Organization and administration of services

§418.106 Condition of participation: Drugs and biologicals, medical supplies, and durable medical equipment and 6 standards

Medical supplies and appliances, as described in §410.36 of this chapter; durable medical equipment,
Organization and administration of services

as described in §410.38 of this chapter; and drugs and biologicals related to the palliation and management of the terminal illness and related conditions, as identified in the hospice plan of care, must be provided by the hospice while the patient is under hospice care.
§418.106 (a) Standard: Managing drugs and biologicals.

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

✓ Pt. Typically use 5 + drugs increasing risk for duplicative therapy, interactions, side effects
✓ Increase focus on drug management
✓ May use pharmacist or other with specialized education/training in drug management, drug effectiveness, identifying side effects, actual or potential interactions, redundant drugs, & how to take appropriate actions
✓ Must be able to demonstrate individual’s knowledge, skills, abilities in managing drugs
(2) A hospice that provides inpatient care directly in its own facility must provide pharmacy services under the direction of a qualified licensed pharmacist who is an employee of or under contract with the hospice. The provided pharmacist services must include evaluation of a patient’s response to medication therapy, identification of potential adverse drug reactions, and recommended appropriate corrective action.
Tips

✓ Patients may bring their own drugs into a hospice inpatient facility
Organization and administration of services

§418.106 (b) Standard: Ordering of drugs.

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

(2) If the drug order is **verbal** or given by or through **electronic** transmission –
Organization and administration of services

§418.106 (b) (2) con’t.

(i) It must be given only to a licensed nurse, nurse practitioner (where appropriate), pharmacist, or physician; and

(ii) The individual receiving the order must record and sign it immediately and have the prescribing person sign it in accordance with State and Federal regulations.
Organization and administration of services

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

The hospice must –

(1) Obtain drugs and biologicals from community or institutional pharmacists or stock drugs and biologicals itself.
Organization and administration of services

§418.106 (c) con’t.

(2) The hospice that provides inpatient care directly in its own facility must:

(i) Have a written policy in place that promotes dispensing accuracy; and

(ii) Maintain current and accurate records of the receipt and disposition of all controlled drugs.
“drugs and biologicals from community or institutional pharmacists or stock drugs and biologicals itself” ……… to prevent obtaining drugs/biologicals from sources outside of US
§418.106 (d) Standard: Administration of drugs and biologicals.

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


Tips

✓ “If a patient and all family members are unable to safely administer drugs themselves, then it is incumbent upon the hospice to identify alternatives to ensure safe administration.”

✓ “….hospices should be able to assume the responsibility to determine when it is and is not appropriate to place drugs in a patient’s home.”
Organization and administration of services

§418.106 (d) con’t.

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

(i) A licensed nurse, physician, or other health care professional in accordance with their scope of practice and State law;
Organization and administration of services

§418.106 (d) (2) con’t.

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

(iii) The patient, upon approval by the interdisciplinary group.
Tips

✓ “…not appropriate to allow the family or primary caregiver of a patient to administer medications in an inpatient facility.”
Organization and administration of services

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

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

§418.106 (e) con’t.

(2) Disposing.

(i) Safe use and disposal of controlled drugs in the patient’s home. The hospice must have written policies and procedures for the management and disposal of controlled drugs in the patient’s home.
Organization and administration of services

§418.106 (e) (2) (i) con’t.

At the time when controlled drugs are first ordered the hospice must:

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

§418.106 (e) (2) (i) Disposing con’t.

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

§418.106 (e) (2) (i) con’t.

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

✓ Drug P&P, unlike notice of patient rights, is more of an educational effort
✓ Discussion of “safe use” educates without a negative connotation
✓ Must discuss drug policies in a language & manner that the patient & family understand
§418.106 (e) (2)

(ii) Disposal of controlled drugs in hospices that provide inpatient care directly. The hospice that provides inpatient care directly in its own facility must dispose of controlled drugs in compliance with the hospice policy and in accordance with State and Federal requirements. The hospice must maintain current and accurate records of the receipt and disposition of all controlled drugs.
§418.106 (e) (3) Storing. The hospice that provides inpatient care directly in its own facility must comply with the following additional requirements
Organization and administration of services

§418.106 (e) (3) con’t.

