American Orthotic & Prosthetic Association

Support the Medicare Orthotics & Prosthetics Improvement Act

Generate Savings to the Medicare Fund, Decrease Fraud & Abuse and Improve the Quality of O&P Care, Assuring a Uniform Standard for Deemed Accrediting Bodies and Recognizing the Validity of the Orthotist's and Prosthetist's Notes

Helping Amputees & Other Patients & 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 and now need to be implemented as a final rule that will benefit both patients and healthcare providers.

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. CMS has subsequently acknowledged that this Transmittal has not been implemented.

The American Orthotic and Prosthetic Association (AOPA) funded 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. 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.

On January 12, 2017, CMS published the proposed rule "Medicare Program; Establishment of Special Payment Provisions and Requirements for Qualified Practitioners and Qualified Suppliers of Prosthetics and Custom-Fabricated Orthotics". This rule would fairly take 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 is 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, there are provisions within the proposed rule, which still require revisions to meet the statutory elements and intents of BIPA 427 and MMA Section 302- - but this rule absolutely needs to be enacted in the form of a final rule.

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. So, 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.

Allow the Orthotist's and Prosthetist's Clinical Notes to Justify Medical Necessity

"For purposes of determining under this title the reasonableness and medical necessity of prosthetic devices and orthotics and prosthetics, documentation created by orthotists and prosthetists relating to the need for such devices, orthotics, and prosthetics shall be considered part of the medical record".

This modest change in language of Section 1834(h) of the Social Security Act would place the same value on the orthotist's and prosthetists's documentation as is currently being placed on other healthcare provider's (i.e. nurse practitioners, physical therapists, occupational therapists, etc.) documentation, especially in the Medicare prepayment and post payment audit process. The fair evaluation of the orthotist's and prosthetist's notes would increase patient's access to care, especially since the long-term bond between the patient and their prosthetic provider is often a major factor in regained mobility and quality of life and the patient routinely seeks out their prosthetic/orthotic provider, instead of the referring physician when they have issues or questions.

The change also has the potential to alleviate the current back log of appeals facing Medicare and the Office of Medicare Hearings and Appeals (OMHA) by eliminating a large number of claims that are being denied due to lack of notes in the medical record, primarily the physician's documentation and not the documentation submitted by the orthotists and prosthetists (who CMS recognizes as health professionals and who must obtain at a minimum a Master's Degree from an O&P accredited academic institution and complete a residency program before they may practice). The concept of placing fair weight to the orthotist's and prosthetist's notes is nothing new prior to the inception of the current CMS audit policy in August of 2011, Medicare relied on the notes and documentation of the orthotist and prosthetist to determine medical necessity and other vital aspects of the claim.

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 that the provision of O&P care to patients. The provision of O&P care traditionally involves extensive follow up care, 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.

Satisfy the Ninety Day Statutory Period for Administrative Law Judge Decisions & Allowing for Voluntary Settlement of All Pending Appeals

There are five levels in the Medicare claims appeal process and the Administrative Law Judge (ALJ) is the third level; and the Office of Medicare Hearings and Appeals (OMHA) is the entity responsible for overseeing the ALJs. The ALJ level allows a provider the opportunity to present their appeal to a person who will independently review the materials provided and render a new decision in accordance with the law and not render a decision solely based on Medicare policy; the ALJs are also under a statutory requirement to issue decisions no more than 90 days from the date the appeal request was filed.

However, the OMHA has routinely and continually not been able to meet this 90 day timeframe for the past several years, and in fiscal year 2015 they only met the requirement in 9.3% of the eligible claims adjudicated. The OMHA reported that for an appeal decided by an ALJ in fiscal year 2015 the average processing time was 661 days, in fiscal year 2016 the average was 877 days, so far in fiscal year 2017 the average tine is1,041days; in essence delaying the appeal process for 2-3 years.

During this unlawful multi-year delay, suppliers/providers are not receiving any additional breaks or relief from the current audit practices, it is only increasing the burden. Any money Medicare previously paid on claims, now denied through audits or reviews, is being recouped, with interest, and held by Medicare until the appeals process is completed. So, even though CMS through the OMHA has delayed the appeals process they have not halted their collection activities; placing a financial burden on the orthotic and prosthetic provider and causing the closing of approximately 200 O&P facilities and delays in patient treatment.

