

information for each hospice patient and provides written certification that it is anticipated that the patient's life expectancy is 6 months or less if the illness runs its normal course. The physician must consider the following when making this determination:

- (1) The primary terminal condition;
- (2) Related diagnosis(es), if any;
- (3) Current subjective and objective medical findings;
- (4) Current medication and treatment orders; and
- (5) Information about the medical management of any of the patient's conditions unrelated to the terminal illness.

(c) *Standard: Recertification of the terminal illness.* Before the recertification period for each patient, as described in §418.21(a), the medical director or physician designee must review the patient's clinical information.

(d) *Standard: Medical director responsibility.* The medical director or physician designee has responsibility for the medical component of the hospice's patient care program.

§418.104 Condition of participation: Clinical records.

A clinical record containing past and current findings is maintained for each hospice patient. The clinical record must contain correct clinical information that is available to the patient's attending physician and hospice staff. The clinical record may be maintained electronically.

(a) *Standard: Content.* Each patient's record must include the following:

- (1) The initial plan of care, updated plans of care, initial assessment, comprehensive assessment, updated comprehensive assessments, and clinical notes.
- (2) Signed copies of the notice of patient rights in accordance with §418.52 and election statement in accordance with §418.24.
- (3) Responses to medications, symptom management, treatments, and services.
- (4) Outcome measure data elements, as described in §418.54(e) of this subpart.
- (5) Physician certification and recertification of terminal illness as required in §§418.22 and 418.25 and de-

scribed in §§418.102(b) and 418.102(c) respectively, if appropriate.

(6) Any advance directives as described in §418.52(a)(2).

(7) Physician orders.

(b) *Standard: Authentication.* All entries must be legible, clear, complete, and appropriately authenticated and dated in accordance with hospice policy and currently accepted standards of practice.

(c) *Standard: Protection of information.* The clinical record, its contents and the information contained therein must be safeguarded against loss or unauthorized use. The hospice must be in compliance with the Department's rules regarding personal health information as set out at 45 CFR parts 160 and 164.

(d) *Standard: Retention of records.* Patient clinical records must be retained for 6 years after the death or discharge of the patient, unless State law stipulates a longer period of time. If the hospice discontinues operation, hospice policies must provide for retention and storage of clinical records. The hospice must inform its State agency and its CMS Regional office where such clinical records will be stored and how they may be accessed.

(e) *Standard: Discharge or transfer of care.* (1) If the care of a patient is transferred to another Medicare/Medicaid-certified facility, the hospice must forward to the receiving facility, a copy of—

(i) The hospice discharge summary; and

(ii) The patient's clinical record, if requested.

(2) If a patient revokes the election of hospice care, or is discharged from hospice in accordance with §418.26, the hospice must forward to the patient's attending physician, a copy of—

(i) The hospice discharge summary; and

(ii) The patient's clinical record, if requested.

(3) The hospice discharge summary as required in paragraph (e)(1) and (e)(2) of this section must include—

(i) A summary of the patient's stay including treatments, symptoms and pain management.

(ii) The patient's current plan of care.

(iii) The patient's latest physician orders. and

(iv) Any other documentation that will assist in post-discharge continuity of care or that is requested by the attending physician or receiving facility.

(f) *Standard: Retrieval of clinical records.* The clinical record, whether hard copy or in electronic form, must 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