State Operations Manual

Appendix E - Guidance to Surveyors: Outpatient Physical Therapy or Speech Pathology Services - (Rev. 1, 05-21-04)

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§485.701 Condition for Coverage: Compliance With Federal, State and Local Laws

Interpretive Guidelines §485.701

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).

Major Sources of Information

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

§485.701(a) Standard: Licensure of Organization

Survey Procedures and Probes: §485.701(a)

Where State law provides for the licensing of clinics, rehabilitation agencies, public health agencies or similar facilities which meet the definitions contained in 485.707, verify at the time of the survey that a current license is valid and in effect. A license must be in effect before the organization can be certified to participate in the program. Where a license for an organization currently participating has been temporarily suspended or revoked, contact the appropriate State department or authority to ascertain the status of the organization's licensure. If a license is not to be issued, initiate termination proceedings.

In the event the organization is out of compliance with State requirements and the appropriate State authority does not take the action necessary to revoke the license, do not initiate termination proceedings solely on the basis of noncompliance with 485.717. If, however, such noncompliance results in other Conditions being not met, initiate termination citing all Conditions that are not met, including 485.717.

Some States may issue provisional licenses. Where this is the case, document the reason(s) for such status and, most importantly, any limitation(s) imposed on the services rendered as a result. Contact the appropriate State department or authority and obtain information concerning the length of time the provisional status is to be in effect. If the limitations stipulated in a provisional license adversely affect the ability to render services in compliance with regulations, another Condition may be not met; in that case, initiate termination if those restrictions are to remain in force.

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

Survey Procedures and Probes: §485.701(b)

Review facility records, a central State listing, or other evidence of current licensure or registration of personnel, such as wallet size identification cards sometimes made available. Where personnel are required to be licensed but are not, notify the appropriate State licensing body(ies).

§485.709 Condition for Coverage: Administrative Management

Interpretive Guidelines §485.709

The clinic or rehabilitation agency has a governing body, or designated persons so functioning, responsible for its policies and operations. 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.

Major Sources of Information

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

§485.709(a) Standard: Governing Body

Interpretive Guidelines §485.709(a)

The governing body is the board of directors or trustees of a corporation, the owner(s) in the case of a proprietary clinic or rehabilitation agency, or others who have legal responsibility for the operation of the clinic or rehabilitation agency. The facility shall have an established and functioning governing body. It is not inappropriate for employees of an incorporated clinic or rehabilitation agency to also serve as members of the governing body.

The names and addresses of all individuals having legal responsibility for the clinic or rehabilitation agency should be available on the provider's CMS-855A.

Survey Procedures and Probes §485.709(a)

Assess the governing body on its effectiveness in providing guidance and direction for the clinic or rehabilitation agency in such terms as program stability and adequacy and in carrying out its legal responsibilities. The governing body shall be responsible for compliance with all applicable laws and regulations pertaining to OPT/SLP facilities. The governing body is responsible for the quality and appropriateness of care. Certain 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 be kept.

§485.709(b) Standard: Administrator

Interpretive Guidelines §485.709(b)

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

The administrator should be familiar with all aspects of the operation of the clinic or rehabilitation agency such as scope of services provided, budgetary and fiscal matters, personnel, and other areas necessary to effectively direct operational activities. The administrator is also responsible for coordinating staff education, sometimes referred to as inservice education, or continuing education. In this regard, the administrator should see that each employee has the opportunity to increase the skills and knowledge necessary to promote effective and efficient patient care. Review listing of inservice program content, type of instruction (e.g., lecture or demonstration), dates of instruction, and attendees.

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

operating hours to assume the administrator's responsibilities. Verify that such an individual has been selected.

§485.709(c) Standard: Personnel Policies

Interpretive Guidelines §485.709(c)

Personnel policies should generally address the relationship between the facility administration and facility staff, e.g., how the administration governs the conduct and performance of its employees, and its responsibility to its staff.

