American Orthotic & Prosthetic Association

Statement of the American Orthotic and Prosthetic Association on Medicare Site of Service & Related Issues of Cost Effectiveness of Orthotic & Prosthetic Care and on RAC Audits, House Energy & Commerce Health Subcommittee, May 21, 2014

The American Orthotic and Prosthetic Association (AOPA) is pleased to provide this statement concerning Medicare fraud and the delivery of care to Medicare beneficiaries who have suffered a loss of a limb or impaired use of a limb or the spine. AOPA, founded in 1917, is the largest orthotic and prosthetic (O&P) trade association, with a national membership that draws from all segments of the field of artificial limbs and customized bracing for the benefit of patients who have experienced limb loss or limb impairment. Members include patient care facilities, manufacturers and distributors of prostheses, orthoses, and related products, and educational and research institutions. The field of providing artificial limbs or customized bracing for those Medicare beneficiaries with limb loss or limb impairment is a highly specialized area representing a small, roughly one-third of 1 percent, slice of Medicare spending but has a huge impact on restoring mobility to those patients served. A replacement limb may mean the difference between returning to work and a former life quality and remaining an active and contributing member of society. Customized orthotic bracing solutions for chronic conditions may have a similar long range impact.

The Cost-Effectiveness of O&P

This statement addresses the cost-effectiveness of O&P and refers to a major new study commissioned by the Amputee Coalition and conducted by Dr. Allen Dobson, health economist and former director of the Office of Research at CMS (then the Health Care Financing Administration)[1]. This study shows that the Medicare program pays more over the long-term in most cases when Medicare patients are not provided with replacement lower limbs, spinal orthotics, and hip/knee/ankle orthotics.

Lower extremity and spinal orthotic and prosthetic devices and related clinical services are designed to provide stability and mobility to patients with lower limb loss or impairment and spinal injury. Supplying bracing or support (an orthosis) where needed or a new artificial limb (prosthesis) when necessary saves our healthcare system significant future costs. Medicare's own data shows this to be the case. Timely treatment that preserves or helps regain mobility not only makes sense; it also saves dollars.

The study's authors used the Medicare Claims database to review all Medicare claims data for patients with conditions that justified the provision of lower limb orthoses, spinal orthoses, and lower limb prostheses. The unprecedented study looked at nearly 42,000 paired sets of Medicare

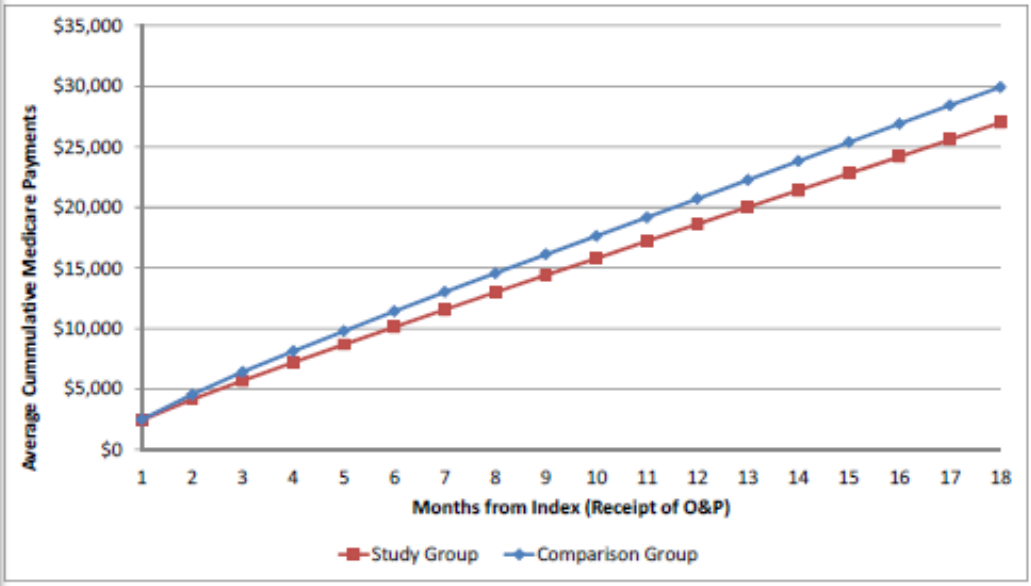
[1] A detailed summary of the research is available online at http://www.amputee-coalition.org/content/documents/dobson-davanzo-report.pdf.

beneficiaries with claims from 2007-2010. The paired patients either received orthotic and prosthetic care or they did not get such care.

