CMS Manual System

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Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

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SUBJECT: Revisions to Appendix E and Chapter 2 sections 2290-2308 of the State Operations Manual (SOM)

I. SUMMARY OF CHANGES: Numerous sections of the appendix and SOM sections 2290-2308 have been updated to give further guidelines regarding Code of Federal Regulations § 485.701- § 485.729 and to assist the surveyor in determining whether or not the provider is meeting the appropriate regulations.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: March 15, 2013
IMPLEMENTATION DATE: March 15, 2013

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
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R	§ 485.707(b) Standard: Licensure or Registration of Personnel
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***Unless otherwise specified, the effective date is the date of service.**

State Operations Manual
Appendix E - Guidance to Surveyors: Outpatient Physical Therapy or Speech Pathology Services

(Rev.83, Issued: 03-15-13)

Transmittals for Appendix E

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State Operations Manual

Appendix E – Guidance to Surveyors: Providers of Outpatient Physical Therapy and Speech-Language Pathology Services

Transmittals for Appendix E

§485.703 Definitions

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

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.

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(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§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.

Interpretive Guidelines §485.707

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;*

- *Organization personnel records containing applicable State and local licenses and up-to-date information; and*

- *All written policies which must conform to applicable Federal, State and local laws.*

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(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§ 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.

Interpretive Guidelines § 485.707(a)

A – General

Where State law provides for the licensing of clinics, rehabilitation agencies or public health agencies, these organizations must meet all requirements for licensure, before the organization is eligible for Medicare certification.

If a State license or local law is applicable, the provider shall provide the surveyor with evidence of that license. Verify at the time of the survey that *all required licenses are valid and in effect.* Contact the appropriate State department or authority to ascertain the status of the organization's *State* licensure when a license for an organization, currently participating in Medicare, has been temporarily suspended or revoked *The surveyor must contact the appropriate State department if the organization is unable to produce the license (in States where licenses are required). Contact the regional office (RO) and begin termination proceedings.*

If a provisional license has been issued, note if there are restrictions as part of the provisional license. If there are restrictions, determine whether the organization is operating within the scope of the imposed restrictions.

If the limitations stipulated in a provisional license adversely affect the *organization's* ability to render services in compliance with *Federal* regulations, and as a result endangers the safety and welfare of the patients, the *organization* should be found in noncompliance with this standard *and this condition. Contact the RO and begin termination proceedings.*

B – Major Sources of Information

- *Licenses or other documentation as appropriate.*

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(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

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

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

Interpretive Guidelines § 485.707(b)

A – General

Qualified personnel providing services at *a certified organization* must be licensed, registered, or certified when licensure, registration, or certification is applicable. This includes personnel providing services directly for, or under arrangement with the *organization*.

Review *the organization's personnel* records *for* 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 licensed*, 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. *Generally, licenses or registration certificates are located in credential files or posted on the clinic or office walls.*

B- Major Sources of Information

- *Personnel licenses; and/or*
- *Personnel registration certificates.*

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(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§ 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.

Interpretive Guidelines § 485.709

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 *clinic or rehabilitation agency*.

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;*
- *Patient care policies; and*
- *Clinical records.*

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(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§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.

Interpretive Guidelines § 485.709(a)

A - General

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 *clinic or rehabilitation agency must* have an established and functioning governing body. The governing body shall be responsible for compliance with all applicable laws and regulations pertaining to *clinics or rehabilitation agencies*. 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 of these meetings are kept.

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 of the services.

As a part of the pre-onsite survey activities, review the CMS-855A form to verify the owner's name or the name(s) of the corporate officers (in the case of corporations) and whether it is a single owner or part of a chain.

B – Major Sources of Information

- *Organization policies;*

- *Governing body committee meeting minutes; and*

- *Form CMS-855A.*

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(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§485.709(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 the absence of the administrator.

Interpretive Guidelines § 485.709(b)

A – General

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

The administrator, as defined in 485.705 (c)(1)(i)(ii), should be knowledgeable regarding the rehabilitation services required by the patients who are served by the agency. Furthermore, the administrator should be aware of the equipment and the modalities required by the organization to ensure adequate therapy programs are available. This knowledge will come from experience in the field of rehabilitation such as a qualified therapist or education that includes the rehabilitation of patients requiring rehabilitation services, healthcare administration, etc. A physician could serve as an administrator but the expectation remains that the physician has experience or education related to the rehabilitation of individuals. The administrator is responsible for ensuring that personnel records contain all appropriate documentation required by the agency.

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 *of patients with rehabilitation needs or other courses in rehabilitation services,* approved by the appropriate State authority, meet the necessary requirements for specialized training.

Verify the qualifications of the administrator *by reviewing the personnel files. CMS describes qualified individuals in § 485.705**(c).***

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

Verify that an alternate to the administrator has been selected and is *identified* in organization*al* policies. *In these policies, it is permissible to list the temporary alternate by position instead of by name. CMS realizes that staff frequently changes positions and if names are used, this may require frequent policy updates. That alternate must be a qualified individual, as noted in § 485.705, who is aware of the operation of both the primary site and any extension locations.*

If an organization's extension location is applying to be a primary site, the current administrator cannot become the administrator of the new primary site unless he/she relinquishes his current position. Additionally, the current administrator cannot serve as an alternate administrator for the new primary site unless he/she will work solely at the newly approved site and the current primary site has hired a new administrator.

B – Major Sources of Information

- *Policies and procedures for selection of alternate administrator;*
- *Personnel file of the administrator;*
- *Policies and procedures for hiring staff ; and*
- *Interview with administrator or designated alternate during the survey.*

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(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§ 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.

Interpretive Guidelines §485.709(c)

A – General

At a minimum, *clinics or rehabilitation agencies must* have:

- *Policies and procedures for selecting qualified personnel;*
- *Policies and procedures for documenting verification of the current licensure and/or certification, and other qualifications for those personnel whose positions or functions require such licensure or certification, and for determining where licenses are maintained and who updates personnel records;*
- *A policy describing the system for assessing competency of all personnel providing healthcare services (upon hire and on an ongoing basis, and on a schedule determined by the organization's policy), as well as describing where competency checklists or other documentation are maintained;*
- *A policy describing the frequency of direct supervision for all qualified personnel;*

- *A policy for continuing education requirements;*

- *A policy for hiring/firing practices;*

- *A policy describing staff evaluations (e.g., frequency of evaluations, types of evaluations—initial, annual or disciplinary, position of person responsible for conducting evaluations, rebuttals for evaluations perceived as poor, etc.); and*

- *Policies and procedures for documentation to be placed in personnel records (e.g., license, certification, competency checklists, adverse actions, annual evaluations, continuing education certificates, etc.).*

These types of organizational practices must be located in the personnel operations manual or the personnel policy and procedure manual, and must be kept current.

Review personnel policies. During interviews with the *organization's* administrator and staff elicit evidence that personnel practices are *consistent with* written personnel policies.

B – Major Sources of Information

- *Updated personnel policies and procedures;*

- *Personnel records; and*

- *Interviews with administrator and staff.*

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(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§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.

Interpretive Guidelines § 485.709(d)

A - General

The *clinic or rehabilitation agency must* 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 *organization* and, where appropriate, outside professionals.

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

The organization annually reviews its policies and procedures. It keeps written documentation of these reviews. Review *the annual policy review documentation* to determine whether the policies of the *clinic or rehabilitation agency* are current and responsive to the needs of patients; and when unresponsive that appropriate policy revisions are undertaken. Verify that patient care policies are being reviewed annually, and revised as needed by the appropriate professional personnel.

B – Major Sources of Information

- *Patient care policies*
- *Annual policy review*

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(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§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.

Interpretive Guidelines § 485.711

A - General

All patients must be treated pursuant to a written plan of care that indicates:

- *the therapy services being provided;*
- *the anticipated goals of therapy; and*
- *the type, amount, frequency, and duration of services to be furnished.*

A plan of care must be developed by a physician or therapist who furnishes the services after assessing the patient. The signature and professional designation (e.g., PT) of the

individual, who established the plan, and the date it was established, must be recorded with the plan. This documentation will be found in the patient's clinical record.

