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**FED - I0000 - INITIAL COMMENTS**

**Title** INITIAL COMMENTS

**Type** Memo Tag

**CFR**

**Regulation Definition**

**Interpretive Guideline**

**FED - I0007 - COMPLIANCE W/ FED, STATE, & LOCAL LAWS**

**Title** COMPLIANCE W/ FED, STATE, & LOCAL LAWS

**Type** Condition

**CFR** 485.707

**Regulation Definition**

**Interpretive Guideline**

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

**FED - I0008 - LICENSURE OF ORGANIZATION**

**Title** LICENSURE OF ORGANIZATION

**Type** Standard

**CFR** 485.707(a)

**Regulation Definition**

**Interpretive Guideline**

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.

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**FED - I0009 - LICENSURE OR REGISTRATION OF PERSONNEL**

**Title** LICENSURE OR REGISTRATION OF PERSONNEL

**Type** Standard

**CFR** 485.707(b)

**Regulation Definition**

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

**Interpretive Guideline**

**FED - I0011 - ADMINISTRATIVE MANAGEMENT**

**Title** ADMINISTRATIVE MANAGEMENT

**Type** Condition

**CFR** 485.709

**Regulation Definition**

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 Guideline**

**FED - I0012 - GOVERNING BODY**

**Title** GOVERNING BODY

**Type** Standard

**CFR** 485.709(a)

**Regulation Definition**

There is a governing body (or designated person(s) so

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functioning) which assumes full legal responsibility for the overall conduct of the clinic or rehabilitation agency and for compliance with applicable law 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.

**FED - I0015 - ADMINISTRATOR**

**Title** ADMINISTRATOR

**Type** Standard

**CFR** 485.709(b)

**Regulation Definition**

The governing body appoints a full time qualified administrator, delegates to the administrator the internal operation of the clinic or rehabilitation agency in accordance with established written policies, defines clearly the administrator's responsibilities for procurement and directions to personnel, and designates a competent individual to act during temporary absence of the administrator.

**Interpretive Guideline**

**FED - I0019 - PERSONNEL POLICIES**

**Title** PERSONNEL POLICIES

**Type** Standard

**CFR** 485.709(c)

**Regulation Definition**

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.

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**FED - I0022 - PATIENT CARE POLICIES**

**Title** PATIENT CARE POLICIES

**Type** Standard

**CFR** 485.709(d)

**Regulation Definition**

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. The policies are evaluated at least annually by the group of professional personnel, and revised as necessary based upon this evaluation.

**Interpretive Guideline**

**FED - I0047 - PLAN OF CARE & PHYSICIAN INVOLVEMENT**

**Title** PLAN OF CARE & PHYSICIAN INVOLVEMENT

**Type** Condition

**CFR** 485.711

**Regulation Definition**

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.

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**FED - I0049 - MEDICAL HISTORY & PRIOR TREATMENT**

**Title** MEDICAL HISTORY & PRIOR TREATMENT

**Type** Standard

**CFR** 485.711(a)

**Regulation Definition**

**Interpretive Guideline**

The following are obtained by the organization before or at the time of initiation of treatment:

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

**FED - I0050 - PLAN OF CARE**

**Title** PLAN OF CARE

**Type** Standard

**CFR** 485.711(b)

**Regulation Definition**

**Interpretive Guideline**

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.

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The plan of care for physical therapy or speech pathology services indicates anticipated goals and specifies for those services the type, amount, frequency, and duration.

The plan of care and results of treatment are reviewed by the physician or by the individual who established the plan at least as often as the patient's condition requires, and the indicated action is taken. (For Medicare patients, the plan must be reviewed by a physician, nurse practitioner, clinical nurse specialist, or physician assistant at least every thirty days in accordance with 42 CFR 410.61(e).)

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.

**FED - I0054 - EMERGENCY CARE**

**Title** EMERGENCY CARE

**Type** Standard

**CFR** 485.711(c)

**Regulation Definition**

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.

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**FED - I0055 - PHYSICAL THERAPY SERVICES**

**Title** PHYSICAL THERAPY SERVICES

**Type** Condition

**CFR** 485.713

**Regulation Definition**

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 Guideline**

**FED - I0056 - ADEQUATE PROGRAM**

**Title** ADEQUATE PROGRAM

**Type** Standard

**CFR** 485.713(a)

**Regulation Definition**

The organization is considered to have an adequate outpatient physical therapy program if it can provide services using therapeutic exercise and the modalities of heat, cold, water, and electricity; conduct patient evaluations; and administer tests and measurements of strength, balance, endurance, range of motion, and activities of daily living.

