comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services.

(ii) Admitting diagnosis.

(iii) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.

(iv) Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.

(v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.

(vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.

(vii) Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow-up care.

(viii) Final diagnosis with completion of medical records within 30 days following discharge.

(d) *Standard: Electronic notifications.* If the hospital utilizes an electronic medical records system or other electronic administrative system, which is conformant with the content exchange standard at 45 CFR 170.205(d)(2), then the hospital must demonstrate that—

(1) The system's notification capacity is fully operational and the hospital uses it in accordance with all State and Federal statutes and regulations applicable to the hospital's exchange of patient health information.

(2) The system sends notifications that must include at least patient name, treating practitioner name, and sending institution name.

(3) To the extent permissible under applicable federal and state law and regulations, and not inconsistent with the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, at the time of:

(i) The patient's registration in the hospital's emergency department (if applicable).

(ii) The patient's admission to the hospital's inpatient services (if applicable).

(4) To the extent permissible under applicable federal and state law and regulations and not inconsistent with the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, either immediately prior to, or at the time of:

(i) The patient's discharge or transfer from the hospital's emergency department (if applicable).

(ii) The patient's discharge or transfer from the hospital's inpatient services (if applicable).

(5) The hospital has made a reasonable effort to ensure that the system sends the notifications to all applicable post-acute care services providers and suppliers, as well as to any of the following practitioners and entities, which need to receive notification of the patient's status for treatment, care coordination, or quality improvement purposes:

(i) The patient's established primary care practitioner;

(ii) The patient's established primary care practice group or entity; or

(iii) Other practitioner, or other practice group or entity, identified by the patient as the practitioner, or practice group or entity, primarily responsible for his or her care.

[51 FR 22042, June 17, 1986, as amended at 71 FR 68694, Nov. 27, 2006; 72 FR 66933, Nov. 27, 2007; 77 FR 29074, May 16, 2012; 84 FR 51819, Sept. 30, 2019; 85 FR 25637, May 1, 2020]

§ 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 to ensure quality pharmaceutical services, including emergency services.

(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.

(b) *Standard: Delivery of services.* In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

(1) All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.

(2)(i) All drugs and biologicals must be kept in a secure area, and locked when appropriate.

(ii) Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.

(iii) Only authorized personnel may have access to locked areas.

(3) Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

(4) When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.

(5) Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.

(6) Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital's quality assessment and performance improvement program.

(7) Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

(8) Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.

(9) A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986; 71 FR 68694, Nov. 27, 2006; 77 FR 29075, May 16, 2012]

§ 482.26 Condition of participation: Radiologic services.

The hospital must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.

(a) *Standard: Radiologic services.* The hospital must maintain, or have available, radiologic services according to needs of the patients.

(b) *Standard: Safety for patients and personnel.* The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

(1) Proper safety precutions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.

(2) Periodic inspection of equipment must be made and hazards identified must be promptly corrected.

(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.