

March 18, 2008

Centers for Medicare & Medicaid Services
Attention: DMEPOS Accreditation Standards
Mailstop C3-06-16
7500 Security Blvd
Baltimore, MD 21244

RE: Revised Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)
Quality Standards Draft dated February 2008

Dear Ms. Bastinelli:

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 Revised Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards posted on the Centers for Medicare and Medicaid Services (CMS) website. AOTA appreciates the efforts that CMS has made to develop and refine quality standards for the provision of orthotics and prosthetics.

Through comments to other DMEPOS documents, AOTA has detailed the role of the occupational therapist in the provision of DMEPOS.¹ AOTA generally believes that CMS had identified appropriate standards related to the Business Services Requirements and the Product-Specific Service Requirements in Sections I and II of the draft, with only a few comments appearing below. The main focus of AOTA’s response is Appendix C titled, Custom Fabricated and Custom Fitted Orthoses, External Breast Prostheses, Therapeutic Shoes and Inserts, and their Accessories and Supplies; Custom Made Somatic, Ocular and Facial Prostheses.

Appendix C

Although AOTA supports CMS’ efforts to delineate quality standards to ensure that beneficiaries receive appropriate orthotics and prosthetics, there are several areas which AOTA believes require clarification and reordering. First, in the introduction to Appendix C, CMS has added language related to specialized training for prostheses. That paragraph states, “Individuals supplying the item(s) set out in this appendix must possess specialized education, training, and experience in fitting these types of prostheses, and, when appropriate, certification and or licensing.” The sentence includes the phrases, “item(s) set out in this appendix” and “these types of prostheses.” Based on this language, it is unclear whether the language is intended to only apply to the fitting of prostheses or whether reference to orthoses was inadvertently omitted. **To the extent that this standard was intended to apply to orthoses, the standard should be written in a manner to clearly indicate that no additional specialized education**

¹ Enclosed for your review is a copy of AOTA’s comments responding to the proposed quality standards submitted on November 28, 2005, which comprehensively addresses some of the unique issues related to the supplying of DMEPOS by an occupational therapist.

or training, licensure or certification is needed for licensed health care practitioners like occupational therapists, who are authorized under the practitioner’s scope of practice to provide orthoses.

Second, the additions to the text under Subsections B. Assessment and C. Treatment Plan has prompted AOTA to suggest a reworking of these subsections. The concepts of in-depth assessment and treatment planning are not currently required for a supplier to provide the DMEPOS items encompassed within Appendix C. Furthermore, although occupational therapists are specially trained to perform a comprehensive clinical assessment and develop a treatment plan to be able to render skilled therapy services in addition to supplying DMEPOS, other DMEPOS suppliers do not have this type of clinical education and training.

Although providing certain orthotic/prosthetic devices may warrant a thorough assessment, such assessment is not needed in all situations and the standards as drafted do not provide the flexibility to only conduct a thorough assessment if one is medically necessary. For example, the fitting of depth shoes would not require a comprehensive beneficiary assessment, especially one that is to include demographic characteristics and family dynamics.

Similarly, treatment planning is a concept that is applicable to a skilled therapy situation where there is an ongoing relationship with the patient and the patient’s condition is expected to change, requiring treatment plan modification over the course of the therapy. Although a beneficiary may need training in the use of an orthosis or prosthesis, or even follow-up services to provide refitting or device modification, the “treatment plan” is to fit and provide the device and then to provide a referral to the appropriate health care professional for follow-up intervention, if medically necessary. Thus, the goals and expected outcome for the DMEPOS supplier may simply be to fabricate or fit a device.

For example, a beneficiary that has had a below-elbow amputation and needs a prosthesis may obtain the prosthesis from a prosthetist, but will receive the training in the use and any necessary modification of the prosthesis from the occupational therapist providing the skilled therapy and not the prosthetist. It is the therapist who would document treatment goals relating to decreasing pain and edema, enhancing function, and achieving a good cosmetic outcome not the individual who fabricated the prosthesis. However, it is important for CMS to understand that an occupational therapist could play the role of both supplier and provider. In a similar example, a beneficiary needs a wrist splint orthosis due to a recent fall and obtains the orthosis from an occupational therapist, who fabricates and fits the orthosis in her role as a DMEPOS supplier (typically billing an L-code). The same occupational therapist in her role as a Medicare provider (billing CPT codes) would provide skilled therapy follow-up and document treatment goals such as decreasing pain and edema, or enhancing function, as needed. **In either example, AOTA asserts that the requirements of assessment and treatment planning are not currently concepts required of a DMEPOS supplier and that suppliers (other than health professionals) are not prepared or credentialed to provide such services, thus are not appropriately included in the CMS Quality Standards.**

Below we have provided suggested language that combines the draft “Assessment” and “Treatment Plan” sections into one section “Design, Fabrication or Fitting, and Application,” in addition to making suggested edits to more clearly track the language of the standard with the type of service that

is and should be provided when supplying orthoses and prostheses. Using similar reasoning relating to the services actually provided by a DMEPOS supplier, rather than a therapist or physician, we have suggested revised language for sections E and F, as well .

