



Medicare Hospice Conditions of Participation (CoPs)

Compliance Guide for Hospice Providers

January 2015

Sec. 418.106 Condition of Participation: Drugs and Biologicals, Medical Supplies, and Durable Medical Equipment

The hospice must provide medical supplies and appliances, durable medical equipment, 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.

- ***Managing drugs and biologicals***

- 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.
 - **It is the decision of the hospice to determine which individual meets this requirement and this individual may include:**
 - Licensed pharmacists;
 - physicians who are board certified in palliative medicine;
 - RNs who are certified in palliative care;
 - Physicians, RNs and nurse practitioners who complete a specific hospice or palliative care drug management course, and other individuals as allowed by State law.
 - The hospice must be able to demonstrate that the individual has specific education and training in drug management.
- 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.

- **Ordering of drugs**
 - Drugs may be ordered in accordance with the plan of care or State law either by:
 - A physician.
 - A nurse practitioner.
 - If the drug order is verbal or given through electronic submission:
 - It must be given only to a licensed nurse, nurse practitioner (where appropriate), pharmacist, or physician; and
 - 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.

- **Dispensing of drugs and biologicals**
 - A Hospice must obtain drugs and biologicals from community or institutional pharmacists or stock drugs and biologicals itself.
 - In addition, the hospice that provides inpatient care directly in its own facility must:
 - Have a written policy in place that promotes dispensing accuracy; and
 - Maintain current and accurate records of the receipt and disposition of all controlled drugs.

- **Administration of drugs and biologicals**
 - **IDG Responsibility:** The IDG, 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.
 - **Patients in hospice inpatient facilities:** Patients in hospices that provide inpatient care directly may only be administered medications by:
 - A licensed nurse, physician, or other health care professional in accordance with their scope of practice and State law;
 - An employee who has completed a State-approved training program in medication administration; and
 - The patient, upon approval by the interdisciplinary group.

- **Labeling, disposing, and storing of drugs and biologicals**
 - Labeling
 - Drugs and biologicals must:
 - Be labeled in accordance with currently accepted professional practice.
 - Include appropriate usage and cautionary instructions.
 - Include an expiration date, if applicable.
 - Disposing
 - For safe disposal of controlled drugs in the patient's home, the hospice must:

- **Provide the actual copy of the hospice written policies and procedures** on the management and disposal of controlled drugs to the patient or patient representative and family.
- 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.
- Document in the patient’s clinical record that the written policies and procedures for managing controlled drugs was provided and discussed.
 - ❖ **NOTE: The above steps must be completed by the hospice at the time that the controlled drugs are first ordered.**
- **Providers must follow state and federal regulations related to disposal of controlled and uncontrolled drugs.**
 - Hospices that provide inpatient care directly must:
 - Dispose of controlled drugs in compliance with the hospice policy and in accordance with State and Federal requirements.
 - Maintain current and accurate records of the receipt and disposition of all controlled drugs.
- Storing.
 - The following additional requirements are to be met by hospices that provide inpatient care directly.
 - Hospices must store all drugs and biological 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 this section may have access to the locked compartments. These authorized personnel are:
 - A licensed nurse, physician, or other health care professional in accordance with their scope of practice and State law;
 - An employee who has completed a State-approved training program in medication administration; and
 - The patient, upon approval by the interdisciplinary group.
- Discrepancies in the acquisition, storage, dispensing, administration, disposal, or return of controlled drugs must be investigated immediately by the pharmacist and hospice administrator.
 - Where required, these discrepancies must be 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.

- ***Use and maintenance of equipment and supplies***
 - A hospice provider must contract with a DMEPOS accredited supplier that meets the Medicare DMEPOS Supplier Quality and Accreditation Standards at 42 CFR § 424.57.
 - If the hospice owns its own DME, then no accreditation is needed.
 - Hospice provider responsibilities:
 - Ensure that manufacturer recommendations for performing routine and preventive maintenance on durable medical equipment are followed.
 - Ensure that the equipment is safe and works as intended for use in the patient's environment.
 - Ensure that repair and routine maintenance policies are developed for equipment that does not come with a manufacturer recommendation.
 - Ensure that the patient, where appropriate, as well as the family and/or other caregiver(s), receive instruction in the safe use of DME and supplies.
 - Hospice providers may:
 - Use persons under contract to ensure patient and family instruction.
 - Use persons under contract to ensure the maintenance and repair of durable medical equipment.
 - Patient/ caregiver/ family expectation:
 - 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.

*****Compliance suggestions for hospice providers*****

- Review and revise (as needed) program policy/procedure at least annually.
- Ensure documented evidence of all designated individual's education and training in drug management.
- Ensure that documentation of the ability of the patient and/or family to safely self-administer drugs and biologicals to the patient in his or her home is included in regular IDT meetings.
- Ensure compliance with state laws regarding ordering, labeling, disposing and storing of drugs and biologicals, as well as the administration of drugs and biologicals.
- Utilize state pharmacy boards for information related to drug distribution and disposal.
- Incorporate education about hospice aide requirements into your orientation program and continuing education for physicians, pharmacists, nurse practitioners, and nurses.
- ❖ **Please note that hospice providers need to comply with the most stringent regulatory requirements (Federal or State).**

Resources

- NHPCO's Regulatory & Compliance Center
 - [DEA Releases New Rules for Safe and Secure Prescription Drug Disposal](#) (Regulatory Alert, October 7, 2014)
 - [Drugs and Medications](#) webpage
 - [Boards of pharmacy](#)
 - [Disposal of Controlled Substances; Final Rule](#) (Federal Register, September 9, 2014)
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References

Part II - Department of Health and Human Services, Centers for Medicare & Medicaid Services

[42 CFR Part 418. Medicare and Medicaid Programs: Hospice Conditions of Participation; last update 2013](#)

Visit <http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR> to check for the most recent updates).