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

§418.106 (e) (3)

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

✓ “...incumbant upon a hospice to obtain assurance that a contracted pharmacist or pharmacist service is free of any potential or real conflicts of interest or financial incentives.”....(manufacture's rebates)
Organization and administration of services

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

(1) The hospice must ensure that manufacturer recommendations for performing routine and preventive maintenance on durable medical equipment are followed. The equipment must be safe and work as intended for use in the patient's environment.
Organization and administration of services

§418.106 (f) (1) con’t.

Where a manufacturer recommendation for a piece of equipment does not exist, the hospice must ensure that repair and routine maintenance policies are developed. The hospice may use persons under contract to ensure the maintenance and repair of durable medical equipment.
(2) The hospice must ensure that the patient, where appropriate, as well as the family and/or other caregiver(s), receive instruction in the safe use of durable medical equipment and supplies. The hospice may use persons under contract to ensure patient and family instruction. The patient, family, and/or caregiver must be able to demonstrate the appropriate use of durable medical equipment to the satisfaction of the hospice staff.
Organization and administration of services

§418.106 (f) con’t.

(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.
Tips

✓ ...requiring a DME company to maintain the equipment that it provides does not absolve the hospice of its ultimate responsibility to ensure that all services provided on its behalf, whether by its employees or through contract, are safe and effective.”

✓ “A written statement from the DME supplier and signed by a person of authority stating that equipment has been services according to manufacturer recommendations or other comparable standards would be one way that the hospice could assure that the equipment is safe and performs as required.”
Organization and administration of services

§418.108 Condition of participation: Short-term inpatient care and five standards

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

§418.108 (a) Standard: Inpatient care for symptom management and pain control. Inpatient care for pain control and symptom management must be provided in one of the following:

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

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

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

(i) A provider specified in paragraph (a) of this section.
Organization and administration of services

§418.108 (b) (1)
(ii) A Medicare or Medicaid-certified nursing facility that also meets the standards specified in §418.110(f).
Tips

✓ Freestanding hospice inpatient facility operated by a Medicare certified hospice would qualify as a participating Medicare/Medicaid facility

✓ No need for 24 hr RN if only patients in a facility are receiving respite care (family-like care)

✓ No respite care in ALF
Organization and administration of services

§418.108 (b) con’t.

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

✓ CMS does not prohibit hospice from sending its own staff to care for the hospice’s patients, if permitted in contractual arrangement and statutorial & reguaultory requirements applicable to the contracted inpatient provider.

✓ ...........(Hospice sending its staff to supplement contracted facility staff to meet inpatient care staffing requirement)
Organization and administration of services

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

If the hospice has an arrangement with a facility to provide for short-term inpatient care, the arrangement is described in a written agreement, coordinated by the hospice, and at a minimum specifies –
§418.108 (c) con’t.

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

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

§418.108 (c) con’t.

(3) That the hospice patient’s inpatient clinical record includes a record of all inpatient services furnished and events regarding care that occurred at the facility; that a copy of the discharge summary be provided to the hospice at the time of discharge; and that a copy of the inpatient clinical record is available to the hospice at the time of discharge;
(4) That the inpatient facility has identified an individual within the facility who is responsible for the implementation of the provisions of the agreement;
Organization and administration of services

§418.108 (c) con’t.

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

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

✓ Training of contacted facility staff does not have to be done by each hospice
✓ Each hospice MUST make sure that training contains any differences in procedures/ philosophy, etc.
Organization and administration of services

§418.108 (d) Standard: Inpatient care limitation.

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

✓ Patients admitted to hospice’s own facility for ‘home care” level of care do not count in 20%
Organization and administration of services

§418.108 (e) Standard: Exemption from limitation.