B. Design, Fabrication, or Fitting and Application

In addition to Section II: Supplier Product-Specific Service Requirements, the supplier shall:

- Determine the beneficiary’s need for the orthoses/prostheses, which may require the provision of a detailed evaluation with or without pretreatment photographic documentation when appropriate;
- Determine the appropriate type and specifications for the orthoses/prostheses, considering material strength, durability, and device functionality, to maximize therapeutic benefits for the beneficiary;
- Communicate to the beneficiary and/or prescribing physician the recommended orthoses/prostheses and any options regarding an alternative device, including disclosure of potential risk, benefits and precautions;
- Inform the beneficiary and/or caregiver(s) of the procedures for repairing, replacing, and/or adjusting the device or items and the estimated time involved in the process;
- In combination with the fabrication and/or fitting, evaluate the orthoses/prostheses for structural safety and ensure that manufacturer guidelines are followed (e.g., beneficiary weight limits, ensuring that closures work properly and there are not observable defects); and
- Establish goals and expected outcomes of the beneficiary’s use of the orthoses/prostheses, which may be accomplished during the fabrication and fitting process, with feedback from the beneficiary and/or prescribing physician as necessary; and
- Assure the orthosis/prosthesis is consistent with the device or item requested in a Medicare approved written plan of care or the prescribing physician’s dispensing order and consult the beneficiary’s physician when appropriate.

E. Training/Instruction to Beneficiary and/or Caregiver(s)

In Section E, AOTA believes limiting language should be added to the first three bullets as set forth below. Similar to the qualifying language regarding the use of an interface in the fourth bulleted item appearing below (i.e., “where appropriate”), the first three bulleted items should additionally contain qualifying language as there would be legitimate reasons for not providing certain training. For example, if a custom orthosis is required to support a fractured bone, it may need to be left in place and not removed by the beneficiary. Therefore, instruction in cleaning, donning/doffing and skin inspection

would not be appropriate training to provide to the beneficiary. We offer the following suggested revisions (i.e., the highlighted text) to these bulleted items:

- How to use, maintain and clean when appropriate, the orthoses/prostheses (e.g., wearing schedules, therapy, residual limb hygiene, other pertinent instructions):
- How to don and doff the orthoses/prostheses, including how to adjust closures for proper fit, when appropriate:
- How to inspect the skin for pressure areas; redness, irritation, skin-breakdown, pain, or edema, when appropriate:
- How to utilize an appropriate interface (e.g., stockinettes, socks, gloves, shoes to accommodate the orthoses/prostheses where appropriate:

AOTA believes that the bulleted item “Establish appropriate wear schedule and schedule for tolerance of the orthoses/prostheses” is duplicative and recommends that it should be deleted. Lastly in section E, we raise two points regarding the bulleted item “Continue to assist the beneficiary until the orthoses/prostheses reaches the optimal level of fit and function.” This particular standard is conceptually one that would be more appropriate to include under the “Follow-up” section. AOTA also suggests that the language “optimal level of fit and function” is problematic in that it is both vague and subjective. Accordingly, we offer a way to address refitting or modification as needed in the comments that appear below.

F. Follow-up

To address the issue raised above, we suggest a change in the first bulleted item, so that the revised standard would read, “Have access to a facility with the equipment necessary to provide follow-up services, including refitting or modification of the specific orthoses/prostheses as necessary.”

The bulleted item “Review recommended maintenance with the beneficiary and/or caregiver(s);” is an aspect of training and since it is already included in the training section, should be deleted as it is duplicative.

The standard “Solicit feedback from the beneficiary and prescribing physician as necessary to determine the effectiveness of the orthoses/prostheses” should not include the listed examples “(e.g., wear schedule/tolerance, comfort, perceived benefits/detriments, ability to don and doff, proper usage and function, overall beneficiary satisfaction).” These examples are suggestive of an ongoing clinical relationship with the beneficiary outside of the provision of the DMEPOS. Including the standard without the examples appropriately requires feedback as needed to determine DMEPOS effectiveness, such as when the beneficiary is being fitting.

For the reasons discussed above, the bulleted item “Review and make changes to the treatment plan based on the beneficiary’s current medical condition” should be deleted.

