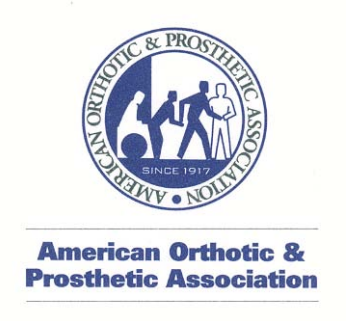

March 13, 2012

Laurence Wilson
Director, Chronic Care Policy Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard, Mail Stop C5-02-23
Baltimore, Maryland 21244-1850

Via Overnight Delivery and E-mail

Dear Mr. Wilson:

The American Orthotic & Prosthetic Association (AOPA), founded in 1917, is the largest national orthotic and prosthetic trade association with a national 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 chronic disease or health condition. These include patient care facilities, manufacturers and distributors of prostheses, orthoses and related products, and educational and research institutions.

We are writing today to submit comments with respect to the list, published via the CMS website in February, of devices being considered by CMS as possible off-the-shelf orthotic devices. We are concerned about this list because we believe it deviates substantially from the statutory definition which Congress articulated in 2003 and which binds the agency. Any efforts by CMS to implement such a list for purposes of a possible extension of competitive bidding would have serious potential impact on patients with limb loss and limb impairment, and the professionals who provide these patients with the prosthetic and orthotic devices that help restore their mobility at over 2,000 patient care facilities across the United States.

AOPA is aware of, and participated in the formulation of a separate set of comments that will be submitted on this topic by the O&P Alliance. AOPA is one of the five members of the O&P Alliance, and we want to state that AOPA is 100% supportive of the separate comments being submitted in the name of the five O&P organizations represented in the O&P Alliance.

We need to underscore that AOPA believes that fixing this very aberrant listing by CMS is a priority of the highest order. The list published by the agency is completely misguided, and its impact on patient care, were it to advance any farther, would be devastating. In large measure our response to this list, below and attached, is divided into two subdivisions – (1) patient harm and (2) the clear violation of the law.

Historically, on August 23, 2011, CMS announced its plans for Round II of competitive bidding, and made clear that it did not intend to include off-the-shelf (OTS) orthotics with Round II. That was the right decision for several reasons and we applaud it. CMS does possess statutory authority to conduct competitive bidding as to OTS orthoses. However, if the agency observes the statutory definition of off-the-shelf orthoses articulated by Congress, we believe the number of eligible devices and the volume of their usage by Medicare beneficiaries are sufficiently small that any very modest 'savings' that might be generated via competitive bidding would be more than offset by the agency's costs in conducting the program. We believe the San Antonio pilot project and similar trial runs over the past ten years or so have demonstrated that fact.

However, in June, 2011, AOPA became aware that some CMS officials had circulated to one or more Senate offices, a document stating that CMS, with assistance from its contractors, had identified a list of over 100 potential OTS orthotic devices, with a total Medicare annual financial impact in the range of $200 million. AOPA spent a significant amount of time reviewing orthotic devices and concluded that there was no way that either the number of devices, or the Medicare dollar volume telegraphed to Hill staffers on this topic could be correct if the very explicit statutory definitional terms for off-the-shelf orthotics were observed by CMS. After the August 23 decision was finalized, requests from some parties within the orthotics field were generated to CMS, asking for the opportunity to review its list of OTS orthotics, and this resulted in placement of the list on the CMS website last month.

On August 15, representatives from AOPA and others in the O&P field, under the aegis of the O&P Alliance, met with Jonathan Blum, CMS Deputy Administrator and Director, Medicare Center, and other CMS officials in a discussion that included competitive bidding. At that meeting, CMS raised the question essentially of "what harm would come if CMS were to expand the envelope for off-the-shelf orthotics a bit beyond the strict statutory definition." AOPA responded by saying that while CMS does have statutory authority to conduct competitive bidding of OTS orthotics within the boundaries of the strict statutory definition of that term, if CMS ventured at all beyond the strict words and clear meaning of that definition: (1) patients would be very significantly harmed; and (2) CMS would be violating the law. The AOPA comments that follow are organized around those two principles.

(1) Patient Harm. We will share with CMS the results of our examining every device on the CMS list. In instances where AOPA disagrees with the CMS OTS classification, we show what it looks like, explain how it is used and with what patients, in many cases supported by the pertinent medical literature. Our comments also articulate the harm that can come to patients/Medicare beneficiaries if, as a result of OTS designation, these devices were distributed to patients without attendant clinical care by an appropriately trained, qualified (and in many states licensed) orthotist or health professional with comparable training who can assure that the device is properly formed and adjusted to the unique anatomical features of the patient and suitable to that patient's medical condition/needs. There are, of course, some instances in which we agree with the CMS thinking that some of the devices do belong on any legitimate OTS list. These codes are clearly identified in the enclosed document that indicates AOPA's agreement or disagreement with the CMS OTS classification for each code.

(2) Violation of Law. Turning to the second point, the violation of the law that would attend any decision by CMS to go beyond the strict terms and clear meaning of the statutory definition of OTS orthotics, AOPA submits a legal memorandum prepared by outside counsel from the law

firm, Winston and Strawn, which examines the statutory language, legislative history and legal precedents in interpreting the definition, and particularly the unambiguous, but pivotal phrase "minimal self adjustment."

AOPA appreciates the opportunity to express the concerns of its members regarding the CMS proposed list of off-the-shelf orthoses and looks forward to continuing to work with CMS to ensure that Medicare beneficiaries continue to receive quality healthcare from properly trained providers.

Sincerely,

Thomas F Fise, JD
Executive Director