

Via online submission

November 14, 2008

Sandra Bastinelli, Director
Division of Medical Review & Education
Program Integrity Group, Office of Financial Management
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: American Occupational Therapy Association (AOTA) Statement on Occupational Therapists' Education in the Provision of Orthotics

Dear Ms. Bastinelli:

AOTA appreciates the opportunity to highlight the qualifications and education of licensed occupational therapists to furnish, fabricate and train in the use of certain custom fabricated orthotics and prosthetics for beneficiaries under the Medicare Program. Following are specific points upon which we respectfully request that the Centers for Medicare and Medicaid Services (CMS) base any future regulation required pursuant to Section 427 of the Benefits Improvement and Protection Act of 2000 ("BIPA").

As you know, AOTA was represented at the table during the 2003 Negotiated Rulemaking to implement the requirements of BIPA and the term "qualified occupational therapist" was discussed in detail. Ultimately, AOTA's interpretation of "qualified occupational therapist" was incorporated into the CMS Draft Compromise Agreement set forth to the rulemaking body for agreement and signing.

Under Section 427 of BIPA, "qualified occupational therapists" are listed as practitioners for purposes of furnishing and fabricating certain custom fabricated orthotics and prosthetics. The term "qualified occupational therapist" is elsewhere established in the Medicare law in Sections 1861(g) and 1861(p)(2) of the Social Security Act ("SSA"). CMS exercised its rulemaking authority and interpreted, through regulations, the term "qualified," consistent with Congressional intent. This definition is found at 42 C.F.R. § 484.4 and ensures that a qualified occupational therapist graduates from an educational program that meet ACOTE's¹ stringent accreditation standards, passes a rigorous certification examination, and is licensed or otherwise regulated by the State in which s/he practices.

In fact, the National Board for Certification in Occupational Therapy (NBCOT) has recently completed two practice analysis studies, one for the Occupational Therapist (OT) and one for the Occupational Therapy Assistant (OTA). The results from these studies have been used to revise and

¹ ACOTE (the Accreditation Council for Occupational Therapy Education) is accredited by the Council for Higher Education Accreditation (CHEA) and the United States Department of Education (USDE).

update the examination test blueprints for the OT and OTA examinations beginning January 2009 using the information from the practice analyses studies to base the tests upon current standards of practice in the field. Practice related to the provision of orthotics and splinting is noted in several places in the occupational therapist practice analysis and thus will likely be covered in the certification exam. For example, with respect to the practice task *“use critical reasoning to select and implement interventions and approaches consistent with general medical, neurological, and musculoskeletal conditions and client needs in order to achieve functional outcomes within areas of occupation”*, the NBCOT blueprint notes that occupational therapists demonstrate knowledge of *“methods for selecting, designing, fabricating splints and/or modifying splints and orthotic devices consistent with general medical, neurological, and/or musculoskeletal conditions.”*²

The term “qualified occupational therapist” and the regulatory definition are used consistently throughout the Medicare manuals and other program issuances. Importantly, Medicare specifically includes the fabrication of orthotics as a Medicare-covered occupational therapy service. Several Medicare Manuals explicitly provide that Medicare covered occupational therapy services include the “design, fabricating, and fitting of orthotic and self-help devices.” If the requisite qualifications for a qualified occupational therapist as set forth in Section 484.4 are not satisfied, an occupational therapist has not met the appropriate qualifications to furnish any Medicare covered occupational therapy services. Accordingly, the definition of “qualified occupational therapist” found in Section 484.4 already applies to the fabrication and furnishing of orthotics and there is no indication that this provision would or should be changed by Section 427 of BIPA. Stated another way, neither the plain language of Section 427 of BIPA nor the Congressional Record, which contains language about Congress’ intent in passing this law, seeks to define the term any differently from the definition of “qualified occupational therapist” already set forth in Section 1861(g) of the SSA, which already applies to the fabrication of orthotics by occupational therapists.

Notably, in a letter dated June 5, 2003 from W. J. “Billy” Tauzin, House Energy and Commerce Committee Chairman, to Thomas A. Scully, CMS Administrator, Chairman Tauzin specifically addresses the issue of Congress’ intent with respect to the definition of “qualified occupational therapists.” That letter states:

[i]t was the intent of the Committees to include any licensed or otherwise regulated physical therapist or occupational therapist within the definition of “qualified practitioner” for the purpose of providing certain custom-fabricated orthotics and prosthetics. Under the statutory language, no further certification or qualification would be necessary for such an individual to provide this service.

Clearly, as evidenced by Chairman Tauzin’s letter, Congress intended the term “qualified occupational therapist” to be interpreted in a manner consistent with prior statutory provisions, regulations and manual provisions and did not intend to require any additional certification or qualifications for occupational therapists. If Congress had intended the word “qualified” to require specialized training in addition to licensure or desired CMS to interpret “qualified” in a manner

² For other examples of occupational therapists’ education and knowledge in the area of orthotics, see the NBCOT Executive Summary of the Practice Analysis Study for the Occupational Therapist Registered OTR at: http://www.nbcot.org/webarticles/articlefiles/PA_OTR_DTKS_2008.pdf

contrary to the current regulations and manuals, Congress would have clearly expressed that intent either by providing an alternative definition in the statute or indicating such a radical departure in the legislative history.

