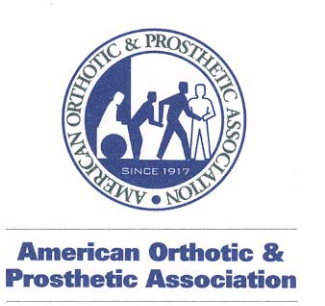


December 22, 2014

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-9944P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted electronically via www.regulations.gov (CMS-9944-P)

Re: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016

Dear Sir/Madam:

We are writing to provide comments on CMS-9944-P, the "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016" proposed rule. This proposed rule was published in the Federal Register on November 26, 2014 Federal Register.

The American Orthotic & Prosthetic Association (AOPA), founded in 1917, is the largest national orthotic and prosthetic trade association with a membership that draws from all segments of the field of artificial limbs and customized bracing for the benefit of patients who have experienced limb loss, or limb impairment resulting from a trauma, chronic disease or health condition. These include patient care facilities, manufacturers and distributors of prostheses, orthoses and related products, and educational and research institutions.

AOPA's comments relative to this proposed rule will be limited to those that address Essential Health Benefits, specifically the provisions of the proposed rule that address the adoption of a uniform definition of the term "habilitative services" as it relates to the provision of essential health benefits through benchmark plans designated by individual states.

Establishment of a Uniform Definition of Habilitative Services

AOPA supports the provision in the proposed rule to establish a uniform definition of habilitative services to address concerns that the existing regulations have, in some instances, resulted in the lack of comprehensive coverage of habilitative services through existing state benchmark plans. AOPA agrees that the establishment of a uniform definition of habilitative services will create better consistency among benchmark plans to provide full coverage for

habilitative services which were clearly identified as one of the ten benefit categories that were considered to be essential health benefits under the original statute. AOPA does have some concern regarding the definition of habilitative services that has been suggested as part of the proposed rule, and we also are concerned that there does not seem to be a parallel concern for a concerted effort to better define rehabilitative services.

The uniform definition of habilitative services in the provision of the proposed rule is taken from the *Glossary of Health Coverage and Medical Terms* which defines habilitative services as "health care services that help a person keep, learn, or improve skills and functioning for daily living. Examples include therapy for a child who is not walking or talking at the expected age. These services may include physical and occupational therapy, speech-language pathology and other services for people with disabilities in a variety of inpatient and/or outpatient settings."

While the proposed definition discusses various therapies that are considered as habilitative services, there is no specific mention of comprehensive orthotic and prosthetic care that provides patients the opportunity to perform activities of daily living that they would not otherwise be able to perform. AOPA believes, for example, that prosthetic limbs for patients who experience congenital limb deficiency and orthoses that support weakened or deformed joints or limbs as a result of conditions such as cerebral palsy, birth injuries, or congenital deficiencies should also be included within the uniform definition of habilitative services.

As recent history has shown, the lack of a uniform definition of habilitative services has led to a deficiency in coverage under several state benchmark plans. The specific inclusion of comprehensive orthotic and prosthetic care within the proposed definition of rehabilitative and/or habilitative services will ensure that all patients who require access to these important services will have it.

Delegation of Excessive Authority to the States Regarding Essential Health Benefits

AOPA would like to take the opportunity to once again express its concern regarding the decision of the Department of Health and Human Services to delegate excessive authority regarding coverage of essential health benefits to the states, through creating the concept of benchmark plans. This was clearly not the original intent of the Patient Protection and Affordable Care Act (PPACA) which was enacted with the purpose of creating consistency in health care coverage on a national level.

Many members of Congress, including the then Chairs of the six House Committees and sub-committees that had jurisdiction at the time the PPACA was implemented articulated in a letter to top officials of HHS and CMS that is was clearly Congress' intent that HHS would establish a national policy on what are and are not "essential health benefits." This setting of a national policy would result in an immense value of having one well-understood national policy, and it would avoid the current situation where true portability of health coverage, one of the prime objectives of PPACA, can be readily averted when a patient relocates from a state with one defining list of essential health benefits to another state that has adopted a much less robust iteration of essential health benefits. These members were troubled with the approach initially

proposed in the Dec. 16, 2011 EHB bulletin, where HHS errantly (and we believe the Chairs of all six authorizing House Committees and Subcommittee are in a dramatically strong position to opine that this step was indeed in error) passed a substantial component of the power to determine Essential Health Benefits to the states, which created state-by-state differences in what is an essential health benefit.

In a letter to Secretary Sebelius, dated Feb. 6, 2012, key committee members (Rep. Waxman, Rep. Levin, Rep. George Miller, Rep. Pallone, Jr., Rep. Stark, Rep. Andrews and Rep. Dingell) expressed their concerns regarding the delegation of EHB to the states. The members stated that:

> "When creating the EHB package, we intended this to be a federal decision. We had not anticipated your decision to delegate the definition of the EHB package to states. While we understand the goal of balancing comprehensiveness and affordability, and ensuring an appropriate role for state input, we would reiterate that one of the primary goals of the Affordable Care Act was to create a consistent and comprehensive level of coverage for people across the country. Without very careful protections, we have serious concerns about delegating the decision for EHB to the States and providing even further discretion to insurers."

Part of the members' concern that "all stakeholders should have the opportunity to understand and comment on what an actual EHB package may be in a state," mirrors AOPA's concerns regarding the nebulous nature of what actual benefits are covered for each state as essential health benefits. This lack of clarity continues to undercut the intent of PPACA and makes it very challenging for stakeholders to fully understand and comment on what the specific EHB benefits are that will be covered within their state's EHB package. AOPA encourages HHS to adopt a stronger national component to its establishment of Essential Health Benefits.