Before October 1, 1986, any hospice that began operation before January 1, 1975, is not subject to the limitation specified in paragraph (d) of this section.
Organization and administration of services

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

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

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

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

§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.
Tips

✓ Hospice only responsible for making the necessary arrangements for inpatient care for terminal illness and related conditions
✓ Hospices only responsible for furnishing & managing care related to terminal illness.
✓ (What is on the POC)
§418.112 (c) Standard: Written agreement.

The hospice and SNF/NF or ICF/MR must have a written agreement that specifies the provision of hospice services in the facility. The agreement must be signed by authorized representatives of the hospice and the SNF/NF or ICF/MR before the provision of hospice services. The written agreement must include at least the following:
§418.112 (c) con’t.

(1) The manner in which the SNF/NF or ICF/MR and the hospice are to communicate with each other and document such communications to ensure that the needs of patients are addressed and met 24 hours a day.
§418.112 (c) con’t.

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

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

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

§418.112 (c) (2) con’t.

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

(iv) A patient dies.
Organization and administration of services

§418.112 (c) con’t.

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

§418.112 (c) con’t.

(4) An agreement that it is the SNF/NF, ICF/MR responsibility to continue to furnish 24 hour room and board care, meeting the personal care and nursing needs that would have been provided by the primary caregiver at home at the same level of care provided before hospice care was elected.
Tips

✓ “Hospices are not required to assume the functions that the SNF/NF or ICF/MR performed for the patient before the patient elected to receive hospice care.”

✓ “Hospices are to use facility staff in the same way that they would use home caregivers to implement the patient’s POC.”
§418.112 (c) con’t.

(5) An agreement that it is the hospice’s responsibility to provide services at the same level and to the same extent as those services would be provided if the SNF/NF or ICF/MR resident were in his or her own home.
Organization and administration of services

§418.112 (c) con’t.

(6) A delineation of the hospice’s responsibilities, which include, but are not limited to the following: providing medical direction and management of the patient; nursing; counseling (including spiritual, dietary and bereavement); social work;
Organization and administration of services

§418.112 (c) (6) con’t.

provision of medical supplies, durable medical equipment and drugs necessary for the palliation of pain and symptoms associated with the terminal illness and related conditions; and all other hospice services that are necessary for the care of the resident’s and terminal illness and related conditions
Organization and administration of services

§418.112 (c) con’t.

(7) A provision that the hospice may use the SNF/NF or ICF/MR nursing personnel where permitted by State law and as specified by the SNF/NF or ICF/MR to assist in the administration of prescribed therapies included in the plan of care only to the extent that the hospice would routinely use the services of a hospice patient’s family in implementing the plan of care.
Tips

✓ “...in contract between it and the facility, address potential crisis situations, and how they would be handles, with the facility staff.”...ex. Titration of pain medication...more sophisticated process that may home caregiver may not be trained to do.
§418.112 (c) con’t

(8) A provision stating that the hospice must report all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by anyone unrelated to the hospice to the SNF/NF or ICF/MR administrator within 24 hours of the hospice becoming aware of the alleged violation.
(9) A delineation of the responsibilities of the hospice and the SNF/NF or ICF/MR to provide bereavement services to SNF/NF or ICF/MR staff.
§418.112 (d) Standard: Hospice plan of care.

In accordance with §418.56, a written hospice plan of care must be established and maintained in consultation with SNF/NF or ICF/MR representatives. All hospice care provided must be in accordance with this hospice plan of care.
Organization and administration of services

§418.112 (d) con’t.

(1) The hospice plan of care must identify the care and services that are needed and specifically identify which provider is responsible for performing the respective functions that have been agreed upon and included in the hospice plan of care.
Organization and administration of services

§418.112 (d) con’t.

(2) The hospice plan of care reflects the participation of the hospice, the SNF/NF or ICF/MR, and the patient and family to the extent possible.