Reevaluations are performed at specific time intervals noted in the organization's policies and procedures, or if there are changes in the patient's medical status. The reevaluations are documented in updated plans of care. The updated plans should contain objective data, which reflects the patient's progress or lack of progress; and the revised type of services, amount, frequency and duration of therapy, as well as updated rehabilitation goals.

B - Major Sources of Information

- *Patients' plans of care; and*
- *Clinical records.*

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(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§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.

(8) If appropriate, the summary of treatment furnished and results achieved during previous periods of rehabilitation services or institutionalization.

Interpretive Guidelines § 485.711(a)

A- General

The regulations do not require the patients be referred to the *organization* by a physician, or that the services be furnished pursuant to a physician's orders.

If the complete and appropriate past history, and/or current medical findings *(regarding the patient),* are not made available to the organization; *then* the organization should *make every effort to* obtain the information from other sources, such as the patient, the family or from follow-up with the referring physician (if any). *It is difficult to write rehabilitation goals in a plan of care if there is no past history available. It is very important to have current medical findings documented in the record in order to avoid providing therapy or other rehabilitation services that may be contraindicated.*

Review *the* clinical record for evidence of prior medical history*, past rehabilitation services the patient may have received (if any), current medical findings,* and treatment. *All of these areas may impact how the patient performs on the rehabilitation evaluation, and the subsequent design of the plan of care and rehabilitation goals.*

B – Major Source of Information

- *Clinical records.*

§485.711(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 in the plan 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.

Interpretive Guidelines § 485.711(b)

A - General

The plan of care must describe the treatment for the diagnosis (es) documented in the medical history and must document treatment goals.

Section 485.711(b)(3) ensures that, whenever a change takes place that affects the patient's response to treatment, the treatment plan is updated and includes updated therapeutic procedures, frequency changes, changes in modalities, etc. The change could be a physical change in the patient's condition or an environmental change that affects the current treatment regimen.

Qualified therapists who provide rehabilitation services, who meet the requirements in part 484 of this chapter, can assess patients without an order. Using the assessment, the therapist then develops the plan of care.

Review patients' records to determine if a plan of care has been established and is periodically reviewed *and updated*. The condition statement and standard permit the plan of care to be established by a physician, or by the appropriate professional (i.e., a physical therapist or speech-language pathologist) and to be reviewed by a physician or the individual who established it.

Review the assessment updates and updated plans of care. Note if the progress notes reflect the services the patient is receiving. Plans of care are based on the patient's condition at the time the plan is written, and updated as the patient's condition changes.

The plan of care should not look identical from month to month. *T*reatment and rehabilitation goals should be updated as the patient makes progress and meets existing goals.

The plan of care may be established by a qualified therapist as defined at § 484.4 (Personnel Qualifications).

There are occasions when patients do not meet the goals identified in the plan of care, perhaps due to medical complications or other reasons. If the patient is not discharged for failure to meet the goals, the surveyor should expect to see a modified plan of care with newly identified rehabilitation goals.

NOTE: The term physician includes a podiatrist or optometrist whose performance of functions is consistent with the *organization's* policies, and whose services are related to functions he/she is legally authorized to perform. *For example, a podiatrist can order physical therapy services for his patient, if the patient requires gait training with an assistive device status post-surgery. However, there is no expectation that the podiatrist order audiology services, which would be better ordered by an audiologist. An optometrist can order occupational therapy for low vision therapy to request training in assistive devices for reading, yet it would be inappropriate for the optometrist to order physical therapy services for gait training which is better ordered by a podiatrist or orthopedic surgeon.*

B – Major Source of Information

- *Clinical records.*

§485.711(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.

Interpretive Guidelines § 485.711(c)

A - General

Anytime a rehabilitation agency seeks or provides emergency care for a patient, the incident should be noted in the patient's clinical record and should include any calls to "911," to the physician, and/or to the patient's family/caregiver.

*The rehabilitation agency is no longer required to have a physician on call to furnish necessary medical care in case of an emergency. However, the agency should have policies and procedures in place that instruct its staff regarding the steps to take in an emergency (including **immediate care of the patient,** notification of the patient's doctor**, and preparation of reports). The agency should also have instructions in place regarding the** documentation in the clinical record for all actions taken **in an emergency.***

*Note: There must be two persons (who are employed by the clinic or rehabilitation agency) on duty **whenever** a patient is being treated by the clinic or rehabilitation agency, as provided under § 485.723(a)(6). This two person requirement applies to any*

location where outpatient therapy services are provided by the organization. If there is any concern regarding whether the organization actually has two staff on duty, review the staff schedules.

Review the medical emergency procedures and interview employees to determine if they know their responsibilities in the case of an emergency.

B – Major Sources of Information

- *Policies and procedures for emergency care,*
- *Clinical records,*
- *Interviews with staff, and*
- *Staff schedules.*

I-55

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§ 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.

Interpretive Guidelines § 485.713

A - General

Physical therapy services are those services provided within the scope of practice of physical therapists and necessary for the diagnosis and treatment of impairments, functional limitations, disabilities or changes in physical function, and health status.

*A range of physical therapy services must be **available** to treat the types of disabilities the rehabilitation agency accepts for service.*

The number of qualified professional personnel is dependent upon the number of patients treated and the types of disabilities accepted for service.

Also, all equipment must be available to treat the type of disabilities accepted by the organization.

When a patient requires services that aren't available from the organization or if a problem is identified that goes beyond the scope of services offered by the organization, the organization should refer the patient to other community services and should be noting that referral in the patient's clinical record.

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 organization must appropriately refer individuals who have needs that exceed their scope of service.*

- *Personnel records—job descriptions, employee qualifications, and current licensure information.*

- *Clinical records.*

- *Interviews with staff and clients.*

- *Personnel rosters for the number of qualified professionals on duty.*

- *Through observation and interview assess the organization for types, and number of equipment available for patients.*

I-56

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§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 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 that makes an onsite supervisory visit at least once every 30 days.

Interpretive Guidelines § 485.713(a)

A - General

NOTE: *If physical therapy services are being provided at an extension location, clinical records should be carefully reviewed to note whether the therapist is the actual professional conducting the evaluations and re-evaluations, and not the physical therapist assistant. Only physical therapists are allowed to conduct evaluations and reevaluations.*

An adequate outpatient physical therapy program includes:

(a) Conducting patient evaluations *to determine the patient's past and present functional abilities, and to set goals for future functional capabilities.*

(b) Administer*ing* 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.

(c) *Providing equipment and modalities* of heat, cold, water and electricity to treat individuals with the types of disabilities the *organization* accepts for service. *A thorough review of the patient's plan of care including treatment procedures and treatment modalities, as well as the rehabilitation goals and documented results can be a guide as to the adequacy of the patient's therapy program.*

(d) Having appropriate clinical record documentation. The clinical record is the only document describing the course of treatment and the outcomes for the patient. Poor documentation may reflect a less than adequate therapy program.

Review patient care policies and procedures, *as well as clinical records* to assess the adequacy of the organizational program. *In addition, observation of the clinic or room where patients are receiving therapy services is important to evaluate the equipment and modalities available.*

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 *physical* therapist must be onsite for evaluations, reevaluations,

and discharges of patients. A physical therapist *must be* present when *special skills are offered to patients* according to the organization's policies and procedures. *Services provided* by a physical therapy assistant *offsite must be* supervised by a qualified physical therapist that 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;
- Discussion between the physical therapist and the physical therapist assistant; and
- Additional supervision requirements *as defined by State law.*

NOTE: This does not mean the physical therapist must be onsite full-time, but rather must be *onsite for evaluations and reevaluations and be* able to respond and 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 and thereby possibly requiring that in the future the physical therapist keep him *or her*self 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 (frequency of supervision, areas discussed, etc.).

B – Major Sources of Information

- *Policies and procedures for supervision of organizational staff;*
- *Policies and procedures for patient care;*
- *State practice acts;*
- *Clinical records—progress notes and treatment plans; and*
- *Staff interviews and facility observation.*

§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.

