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**Title 42: Public Health**

[PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS](#)

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**Subpart H—Conditions of Participation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services**

**§ 485.701 Basis and scope.**

This subpart implements section 1861(p)(4) of the Act, which—

- (a) Defines outpatient physical therapy and speech pathology services;
- (b) Imposes requirements with respect to adequate program, facilities, policies, staffing, and clinical records; and
- (c) Authorizes the Secretary to establish by regulation other health and safety requirements.

[60 FR 2327, Jan. 9, 1995]

**§ 485.703 Definitions.**

*Clinic.* A facility that is established primarily to furnish outpatient physician services and that meets the following tests of physician involvement:

- (1) The medical services are furnished by a group of three or more physicians practicing medicine together.
- (2) A physician is present during all hours of operation of the clinic to furnish medical services, as distinguished from purely administrative services.

*Extension location.* A location or site from which a rehabilitation agency provides services within a portion of the total geographic area served by the primary site. The extension location is part of the rehabilitation agency. The extension location should be located sufficiently close

to share administration, supervision, and services in a manner that renders it unnecessary for the extension location to independently meet the conditions of participation as a rehabilitation agency.

*Organization.* A clinic, rehabilitation agency, or public health agency.

*Public health agency.* An official agency established by a State or local government, the primary function of which is to maintain the health of the population served by performing environmental health services, preventive medical services, and in certain cases, therapeutic services.

*Rehabilitation agency.* An agency that—

(1) Provides an integrated interdisciplinary rehabilitation program designed to upgrade the physical functioning of handicapped disabled individuals by bringing specialized rehabilitation staff together to perform as a team; and

(2) Provides at least physical therapy or speech-language pathology services.

*Supervision.* Authoritative procedural guidance that is for the accomplishment of a function or activity and that—

(1) Includes initial direction and periodic observation of the actual performance of the function or activity; and

(2) Is furnished by a qualified person—

(i) Whose sphere of competence encompasses the particular function or activity; and

(ii) Who (unless otherwise provided in this subpart) is on the premises if the person performing the function or activity does not meet the assistant-level practitioner qualifications specified in §485.705.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988; 54 FR 38679, Sept. 20, 1989. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995; 73 FR 69941, Nov. 19, 2008]

#### **§ 485.705 Personnel qualifications.**

(a) *General qualification requirements.* Except as specified in paragraphs (b) and (c) of this section, all personnel who are involved in the furnishing of outpatient physical therapy, occupational therapy, and speech-language pathology services directly by or under arrangements with an organization must be legally authorized (licensed or, if applicable, certified or registered) to practice by the State in which they perform the functions or actions,

and must act only within the scope of their State license or State certification or registration.

(b) *Exception for Federally defined qualifications.* The following Federally defined qualifications must be met:

(1) For a physician, the qualifications and conditions as defined in section 1861(r) of the Act and the requirements in part 484 of this chapter.

(2) For a speech-language pathologist, the qualifications specified in section 1861(11)(1) of the Act and the requirements in part 484 of this chapter.

(c) *Exceptions when no State Licensing laws or State certification or registration requirements exist.* If no State licensing laws or State certification or registration requirements exist for the profession, the following requirements must be met—

(1) An *administrator* is a person who has a bachelor's degree and:

(i) Has experience or specialized training in the administration of health institutions or agencies; or

(ii) Is qualified and has experience in one of the professional health disciplines.

(2) An *occupational therapist* must meet the requirements in part 484 of this chapter.

(3) An *occupational therapy assistant* must meet the requirements in part 484 of this chapter.

(4) A *physical therapist* must meet the requirements in part 484 of this chapter.

(5) A *physical therapist assistant* must meet the requirements in part 484 of this chapter.

(6) A *social worker* must meet the requirements in part 484 of this chapter.

(7) A *vocational specialist* is a person who has a baccalaureate degree and—

(i) Two years experience in vocational counseling in a rehabilitation setting such as a sheltered workshop, State employment service agency, etc.; or

(ii) At least 18 semester hours in vocational rehabilitation, educational or vocational guidance, psychology, social work, special education or personnel administration, and 1 year of experience in vocational counseling in a rehabilitation setting; or

(iii) A master's degree in vocational counseling.

