

# State Operations Manual

## Appendix E - Guidance to Surveyors: Outpatient Physical Therapy or Speech Pathology Services

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*(Rev. 16, 01-10-06)*

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## ***I-7***

***(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)***

### **§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 - General***

In order to assure that the clinic, rehabilitation agency, or public health agency and staff are in possession of current licenses as required by Federal, State and local laws, licenses should be available for review. Compliance with this Condition may have a direct bearing on other Conditions; e.g., physical therapy services (§[485.713](#)), speech pathology services (§[485.715](#)), rehabilitation program (§[485.717](#)), and physical environment (§[485.723](#)).

Review the licenses to assure the licenses are current and are applicable to the State in which the provider is providing services.

#### ***B - Major Sources of Information:***

- Federal, State and local laws governing health care; building, fire and safety codes;
- Applicable State and local licenses and organization personnel records containing up-to-date information; and
- Written policies pertaining to communicable and reportable diseases, conforming to applicable Federal, State and local laws.

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## ***I-8***

***(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)***

### **§485.707(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.*

Where State law provides for the licensing of clinics, rehabilitation agencies or public health agencies, *the organization must meet all building, fire and safety codes, where required for licensure, before the organization is eligible for certification.*

*Verify* at the time of the survey that a current license is valid and in effect. A license must be in effect before the organization can be certified to participate in the program. Where a license for an organization currently participating has been temporarily suspended or revoked, contact the appropriate State department or authority to ascertain the status of the organization's licensure. If a license is not to be issued, *the facility should be found in noncompliance with this standard and* termination proceedings initiated.

Some States may issue provisional licenses. Contact the appropriate State department or authority and obtain information concerning the length of time the provisional status is to be in effect. If the limitations stipulated in a provisional license adversely affect the ability to render services in compliance with regulations, *the facility should be found in noncompliance with this standard.*

*Document the reason(s) for such status and, most importantly, any limitation(s) imposed on the services rendered as a result.*

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## **I-9**

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

### **§485.707(b) Standard: Licensure or Registration of Personnel**

*Staff of the organization are licensed or registered in accordance with applicable laws.*

*Qualified personnel providing services at an OPT must be licensed, registered, or certified when licensure, registration or certification is applicable. This includes personnel providing services directly or under arrangement.*

Review facility records, a central State listing, or other evidence of current licensure or registration of personnel, such as wallet size identification cards sometimes made available. Where personnel are required to be licensed but are not, notify the appropriate State licensing body. *If extension locations are located in other States, ensure that personnel who are providing services are licensed in the State in which the services are provided.*

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## **I-11**

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

## **§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 – General**

*The clinic or rehabilitation agency has a governing body responsible for developing, reviewing, and updating its administrative and clinical policies and procedures. The provision of adequate and effective services requires that the clinic or rehabilitation agency be responsive to internal and external needs and demands which may necessitate changes in program operation. The governing body is responsible for designating an administrator.*

*Review documentation of governing body activities to assess the effectiveness of the governing body's management and operation of the rehabilitation agency or clinic.*

### **B – Major Sources of Information**

- Articles of incorporation, bylaws, policy statements, etc.;
- Minutes of governing body; staff and patient care policy committee meetings;
- Organizational chart showing administrative framework;
- Personnel records—employee qualifications and licenses;
- Patient care policies; and
- Clinical records.

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## ***112***

***(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)***

### **§485.709(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.*

The governing body is the board of directors or trustees of a corporation, the owner(s) in the case of a proprietary clinic or rehabilitation agency, or others who have legal responsibility for the operation of the clinic or rehabilitation agency. The facility shall have an established and functioning governing body. It is not inappropriate for employees of an incorporated clinic or rehabilitation agency to also serve as members of the governing body. The governing body shall be responsible for compliance with all applicable laws and regulations pertaining to OPT/SLP facilities. The governing body is responsible for the quality and appropriateness of care. *Written* provisions should appear in the bylaws or equivalent, specifying:

- The basis upon which members of the governing body are selected (where applicable), their terms of office, and their duties and responsibilities;
- To whom responsibilities for direction of the program and evaluation of practices may be delegated, and the methods established by the governing body for holding appropriate individuals responsible; and
- The frequency of governing body meetings and that minutes are kept.

*Verify that the names and addresses of all individuals having legal responsibility for the clinic or rehabilitation agency are available on the provider's CMS-855A. Verify that the Governing Body has by-laws, meetings and minutes of its meetings. Verify that the organization has policies and procedures that address who monitors the quality of care provided and methods to evaluate the quality (QI) of the services.*

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## ***I-15***

***(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)***

### **§485.709(b) Standard: Administrator**

*The governing body:*

- *Appoints a qualified full time administrator;*
- *Delegates to the administrator the internal operation of the clinic or rehabilitation agency in accordance with written policies;*
- *Defines clearly the administrator's responsibilities for procurement and direction of personnel; and*
- *Designates a competent individual to act in the temporary absence of the administrator.*

***NOTE:** One qualified full-time administrator assumes overall administrative responsibility for the entirety of the rehabilitation agency's operation, including extension locations and any off-premises activities.*

The administrator who does not possess the required experience or specialized training in the administration of an outpatient physical therapy provider (rehabilitation agency, clinic, public health agency) may use training or experience acquired in the management or supervision of health institutions and agencies similar in scope to an outpatient physical therapy provider. College-level courses in health services administration and management approved by the appropriate State authority meet the necessary requirements for specialized training.

