American Orthotic & Prosthetic Association

Support the Medicare Orthotics & Prosthetics Improvement Act (S.1191, H.R. 2599)

Generate Savings to the Medicare Fund, Decrease Fraud & Abuse, Improve the Quality of O&P Care through Qualified Providers Per BIPA 427, and Assure Both a Uniform Standard for Deemed Accrediting Bodies; and That the Existing Statutory Definition for Off-the-Shelf Orthotics (Minimal Self-Adjustment) Returns to Being Observed by CMS

Uniform Standard for Deemed Accrediting Bodies in Orthotics & Prosthetics

Recognizing the wide range of skills necessary to provide quality orthotic & prosthetic care, Congress passed Section 427 of the BIPA in 2000, Section 302 of the Medicare Modernization Act (MMA), and CMS issued Transmittal 656.

BIPA Section 427: Mandated regulations within one year of enactment to limit payment for custom fabricated orthotics and all prosthetics to only those provided by "qualified practitioners" (defining which professionals could provide O&P care to Medicare beneficiaries) and "qualified suppliers" (linking supplier qualifications to two O&P accrediting organizations or their equivalent" determined by the Secretary). These regulations were finally issued in January 2017 but the proposal was subsequently withdrawn by CMS in October 2017.

MMA Section 302: Requires all DMEPOS suppliers to become accredited in order to bill Medicare. CMS granted deemed status to 11 accrediting organizations (every organization that applied) to accredit O&P suppliers, some with no experience with the O&P field or any track record with accreditation in general; CMS also developed very broad quality standards for O&P suppliers, without incorporating the uniform appropriate standards in BIPA 427.This will and has resulted in far more suppliers having explicit federal approval to provide comprehensive and complex O&P care who are simply not qualified to do so, the opposite of the intent of the statute.

Transmittal 656: Effective October 1, 2005, CMS issued Transmittal 656, which required Medicare to only pay for O&P claims from practitioners and suppliers that meet the requirements of state O&P licensure laws. This Transmittal applied to the nine states that had O&P licensure in 2005, but there are now 15 states with O&P licensure laws and two states with certification requirements. CMS has subsequently acknowledged that this Transmittal has not been implemented.

The American Orthotic and Prosthetic Association (AOPA) and the Amputee Coalition commissioned Dobson DaVanzo & Associates, LLC (Dobson | DaVanzo) to analyze Medicare claims data from 2007 through 2011 to determine the extent to which Medicare

is reimbursing non-certified providers in states with a licensure statute for selected O&P services. The analyses conducted by Dobson | DaVanzo was then compared to prior analyses of claims data conducted on behalf of AOPA from 2001 through 2006. The findings and trends of the data analyses from 2007 to 2011 were compared to the trends from 2001 to 2006.

The data from 2001 to 2006, and from 2007 to 2011, show that there has not been any significant progress by CMS to eliminate payments to unlicensed providers in O&P licensure states. Specifically, no reduction in the proportion of payments to non-certified O&P personnel has been evidenced since 2009. In fact, the data show an increase in the proportion of Medicare payments to non-certified personnel in licensure states, actions that violate those state laws. The analytic results are consistent with the results of a third party independent survey that confirmed that non-certified providers are continuing to provide O&P services to Medicare beneficiaries. If any CMS enforcement to eliminate payments to unlicensed providers in O&P licensure states has occurred, it does not appear to have to been effective.

We would like to recognize CMS for issuing the proposed rule "Medicare Program; Establishment of Special Payment Provisions and Requirements for Qualified Practitioners and Qualified Suppliers of Prosthetics and Custom-Fabricated Orthotics" in January 2017, and appreciate CMS responding to the many congressional requests over multiple congresses for BIPA section 427 to be implemented. This rule would have fairly taken into account the appropriate roles for the range of licensed or certified qualified providers who have traditionally been involved in managing treatment for patients with limb loss, chronic limb-impairment, or other conditions that require orthopedic bracing. After 17 years, the publication of the proposed rule was taking the first step toward reducing inferior care and risk to patients by unqualified providers as well as fraud and abuse by bad operators; by re-introducing the statutory requirements of BIPA section 427; and elements of MMA Section 302 and Transmittal 656.

