



Center for Clinical Standards and Quality

Ref: QSO-24-18-OPT

DATE: August 23, 2024

TO: State Survey Agency Directors

FROM: Directors, Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Revisions and clarifications for survey and certification activities for the Outpatient Physical Therapy (OPT)/ Speech-Language Pathology (SLP) Programs

Memorandum Summary

- The Centers for Medicare & Medicaid Services (CMS) is revising survey and certification expectations for Outpatient Physical Therapy (OPT)/ Speech-Language Pathology (SLP) programs related to extension locations. Specifically, CMS is clarifying requirements for:
 - Primary Site and Extension Location Surveys;
 - Surveying All Extension Locations;
 - Surveying All Conditions of Participation at Extension Locations; and,
 - Extension Locations beyond a 30-mile radius.
- CMS has also revised Forms CMS-381 and CMS-1856 to align with the recent certification transition work (Admin Info 24-22-ALL) and to further streamline enrollment and certification processes for OPTs, such as adding extension site locations. See: <https://www.cms.gov/medicare/cms-forms/cms-forms/downloads/cms381.pdf>
- CMS is currently in the process of revising Chapter 2 and Appendix E of the State Operations Manual (SOM) to incorporate these changes.

Background

Clinics (operated by physicians), rehabilitation agencies, and public health agencies operating as providers of Outpatient Physical Therapy (OPT) and Speech-Language Pathology (SLP) Services are required to comply with the Federal requirements set forth in the Medicare Conditions of Participation (CoPs). Outpatient rehabilitation therapy services may include physical therapy (PT), occupational therapy (OT), and SLP services. Providers of OPT and SLP services under 42 CFR Part 485, Subpart H, must provide the required services at their primary Medicare-approved site.

Rehabilitation agencies are the only entity who may apply to CMS for approval of another location near its primary site, for the purpose of providing additional access to care. These locations are known as “Extension Locations” and are defined at 42 CFR §485.703. Extension

locations share administration, supervision, and services with the primary site. CMS must approve additional sites of service as Extension Locations.

Chapter 2 of the State Operations Manual (SOM) provides guidance to State Survey Agencies (SAs) and CMS Survey & Operations Group (SOG) Locations for surveying and approving extension locations. Accrediting Organizations (AOs) must have comparable processes, as defined at 42 CFR §488.5.

Discussion

We are providing additional guidance for four areas (outlined below) of survey and certification activities related to extension locations in order to address the evolving expansion of OPT/OSP services provided across settings and locations. Additionally, on May 30, 2022, CMS streamlined Medicare enrollment and certification activities, including those for OPT/SLP organizations (refer to [Admin Info 24-22-ALL](#)). The additional guidance and clarifications discussed here align with CMS' processes for these streamlined activities.

CMS is clarifying requirements for enrollment and certification of OPT/SLP organizations, including new instructions for the revised Form CMS-381, which has been updated to combine information from the Form CMS-1856 (which will be retired). The newly revised Form CMS-381 will be required upon initial enrollment, and with recertification or expansion requests. The OPT will submit the form per the instructions in [Admin Info 24-22-ALL](#) for initial certification, administrative changes (such as extension locations), changes of ownership, and during recertification surveys.

1. Primary Site and Extension Location Surveys

Current language in Chapter 2, Section 2298D of the SOM states that an AO can only survey an extension location and recommend approval to CMS if the primary site is already accredited by the AO and has been certified by CMS as a provider, through deemed status. Furthermore, previous versions of the Form CMS-381 and CMS-1856 instructions did not align with the recent revisions CMS implemented to streamline Medicare enrollment and certification.

Initial Enrollment & Certification

- a) An organization wishing to participate in the Medicare program as an OPT must complete the revised Form CMS-381 when submitting the Form CMS-855 to the Medicare Administrative Contractor (MAC).
- b) If the organization wishes to establish an extension site at the same time as requesting initial CMS-approval of its primary site location, it may annotate the request on the Form CMS-381 along with the application. **Surveys of both the primary site and extension location are required by the SA or AO (if applicable) for initial approval.**
- c) If the extension site is across state lines, a reciprocal agreement between the applicable SAs must be in place for OPTs, and the SAs are expected to coordinate survey activities for approval of the primary site and extension location.

