

§ 486.163

(1) That determined by the respective State statute or the statute of limitations in the State, or

(2) In the absence of a State statute: (i) 5 years after the date of discharge or, (ii) in the case of a minor, 3 years after the patient becomes of age under State law, or 5 years after the date of discharge, whichever is longer.

(e) *Standard: Indexes.* Clinical records are indexed at least according to name of patient to facilitate acquisition of statistical clinical information and retrieval of records for administrative action.

[41 FR 20865, May 21, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated and amended at 60 FR 2326, 2329, Jan. 9, 1995]

§ 486.163 Condition for coverage—physical environment.

The physical environment of the office or facility of the physical therapist in independent practice affords a functional, sanitary, safe, and comfortable surrounding for patients, personnel, and the public.

(a) *Standard: Building construction.* The construction of the building housing the physical therapy office meets all applicable State and local building, fire, and safety codes.

(b) *Standard: Maintenance of the physical therapy office and equipment.* There is a written preventive-maintenance program to ensure that equipment is operative and that the physical therapy office is clean and orderly. All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition, and is properly calibrated.

(c) *Standard: Other environmental considerations.* The building housing the physical therapy office is accessible to, and functional for, patients, personnel, and the public. Written effective procedures in aseptic techniques are followed by all personnel and the procedures are reviewed annually, and when necessary, revised.

(d) The physical therapist is alert to the possibility of fire and other non-medical emergencies and has written plans that include—

(1) The means for leaving the office and the building safely, demonstrated, for example, by fire exit signs; and

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(2) Other provisions necessary to ensure the safety of patients.

[41 FR 20865, May 21, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated and amended at 60 FR 2326, 2329, Jan. 9, 1995]

Subparts E-F [Reserved]

Subpart G—Conditions for Coverage: Organ Procurement Organizations

SOURCE: 53 FR 6549, Mar. 1, 1988, unless otherwise noted. Redesignated at 60 FR 50447, Sept. 29, 1995.

§ 486.301 Basis and scope.

(a) *Statutory Basis.* (1) Section 1138(b) of the Act sets forth the requirements that an organ procurement organization must meet to have its organ procurement services to hospitals covered under Medicare and Medicaid. These include certification as a “qualified” organ procurement organization (OPO) and designation as the OPO for a particular service area.

(2) Section 371(b) of the PHS Act sets forth the requirements for certification and the functions that a qualified OPO is expected to perform.

(b) *Scope.* This subpart sets forth—

(1) The conditions and requirements that an OPO must meet;

(2) The procedures for certification and designation of OPOs; and

(3) The terms of the agreement with HCFA, and the basis for, and the effect of, termination of the agreement.

[61 FR 19743, May 2, 1996]

§ 486.302 Definitions.

As used in this subpart, the following definitions apply:

Certification or *recertification* means a HCFA determination that an entity meets the standards for a *qualified OPO* at § 486.304 of this subpart and is eligible for designation if it meets the additional conditions for designation at §§ 486.306 and 486.308. No payment ensues from certification alone.

Designation or *redesignation* means HCFA approval of an OPO for Medicare and Medicaid payment purposes under section 1138(b)(1)(F) of the Act. The