*Verify the qualifications of the administrator.*

The administrator should be familiar with all aspects of the operation of the clinic or rehabilitation agency such as scope of services provided, budgetary and fiscal matters, personnel, and other areas necessary to effectively direct operational activities. The administrator is also responsible for coordinating staff education, sometimes referred to as in-service education, or continuing education. In this regard, the administrator should see that each employee has the opportunity to increase the skills and knowledge necessary to promote effective and efficient patient care.

**Review listing of in-service program content, type of instruction (e.g., lecture or demonstration), dates of instruction, and attendees.**

When the administrator is unable to carry out delegated duties, a similarly qualified alternate is to be readily available (on the premises or by telephone) at all times during operating hours to assume the administrator's responsibilities.

Verify that an *alternate to the administrator* has been selected *and is noted in organization policies*.

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**I-19**

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

**§485.709(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.*

*At a minimum, facilities should have procedures for selecting qualified personnel; a system for documenting the current licensure and/or certification status for those*

*personnel whose positions or functions require such licensure or certification; and a system for assessing competency of all personnel providing healthcare services, upon hire and on an ongoing basis, on a schedule determined by the facility policy. Practices pertaining to the personnel of the organization should be written in personnel policies, be available to all personnel, and be updated and/or revised as appropriate. Such items as qualifications of staff employed, frequency of supervision, continuing education, hiring/firing practices, evaluations, etc. should be located in the personnel policies.*

Review *personnel policies*. During interviews with the facility administrator and staff, elicit evidence that personnel practices are based on written personnel policies.

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## **I-22**

**(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)**

### **§485.709(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.*

The facility should have *written* patient care policies, based on accepted standards of practice for all services provided, that govern the outpatient physical therapy and/or speech pathology services and related services that are provided. Patient care policies are established by the professional staff of the clinic or rehabilitation agency and, where appropriate, outside professionals who function as a patient care policy committee. The professional staff preparing the patient care policies should include at least one physician and at least one qualified physical therapist (if physical therapy services are provided) and at least one qualified speech pathologist (if speech pathology services are provided). Patient care policies should be reviewed for appropriateness at least annually by the group of professional personnel that prepared them.

Review the written patient care policies and determine whether the facility operates in conformity with them.

Review minutes of meetings to determine whether the policies of the clinic or rehabilitation agency are current and responsive to the needs of patients, and whether, when unresponsive, appropriate policy revisions are undertaken. Verify that patient care policies are being reviewed annually and revised as needed.

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## ***I-47***

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

### **§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. The organization has a physician available to furnish necessary medical care in case of emergency.*

#### ***A - General***

All patients must be treated pursuant to a written plan of care that indicates anticipated goals and specifies the type, amount, frequency, and duration of services to be furnished. Non-Medicare patients are neither required to be under the care of a physician nor to have a plan of care established by a physician. *A physician will be available on call to furnish necessary medical care in case of an emergency.*

*Review medical records to ensure Medicare patients have a written plan of care.*

#### **B - Major Sources of Information**

- Patients' plans of care;
  - Emergency Procedures;
  - Patient care policies; and
  - Clinical records.
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## ***I-49***

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

### **§485.711(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;  
and*
- (8) *If appropriate, the summary of treatment furnished and results achieved  
during previous periods of rehabilitation services or institutionalization.*

The regulations do not require the patients be referred to be the facility by a physician or that the services to be furnished pursuant to a physician's orders. However, since Medicare patients are still required under the statute to be under the care of a physician and to have the plan of care periodically reviewed by a physician to receive payment for Medicare covered services, *the organization should, if possible, obtain the following information at, or prior to, the time that therapy is initiated: Significant past medical history*, current medical findings, diagnosis(es), physician's orders (if any), rehabilitation goals and contraindications, (normally be made available to the facility by the attending physician) *and any previous therapy or hospitalization related to the current medical condition*. Non-Medicare patients are not required to be under the care of a physician, *or to* have a plan of care established or periodically reviewed by a physician, *though* you should *nevertheless* expect to find medical records maintained for the *non*-Medicare patients. When complete and appropriate past history *and/or* current medical findings are not made available to the organization, the organization should obtain the information from *other sources such as* the patient, family or from follow-up with the referring physician, if any.

*Review medical record for evidence of prior medical history and/or treatment.*

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## ***I-50***

***(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)***

### **§485.711(b) Standard: Plan of Care**

- (1) *For each patient there is a written plan of care established by the physician;  
or (i) by the physical therapist; or (ii) by the 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 taken. (For Medicare patients, the plan must be reviewed by a physician, nurse practitioner, clinical nurse specialist, or physician assistant at least every 30 days, in accordance with §410.61(e) of this chapter.)*
- (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.*

When you review a patient's record to determine if a plan of care has been established and is periodically reviewed, it is not necessary to establish whether the patient is a Medicare or non-Medicare patient. The condition statement and standard permit, for each patient, the plan of care to be established by a physician, or by the appropriate professional (i.e., a physical therapist or speech pathologist) and *to be* reviewed by a physician or the individual who established it. However, as a condition for Medicare payment, a physician must certify the necessity of the services. *As part of the certification, a* physician, nurse practitioner, clinical nurse specialist, or physician assistant must review the plan of care every 30 days. *For* each Medicare patient, *a physician must* re-certify the continued need for those services. This review will probably be the review the facility uses for Medicare patients to meet the Condition of Participation. Since Medicare patients must be under the care of a physician for purposes of receiving payment for Medicare covered services, the attending physician must be notified of any changes in current treatment or the patient's condition. A change requires a revision to the plan of care. The medical record should contain documentation regarding the notification (a dated written order signed by the physician or a dated verbal order signed by the professional receiving the order).