Survey Procedures and Probes: §485.709(c)

During interviews with the facility administrator and staff, elicit evidence that personnel practices are based on written personnel policies. For example, if the facility administration conducts performance evaluations on its staff, do written personnel policies address how and when the evaluations are conducted?

§485.709(d) Standard: Patient Care Policies

Interpretive Guidelines §485.709(d)

Patient care policies are established by the professional staff of the clinic or rehabilitation agency and outside professionals, where appropriate, who function as a patient care policy committee.

Survey Procedures and Probes: §485.709(d)

Review minutes of meetings to determine whether the policies of the clinic or rehabilitation agency are current and responsive to the needs of patients, and whether, when unresponsive, appropriate policy revisions are undertaken. At a minimum, facilities should have procedures for selecting qualified personnel; a system for documenting the current licensure and/or certification status for those personnel whose positions or functions require such licensure or certification; and a system for assessing competency of all personnel providing healthcare services, upon hire and on an ongoing basis, on a schedule determined by the facility policy.

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

§485.711 Condition for Coverage: Plan of Care and Physician Involvement

Interpretive Guidelines §485.711

All patients must be treated pursuant to a written plan of care that indicates anticipated goals and specifies the type, amount, frequency, and duration of services to be furnished. Patient care policies should be based on accepted standards of practice and reviewed periodically by a physician or physical therapist for appropriateness. The facility should have patient care policies for all services provided. Non-Medicare patients are neither required to be under the care of a physician nor have a plan of care established by a physician.

Major Sources of Information

- Patients' plans of care;
- Emergency procedures;
- Patient care policies;
- Clinical records.

§485.711(a) Standard: Medical History and Prior Treatment

Interpretive Guidelines §485.711(a)

The regulations do not require the patient be referred to the facility by a physician or that the services are furnished pursuant to a physician's orders. However, since Medicare patients are still required under the statute to be under the care of a physician and have the plan of care periodically reviewed by a physician to receive payment for Medicare covered services, current medical findings, diagnosis(es), physician's orders, rehabilitation goals and contraindications would normally be made available to the facility by the attending physician. Non-Medicare patients are not required to be under the care of a physician, have a plan of care established by a physician and have the plan of care periodically reviewed by a physician. However, you should expect to find medical records maintained for the Non-Medicare patients. When reviewing patients' records, if you find a referral from a physician for a non-Medicare patient, do not cite a deficiency if the referral fails to include the specified items. When complete and appropriate past history along with current medical findings are not made available to the organization, the organization should obtain the information either from the patient or from follow-up with the referring physician, if any.

§485.711(b) Standard: Plan of Care

Interpretive Guidelines §485.711(b)

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

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

§485.711(c) Standard: Emergency Care

Survey Procedures and Probes: §485.711(c)

Verify that the names and telephone numbers are readily available for the physician(s) the organization has arranged to be on-call to provide medical care in case of an emergency during operating hours. Review the medical emergency procedures, and make certain in discussions with the appropriate persons that these procedures, when necessary, can be made immediately operational. Interview employees to determine whether individual responsibilities are known. There may be instances in which the on-call physician provides emergency medical triage which results in a 911 call. The physician's emergency medical treatment plan and communication should be documented in the patient's medical record.

§485.713 Condition for Coverage: Physical Therapy Services

Interpretive Guidelines §485.713

The range of medically necessary physical therapy services should be adequate to treat the types of disabilities accepted for service.

Major Sources of Information

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

§485.713(a) and (b) Standards: Adequate Program; Facilities, and Equipment

Interpretive Guidelines §485.713(a) and (b)

Following are guidelines to assist in evaluating equipment commonly used in the provision of physical therapy services. Of course, an organization may meet this condition without having all the equipment referred to below.

1. Ultraviolet Equipment (UV Lamps Using Mercury Vapor Tubes):
    - Safety goggles present for patients and therapists;
    - Evidence of periodic testing of lamps to determine minimal erythemal dose;
    - Suitable room for ultraviolet treatment (light not visible so that effects of the inverse square law may be taken into account);
    - Suitable measuring device (tape, ruler, yardstick) available so that effects of the inverse square law may be taken into account.

