United States Senate
WASHINGTON, DC 20510

October 15, 2014

Marilyn Tavenner, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Administrator Tavenner:

We are writing to you today to express our concerns about actions of the Centers for Medicare and Medicaid Services (CMS) with respect to publishing a list of off-the-shelf (OTS) orthotic devices and a new set of Healthcare Common Procedure Coding System (HCPCS) codes relating to these devices. Ensuring that Medicare beneficiaries receive high quality care and services has been a longstanding priority of ours, and the appropriate use of these devices is an important part of ensuring beneficiary safety.

As you know, section 302 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established requirements for a competitive bidding program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). While OTS orthotics are included in competitive bidding, Congress unambiguously defined OTS orthotics as orthotic devices that "require *minimal self-adjustment* for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual."[1] (Emphasis added).

Despite support on the applicability of this statutory OTS definition by orthotic professionals, it is our understanding that CMS ventured beyond both the language and intent of MMA Section 302 when on April 10, 2007, CMS published a final rule that, *inter alia*, defines "minimal self-adjustment" to mean "an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training."[2] As a result of this expansion from the statutory definition, we are concerned about the quality of care that beneficiaries will receive. Under CMS' definition, beneficiaries are at risk of receiving orthotic devices without the services that are necessary to ensure that these devices provide proper bracing, which can result in serious beneficiary harm.

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[1] 42 U.S.C. 1395w–3(a)(2)(C).
[2] 42 C.F.R. § 414.402.

We have become more concerned that this risk will become reality since CMS recently published both a list of purported OTS devices and corresponding HCPCS codes using this errant definition instead of the statutory definition. The result is that CMS has classified many devices as OTS orthotics even though they do not meet the statutory definition. It is our understanding that the orthotics and prosthetics community provided feedback about classifying many of these orthotic devices as OTS including issues of potential patient harm, findings of the medical literature, and the fact that the FDA-approved manufacturer's labeling for these devices is indecipherable for the average patient to use themselves. Despite this feedback on the inappropriateness of classifying these devices as OTS as well as the consequences to beneficiary mobility and wellbeing, it appears that the agency has finalized the list and HCPCS codes.

In order to ensure that beneficiaries receive quality orthotics and related services and avoid beneficiary harm, we would request that CMS consider: (1) revising the regulatory definition of off-the-shelf orthotics in 42 C.F.R. § 414.402 to conform with the statutory definition, recognizing the clear meaning and limitation of "minimal self-adjustment" and clarifying that this does not include adjustments either by a caretaker or by unregulated suppliers; and (2) modifying the OTS list and codes to eliminate from that list any device which does not meet fully and unambiguously the statutory definition of OTS orthotics including "minimal self-adjustment." (Emphasis added) Furthermore, we encourage you to work with the American Orthotic and Prosthetic Association (AOPA) and the Orthotic and Prosthetic Alliance when establishing the new list of OTS devices that meet standards set by regulatory definition.

Please do not hesitate to contact Rodney Whitlock (Grassley) at 202-224-3744 or Colin Goldfinch (Harkin) at 202-224-5375 should you need any additional information. Thank you for your attention to this request; we look forward to your response.

Sincerely,

Chuck Grassley
United States Senator

Tom Harkin
United States Senator