corporate Compliance Committee) charged with the responsibility for operating and monitoring the compliance program and who report directly to the CEO and the governing body;
3. The development and implementation of regular effective education and training programs in compliance for all affected employees;
4. The creation and maintenance of a process such as a hotline or other reporting system to receive complaints and ensure effective lines of communication between the Compliance Officer and all employees and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation;
5. The use of audits and/or other evaluation techniques to monitor compliance and identify problem areas to assist in the reduction of identified problem areas;
6. The development of appropriate disciplinary mechanisms to enforce standards and the development of policies to address:

    a. Employees who have violated internal compliance policies, applicable statutes, regulations or federal healthcare program requirements; and
    b. The employment of sanctioned, excluded, and other specified individuals.

7. The development of policies that direct prompt and proper responses to detected offenses including the initiation of appropriate corrective action and preventive measures.

Practice Examples:

- The hospice has a process in place to incorporate regulatory changes into the policies and procedures of the hospice and offers training for employees to ensure compliance.
- Results of surveys are documented in governing body meeting minutes.
- Ongoing mock surveys or self-assessments are conducted to identify areas for improvement and changes are made based on the findings.
- The hospice has a procedure for reporting and investigating compliance concerns.

Standard:

CLR 2: The hospice has a program to identify, prevent, and correct practices that are fraudulent or abusive.

CLR 2.1 Medicare-certified hospices provide care, treatment, and services as specified in Medicare hospice regulations.

CLR 2.2 The hospice uses specific guidelines to determine eligibility for hospice at admission and throughout the hospice service period.

CLR 2.3 The hospice regularly monitors its compliance with regulatory requirements and business practices.

CLR 2.4 Hospice organizations follow state licensure regulations and reporting requirements for fraud and abuse.

Practice Examples:

- The hospice uses resources available for regulatory questions and interpretive guidance. Resources include but are not limited to: NHPCO, Medicare Administrative Contractors (MACs), state hospice organizations, and accrediting bodies.
- The hospice seeks voluntary accreditation from an accrediting body with hospice deeming authority status from CMS.
- There is a process for review of patient eligibility for hospice services prior to admission as well as at the time of recertification. The recertification process includes a hospice physician or nurse practitioner conducting a face-to-face encounter.
- The hospice utilizes CMS regulations, Medicare Administrative Contractors' (MAC) Local Coverage Determinations (LCDs), and clinical assessments in keeping with professional standards of practice for admission to hospice services and recertification for continued provision of services.
- The hospice regularly audits compliance with regulatory requirements and business practices.
- The hospice monitors OIG risk areas and develops a compliance plan based on those risk areas.

Standard:

CLR 3: The hospice maintains a comprehensive, timely, and accurate clinical record of services provided in all care settings for each patient and family/caregiver.

CLR 3.1 The hospice has written policies and procedures that address the content, maintenance, security, storage, retention, and access to hospice clinical records. These policies and procedures conform to all state and federal laws.

CLR 3.2 A professional consistent format is used to document the services provided in all care settings.

CLR 3.3 Documentation in the hospice clinical record is descriptive, timely, and accurate and includes at a minimum:

1. A medical history including clinical evidence of the terminal prognosis on admission;
2. An age-appropriate physical assessment of the patient by the hospice nurse;
3. A comprehensive medication reconciliation;
4. A psychosocial assessment of the patient, family, and caregiver;
5. A spiritual assessment of the patient, family, and caregiver;
6. A bereavement assessment of the patient, family, and caregiver;
7. Physician certification and recertification of terminal illness form(s);
8. Physician certification and recertification of terminal illness and narrative statement(s);
9. Attestation and documentation of face-to-face encounters;

10. CMS quality measure data elements;
11. The hospice interdisciplinary team plan of care;
12. A record of the care provided by all disciplines from admission through bereavement;
13. Patient responses to medications, symptom management, treatments, and services;
14. Signed physician's orders for care;
15. Persons to contact in an emergency;
16. Hospice election statement form signed by patient or representative;
17. Informed consent and acknowledgment signed by patient or representative that a copy of the notice of rights and responsibilities, privacy practices, and information about advance directive were provided;
18. The patient's decisions regarding end-of-life care;
19. Advance care directive choices;
20. A record of military service for all patients;
21. Identification of other agencies involved in care;
22. Communication regarding care or services to be provided and care coordination;
23. Additional information as required by law and regulation;
24. Evidence that the patient or representative received written patient rights and information about how to voice a complaint; and
25. A record that drug disposal was carried out in accordance with federal, state, and local regulations.

CLR 3.4 When services are provided under a contractual agreement, clinical documentation or a summary of services provided by the contracted organization or individual is included in the hospice clinical record.

CLR 3.5 Clinical records of patients who transition between levels of care, or transfer to or from the hospice, contain detailed information to promote continuity of care and support care coordination across treatment settings.

CLR 3.6 Forms utilized in the clinical record are reviewed according to established policy and revised as appropriate.

CLR 3.7 The clinical record contains a physician order and discharge summary for every patient discharged alive.

CLR 3.8 The clinical record is completed within the time frame specified by the hospice for every discharged patient and per state regulations if any.

Practice Examples:

- Clinical records of discharged patients are reviewed to verify that a discharge physician order and summary was completed in a timely manner.
- All documentation for discharged patients is submitted in a timely manner in accordance with the hospice's policies and filed in the clinical record.
- The military history checklist is used to identify a patient who is a Veteran, evaluate the impact of the military experience, develop a care plan specific to the unique issues faced by the

Veteran, and determine benefits to which the Veteran and surviving dependents may be entitled.

- The following documents are provided to the nursing facility for each resident for whom the hospice is providing services:

  – An up-to-date hospice plan of care;
  – Hospice election form and any advance directives;
  – Physician certification and recertification of the terminal illness;
  – Names and contact information for hospice personnel involved in the patient's care;
  – Instructions on how to access the hospice's 24-hour on-call system;
  – Hospice medication information; and
  – Hospice physician and attending physician (if any) orders.

- Patients and caregivers are given are a Notice of Privacy Practices informing them that protected health information is collected and maintained and may be shared with other providers as a part of their plan of treatment.
- When transferring to a different level of care, or a different service location, the patient's clinical record contains a transfer summary with the reason for transfer, a copy of the interdisciplinary plan of care, and other appropriate information for caregivers in the new level of care.
- When transferring to another hospice, the transferring hospice provides a transfer summary of all care provided, as well as a copy of the interdisciplinary plan of care, copies of signed consents for care, copies of certifications of terminal illness, and other information as requested by the receiving hospice.
- The hospice routinely evaluates the application of advancing technology including evaluating risks in the use of the technology, and addressing potential HIPAA privacy and security regulation violations.