Section I: Supplier Business Services Requirements

The first bulleted item under Consumer Services, subsection D.1, requires “clear, written and oral instructions related to the use, maintenance, infection control practices for, and potential hazards of equipment and/or item(s).” It may not be practical or even clinically necessary for an occupational therapist supplying an orthosis to provide written instructions. Additionally, depending upon the use of a particular orthosis, there may or may not be infection control practices to discuss. Using the example provided above of an orthosis used to stabilize a fracture, there would be no infection control practices to discuss with the beneficiary as the orthosis remains in place and should not be disturbed.

With regard to the draft standard in subsection D.2, AOTA is concerned about the short time frame for the five calendar day notification requirement. Scheduling issues alone may prevent a supplier from providing the equipment within a five-day period.

The last standard under Section E, Performance Management requires the supplier to “seek input from employees, customers, and outside sources when assessing the quality of its operations and services.” AOTA requests clarification as to who “outside sources” are other than employees and customers.

Under subsection F. Product Safety, AOTA raises concern about how an occupational therapist would verify and authenticate that a product was not adulterated, counterfeit, or misbranded and seeks clarification from CMS as to this issue.

* * * * *

AOTA appreciates the opportunity to provide comments on the Revised Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards. AOTA strongly suggests that CMS consider each standard as it would apply to the variety of items that could be supplied under these draft standards, and the types of persons, including occupational therapists, who would be supplying the orthosis or prosthesis. AOTA urges that due consideration be given to these comments.

AOTA thanks CMS for the opportunity to provide comments and 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

Enclosures

DMEPOS Quality Standards Draft February 2008

Key: Black Text = Original Version
Red Text = Additions by CMS in February 2008 Draft
Grey Highlighted Text = Recommended Changes

B. Design, Fabrication or Fitting, and Application

In addition to Section II: Supplier Product-Specific Service Requirements, the supplier shall:

- Determine the beneficiary's need for the orthoses/prostheses, which may require the provision of a detailed evaluation with or without pretreatment photographic documentation when appropriate;
- Determine the appropriate type and specifications for the orthoses/prostheses, considering material strength, durability, and device functionality, to maximize therapeutic benefits for the beneficiary;
- Communicate to the beneficiary and/or prescribing physician the recommended orthoses/prostheses and any options regarding an alternative device, including disclosure of potential risk, benefits and precautions;
- Inform the beneficiary and/or caregiver(s) of the procedures for repairing, replacing, and/or adjusting the device or items and the estimated time involved in the process;
- In combination with the fabrication and/or fitting, evaluate the orthoses/prostheses for structural safety and ensure that manufacturer guidelines are followed (e.g., beneficiary weight limits, ensuring that closures work properly and there are not observable defects); and
- Establish goals and expected outcomes of the beneficiary's use of the orthoses/prostheses, which may be accomplished during the fabrication and fitting process, with feedback from the beneficiary and/or prescribing physician as necessary; and
- Assure the orthosis/prosthesis is consistent with the device or item requested in a Medicare approved written plan of care or the prescribing physician's dispensing order and consult the beneficiary's physician when appropriate.

D. Delivery and Set-up

Not applicable to this appendix.

**DMEPOS Quality Standards
Draft February 2008**

E. Training/Instruction to Beneficiary and/or Caregiver(s)

In addition to Section II: Supplier Product-Specific Service Requirements, the supplier shall:

- Provide instructions to the beneficiary and/or caregiver(s) for the specific orthoses, prostheses; or therapeutic shoe/insert as follows:
 - How to use, maintain and clean when appropriate, the orthoses/prostheses (e.g., wearing schedules, therapy, residual limb hygiene, other pertinent instructions);
 - How to don and doff the orthoses/prostheses, including how to adjust closures for proper fit, when appropriate;
 - How to inspect the skin for pressure areas; redness, irritation, skin-breakdown, pain, or edema, when appropriate;
 - How to utilize an appropriate interface (e.g., stockinettes, socks, gloves, shoes to accommodate the orthoses/prostheses where appropriate;
 - How to report any problems related to the orthoses/prostheses to the supplier or the prescribing physician if changes are noted (e.g., changes in skin condition, heightened pain, increase in edema, wound concerns; changes in general health, height, weight, or intolerance to wearing the orthoses/prostheses as applicable); and
 - How to schedule follow-up appointments as necessary.
- Provide necessary supplies (e.g., adhesives, solvents, lubricants) to attach, maintain, and clean the items, as applicable, and information about how to subsequently obtain necessary supplies;
- Refer the beneficiary back to the prescribing physician as necessary for intervention beyond the supplier's scope of practice; and

F. Follow-up

In addition to Section II: Supplier Product-Specific Service Requirements, the supplier shall:

- Have access to a facility with the equipment necessary to provide follow-up services, including refitting or modification of the specific orthoses/prostheses as necessary;
- Solicit feedback from the beneficiary and prescribing physician as necessary to determine the effectiveness of the orthoses/prostheses;
- Set up follow-up appointments as necessary; and
- Provide appropriate beneficiary follow-up care consistent with the type of orthoses/prostheses or therapeutic shoe/insert provided, the beneficiary's diagnosis, specific care rendered, and recommendations.