*Review the medical record to determine that the patient has a plan of care that is being reviewed and updated every 30 days (for Medicare patients). The plan of care should not look identical from month to month as treatment and goals should be updated as the patient makes progress and meets existing goals. The plan of care must have the signature of the reviewing physician, non-physician practitioner, or therapist. If, for any reason, therapy services are discontinued prior to the end date indicated on the plan of care, the physician must be notified.*

**NOTE:** The term physician includes a podiatrist *or optometrist* whose performance of functions are consistent with the OPT's *policies* and whose services are related to functions he/she is legally authorized to perform.

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## **I-54**

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

### **§485.711(c) Standard: Emergency Care**

*The organization provides for one or more doctors of medicine or osteopathy to be available on call to furnish necessary medical care in the case of emergency. The established procedures to be followed by personnel in an emergency cover immediate care of the patient, persons to be notified, and reports to be prepared.*

*Organizational policies should contain the names and telephone numbers of physician(s) the organization has arranged to be on-call to provide medical care in case of an emergency during operating hours. (This can include physicians at a near-by hospital emergency room.) There may be instances in which the on-call physician provides emergency medical triage which results in a 911 call. The OPT procedure to call 911 in cases of emergency doesn't supersede the requirement to have on-call physicians for emergencies.*

**NOTE:** *If an OPT/OSP is providing services at a community facility (such as a pool), the OPT staff must have a way to contact emergency medical care (i.e., if therapy services are being provided at a community pool, is another individual on duty and available to call for help?)*

*Review the medical emergency procedures, and make certain in discussions with the appropriate persons that these procedures, when necessary, can be made immediately operational. Interview employees to determine whether their individual responsibilities, in case of an emergency, are known. There must be two persons on duty whenever a patient is being treated (no matter where the services are being provided (§485.723(a)(6)) and no matter whether the facility is large or small.)*

**NOTE:** *If a patient receives emergency medical treatment at the organization, the physician's emergency medical treatment plan and communication should be documented in the patient's medical record.*

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## **I-55**

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

### **§485.713 Condition of *Participation*: Physical Therapy Services**

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

### **A - General**

The range of medically necessary physical therapy services should be adequate to treat the types of disabilities accepted for service. There should be an adequate number of qualified professionals to accommodate the number of patients treated by the organization. Also, there should be adequate equipment to treat the type of disabilities accepted by the organization.

**NOTE:** *OCCUPATIONAL THERAPY SERVICES CANNOT BE SUBSTITUTED FOR PHYSICAL THERAPY SERVICES. In other words, the OPT cannot provide solely occupational therapy services. Occupational therapy services may be provided in addition to physical therapy or speech-language pathology services.*

*Review personnel rosters for adequacy of qualified professionals. Review facility for types and number of equipment available for patients.*

**NOTE:** *If the rehabilitation agency is not providing either physical therapy or speech pathology services, the most appropriate Tag to cite would be I7 since the organization would not be in compliance with all applicable Federal, State, local laws and regulations.*

### **B - Major Sources of Information**

- Physician orders, plans of care, and physical therapy evaluations and progress notes;
- Patient care policies—such policies should include a description of their scope of services, admission and discharge criteria. The facility must appropriately refer individuals who have needs that exceed their scope of service;
- Personnel records--job descriptions, employee qualifications, and current licensure information; and
- Clinical records.

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**I-56**

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

**§485.713(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 test 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, evaluation and re-evaluation.*
  - (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.*

*An adequate outpatient physical therapy program includes:*

- (a) *Provision of services using therapeutic exercises and the modalities of heat, cold, water and electricity to provide the range of therapy services necessary to treat individuals with the types of disabilities it accepts for service;*
- (b) *Conduct patient evaluations; and*
- (c) *Administer tests and measurements of strength, balance, endurance, range of motion and activities of daily living. It is possible that not all patients will receive every modality listed above. The plan of care should address the modalities that are medically necessary for the treatment of the patient's condition.*

***Review patient care policies and procedures to assess the adequacy of the organizational program.***

*Physical therapy services are to be rendered only by qualified physical therapists or qualified physical therapist assistants under the supervision of qualified physical therapists. A qualified therapist must be onsite for evaluations and re-evaluations of patients. A physical therapist is readily available to offer supervision to a physical therapy assistant according to the organization's policies and procedures but when a*

*physical therapy assistant furnishes services offsite, those services are supervised by a qualified physical therapist who makes an onsite supervisory visit at least every 30 days to observe the actual performance of the assistant. Only physical therapists may supervise physical therapy assistants. Only occupational therapists may supervise occupational therapy assistants.*

Such supervision may include:

- Specific instructions regarding the treatment regimen;
- An explanation of responses to treatment indicative of adverse patient reactions;
- Discussions between the physical therapist and the physical therapist assistant; and
- *State practice acts and rules may include additional supervision requirements.*

**NOTE:** *This does not mean the physical therapist must be onsite full-time but must be able to respond and to be physically available onsite within a reasonable period of time to provide consultation in case of an unusual occurrence.* Response time is based on the condition of the patient, the patient's previous response to treatment, organization staffing, and competency of available personnel. For example, where the patient's previous response to treatment had been adverse, thereby possibly requiring that, in the future, the physical therapist keep himself readily available to provide needed supervisory assistance, the physical therapist should arrange times and schedules to allow for minimal delay in providing such assistance.

