

issues localized to particular hospitals are duly considered and addressed.

(c) *Standard: Medical staff bylaws.* The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:

(1) Be approved by the governing body.

(2) Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.)

(3) Describe the organization of the medical staff.

(4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.

(5) Include a requirement that—

(i) A medical history and physical examination be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

(ii) An updated examination of the patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration. The updated examination of the patient, including any changes in the patient's condition, must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

(6) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. For distant-site physicians and practitioners requesting privileges to furnish telemedicine services under an agreement with the hos-

pital, the criteria for determining privileges and the procedure for applying the criteria are also subject to the requirements in § 482.12(a)(8) and (a)(9), and § 482.22(a)(3) and (a)(4).

(d) *Standard: Autopsies.* The medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. The mechanism for documenting permission to perform an autopsy must be defined. There must be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.

[51 FR 22042, June 17, 1986, as amended at 59 FR 64152, Dec. 13, 1994; 71 FR 68694, Nov. 27, 2006; 72 FR 66933, Nov. 27, 2007; 76 FR 25563, May 5, 2011; 77 FR 29074, May 16, 2012; 79 FR 27154, May 12, 2014]

§ 482.23 Condition of participation: Nursing services.

The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.

(a) *Standard: Organization.* The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

(b) *Standard: Staffing and delivery of care.* The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

(1) The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24-

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hour nursing waiver granted under § 488.54(c) of this chapter.

(2) The nursing service must have a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licensure.

(3) A registered nurse must supervise and evaluate the nursing care for each patient.

(4) The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient. The nursing care plan may be part of an interdisciplinary care plan.

(5) A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

(6) Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service.

(c) *Standard: Preparation and administration of drugs.* (1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under § 482.12(c), and accepted standards of practice.

(i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under § 482.12(c) only if such practitioners are acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

(ii) Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of § 482.24(c)(3).

(2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable

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licensing requirements, and in accordance with the approved medical staff policies and procedures.

(3) With the exception of influenza and pneumococcal vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy, and who is responsible for the care of the patient as specified under § 482.12(c).

(i) If verbal orders are used, they are to be used infrequently.

(ii) When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with Federal and State law.

(iii) Orders for drugs and biologicals may be documented and signed by other practitioners not specified under § 482.12(c) only if such practitioners are acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

(4) Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures.

(5) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

(6) The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures.

(i) If the hospital allows a patient to self-administer specific hospital-issued medications, 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.

(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.

[51 FR 22042, June 17, 1986, as amended at 67 FR 61814, Oct. 2, 2002; 71 FR 68694, Nov. 27, 2006; 72 FR 66933, Nov. 27, 2007; 77 FR 29074, May 16, 2012; 78 FR 50970, Aug. 19, 2013; 79 FR 44129, July 30, 2014]

§ 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 authentication 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