A clear example of the negative impact of the HHS decision to delegate significant authority regarding essential health benefits can be seen in Arizona where the state Medicaid program has significantly reduced access to needed orthotic and prosthetic services to its beneficiaries. In an effort to reduce costs to the program, Arizona eliminated coverage for orthoses for beneficiaries over the age of 21 and eliminated coverage of microprocessor controlled prosthetic components. The decision by the state to arbitrarily eliminate coverage of these essential services has already impacted the lives of many beneficiaries in Arizona that rely on prostheses and orthoses to maintain a functional lifestyle.

Another exampleof this negative impact, which has been noted also in the comments from the Orthotic & Prosthetic Alliance, can be seen in New York State where the healthplans that have been selected as "benchmarks" limit coverage of prosthetic limbs to one limb per lifetime. This is an unacceptable benefit limitation as prosthetic limbs will eventually wear out or need to be replaced due to growth, especially for children. These arbitrary benefit limits are clearly inconsistent with the goal of the PPACA to provide affordable healthcare options on a national level.

Without a clear and consistent national approach regarding the provision of essential health benefits, other states may soon follow suit and begin eliminating benefits that are clearly designated as essential health benefits solely for the purpose of reducing expenditures. This is completely contrary to the purpose and goals of the PPACA.

In addition to its continued concern regarding inconsistencies among state benchmark plans regarding what services are covered as essential health benefits, AOPA remains concerned that the current environment continues to support the concept that if an existing benchmark plan does not cover any items or services within an EHB category such as habilitative services which HHS has specifically emphasized, the category must be added by supplementing the base-benchmark plan with that particular category in its entirety from another base-benchmark plan option." This approach indicates that if "any" benefit is provided then no supplementation of the category is required. Allowing a category to be satisfied by the inclusion of "any" benefit encourages benefit categories to cover the least amount, lowest cost and quantity/quality of services. This incentive to choose the lowest coverage of benefit remains even when required to supplement a category. This is clearly NOT consistent with the intent of either PPACA as a whole, not with the statute's provisions on essential health benefits, and AOPA remains concerned that this minimalistic approach has and will continue to operate to the detriment of patients. This would be even more tragic if it occurred as to prosthetic/orthotic patients with limb loss or chronic limb impairment since the law is intended to provide special protections for persons who are disabled. While the PPACA requires protections from discrimination in benefit design and balance among categories, the actual mechanism for ensuring against such discrimination and ensuring balance has already been proven as insufficient based on HHS' own acknowledgement of deficiencies regarding coverage of habilitative services under existing benchmark plans .

AOPA encourages HHS to adopt an approach that ensures requisite benefits are covered in a more comprehensive manner under the statutorily defined categories rather than only requiring supplementation when the category does not include "any" benefits whatsoever.

Inclusion of Orthotics and Prosthetics as Essential Health Benefits

AOPA would also like to take the opportunity to reiterate its understanding that orthotics and prosthetics very clearly have been specifically designated as essential health benefits under the category of habilitative and rehabilitative services initially outlined in HHS Dec. 16, 2011 EHB Bulletin. This is supported by the legislative history, which is replete with statements by leading legislators clarifying that habilitative and rehabilitative services indeed was inexorably intended to include orthotics and prosthetics.

Rep. George Miller, the Chair of the House Education and Labor Committee, and as such a key author of the original bill, stated:

> "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 the 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, p.H1882 (March 21, 2010).

In parallel, another legislator, Rep. William Pascarell, a member of the House Ways and Means Committee, the House Committee of jurisdiction at the time the Affordable Care Act was enacted, re-stated the identical standard:

> “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 HHS to develop, through regulation, standard definitions of many terms, including durable medical equipment 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’ and the Secretary is not to define durable medical equipment for purposes of ‘in-home” use only.’”

Congressional Record, p.E462 (March 23, 2010).

As demonstrated above, there is clear congressional intent that orthotics and prosthetics falls under the statutorily defined EHB category of Rehabilitative and Habilitative services. This intent was confirmed through a direct reference to orthotics and prosthetics in the EHB Bulletin. On the carry-over paragraph from page 4 to page 5 it is stated:

> *“For example, across the markets and plans examined, it appears that the following benefits are consistently covered: physician and specialist office visits, inpatient and outpatient surgery, hospitalization, organ transplants, emergency services, maternity care, inpatient and outpatient mental health and substance use disorder services, generic and brand prescription drugs, physical, occupational and speech therapy, durable medical equipment,* ***prosthetics and orthotics****, laboratory and imaging services, preventive care and nutritional counseling services for patients with diabetes, and well child and pediatric services such as immunizations. As noted in a previous HHS analysis, variation appears to be much greater for cost-sharing than for covered services.”*
>
> [Emphasis added].

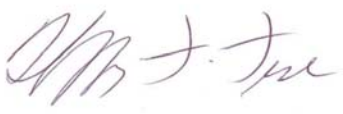
The specific identification of orthotics and prosthetics as an essential health benefit under the umbrella of habilitative and rehabilitative services, both in the congressional record as well as the EHB bulletin published by the Department of Health and Human Services, clearly indicates

the intent to include coverage for orthotic and prosthetics services as essential benefits in any healthcare plan that is designated by the states as a benchmark plan for determining essential health benefits.

AOPA recommends the specific inclusion of orthotics and prosthetics in any final rule that creates uniform definitions of either habilitative or rehabilitative services as essential benefits.

In closing, AOPA appreciates the opportunity to submit comments on proposed rule CMS-9944-P. If you have any questions or need any additional information, please contact myself, at (571) 431-0876 or tfise@aopanet.org, or Joseph McTernan, Director of Reimbursement Services, Education and Programming at (571)431-0811 or jmcternan@aopanet.org.

Sincerely,



Thomas F. Fise, JD
Executive Director