As you know, a Medicare provider number is required before any occupational therapy service can be furnished. In addition, in most settings, a DMEPOS supplier number also is required in order to bill for orthotics and prosthetics devices. Occupational therapists generally furnish and fabricate orthotics and prosthetics in the context of a total treatment program, integral to ongoing patient care, and often with frequent modifications to reflect changes in clinical status. Thus, occupational therapists working with orthotics and prosthetics bill both CPT codes for the therapy service intervention, as well as HCPCS codes for the device itself.

Occupational therapists have the requisite training, credentialing and educational experience to appropriately furnish and fabricate orthotics and prosthetics. Occupational therapists receive education and training specifically in the fabrication of orthotics and training in the use of prosthetics through coursework, laboratory training in practical applications, and fieldwork (clinical internships). In addition to specific splinting coursework, occupational therapy curricula include a solid medical foundation.³ AOTA provides guidance to occupational therapists on specific continuing education requirements that should be maintained to assure competency in various specialties. Entry level for occupational therapists is currently a Master's degree.

In contrast, the Negotiated Rulemaking exposed the fact that a large segment of the legitimate orthotic and prosthetic workforce is comprised of individuals with as little education as a general education degree (GED) and a few years of on the job training prior to providing orthotics and prosthetics. This industry also permits such individuals to work with Medicare beneficiaries with little or no supervision. Further, the orthotic and prosthetic industry disclosed that often the orthotist or prosthetist does not personally fabricate the device. Rather, a technician who may have even less education and training fabricates it.

Occupational therapy is a regulated profession and there are numerous safeguards in place to protect and provide recourse for the public, including state licensure, Medicare standards for providers and suppliers, and the profession's ethical and competency requirements. The profession of occupational therapy is regulated in all fifty states. Occupational therapy practitioners additionally are bound by a code of ethics that requires them to only render care where they are appropriately trained. See AOTA Occupational Therapy Code of Ethics (2005) (Principle 2, "Occupational therapy personnel shall take measures to ensure a recipient's safety and avoid imposing or inflicting harm (NonMaleficence);" Principle 4, "Occupational therapy personnel shall achieve and continually maintain high standards of competence;" Principle 4C, "Occupational therapy personnel shall take responsibility for maintaining and documenting competence in practice, education, and research by participating in professional development and educational activities...").

³ Clinical courses include: biomechanics, disease process, physiology, neuroanatomy, human anatomy and physiology with lab, etiology of disease process/ pathology, neuroscience, kinesiology/ dynamics of human motion, movement and activity analysis, clinical physiology, physical disabilities, orthopedics, motor assessment and treatment, occupational therapy for musculoskeletal conditions, occupational performance, occupational adaptation, neurophysiology, intervention techniques, evaluation and intervention foundations, neuro-rehabilitation, clinical neurology, neuro-behavioral science, rehabilitation theory and practice, and physical agent modalities.

According to Medicare supervision rules, occupational therapists must make the orthotic or prosthetic device. Occupational therapists cannot delegate these duties to technicians or aides. The rigorous occupational therapy curriculum, which is grounded in anatomy and kinesiology and has specific courses on furnishing and fabricating certain custom fabricated orthotics and prosthetics, prepares occupational therapists to provide these items and related services. It is illogical to say that individuals with far less education are more qualified.

The only way to ensure that Medicare beneficiaries continue to have access to medically necessary and appropriate orthotic and prosthetic services is to reimburse for occupational therapy intervention as currently provided for under the law. It is our sincere hope that in the forthcoming regulation required by Section 427 of BIPA, CMS will continue to define “qualified occupational therapists” using the same definition stated in its regulations at 42 C.F.R. § 484.4. This definition is amply supported by existing law, historical precedent and sound clinical practice and is in the best interest of Medicare beneficiaries. This definition was fully reviewed, vetted, and updated by Medicare program staff working closely with AOTA during the notice and comment process for the 2008 Medicare Physician Fee schedule final rule issuance in November 2008.

Once again, we would like to thank you and your staff for the time and effort put forth in this process. In addition, we would like to thank you for working closely with AOTA and other licensed health professionals to obtain appropriate exemptions from the DMEPOS competitive bidding program and later from the DMEPOS accreditation requirements. Similarly, our arguments regarding occupational therapy licensure and education as safeguards to assure quality provision of orthotics as part of a patient’s ongoing treatment plan also apply with respect to the regulation required by Section 427 of BIPA. Should you have any questions or comments, please contact me at (301) 652-2682 ext. 2863 or via email at ssandhu@aota.org.

Sincerely,

A handwritten signature in blue ink that reads "Sharmila Sandhu".

Sharmila Sandhu, Esq.
Regulatory Counsel