April XX, 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, I 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) or Kalina Bakalov (kalina.bakalov@mail.house.gov).

Sincerely,

Ryan Costello (PA-06)
MEMBER OF CONGRESS

Tammy Duckworth (IL-08)
MEMBER OF CONGRESS

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.

---

[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
Chuck Grassley
United States Senator

Tom Harkin
Tom Harkin
United States Senator

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

CMS HAS NOT PROMULGATED REGULATIONS TO ESTABLISH PAYMENT REQUIREMENTS FOR PROSTHETICS AND CUSTOM-FABRICATED ORTHOTICS

Daniel R. Levinson
Inspector General

October 2012
OEI-07-10-00410

EXECUTIVE SUMMARY: CMS HAS NOT PROMULGATED REGULATIONS TO ESTABLISH PAYMENT REQUIREMENTS FOR PROSTHETICS AND CUSTOM-FABRICATED ORTHOTICS
OEI-07-10-00410

WHY WE DID THIS STUDY

Section 427(a) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) prohibits Medicare payments for prosthetics and custom-fabricated orthotics unless the items are (1) furnished by a qualified practitioner and (2) fabricated by either a qualified practitioner or a qualified supplier. Section 427(b) of the BIPA required the Secretary to promulgate regulations to implement the requirements at section 427(a) of the BIPA. As required by 42 CFR § 424.57(c)(12), Medicare suppliers must also maintain documentation supporting that prosthetics and custom-fabricated orthotics were delivered to beneficiaries. In 2010, the Centers for Medicare & Medicaid Services (CMS) allowed $276 million in Medicare payments for 257,797 prosthetic and custom-fabricated orthotic claims (excluding accessories, additions, and other supplemental prosthetic and orthotic items).

HOW WE DID THIS STUDY

We selected a sample of 1,135 Medicare-allowed claims for prosthetics and custom-fabricated orthotics in 2010 to determine whether the claimed items were (1) furnished by qualified practitioners, (2) fabricated by either qualified practitioners or qualified suppliers, and (3) met delivery documentation requirements. We interviewed CMS staff regarding the implementation status of the BIPA payment requirements.

WHAT WE FOUND

To date, CMS has not promulgated regulations related to BIPA payment requirements for practitioner and supplier qualifications for prosthetics and custom-fabricated orthotics. CMS used other legal authorities that limit who can be paid for prosthetics and custom-fabricated orthotics; notwithstanding, in 2010, Medicare allowed nearly 1,000 claims inappropriately. Despite the lack of regulations, most claims were allowed for prosthetics and custom-fabricated orthotics furnished and/or fabricated by practitioners and/or suppliers that were licensed, certified, or accredited. Finally, Medicare inappropriately allowed 12 percent of claims for prosthetics and custom-fabricated orthotics that did not meet Federal requirements for delivery documentation.

WHAT WE RECOMMEND

We recommend that CMS (1) promulgate regulations to implement the BIPA payment requirements, (2) ensure that suppliers maintain delivery documentation that meets Federal requirements, and (3) take appropriate action to address inappropriately allowed claims identified in the population related to payment edits and in our sample related to delivery documentation. CMS concurred with all three recommendations.