Via email to [DMEPOS Quality Standards Public Comments@cms.hhs.gov](mailto:DMEPOS_Quality_Standards_Public_Comments@cms.hhs.gov)
Via first class mail

November 28, 2005

Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Mail Stop C5-11-24
Baltimore, Maryland 21244-1850

RE: Proposed Recommendations on Quality Standards for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Items and Services

Dear Doctor McClellan:

The American Occupational Therapy Association (AOTA) appreciates the opportunity to submit the comments below in response to the proposed "Quality Standards of Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and other items and services" ("Draft Quality Standards"), prepared by Abt Associates Inc. for the Centers for Medicare and Medicaid Services (CMS) and posted to the CMS website on September 26, 2005.

The AOTA represents more than 35,000 occupational therapy professionals, many of whom provide services to Medicare beneficiaries. Occupational therapy is a health, wellness, and rehabilitation profession working with people experiencing stroke, spinal cord injuries, brain injury, congenital conditions, developmental delay, joint replacements and surgeries, mental illness, and other conditions. Occupational therapists help people regain, develop, and build skills that are essential for independent functioning, health, and well-being in the home and community. Occupational therapy professionals have unique expertise in evaluating participation and enabling engagement in meaningful occupations (e.g., activities of daily living). Specifically, occupational therapy evaluation and treatment often is used pre or post orthopedic surgery or injury. It includes a multifaceted evaluation of a patient's range of motion, functional abilities, limitations (sensory, motor function, judgment, etc.), home and community needs, and other elements. Often a patient's occupational therapy plan of care includes the use of orthotics to help perform activities of daily living or as a preparatory tool to enable a patient to regain functional abilities and range of motion. Medicare-covered occupational therapy services include the design, fabrication, fitting, provision of, and training in the use of orthotics as part of a Medicare beneficiary's plan of care. Accordingly, occupational therapists are impacted by the draft standards developed by Abt Associates.

AOTA's comments will address several issues. First, the application of the Draft Quality Standards and accreditation requirements to occupational therapists; Second, the unnecessary duplication of safeguards for occupational therapists created by the Draft Quality Standards, Third, issues specifically related to the particular Draft Quality Standards relating to Supplier Product Specific Service Requirements for Customized Orthotics and Prosthetics ("O&P Standards") and Fourth, consistency with

CMS' proposal for fabrication and furnishing of custom orthotics and prosthetics offered during the negotiated rule making under §427 of the Benefits Improvement and Protection Act of 2000 ("BIPA") regarding Special Payment Provisions for Prosthetics and Certain Custom Fabricated Orthotics.

I. Application of the Draft Quality Standards and Accreditation Requirements to Occupational Therapists

Section 302(a) of the Medicare Modernization Act of 2003 (Pub. Law 108-173) ("MMA") establishes quality standards and accreditation requirements for the provision of DMEPOS. Section 302(a)(B) states that the Secretary of the Department of Health and Human Services may develop quality standards after consultation with representatives of relevant parties. The AOTA has reviewed the list of individuals and organizations that were consulted with respect to the Draft Quality Standards.¹ Specifically, AOTA notes that out of twenty experts consulted for all of the various supplier specific requirements, ten were representing orthotists and prosthetists according to the Draft Quality Standards. The AOTA respectfully submits that occupational therapists and other practitioners, such as physicians and physical therapists, were not consulted by Abt Associates as experts with respect to the O&P Standards, nor were adequately represented on the Program Advisory Oversight Committee (PAOC), which Abt consulted. Without the adequate consultation of occupational therapists and other practitioners, CMS has not met the statutory mandate of the MMA to develop quality standards "after consultation with representatives of relevant parties" if the Draft Quality Standards are to apply to such practitioners. *Accordingly, the lack of consultation with occupational therapists or their representatives suggests that CMS has assumed that the quality standards do not apply to occupational therapists. AOTA proposes that CMS clarify that it does not intend the quality standards to apply to occupational therapists.*

II. Quality and Accreditation Standards For Occupational Therapists Providing DMEPOS Is Unnecessary and Duplicative

AOTA supports CMS in its efforts to implement the law to develop quality standards for providers of DMEPOS to ensure that Medicare beneficiaries receive high quality items. AOTA understands that due to the lack of state licensure for DME suppliers, as well as for orthotists and prosthetists (except in nine states)², that unregulated DME suppliers with little or no relevant education or training may provide ill-fitting orthotics to Medicare beneficiaries. AOTA agrees that only licensed or appropriately trained professionals should be providing such supplies to Medicare beneficiaries.