The study's key finding was that Medicare costs are lower or similar for patients who received orthotic or prosthetic services, compared to patients who need, but do not receive, these services. According to the study, Medicare could save 10 percent ($2,920 on average) for those receiving lower extremity orthoses, and there also are modest savings for patients receiving spinal orthoses and lower extremity prostheses.

Without question, the orthotic solutions, as demonstrated by the following two exhibits, reduced healthcare costs in the eighteen months that followed treatment as compared with healthcare costs incurred by the untreated comparison group.

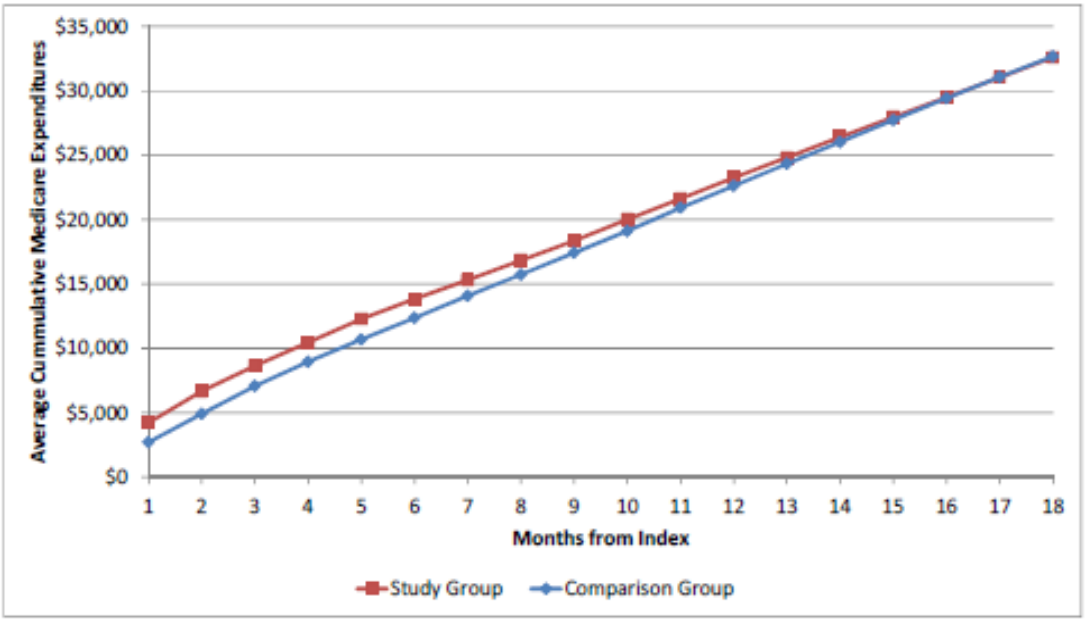
Exhibit 4.3: Lower Extremity Orthoses: Cumulative Medicare Episode Payment by Cohort (18 Month Episodes from 2008-2010)



Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), according to custom cohort database definition.

Summary of Findings: Based on the rigorous propensity score matching used to develop the two patient cohorts, we are able to conclude from this analysis that patients who received lower extremity orthoses had better outcomes, defined as fewer acute care hospitalizations and emergency room admissions, and reduced overall cost to Medicare. Study group patients achieved better outcomes with Medicare episode payments that were $2,920 – or 10 percent – less than the comparison group (including the price of the orthotic). Additionally, these patients were able to sustain more rehabilitation, and were able to remain in their homes as opposed to needing placement in facility-based settings.

Exhibit 4.6: Spinal Orthoses: Cumulative Medicare Episode Payment by Cohort (18 Month Episodes from 2008-2010)



Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), according to custom cohort database definition.

Summary of Findings: Our analytic results indicated that patients who received spinal orthoses had comparable cumulative Medicare payments over 18 months to those who did not receive the orthotic. Furthermore, these patients had a higher rate of ambulatory and home-based care (as opposed to facility-based care), which could suggest that the use of spinal orthoses allows patients to be less bedbound and remain independent in their homes. These patients had a slightly higher prevalence of fractures and falls, which may have been due to their increased ambulation and independence. By Month 18, study group patients had Medicare episode payments that were $93 (or 0.3 percent) lower than comparison group patients.

Prosthetics are typically higher cost items, yet the data analysis that compares the two groups showed that in the ensuing twelve months, those not receiving prostheses incurred almost as much total healthcare expense as those who did receive prostheses. The following two exhibits suggest that the Medicare program may save on the costs associated with providing prostheses if a slightly longer term is measured.

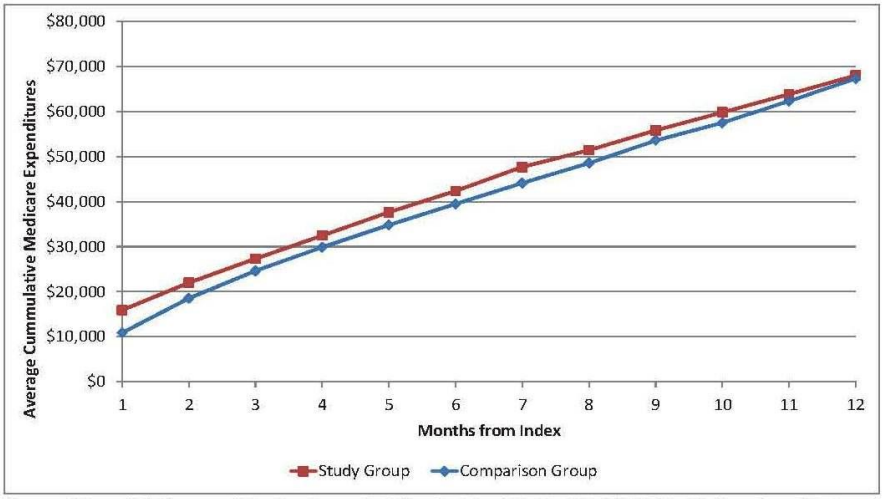
Exhibit 4.8: Lower Extremity Prostheses: Average Use of Inpatient and Outpatient Therapy and Patient Outcomes by Cohort (18 Month Episodes from 2008-2010)

Therapy Use and Outcomes	Study Group	Comparison Group	Difference
Average Number of IRF Days	1.61	1.19	0.42
Average Number of OP Therapy Visits	56.1	28.9	27.18*
Average Number of Fractures and Falls	0.90	0.72	0.18
Average Number of ER Admissions	1.55	2.10	-0.55*
Total Average Medicare Episode Payments	$68,040	$67,312	$728

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), according to custom cohort database definition.

Exhibit 4.9 presents the cumulative episode payment for the study and comparison group by episode month. This chart indicates that the cost of the prosthetic in Month 1 was slowly amortized over time; by the end of Month 12, the cumulative Medicare episode payment for the study group was $728 (1 percent) higher than the comparison group patient, indicating that the cost of the prosthetic was nearly fully amortized. Due to the correlation between the monthly payments each month after the receipt of the prosthetic, we were unable to draw conclusions beyond Month 12.

Exhibit 4.9: Lower Extremity Prostheses: Cumulative Medicare Episode Payment by Cohort (18 Month Episodes from 2008-2010)



Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), according to custom cohort database definition.

Of course the data cannot reflect the improved quality of life enjoyed by beneficiaries in both groups.

This is a clear win for patients and a win for taxpayers, the Medicare system, and private payers. Not only do patients who get O&P treatment benefit the most, but it also ends up costing taxpayers and insurers less in most cases. Medicare and other payers' preconception that prosthetic limbs and bracing cost money have been disproven by Medicare data. For the first time, actual data demonstrate that O&P devices save health care dollars, confirming the value of O&P intervention based on economic criteria. The goal of restoring function is emphasized in many of Medicare's covered services and therefore supports the targeted use of O&P services for

patients who are able to benefit from and receive the requisite therapy. Increased physical therapy among O&P users allows patients to become less bedbound and more independent, which may be associated with slightly higher rates of falls and fractures but fewer emergency room admissions and acute care hospital admissions. This reduction in health care utilization ultimately makes O&P services cost-effective for the Medicare program and other payers, while improving the quality of life and independence of the patient.