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

If a qualified physical therapist is not on the premises during all hours of operation, patients are scheduled so as to ensure

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that the therapist is present when special skills are needed, for example, for evaluation and reevaluation.

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

**FED - I0057 - FACILITIES AND EQUIPMENT**

**Title** FACILITIES AND EQUIPMENT

**Type** Standard

**CFR** 485.713(b)

**Regulation Definition**

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 Guideline**

**FED - I0058 - PERSONNEL QUALIFIED TO PROVIDE P.T.**

**Title** PERSONNEL QUALIFIED TO PROVIDE P.T.

**Type** Standard

**CFR** 485.713(c)

**Regulation Definition**

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 Guideline**



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**FED - I0063 - SUPPORTIVE PERSONNEL**

**Title** SUPPORTIVE PERSONNEL

**Type** Standard

**CFR** 485.713(d)

**Regulation Definition**

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 Guideline**

**FED - I0067 - REHABILITATION PROGRAM**

**Title** REHABILITATION PROGRAM

**Type** Condition

**CFR** 485.717

**Regulation Definition**

This condition and standards apply only to a rehabilitation agency's own patients, not to patients of hospitals, skilled nursing facilities (SNFs), or Medicaid nursing facilities (NFs) to which the agency furnishes services. The hospital, SNF, or NF is responsible for ensuring that qualified staff furnish services for which they arrange or contract for their patients. The rehabilitation agency provides physical therapy and speech-language pathology services to all of its patients who need them.

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**FED - I0068 - QUALIFICATION OF STAFF**

**Title** QUALIFICATION OF STAFF

**Type** Standard

**CFR** 485.717(a)

**Regulation Definition**

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

**Interpretive Guideline**

**FED - I0069 - ARRANGEMENTS FOR SERVICES**

**Title** ARRANGEMENTS FOR SERVICES

**Type** Standard

**CFR** 485.717(b)

**Regulation Definition**

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 Guideline**

**FED - I0079 - SERVICES PROVIDED UNDER ARRANGEMENTS**

**Title** SERVICES PROVIDED UNDER ARRANGEMENTS

**Type** Condition

**CFR** 485.719

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**Regulation Definition**

Arrangements for physical therapy and speech pathology services to be performed by other than salaried organization personnel.

**Interpretive Guideline**

**FED - I0080 - CONDITIONS**

**Title** CONDITIONS

**Type** Condition

**CFR** 485.719(a)

**Regulation Definition**

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 Guideline**

**FED - I0081 - CONTRACT PROVISIONS**

**Title** CONTRACT PROVISIONS

**Type** Standard

**CFR** 485.719(b)

**Regulation Definition**

The contract specifies the term of the contract and the manner of termination or renewal, requires that personnel who furnish the services meet requirements that are set forth in this subpart for salaried personnel; and 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

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Act, which provides that only the provider may bill the beneficiary for covered services furnished under arrangements; and 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.

**FED - I0090 - CLINICAL RECORDS**

**Title** CLINICAL RECORDS

**Type** Condition

**CFR** 485.721

**Regulation Definition**

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 Guideline**

**FED - I0091 - PROTECTION OF CLINICAL RECORD INFORMATION**

**Title** PROTECTION OF CLINICAL RECORD INFORMATION

**Type** Standard

**CFR** 485.721(a)

**Regulation Definition**

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.

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FED - I0093 - CONTENT

**Title** CONTENT

**Type** Standard

**CFR** 485.721(b)

**Regulation Definition**

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 must 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 Guideline**

FED - I0095 - RECORDS COMPLETION & REPORT CENTRALIZATION

**Title** RECORDS COMPLETION & REPORT CENTRALIZATION

**Type** Standard

**CFR** 485.721(c)

**Regulation Definition**

Current clinical records and those of discharged patients are completed promptly. All clinical information pertaining to a

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patient is centralized in the patient's clinical record. Each physician signs the entries that he or she makes in the clinical record.

**FED - I0096 - RETENTION & PRESERVATION**

**Title** RETENTION & PRESERVATION

**Type** Standard

**CFR** 485.721(d)

**Regulation Definition**

Clinical records are retained for at least the period determined by the respective State statute, or the statute of limitations in the State; or, in the absence of a State statute, five years after the date of discharge; or, 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 Guideline**

**FED - I0097 - INDEXES**

**Title** INDEXES

**Type** Standard

**CFR** 485.721(e)

**Regulation Definition**

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.