¹ In addition to consulting with experts, Abt Associates requested advice from the Program Advisory Oversight Committee (PAOC) in completing its Draft Quality Standards. The PAOC was formed according to statute to provide advice on the development and implementation of the Competitive Acquisition Program. AOTA notes that the Quality Enhancement and Fraud Reduction provisions of Section 302(a) are separate and apart from the Provisions establishing Competitive Acquisition Programs, which are found in Section 302(b). In addition to Abt Associates failing to consult with any occupational therapy experts, neither highly qualified AOTA nominated representative was selected as a member of the PAOC.

² Those states that have granted licensure to orthotists and prosthetists have not precluded occupational therapists from designing, fabricating, fitting, furnishing, and training in orthotics and prosthetics.

A. Enrollment Status as Qualified Occupational Therapists

When considering to whom the quality standards for suppliers should apply, AOTA recommends that CMS first consider the enrollment status of the supplier. Although the terminology that is used to enroll Medicare Part B practitioners is to call them "suppliers," this term of art has a different meaning outside of the DMEPOS environment. Occupational therapists and their employers (e.g., hospitals and skilled nursing facilities (SNF)) are more appropriately viewed as providers.

An occupational therapist in private practice is required to have enrolled in Medicare and receive a provider number, separate and apart from a DME supplier number, prior to furnishing occupational therapy services to Medicare beneficiaries.³ This requirement applies equally to other practitioners, such as physicians and physical therapists.

In order for an occupational therapist to enroll in Medicare or provide services through any other provider (e.g., hospital or SNF), they must first meet the definition of "Qualified Occupational Therapists." See Social Security Act §§1861(g), 1861(p)(2). The regulations defining "Qualified Occupational Therapists" require graduation from an accredited program. Specifically, the regulations define a "Qualified Occupational Therapist" as: a person who:

- (a) is a graduate of an occupational therapy curriculum **accredited** jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or
- (b) is eligible for the National Registration examination of the American Occupational Therapy Association; or
- (c) has two years of appropriate experiences as an occupational therapist, and has achieved a satisfactory grade on a proficiency exam conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a state or seeking initial qualifications as an occupational therapist after December 31, 1977.

42 C.F.R. § 484.4 (emphasis added).

In addition, occupational therapists are professional practitioners who are licensed or otherwise regulated in every state. According to state regulations and the AOTA Code of Ethics, occupational therapists must have or obtain competency for any service they provide, whether it is specific patient treatment or the fabrication and fitting of DMEPOS. By contrast, most states do not require DME suppliers or orthotists/prosthetists to meet any requirements.

³ In the alternative, occupational therapy services may be provided by enrolled providers (i.e., skilled nursing facilities, hospitals, comprehensive outpatient rehabilitation facilities) who either employ or contract with qualified occupational therapy practitioners who meet the regulatory definition of qualified occupational therapists and qualified occupational therapy assistants.

CMS plans to update the definition of “Qualified Occupational Therapist” to conform to state law and occupational therapy certification references. AOTA’s understanding is that the updated definition under review is:

A qualified occupational therapist is a person who is licensed or who is otherwise regulated as an occupational therapist by the state in which he or she is practicing. In addition, the occupational therapist has graduated from an occupational therapy program **accredited** by the American Occupational Therapy Association’s accreditation counsel for occupational therapy education (ACOTE) and is eligible for a national entry-level certification examination recognized by the American Occupational Therapy Association. (emphasis added).

Accordingly, prior to becoming a Medicare provider of occupational therapy services, an occupational therapist must demonstrate that she has met certain quality standards as determined by each State, as well as national accreditation bodies. There are no similar requirements for DME suppliers or orthotists or prosthetists in every State.

Thus, by virtue of becoming a “Qualified Occupational Therapist” under current and proposed Medicare regulations, occupational therapists must have successfully completed an accredited educational program. *AOTA urges CMS to consider state licensure and completion of an education at an accredited educational program of occupational therapy – the same standards that CMS already relies upon as proof of qualification for providing occupational therapy services to Medicare beneficiaries - as meeting the accreditation standards under MMA section 302(a).*