However, in October 2017 CMS announced that it had withdrawn the proposed rule due to concerns from select provider groups, who viewed the proposed rule as a threat to their ability to continue to provide services within their scope of practice. The proposed rule was not perfect but the issues that were of concern to other providers could have been addressed through changes to the final rule rather than through the complete withdrawal of the proposed rule. The withdrawal of the proposed rule once again delays the implementation of a law passed eighteen years ago and exposes the Medicare population to no regulation regarding what qualifications are required to provide custom orthotic and prosthetic services.

CMS Should Establish a Link Between Provider Qualifications and the Complexity of O&P Care Provided

The statute contemplates a division consistent with assigning four categories of O&P products, ranging from off-the-shelf to custom fabricated. In 2014 in the draft OTS orthotics proposal CMS took a step in the direction of linking device complexity with eligibility for reimbursement and provider expertise/licensing, but CMS ultimately withdrew that proposal. CMS has never established a regulation that links payment with both device complexity and provider qualifications. The services and time involved in O&P care has become increasingly more complex as you move across the spectrum from off-the-shelf in the direction of custom fabricated, and require greater qualifications for providers. Implementing a modification for eligibility to access Medicare payment that would specifically link payment, device complexity and provider qualifications would assure better outcomes for patients, and create savings by eliminating payment to

under-qualified persons (often duplicative payments if the beneficiary ultimately requires corrective modifications or a new device) who currently receive Medicare payment.

Separate Orthotics & Prosthetics from Durable Medical Equipment

Currently orthotic and prosthetic providers are grouped together with suppliers of durable medical equipment (DME), even though the process of becoming an orthotic and prosthetic provider is much greater than that of a DME supplier. For example, the provision of O&P care requires practitioners to undergo extensive education (Master's Degree is required), a year-long clinical residency for each discipline (orthotics and prosthetics) before they may practice. Also, the provision of DME to patients is much different than the provision of O&P care to patients. The provision of O&P care traditionally involves extensive follow up care—often a life-long patient care relationship, and this follow up care can create a bond between the patient and their O&P provider; and this bond is often a major factor in regained mobility and quality of life for the patient. These differences are sometimes acknowledged by CMS regulations, but at times a one-size fit all approach is taken when creating legislation or regulation for orthotics, prosthetics and durable medical equipment. The official separation of O&P from DME will allow CMS to create regulations which will take into account the O&P providers education, skill set and patient treatment modalities.

Clarification on Minimal-Self-Adjustment

The statutory definition, contained in section 1847(a) (2) (C) of the Social Security Act, defines off the shelf orthoses as those: which can be used by the patient with minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual.

However, CMS expanded the definition of the term "minimal self adjustment", contrary to the federal statute, 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 of Certification/Accreditation) or an individual who has specialized training.

The four DME MAC contractors further expanded the statutory and regulatory definition of the term "minimal self adjustment" beyond the intent of the original statute when it indicated that in order for an orthosis to be classified as custom fitted, "substantial modification" to the orthosis to achieve proper fit and function must occur. [The DME MACs were seeking to create new policy without any clear statutory authority and without following the required rulemaking process of notice, comment, and stakeholder input.]

Congress was very specific in stating that only those off-the-shelf orthoses that can be used by the patient with "**minimal self adjustment"** (emphasis added) by the individual user could be considered as off-the-shelf orthotics, and thereby eligible for the competitive bidding program; any expanded regulatory definition of minimal self adjustment goes beyond the intent of the statute, and the use of any expanded definition will result in the classification of orthotic items and services as off-the-shelf; which in reality involves a device and FDA product labeling of such complexity to require a level of professional care to avoid potential harm to Medicare beneficiaries.