(3) Any changes in the hospice plan of care must be discussed with the patient or representative, and SNF/NF or ICF/MR representatives, and must be approved by the hospice before implementation.
“Hospices and SNFs/NFs and ICFs/MR must have a single plan for each patient. We would expect the hospice & the facility to develop & update this plan in full consultation with each other. The hospice portion of the POC governs the actions of the hospice and describes the services that are needed to care for the patient. The patient’s single, coordinated POC must identify which provider (hospice or facility) is responsible for performing a specific service.
The POC may be divided into two portions, one of which is maintained by the LTC facility and the other which is maintained by the hospice. These two sections must work together to ensure that the needs of the patient for both hospice care and LTC facility care are met at all times. The facility is required to update its portion of the POC in accordance with any Federal, state, or local laws and regulations governing the particular facility just as hospices would need to update their POCs according to...COPs.”
Tips

✓ “Services provided by ..... facility will vary based on POC.” Written agreement is not appropriate place for a list of the services to be provided.”

✓ “The services provided by the facility are included in the POC and coordinated by the hospice and the facility in accordance with..418.112(d)”
Organization and administration of services

§418.112 (e) Standard: Coordination of services. The hospice must:

(1) **Designate a member of each interdisciplinary group** that is responsible for a patient who is a resident of a SNF/NF or ICF/MR. **The designated interdisciplinary group member is responsible for:**

   (i) Providing **overall coordination** of the hospice care of the SNF/NF or ICF/MR resident with SNF/NF or ICF/MR representatives; and
Organization and administration of services

§418.112 (e) (1) con’t.

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

✓ Facility has to identify those with whom the POC discussions must occur & provide hospices with a defined list of those individuals who must be consulted before a change in the hospice portion of the POC is implemented.
Organization and administration of services

§418.112 (e) con’t.

(2) Ensure that the hospice IDG communicates with the SNF/NF or ICF/MR medical director, the patient’s attending physician, and other physicians participating in the provision of care to the patient as needed to coordinate the hospice care of the hospice patient with the medical care provided by other physicians.
Tips

✓ “Whenever physician orders are issued, whether by the hospice physician or the attending physician in coordination with the hospice, a copy of those orders must be provided to the……..in a timely manner.”

✓ “In contract hospice is responsible for ensuring that the management of the residential facility communicates with its staff regarding the acceptability of the hospice physicians orders.”
Organization and administration of services

§418.112 (e) con’t.

(3) Provide the SNF/NF or ICF/MR with the following information:

(i) The most recent hospice plan of care specific to each patient;

(ii) Hospice election form and any advance directives specific to each patient;

(iii) Physician certification and recertification of the terminal illness specific to each patient;
§418.112 (e) (3) con’t.

(iv) Instructions on how to access the hospice’s 24-hour on-call system;
(v) Hospice medication information specific to each patient; and
(vi) Hospice physician and attending physician (if any) orders specific to each patient.
§418.112 (f) Standard: Orientation and training of staff.

(f) Hospice staff must assure orientation of SNF/NF or ICF/MR staff furnishing care to hospice patients in the hospice philosophy, including hospice policies and procedures regarding methods of comfort, pain control, symptom management, as well as principles about death and dying, individual responses to death, patient rights, appropriate forms, and record keeping requirements.
✓ “...hospices are not expected to replace the role of the family....”
✓ “...hospice’s responsibility to provide services to residents...at same level and to the same extent as those services would be provided to patients residing in the own private home.”
Tips

✓ “….facility staff should not be oriented multiple times using the same basic information.”
✓ Hospices responsibility to determine frequency of training and coordinate with facility.
✓ “Facility staff members acting as the patient’s primary caregivers are expected to receive education specific to each patient’s hospice POC and the caregiver’s role in implementing the content of the hospice portion of the POC.”
Tips

✓ CMS will be issuing a new requirement on hospice services to the LTC CoPs after December.

✓ State surveyors have been directed to report issues involving LTC facility residents who are hospice patients.

✓ Facility medical director may be hospice medical director.