(8) A nurse practitioner is a person who must:

(i) Be a registered professional nurse who is authorized by the State in which the services are

turned to practice as a nurse practitioner in accordance with State law; *and*

(ii) Be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners; *or*

(iii) Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law and have been granted a Medicare billing number as a nurse practitioner by December 31, 2000; *or*

(iv) Be a nurse practitioner who on or after January 1, 2001, applies for a Medicare billing number for the first time and meets the standards for nurse practitioners in paragraphs (c)(8)(i) and (c)(8)(ii) of this section; *or*

(v) Be a nurse practitioner who on or after January 1, 2003, applies for a Medicare billing number for the first time and possesses a master's degree in nursing and meets the standards for nurse practitioners in paragraphs (b)(1)(i) and (b)(1)(ii) of this section.

(9) *A clinical nurse specialist* is a person who must:

(i) Be a registered nurse who is currently licensed to practice in the State where he or she practices and be authorized to perform the services of a clinical nurse specialist in accordance with State law;

(ii) Have a master's degree in a defined clinical area of nursing from an accredited educational institution; and,

(iii) Be certified as a clinical nurse specialist by the American Nurses Credentialing Center.

(10) *A physician assistant* is a person who:

(i) Has graduated from a physician assistant educational program that is accredited by the Commission on Accreditation of Allied Health Education Programs; or

(ii) Has passed the national certification examination that is administered by the National Commission on Certification of Physician Assistants; and

(iii) Is licensed by the State to practice as a physician assistant.

[63 FR 58912, Nov. 2, 1998; 64 FR 25457, May 12, 1999; 64 FR 59442, Nov. 2, 1999]

**§ 485.707 Condition of participation: Compliance with Federal, State, and local laws.**

The organization and its staff are in compliance with all applicable Federal, State, and local laws and regulations.

(a) *Standard: Licensure of organization.* In any State in which State or applicable local law

provides for the licensing of organizations, a clinic, rehabilitation agency, or public health agency is licensed in accordance with applicable laws.

(b) *Standard: Licensure or registration of personnel.* Staff of the organization are licensed or registered in accordance with applicable laws.

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

**§ 485.709 Condition of participation: Administrative management.**

The clinic or rehabilitation agency has an effective governing body that is legally responsible for the conduct of the clinic or rehabilitation agency. The governing body designates an administrator, and establishes administrative policies.

(a) *Standard: Governing body.* There is a governing body (or designated person(s) so functioning) which assumes full legal responsibility for the overall conduct of the clinic or rehabilitation agency and for compliance with applicable laws and regulations. The name of the owner(s) of the clinic or rehabilitation agency is fully disclosed to the State agency. In the case of corporations, the names of the corporate officers are made known.

(b) *Standard: Administrator.* The governing body—

(1) Appoints a qualified full-time administrator;

(2) Delegates to the administrator the internal operation of the clinic or rehabilitation agency in accordance with written policies;

(3) Defines clearly the administrator's responsibilities for procurement and direction of personnel; and

(4) Designates a competent individual to act during temporary absence of the administrator.

(c) *Standard: Personnel policies.* Personnel practices are supported by appropriate written personnel policies that are kept current. Personnel records include the qualifications of all professional and assistant level personnel, as well as evidence of State licensure if applicable.

(d) *Standard: Patient care policies.* Patient care practices and procedures are supported by written policies established by a group of professional personnel including one or more physicians associated with the clinic or rehabilitation agency, one or more qualified physical therapists (if physical therapy services are provided), and one or more qualified speech pathologists (if speech pathology services are provided). The policies govern the outpatient

physical therapy and/or speech pathology services and related services that are provided. These policies are evaluated at least annually by the group of professional personnel, and

revised as necessary based upon this evaluation.

[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, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

**§ 485.711 Condition of participation: Plan of care and physician involvement.**

For each patient in need of outpatient physical therapy or speech pathology services, there is a written plan of care established and periodically reviewed by a physician, or by a physical therapist or speech pathologist respectively.