Interpretive Guidelines § 485.713(b)

A – General

The organization must provide space for treatment, and offer areas of privacy when needed during treatment or when requested by the patient. Screens, curtains, or other methods for ensuring privacy should be available when needed. For example, times when a patient might require privacy are when the patient is receiving instruction for activities of daily living or if a patient is receiving modalities such as heat or ultra sound for back pain.

Review patient care policies and procedures, *clinical records,* and tour *the organization's facility* to assess the adequacy *and condition* of equipment to treat the patients it has accepted for service. Review organizational procedures *and maintenance logs; interview* staff to ensure equipment is being maintained according to manufacturer*'s* guidelines.

B – Major Sources of Information

- *Policies and procedures regarding the equipment maintenance;*
- *Policies and procedures for ensuring privacy;*
- *Patient Care Policies and Procedures;*
- *Maintenance Logs;*
- *Manufacturers recommended guidelines for each piece of equipment;*
- *Amount and types of equipment in the clinic at the time of survey;*
- *Clinical Records; and*
- *Staff interviews and clinic observations.*

§ 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.

Interpretive Guidelines § 485.713(c)

A – General

Some of the requirements for a qualified physical therapist are that they be licensed as a physical therapist by the State in which he or she is practicing (unless licensure does not apply), has graduated from an accredited physical therapist education program, and has passed a national examination approved by the State in which physical therapy services are provided. For the remaining requirements refer to §484.4 Personnel qualifications.

In addition, some of the requirements for a qualified physical therapist assistant (PTA) are: a person who is licensed, unless licensure does not apply, registered, or certified as a physical therapist assistant, if applicable, by the State in which practicing. For the remaining requirements refer to §484.4 Personnel Qualifications: Physical therapist assistant qualifications.

The number of qualified physical therapists and qualified physical therapist assistants (if applicable) must be able to adequately and effectively provide services to patients. Adequate service cannot be determined based merely upon the staff to patient ratio, but rather, it is to be based on staff's knowledge of the various types of medical conditions the organization treats and the type, amount, frequency, and duration of treatment required.

Interview staff and patients to determine if there are issues with excessive waiting times or delays in therapy caused by therapists treating more than one person at a time.

Observe the number of patients waiting for treatment. Are there several patients sitting and waiting for treatment, or does it appear that patients are being seen at their scheduled times. Is there a single therapist treating several patients at one time or are there several therapists or PTAs that are providing treatments.

A qualified physical therapist must be on the premises *or readily available telephonically as well as readily available to be onsite if needed during all hours of operation.*

Physical therapist assistants and certified occupational therapy assistants are not permitted to evaluate new patients or re-evaluate current patients.

Surveyors should verify through clinical record review, observation, and interview:

- That patient evaluations or reevaluations, *or situations where special skills are required are being performed by a PT;*
- That a PT is either present or available telephonically during hours of operation of the *organization*; *and*
- The clinical record notes and/or observations indicate that the plan of care is being followed.

For example, if a patient is required to be seen three times a week for 4 weeks (according to the plan of care), but is only seen two times a week for 4 weeks, this could indicate a staff shortage. The progress notes in the clinical record should indicate the reason why the patient is not being treated per the patient's plan of care. The surveyor should interview the staff if the answer is not readily apparent. The surveyor may cite the organization under this standard if it is determined there are not sufficient staff to treat patients according to the patient's plan of care.

B – Major Sources of Information

- *Clinical record (plan of care and progress notes);*
- *Personnel records and credential files;*
- *Policies and procedures for personnel and patient care;*
- *Treatment schedules;*
- *Staff and patient interviews; and*
- *Observations of staff and clinical areas.*

I-63

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§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.

Interpretive Guidelines § 485.713(d)

A - General

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 *the* organization*'s* policies and procedures to determine the job responsibilities and training of the supportive personnel.

Observe services provided by therapists' aides to determine if these individuals are providing an appropriate level of assistance. Interview supportive personnel regarding the services they provide and the instruction they received.

B – Major Sources of Information

- *In-service training logs for supportive personnel;*
- *Policies and procedures for training supportive personnel;*
- *Policies and procedures for supportive personnel job responsibilities;*
- *Observation of clinical areas; and*
- *Interview staff.*

I-150

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§ 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.

Interpretive Guidelines § 485.715

A - General

Speech-language pathology services are those services (examples are provided below) that are provided within the scope of practice of speech-language pathologists and are necessary for the diagnosis and treatment of speech and language disorders.

The speech pathology services provided should be such that patients accepted for treatment are able to receive services as medically indicated. *The equipment used by speech-language pathologists may vary from organization to organization, depending upon the types of patients that each organization accepts for service. Equipment must be available that is necessary for the patient's treatment.*
Review personnel rosters and patient census to determine that the organization provides sufficient qualified personnel to adequately serve the patients it accepts for services.

B - Major Sources of Information

- *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.*

I-151
(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§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.

Interpretive Guidelines § 485.715(a)

A – General

In order for the organization to have an adequate speech-language pathology program, it must have available qualified speech-language pathologists (refer to § 484.4 for the requirements), and the necessary equipment to diagnose and treat the patients that it accepts for services. Speech-language pathology services are aimed at improving a

patient's communication, cognitive and linguistic skills, and hearing and swallowing abilities.

Clinical services provided by speech-language pathologists may include, but are not limited to, the following:

- *Dysphagia (swallowing) evaluation and treatment;*
- *Selecting, fitting, and establishing effective use of prosthetic/adaptive devices for communication and swallowing;*
- *Using instrumentation such as video fluoroscopy and computer technology to observe, collect data, and measure parameters of communication and swallowing;*
- *Voice therapy to remediate disorders in vocal quality and volume;*
- *Language therapy to improve comprehension and expression; and*
- *Cognitive retraining.*

Review the patient's clinical record to ascertain what type of equipment, if any, is used for the patient and if that equipment is available on the day of the survey.

B. Major Sources of Information

- *Patient care policies and procedures;*
- *Clinical records; and*
- *Staff interviews and observations of therapies.*

I-152

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§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.

Interpretive Guidelines § 485.715(b)

A – General

All equipment must be maintained according to manufacturer's guidelines.

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

Space suitable for treatment must be available. The facility must include areas of privacy for patients during therapy treatment as needed and/or when requested by the patient. Screens or curtains or other method for ensuring privacy should be available when needed. For example, times when a patient might require privacy are when the patient is receiving training for activities of daily living, using communication devices, etc.

B – Major Sources of Information

- *Policies and procedures regarding patient care, treatment and equipment;*
- *Policies and procedures regarding the privacy of patients;*
- *Interviews—staff and patients;*
- *Clinical record review;*
- *Review of maintenance logs; and*
- *Review of manufacturers' guidelines.*

I-153

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§ 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.

Interpretive Guidelines § 485.715(c)

A - General

A qualified speech-language pathologist meets the requirements found in § 484.4.

Adequate service cannot be determined based upon the mere proportion of the staff to patient ratio. Qualified staff must possess the knowledge and skills required for the treatment of the various patients' diagnoses.

Surveyors should verify through record review, observation, and interview:

- *That patient evaluations or reevaluations are being performed by **or under the supervision of** a SLP a speech-language pathologist;*
- *That a qualified speech-language pathologist is providing speech-language pathology services; and*
- *That the clinical record notes and/or observations show that the plan of care is being followed.*

B – Major Sources of Information

- *Personnel records for licensure, certification, or registration;*
  .
- *Policies and procedures regarding patient care;*
- *Observations and interviews; and*
- *Clinical record review (plans of care and progress notes).*

I-67
(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§ 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 furnishes 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.*

Interpretive Guidelines § 485.717

A - General

The concept of rehabilitative therapy includes recovery or improvement in function and, when possible restoration to a previous level of health and well-being. A rehabilitation agency must provide either physical therapy and/or speech pathology services.

The rehabilitation agency may either hire its staff directly or under a contract. Also, a facility such as a SNF may contract with a rehabilitation agency to provide to provide the therapy services for the SNF inpatients or outpatients.

The rehabilitation agency must have a coordinated approach to providing therapy to the patients it accepts for service if the patient receives more than one service.

