

therapist who furnishes the services promptly notifies him or her of any change in the patient's condition or in the plan of care. (For Medicare patients, the plan must be reviewed by a physician in accordance with § 410.61(e).)

[54 FR 38679, Sept. 20, 1989. Redesignated and amended at 60 FR 2326, 2329, Jan. 9, 1995]

§ 486.157 Condition for coverage: Physical therapy services.

The physical therapist in independent practice provides an adequate program of physical therapy services and has the facilities and equipment necessary to carry out the services offered.

(a) *Standard: Adequate program.* The physical therapist will be considered to have an adequate physical therapy program when services can be provided, utilizing therapeutic exercise and the modalities of heat, cold, water, and electricity; patient evaluations are conducted; and tests and measurements of strength, balance, endurance, range of motion, and activities of daily living are administered.

(b) *Standard: Supervision of physical therapy services.* Physical therapy services are provided by, or under the supervision of, a qualified physical therapist.

[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]

§ 486.159 Condition for coverage: Coordination of services with other organizations, agencies, or individuals.

The physical therapist coordinates her physical therapy services with the health and medical services the patient receives from organizations or agencies or other individual practitioners through exchange of information that meets the following standard:

If a patient is receiving or has recently received, from other sources, services related to the physical therapy program, the physical therapist exchanges pertinent documented information with those other sources—

(a) On a regular basis;

(b) Subject to the requirements for protection of the confidentiality of

medical records, as set forth in § 485.721 of this chapter; and

(c) With the aim of ensuring that the services effectively complement one another.

[60 FR 2329, Jan. 9, 1995]

§ 486.161 Condition for coverage: Clinical records.

The physical therapist in independent practice maintains clinical records on all patients in accordance with accepted professional standards and practices. The clinical records are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.

(a) *Standard: Protection of clinical record information.* Clinical-record information is recognized as confidential and is safeguarded against loss, destruction, or unauthorized use. Written procedures govern use and removal of records and include conditions for release of information. A patient's written consent is required for release of information not authorized by law.

(b) *Standard: Content.* The clinical record contains sufficient information to identify the patient clearly, to justify the diagnosis(es) and treatment, and to document the results accurately. All clinical records contain the following general categories of data:

(1) Documented evidence of the assessment of the needs of the patient, of an appropriate plan of care, and of the care and services provided,

(2) Identification data and consent forms,

(3) Medical history,

(4) Report of physical examination(s), if any,

(5) Observations and progress notes,

(6) Reports of treatments and clinical findings, and

(7) Discharge summary including final diagnosis(es) and prognosis.

(c) *Standard: Completion of records and centralization of reports.* Current clinical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's clinical record.

(d) *Standard: Retention and preservation.* Clinical records are retained for a period of time not less than:

§ 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

42 CFR Ch. IV (10–1–04 Edition)

(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.