

(2) If the facility chooses to refer specimens for laboratory testing, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the requirements of part 493 of this chapter.

[48 FR 56293, Dec. 15, 1982, as amended at 56 FR 8852, Mar. 1, 1991; 57 FR 7137, Feb. 28, 1992; 73 FR 69941, Nov. 19, 2008]

§ 485.60 Condition of participation: Clinical records.

The facility must maintain clinical records on all patients in accordance with accepted professional standards and practice. The clinical records must be completely, promptly, and accurately documented, readily accessible, and systematically organized to facilitate retrieval and compilation of information.

(a) *Standard: Content.* Each clinical record must contain sufficient information to identify the patient clearly and to justify the diagnosis and treatment. Entries in the clinical record must be made as frequently as is necessary to insure effective treatment and must be signed by personnel providing services. All entries made by assistant level personnel must be countersigned by the corresponding professional. Documentation on each patient must be consolidated into one clinical record that must contain—

(1) The initial assessment and subsequent reassessments of the patient's needs;

(2) Current plan of treatment;

(3) Identification data and consent or authorization forms;

(4) Pertinent medical history, past and present;

(5) A report of pertinent physical examinations if any;

(6) Progress notes or other documentation that reflect patient reaction to treatment, tests, or injury, or the need to change the established plan of treatment; and

(7) Upon discharge, a discharge summary including patient status relative to goal achievement, prognosis, and future treatment considerations.

(b) *Standard: Protection of clinical record information.* The facility must safeguard clinical record information against loss, destruction, or unauthor-

ized use. The facility must have procedures that govern the use and removal of records and the conditions for release of information. The facility must obtain the patient's written consent before releasing information not required to be released by law.

(c) *Standard: Retention and preservation.* The facility must retain clinical record information for 5 years after patient discharge and must make provision for the maintenance of such records in the event that it is no longer able to treat patients.

§ 485.62 Condition of participation: Physical environment.

The facility must provide a physical environment that protects the health and safety of patients, personnel, and the public.

(a) *Standard: Safety and comfort of patients.* The physical premises of the facility and those areas of its surrounding physical structure that are used by the patients (including at least all stairwells, corridors and passageways) must meet the following requirements:

(1) Applicable Federal, State, and local building, fire, and safety codes must be met.

(2) Fire extinguishers must be easily accessible and fire regulations must be prominently posted.

(3) A fire alarm system with local (in-house) capability must be functional, and where power is generated by electricity, an alternate power source with automatic triggering must be present.

(4) Lights, supported by an emergency power source, must be placed at exits.

(5) A sufficient number of staff to evacuate patients during a disaster must be on the premises of the facility whenever patients are being treated.

(6) Lighting must be sufficient to carry out services safely; room temperature must be maintained at comfortable levels; and ventilation through windows, mechanical means, or a combination of both must be provided.

(7) Safe and sufficient space must be available for the scope of services offered.

(b) *Standard: Sanitary environment.* The facility must maintain a sanitary environment and establish a program

§ 485.64

42 CFR Ch. IV (10–1–11 Edition)

to identify, investigate, prevent, and control the cause of patient infections.

(1) The facility must establish written policies and procedures designed to control and prevent infection in the facility and to investigate and identify possible causes of infection.

(2) The facility must monitor the infection control program to ensure that the staff implement the policies and procedures and that the policies and procedures are consistent with current practices in the field.

(3) The facility must make available at all times a quantity of laundered linen adequate for proper care and comfort of patients. Linens must be handled, stored, and processed in a manner that prevents the spread of infection.

(4) Provisions must be in effect to ensure that the facility's premises are maintained free of rodent and insect infestation.

(c) *Standard: Maintenance of equipment, physical location, and grounds.* The facility must establish a written preventive maintenance program to ensure that—

(1) All equipment is properly maintained and equipment needing periodic calibration is calibrated consistent with the manufacturer's recommendations; and

(2) The interior of the facility, the exterior of the physical structure housing the facility, and the exterior walkways and parking areas are clean and orderly and maintained free of any defects that are a hazard to patients, personnel, and the public.

(d) *Standard: Access for the physically impaired.* The facility must ensure the following:

(1) Doorways, stairwells, corridors, and passageways used by patients are—

(i) Of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs); and

(ii) In the case of stairwells, equipped with firmly attached handrails on at least one side.

(2) At least one toilet facility is accessible and constructed to allow utilization by ambulatory and non-ambulatory individuals.

(3) At least one entrance is usable by individuals in wheelchairs.

(4) In multi-story buildings, elevators are accessible to and usable by the physically impaired on the level that they use to enter the building and all levels normally used by the patients of the facility.

(5) Parking spaces are large enough and close enough to the facility to allow safe access by the physically impaired.

§ 485.64 Condition of participation: Disaster procedures.

The facility must have written policies and procedures that specifically define the handling of patients, personnel, records, and the public during disasters. All personnel associated with the facility must be knowledgeable with respect to these procedures, be trained in their application, and be assigned specific responsibilities.

(a) *Standard: Disaster plan.* The facility's written disaster plan must be developed and maintained with assistance of qualified fire, safety, and other appropriate experts. The plan must include—

(1) Procedures for prompt transfer of casualties and records;

(2) Procedures for notifying community emergency personnel (for example, fire department, ambulance, etc.);

(3) Instructions regarding the location and use of alarm systems and signals and fire fighting equipment; and

(4) Specification of evacuation routes and procedures for leaving the facility.

(b) *Standard: Drills and staff training.*

(1) The facility must provide ongoing training and drills for all personnel associated with the facility in all aspects of disaster preparedness.

(2) All new personnel must be oriented and assigned specific responsibilities regarding the facility's disaster plan within two weeks of their first workday.

§ 485.66 Condition of participation: Utilization review plan.

The facility must have in effect a written utilization review plan that is implemented at least each quarter, to assess the necessity of services and promotes the most efficient use of services provided by the facility.