The term rehabilitation agency will be used throughout this section as § 485.717 applies only to a rehabilitation agency and not a clinic or public health agency.

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.*

I-68

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§485.717(a) Standard: Qualifications of Staff

The agency's therapy services are furnished by qualified individuals as direct services and/or services provided under contract.

Interpretive Guidelines § 485.717(a)

A – General

All individuals who furnish therapy services in a rehabilitation agency must meet the qualifications of § 484.4; and have the required license, registration or certification as required by national certification organizations, State practice acts, and Federal, State and local laws.

The licenses must be for the States in which the services are being provided.

B – Major Sources of Information

- *Personnel records containing current licenses and/or certificates of registration or certification;*

- *State licensure laws for health care providers; and*
- *State practice acts.*

I-69

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§485.717(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.

Interpretive Guidelines § 485.717(b)

A – General

For guidelines, refer to I-80, §485.719(a).

I-79

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§485.719 Condition of Participation: Arrangements for Physical Therapy and Speech Pathology Services to be Performed by other than Salaried Organization Personnel

Interpretive Guidelines § 485.719

Organizations may hire their own personnel to provide outpatient physical therapy or speech pathology services or they may arrange to provide these services under a contract.

I-80

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

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

Interpretive Guidelines § 485.719(a)

A – General

An organization that does not provide services using its own employees (i.e., salaried personnel) may obtain those services by means of written agreements or contracts with individuals or organizations. The employees hired under contract may provide services wherever the organization provides therapy services.

The contracts must specify the time frame of the contract (beginning and end dates), the organization's administrative responsibility and its control and supervision over the services, and must detail the manner of termination or renewal of the contract.

Review contracts to assure that the organization's responsibility is specified and described in detail. The contract should contain both the names of a representative of the organization requesting therapy services and the name of the contracted employee or the representative of the organization that is supplying the contracted employees. The signatures of both parties indicate both the knowledge of the terms of the contract and the responsibilities of both parties.

B - Major Source of Information

- *Contract for services under arrangement.*

I-81

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§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 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.

Interpretive Guidelines § 485.719(b)

A - General

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 *organization,* 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.

B – Major Sources of Information

- *Contracts; and*
- *Policies and procedures regarding contract specifications.*

I-90

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§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.

Interpretive Guidelines § 485.721

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: *evaluations/reevaluations, plan of care,* progress notes, monthly summaries, records of communication with the patient's physician and other therapists, *family or caregivers*

who may supply additional information such as the patient's prior level of functional abilities, and discharge summaries. *Refer to § 485.721(b) for further details on the contents of the clinical records.*

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.

All entries in the clinical record must be signed, dated, legible, and applicable to current treatment. Note: outpatient clinical entries are only required to have the date documented, not the time associated when the clinical notes are entered. However, inpatient clinical entries must have all entries documented with time and date.

Documentation written by those employees providing services under contract or arrangement must meet the documentation standards of the organization.
Sample a minimum of 25 clinical records, representing both the organization's current roster of patients, as well as records from discharged patients, from the past six months. The sample must include records from both the primary site and any extension locations. Include in the sample those patients whose treatment *are/were* provided by a contracted employee, to *ascertain whether* evaluations, *plans of care,* progress notes, and other pertinent clinical material are present and that the clinical records for all patients are maintained on the premises of any location at which services are rendered.

The sample should be representative of all the services that are provided at the facility (e.g., OT, PT, SLP and any other services that are provided by the organization.

Electronic records, if part of the sample review, must be available to surveyors during the survey.

Organizations must maintain policies regarding the protection and confidentiality , of clinical records. Some examples might include: the location of locked cabinets, passwords required to access electronic clinical records, securing the records from unauthorized use, etc.

B - Major Sources of Information

- *Active and closed clinical records; and*

- *Policies regarding retention, protection, unauthorized use of, and the confidentiality of patient information contained in clinical records.*

I-91
(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§485.721(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.

Interpretive Guidelines § 485.721(a)

A – General

Clinical records are to be stored according to all Federal, State, and *local* privacy laws where they are protected from unauthorized use. *All locations, including extension locations that store clinical records, are to be secure in order to protect the records from loss, destruction, unauthorized use, and patient confidentiality. For example, records left in patients' rooms, in common areas, waiting rooms, and on staff desks after work hours are not protected from visitors who may read the charts.*

B – Major Sources of Information

- *Policies and procedures should reflect protections of clinical records from unauthorized use and ensure that all Federal, State, and local laws are followed; and*

- *Observations of common areas where clinical records may not be protected.*

I-93
(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§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.

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

Interpretive Guidelines § 485.721(b)

A – General

***Assessment and Plan of Care**: Each patient's* clinical records must contain an assessment of the *patient (initial evaluation and reevaluations where appropriate). The assessment should address areas, including the immediate therapy needs, which may affect the outcome of therapy such as family, home, employment, etc.*

The clinical record must have a plan of care (including the types, amount, duration, and frequency of services provided), identification data (name and address of patient), and should have documented observations, *treatment notes*, *progress reports* of treatments and clinical findings, and discharge summary. Other documentation should include coordination efforts between professionals providing services, *as well as communication between the professionals, physicians, and families/caregivers*.

***Identification Data and Consent:** Does the documentation in the clinical record contain adequate patient identification information—have entries in the clinical record been misfiled due to lack of identification information? Have consent forms been signed (patients are often asked to sign consent forms either to obtain information about the patient or for pictures to be taken of the patient), and are they in the clinical record? It may be an authorized family member or guardian who signs the consent forms, as permitted under State law.*

***Medical History & Reports**:* Medical history and report of the physician's physical examination may or may not appear in clinical records. Where medical history does appear in clinical records, it may not have been transmitted by the physician, but rather may have been obtained from the patient when their past and present history was related *verbally*. *It is acceptable for the patient to provide his/her present and past history for documentation by the therapist. The therapist may also gather information from the family, caregivers, and /or physician.*

***Observations and Progress notes:** The progress note is a summary of treatment, and should include observations and an assessment of the patient's improvement or lack thereof. It should also include the extent of progress toward goals, any changes to the goals, and the patient's potential for improvement. Physical therapist assistants or*

occupational therapy assistants may write subjective elements of the progress notes, but the objective elements of the progress notes (results of evaluation, revision of type of therapy, and therapeutic goals) must be written by the qualified therapist. Do we have to limit this entry to the therapist? Can the assistant make more substantive entries if they are reviewed by the therapist?

Reports of treatments and Clinical Findings: *Treatment notes are often written after each treatment session. The purpose of treatment notes are to create a record of all treatments and skilled interventions that are provided, and to record the time spent in treatment.*

Discharge note/discharge summary: *The discharge note or discharge summary is required when a patient is discharged from the rehabilitation agency. The discharge note should contain the final diagnoses, information regarding the patient status at the time treatment was initiated, current status of the patient, outcomes of treatment, whether goals were met, and the final prognosis (whether the patient will benefit from any further therapeutic intervention). The discharge summary may indicate if the patient is being referred to another facility for further therapeutic intervention; the name and location of the facility and if the patient will be living independently or will require assistance.*

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.

B – Major Sources of Information

- *Policies and procedures for required documentation in clinical records; and*
- *Clinical Records.*

I-95

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§ 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.

Interpretive Guidelines § 485.721(c)

A - General

Regardless of whether the organization provides services through its own employees or through an arrangement with others, all information and materials that are pertinent to the patient's treatment are to be part of the clinical record; which is to be securely 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.

If omission of any pertinent information is noted in the clinical records, complete additional clinical record reviews to determine the prevalence of such omissions. *If there is evidence of many instances of non-compliance, the surveyor should expand the sample and pull an additional 5 records.*

A discharge summary should include: the date and reason for discharge, a brief summary of the status of the patient from the date of the last report to the last day of treatment, and, where applicable, provision for referral of the patient to another source for continuing care.

B – Major Sources of Information

- *Policies and procedures for required documentation in the clinical record; and*
- *Clinical records.*

I-96

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§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.

Interpretive Guidelines § 485.721(d)

A - General

Review the organization's 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.