B. The Breadth of Services and Supplies Furnished are Reflected in Both CPT and HCPCS

When an occupational therapist provides DMEPOS it is integral to the occupational therapy treatment plan for the patient. In fact, the design, fabrication, fitting and provision of orthotic devices are specific Medicare covered occupational therapy services.⁴ The occupational therapy services, as well as the purpose and type of orthotics provided therein, are always documented in the patient’s plan of care. When occupational therapists bill Medicare Part B for these services, they use the Current Procedural Terminology (“CPT”) codes for the services they provide. The payment that is associated with each CPT code is established based upon a variety of factors, including practice expenses such as supplies and equipment. The payment is established through an elaborate process of the American Medical Association (AMA) Relative Value Update Committee (RUC), in which CMS is an active participant. The RUC, with CMS’ input, determines that the relative value for a particular CPT code will or will not include the cost of certain supplies in the practice expense. In those situations where the supply costs are not included, such as with the serial casting CPT codes (25XXX), the physicians and practitioners are directed to report their services using both the appropriate CPT code as well as the Healthcare Common

⁴ Medicare covers occupational therapy as a covered category. As an aside, there is no subset of covered Medicare services, such as hand therapy and, in fact, hand therapy, is not recognized by Medicare as a separately reimbursable service.

Procedure Coding System (HCPCS) code that encompasses the supply that has been excluded from the practice expense. Consequently, there is a vast range of HCPCS codes that physicians and occupational therapists report in conjunction with the CPT codes. If one only considers the HCPCS codes that physicians, therapists and other enrolled practitioners report, then the full range of services that they provide to Medicare beneficiaries cannot be appreciated.

To make a determination of whether an individual or entity should be required to meet the supplier standards based solely on the HCPCS codes that they report fails to consider the totality of their role in the Medicare program. Therefore, we recommend that CMS first consider all of the ways that the individual or entity participates in the Medicare program. This would include whether they are independently enrolled in Medicare Part B or whether their services are provided through enrolled providers (e.g., SNF, hospitals, etc.) and the entire scope of how they interact with beneficiaries, including whether they provide services reported through CPT. Those individuals and entities who also are enrolled as independent providers or bill their services through enrolled providers should be treated differently than those who merely provide beneficiaries with a product.

Simply because a Durable Medical Equipment Regional Carrier (DMERC) must be billed because a HCPCS number is utilized, which in turn requires a separate DMERC supplier number, should not change the fact that practitioners are otherwise separately enrolled in Medicare and interact with Medicare beneficiaries in a completely different way than pure DMEPOS suppliers. In fact, CMS has created specialty code 67⁵ for use by an occupational therapist currently enrolled in Medicare when filing a DMERC supplier application, thus acknowledging that the DMEPOS items and supplies provided will be integral to the occupational therapy services and otherwise part of the occupational therapist's plan of care for the Medicare beneficiary. *AOTA submits that CMS, through the National Supplier Clearinghouse, has the data it needs to distinguish physicians, occupational therapists, physical therapists, and other enrolled practitioners from those who solely bill a DMERC for supplies. AOTA suggests that the use of HCPCS codes to determine who should be subject to the quality standards is inappropriate and inadequate.*

C. Relevant Precedent Exists to Treat Occupational Therapists Distinctly from DMEPOS Suppliers

In an analogous situation, CMS has taken the position that physicians providing diagnostic testing to their own patients could bill for such diagnostic services under their group practice number and would not need to also enroll as an independent diagnostic testing facility ("IDTF"). See 42 C.F.R. § 410.33; CMS Program Integrity Manual Pub. 108 § 5.1. This Manual provision provides that a physician group will not need to enroll as an IDTF if it meets certain criteria demonstrating that the diagnostics tests it performs are part and parcel of the other medical services it is providing to the patients its routinely treats. To avoid IDTF enrollment, a physician group must show the following:

⁵ The enrollment of an occupational therapist using specialty code 67 as a DMEPOS supplier is not intended to permit the occupational therapist to hold him or herself out to the general public as a DME supplier for items or services unrelated to an occupational therapy plan of care.

- 1) The entity providing the test is a physician practice that is owned, directly or indirectly, by one or more physicians or by a hospital;
- 2) The entity primarily bills for physician services (e.g., evaluation and management (E &M) codes) and not for diagnostic tests;
- 3) The entity furnishes diagnostic tests primarily to patients whose medical conditions are being treated or managed on an ongoing basis by one or more physicians in the practice; and
- 4) The diagnostic tests are performed and interpreted at the same location where the practice physicians also treat patients for their medical conditions.