Existing Medicare-Participating OPTs

As outlined in [Admin Info 24-22-ALL](#) (see Part II, Section III- General Processing Instructions for CMS in Attachment 1), the MAC receives the enrollment application and reviews it for completeness. However, the OPT provides the Form CMS-381 to the SA or AO. As a reminder,

it is the responsibility of the SA and AO to collect the Form CMS-381 (as outlined in the Admin [Admin Info 24-22-ALL](#) Addendum Attachment 3) based on the request of the organization.

- a) An existing CMS-approved OPT requesting a new or an additional extension location must complete the revised Form CMS-381 when submitting the modified Form CMS-855 to the MAC.
- b) If the organization is requesting multiple extension sites at the same time, one Form CMS-855 will suffice. However, the organization must list all extension sites on the Form CMS-381.
- c) If an organization is requesting a conversion of their extension location to become the primary location, it must submit both requests to the MAC via the CMS-855, including the revised Form CMS-381.

Note: Extension locations include a special identifier within the CMS Certification Number (CCN). Therefore, any adjustments to an extension location or primary site conversion to an extension location would require adjustments to the CCNs.

2. Surveying all Extension Locations

Chapter 2, Section 2298D of the SOM currently states that for organizations seeking certification or recertification through accreditation by an AO with an approved program, the AO surveys the primary site and any proposed or existing extension locations for compliance with the applicable CoPs. However, in the guidance under Chapter 2, Section 2298B - Extension Location Approval Process, the existing language states that the CMS Location “will determine whether a survey needs to be conducted and will instruct the SA/AO appropriately.” Our intent is to reconcile this language and expectations.

Therefore, we are removing the language in section 2298D that reads: “and any proposed or existing extension locations.” Further, we are removing the language which requires the CMS Location to instruct the AO to conduct survey activities. The removal of the language ensures the SA and AO survey expectations are the same and consistent with [Admin Info 24-22-ALL](#). AOs may choose to continue to exceed these requirements by conducting surveys at all locations, as part of their deeming program for OPTs.

In accordance with [Admin Info 24-22-ALL](#), if a CMS-approved OPT submits the request for an extension location via the MAC, the MAC will provide its recommendation to the SA and AO (if applicable). Both the SA and AO will determine the need for a survey of the extension location based on criteria, which may include, but is not limited to:

- Review of survey history and non-compliance of the primary site;
- Number of substantiated complaints against the primary site;
- Number of total extension sites already approved, as applicable;
- Services being offered; and
- Size and geographic location of the extension site (same service population).

If the OPT has deemed status, the AO will determine the need for survey in accordance with Admin Info 22-02, and send the recommendation back to the MAC, with copy to the SA. If the AO has concerns about an organization’s extension site request, the AO should coordinate with the SA prior to submitting any recommendation of approval to the MAC. For denials, the AO will also copy the CMS Location.

Note: For an initial certification request of a primary site with extension location at the same time, the SA and AO (if applicable) must conduct a survey of both locations. Note, SAs and AOs must survey the primary site for all new initial Medicare OPT applicants.

3. Surveying all Conditions for Participation (CoPs) at Extension Locations

The current Chapter 2 language in section 2298D directs AOs to evaluate each condition and standard in the CoPs at all surveyed sites. However, Chapter 2 also states that the extension location shares administration, supervision, and services with the primary site in a manner that renders it unnecessary for the extension location to independently meet the CoPs. Because the primary site is responsible for the administration at the extension locations, we are reinforcing that the extension locations must be assessed for compliance consistent with the guidance in this memorandum and [Admin Info 24-22-ALL](#). Additionally, extension locations do not independently have to meet all of the CoPs.

For example, under the Administrative Management CoP at §485.709, the OPT must have, among other things, a Governing Body §485.709(a), Personnel Policies §485.709(c), Patient Care Policies §485.709(d), and an Emergency Preparedness Program §485.727. The governing body is responsible for oversight of the primary site location and extension location(s). While overarching policies may exist for the “system” (primary and extension location), policies and procedures at the extension location are based on its geographic location, services provided, and population served. Additionally, if noncompliance under any of the requirements is identified at an extension location, the primary site would also be non-compliant since the extension location does not independently meet all conditions and standards.