2. Ultrasound Generators--Meets Federal Communications Commission requirements; applicators in good condition.

3. Electrical Muscle Stimulators and Testing Equipment--In good condition; appropriate amperage and voltage limitations.

4. Hydrotherapy Equipment:

    - Separate area;
    - Tanks clean, in good condition; electrical equipment properly grounded;
    - Cranes, lifts, and frames used in conjunction with hydrotherapy equipment in good condition.

5. Exercise Equipment

    - Weight boots and bars are equipped with safe clamping collars and straps;
    - Therapeutic exercise tables in good condition with special attention given to cable rigging and pulleys;
    - Overhead pulleys, shoulder wheels, and stall bars are sturdy and mounted securely;
    - Exercise mats are clean and in good condition; provisions are made for altering body contact surface to maintain cleanliness;
    - Sand and shot bags in good condition; no tears or leaks;
    - An adequate range of weight sizes or other means for varying the load applied to patients.

6. Cervical and Other Traction Devices--In good condition with safety devices operative.

7. Hot Packs--In good condition with no tears or leaks; heating units have functional thermostats that provide acceptable temperature limits and units are properly grounded.

8. Paraffin Baths--Paraffin clean and odor free; thermometer available for temperature check prior to use; heater in good condition and properly grounded.

9. Tilt Tables-- Properly grounded if electrically operated; mechanically in good condition.

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

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

Survey Procedures and Probes: §485.713(a) and (b)

Review the organization's patient care policies and clinical records to ascertain the adequacy of the physical therapy program. Compare the type of equipment available with the types of patients treated to determine whether the organization can provide the range of services required. Patients are not to be accepted for treatment unless appropriate equipment is 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.

The physical therapist must be present:

- For the initiation of patient treatment for newly admitted patients or for those previously treated, discharged, and readmitted; prior to the provision of physical therapy services where a change in the physician's plan of care necessitates a change in treatment; and

- Immediately prior to the discontinuing of treatment and discharge of patients.

An evaluation or reevaluation of a patient's needs, performed by a qualified physical therapist, should precede initial treatment or treatment altered by a change in the plan of care. The physical therapist should be readily available (i.e., physically accessible to organization personnel and patients within a certain response time) to offer continuing onsite supervision regardless of whether patients are treated on the premises of the organization or in their homes. Such supervision may include:

- Specific instructions regarding the treatment regimen;

- An explanation of responses to treatment indicative of adverse patient reactions; and

- Discussions between the physical therapist and the physical therapist assistant.

Onsite supervision is the responsibility of the physical therapist. Response time is based on the condition of the patient, the patient's previous response to treatment, organization staffing, and competency of available personnel. For example, where the patient's previous response to treatment had been adverse, thereby possibly requiring that, in the future, the physical therapist keep himself readily available to provide needed supervisory assistance, the physical therapist should arrange times and schedules to allow for minimal delay in providing such assistance. Additionally, when services are provided off the premises of the organization, an onsite supervisory visit at least once every 30

days is to be made by the physical therapist during the time that services are actually being furnished, in order to evaluate the quality of the assistant's performance. Review the personnel records to ascertain whether the physical therapist(s), and physical therapist assistant(s) where applicable, meet the qualifications stated in 485.705(c).

§485.713(c) Standard: Personnel Qualified to Provide Physical Therapy Services

Interpretive Guidelines §485.713(c)

The number of qualified physical therapists and qualified physical therapist assistants (if applicable) should be able to adequately and effectively provide services to patients. Adequate service cannot be determined by the mere proportion of staff to patient ratio. It is to be based on knowledge of the types of patients treated and the type, amount, frequency, and duration of treatment required. To more accurately determine the sufficiency of personnel, review clinical records, together with the patient care policies, personnel records and patient treatment schedules.

