

be made about whether to obtain HIV or HCV testing and counseling; and

(iii) A list of programs or places where the person can obtain HIV or HCV testing and counseling, including any requirements or restrictions the program may impose.

(9) *Policies and procedures.* The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for the confidentiality of medical records and other patient information.

(10) *Notification to legal representative or relative.* If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. For possible HIV infectious transfusion recipients that are deceased, the physician or hospital must inform the deceased patient's legal representative or relative. If the patient is a minor, the parents or legal guardian must be notified.

(11) *Applicability.* HCV notification requirements resulting from donors tested before February 20, 2008 as set forth at 21 CFR 610.48 will expire on August 24, 2015.

(c) *General blood safety issues.* For lookback activities only related to new blood safety issues that are identified after August 24, 2007, hospitals must comply with FDA regulations as they pertain to blood safety issues in the following areas:

(1) Appropriate testing and quarantining of infectious blood and blood components.

(2) Notification and counseling of recipients that may have received infectious blood and blood components.

[57 FR 7136, Feb. 28, 1992, as amended at 61 FR 47433, Sept. 9, 1996; 72 FR 48573, Aug. 24, 2007]

§ 482.28 Condition of participation: Food and dietetic services.

The hospital must have organized dietary services that are directed and staffed by adequate qualified per-

sonnel. However, a hospital that has a contract with an outside food management company may be found to meet this Condition of participation if the company has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.

(a) *Standard: Organization.* (1) The hospital must have a full-time employee who—

(i) Serves as director of the food and dietetic service;

(ii) Is responsible for the daily management of the dietary services; and

(iii) Is qualified by experience or training.

(2) There must be a qualified dietitian, full-time, part-time, or on a consultant basis.

(3) There must be administrative and technical personnel competent in their respective duties.

(b) *Standard: Diets.* Menus must meet the needs of the patients.

(1) Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the patients.

(2) Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patients.

(3) A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.

§ 482.30 Condition of participation: Utilization review.

The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.

(a) *Applicability.* The provisions of this section apply except in either of the following circumstances:

(1) A Utilization and Quality Control Quality Improvement Organization

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(QIO) has assumed binding review for the hospital.

(2) CMS has determined that the UR procedures established by the State under title XIX of the Act are superior to the procedures required in this section, and has required hospitals in that State to meet the UR plan requirements under §§ 456.50 through 456.245 of this chapter.

(b) *Standard: Composition of utilization review committee.* A UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathy. The other members may be any of the other types of practitioners specified in § 482.12(c)(1).

(1) Except as specified in paragraphs (b) (2) and (3) of this section, the UR committee must be one of the following:

(i) A staff committee of the institution;

(ii) A group outside the institution—

(A) Established by the local medical society and some or all of the hospitals in the locality; or

(B) Established in a manner approved by CMS.

(2) If, because of the small size of the institution, it is impracticable to have a properly functioning staff committee, the UR committee must be established as specified in paragraph (b)(1)(ii) of this section.

(3) The committee's or group's reviews may not be conducted by any individual who—

(i) Has a direct financial interest (for example, an ownership interest) in that hospital; or

(ii) Was professionally involved in the care of the patient whose case is being reviewed.

(c) *Standard: Scope and frequency of review.* (1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of—

(i) Admissions to the institution;

(ii) The duration of stays; and

(iii) Professional services furnished, including drugs and biologicals.

(2) Review of admissions may be performed before, at, or after hospital admission.

(3) Except as specified in paragraph (e) of this section, reviews may be conducted on a sample basis.

(4) Hospitals that are paid for inpatient hospital services under the prospective payment system set forth in Part 412 of this chapter must conduct review of duration of stays and review of professional services as follows:

(i) For duration of stays, these hospitals need review only cases that they reasonably assume to be outlier cases based on extended length of stay, as described in § 412.80(a)(1)(i) of this chapter; and

(ii) For professional services, these hospitals need review only cases that they reasonably assume to be outlier cases based on extraordinarily high costs, as described in § 412.80(a)(1)(ii) of this chapter.

(d) *Standard: Determination regarding admissions or continued stays.* (1) The determination that an admission or continued stay is not medically necessary—

(i) May be made by one member of the UR committee if the practitioner or practitioners responsible for the care of the patient, as specified of § 482.12(c), concur with the determination or fail to present their views when afforded the opportunity; and

(ii) Must be made by at least two members of the UR committee in all other cases.

(2) Before making a determination that an admission or continued stay is not medically necessary, the UR committee must consult the practitioner or practitioners responsible for the care of the patient, as specified in § 482.12(c), and afford the practitioner or practitioners the opportunity to present their views.

(3) If the committee decides that admission to or continued stay in the hospital is not medically necessary, written notification must be given, no later than 2 days after the determination, to the hospital, the patient, and the practitioner or practitioners responsible for the care of the patient, as specified in § 482.12(c);

(e) *Standard: Extended stay review.* (1) In hospitals that are not paid under the prospective payment system, the UR committee must make a periodic review, as specified in the UR plan, of

each current inpatient receiving hospital services during a continuous period of extended duration. The scheduling of the periodic reviews may—

- (i) Be the same for all cases; or
- (ii) Differ for different classes of cases.

(2) In hospitals paid under the prospective payment system, the UR committee must review all cases reasonably assumed by the hospital to be outlier cases because the extended length of stay exceeds the threshold criteria for the diagnosis, as described in § 412.80(a)(1)(i). The hospital is not required to review an extended stay that does not exceed the outlier threshold for the diagnosis.

(3) The UR committee must make the periodic review no later than 7 days after the day required in the UR plan.

(f) *Standard: Review of professional services.* The committee must review professional services provided, to determine medical necessity and to promote the most efficient use of available health facilities and services.

§ 482.41 Condition of participation: Physical environment.

The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.

(a) *Standard: Buildings.* The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.

(1) There must be emergency power and lighting in at least the operating, recovery, intensive care, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.

(2) There must be facilities for emergency gas and water supply.

(b) *Standard: Life safety from fire.* (1) Except as otherwise provided in this section—

(i) The hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Reg-

ister has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to hospitals.

(2) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects patients in hospitals.

(4) Beginning March 13, 2006, a hospital must be in compliance with Chapter 19.2.9, Emergency Lighting.

(5) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to hospitals.

(6) The hospital must have procedures for the proper routine storage and prompt disposal of trash.

(7) The hospital must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.

(8) The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies.