

Via first class mail and online submission to <http://www.cms.hhs.gov/erulemaking>

March 25, 2008

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6036-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Establishing Additional Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Enrollment Safeguards

Dear Sir or Madam:

On behalf of the more than 38,000 occupational therapy professionals, the American Occupational Therapy Association (“AOTA”) submits the enclosed comments in response to the proposed rule “Establishing Additional Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Enrollment Safeguards” published in the Federal Register on January 25, 2008. AOTA appreciates the efforts that CMS has and continues to make to ensure appropriate DMEPOS supplier standards.

Participation Standard at 42 C.F.R. § 424.57(c)(1)

AOTA has a concern with the CMS proposed rule that would prohibit a DMEPOS supplier from furnishing services through the use of contractors where a license is required to furnish such DMEPOS. Under the proposed rule, the DMEPOS supplier would need to provide such licensed services using only W-2 employees. This proposed standard is not consistent with more recent changes that have increased the flexibility regarding the business structure of Medicare-enrolled entities.

The change in the reassignment rules in the Medicare Modernization Act and the subsequent CMS policy changes have allowed greater utilization of independent contractors, rather than W-2 employees. For example, a certified rehabilitation agency may choose to utilize independent contractors who separately enroll in Medicare and then reassign their rights to the rehabilitation agency to bill for the services they provide. If the rehabilitation agency enrolls as a DMEPOS supplier to be able to supply custom-made orthotics, for example, this standard would prohibit the rehabilitation agency from doing so without first employing the occupational therapists. Irrespective of whether an occupational therapist is employed or working as an independent contractor, the occupational therapist is held to the same state licensure laws and professional standards. As such, there is no enhanced program safeguard or improved supplier quality by implementing this proposed regulation.

To the extent that CMS believes that other situations may warrant such a rule change, AOTA requests that practitioners, including occupational therapists, who provide DMEPOS under their own professional licenses should be exempt from adherence to this standard.

Appropriate Physical Site Standard at 42 C.F.R. § 424.57(c)(7)

AOTA understands CMS' concern regarding the need to have an appropriate physical site and supports certain of the proposed "features" including the need for beneficiaries and CMS to be able to access the DMEPOS facility during hours of operation. AOTA is, however, concerned with the level of detail regarding the features that a physical facility would need to meet to be considered an appropriate facility.

The requirement to have a "permanent, durable sign that is visible at the main entrance" and "posted hours of operation" with advance notice of any changes, would hold DMEPOS suppliers to standards in excess of other Medicare-enrolled providers and suppliers and is not warranted for the provision of DMEPOS by practitioners who otherwise have an ongoing relationship with the beneficiaries they serve. AOTA appreciates the desire to ensure that DMEPOS suppliers do not operate as shell companies, but rather, are legitimate businesses.

AOTA supports the need for appropriate signage to identify the supply business, but raise concerns with the detail of this feature regarding where the signage should appear. We understand that the NSC looks for outside signage to identify the supplier's practice location. It is quite common for occupational therapists and other practitioners to lease space in medical office buildings and often the landlords place restrictions on the type of signage that the tenant may use. It is not necessary to require outside signage for beneficiaries who are otherwise receiving services from enrolled practitioners as they already know where the therapist is located. Additionally, the NSC would be able to locate the practice location by use of the address that is required to be included on the enrollment forms. For these reasons, there is no need to require an additional "permanent, durable sign that is visible at the main entrance."

Similarly, AOTA could support a standard requiring notice of hours of operation, but is concerned about a specific requirement to post hours of operation (using permanent signage) and the requirement to provide advance notice to the NSC of any change in the hours.

With respect to posted hours, the same signage restrictions discussed above are applicable to the posting of hours. Posting using permanent signage is additionally burdensome on certain suppliers, such as a supplier entering the business that may need to modify hours as the business grows.

The advance notice requirement is particularly problematic from an operations perspective. Under the current DMEPOS enrollment rules, the supplier must notify the NSC of a change in its enrollment data within 30 days following the change. The current CMS 855S forms do not, however, require the reporting of hours of operation. To require DMEPOS suppliers to provide advance notice of a change in hours of operation would require the DMEPOS supplier to follow two different procedures to report data updates. Hours of operation would be reported through

some form of letter or other correspondence, with updated information sent in advance of the change, while other changes in the supplier's enrollment data would require the submission of a change of information CMS 855S filing within 30 days after the change occurred.

Additionally, AOTA would caution CMS against establishing a minimum square footage requirement for all DMEPOS suppliers. Due to the diversity of the type of DMEPOS services and items, appropriate square footage requirements will vary significantly. A supplier of wheelchairs, beds and other large DME items will need significantly more square footage than an occupational therapist who is supplying hand orthotics.

Liability Insurance Standard at 42 C.F.R. § 424.57(c)(10)

AOTA is concerned with the procedures that the NSC will be required to follow to verify the validity of an insurance policy before being able to revoke billing privileges. Currently, the NSC verifies coverage with the insurance agent or underwriter at the time of enrollment. Enrollment applications have, in the past, been rejected by the NSC because the insurance agent was not able at the time of the call to retrieve the policy and verify coverage. Any rule granting the NSC the right to revoke billing privileges, based on an inability to verify insurance coverage, should have some procedural safeguards so that the supplier is notified if the insurance agent or underwriter did not provide the necessary validation with some ability for the supplier to work with the NSC on getting the validation before a revocation action is taken.