To meet the definition of an extension location in §485.703, it should be located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the extension location to independently meet the conditions of participation as a rehab agency. Using the criteria above consistent with [Admin Info 24-22-ALL](#) to determine survey needs at extension locations, CMS would expect the extension locations to meet the following CoPs independently of the primary site location, even if the organization had overarching policies and procedures which govern all sites:

- §485.711 Condition of Participation: Plan of Care and Physician Involvement
- §485.713 Condition of Participation: Physical Therapy Services
- §485.715 Condition of Participation: Speech Pathology Services
- §485.721 Condition of Participation: Clinical Records
- §485.723 Condition of Participation: Physical Environment
- §485.725 Condition of Participation: Infection Control

Surveyors are expected to use their discretion in expanding their survey activities beyond the listed minimum CoPs and related standards at extension locations. If the surveyor reviews clinical records during an extension location survey and determines systemic concerns which may appear widespread within the extension location, then the surveyor should expand their scope of review to any potentially relevant standards and investigate to ensure compliance at the extension location(s). In the event of an initial certification request for primary site and extension location at the same time, the SA and AO (if applicable) should consider denial if either location has systemic issues.

4. Extension Locations beyond the 30-Mile Radius

Extension locations were generally approved if they were situated within 30 miles of the agency's primary site location and serving approximately 90 percent of the same patient population. In 2015, CMS made clarifications to the 30-mile radius guidance via a [policy memorandum](#) (S&C15-33-OPT) and updated Chapter 2 of the SOM. Specifically, the SOM guidance was revised to indicate that there may be individual extension locations that may be approved at locations outside the immediate vicinity of the primary site. The guidance also stated that requests for approval of extension locations beyond 30 miles must include adequate documentation to support the OPT's ability to maintain oversight.

Consistent with that guidance, we are reiterating that OPT extension locations may continue to be approved for distances beyond 30 miles. We recognize that OPTs have been operating extension locations beyond the 30-mile radius with sufficient oversight and administrative control due, for example, to evolved organizational structures and participation in state licensure compacts. We note that the State Survey Agencies need to have a reciprocal agreements with each other when organizations cross state lines to address responsibilities of each state and ensure appropriate oversight. Additionally, SAs and AOs will determine survey needs based on the guidance outlined in [Admin Info 24-22-ALL](#) and based on the below guidance.

We are specifying the SA and AO (as applicable) will use the following criteria when reviewing extension locations for approval recommendation:

- a) Submission by the OPT of their process outlining the organization's strategies and policies for implementing and maintaining oversight of the extension location(s). The strategies and policies should describe the manner in which administration, supervision, and services are provided that make it unnecessary for the extension location to independently meet the conditions of participation as a rehabilitation agency. This should include, but is not limited to, the following:
 - Organizational Charts;
 - Staffing - CMS will review the plans for staffing of the extension locations;
 - Scheduled onsite or virtual visits to the extension location by the Administrator or Governing Body;
 - Written documentation related to updates on staffing and regular meetings with staff at the proposed extension location; and
 - Consolidated audits of performance or any changes in policy implementation (e.g., QAPI).
- b) An out-of-state extension location should, at a minimum, be located in an adjoining state to the state of the primary site to ensure the primary site can reasonably maintain oversight.
- c) Compliance history of the primary site, especially related to the governing body and infection control committee.
- d) 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 SA and AO.

SOM and Training: CMS is currently working on revisions to Chapter 2 and Appendix E of the SOM. We will provide additional guidance as it becomes available.

ASPEN/ACO: Although we understand ASPEN/ACO will not be updated to reflect the removal of the CMS-1856, the information on the new CMS-381 does contain the required fields on the CMS-1856 tab in ASPEN. SA's must continue to enter the information in the CMS-1865 tab in ASPEN based on the information on the new CMS-381 form.

Contact: For questions or concerns, please contact QSOG_OPT@cms.hhs.gov.

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

/s/

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Attachment(s):

1- Revised Form CMS-381

Resources to Improve Quality of Care:

Check out CMS's new [Quality in Focus](#) interactive video series. The series of 10–15 minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid.

Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the [Quality, Safety, & Education Portal Training Catalog](#), and select [Quality in Focus](#)

Get guidance memos issued by the Quality, Safety and Oversight Group by going to [CMS.gov](https://www.cms.gov) [page](#) and entering your email to sign up. Check the box next to "CCSQ Policy, Administrative, and Safety Special Alert Memorandums" to be notified when we release a memo.