*Review organizational policies regarding supervision and supervisory visits. Interview staff regarding supervision of assistants.*

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## ***I-57***

***(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)***

### **§485.713(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.*

*All equipment should be maintained according to manufacturer's guidelines.*

**NOTE:** Where patient privacy is required, this may be accomplished through utilization of individual treatment booths, folding screens, draw curtains, etc.

*Review patient care policies and procedures and tour clinic to assess the adequacy of equipment and facility to treat the disabilities it has accepted for service. Review organizational procedures and speak with staff to ensure equipment is being maintained according to manufacturer guidelines.*

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## **I-58**

**(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)**

### **§485.713(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.*

The number of qualified physical therapists and qualified physical therapist assistants (if applicable) should be able to adequately and effectively provide services to patients. Adequate service cannot be determined *based upon* the mere proportion of the staff to patient ratio, *but rather*, it is to be based on knowledge of the types of patients treated and the type, amount, frequency, and duration of treatment required. *The qualified physical therapist is either on the premises or readily available during all hours of operation.*

*To more accurately determine the sufficiency of personnel, review clinical records, together with the patient care policies, personnel records, and patient treatment schedules. Interview patients regarding availability of staff during scheduled treatment times.*

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## **I63**

**(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)**

### **§485.713(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.*

Physical therapy aides, or individuals with less than assistant level qualifications, must be directly supervised by a qualified physical therapist. The physical therapist must be in the immediate vicinity and available to provide assistance and direction throughout the time services are provided.

Even if an aide is assisting a qualified physical therapy assistant in some activity, ultimate responsibility for the aide's activities rests with the qualified physical therapist. *In the provision of physical therapy services, any staff other than the qualified physical therapist or physical therapy assistant is considered supportive personnel.*

*Review organization policies and procedures to determine the job responsibilities of the supportive personnel.*

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## ***I-150***

***(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)***

### **§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 objective.*

#### ***A - General***

The speech pathology services provided should be such that patients accepted for treatment are able to receive services as medically indicated. The personnel and equipment necessary to effectively treat those patients may, in part, be dictated by the type of patients ordinarily accepted for treatment.

*Review personnel rosters and patient census to determine that the organization provides sufficient personnel to adequately serve the patients it accepts for services.*

#### ***B - Major Sources of Information***

- Physician orders, plans of care, and speech pathology evaluations and progress notes;
  - Patient care policies;
  - Personnel records--job descriptions, employee qualifications, and current licensure information; and
  - Clinical records.
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## **I-151**

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

### **§485.715(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.*

*Review the organization's patient care policies and clinical records to ascertain the adequacy of the speech pathology program.*

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## **I-152**

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

### **§485.715(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.*

Space suitable for treatment must be available. Observe the clinic area to determine the adequacy of space and equipment.

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## **I-153**

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

### **§485.715(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.*

The number of qualified speech pathologists should be adequate to effectively provide services to patients. As in the case of the physical therapist, this number is related to types of patients treated, the specifics of the plan of care, and the time required to carry out the plan.

Unlike physical therapy services where, at certain times, the application of certain modalities does not require the presence of the physical therapist, effective speech pathology treatment necessitates the continuing presence of the speech pathologist. Therefore, no formula utilizing numbers of physical therapists as a base for comparison can be used when determining whether or not the number of qualified speech pathology personnel is adequate.

*At least one qualified speech pathologist must be present at all times when speech pathology services are provided as there are no recognized speech pathology assistants. Review personnel records to determine whether the speech pathologist is qualified to perform speech pathology services (most states require licensure or certification).*

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## **I-67**

**(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)**

### **§485.717 Condition for Coverage: Rehabilitation Program**

*This condition and its 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 whom 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, in addition to physical therapy and/or speech-language pathology services, social or vocational adjustment services to all of its patients who need them. The agency provides for special qualified staff to evaluate the social and vocational factors, to counsel and advise on the social or vocational problems that arise from the patient's illness or injury, and to make appropriate referrals for needed services.*

#### **A - General**

A rehabilitation agency must provide either physical therapy or speech pathology services plus a rehabilitation program which includes, at a minimum, social and/or vocational adjustment services. Such services may be furnished directly or under arrangement.