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**FED - I0099 - LOCATION & FACILITIES**

**Title** LOCATION & FACILITIES

**Type** Standard

**CFR** 485.721(f)

**Regulation Definition**

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

**Interpretive Guideline**

**FED - I0117 - PHYSICAL ENVIRONMENT**

**Title** PHYSICAL ENVIRONMENT

**Type** Condition

**CFR** 485.723

**Regulation Definition**

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 Guideline**

**FED - I0118 - SAFETY OF PATIENTS**

**Title** SAFETY OF PATIENTS

**Type** Standard

**CFR** 485.723(a)

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**Regulation Definition**

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 of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs), free from obstruction at all times, and, 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 Guideline**

**FED - I0121 - MAINTENANCE OF EQUIPMENT/BUILDINGS/GROUNDS**

**Title** MAINTENANCE OF EQUIPMENT/BUILDINGS/GROUNDS

**Type** Standard

**CFR** 485.723(b)

**Regulation Definition**

The organization establishes a written preventive maintenance program to ensure that the equipment is operative and is

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properly calibrated, and the interior and exterior of the building are clean and orderly and maintained free of any defects which are a potential hazard to patients, personnel, and the public.

**FED - I0123 - OTHER ENVIRONMENTAL CONSIDERATIONS**

**Title** OTHER ENVIRONMENTAL CONSIDERATIONS

**Type** Standard

**CFR** 485.723(c)

**Regulation Definition**

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 must be accessible and constructed so as to allow use by nonambulatory and semiambulatory individuals.

(3) Whatever the size of the building, there must be an adequate amount of space for the services provided and disabilities treated, including reception area, staff space, examining room, treatment areas, and storage.

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**FED - I0150 - SPEECH PATHOLOGY SERVICES**

**Title** SPEECH PATHOLOGY SERVICES

**Type** Condition

**CFR** 485.715

**Regulation Definition**

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 to fulfill its objectives.

**Interpretive Guideline**

**FED - I0151 - ADEQUATE PROGRAM**

**Title** ADEQUATE PROGRAM

**Type** Standard

**CFR** 485.715(a)

**Regulation Definition**

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 Guideline**

**FED - I0152 - FACILITIES AND EQUIPMENT**

**Title** FACILITIES AND EQUIPMENT

**Type** Standard

**CFR** 485.715(b)

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**Regulation Definition**

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 Guideline**

**FED - I0153 - PERSONNEL QUALIFIED/PROVIDE SPEECH PATH**

**Title** PERSONNEL QUALIFIED/PROVIDE SPEECH PATH

**Type** Standard

**CFR** 485.715(c)

**Regulation Definition**

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 Guideline**

**FED - I0160 - INFECTION CONTROL**

**Title** INFECTION CONTROL

**Type** Condition

**CFR** 485.725

**Regulation Definition**

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

**Interpretive Guideline**

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

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and transmission of infection.

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

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

**FED - I0161 - INFECTION CONTROL COMMITTEE**

**Title** INFECTION CONTROL COMMITTEE

**Type** Standard

**CFR** 485.725(a)

**Regulation Definition**

The infection control committee establishes policies and

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procedures for investigating, controlling, and preventing infections in the organization and monitors staff performance to ensure that the policies and procedures are executed.

**FED - I0163 - ASEPTIC & ISOLATION TECHNIQUES**

**Title** ASEPTIC & ISOLATION TECHNIQUES

**Type** Standard

**CFR** 485.725(b)

**Regulation Definition**

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

**Interpretive Guideline**

**FED - I0165 - HOUSEKEEPING**

**Title** HOUSEKEEPING

**Type** Standard

**CFR** 485.725(c)

**Regulation Definition**

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.

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 both meet requirements of the standard.

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FED - I0167 - LINEN

**Title** LINEN

**Type** Standard

**CFR** 485.725(d)

**Regulation Definition**

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 Guideline**

FED - I0169 - PEST CONTROL

**Title** PEST CONTROL

**Type** Standard

**CFR** 485.725(e)

**Regulation Definition**

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

**Interpretive Guideline**

FED - I0180 - PROGRAM EVALUATION

**Title** PROGRAM EVALUATION

**Type** Condition

**CFR** 485.729

**Regulation Definition**

The organization has procedures that provide for a systematic

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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.

**FED - I0181 - CLINICAL RECORD REVIEW**

**Title** CLINICAL RECORD REVIEW

**Type** Standard

**CFR** 485.729(a)

**Regulation Definition**

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 Guideline**

**FED - I0183 - ANNUAL STATISTICAL EVALUATION**

**Title** ANNUAL STATISTICAL EVALUATION

**Type** Standard

**CFR** 485.729(b)

**Regulation Definition**

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.

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FED - I9999 - FINAL OBSERVATIONS

**Title** FINAL OBSERVATIONS

**Type** Memo Tag

**CFR**

**Regulation Definition**

**Interpretive Guideline**