(B) Assess the capacity of the patient (or the patient’s caregiver/support person where appropriate) to self-administer the specified medication(s).

(C) Instruct the patient (or the patient’s caregiver/support person where appropriate) in the safe and accurate administration of the specified medication(s).

(D) Address the security of the medication(s) for each patient.

(E) Document the administration of each medication, as reported by the patient (or the patient’s caregiver/support person where appropriate), in the patient’s medical record.

(ii) If the hospital allows a patient to self-administer his or her own specific medications brought into the hospital, then the hospital must have policies and procedures in place to:

(A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration of medications the patient brought into the hospital.

(B) Assess the capacity of the patient (or the patient’s caregiver/support person where appropriate) to self-administer the specified medication(s), and also determine if the patient (or the patient’s caregiver/support person where appropriate) needs instruction in the safe and accurate administration of the specified medication(s).

(C) Identify the specified medication(s) and visually evaluate the medication(s) for integrity.

(D) Address the security of the medication(s) for each patient.

(E) Document the administration of each medication, as reported by the patient (or the patient’s caregiver/support person where appropriate), in the patient’s medical record.


§ 482.24 Condition of participation: Medical record services.

The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.

(a) Standard: Organization and staffing. The organization of the medical record service must be appropriate to the scope and complexity of the services performed. The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records.

(b) Standard: Form and retention of record. The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentification and protects the security of all record entries.

(1) Medical records must be retained in their original or legally reproduced form for a period of at least 5 years.

(2) The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.

(3) The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas.

(c) Standard: Content of record. The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient’s progress and response to medications and services.

(1) All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.

(2) All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who
§ 482.25 Condition of participation: Pharmaceutical services.

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital’s organized pharmaceutical service.

(a) Standard: Pharmacy management and administration. The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

(1) A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

(2) The pharmaceutical service must have an adequate number of personnel

(3) Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:

(i) Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital’s nursing and pharmacy leadership;

(ii) Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines;

(iii) Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff and the hospital’s nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols; and

(iv) Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient’s medical record by the ordering practitioner or another practitioner responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

(b) Standard: Medication administration and record keeping. The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

(1) A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

(2) The pharmaceutical service must have an adequate number of personnel

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