§485.713(d) Standard: Supportive Personnel

Interpretive Guidelines §485.713(d)

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.

§485.715 Condition for Coverage: Speech Pathology Services

Interpretive Guidelines §485.715

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

Major Sources of Information to Determine Whether Conditions of Participation are Met:

- Physician orders, plans of care, and speech pathology evaluations and progress notes;

- Patient care policies;

- Personnel records--job descriptions, employee qualifications, and current licensure information;

- Clinical records.

§485.715(a) and (b) Standards: Adequate Program; Facilities and Equipment

Survey Procedures and Probes: §485.715(a) and (b)

Review the organization's patient care policies and clinical records to ascertain the adequacy of the speech pathology program. Space suitable for treatment must be available. When evaluation reveals a hearing disorder, the necessary treatment, either directly or through referral, must be provided the patient.

§485.715(c) Standard: Personnel Qualified to Provide Speech Pathology Services

Survey Procedures and Probes: §485.715(c)

Review personnel records to ascertain whether the speech pathologist(s) meets the qualifications as stated in 485.705(b)(2). Speech pathologists who meet the educational requirements, thereby making them eligible for a certificate of clinical competence in speech pathology granted by the American Speech and Hearing Association, and who are in the process of accumulating the supervised experience also necessary for certification (485.705(b)(2)), qualify as speech pathologists.

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

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

§485.717 Condition for Coverage: Rehabilitation Program

Interpretive Guidelines §485.717

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

Section 485.717 requires the rehabilitation agency to provide social or vocational adjustment services to all patients in need of such services. The agency's qualified staff (485.717(a) (psychologist, social worker or vocational specialist) must evaluate (through a face-to-face assessment) the social or vocational factors involved in a patient's rehabilitation program, counsel and advise on social or vocational problems due to the patient's injury or illness, and make appropriate referrals for required services. However, there are circumstances when the provision of these services to certain patients by the rehabilitation agency would be unnecessary or would duplicate similar services provided by other organizations. The rehabilitation agency is neither required to evaluate patients nor to provide social or vocational adjustment services to patients under any of the following situations:

- The patient's file is clearly documented to indicate that the patient does not require social vocational adjustment services. The documentation must be provided by a physician, qualified psychologist, social worker, or vocational specialist.

- The patient is receiving social or vocational adjustment services as an inpatient or outpatient of another provider or supplier of services, and a written agreement or contract between the rehabilitation agency and the provider or supplier specifies that the provider or supplier is responsible for social or vocational adjustment services for all patients receiving OPT/OSP from the rehabilitation agency.

- The other provider or supplier agrees in the written contract with the rehabilitation agency to clearly mark or identify the files of patients receiving OPT/OSP who have previously been evaluated for social or vocational adjustment services. A separate evaluation by the rehabilitation agency of those patients for social or vocational adjustment services is not required.

- The OPT/OSP provider provides diagnostic or therapeutic services to individuals for whom another agency or organization has overall responsibility. For example, if a speech pathology evaluation and therapy services are provided to students under a contract with a school system, the OSP provider is neither required to evaluate the need for, nor provide, speech pathology services since the school system is responsible for meeting the overall needs of students within its jurisdiction.

When a rehabilitation agency accepts a patient whose social or vocational status is not covered by one of the above situations, the agency's qualified staff must determine whether the patient's physical illness or injury indicates the need for social or vocational adjustment services. The patient's clinical record should indicate that this determination is based on information collected and reviewed by the qualified staff. Social or vocational adjustment services may be provided either on the premises or off the premises of the organization (e.g., in the office of the psychologist).

Major Sources of Information

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

§485.717(a) Standard: Qualifications of Staff

Interpretive Guidelines §485.717(a)

All personnel providing social or vocational adjustment services must meet the qualifications for psychologist, social worker (485.705(c)(6)), or vocational specialist (485.705(c)(7)), as appropriate).