See attached on page six for a review of actions related to "minimal self adjustment".

Recommendations

H.R 2599/S.1191 is the O&P Medicare Improvements Act. The bill has eight sections. Only one section, #5, has been enacted into law. Remaining provisions, for example minimal self-adjustment for OTS orthotics, CMS enacting final BIPA regulations, and separation of O&P from DME (section 6,7and 8) are absolutely essential gains for which we have to advocate.

We would like to commend Congress for enacting one provision of the Medicare Orthotics & Prosthetics Improvement Act of 2017, recognizing the validity of orthotist's and prosthetist's notes in justifying medical necessity. This provision of the Act was included as part of the Continuing Resolution/Spending Bill (H.R. 1892- Bipartisan Budget Act of 2018, Section 50402) signed into law by President Trump on February 9, 2018. Unfortunately, this single provision is not nearly enough to meet the needs of our patients with limb loss, or mobility impairment.

We now encourage Congress to take the next step in improving the quality of patient care for amputees and patient's with limb-impairment, assisting small businesses, reducing fraud and waste within the Medicare program, and ensuring that Medicare beneficiaries receive the highest quality orthotic & prosthetic care in a timely manner. We ask that you direct CMS and its contractors to implement the law as directed.

We also ask you to support the enactment of the remaining sections of the Medicare Orthotics & Prosthetics Improvement Act (S.1191 and H.R. 2599) and similar pieces of legislation, including but not limited to H.R. 4772, and/or to ensure that the following key provisions of the Act be included in any similar pieces of future legislation in which Congress should:

1) Require CMS to remove the terms "orthotics" and "prosthetics" from the definition of "medical equipment and supplies" and create a new section with requirements for suppliers of orthotics and prosthetics for purposes of Medicare payment, distinguishing O&P patient care from DME commodities.
2) Ensure that the term "off-the shelf orthoses" is appropriately defined, and that only those items which meet the statutory definition of off-the-shelf (i.e. usable by the patient with "minimal self-adjustment" by the patient and not another person) are considered eligible to be included in possible future rounds of the competitive bidding program. *{This provision may also be found in H.R. 4772}*
3) Require CMS to adopt the framework of a revised payment system in O&P that would explicitly link practitioner and supplier qualifications with the level of complexity of the care being provided to the patient. These levels of complexity would be consistent with, but more specific than, the existing statutory language, thereby improving quality and reducing claims from unqualified suppliers and potentially generating savings.
4) Instruct CMS to: (a) implement the regulation under Section 427 of BIPA 2000, which has been delayed eighteen years; and (b) limit its recognition to those certifying bodies which in fact meet the legislative quality criteria already established in BIPA 427. Assuring that providers must meet the stricter qualifications of one of these established certifying bodies will meet the original Congressional intent of narrowing Medicare providers to those who are truly

qualified, and thereby generate savings by eliminating payments to unqualified providers, who are more likely to be the perpetrators of fraud and abuse.(These recommendations were also echoed by the Department of Health & Human Services Office of Inspector General in its October 2012 report *CMS Has Not Promulgated Regulations to Establish Payment Requirements for Prosthetics & Custom Fabricated Orthotics).*

Thank you for your time and support.

For more information contact the American Orthotic & Prosthetic Association (AOPA) at (571) 431-0876 or www.AOPAnet.org