B – Major Sources of Information

- *State statutes regarding clinical record retention; and*
- *Policies and procedures detailing length of time to retain records, and methods for preserving clinical records.*

I-97
(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§485.721(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.

Interpretive Guidelines § 485.721(e)

A – General

Clinical records are indexed according to the last name of each patient. *The organization will determine its system for indexing its electronic health records. These* systems may be utilized for indexing either active and/or discharged patient clinical records as determined by organizational need.

B – Major Source of Information

- *Policy or procedure for indexing clinical records.*

I-99
(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§485.721(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).

Interpretive Guidelines § 485.721(f)

A – General

The clinical records are to be easily retrievable, and available to all professional staff members of the organization as well as other authorized individuals. Clinical records may be maintained at a site other than the primary location (*e.g., the extension location*) if the patient receives outpatient therapy services at that other site. However, 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 in person*, as long as the delivery is within a reasonable amount of time during the course of the onsite survey. Delivery is essential *to enable the surveyor to review the records within the time of the onsite survey*.

B – Major Source of Information

- *Policy and procedure manual (clinical records section).*

I-117

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§ 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.

Interpretive Guidelines § 485.723

A - General

This Condition of Participation relates to all of the organization's treatment areas and physical environment (for example, the organization's portion of the building when it is co-located with a physician's office or within a comprehensive outpatient rehabilitation facility (CORF)).

Patient treatment areas are to be physically separate from the non-treatment areas (e.g., storage). A handicapped accessible restroom must be available for patient use. However, the restrooms need not be located directly in the treatment area, but may be located down a hallway.

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 the surveyor should examine the physical plant of the organization and ascertain whether it is consistent with State and local building, fire, and safety codes. This examination is done *by reviewing the inspection reports of State and local building and fire inspectors; observing whether areas of egress, entrance, and stairwells are hazard free; whether there are any fire hazards; and whether sinks are working properly (e.g., noticeable leaks that could endanger staff or patients walking in the area).*

B - Major Sources of Information

- *Applicable federal, State and local laws;*
- *Inspection reports of State and local building and fire authorities;*
- *Organization policies regarding maintenance of equipment, building, and grounds;*
- *Observation of treatment and non-treatment areas; and*
- *Interviews with staff regarding physical environment issues.*

I-118

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§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.

Interpretive Guidelines § 485.723(a)

A – General

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 rest of the building by 1-hour rated fire resistant doors. 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. *State or local laws should define what type of fire extinguisher is considered to be easily accessible and appropriate for the organization's building.*

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 wheelchairs, gurneys or stretchers, etc. Stairwells should include handrails on at least one side, and should be free from obstruction at all times.

During emergency operation, an emergency power source (e.g., battery or auxiliary generator) is available to assure adequate lighting within the treatment areas and those passageways, stairwells, and exits (as noted above) that are 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 internal 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 inactivated by a disruption in the organization's electrical system such as a power outage, 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.

Anytime a patient is being treated by the organization, at least two organization staff will be on duty on the premises. This requirement is for the safety of the patients. It is not a

new requirement, but is sometimes overlooked, at either the primary site of the rehabilitation agency or the rehab agency's extension location(s).

This duty requirement can be verified by requesting staff or personnel time cards. The staff time cards can be compared against patient sign-in sheets if there are concerns regarding the two person duty requirement.

B – Major Sources of Information

- *State/local building, fire and safety code; and*
- *Staff schedules and patient logs.*

I-121

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§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.

Interpretive Guidelines § 485.723(b)

A – General

All equipment should be inspected by the organization at least yearly, or in accordance with manufacturers' guidelines, and a maintenance scheduled should be maintained. Such inspection is determined in part by present equipment condition, its frequency of use, and is to be outlined in the *organization's* 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 will review the manufacturer's instructions; and interview staff to ensure they are familiar with the instructions and that they are following the instructions. The organization's staff must make equipment calibration checks, periodic maintenance procedures, etc. Review copies of service repair statements, maintenance checklists or other documentation, to determine whether such recommendations were followed.*

Request a copy of the procedures for performing ongoing maintenance for the organization's physical plant. Cite hazards to the health and safety of patients, staff, and general public on the Form CMS- 2567. Examples of such hazards are broken window panes and/or door panels, obstruction of passageways, and dangerous floor surfaces. Review maintenance checklists to ensure that staff are following the recommended schedules for equipment maintenance and for problems areas are require repair.

Observations will also tell the surveyor if problem areas exist. Are cords on electrical equipment frayed, are the plugs on the cords broken, does the whirlpool work (if not, why not and how long has it been unusable?)?

B – Major sources of information

- *Policies and procedures regarding individuals responsible for equipment inspection, frequency of inspections, and disposition of broken equipment;*
- *Logs with dates of equipment inspections;*
- *Information fact sheets from equipment manufacturers regarding care of equipment;*
- *Interviews with staff/patients/administrator; and*
- *Clinic observations including equipment maintenance and functioning.*

I-123

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§ 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.

(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.

Interpretive Guidelines § 485.723(c)

A – General

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. Ramps must be available to provide for easy access to facilities. Examination and treatment areas *must* 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 at least one restroom/toilet facility is handicap accessible. Observe all areas within the organization. Is the space adequate for storage, treatment, etc.?

B – Major Sources of Information

- *Policies and procedures for housekeeping and facility operations;*
- *Interviews with patients and staff; and*
- *Surveyor observations.*

I-160

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§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.

Interpretive Guidelines § 485.725

A - General

This condition applies to all organizations as providers of physical therapy and/or speech-language pathology services. Any services provided by a rehabilitation agency are subject to the agency's Infection Control policies and procedures.

An infection control committee, applicable for organizations offering physical therapy *or speech-language pathology* 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; as well as monitors staff performance to ensure that the policies and procedures are being executed.

Review the organization's Infection control policies and procedures. The organization *must* have the necessary housekeeping staff and supplies to maintain a sanitary environment.

The organization must investigate infections acquired by patients that occur after treatment using equipment such as a whirlpool or instruments used in debriding a wound.

If the organization is providing services at more than one location per day, there should be infection control policies in place for all locations. These policies should set forth the techniques agency employees must use to prevent cross-contamination of patients between locations. For example, when an organization is providing services to patients in a skilled nursing facility and then they travel next door to provide treatment to patients in an assisted living facility, the staff will wash their hands before treating patients.

B - Major Sources of Information

- *Written policies and procedures;*
- *Minutes of the infection control committee meetings;*
- *Interviews with staff, patients, and administrator; and*
- *Observations.*

I-161

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§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.

Interpretive Guidelines § 485.725(a)

A – General

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., *PT, SLP, OT,* and other qualified professionals) is adequate to perform this function. The administrator 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 equipment used by occupational therapy or speech-language pathology.

B – Major Sources of Information

- *Policies and procedures regarding management of infection control;*
- *Interviews and observations to determine if the policies and procedures are being executed and followed;*
- *Minutes of Infection control committee meetings; and*
- *Reports of patients acquiring infections or communicable diseases.*

I-163

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§485.725(b) All Personnel Follow Written Procedures for Effective Aseptic Techniques. The Procedures are Reviewed Annually and Revised if Necessary to Improve Them.

Interpretive Guidelines § 485.725(b)

A – General

Aseptic or isolation techniques are generally used to prevent others (staff and patients) from acquiring an infection or communicable disease that the patient has. Some patients may be isolated to prevent them from being exposed to others (e.g. a patient with a compromised immune system).

Staff is to follow *the organization's* written procedures for effective aseptic techniques. Review the aseptic procedures developed and ascertain, through *interviews, observations, and, document reviews;* that the procedures *are followed* by the staff.

Infection control guidelines issued by the Center for Disease (CDC) are accepted industry standards and can be found at: http://www.premierinc.com/safety/topics/guidelines/cdc_guidelines.jsp.

Review the organization's documentation of its aseptic procedures. *The procedures must be reviewed annually and updated as needed (look for dates and signatures).*

B – Major Sources of Information

- *Policies and procedures detailing aseptic techniques to be implemented by staff;*
- *Staff interviews regarding their knowledge of those policies and procedures; and*
- *Staff observations.*

I-165

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§ 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 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.