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

Interpretive Guidelines §485.717(b)

If an agency does not provide social or vocational adjustment services through its own employees, such services may be provided by means of written agreements with individuals or organizations. Their contracts must retain the agency's responsibility, control and supervision over the services and must contain details prescribed in 485.717(b). These details are listed on the CMS-1893. The appropriate professional staff of the organization (psychologists, social workers, vocational specialists) are responsible for developing, in conjunction with the physician, the regimen of social or vocational adjustment services to be provided to individuals requiring such services and must assume the professional and administrative responsibility for services provided under arrangements.

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

Interpretive Guidelines §485.719

Professional and administrative responsibility for the physical therapy and speech pathology services provided through an arrangement rests with the rehabilitation agency , even though such services may be arranged for with others.

Major Sources of Information

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

§485.719(b) Standard: Contract Provisions

Survey Procedures and Guidelines §485.719(b)

Review the written contract between the organization and the outside resources item-by-item to ensure that the applicable provisions listed under standard 485.719(b) are included.

Documentation, such as notes in the clinical records and minutes of joint policy meetings, should verify that communication exists between the outside resource (i.e., the physical therapist where physical therapy services are rendered or the speech pathologist where speech pathology services are rendered) and staff of the organization.

Review the clinical records of those patients whose treatment is provided under arrangement (the location of treatment as specified in 485.719(b)) to make certain that evaluations, progress notes, and other pertinent clinical material are present and that the clinical records containing applicable information for all patients are maintained on the premises of any location at which services are rendered.

§485.721 Condition for Coverage: Clinical Records

Interpretive Guidelines §485.721

The clinical record serves as a basis for documentation of medical care rendered to the patient, for communication between the physician and the personnel providing services, and for communication between personnel providing services. The surveyor determines whether the content of the clinical record presents a total or, at a minimum, an adequate picture of the care being given.

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.

Major Sources of Information

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

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

Interpretive Guidelines §485.721(a)

Clinical records are to be stored where they are protected from fire and unauthorized use. Organization policies are to note to whom records or copies thereof may be provided, the use to which the material may be put, and the circumstances describing the return of such material. For the release of all material not authorized by law, the patient's written consent is required.

§485.721(b) and (c) Standard: Content; Completion of Records and Centralization of Reports

Survey Procedures and Probes §485.721(b)

Examine a substantial number of both active and closed clinical records, selected on a random basis and not restricted to those of Medicare patients only, to ascertain whether the appropriate material as specified in 485.721(b) is included. The assessment of the needs of the patient (initial evaluation and reevaluations where appropriate), plan of care (including the types, amount, duration and frequency of services provided), identification data (name and address of patient), observations and progress notes, reports of treatments and clinical findings, and discharge summary should be contained in virtually all clinical records. (Surveyors should also look for documentation of communication efforts between professionals providing services). However, consent forms, medical history and report of the physician's physical examination may or may not appear in clinical records.

This information would need to appear only where relevancy to patient treatment is shown. Where medical history does appear in clinical records, it may not have been that transmitted by the physician but, rather, may have been obtained from the patient when the past and present history was related.

If omission of any pertinent information is noted in the clinical records, additional clinical record reviews should be undertaken to determine the prevalence of such omissions. The survey should state on the Survey Report Form the number of clinical records reviewed and the number and types of deficiencies found in each. Where record reviews prompt questions concerning patient care, the surveyor should request additional information and assistance from the appropriate organization personnel.

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.

A discharge summary should include the date and reason for discharge; a brief summary of the current status of the patient at the time of discharge; and, where applicable, provision for referral of the patient to another source for continuing care. Progress notes should be updated in the patient's clinical record weekly at least weekly.

Regardless of whether the organization provides services through its own employees or through an arrangement with others, all materials which are pertinent to the patient's treatment are to be part of the clinical record, which is to be maintained on the premises of any location at which services are rendered.

All information appearing in the clinical record is to be dated appropriately, signed and incorporated weekly.