(a) *Standard: Medical history and prior treatment.* The following are obtained by the organization before or at the time of initiation of treatment:

- (1) The patient's significant past history.
- (2) Current medical findings, if any.
- (3) Diagnosis(es), if established.
- (4) Physician's orders, if any.
- (5) Rehabilitation goals, if determined.
- (6) Contraindications, if any.
- (7) The extent to which the patient is aware of the diagnosis(es) and prognosis.
- (8) If appropriate, the summary of treatment furnished and results achieved during previous periods of rehabilitation services or institutionalization.

(b) *Standard: Plan of care.* (1) For each patient there is a written plan of care established by the physician or by the physical therapist or speech-language pathologist who furnishes the services.

(2) The plan of care for physical therapy or speech pathology services indicates anticipated goals and specifies for those services the—

- (i) Type;
- (ii) Amount;
- (iii) Frequency; and
- (iv) Duration.

(3) The plan of care and results of treatment are reviewed by the physician or by the individual who established the plan at least as often as the patient's condition requires, and the indicated action is taken.

(4) Changes in the plan of care are noted in the clinical record. If the patient has an attending physician, the therapist or speech-language pathologist who furnishes the services promptly notifies him or her of any change in the patient's condition or in the plan of care.

(c) *Standard: Emergency care.* The rehabilitation agency must establish procedures to be followed by personnel in an emergency, which cover immediate care of the patient, persons to be notified, and reports to be prepared.

[54 FR 38679, Sept. 20, 1989. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 63 FR 58913, Nov. 2, 1998; 73 FR 69941, Nov. 19, 2008]

**§ 485.713 Condition of participation: Physical therapy services.**

If the organization offers physical therapy services, it provides an adequate program of physical therapy and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.

(a) *Standard: Adequate program.* (1) The organization is considered to have an adequate outpatient physical therapy program if it can:

(i) Provide services using therapeutic exercise and the modalities of heat, cold, water, and electricity;

(ii) Conduct patient evaluations; and

(iii) Administer tests and measurements of strength, balance, endurance, range of motion, and activities of daily living.

(2) A qualified physical therapist is present or readily available to offer supervision when a physical therapist assistant furnishes services.

(i) If a qualified physical therapist is not on the premises during all hours of operation, patients are scheduled so as to ensure that the therapist is present when special skills are needed, for example, for evaluation and reevaluation.

(ii) When a physical therapist assistant furnishes services off the organization's premises, those services are supervised by a qualified physical therapist who makes an onsite supervisory visit at least once every 30 days.

(b) *Standard: Facilities and equipment.* The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of disabilities

it accepts for service.

(c) *Standard: Personnel qualified to provide physical therapy services.* Physical therapy services are provided by, or under the supervision of, a qualified physical therapist. The number of qualified physical therapists and qualified physical therapist assistants is adequate for the volume and diversity of physical therapy services offered. A qualified physical therapist is on the premises or readily available during the operating hours of the organization.

(d) *Standard: Supportive personnel.* If personnel are available to assist qualified physical therapists by performing services incident to physical therapy that do not require professional knowledge and skill, these personnel are instructed in appropriate patient care services by qualified physical therapists who retain responsibility for the treatment prescribed by the attending physician.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

**§ 485.715 Condition of participation: Speech pathology services.**

If speech pathology services are offered, the organization provides an adequate program of speech pathology and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.

(a) *Standard: Adequate program.* The organization is considered to have an adequate outpatient speech pathology program if it can provide the diagnostic and treatment services to effectively treat speech disorders.

(b) *Standard: Facilities and equipment.* The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of speech disorders it accepts for service.

(c) *Standard: Personnel qualified to provide speech pathology services.* Speech pathology services are given or supervised by a qualified speech pathologist and the number of qualified speech pathologists is adequate for the volume and diversity of speech pathology services offered. At least one qualified speech pathologist is present at all times when speech pathology services are furnished.

[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]

**§ 485.717 Condition of participation: Rehabilitation program.**

This condition and standards apply only to a rehabilitation agency's own patients, not to patients of hospitals, skilled nursing facilities (SNFs), or Medicaid nursing facilities (NFs) to



which the agency furnishes services. The hospital, SNF, or NF is responsible for ensuring that qualified staff furnish services for which they arrange or contract for their patients. The rehabilitation agency provides physical therapy and speech-language pathology services to all of its patients who need them.