*The rehabilitation agency is required to provide social or vocational adjustment services to all patients in need of such services. A qualified therapist can gather and document evidence regarding the need for social or vocational services via a screening tool or other written method deemed appropriate by the rehabilitation agency. This written documentation must be reviewed by the social worker, vocational adjustment specialist, or psychologist who will then determine the patient's needs for further evaluation. This process must be documented in the patient's clinical record. If further evaluation or services are needed, the agency's special qualified staff must provide them or make*

*appropriate referrals. Under no circumstances may a patient determine his or her vocational needs.*

However, there are circumstances when the provision of these services to certain patients by the rehabilitation agency would be unnecessary or would duplicate similar services provided by other organizations. The rehabilitation agency is neither required to evaluate patients, nor to provide social or vocational adjustment services to patients, under any of the following situations:

- The patient is receiving social or vocational adjustment services as an inpatient or outpatient of another provider or supplier of services, and a written agreement or contract between the rehabilitation agency and the provider or supplier specifies that the provider or supplier is responsible for social or vocational adjustment services for all patients receiving OPT/OSP from the rehabilitation agency.
- The other provider or supplier agrees in the written contract with the rehabilitation agency to clearly mark or identify the files of patients receiving OPT/OSP who have previously been evaluated for social or vocational adjustment services. A separate evaluation of those patients for social or vocational adjustment services by the rehabilitation agency is not required.
- The OPT/OSP provider provides diagnostic or therapeutic services to individuals for whom another agency or organization has overall responsibility.

Social or vocational adjustment services may be provided either on the premises or off the premises of the organization (e.g., in the office of the psychologist).

Review the organization's policies and procedures and discuss with staff the methods to determine whether a patient requires social/vocational services. Review staff meeting minutes or patient care meeting minutes. *Is the social worker or vocational specialist part of this meeting?*

***B - Major Sources of Information:***

- Contract for services under arrangement;
- Personnel records - job descriptions, employee qualifications and health examinations as specified;
- Clinical records; and
- Patient care policies.

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

### **§485.717(a) Standard: Qualifications of Staff**

The agency's social or vocational adjustment services are furnished as appropriate, by qualified psychologist, qualified social workers, or qualified vocational specialists. Social or vocational adjustment services may be performed by a qualified psychologist or qualified social worker. Vocational adjustment services may be furnished by a qualified vocational specialist.

Review personnel folders to determine if the individuals providing social or vocational services meet the licensure, certification, registration, or other applicable qualifications of the state in which the services are being provided.

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### **I-72**

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

### **§485.717(b) Standard: Arrangements for Social or Vocational Adjustment Services**

- (1) If a rehabilitation agency does not provide social or vocational adjustment services through salaried employees, it may provide those services through a written contract with others who meet the requirements and responsibilities set forth in this subpart for salaried personnel.*
- (2) The contract must specify the term of the contract and the manner of termination or renewal, and provide that the agency retains responsibility for the control and supervision of the services.*

If an agency does not provide social or vocational adjustment services through its own employees, such services may be provided by means of written agreements with individuals or organizations. Their contracts must specify the agency's responsibility, control and supervision over the services and must *detail the manner of termination or renewal of the contract*. The appropriate professional staff (psychologists, social workers, vocational specialists) are responsible for developing, in conjunction with the physician, the regimen of social or vocational adjustment services to be provided to individuals requiring such services, and must assume the professional and administrative responsibility for services provided under arrangements.

**Review the contracts to assure that the agency's responsibility is detailed.**

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### **I-79**

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

**§485.719 Condition of *Participation*: Arrangements for Physical Therapy and Speech Pathology Services to be Performed by Other Than Salaried Rehabilitation Agency Personnel**

*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 professional and administrative responsibility for, and control and supervision of, the services.*

***A - General***

The rehabilitation agency has professional and administrative responsibility for the physical therapy and speech pathology services provided under an arrangement.

**Review contracts to assure that the agency retains professional and administrative responsibility for any services provided under arrangement.**

***B - Major Sources of Information***

- Contract for services under arrangement;
- Personnel records - job descriptions, employee qualifications and health examinations as specified;
- Clinical records; and
- Patient care policies.

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***I-80***

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

**§485.719(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 §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.*

*Organizations can provide outpatient therapy services under arrangement with others. These services are to be furnished in accordance with a written contract. The terms of the contract provide that the organization maintains professional and administrative responsibility for, and control and supervision of, the services. The terms also include termination/renewal procedures as well as qualifications to be met by those furnishing services under arrangements. Only the agency, not the contracted outside resource, may bill for services performed by the contracted resource.*

Review the contracts to assure that the organization has specified the qualifications the outside service provider must meet. The contract should state that the outside service provider may not bill for services rendered.

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## ***I-96***

***(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)***

### **§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 - General***

The clinical record serves as a basis for documentation of medical care rendered to the patient. Clinical records should contain at least the following documentation: *Progress notes, monthly summaries, records of communication with the patient's physician and other therapists and discharge summaries.*

In addition to serving as a basis for documentation of care rendered to patients, clinical records provide evidence of the organization's implementation of policies and procedures as they relate to patient care.