Interpretive Guidelines § 485.725(c)

A – General

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. If the organization contracts with outside housekeeping services. then review contracts to ensure that the organization has retained responsibility and oversight for the housekeeping services performed by the outside source.

B – Major Sources of Information

- *Contract with outside agency detailing housekeeping services;*
- *Policies and procedures identifying responsibilities for housekeeping duties; and*
- *Evidence that the agency maintains responsibility and oversight for the housekeeping services.*

I-167

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§ 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.

Interpretive Guidelines § 485.725(d)

A – General

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.

B – Major Sources of Information

- *Policies and procedures regarding care and proper storage of linens;*
- *Staff interview; and*
- *Clean linen storage area.*

I-169

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§485.725(e) Standard: Pest Control

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

Interpretive Guidelines § 485.725(e)

A – General

The organization's premises *must* be free from insects and rodents. Review the organization's written policy covering the pest control program.

B – Major Sources of Information

- *Organizational policies and procedures for the facility's pest control program; and*
- *Observe premises for pests.*

I-170

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§ 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.

Interpretive Guideline § 485.727

A - General

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

B - Major Sources of Information

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

I-171

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§ 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) 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.

Interpretive Guidelines § 485.727(a)

A – General

The disaster plan must be developed with the assistance of fire, safety, and other appropriate experts. Ensure that the written *disaster* plan *(which includes each of the five specified items under this standard)* is operational, 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. Fire extinguishers must not be expired.*

B – Major Sources of Information

- *Organization's disaster plan;*

- *Organization policies and procedures; and*

- *Surveyor observations.*

I-173
(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§ 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.

Interpretive Guidelines § 485.727(b)

A – General

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 to review and practice their responsibilities as stated in the disaster plan.

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

B – Major Sources of Information:

- *Organization policies and procedures;*

- *Schedules of organization-sponsored training activities and drills, including use of fire extinguishers;*

- *Staff interviews regarding knowledge and execution of role in event of a disaster; and*

- *Employee in-service education sign-in sheets.*

I-180
(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§ 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.

Interpretive Guidelines § 485.729

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.*

I-181

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§ 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.

Interpretive Guidelines § 485.729(a)

A – General

The organization randomly selects a sample of clinical records *from* active and closed *files*. *The sample size should reflect* each service offered by the organization. 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.

*Surveyors will r*eview minutes *or reports* of the *organization's* clinical record review committee, *and determine if the agency reviewed open and closed records that reflected the services provided.*

B – Major Sources of Information

- *Minutes of meetings on clinical record review;*
- *The actual sample size and the types of clinical records selected (open and closed records; reflect various services the organization provides);*
- *Organization policies and procedures regarding clinical record review, and sample selection size; and*
- *Organizational chart.*

I-183

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

§ 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.

Interpretive Guidelines § 485.729(b)

A – General

The *organization* must conduct an annual evaluation of statistical data. Each agency 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.

B – Major Source of Information

- *Annual organization statistical reports*

State Operations Manual
Chapter 2 - The Certification Process

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2290 – Providers of Outpatient Physical Therapy and Speech-Language Pathology Services - Citations

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

The statutory basis for providers of outpatient physical therapy and outpatient speech-language pathology services is found under § 1861(p) of the Social Security Act. The Conditions of Participation (CoPs) for rehabilitation agencies, clinics (operated by physicians) and public health agencies as providers of outpatient physical therapy and speech-language pathology services, are specified in 42 CFR Part 485, Subpart H. Appendix E of the State Operations Manual (SOM) and sections 2290-2306 of the SOM contain interpretive guidelines for regional offices (ROs), State Agencies (SAs) and accreditation organizations (AOs).

2292 - Types of Organizations, Who May Provide Outpatient Physical Therapy and Speech-Language Pathology Services, Specified in §§ 485.701-485.729

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

There are three types of organizations that may qualify as providers of outpatient physical therapy and speech-language pathology services under 42 CFR Part 485, Subpart H: clinics, public health clinics, and rehabilitation agencies. However, rehabilitation agencies are the only organizations that are currently enrolled as a Medicare provider with a CMS Certification Number (CCN). The general term "organization" is defined as a clinic, rehabilitation agency, or public health agency and is used throughout this chapter and the interpretive guidance to collectively reference these providers of outpatient therapy services (i.e. outpatient physical therapy and speech-language pathology that were formerly referred to as OPTs). Any specific organization, such as a rehabilitation agency, will be noted in the guidance as appropriate for requirements that are specific to that organization alone.

2292A - Rehabilitation Agency

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

The primary purpose of a rehabilitation agency is to improve or rehabilitate an injury or disability, and to tailor a rehabilitation program to meet the specific rehabilitation needs of each patient referred to the agency. A rehabilitation agency must provide, at a minimum, physical therapy and/or speech language pathology services to address those needs of the patients. ***Social/vocational services are no longer a requirement****.*

The rehabilitation agency must be able to provide therapeutic procedures as well as the modalities of heat, cold, water and electricity for physical therapy treatments for the patients it accepts for service at any of its practice locations. The rehabilitation

agency must also be able to provide any equipment required by the speech-language pathologist to treat patients accepted for such service.

*As noted above, rehabilitation agencies must provide at least physical therapy and/or speech language pathology services to comply with the CoPs. Occupational therapy is an optional service and **cannot** be substituted for either of these two services. It may be provided in addition to physical therapy and/or speech-language pathology services.*

A rehabilitation agency is no longer required to have a physician on call to furnish necessary medical care in case of an emergency. However, the rehabilitation agency must have policies and procedures in place that instruct its staff regarding the steps to take in an emergency (including notification of the patient's doctor) and appropriate documentation. Refer to 42 CFR 485.711(c).

2292B – Rehabilitation Agency, Clinic and Public Health Agency

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

***Two person duty requirement**: Organizations must always have at least two persons (either of its own personnel or its contracted personnel) on duty on the premises **anytime** rehabilitation treatment is being provided to a patient. The two person requirement does not specify which staff must be on duty (in other words, professional staff or a combination of professional staff and support staff), but the organizations must consider the supervision required of support staff.*

*Rehabilitation agencies must have at least two persons are duty **anywhere** that it provides rehabilitation services, including in assisted living and independent living facilities, in order to meet the regulation at 42 CFR 485.723(a)(6). However, the only exception for the two person duty requirement is when rehabilitation services are being provided a patient's private residence.*

This duty requirement can be verified by requesting staff or personnel time cards. The staff time cards can be compared against patient sign-in sheets if there are concerns regarding the two person duty requirement.

This requirement is for the safety of the patients. It is not a new requirement, but is sometimes overlooked, particularly at a rehabilitation agency's extension location(s). Refer to Interpretive Guidance Tag I-118 in Appendix E of the SOM.

***Supervision:** A physical therapist may not supervise an occupational therapy assistant, nor, may an occupational therapist supervise a physical therapist assistant. Nonprofessional personnel (generally physical and occupational therapy aides) cannot be supervised by anyone other than the qualified physical or occupational therapist while performing patient care activities.*

***Clinical records:** The regulations at § 485.721 require clinical records be maintained on **all patients** served by the organization. A copy of the patient's current*

clinical record should be kept at the practice location and readily accessible for prompt retrieval. Electronic records are acceptable but should be password or other method protected to maintain security and patient privacy.