Similarly, occupational therapists providing orthotics may do so as independent practitioners through practices they own or through another provider, such as a hospital or skilled nursing facility. An independent occupational therapy practice (otherwise referred to as an occupational therapist in private practice OTPP or OTPP group) overwhelmingly bills for occupational therapy services, and not for DMEPOS. As explained above, the occupational therapist furnishes the orthotics or other DMEPOS such as canes and walkers to patients whose medical conditions are being managed by the occupational therapist through an occupational therapy plan of care. The orthotics or other DMEPOS will be furnished at the same location where the occupational therapy services are provided and are an integral part of these occupational therapy services. *Based on the above, the precedence exists for CMS to treat occupational therapists that provide DMEPOS tangential to occupational therapy services differently than other DMEPOS suppliers and to not require occupational therapists to meet the same requirements as DMEPOS suppliers.*

D. Sufficient Safeguards Exist

Finally, AOTA urges CMS to consider that the educational and state regulatory requirements for Medicare enrolled occupational therapists provides more than adequate safeguards to protect Medicare beneficiaries from receiving substandard orthotics from occupational therapists. Accordingly, separate DMEPOS qualifications standards are not necessary, would be duplicative and could be contradictory and unnecessarily costly. In addition, CMS has not designated which accreditation bodies it will designate or what separate requirements they will place on DMEPOS suppliers. It is possible that an accreditation body could place requirements on occupational therapists that are contradictory to those regulatory requirements already required by CMS. *Consequently, AOTA urges CMS to deem occupational therapists as already meeting the supplier quality standards by virtue of their regulatory requirements as qualified occupational therapy practitioners.*

III. The Particular Draft Quality Standards Relating to Supplier Product-Specific Service Requirements for Customized Orthotics and Prosthetics Are Not Necessary to be Applied to Occupational Therapists and Other Medicare-Recognized Practitioners

A. The Standards are Duplicative for Occupational Therapy Practitioners

As stated above, AOTA recognizes that the Draft Quality Standards may be meaningful for orthotists and prosthetists and other non-licensed DME suppliers that provide orthotics and prosthetics to Medicare beneficiaries in order to ensure quality. Establishing such standards will prevent unlicensed and unscrupulous DME providers who have no licensure or relevant education and training from providing substandard items or services to Medicare beneficiaries. Since only nine states regulate orthotists and prosthetists, AOTA agrees with the recommendation contained in the O&P Standards that CMS should require individuals in states where licensure is not required to be certified by ABC or BOC.

However, the O&P Standards within the Draft Quality Standards were clearly developed by the orthotists and prosthetists and reflect their large presence as expert consultants to Abt Associates. As stated above, the Draft Quality Standards, and particularly, these O&P Standards are not necessary for occupational therapists. Similarly, they are not necessary for physicians or other practitioners. Two statements in the general description of the O&P Standards particularly highlight the duplicative nature of the O&P Standards for occupational therapists.

Specifically, the O&P Standards state that the provision of orthotics and prosthetics “involves knowledge and understanding of human anatomy and beneficiary factors such as height, weight, level of physical activity, overall health, comorbidities and the specific diagnosis to make each fitting unique to that beneficiary.” See Draft Quality Standards pg. 76. In addition, the O&P Standards state that the “suppliers should be trained in a broad range of treatment options to ensure that the item prescribed is optimal for the beneficiary’s condition.”

Occupational therapists, by virtue of their education and training through an accredited educational program and their overall treatment of the patient already are in the best position to understand human anatomy, beneficiary factors, and specific patient diagnoses and are able to uniquely fit each patient with the orthotic necessary for the continuation of the patient’s care. Because occupational therapists provide not just an orthotic, but develop an entire occupational therapy plan of care specific to a particular patient and their condition(s), that plan of care requires the knowledge and understanding of human anatomy, beneficiary factors, specific diagnosis, and the ability to make each fitting unique to that beneficiary. Furthermore, since the occupational therapist is intimately involved in the beneficiary’s plan of care, the occupational therapist is in the best position to know the patient’s broad range of treatment options and to ensure that the item prescribed is optimal for the beneficiary’s condition.

Occupational therapists providing care to Medicare patients also are already required to perform the services required in the Inspection and Preparation provision, including the requirements for Intake and Service Plan; the Training/Instructions to Beneficiary and Caregiver(s); and Follow-Up, by virtue of creating an occupational therapy treatment plan unique to each Medicare beneficiary for whom the occupational therapist provides occupational therapy, including the furnishing of DMEPOS. The patient’s treatment plan is documented in the patient’s plan of care, including progress notes, as required by Medicare. By urging CMS to not apply the Draft Quality Standards to occupational therapists and other practitioners, AOTA is not suggesting that occupational therapists would therefore have the ability to provide less than outstanding care to Medicare beneficiaries. ***AOTA requests that CMS articulate that occupational therapists already meet rigorous standards by virtue of the standards they meet to provide covered services as Medicare enrolled Qualified Occupational Therapists. Requiring compliance with***

these separate Draft Quality Standards, including the specific draft O&P Standards, would be duplicative and unnecessary.