§485.721(d) Standard: Retention and Preservation

Survey Procedures and Probes §485.721(d)

The surveyor reviews the organization policy pertaining to retention and preservation of clinical records and verifies that such policy is consistent with applicable State law or regulation where such exists. There is also to be a provision in organization policies for the retention and transfer of clinical records if, in the latter instance, the organization ceases to function.

§485.721(e) Standard: Indexes

Survey Procedures and Probes §485.721(e)

Clinical records are normally indexed according to the last name of each patient, but in some cases indexing may be according to file identification numbers assigned to patients

on admission to the organization. This system may be utilized for indexing either active and/or discharged patient clinical records as determined by organizational need.

§485.721(f) Standard: Location and Facilities

Survey Procedures and Probes §485.721(f)

The clinical records are to be easily retrievable and available to all professional staff members of the organization and other authorized individuals. Clinical records may be maintained at a site other than the primary location (the site issued the provider agreement/number) if the beneficiary receives outpatient therapy services at that other site. All records must be **available** to the surveyor during the course of the survey regardless of where the records are kept. Records can be delivered to the surveyor electronically or by other means as long as the delivery is within a reasonable amount of time during the course of the onsite survey.

§485.723 Condition for Coverage: Physical Environment

Interpretive Guidelines §485.723

In order to ensure the safety of patients, personnel, and the public, the surveyor examines the physical plant of the organization and ascertains whether or not it is maintained consistent with State and local building, fire and safety codes. The structure housing the organization is such that it is held "open to the public" and patient treatment areas and other locations associated with organization function (e.g., storage and toilet rooms) are to be physically separated from non-organization areas. However, the toilet rooms do not have to be located directly in the treatment area. They can be located down the hall as long as they are easily accessible by non-ambulatory and semi-ambulatory individuals.

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.

§485.723(a) Standard: Safety of Patients

Survey Procedures and Probes §485.723

The surveyor verifies that applicable State and local building, fire and safety codes are met, and reviews available reports of State and local personnel responsible for enforcement of the above. Areas 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 automatic fire extinguishing system, or shall be separated from the balance of the building by one-hour fire resistance barriers. All areas occupied or accessible to the organization for use during emergency or non-emergency activity, including corridors and stairwells, are to be protected by easily accessible fire extinguishers (e.g., the case of an organization being located in a multilevel structure whether the entire structure is utilized or only a portion thereof). The width of the doorways and passageways shall be such as to allow for ease in patient movement into and within the organization and may depend upon factors such as type and condition of patients accepted for treatment.

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

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

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

§485.723(b): Standard: Maintenance of Equipment, Building, and Grounds

Survey Procedures and Probes §485.723(b)

Hazards to the health and safety of patients, personnel, and the public (e.g., broken window and door panes, obstruction of passageways, and dangerous floor surfaces) are to be noted on the Survey Report Form (CMS-1893). All equipment should be inspected by the organization at least yearly or in accordance with manufacturers' guidelines. Such inspection is determined in part by present equipment condition and its frequency of use, and is to be outlined in written procedures which include the following:

- Equipment to be inspected;

- A brief statement concerning the general inspection process; and

- Frequency of inspection for each piece of equipment.

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

§485.723(c) Standard: Other Environmental Considerations

Survey Procedures and Probes §485.723(c)

The surveyor should verify that temperature control mechanisms maintain the temperature at a comfortable and constant level. Where mechanical means of ventilation such as air conditioners are utilized, placement of the unit(s) and vents should be such that the air is dispersed uniformly throughout the facility.

Where necessary, ramps are available to provide for easy access to facilities and equipment. Examination and treatment areas are large enough to enable effective application of the plan of care. Patient privacy may be assured through utilization of individual treatment booths, folding screens, draw curtains, etc. Where underwater exercise is utilized, a safe and effective patient lift device is available.

§485.725 Condition for Coverage: Infection Control

Interpretive Guidelines §485.725

An infection control committee, applicable for organizations offering physical therapy services has overall responsibility for ensuring that environmental infection hazards are controlled.