**Review the clinical record to determine whether the content of the clinical record presents a total or, at a minimum, an adequate picture of the care being given and that documentation by those under contract meets the documentation standards of the organization.**

**Review a sample of all clinical records, including those patients whose treatment is provided under arrangement, to make certain that evaluations, progress notes, and other pertinent clinical material are present and that the clinical records containing applicable information for all patients are maintained on the premises of any location at which services are rendered. However, if the surveyor is surveying only the primary location, clinical records should be available to the surveyor for review, during the course of the survey, regardless of where the records are kept.**

***B* - Major Sources of Information**

- Active and closed clinical records; and
  - Policies regarding retention and confidentiality of clinical records.
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***I-154***

***(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)***

**§485.721(a) Standard: Protection of Clinical Record Information**

Clinical records are to be stored where they are protected from fire and unauthorized use. *The organization must make every effort to safeguard the medical records against unauthorized access/use particularly if the organization shares space with another entity.* Organization policies are to note to whom records or copies thereof may be provided, the use to which the material may be put, and the circumstances describing the return of such material. For the release of all material not authorized by law, the patient's written consent is required.

**Review the organization's policies for securing and safeguarding clinical records against loss, destruction, or unauthorized use.**

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***I-97***

***(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)***

**§485.721(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; and*
- (7) Discharge summary including final diagnosis(es) and prognosis.*

Virtually all clinical records should contain an assessment of the needs of the patient (initial evaluation and reevaluations where appropriate), plan of care (including the types, amount, duration and frequency of services provided), identification data (name and address of patient), observations and progress notes, reports of treatments and clinical findings, and discharge summary. Other documentation should include coordination efforts between professionals providing services.

However, consent forms, medical history and report of the physician's physical examination may or may not appear in clinical records. This information would need to appear only where *demonstrably* relevant to patient treatment. Where medical history does appear in clinical records, it may not have been that transmitted by the physician but, rather, may have been obtained from the patient when the past and present history was related. *Progress notes should be updated in the patient's clinical record at least weekly.*

Where emergency care is provided, the clinical record should include the following: Type of care rendered, date, personnel involved, and the incident that precipitated the need for such care.

**Examine a substantial number of both active and closed clinical records, selected on a random basis and not restricted to those of Medicare patients.**

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***I-155***

***(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)***

## **§485.721(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.*

If omission of any pertinent information is noted in the clinical records, additional clinical record reviews should be undertaken to determine the prevalence of such omissions.

A discharge summary should include the date and reason for discharge; a brief summary of the current status of the patient at the time of discharge; and, where applicable, provision for referral of the patient to another source for continuing care.

Regardless of whether the organization provides services through its own employees or through an arrangement with others, all materials that are pertinent to the patient's treatment are to be part of the clinical record, which is to be maintained on the premises of any location at which services are rendered. All information appearing in the clinical record is to be dated appropriately, signed, and incorporated weekly into the clinical record.

**The survey should indicate on the Survey Report Form the number of clinical records reviewed and the number and types of deficiencies found in each. Where record reviews prompt questions concerning patient care, the surveyor should request additional information and assistance from the appropriate organization personnel.**

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### ***I-108***

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

## **§485.721(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.**

**Review the organization policy pertaining to retention and preservation of clinical records and verify that such policy is consistent with applicable State law or regulation where such exists. Verify that there is a provision in organization policies for the retention and transfer of clinical records if the organization ceases to function.**

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### ***I-156***

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

#### **§485.721(e) Standard: Indexes**

*Clinical records are indexed at least according to name of patient to facilitate acquisition of statistical information and retrieval of records for research or administrative action.*

Clinical records are indexed according to the last name of each patient, but in some cases indexing may be according to file identification numbers assigned to patients on admission to the organization. This system may be utilized for indexing either active and/or discharged patient clinical records as determined by organizational need.

**Review the organizational policies/procedures regarding the system for indexing clinical records.**

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### ***I-157***

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

#### **§485.721(f) Standard: Location and Facilities**

The clinical records are to be easily retrievable and available to all professional staff members of the organization and other authorized individuals. Clinical records may be maintained at a site other than the primary location (the site issued the provider agreement/number) if the beneficiary receives outpatient therapy services at that other site. All records must be **available** to the surveyor **during the course of the survey regardless of where the records are kept.**

**NOTE: Records may be delivered to the surveyor electronically or by other means as long as the delivery is within a reasonable amount of time during the course of the onsite survey.**

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### ***I-117***

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

## **§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 - General***

The structure housing the organization is such that it is held "open to the public." Patient treatment areas and other locations associated with organization function (e.g., storage and restrooms) are to be physically separated from non-organization areas. Restrooms, however, need not be located directly in the treatment area, but may be located, for example, down a hallway so long as they are easily accessible by non-ambulatory and semi-ambulatory individuals.

The physical environment should be considerate of patient privacy (away from public viewing). Patient privacy may be assured through utilization of individual treatment booths, folding screens, draw curtains, etc.

**In order to ensure the safety of patients, personnel, and the public, examine the physical plant of the organization and ascertain whether or not it is maintained consistent with State and local building, fire, and safety codes.**

### ***B - Major Sources of Information***

- Applicable Federal, State and local laws;
  - Inspection reports of State and local building and fire authorities; and
  - Organization policies regarding maintenance of equipment, building and grounds.
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## ***I-118***

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

### **§485.723(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.*

Areas *of the organization* considered to be especially hazardous (e.g., rooms or spaces used for combustible supplies and equipment) are to be equipped with a State fire authority approved, **permanently attached**, automatic fire extinguishing system, or shall be separated from the balance of the building by 1-hour *rated* fire resistant barriers. All areas occupied or accessible to the organization for use during emergency or non-emergency activity, including corridors and stairwells, are to be protected by easily accessible fire extinguishers (e.g., the case of an organization located in a multilevel structure, *irrespective of* whether the entire structure, or only a portion thereof, is utilized). The doorways and passageways shall be *free of obstruction* to allow for ease in patient movement into and within the organization and shall be wide enough to *accommodate the type and condition of patients (i.e., in wheelchairs, etc.) accepted for treatment*. Stairwells should include handrails on at least one side and should be free from obstruction at all times.