(a) *Standard: Qualification of staff.* The agency's therapy services are furnished by qualified individuals as direct services and/or services provided under contract.

(b) *Standard: Arrangements for services.* If services are provided under contract, the contract must specify the term of the contract, the manner of termination or renewal and provide that the agency retains responsibility for the control and supervision of the services.

[73 FR 69942, Nov. 19, 2008]

**§ 485.719 Condition of participation: Arrangements for physical therapy and speech pathology services to be performed by other than salaried organization personnel.**

(a) *Conditions.* If an organization provides outpatient physical therapy or speech pathology services under an arrangement with others, the services are to be furnished in accordance with the terms of a written contract, which provides that the organization retains of professional and administrative responsibility for, and control and supervision of, the services.

(b) *Standard: Contract provisions.* The contract—

(1) Specifies the term of the contract and the manner of termination or renewal;

(2) Requires that personnel who furnish the services meet the requirements that are set forth in this subpart for salaried personnel; and

(3) Provides that the contracting outside resource may not bill the patient or Medicare for the services. This limitation is based on section 1861(w)(1) of the Act, which provides that—

(i) Only the provider may bill the beneficiary for covered services furnished under arrangements; and

(ii) Receipt of Medicare payment by the provider, on behalf of an entitled individual, discharges the liability of the individual or any other person to pay for those services.

[56 FR 46562, Sept. 13, 1991. Redesignated and amended at 60 FR 2326, 2328, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

**§ 485.721 Condition of participation: Clinical records.**

The organization 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.* The organization recognizes the confidentiality of clinical record information and provides safeguards against loss, destruction, or unauthorized use. Written procedures govern the use and removal of records and the conditions for release of information. The 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 furnished.

(2) Identification data and consent forms.

(3) Medical history.

(4) Report of physical examinations, if any.

(5) Observations and progress notes.

(6) Reports of treatments and clinical findings.

(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. Each physician signs the entries that he or she makes in the clinical record.

(d) *Standard: Retention and preservation.* Clinical records are retained for at least:

(1) The period determined by the respective State statute, or the statute of limitations in the State; or

(2) In the absence of a State statute—

(i) Five 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 medical information and retrieval of records for research or administrative action.

(f) *Standard: Location and facilities.* The organization maintains adequate facilities and equipment, conveniently located, to provide efficient processing of clinical records (reviewing, indexing, filing, and prompt retrieval).

[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]

**§ 485.723 Condition of participation: Physical environment.**

The building housing the organization is constructed, equipped, and maintained to protect the health and safety of patients, personnel, and the public and provides a functional, sanitary, and comfortable environment.

(a) *Standard: Safety of patients.* The organization satisfies the following requirements:

(1) It complies with all applicable State and local building, fire, and safety codes.

(2) Permanently attached automatic fire-extinguishing systems of adequate capacity are installed in all areas of the premises considered to have special fire hazards. Fire extinguishers are conveniently located on each floor of the premises. Fire regulations are prominently posted.

(3) Doorways, passageways and stairwells negotiated by patients are:

(i) Of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs), (ii) free from obstruction at all times, and (iii) in the case of stairwells, equipped with firmly attached handrails on at least one side.

(4) Lights are placed at exits and in corridors used by patients and are supported by an emergency power source.

(5) A fire alarm system with local alarm capability and, where applicable, an emergency power source, is functional.

(6) At least two persons are on duty on the premises of the organization whenever a patient is being treated.

(7) No occupancies or activities undesirable or injurious to the health and safety of patients are located in the building.

(b) *Standard: Maintenance of equipment, building, and grounds.* The organization establishes a written preventive-maintenance program to ensure that—

(1) The equipment is operative, and is properly calibrated; and

(2) The interior and exterior of the building are clean and orderly and maintained free of any defects that are a potential hazard to patients, personnel, and the public.

(c) *Standard: Other environmental considerations.* The organization provides a functional, sanitary, and comfortable environment for patients, personnel, and the public.

(1) Provision is made for adequate and comfortable lighting levels in all areas; limitation of sounds at comfort levels; a comfortable room temperature; and adequate ventilation through 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 nonambulatory 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.

(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]

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