B. Occupational Therapists Are Qualified to Furnish Custom Fabricated Orthotics

AOTA is particularly troubled by the statement in the opening section of the O&P Standards that states that customized orthotics and prosthetics “require the qualification and expertise of certified or licensed orthotists and prosthetists, and/or staff certified by the American Board for Certification and orthotists and prosthetics (ABC) or the Board for Orthotists/Prosthetists certification (BOC).” *Id.*

AOTA strongly disagrees with this statement. Occupational therapists are qualified to design, fit and fabricate customized orthotics. In fact, CMS has specifically acknowledged that occupational therapists and other practitioners are qualified to provide custom-fabricated orthotics and prosthetics and has specifically devised a methodology to allow occupational therapists and other practitioners to be recognized as providers of customized orthotics in the nine states where there is licensure for orthotists and prosthetists. *See* CMS Change Request 3959 “Full Replacement of Change Request 3607 Payment Edits in Applicable States for DMEPOS Suppliers of Prosthetics and Certain Custom-Fabricated Orthotics.” (August 19, 2005) (In those nine states that have indicated that provision of prosthetics and orthotics must be made by licensed/certified orthotist or prosthetist, Medicare payment may only be made for prosthetics and certain custom-fabricated orthotics when furnished by physicians, pedorthists, physical therapists, **occupational therapists**, orthotics personnel and prosthetics personnel) (emphasis added).

In addition, during the negotiated rulemaking under Section 427 of BIPA, CMS agreed to specifically include in the text of the notice of proposed rulemaking that occupational therapists are qualified to furnish custom fabricated orthotics. CMS also stated its intent that qualified occupational therapists who fabricate definitive prostheses will have additional education and training. *See* CMS Statement of Intent and Final Compromise Document (attached). It is imperative that all of the Draft Quality Standards, including the O&P Standards, be consistent with current Medicare policy. *Consequently, AOTA respectfully urges CMS to remove from the final standards that any language implying that only orthotists or prosthetists are qualified to fabricate, fit and furnish orthotics and prosthetics.*

IV. Any New Quality Standards Must Be Consistent with CMS’ Proposal for Fabrication and Furnishing of Custom Orthotics and Prosthetics Offered During the Negotiated Rulemaking Under Section 427 of the Benefits Improvement and Protection Act of 2000 (“BIPA”)

The impetus for Section 427 of BIPA is the same as the quality and accreditation standards requirement found in section 302(a) of the MMA; Congress’ goal has been to prevent unscrupulous individuals having no relevant education or training and no licensure requirements from providing DMEPOS to Medicare beneficiaries. Under Section 427 of BIPA, occupational therapists were defined as “qualified practitioners” for purposes of furnishing and fabricating orthotics. During the negotiation, CMS agreed that occupational therapists are separate and apart from qualified suppliers, as reflected in the statutory language defining them as “qualified occupational therapists.” CMS applied the term “qualified suppliers” to DMEPOS suppliers and other entities which fabricated or furnished certain custom orthotics

or prosthetics, but who were not otherwise qualified practitioners (e.g., orthotists, prosthetists and manufacturers). In order for these others to be a "qualified supplier" BOC or ABC certification was required. During the Negotiated Rulemaking, CMS acknowledged that occupational therapists only use their DMEPOS supplier number in conjunction with their occupational therapy practice. ***Accordingly, requiring the O&P Standards to apply to qualified practitioners such as occupational therapists would be inconsistent with Section 427 of BIPA.***

Finally, in the O&P Standards, Abt defined terms such as custom-fabricated in its recommendations. These terms are required to be defined by regulation pursuant to Section 427 of BIPA. In the absence of such final regulations, the definitions of the term custom-fabricated should be the definition that CMS offered in its compromise document at the conclusion of the negotiated rulemaking. ***CMS Should Not Adopt the Definitions contained in the O&P Standards, including "Custom Fabricated," "Custom Fitted High," and "Custom Fitted Low" since they are inconsistent with either CMS' compromise document or current policies.***

V. Conclusion

AOTA appreciates the opportunity to submit these comments on CMS' proposed quality standards for suppliers of DMEPOS. AOTA urges CMS to consider the impact of the Draft Quality Standards and accreditation requirements on occupational therapists as well as physicians, physical therapists, and other enrolled practitioners. AOTA strongly recommends that CMS specifically deem occupational therapists as already meeting the supplier quality standards by virtue of meeting the rigorous regulatory requirements required of qualified occupational therapy practitioners.

AOTA requests that due consideration be given to these comments. Thank you, again, for the opportunity to comment on the Draft Quality Standards. We look forward to a continuing dialogue with CMS on these issues.

Sincerely yours,

Leslie Stein Lloyd, Esq.
Director
Reimbursement and Regulatory Policy Department

Attachment: CMS Statement of Intent and Final Compromise Document, Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom Fabricated Orthotics, Dated July 14, 2003

cc: Herb Kuhn
Carol Blackford
Linda Smith
Pam West