(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.


§ 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).


§ 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
§ 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

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