

Don Berwick, M.D., M.P.P. Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-9982-P, CMS-9982-NC P.O. Box 8016 Baltimore, MD 21244-1850

October 11, 2011

Re: Recommendation for a Separate Definition of "Orthotics and Prosthetics" within Summary of Benefits and Uniform Glossary Material [CMS-9982-P], [CMS-9982-NC]

Dear Dr. Berwick:

The Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition appreciates the opportunity to comment on the proposed rules regarding the Summary of Benefits and Coverage and the Uniform Glossary and the related Templates, Instructions, and Related Materials, published on August 22, 2011 (76 Fed. Reg. 52,442; 76 Fed. Reg. 52,475). The ITEM Coalition is a consumer-led coalition of disability-related organizations with the goal of improving access to assistive devices, technologies and related services for individuals with disabilities of all ages. We believe individuals with disabilities and chronic conditions should have access to specialized assistive devices to ensure quality care and the greatest function and independence possible for the individual.

In response to the proposed definitions of medical terminology subject to Section 1001 of the Patient Protection and Affordable Care Act (PPACA), Pub. L. 111-148, the ITEM Coalition writes to reinforce the need for a separate definition for the term, "orthotics and prosthetics" (O&P) from the term "durable medical equipment" (DME). As the Secretary of Health and Human Services implements the essential health benefits provisions of the Patient Protection and Affordable Care Act ("ACA" or "Affordable Care Act")ⁱ, it is important that consumers understand basic benefits such as orthotics and prosthetics ("O&P").

There are more than 1,700,000 people in the United States living with limb loss.ⁱⁱ Every year, more than 130,000 people in the United States undergo amputation of a limb.ⁱⁱⁱ A comparable number of Americans experience strokes, spina bifida, cerebral palsy or other impairments which are chronic, recurring, or lifetime in nature and require the use of orthoses. In addition, U.S. military personnel serving in Iraq and Afghanistan and around the world have sustained traumatic injuries resulting in amputation and musculoskeletal injuries resulting in the need for prosthetic and orthotic care.

Appropriate O&P care can mean the difference between a life of disability and dependency and a life of full function, self-sufficiency, and independence. The ACA calls on the HHS Secretary to define the term "durable medical equipment," among other medical terms. We recommend CMS should exercise its discretion and define "orthotics and prosthetics" to inform private health insurance consumers of the separate definitions of DME and O&P.

Legislative History

It is clear from the legislative history of PPACA that both sets of benefits, DME and O&P, were intended to be covered in the essential benefits package and we, therefore, believe that a separate definition of "orthotics and prosthetics" for purposes of comparing medical benefits across different health plans is appropriate. To define O&P care under the DME benefit would be inappropriate as these are two entirely different benefits and would result in unintended negative consequences for patients that need artificial limbs and orthopedic braces.

While the majority of DME items are largely product or commodity-based, orthotics and prosthetics entail a high level of clinical service by educated and trained practitioners who design, fabricate and fit custom orthoses and prostheses. Categorizing O&P care under the definition as DME applies a spectrum of rules intended for DME to a field that is very different in critical respects and causes major problems in appropriately regulating the provision of orthotic and prosthetic care. This is the reason why Medicare defines DME separately from O&P and uses the term "DMEPOS," (durable medical equipment, prosthetics, orthotics, and supplies).

The Congressional Record lays the foundation for CMS to use its discretion to include a separate definition in the list of medical terms for "Orthotics and Prosthetics." House Education and Labor Committee Chairman George Miller explicitly stated that Congress intended to include prosthetics and orthotics in the new health care law's essential benefits package under the term "rehabilitation and habilitation services and devices," but also intended to define prosthetics and orthotics separately from DME in the definitions section of the Affordable Care Act. "It is my expectation 'prosthetics, orthotics, and related supplies' will be defined separately from 'durable medical equipment," Miller stated. (Congressional Record, H-1882, March 21, 2010).

Recommended Definition of the Term "Orthotics and Prosthetics":

For purposes of defining medical terms under Section 1001 of PPACA, the ITEM Coalition recommends that CMS adopts the following definition of the term "Orthotics and Prosthetics" so that private health plan consumers can understand and easily compare these benefits across different health plans.

"Prosthetics" include artificial legs, arms, and eyes and "orthotics" include leg, arm, back and neck braces that are ordered by a health care provider, including replacements due to wear, damage, or a change in the person's condition.

Thank you for your consideration of our views on these important issues. Please feel free to contact Peter Thomas, ITEM Coalition Counsel, at 202.466.6550 or Peter.Thomas@ppsv.com.

Sincerely,

American Association of People with Disabilities
American Congress of Rehabilitation Medicine
American Foundation for the Blind
American Medical Rehabilitation Providers Association
American Therapeutic Recreation Association
Amputee Coalition
Association of Assistive Technology Act Program
Association of University Centers on Disabilities
Blinded Veterans Association
Christopher & Dana Reeve Foundation
Easter Seals
National Multiple Sclerosis Society
Paralyzed Veterans of America
Spina Bifida Association
The Arc of the United States

United Spinal Association

ⁱ Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 129 (2010).

ii Insurance Fairness for Amputees Act of 2011, S. 773, 112th Cong. (2011).

iii Id.