



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 15-33-OPT

DATE: April 3, 2015

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Clarification of Requirements for Off-Premises Activities and Approval of Extension Locations for Providers of Outpatient Physical Therapy (OPT) and Speech-Language Pathology Services and Off-Premises Activities

Memorandum Summary

Guidance Updated: The Centers for Medicare & Medicaid Services (CMS) has added guidelines to the State Operations Manual (SOM) Chapter 2 to clarify certification requirements for providers of OPTs.

- **Off-Premises Activity:** OPTs may only provide services at off-premises locations, such as ALFs/ILFs, on an intermittent basis when there is no ongoing or permanent presence of the OPT.
- **Two Person Duty Requirement:** We are clarifying that a patient's room, and by extension, common areas within an assisted living facility (ALF) or independent living facility (ILF) may be considered a patient's residence and may be exempt from the OPT two-person duty requirement.
- **Extension Location Approval and Administration Requirement:** Extension locations may be approved when they are located outside the immediate vicinity of the primary site.

Off Premises Activities

Providers of OPT and speech-language pathology services under 42 CFR Part 485, Subpart H must provide the required services at their primary Medicare-approved site. Additional sites of service must be approved by the CMS Regional Office as extension locations. When the OPT provides services away from the primary site or extension location/s, this is referred to as "off-premises activity" at other locations.

Section 2300 of the SOM provides guidance on permissible off-premises activities at other locations. The OPT 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 without qualifying as an extension location. We are clarifying that these are services provided

on an intermittent basis where there is no ongoing or permanent presence of the OPT. An OPT would be considered to have an ongoing or permanent presence if it has a dedicated therapy gym; stores equipment, supplies, or medical records at the facility; or, has OPT staff regularly assigned to work at that facility directing a coordinated and ongoing rehabilitation program at the facility. Any of these situations would require the OPT to have the other location become separately certified or approved as an extension location. Additionally, these locations must meet the two-person duty requirement and be closed to non-therapy participants while therapy is being conducted.

In certain circumstances, a community facility may be utilized by an OPT to provide certain therapeutic activities or services without qualifying as an extension location. The SOM provides guidance on use of a community pool under these circumstances and we are not revising the guidance for this activity.

Two Person Duty Requirement

Section 2292B of the SOM requires OPTs to have “at least two persons (either of its own personnel or its contracted personnel) on duty anytime rehabilitation treatment is being provided to a patient.” This requirement was extended to “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).” Currently, the only exception for the two person duty requirement is when rehabilitation services are being provided at a patient’s private residence. We are clarifying this requirement to consider that services provided in a patient’s room within an ALF or ILF are considered to be provided in a private residence and therefore exempt from the two person requirement. Common or general use area of the facility, such as a hallway, are considered to be an extension of the patient’s room and residence and also exempt from the two person requirement.

Extension Location Approval

Section 2298 of the SOM provides guidance on the geographic area for which extension sites may be approved. This guidance indicates that an “extension location is situated within a 30 mile radius of where 90 percent of the agency’s primary site’s population lives”. We are clarifying this requirement to indicate that there may be individual extension locations that may be approved at locations outside the immediate vicinity of the primary site. 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. An example of evidence supporting this requirement would include 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, further describing their supervision and oversight of extension locations, to the CMS RO. The oversight program must ensure that the extension locations maintain compliance with all applicable aspects of the Conditions of Participations. The administrator may delegate administrative aspects of operations at extension locations provided the agency has internal

policies and procedures to coordinated oversight of all locations. Surveyors must verify the agency has processes established for coordinated oversight.

Contact: Questions or comments regarding this memorandum should be addressed to James Cowher at (410) 786-1948 or james.cowher@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/

Thomas E. Hamilton

Attachment- State Operations Manual Chapter 2

cc: Survey and Certification Regional Office Management

CMS Manual System

Pub. 100-07 State Operations

Provider Certification

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

Transmittal

Date:

SUBJECT: 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 have been made to Chapter 2, Sections 2292B, 2298, 2298A, and 2300 to clarify guidance for the 2-person duty requirement, approval of extension locations, and permissible off-premises activities.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Immediately
IMPLEMENTATION DATE: Immediately

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	2/2292B/Rehabilitation Agency, Clinic and Public Health Agency
R	2/2298/Extension Locations for Rehabilitation Agencies
R	2/2298A/Criteria for Extension Location Approval
R	2/2300/ 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.**

SOM Chapter 2 Revisions

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.

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.

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 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 adequate supervision of the staff at all extension locations *to include management and overseeing 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. An example of evidence supporting this requirement would include 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, further describing their supervision and oversight of extension locations, to the CMS RO. The oversight program must ensure that the extension locations maintain compliance with all applicable aspects of the COPs.*
- 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 two State Survey Agencies involved must have a signed reciprocal agreement allowing approval of the extension location.*

2300 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. *These are services that are provided on an intermittent basis where there is no ongoing or permanent presence of the OPT. In contrast, an OPT would be considered to have an ongoing or permanent presence if it has a dedicated therapy gym; stores equipment, supplies, or medical records at the facility; or has OPT staff regularly assigned to work at that facility directing a coordinated and ongoing rehabilitation program at the facility. Any of these situations 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.