Administrator: *The administrator (§ 485.709) is given internal control of the clinic or rehabilitation agency by the governing body. The administrator must assume overall administrative responsibility for the entirety of the organization's operation including extension locations and/or off-premises activities. Furthermore, the administrator must serve as a full time administrator, meaning he can only be responsible for a single Medicare certified organization. It is important to determine whether the administrator can efficiently and effectively serve as administrator if the agency has several extension locations. Also, a competent individual must be available at each extension location to manage the day to day operations of that location on the days when the administrator is not onsite. That individual is responsible for reporting to the administrator.*

Governing body: *The governing body (§ 485.709) (or designated person so functioning) has the legal responsibility for the overall clinic or rehabilitation agency operations (including conduct and compliance of the clinic or rehabilitation agency) and may be legally responsible for more than one clinic or rehabilitation agency. The governing body's legal responsibility for the overall conduct of the clinic or rehabilitation agency cannot be delegated to any other entity (for example, a parent corporation). The number of individuals who serve on the governing body is determined by the organization/individuals who own the clinic or rehabilitation agency. The name of the owner(s) or corporate officer(s) (for a corporate entity) is fully disclosed to the State Agency. The governing body is expected to meet periodically, consistent with its by-laws.*

Contracts: *An organization may provide services with direct hire employees (i.e., salaried personnel) and with those employees under arrangement (or contract) (§ 485.719). The employees hired under contract may provide services wherever the organization provides therapy services.*

Not covered under § 485.719 directly but a point worth discussing is the ability of a SNF/NF to contract with a rehabilitation agency to provide physical therapy and speech-language pathology services to its residents. Outpatient therapy services may be provided to SNF/NF residents who have exhausted their Part A benefits or patients from the community who come to the nursing home for the therapy services. The contract should designate the specific responsibilities of both the SNF/NF and the rehabilitation agency. The SNF/NF is responsible for the care received by its residents and patients including, ensuring the resident receives the appropriate services ordered by the physician. The SNF/NF has administrative responsibility for ensuring clinical records documentation is completed by the rehabilitation agency therapists. The SNF/NF will be responsible for billing for those services and reimbursing the rehabilitation agency per contract provisions.

On the other hand, the rehabilitation agency has responsibility for the actions of the therapists while they are providing the services to the SNF/NF residents. The

rehabilitation therapists should be following the documentation principles outlined by the rehabilitation agency when documenting services in the SNF/NF medical records.

The rehabilitation services provided at the SNF/NF are observed by surveyors of long term care facilities.

In addition to SNFs/NFs, rehabilitation agencies may also contract to provide outpatient therapy services at assisted living facilities (ALFs). In this instance, the rehabilitation agency has the administrative responsibility and supervisory oversight for the delivery of services in facilities that are not participating in the Medicare and/or Medicaid programs. In addition, the rehabilitation agency is responsible for maintaining clinical records for therapy services provided to the ALF patients.

When the agency is using a "general use" area in an ALF to treat patients, that area should be closed to residents of the ALF during the time treatment is being provided by the rehabilitation agency. The closed space offers privacy for the patients who are receiving outpatient therapy services.

2294 - Change of Address

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

When an existing organization intends to move its Medicare approved primary site or a rehabilitation agency intends to move any of its approved extension locations to a new practice location or the rehabilitation agency desires to add a new practice location , it must first notify CMS within 90 days of the expected move and seek approval from the RO before it can bill Medicare for covered services from the new address. Refer to §424.515 and §424.516

Process:

The organization must submit written notification to the RO regarding its intended move 90 days prior to the intended move. Concurrently, the organization submits a modified Form CMS-855A to its Medicare administrative contractor (MAC) or fiscal intermediary (FI).

The MAC/FI notifies the RO/SA when it has verified the information.

The RO will evaluate all supporting documentation from the MAC/FI and the SA/AO in making its decision to approve or deny the new practice location.

A survey must be completed in the case of a primary site change of address.

The RO will notify the agency in writing of its decision and provide copies to the SA/AO and MAC/FI.

2296 – Medicare Approved Sites of Service Provision
(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

A rehabilitation agency must provide services at its approved primary site (the site that was issued the CCN). The organization may apply to CMS for approval of another location ***near*** *the primary site* for the purpose of providing additional access to care. *These locations are known as "extension locations" and are defined in 42 CFR 485.703.*

The mandatory services to be provided at the primary site are physical therapy and/or speech-language pathology services. Occupational therapy is an optional service. The extension location must also provide physical therapy and/or speech-language pathology services.

The primary site and extension locations must have sufficient equipment and modalities to demonstrate that it has an adequate therapy program and can appropriately treat the patients that it has accepted for services. The extension location shares administration, supervision, and services with the primary site in a manner that renders it unnecessary for the extension location to independently meet the CoPs.

2298 – Extension Locations for Rehabilitation Agencies
(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

Currently, only rehabilitation agencies are permitted to have extension locations. The clinics operated by physicians and public health clinics are not permitted extension locations. These two providers must provide outpatient therapy services at their Medicare approved location.

An extension location is defined at 42 CFR 485.703 as "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 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."

This means the extension location and the primary location have the same:

- *Governing body,*
- *Administration; and*
- *Policies and procedures (e.g., housekeeping, infection control). However, it is important that evacuation plans are specific to the building where the services are provided.*

The rehabilitation agency may provide a therapeutic service directly at one location

while providing it under arrangement at another. A therapeutic service refers to a type of professional discipline (i.e., physical therapy, occupational therapy, speech language pathology, etc.). Therapeutic services do not refer to particular types of treatment modalities (such as ultrasound or other types of physical agents) applied to produce therapeutic changes to biologic tissue.

2298A - Criteria for Extension Location Approval:

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

It is the CMS RO (not the SA or AO) that has the final authority for approving the request for an extension location. The following criteria should be reviewed and assessed in a decision regarding the approval or denial of extension locations:

- *The extension location must have equipment and modalities appropriate for the needs of the patients it accepts for service.*

- *The administrator and other supervisors at the primary site must be capable of adequately supervision of the staff at the extension location(s) as well as manage and oversee all operations of the extension location. The administrator or his/her designee should be available by telephone, at a minimum, and be able to drive to the extension location in a reasonable amount of travel time.*

- *The extension location is situated within a 30 mile radius of where 90 percent of the agency's primary site's population lives. Sites beyond that area may require the extension location to be independently certified as a primary site. Consideration may be given for greater or shorter distances based on unusual geographic features.*

- *The extension location must provide the same level of privacy and dignity for its patients as the primary site does.*

2298B - Extension Location Approval Process:

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

All extension locations must be approved by CMS before any services are provided and billed to Medicare:

- *Any proposed extension location, where the rehabilitation agency wishes to provide services for its own patients, must be listed on a modified Form CMS-855A and submitted to the MAC/FI for verification.*

- *The MAC/FI notifies the RO and/or the SA after it has verified the information contained on the Form CMS-855A.*

- *Concurrently, the rehabilitation agency must submit written notification to the RO regarding its intent to open an extension location 90 days prior to opening the new location.*

- *The RO will evaluate all supporting documentation from the MAC/FI and the SA/AO in making its decision to approve or deny the new extension location.*

- *The RO will determine whether a survey needs to be conducted and will instruct the SA/AO appropriately.*

*The RO will notify the rehabilitation agency in writing of its decision to approve or deny the extension location and will provide copies of its decision to the SA/AO and MAC/FI. The **CMS notice** letter includes:*

- *Approval decision for the added practice (extension) location and the date that the RO determined the added practice location met all appropriate CoPs, or complete reasons for denial if the request was denied:*

- *The assigned Federal extension location identification number, if approved:*

    - ***The identification numbers are not used when submitting claims**. Only the NPI is used by the provider to file a claim.*

    - *NOTE: The RO enters the extension location identification number into the Automated Survey Processing Environment (ASPEN) prior to sending the notice letter to the agency, so that the rehabilitation agency can begin providing services at the new extension location upon receipt of the CMS approval letter.*

- *The effective date:*

    - *The effective date of coverage for services provided from the extension location is the date the RO determines that the extension location meets all Federal requirements. This date will be included in the CMS notice letter. The organization should not begin providing services at the newly added practice location until it receives CMS's notice of its decision to approve or deny the new location.*

2298C- Survey of Rehabilitation Agency Extension Locations by SAs

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

The surveyor must evaluate each condition and standard in the CoPs at all surveyed sites. The surveyor should conduct record reviews, observations and interviews to reach conclusions regarding the agency's compliance with the CoPs for care provided at all practice locations before recommending approval by the RO.

The extension location must meet all applicable CoPs. The approved extension locations will not have their own governing body since each location must share administration, supervision and services with its primary site. However, if there are concerns with the day-to-day operations of the extension location, assess the effectiveness of the governing body. Condition § 485.713 will be surveyed only if the extension location provides physical therapy services. Condition § 485.715 will only be surveyed if speech language pathology services are provided. Condition § 485.717 is applicable only to a rehabilitation agency's own patients.