Major Sources of Information

- Written policies and procedures which correspond to standards (a) through (e);

- Minutes of the infection control committee.

§485.725(a) Standard: Infection Control Committee

Survey Procedures and Probes: §485.725(a)

The surveyor should review the policies and procedures for preventing, controlling, and investigating infections and should ascertain whether the recommendations of the committee are acted upon. Meetings are to be held at least yearly with minutes being kept, and at least two or more individuals should constitute the committee. The committee should be composed of persons whose educational background and experience (e.g., M.D., R.N., and other interested professionals) is adequate to perform this function. The administrator, in the case of a clinic or rehabilitation agency, should assume responsibility for selecting the professionals to serve on the committee.

Written procedures covering infection control and cleanliness of certain physical therapy equipment such as whirlpools, paraffin baths, and moist hot pack units, etc., should be available for review. This is particularly important in cases where whirlpools are used for debridement of wounds.

§485.725(b) Standard: Aseptic Techniques

Survey Procedures and Probes: §485.725(b)

Review the aseptic procedures developed and ascertain, through a discussion with available professional personnel and review of major sources of information, that the procedures are communicated to the staff. Review the organization's documentation of its aseptic procedures.

§485.725(c) Standard: Housekeeping

Survey Procedures and Probes: §485.725(c)

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. Survey or inspection should serve to verify the cleanliness and orderliness of the premises.

§485.725(d) Standard: Linen

Survey Procedures and Probes: §485.725(d)

Organization has a supply of new supply of fresh linen, essential for proper care and comfort of all patients treated, plus an additional supply to provide for increased usage and is to be stored in clean areas and available for daily use. Verify that soiled linen is removed from patient areas at least daily and stored in an area away from patients, personnel, and the public.

§485.725(e) Standard: Pest Control

Survey Procedures and Probes: §485.725(e)

Review the written policy covering the pest control program.

§485.727 Condition for Coverage: Disaster Preparedness

Interpretive Guidelines §485.727

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

Major Sources of Information

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

§485.727(a) Standard: Disaster Plan

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

§485.727(b) Standard: Staff Training and Drills

Survey Procedures and Probes §485.727(b)

Discuss with employees their specific roles in an emergency. Verify that disaster drills are carried out at least annually, and that the date and the names of those persons taking part are documented. All personnel are to be exposed to drill situations calling for the exercising of their disaster responsibilities as stated in the disaster plan.

§485.729 Condition for Coverage: Program Evaluation

Interpretive Guidelines §485.729

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 are to be present

which provide for an evaluation of the total organization program. The facility should have a performance improvement plan that collects data about the organization's performance on an ongoing basis.

Review dated reports of the most recent program evaluations. These reports should contain the names of those participating in the evaluation, the results, and expected action, if indicated. The evaluation should be conducted by the professional staff of the organization and outside professionals, where appropriate. Determine whether, in the case of a clinic or rehabilitation agency, the governing body has been made aware of the findings. In the case of a public health agency, the group or individual (at the local level) delegated the responsibility of total program operation should be aware of the findings.

Major Sources of Information

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

§485.729(a) Standard: Clinical Record Review

Survey Procedures and Probes §485.729(a)

A substantial sample of records reviewed should be randomly selected from the active and closed files. Each service offered by the organization should be represented in the sample. In instances where a patient is receiving both physical therapy and speech pathology services, the record may be included in the sample of each service rendered. The clinical record review committee is composed of health professionals representing those services provided by the organization or under arrangement. It is not necessary that those committee members be employees of the organization. Administrative personnel would ordinarily be committee participants.

§485.729(b) Standard: Annual Statistical Evaluation

Survey Procedures and Probes §485.727(b)

The surveyor should review and compare the prior years and current statistical reports to determine that the data noted in the regulation, or data similar in character and more suited to the clinic's or agency's program evaluation purposes, is being kept. For example, the number and cost of units of service is a statistic more commonly retained and utilized by public health agencies and, therefore, may not be selected for use by other types of outpatient providers. 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 necessary change.