Attachment #1: Minimal Self-Adjustment Timeline

1. When Competitive Bidding was authorized, OTS orthoses were designated as appropriate for possible inclusion in competitive bidding. The statutory definition, contained in section 1847(a) (2) (C) of the Social Security Act, defines off-the-shelf orthoses as those: which can be used safely by the patient with only minimal self adjustment and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual.
2. April 2007: CMS expanded the definition of the term "minimal self adjustment" in C.F.R. 414.402 well beyond the statutory definition, instead as follows: CMS said minimal self-adjustment means 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 of Certification/Accreditation) or an individual who has specialized training.
3. December 2013:CMS created a new subset of prefabricated items/services/procedures, 55 in total, which they deemed to be OTS orthoses, including 23 devices (so-called exploded codes or split codes) which can either be OTS or custom fitted depending on the patient and physician prescription.
4. March 2014: The four DME MAC contractors further expanded the statutory and regulatory definition of the term "minimal self adjustment" beyond the intent of the original statute when it indicated that in order for an orthosis to be classified as custom fitted, "**substantial modification**" to the orthosis to achieve proper fit and function must occur. [The DME MACs appear to have been seeking to create new policy without any clear statutory authority and without following the required rulemaking process of notice, comment, and stakeholder input.]
5. August 2014 CMS' HCPCS Coding Workgroup increased the number of split codes from 23 to 25, with the release of two "K" codes, temporary codes, to describe the off-the-shelf versions of products described by L1843 and L1845. In less than 12 months CMS has made a complete reversal. In the August 2013 response to public comments regarding the proposed list of OTS orthotic codes, CMS stated that L1843 and L1845 were being removed from the proposed OTS list "as these orthoses require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual and do not meet the definition of an OTS orthosis. [The creation of these two "K" codes took place without the appropriate notice and comment process or stakeholder input.]
6. June 2014: An update to Appendix C of the Medicare DMEPOS Quality Standards, adopts several provisions of the proposed rule on End-Stage Renal Disease (ERSD) Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics and Supplies; a proposed rule which had not even been published as of June 2014. [The incorporation of this information from the proposed rule into the DMEPOS Quality Standards document prior to completion of the notice and rulemaking process is entirely inappropriate].
7. July 2014: CMS released its proposed rule on Off-the-Shelf Orthotics with the ESRD Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics and Supplies. The proposed rule reiterated the earlier errant CMS definition, stating that CMS would expand beyond the Congressional statutory definition so that they would consider 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 a physician as defined in section 1861(r) of the Act, a treating practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as defined in section 1861(aa)(5) of the Act, an occupational therapist as defined in 42 CFR §484.4, or physical therapist as defined in 42 CFR §484.4 in compliance with all applicable Federal and State licensure and regulatory requirements.

8. October 2014: CMS published the final ESRD rule, which included the following statement : *"C. Summary of the Proposed Provisions and Responses to Comments on the Definition of Minimal Self-Adjustment of Orthotics Under Competitive Bidding*

   At this time, we have decided not to finalize any changes to the definition of minimal self-*adjustment in § 414.402 to recognize as an individual with specialized training. We may* address *this provision in future rulemaking."*

9. February 2015: CMS Frequently-Asked-Questions about Competitive Bidding included the following question and answer:

   "1Q. CMS proposed a revision to the definition of "minimal self-adjustment" at 42 CFR 414.402 of the Federal regulations, specifically to expand on the part of the definition related to individuals who have specialized training that enables them to furnish orthotics beyond those that require minimal self-adjustment (e.g., custom fitted orthotics). This proposed revision was not finalized. Does this mean that the guidance regarding which individuals have specialized training that enables them to furnish custom fitted orthotics is not valid?

   1A. No. The guidance regarding which individuals have specialized training that enables them to furnish custom fitted orthotics remains in effect. Although the regulation was not updated to reflect this guidance, it remains in effect under the Durable Medical Equipment Medicare Administrative Contractor (DME MAC) articles discussing when orthotics can be considered custom fitted and coded using HCPCS codes specific to custom fitted orthotics. The DME MACs have discretion to define what constitutes custom fitting for accurate coding and payment of claims. It also remains in effect under Appendix C of the DMEPOS Quality Standards related to specialized training necessary for furnishing custom fitted orthotics." Again, this definition/interpretation was advanced without the benefit of any notice and comment rulemaking process, and therefore contrary to the Administrative Procedures Act.