American Orthotic & Prosthetic Association

Support the Medicare Orthotics & Prosthetics Improvement Act (S. 829; H.R. 1530)

Generate Savings to the Medicare Fund, Decrease Fraud & Abuse and Improve the Quality of O&P Care by Enhanced Enforcement of Existing Regulations, Limiting the Number of Deemed Accrediting Bodies and Recognizing the Validity of the Orthotist's and Prosthetist's Notes

Enhanced Enforcement & Reduce the Number of Deemed Accrediting Bodies in Orthotics & Prosthetics

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 never issued and this provision was never implemented.

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 generally. CMS also developed weak, very general quality standards for O&P suppliers. This will result 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, including Florida, Texas, and Illinois. There are now 15 states with O&P licensure laws. CMS has subsequently acknowledged that this Transmittal has not been implemented.

Congress should mandate that CMS adopt and fully implement within 90 days the content of Transmittal 656 for all states with O&P licensure laws (now and in the future) to assure that Medicare payments for O&P services and devices are made only to qualified O&P practitioners and suppliers. Within 180 days, CMS should take the next logical step to fully implementing Section 427 of the BIPA law, which requires Medicare to only pay qualified providers for custom fabricated orthotics and all prosthetics in every

state. *[Cost Implications: Since both of these provisions are not currently implemented, mandating CMS to do so would clearly be a saver, whether CMS recognizes these savings or not. Since only a few states had licensure at the time that BIPA was enacted, there is a strong argument that implementing these provisions would generate additional savings.]*

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 change 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 as recently as in 2013. 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.

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, but CMS has never established a regulation that links payment with both device complexity and provider qualifications. The services/equipment in O&P 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.

Congress should 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 (i.e., off-the-shelf, pre-fabricated (low skill), pre-fabricated (high skill), custom fabricated), thereby improving quality and reducing claims from unqualified suppliers and potentially generating savings. Guidance on what devices correspond to each of these categories is already provided in existing statutory and regulatory documentation

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 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 must obtain at a minimum a Masters 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 orthotis'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 patient evaluating notes of the orthotist and prosthetist to determine medical necessity and other 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 (Masters 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 provisions of O&P care to patients. The provision of O&P care traditional 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 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 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 indicated that the average processing time for an appeal decided by an ALJ in fiscal year 2015 is 547 days, and OMHA has temporarily suspended the assignment of any new ALJ hearing requests as to claims appeals by providers and anticipates that assignment of requests for ALJ hearings may be delayed for up to 24 months, in essence halting the appeal process for up to two years.

During this OMHA imposed two year delay 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 halted the appeals process they have not halted their collection activities; placing a financial burden on the orthotic and prosthetic provider and in some dire circumstances caused the closing of O&P facilities and patient treatment delays.

However, this temporary delay doesn't halt all aspects of the audit process or provide any solace or break to suppliers/providers. During this two year delay any money CMS previously paid on claims, now denied through audits, is being recouped, with interest, and held by Medicare until the appeals process is completed.

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 fighting over 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.

Alternate Voluntary Process to Resolve Appeals

Other Medicare providers have been offered an opportunity to enter into negations to receive a prompt and equitable settlement, to alleviate their financial burdens and receive a partial payment for money for being withheld/recouped during the formal Medicare appeals process; however these types of arraignments have not been extended to O&P providers. By allowing O&P providers to bring their appealed claims to a prompt and equitable settlement would reduce the ongoing backlog of claims awaiting an ALJ hearing and would alleviate the financial burdens being placed on companies as they wait for their chance for a fair ALJ hearing.

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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

Congress was very specific in specifying that only those off-the-shelf orthoses that can be used by the patient with "minimal self adjustment" 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 requires a level of professional care to avoid potential harm to Medicare beneficiaries.

Recommendations

1) Congress should instruct CMS to: (1) implement the regulation under Section 427 of BIPA 2000, which has been delayed fifteen years; and (2) limit its recognition to those certifying bodies which in fact meet the legislative quality criteria already established in BIPA 427, and to rescind the certifications of any bodies currently recognized, that do not measure up to that legislative quality standard. 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 likely to be the perpetrators of fraud and abuse.

2) Congress should communicate to acting CMS Administrator Slavitt that CMS/OMHA continues to violate their statutory requirement to provide an ALJ hearing within 90 days, and compel them to embrace the legislative proposal to delay the recoupment date for audits until after the ALJ hearing, at least until such time as CMS/HHS/OMHA can demonstrate that they are complying with the 90-day statutory time frame for an ALJ decision. The delay will both save the government money, by limiting the repayment of high interest rates to providers scionswww.aopanet.org.
3) Congress should request that the OMHA work in conjunction with HHS/CMS to assure that alternate ways of ending the ALJ backlog with voluntary settlement methods are not limited to hospitals alone, but that a parallel settlement offer is accorded to Part B providers as well. However, based on the higher success rate of orthotic and prosthetic claims when they reach the ALJ, the settlement offer for O&P claims should be at 87 cents on the dollar; instead of the current 68 cents on the dollar for hospital based settlements.
4) Congress should require HHS to create separate categories for O&P and for durable DME; when compiling and publicly reporting information on appeals filed and success of appeals for providers at each level (Redetermination, Reconsideration, ALJ, Departmental Appeals Board and Judicial Review).

Lastly, please consider becoming a co-sponsor of the Medicare Orthotics & Prosthetics Improvement Act of 2015; your support will both save the government money and will keep small business providers out of bankruptcy.

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