

§ 485.725

windows, mechanical means, or a combination of both.

(2) Toilet rooms, toilet stalls, and lavatories are accessible and constructed so as to allow use by non-ambulatory and semiambulatory individuals.

(3) Whatever the size of the building, there is an adequate amount of space for the services provided and disabilities treated, including reception area, staff space, examining room, treatment areas, and storage.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326-2328, Jan. 9, 1995]

§ 485.725 Condition of participation: Infection control.

The organization that provides outpatient physical therapy services establishes an infection-control committee of representative professional staff with responsibility for overall infection control. All necessary housekeeping and maintenance services are provided to maintain a sanitary and comfortable environment and to help prevent the development and transmission of infection.

(a) *Standard: Infection-control committee.* The infection-control committee establishes policies and procedures for investigating, controlling, and preventing infections in the organization and monitors staff performance to ensure that the policies and procedures are executed.

(b) All personnel follow written procedures for effective aseptic techniques. The procedures are reviewed annually and revised if necessary to improve them.

(c) *Standard: Housekeeping.* (1) The organization employs sufficient housekeeping personnel and provides all necessary equipment to maintain a safe, clean, and orderly interior. A full-time employee is designated as the one responsible for the housekeeping services and for supervision and training of housekeeping personnel.

(2) An organization that has a contract with an outside resource for housekeeping services may be found to be in compliance with this standard provided the organization or outside resource or both meet the requirements of the standard.

42 CFR Ch. IV (10-1-06 Edition)

(d) *Standard: Linen.* The organization has available at all times a quantity of linen essential for proper care and comfort of patients. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

(e) *Standard: Pest control.* The organization's premises are maintained free from insects and rodents through operation of a pest-control program.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, 2328, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.727 Condition of participation: Disaster preparedness.

The organization has a written plan, periodically rehearsed, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from a disaster.

(a) *Standard: Disaster plan.* The organization has a written plan in operation, with procedures to be followed in the event of fire, explosion, or other disaster. The plan is developed and maintained with the assistance of qualified fire, safety, and other appropriate experts, and includes:

- (1) Transfer of casualties and records;
- (2) The location and use of alarm systems and signals;
- (3) Methods of containing fire;
- (4) Notification of appropriate persons; and
- (5) Evacuation routes and procedures.

(b) *Standard: Staff training and drills.* All employees are trained, as part of their employment orientation, in all aspects of preparedness for any disaster. The disaster program includes orientation and ongoing training and drills for all personnel in all procedures so that each employee promptly and correctly carries out his assigned role in case of a disaster.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988. Redesignated and amended at 60 FR 2326-2327, 2329, Jan. 9, 1995]

§ 485.729 Condition of participation: Program evaluation.

The organization has procedures that provide for a systematic evaluation of its total program to ensure appropriate

utilization of services and to determine whether the organization's policies are followed in providing services to patients through employees or under arrangements with others.

(a) *Standard: Clinical-record review.* A sample of active and closed clinical records is reviewed quarterly by the appropriate health professionals to ensure that established policies are followed in providing services.

(b) *Standard: Annual statistical evaluation.* An evaluation is conducted annually of statistical data such as number of different patients treated, number of patient visits, condition on admission and discharge, number of new patients, number of patients by diagnosis(es), sources of referral, number and cost of units of service by treatment given, and total staff days or work hours by discipline.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326-2327, 2329, Jan. 9, 1995]

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

Subpart A—General Provisions

Sec.

486.1 Basis and scope.

Subpart B [Reserved]

Subpart C—Conditions for Coverage: Portable X-Ray Services

- 486.100 Condition for coverage: Compliance with Federal, State, and local laws and regulations.
- 486.102 Condition for coverage: Supervision by a qualified physician.
- 486.104 Condition for coverage: Qualifications, orientation, and health of technical personnel.
- 486.106 Condition for coverage: Referral for service and preservation of records.
- 486.108 Condition for coverage: Safety standards.
- 486.110 Condition for coverage: Inspection of equipment.

Subparts D–F [Reserved]

Subpart G—Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations

- 486.301 Basis and scope.
- 486.302 Definitions.

REQUIREMENTS FOR CERTIFICATION AND DESIGNATION

- 486.303 Requirements for certification.
- 486.304 Requirements for designation.
- 486.306 OPO service area size designation and documentation requirements.
- 486.308 Designation of one OPO for each service area.
- 486.309 Re-certification from August 1, 2006 through July 31, 2010.
- 486.310 Changes in control or ownership or service area.

Re-certification and De-certification

- 486.312 De-certification.
- 486.314 Appeals.
- 486.316 Re-certification and competition processes.

ORGAN PROCUREMENT ORGANIZATION OUTCOME REQUIREMENTS

- 486.318 Condition: Outcome measures.

ORGAN PROCUREMENT ORGANIZATION PROCESS PERFORMANCE MEASURES

- 486.320 Condition: Participation in Organ Procurement and Transplantation Network.
- 486.322 Condition: Relationships with hospitals, critical access hospitals, and tissue banks.
- 486.324 Condition: Administration and governing body.
- 486.326 Condition: Human resources.
- 486.328 Condition: Reporting of data.
- 486.330 Condition: Information management.
- 486.342 Condition: Requesting consent.
- 486.344 Condition: Evaluation and management of potential donors and organ placement and recovery.
- 486.346 Condition: Organ preparation and transport.
- 486.348 Condition: Quality assessment and performance improvement (QAPI).

AUTHORITY: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b-8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C. 273).