CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal 150	Date: October 30, 2015
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SUBJECT: Revisions to State Operations Manual (SOM), Chapter 2, Clarification of Requirements for Off-Premises Activities and Approval of Extension Locations for Providers of Outpatient Physical Therapy and Speech-Language Pathology Services

I. SUMMARY OF CHANGES: Revisions are being made to Chapter 2, sections 2292B, 2298A, and 2300 to clarify guidance for the two-person duty requirement, approval of extension locations, and permissible off-premises activities.

NEW/REVISED MATERIAL - EFFECTIVE DATE: October 30, 2015 IMPLEMENTATION DATE: October 30, 2015

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	2/Providers of Outpatient Physical Therapy and/or Outpatient Speech
	Pathology Services Specified in §485.701 - §485.729/2292B - Rehabilitation
	Agency, Clinic and Public Health Agency
R	2/Providers of Outpatient Physical Therapy and/or Outpatient Speech
	Pathology Services Specified in §485.701 - §485.729/2298A - Criteria for
	Extension Location Approval
R	2/Providers of Outpatient Physical Therapy and/or Outpatient Speech
	Pathology Services Specified in §485.701 - §485.729/2300 - 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

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	One-Time Notification -Confidential
	Recurring Update Notification

^{*}Unless otherwise specified, the effective date is the date of service.

2292B - Rehabilitation Agency, Clinic and Public Health Agency

(Rev. 150, Issued: 10-30-15, Effective: 10-30-15, Implementation: 10-30-15)

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.

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.

Services provided in a patient's residence are exempt from the two person duty requirement. Additionally, services provided in a patient's room within an assisted living facility (ALF) or independent living facility (ILF) may be considered to be a patient's residence and therefore also exempt from the two person on duty requirement. A common or general use area of the facility, such as a hallway, may be considered to be an extension of the patient's room and residence and also exempt from the two person on 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.

Rehabilitation agencies may 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 these facilities. In addition, the rehabilitation agency is responsible for maintaining clinical records for therapy services provided to the ALF patients.

In situations when the OPT is seeing patients in an ALF or ILF, where there is no ongoing or permanent presence of the OPT, common areas do not need to be closed off when an individual therapy session extends beyond the patient's room. However, OPTs must afford patients the opportunity for privacy at the patient's request or when clinical situations warrant privacy.

Any space leased, rented, or dedicated for the provision of OPT services, including space within an ALF or ILF that is designated for therapy service, must meet the two person on duty requirement and become a separately certified OPT or become approved as an extension location of a currently certified OPT. Leased or rented space that is dedicated to therapy services must be closed to non-therapy participants when services are being provided. See Section 3100 for additional guidance for situations and when a location must be approved as an extension site or separately certified.

2298A - Criteria for Extension Location Approval

(Rev. 150, Issued: 10-30-15, Effective: 10-30-15, Implementation: 10-30-15)

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 adequate supervision of the staff at all extension locations *to include* manage*ment* and oversee*ing* operations of the extension location. *The administrator may delegate aspects of administrative operations at extension locations provided the agency has internal policies and procedures ensuring coordinated oversight of all locations.* The administrator or his/her designee should be available by telephone, at a minimum, and be able to *arrive at* the extension location in a reasonable amount of travel time.

- Primary sites are generally able to meet the requirements for supervision and oversight when the extension location being requested is within 30 miles of the primary site. Requests for approval of extension locations beyond 30 miles must include adequate documentation to support the OPT's ability to maintain supervision and oversight of these locations and that the services are being provided to a portion of the total geographic area served by the primary site. An example of evidence supporting this would include, but is not limited to, policies and procedures describing a structured program for supervision and oversight of activities at extension locations. This may include items such as scheduled teleconferences, videoconferencing, and site visits to facilitate administrative and personnel management. Additionally, OPTs may provide a written narrative to the CMS RO further describing their supervision and oversight of extension locations. The oversight program must ensure that the extension locations maintain compliance with all applicable aspects of the CoPs, even though they are not required to independently meet all the CoPs as a rehabilitation agency.
- The extension location must provide the same level of privacy and dignity for its patients as the primary site does.
- For a rehabilitation agency to establish an extension location across State lines, the affected State Survey Agencies must have a signed reciprocal agreement allowing approval of the extension location.

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. 150, Issued: 10-30-15, Effective: 10-30-15, Implementation: 10-30-15)

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. These are services that are provided on an intermittent basis where there is no ongoing or permanent presence of the OPT. Examples of an ongoing or permanent presence may be indicated by a dedicated therapy gym; storing of equipment, supplies, or medical records at the facility; or having OPT staff regularly assigned to work at that facility directing a coordinated and ongoing rehabilitation program at the facility. These situations are examples that would require the OPT to have the other location become separately certified or become approved as an extension location.

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.