



**American Orthotic &
Prosthetic Association**

October 17, 2011

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-9982-P, CMS-9982-NC
P.O. Box 8016
Baltimore, MD 21244-1850

Dear Sirs:

We are writing to provide comments to the proposed rules (CMS-9982-P) regarding the Summary of Benefits and Coverage and the Uniform Glossary and the corresponding Templates, Instructions, and Related Materials (CMS-9982-NC) under the Public Health Service Act that was published in the August 22, 2011 Federal Register. 76 Fed. Reg. 52,442; 76 Fed. Reg. 52,475. The American Orthotic & Prosthetic Association (AOPA) is the largest national orthotic and prosthetic trade association with a membership of approximately 2000 distinct locations, nationwide, that draw from all segments of the field. These include patient care facilities, manufacturers and distributors of prostheses, orthoses and related products, and educational and research institutions.

We offer the following comments in the hope that the final regulations will take into account the need for a separate and distinct definition of Orthotics and Prosthetics (O & P) within the Health-coverage-related terms and medical terms section of the Uniform Glossary.

The Patient Protection and Affordable Care Act (PPACA), P.L. 111-148, requires that the term DME, along with certain other terms, be defined by the Secretary of the Department of Health and Human Services (HHS). Although O & P is not specifically stated among terms to be defined under PPACA, we believe, as have selected members of Congress, that the need for such a distinct definition is implied, and we recognize that it is within HHS' discretion to define additional important terms. As a result, we urge the Secretary of HHS to clearly define the term O & P. There are two critical reasons why separately defining the term O & P is necessary.

First, the legislative history supports that O & P benefits were intended to be covered under the Essential Health Benefits Package and separately defined from DME.

The House bill was very clear, enumerating eleven benefits categories, including orthotics and prosthetics by name. The Senate bill, while less clear, still references

rehabilitative and habilitative services and devices. Additionally, the legislative history supports the interpretation that Congress indeed did intend to assure that these needed orthotics and prosthetics would be provided for in the essential health benefits package.

Here is what the Chairman of the House Committee on Education and Labor, Rep. George Miller (D-CA) said:

“I am pleased that the essential benefits in the Patient Protection and Affordable Care Act include rehabilitative and habilitative services and devices, as these benefits are of particular importance to people with disabilities and chronic conditions...The term “rehabilitative and habilitative devices” includes durable medical equipment, prosthetics, orthotics, and related supplies. It is my understanding that the Patient Protection and Affordable Care Act requires the Secretary of Health and Human Services to develop, through regulation, standard definitions of many terms for purposes of comparing benefit categories from one private health plan to another. **It is my expectation “prosthetics, orthotics and related supplies” will be defined separately from “durable medical equipment.”**”

Congressional Record, H-1882, March 21, 2010 (emphasis added).

Toward this same end, here is an excerpt from Rep. Rob Andrews letter, dated May 14, 2010, to Secretary Sebelius on this topic:

“I am writing to urge that in developing regulations and implementing provisions of the Patient Protection and Affordable Care Act (PPACA) that you ensure protections for those who need prosthetics and custom orthotics and related services. This would include making clear that the term “rehabilitative and habilitative services and devices” in Section 1302 of the new law includes coverage of orthotics and prosthetics in the essential benefit package and that insurance policies can no longer impose arbitrary limits on coverage. These services and devices are critical for those who have lost a limb or have sustained significant limb impairment and need orthotics to assist in mobility.”

Second, since the legislative history supports inclusion of O & P coverage, it is fundamental that O & P (a health-coverage-related term) is clearly defined for consumers.

As part of this process the Secretary of HHS has discretion to include additional terms that are important to define. Specifically, defining the term O & P is needed so that, “individuals and employers may compare and understand the terms of coverage and medical benefits (including any exceptions to those benefits), as specified in the guidance.” Proposed language for 45 CFR §147.200(a)(5)(c)(2)(ii).

When considering how to define O & P it is necessary to define O & P separately from DME as the two categories cover different benefits and to inappropriately group the categories would result in inadvertent results that negatively impact patients. The provision of orthotics and prosthetics requires clinical care by specially educated and/or trained practitioners who utilize those skills to design, fabricate and fit custom orthoses and prostheses. Meanwhile, DME refers mainly to commodity-based equipment, such as wheelchairs (manual and electric), walkers, scooters, canes, crutches and home

oxygen therapy. Receiving a standard wheelchair from a supplier is much different from receiving a custom-fit orthotic brace molded specifically for the patient by a skilled provider. CMS has already recognized some of the differences between O&P and DME in its quality and supplier standards. CMS also defines DME separately and uses the term DMEPOS to refer to Durable Medical Equipment, Prosthetics, Orthotics and Supplies, which makes it clear that the term DME in of itself does not include O & P. Given DME and O & P categories have different characteristics; rules applicable to each category are structured to address those unique characteristics. If O & P were included under the DME definition and subject to DME-based rules, there would be problems and difficulties as a result of applying those rules that were formulated to address DME specific concerns rather than O & P specific concerns.

Consequently, we urge CMS to include a definition of O & P, separate and distinct from DME, to account for the differences in benefits and to make comparing medical benefits more understandable for “the average plan enrollee.” We are including a recommended proposed definition for O & P as follows:

Proposed definition

“Prosthetics” include artificial legs, arms, and eyes, and “orthotics” includes 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 patient’s condition.

AOPA appreciates the opportunity to provide comments on these provisions and would be happy to provide any additional information that might be helpful to finalizing these regulations. If you have any questions or need any additional information, please contact Catherine Graf, Director of Regulatory Affairs, at 571 431-0807 or cgraf@aopanet.org.

Sincerely,



Thomas F. Fise, JD
Executive Director