Congress emphasized the importance of quickly processing Medicare appeals when it passed the Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Benefits Improvement and Protection Act of 2000 (BIPA), which included a statutory requirement that ALJ's issue decisions no more than 90 days from the date the appeal request filing date. CMS/OMHA continues to exceed the timeframe established by the SCHIP statute and leaves Medicare providers without an adequate avenue of challenging payment denials in a timely and equitable fashion. Moreover, the growing backlog in provider appeals continues to put financial pressure on providers, many of whom operate small businesses that cannot afford to have cash flows endlessly held up in the appeal process. CMS/HHS/OMHA should not have the ability to recoup any overpayments until they can demonstrate that they are complying with the 90-day statutory time frame for an ALJ decision.

Provide Greater Transparency in the Recovery Audit Process

Currently any information related to the success of appeals as the result of a recovery (RAC) audits are convoluted, DME claims and O&P claims are routinely reported together or the information is not made readily available. To provide a greater understanding and accurate picture of where fraud and abuse is occurring, all information related to RAC audit rates and appeals outcomes (at each level) should be published; and when compiling statistics on the RAC appeals process CMS should also separate O&P from DME. This separation and publication of results will provide more concise data on where fraud and abuse is occurring and allow CMS to direct its educational and enforcement activities appropriately and effectively.

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 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.

Recommendations

We urge you to become a co-sponsor of the Medicare Orthotics & Prosthetics Improvement Act, and/or to ensure that the following key provisions of the Act be included in any similar pieces of legislation. Congress should:

1) Require CMS to recognize that an order or any other document created by the treating orthotist or prosthetist is part of the patient's medical record for purposes of determining whether an item or service is reasonable and medically necessary.
2) 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. For example, information that an orthotist or prosthetist provides on an order may include diagnosis codes, a description of the beneficiary's medical and functional condition, and information about the need for the orthosis or prosthesis.
3) Compel CMS and OMHA to embrace the legislative proposal to limit the recoupments until after the ALJ hearing, at least until such time as CMS and OMHA can demonstrate that they are complying with the 90-day statutory time frame for an ALJ decision.
4) Clarify that the "off-the-shelf orthotics" that continue to be subject to a Medicare competitive bidding program are those that meet the statutory standard, i.e. usable by the patient with "minimal self-adjustment" by the patient and not another person.
5) 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 orthotic and prosthetic 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.

6) Instruct CMS to: (a) implement the regulation under Section 427 of BIPA 2000, which has been delayed seventeen 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).* [We would like to commend CMS for issuing the proposed rule in January 2017and appreciate CMS responding to the many congressional requests over multiple congresses for BIPA section 427 to be implemented; and we believe that the need for this rule is still as important and evident today as it was when BIPA 427 was passed in 2000.]
7) Require CMS to publish RAC audit rates and appeals outcomes at each level of review; and establish reporting requirements for separate categories of providers (i.e., a category for O&P providers that is separate from DME providers).

By supporting the Medicare Orthotics & Prosthetics Improvement Act (which in 2016 had widespread bi-partisan support and the Congressional Budget Office confirmed the Act would not cost the government any money), and/or ensuring its contents are included in similar pieces of legislation you will be improving quality of patient care for amputees and patient's with limb-impairment, assisting small businesses, reducing fraud within the Medicare program and will be ensuring that Medicare beneficiaries receive the highest quality orthotic & prosthetic care in a timely manner.

We would also like to ensure that Congress aides in the timely implementation of the proposed rule Medicare Program; Establishment of Special Payment Provisions and Requirements for Qualified Practitioners and Qualified Suppliers of Prosthetics and Custom-Fabricated Orthotics, issued in January 2017. The enactment of the legislation in the proposed rule, in conjunction with Medicare Orthotics & Prosthetics Improvement Act, would add greater clarity on key issues, and would serve to make the final BIPA 427 regulations better, fairer, and stronger; ultimately improving quality patient care. We look forward to working with CMS and Congress to ensure that the final rule makes the necessary improvements and corrections, so that it ultimately protects the health of Medicare beneficiaries while ensuring that access to quality care from qualified O&P providers remains available.

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