The surveyor will record results of interviews and record reviews on the survey report, Form CMS-1893 (Outpatient Physical Therapy – Speech Pathology Survey Report), for the surveyed locations. The surveyor completes only one Form CMS-2567(Statement of Deficiencies and Plan of Correction) and one Form CMS-1539(Medicare and Medicaid Certification and Transmittal) for each agency (primary site and extension locations) surveyed. The names of all practice locations (primary and/or extension location) found not to be in compliance with each regulation is to be documented on the Form CMS-2567. On the CMS-1539, the surveyor notes the names of extension locations in "State Agency Remarks." Surveys of all locations must be coordinated; therefore, the surveyor should schedule and complete surveys of all locations within the same time period.

When the surveyor is certifying compliance, findings at all locations are to be considered as a whole. Failure to correct cited deficiencies at any location (extension location or primary site) will jeopardize the certification status of the agency in its entirety. If the agency has deficiencies in only some locations, but they are judged significant enough to warrant termination, the SA may recommend initiation of termination proceedings to the RO. [Refer to SOM Appendix Q or SOM section 3010].

NOTE: *For a rehabilitation agency to establish an extension location across State lines, the two States involved must have a signed reciprocal agreement with each other allowing approval of the extension location. Whether the extension location is in the same State as the primary site or in another State, it must conform to all regulatory requirements. An extension location that is situated in a different State should bill under the primary site's provider number.*

2298D - Accreditation Organization (AO) Surveys of Rehabilitation Agencies

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

For organizations seeking certification or recertification through accreditation by an AO with an approved program, the AO surveys the primary site and any proposed or existing extension locations (of a rehabilitation agency) for compliance with the applicable CoPs.

After the survey is completed, the AO will recommend to the RO whether a specific primary and any extension locations should be approved or denied as practice locations for the agency.

If the RO approves the addition of practice locations based upon the recommendations of the AO, the RO will issue identifiers for those locations and will send a notice letter to the rehabilitation agency regarding the RO approval.

The AO may cross state lines to survey an extension location only if there is a reciprocal agreement between the two states. However, the AO should determine whether the extension location in the second state is in close enough proximity to the Medicare certified primary site to be adequately supervised.

The AO can only survey an extension location and recommend approval to CMS if the primary site is already accredited by the AO and has been certified by CMS as a provider through deemed status. If a provider is currently accredited by a CMS-approved AO and has been certified by CMS as a provider through deemed status, it may submit a request to open an extension location by completing and submitting to the MAC/FI a modified Form CMS-855A. The agency must also notify the AO of its intention to open an extension location.

The AO must evaluate each condition and standard in the CoPs at all surveyed sites. The survey should include record reviews, observations and interviews to reach conclusions regarding the agency's compliance with regulations for care provided at all practice locations before recommending approval by the RO.

2300 - Outpatient Physical Therapy and/or Speech-Language Pathology Services at Other Locations such as a Patient's Private Residence, Assisted Living or Independent Living Facility

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

In addition to the primary site and any extension locations, the organization may provide therapy services in the patient's private residence or in a patient's room in a SNF/NF, in an assisted living facility, or in an independent living facility.

The agency must provide an adequate therapy program whenever and wherever it provides services at locations away from the primary site. The agency must have adequate equipment and modalities available, at any location, to treat the patients accepted for service. If the agency is providing services at more than one location each day, the agency must have infection control policies in place that set forth the techniques the agency employees will use at all locations.

The agency is responsible for providing any modality that is designated on the plan of care or requested by the physician. It is not acceptable for agencies to ask patients to sign waivers for modalities that are not available. The agency should refer the patient to another agency if needed services are not available at the agency practice location. The surveyor should see evidence of the referral in the patient's clinical record.

The current plan of care and progress notes must be accessible to service providers anytime that the patient is receiving care in order to promote continuity of care.

Periodically, an organization may wish to use a community facility to provide certain therapeutic services. For example, the organization may want to use a community pool to provide aquatic therapy. The SA or AO shall verify that the community pool meets all applicable State laws (i.e., health and safety, infection control requirements, etc.) governing the use of the community facility. Also the SA or AO shall review the organization's policies and procedures regarding the type of therapy being provided, training for staff, supervision, etc. The pool must be closed to public use during the time the organization is providing therapy to protect the privacy and safety of the patients being treated. The hours of operation and days of the week during which the facility will be used for therapy services, supervision, etc. must be clearly stated in the organization's policies and procedures as well as the contractual agreement between the community pool and the organization. Verify that the organization has a carefully detailed policy regarding specific arrangements for emergency services in the event of a medical emergency at the community location (i.e., is a telephone in close proximity to the qualified professional providing the service, is there a second organization staff person on site, etc.

2302 - CMS -381 Model Letter Requesting Identification of Extension Locations.

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

*Form CMS 381 is **no longer required** to be collected by the SA **on an annual basis** as it is overly burdensome for the SAs. The rehabilitation agency must notify both the MAC and CMS of its intent to add a new practice location prior to providing physical therapy and speech-language pathology services at the new location. The agency submits its request on a modified Form CMS-855A. The SA should request the agency to submit the Form CMS 381, in addition to the modified 855A **whenever the agency requests to add a new practice location.** The SA must continue to notify the RO when new practice locations are added to ensure that*

identifiers are issued to the new practice locations. As indicated previously, a provider cannot provide services at a new practice location until this location has been approved by CMS.

2304-- Operation of an Organization on the Premises of a Supplier/Provider

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

There is no prohibition against an organization operating on the premises of a supplier (e.g., physician or chiropractor) or another provider as long as they are not operating in the same space at the same time.

At no time can Medicare be billed twice for the same service. For example, a physician and a rehabilitation agency cannot both bill Medicare for therapy services provided by the agency for the same patient.

In addition, the supplier must adhere to sections of the Social Security Act that prohibit suppliers from referring Medicare patients for certain designated health services (DHS) to an entity with which the supplier or a member of the supplier's immediate family has a financial relationship, unless an exception applies.

2306 – When a Rehabilitation Agency's Extension Location Becomes Its Primary Site

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

The rehabilitation agency, following the conversion of its primary site to a CORF, may select one of its extension locations as its new primary site. The SA notifies the RO via Form CMS-1539 of the new primary location and any existing, approved, extension locations for outpatient physical therapy and/or speech-language pathology services. A new survey must be conducted to certify that the rehabilitation agency's new primary location meets the CoPs. However, any of the rehabilitation agency's other extension locations that have already been approved do not require a survey or re-approval as an extension location to the new primary site.

2308 - Relocations of Providers of Outpatient Physical Therapy and Outpatient Speech-Language Pathology Services Concurrent with CHOWs

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

When an agency undergoes a change of ownership (CHOW), the provider agreement is automatically assigned to the new owner unless the new owner rejects assignment of the agreement. Automatic assignment of the existing provider agreement to the new owner means that the new owner is subject to all the terms and conditions under which the existing agreement was issued. In other words, the new owner must accept all assets and

liabilities (including, but not limited to, any Medicare payments owed by or due to the provider, adhering to existing plans of correction, and maintaining compliance with health and safety standards, ownership and financial interest disclosure, and civil rights requirements, etc.) of the entity that is being purchased in order to receive the existing Medicare Provider Agreement and the CCN. If the owner accepts assignment, a survey is generally not required.

If the new owner does not accept assignment of the provider agreement, the existing Medicare Provider Agreement and the CCN will be terminated and the new owner must follow the same process as any other prospective provider (i.e., enrolling with the MAC/FI, applying for participation, undergoing Office of Civil Rights (OCR) clearance and an initial survey, having a new effective date of participation assigned, etc.). See SOM section 3210.

A new owner may propose to relocate the organization concurrent with the CHOW. This would be considered as an address change of the existing provider and the new location will be surveyed to ensure that it meets all the applicable CoPs. However, if the relocation is to a site that is located in a different geographic area serving different patients than previously served and employing different personnel to serve those patients, then the new owner must be treated as a new provider in the Medicare program. Refer to SOM section 3210.1B5 if there are questions regarding this process.