

§ 482.28

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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