

## § 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 CMS, and the basis for, and the effect of, termination of the agreement.

(4) The requirements for an OPO to be recertified for the performance data cycle from January 1, 2002 through December 31, 2005.

[61 FR 19743, May 2, 1996, as amended at 66 FR 67111, Dec. 28, 2001]

#### § 486.302 Definitions.

As used in this subpart, the following definitions apply:

*Certification* or *recertification* means a CMS 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 CMS approval of an OPO for Medicare and Medicaid payment purposes under section 1138(b)(1)(F) of the Act. The terms are used interchangeably except when otherwise specifically indicated.

*Entire standard metropolitan statistical area* means a metropolitan statistical area, a consolidated metropolitan statistical area, or a primary statistical area listed in the State and Metropolitan Area Data Book published by the U.S. Bureau of the Census.

*Open area* means a service area for which CMS has notified the public that it is accepting applications for designation.

*Organ* means a human kidney, liver, heart, lung, pancreas, or intestines (or multivisceral organs).

*Organ procurement organization* means an organization that performs or coordinates the performance of retrieving, preserving and transporting organs and maintains a system of locating prospective recipients for available organs.

*Potential donor* means a person who dies in circumstances (causes and conditions of death, and age at death) that are generally acceptable for donation of at least one solid organ if the donor can be identified timely and permission for donation can be obtained.

*Service area* means a geographical area of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs and that either includes an entire standard metropolitan statistical area or does not include any part of such an area and that meets the standards of this subpart.

*Transplant center* means a hospital certified by Medicare to furnish directly, for a specific organ(s), transplant and other medical and surgical specialty services required for the care of transplant patients.

[53 FR 6549, Mar. 1, 1988, as amended at 59 FR 46514, Sept. 8, 1994. Redesignated and amended at 60 FR 50447, 50448, Sept. 29, 1995; 66 FR 39938, Aug. 1, 2001]

#### § 486.304 General requirements.

(a) *Designation—a condition for payment.* Payment may be made under the Medicare and Medicaid programs for organ procurement costs attributable

to payments made by an OPO only if the organization has been designated by the Secretary as an OPO, payment to which may be treated as organ procurement costs for reimbursement of hospitals under Medicare and Medicaid.

(b) *Requirements for designated status.* To be the designated OPO for a service area, an entity must do the following:

(1) Submit to CMS a written application for designation, using the application form prescribed by CMS.

(2) Be certified as a qualified OPO.

(3) Participate in the Organ Procurement and Transplantation Network as specified in § 486.308.

(4) Enter into an agreement with CMS that meets the requirements set forth in paragraph (c) of this section.

(5) Upon its initial designation, meet the requirements at § 486.310(a)(3) or § 486.310(b)(4), as appropriate, concerning working relationships with hospitals or transplant centers. During the initial designation period, the OPO is not required to demonstrate compliance with §§ 486.310(a)(1) and (a)(2) or § 486.310(b)(1), which set forth performance standards for OPOs.

(6) To be redesignated after an initial designation period, comply with all the requirements of this subpart, including those at § 486.310, which set forth performance standards for OPOs.

(7) Obtain CMS approval before entering into any change of ownership, merger, consolidation, or change in its service area (see § 486.318, which sets forth requirements concerning approval for changes in ownership and service area). Failure to do so could result in termination.

(8) Enter into a working relationship with any hospitals, including transplant centers, in the OPO's service area that request a working relationship.

(c) *Agreement with CMS.* An OPO must enter into an agreement with CMS. The agreement is effective upon submission by the OPO and acceptance by CMS, but may be terminated by either party. If an OPO agreement is terminated, payment for organ procurement services attributable to that OPO will not be made for services furnished on or after the effective date of termination. In the agreement, the OPO must agree to do the following: