

be made readily available on request by an appropriate authority.

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

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

(a) *Standard: Managing drugs and biologicals.* (1) 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.

(2) [Reserved]

(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 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.

(2) If the drug order is verbal or given by or through electronic transmission—

(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.

(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.

(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.

(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.

(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;

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

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

(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).

(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. 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;

(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

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

(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.

(3) *Storing.* The hospice that provides inpatient care directly in its own facility must comply with the following additional requirements—

(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

(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.

(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. 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.

(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.

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§418.108 Condition of participation: Short-term inpatient care.

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

(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 (f) regarding 24-hour nursing services and patient areas.

(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.

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

(2) The facility providing respite care must provide 24-hour nursing services