An emergency power source (e.g., battery or auxiliary generator) is available to assure adequate lighting during emergency operation within the treatment areas and those passageways, stairwells, and exits (as noted above) accessible to the organization. In cases of power outage, the emergency power source should respond either automatically or require only minimal activation effort.

The fire alarm system should be adequate to alert organizational personnel in time to *permit* safe evacuation of the building. The premises of the organization are to be safeguarded by a fire alarm system or automatic detection system that is in operational condition. Provision is also to be made for an internally audible manual alarm capability, either separately contained, or functioning in combination, with the fire alarm or automatic detection system. In the absence of State or local requirements, the above systems are to be approved by the State Fire Marshal's Office. A system without the capacity for manual activation in response to a fire would not serve to alert other personnel, patients, and the public of danger and the need for action. Where the alarm system is activated by a disruption in the organization's electrical system, or is in other ways dependent on it, an emergency power source (e.g., battery or auxiliary generator) should be available to serve as backup.

The building housing the organization should be free of hazardous occupancies or activities such as the manufacturing of combustible materials.

Verify that applicable State and local building, fire, and safety codes are met and review available reports of State and local personnel responsible for enforcement of the above.

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## ***I-158***

***(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)***

### **§485.723(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.*

All equipment should be inspected by the organization at least yearly or in accordance with manufacturers' guidelines and a *maintenance scheduled maintained*. Such inspection is determined in part by present equipment condition and its frequency of use, and is to be outlined in written procedures that include the following:

- Equipment to be inspected;
- A brief statement concerning the general inspection process; and

- Frequency of inspection for each piece of equipment.

For all electrically powered patient care equipment, appropriate manufacturer's operating and maintenance information should be on file. The surveyor should review this information and ascertain what specific recommendations, if any, are made for equipment calibration checks, periodic maintenance procedures, etc. Then, through copies of service repair statements or other documentation, determine whether such recommendations were followed.

Review organization maintenance checklists. Note any hazards to the health and safety of patients, personnel, and the public (e.g., broken window and door panes, obstruction of passageways, and dangerous floor surfaces) on the Survey Report Form (CMS-1893).

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## ***I-130***

***(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)***

### **§485.723(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 non-ambulatory and semi-ambulatory individuals; and*
- (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.*

*In order to make the organization's environment comfortable, sanitary and functional for patients, personnel and the public, the following provisions should be considered: lighting, sounds, temperature, ventilation, toilet facilities and space for the organization to comfortably function.* Where necessary, ramps should be available to provide for easy access to facilities and equipment. Examination and treatment areas should be large enough to enable effective application of the plan of care. Where underwater exercise is utilized, a safe and effective patient lift device is available.

**Verify that temperature control mechanisms maintain the temperature at a comfortable and constant level. Verify that restroom/toilet facilities are**

handicapped accessible. Observe all areas within the organization. Is the space adequate for storage, treatment, etc?

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## **I-159**

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

### **§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 - General**

An infection control committee, applicable for organizations offering physical therapy services, has overall responsibility for ensuring that environmental infection hazards are controlled. *The committee should consist of staff representing the various professional services provided by the organization and should ensure that the organization has up-to-date infection control policies and procedures for investigating, controlling, and preventing infections in the organization and monitors staff performance to ensure that the policies and procedures are being executed.*

Review the organization's Infection Control policies and procedures. Does the organization have the necessary housekeeping staff and supplies to maintain a sanitary environment.

#### **B - Major Sources of Information**

- Written policies and procedures; and
  - Minutes of the infection control committee.
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## **I-160**

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

### **§485.725(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*

Meetings are to be held at least annually with minutes being kept, and at least two or more individuals should constitute the committee. The committee should be composed of persons whose educational background and experience (e.g., M.D., R.N., and other interested professionals) is adequate to perform this function. The administrator, in the case of a clinic or rehabilitation agency, should assume responsibility for selecting the professionals to serve on the committee.

Written procedures covering infection control and cleanliness of certain physical therapy equipment such as whirlpools, paraffin baths, and moist hot pack units, *as well as provisions for disposal of bio-hazardous materials* should be available for review. This is particularly important in cases where whirlpools are used for debridement of wounds. *Written procedures covering infection control should also be available for any of the other professional services (i.e., equipment used by occupational therapy or speech-language pathology).*

The surveyor should review the policies and procedures *and minutes of the annual meeting* for preventing, controlling, and investigating infections and should ascertain whether the recommendations of the committee are acted upon.

