

**Congress of the United States**  
**House of Representatives**  
Washington, DC 20515-1308

May 19, 2015

The Honorable Sylvia Mathews Burwell  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Secretary Burwell:

We are writing to express our concerns regarding activities being conducted by the U.S. Department of Health and Human Services (HHS) in relation to Medicare's policies related to orthotics and prosthetics (O&P). Specifically, we're concerned that examples of deviation from clear statutory instructions from Congress to the Administration may jeopardize patient access to proper treatments and access to appropriately trained providers for Medicare's limb loss and limb-impaired beneficiaries. Given the drastic positive impact these devices can have on a beneficiary's ability to conduct activities of everyday life, and the associated contribution potential for this at-risk population, it is our hope that appropriate remedies can be identified and implemented.

**Congress has already defined "Minimal Self-Adjustment" in Off-the-Shelf Orthotics**

Last year, Senators Grassley and Harkin wrote to you expressing concern about the Center for Medicare and Medicaid Services' (CMS) attempt to negate Congress' narrow definition of the type of orthotics for which it made sense to competitively bid. We agree that CMS is blurring the distinctions Congress made in section Section 302 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and is attempting to go beyond the definition contained in the legislation. That section, established both authority and requirements for a competitive bidding program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Only off-the shelf (OTS) orthotics are authorized for possible competitive bidding. Congress unambiguously defined OTS orthotics as orthotic devices that can be used by the Medicare beneficiary/patient with only "minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual."

Unfortunately, CMS has 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 or an individual who has specialized training." Compounding these errors, on August 15, the DME MAC Medical Directors announced the adoption of a medical policy providing guidance

concerning who can furnish custom fitted orthotics taken from a proposed rule for which the comment period had not been completed and was not part of the final rule. On February 18, 2015, the DME MAC medical directors stated that although the regulation was not updated to reflect the new guidance, it remains in effect.

We want to stress our concern that any expansion from the statutory definition carefully crafted by Congress in MMA will negatively impact the quality of care that beneficiaries will receive. Under CMS' definition, beneficiaries are at risk of receiving orthotic devices without the services, adjustment and fitting to the patient's unique anatomical characteristics that are necessary to ensure that these devices provide proper bracing, "minimal self-adjustment" means adjustment that can be done by the patient himself or herself, and without the need for involvement of any other person. In essence, as CMS has sought persistently to expand Congress' statutory definition, you have placed Medicare beneficiaries at risk for serious harm.

**A Fifteen Year Delay in Promulgating Rules Under Section 427 of the Beneficiary Improvement and Protection Act of 2000 Must be Remedied with a Timely, Thoughtful Regulation that Closely Tracks the Statute**

The Beneficiary Improvement and Protection Act of 2000 (BIPA) instructed Medicare to not pay for prosthetic or orthotic services unless the provider is either licensed in accordance with any existing state statute, or if there is none, then no payment unless the provider has met accreditation standards established in the statute. As we approach the 15th year after enactment of that statute, patients are still waiting while Medicare's fraud and abuse efforts seem to have overlooked this basic step.

Medicare beneficiaries, disabled by virtue of limb loss or chronic limb impairment deserve the assurance of quality controls on the providers Medicare pays to serve their needs. We encourage you to act with urgency and address this egregious failure by (CMS) by issuing both a proposed and final rule as soon as possible. CMS' failure to act on this common sense step as mandated by BIPA 427 is a blemish on both the Department of Health and Human Services and CMS. When Congress acts, it is the responsibility of CMS to act within a reasonable time frame. Fifteen years is an unreasonably long period to wait for a rule to be promulgated. We are requesting a response outlining how you plan to publish at least a proposed rule on this within 30-60 days of this letter.

**Actions HHS/Medicare Needs to Take on Both Matters**

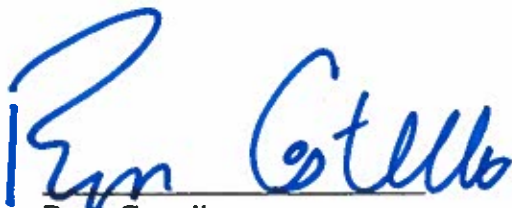
The undersigned Members of the House urge you to ensure that Congress' intent in both these matters is carried out. Congress defined minimal self-adjustment and CMS should not unilaterally decide to define what was meant. It is our belief that Congress acted to define minimal self-adjustment and CMS should not create its own definition. Specifically, in order to ensure that beneficiaries receive quality orthotics and related services and avoid beneficiary harm, CMS needs to: (1) revise 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) modify 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.), and ensure that the rulemaking process is followed and reverse those DME MAC policies (August 15, 2014 and February 18, 2015) that were not included in the final rule. 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.

In addition, CMS must promptly issue a rule with respect to orthotics and prosthetics licensure and certification requirements established under BIPA, Section 427. Limb loss and limb-impaired Medicare beneficiaries, as well as American taxpayers, deserve to know that CMS is taking sufficient measures to block unqualified providers from accessing Medicare patients and payments.

Thank you for your consideration of this request. We look forward to working with you to implement solutions to ensure patients are able to access the care they need. If you have any questions, please contact Dante Cutrona ([dante.cutrona@mail.house.gov](mailto:dante.cutrona@mail.house.gov)) or Kalina Bakalov ([kalina.bakalov@mail.house.gov](mailto:kalina.bakalov@mail.house.gov)).

Sincerely,



Ryan Costello  
MEMBER OF CONGRESS



Tammy Duckworth  
MEMBER OF CONGRESS



Glenn "GT" Thompson  
MEMBER OF CONGRESS



Erik Paulsen  
MEMBER OF CONGRESS



Mike Thompson  
MEMBER OF CONGRESS



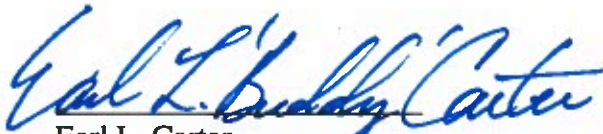
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MEMBER OF CONGRESS



Peter T. King  
MEMBER OF CONGRESS



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Earl L. Carter  
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MEMBER OF CONGRESS

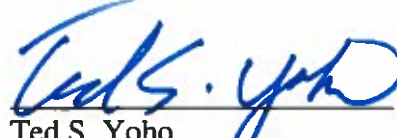
  
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