Beneficiary Contact Standard at 42 C.F.R. § 424.57(c)(11)

Supplier Standard Number 11 seeks to limit certain beneficiary contacts for marketing purposes. AOTA would like to confirm its understanding that this standard and the proposed changes only apply to communications with beneficiaries related specifically to the DMEPOS services. For example, when an occupational therapist is providing both skilled therapy services and a DMEPOS item to a Medicare beneficiary, the occupational therapist would not be restricted in communications related to the services being provided under a skilled therapy plan of care currently or in the future.

Sharing Practice Location Standard at 42 C.F.R. § 424.57(c)(29)

The proposed new standard to restrict a DMEPOS supplier from sharing a practice location with another Medicare supplier is problematic with respect to occupational therapists. AOTA appreciates that CMS is soliciting comments on exceptions to this space-sharing proposal and provide those below.

AOTA is concerned generally about having a shared space standard for any DMEPOS supplier. Under the proposed standard, a DMEPOS supplier could not operate its business in a practice location reported by another supplier even if the two suppliers had completely separate operations. The standard requiring an "appropriate space" already exists and the NSC has successfully prohibited DMEPOS suppliers from enrolling in Medicare when the supplier does not have an appropriate space. This added layer of regulation regarding the practice location is unnecessary for identifying unscrupulous suppliers.

Should a shared space standard be adopted, AOTA urges CMS to exempt occupational therapists from being required to adhere to the standard. As acknowledged in the commentary, nonphysician practitioners, including occupational therapists, may enroll in Medicare both as a supplier to furnish outpatient therapy services and as a DMEPOS supplier. For the occupational therapist, the provision of DMEPOS is an integral component of the skilled therapy services being provided. To require a practitioner to maintain a separate practice location simply to be able to provide DMEPOS items and services is both burdensome and unnecessary.

To illustrate this point, AOTA offers the following scenario. A Medicare beneficiary with cervical degenerative arthritis sustains neurological involvement resulting in decreased upper extremity function in the beneficiary's dominant hand. The beneficiary receives outpatient occupational therapy from an occupational therapist who is enrolled as an occupational therapist in private practice, i.e., a Part B supplier. During the course of rendering skilled occupational therapy, the occupational therapist determines that the patient requires an off-the-shelf hand splint to stabilize the wrist to improve hand function. Under the proposed supplier standard, the occupational therapist would need to maintain a separate practice space to be able to incidentally provide the necessary orthosis. Such a requirement is clearly not beneficial to the patient under these circumstances.

Additionally, AOTA urges CMS to establish an exception to address situations in which physicians and non-physician practitioners share office space. It is common for therapists to share medical office space with another type of practitioner, including physicians.

To illustrate this point, AOTA offers a slight change in the facts of the scenario discussed above. In this scenario, the occupational therapist is employed by a physician and providing skilled therapy services to the Medicare beneficiary under the "incident to" rules. Under the proposed standard, neither the physician practice nor the occupational therapist could enroll as a DMEPOS supplier to incidentally provide the needed orthosis without securing additional separate space.

Exceptions to the shared space standard should consider how health care practitioners currently share space and the need for flexibility in the supplier standards so that the practices of health care providers that provide DMEPOS to the patients under their care are not disrupted.

Hours of Operation Standard at 42 C.F.R. § 424.57(c)(30)

For similar reasoning discussed above, AOTA has concern about a requirement to operate the DMEPOS business a minimum of 30 hours per week, especially for practitioners who supply DMEPOS items as an integral, but significantly smaller, part of their health care practice. AOTA supports CMS' desire to be sure that DMEPOS suppliers operate legitimate businesses, but does not support a required minimum number of hours of operation for practitioners that additionally enroll as DMEPOS suppliers.

In order to provide ongoing skilled therapy services, occupational therapists need to maintain appropriate hours of operation, so a specific supplier standard regarding hours of operation is not necessary. And, depending upon the type of practice, an occupational therapist may provide

services only on a part-time basis or through more than one practice location. For an occupational therapist who additionally desires to supply DMEPOS items, a 30-hour per week required hours of operation rule is likely to preclude the ability to work part-time or maintain multiple practice locations.

Should CMS adopt a minimum standard then, in addition to an exception for custom-made or fitted orthotics and prosthetics, there should be an exception for health care practitioners who supply other DMEPOS items, such as off-the-shelf orthotics, as an integral part of their existing practice.

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AOTA appreciates the opportunity to provide comments on proposed rule “Establishing Additional Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Enrollment Safeguards”. AOTA strongly suggests that CMS consider each standard as it would apply to the different types of DMEPOS suppliers, particularly to enrolled practitioners who additionally provide DMEPOS services and items integral to ongoing patient care. We look forward to continued dialogue with CMS on these types of matters. Should you have any questions or comments, please contact me at (301) 652-2682 ext. 2863 or via email at ssandhu@aota.org.

Sincerely,



Sharmila Sandhu, Esq.
Regulatory Counsel