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## ***I-161***

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

### **§485.725(b) Standard: Aseptic and isolation techniques**

*All personnel follow written procedures for effective aseptic techniques. The procedures are reviewed annually and revised if necessary to improve them.*

*Personnel are to follow written procedures for effective aseptic techniques.*

Review the aseptic procedures developed and ascertain, through a discussion with available professional personnel and review of major sources of information, that the procedures are communicated to the staff. *Observe staff during the survey and note if staff are not following the correct procedures outlined in policies. Review the organization's documentation of its aseptic procedures—is it reviewed annually and updated as needed (look for dates).*

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## ***I-162***

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

### **§485.725(c) Standard: Housekeeping**

- (1) *The organization employs sufficient housekeeping personnel and provides all necessary equipment to maintain a safe, clean, and orderly interior. A fulltime 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.*

The organization identifies the individual(s) assigned primary responsibility for housekeeping duties. When there is a contract with an outside resource to provide such services, the organization retains responsibility for the housekeeping duties. *The organization is responsible for employing sufficient housekeeping staff to maintain a clean, safe environment.*

*Inspect the organization for cleanliness and orderliness especially with regards to equipment, floors, tables, etc. Review contracts (if the organization contracts with outside housekeeping services) to ensure that the organization has retained responsibility and oversight for the housekeeping services performed by the outside source.*

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## ***I-163***

***(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)***

### **§485.725(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.*

Organization has a new supply of fresh clean linen, essential for proper care and comfort of all patients treated, plus an additional supply to provide for any possible increased usage that is to be stored in clean areas and available for daily use.

Verify that soiled linen is removed from patient areas at least daily and stored in an area away from patients, personnel, and the public and is stored away *from clean linen*. *Review policies and procedures for handling linen and see that policies and procedures are being followed.*

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## ***I-164***

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

**§485.725(e) Standard: Pest Control**

*The organization premises are maintained free from insects and rodents through operation of a pest control program.*

*The organization's premises should be free from insects and rodents.*

Review the organization's written policy covering the pest control program.

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***I-165***

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

**§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 - General***

A well developed disaster plan must be documented and posted in areas accessible for continuing personnel review.

*During the survey, ask staff members to describe their individual roles in the disaster plan.*

***B - Major Sources of Information***

- Disaster plan; and
  - Documentation as to ongoing training sessions and dates of disaster drills.
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***I-166***

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

**§485.727(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) Location and use of alarm systems and signals;*
- (3) Methods of containing the fire;*
- (4) Notification of appropriate persons; and*
- (5) Evacuation routes and procedures.*

Ensure that the written plan is operational and contains procedures to be followed, evacuation routes and assignment of staff responsibilities in the event of a disaster.

Verify that the description of the location of the alarms systems is accurate. *Verify that staff members know the sequence of events for which they are responsible during a fire or other disaster. Do staff members know the evacuation routes for patients in wheelchairs or with crutches?*

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## ***I-167***

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

### **§485.727(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.*

The organization should have annual staff training and disaster drills for all salaried and contracted employees. All personnel are to be exposed to practice drill situations calling for the exercise of their responsibilities as stated in the disaster plan.

Verify that disaster drills are carried out at least annually and include all salaried and contracted employees, and that the date and the names of those persons taking part are documented. Annual drill disasters must be carried out annually at extension locations.

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## ***I-168***

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

## §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 - General**

At least once a year the organization should assess the performance of its total operation. Total operation refers not only to those services provided to patients, but also to the broader concepts of overall organization administration, including, but not limited to, policies and procedures, personnel, fiscal, patient care, etc. Procedures *must be in place* which provide for an evaluation of the total organization program. *Written reports of the results of the evaluation should be maintained and the facility should have a performance improvement plan that collects data about the organization's performance on an ongoing basis.* The evaluation should be conducted by the professional staff of the organization and outside professionals, where appropriate. These reports should contain the names of those participating in the evaluation, the results, and expected action, if indicated.

Review dated reports of the most recent program evaluations.

### **B - Major Sources of Information**

- Written policies and procedures concerning the evaluation process;
- Patient care policies; and
- Minutes of meetings on program evaluation.

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## **I-169**

*(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)*

### §485.729(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.*

A substantial sample of records reviewed should be randomly selected from the active and closed files. Each service offered by the organization should be represented in the sample. In instances where a patient is receiving both physical therapy and speech pathology services, the record may be included in the sample of each service rendered.

The clinical record review committee is composed of health professionals representing those services provided *directly and, if applicable*, under arrangement, by the organization. It is not necessary that those committee members be employees of the organization. Administrative personnel would ordinarily be committee participants.

Review minutes of the organization's clinical record review committee. *Do the minutes indicate corrective action to be taken if the organization finds that established policies are not being followed?*

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## ***I-170***

***(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)***

### **§485.729(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.*

*The organization must conduct an annual evaluation of statistical data. Each organization may decide the types of data it wishes to collect (in addition to numbers of patient visits, types of patients, etc.). Some organizations may find that a quarterly report, as opposed to an annual report, would prove more beneficial in determining the effect of organizational policies. Correct and consistent application of policies will, to some extent, be reflected in the statistical evaluation, and, where policy has not been followed, the evaluation can serve as a guidepost for any necessary change.*

The surveyor should review and compare the prior years and current statistical reports to determine that the data similar in character to the organization's program evaluation purposes, is being kept.

#### ***GENERAL NOTE:***

***If during the survey process, the extension location(s) is found to be out of compliance with a CoP, the provider as a whole is considered out of compliance.***