The Rationale for Excluding O&P from Post-acute Care Bundles

For several reasons, O&P and related services should be excluded from any post-acute care bundles. First, prosthetics and orthotics (artificial limbs and orthopedic braces) differ markedly from durable medical equipment (DME). Furnishing O&P is not the distribution of commodities like DME; rather O&P care involves an ongoing series of clinical services provided by licensed and/or certified professionals that results in the ability to regain or maintain ambulation and full function. Under the present Medicare structure, beneficiaries with limb-loss or limb-impairment are permitted to choose the licensed and/or certified health care professional with whom they establish a patient care relationship. The patient has the right to choose a provider with whom he or she is comfortable and who best addresses his or her mobility needs. This relationship should be determined on more than the lowest price.

Experience with hospital DRGs and with SNFs shows that some providers have responded to comparable bundling systems by delaying and denying O&P patient care until a patient was discharged, allowing Medicare Part B to cover the cost of O&P treatment, rather than the Part A bundle. Patient quality of care declined with these inappropriate delays in access to O&P care, often irreversibly compromising independent living and relegating the patient to nursing home care. It is imperative to avoid this same kind of result for mobility-compromised patients, militating in favor of exempting O&P from the post-acute care bundle.

In addition, Congress and CMS have determined that competitive bidding is an ill-suited means of providing complex O&P care to Medicare patients. Bundled payments are poorly suited for the delivery of custom O&P care because the devices and related clinical services are unique, matched to the patient/beneficiary's specific anatomical features, and cannot be accommodated by a system that relies on a comparison between what may seem to be similar or substitute items and services. To include O&P in bundling would be a radical change to the Medicare system and catastrophic for these limb-impaired individuals.

Congress dealt with this appropriately in 2003 when it exempted all prosthetics and custom orthotics from Medicare competitive bidding. Congress limited competitive bidding to only "off-the-shelf" orthotics, which Congress defined as devices that could be used by the patient with "minimal self-adjustment" and that do not require any expertise in trimming, bending, molding, assembling, or customizing to fit to the individual. The number of "off-the-shelf" orthotic devices is limited, both in number and in potential savings from bidding and bundling.

We believe Medicare beneficiaries would be served best by exempting O&P care from bundled payments and preserving the licensed and/or certified prosthetist/orthotist relationship in the same way the patient's right to select a physician or a physical/occupational/speech therapist is

protected. That would be the safest route to protect these limb-impaired Medicare beneficiaries. We appreciate that Rep. McKinley's legislative proposal, the Bundling and Coordinating Post-Acute Care (BACPAC) Act of 2014 contains such an exemption, and we urge that this exemption be maintained.

Other Key Issues Relating to Fraud, Abuse, RACs and ALJ Delays

Section 427 of the Beneficiary Improvement and Protection Act (BIPA) of 2000 requires CMS to ensure that Medicare payments for custom fabricated orthotics and all prosthetics are furnished by "qualified practitioners" and "qualified suppliers." The O&P profession supported this effort and consistently has pushed to have this requirement implemented. Currently, 16 states have enacted O&P licensure statutes. In 2005, CMS issued Transmittal 656 to Medicare payment contractors specifying that contractors must have claims processing edits in place to make sure that in those states where O&P must be provided by a licensed or certified orthotist or prosthetist, payments are made only to practitioners and suppliers that meet relevant state O&P licensure laws. However, CMS has not taken concrete steps to enforce this requirement.

H. R. 3112, the Medicare Orthotics and Prosthetics Improvement Act of 2013, has been introduced in Congress and would build upon the fraud-fighting provisions included in BIPA. It would help reduce fraud, protect patients, and save Medicare funds by keeping out fraudulent providers in the first place. As the Dobson-DaVanzo report notes: "If CMS was to actively enforce that unlicensed providers cannot receive payment for providing orthotics and prosthetics services to Medicare beneficiaries within a licensure state, Medicare savings could be realized. Under such enforcement of limiting payments to providers with proven licensure and standards of training and experience, payments to unqualified providers would be eliminated. As the '60 Minutes' special suggested, allowing non-certified/unlicensed personnel to provide these services, especially in states with licensure, could lead to fraud and abuse in orthotics and prosthetics services, as well as expose patients who received these services to inappropriate or substandard care. Therefore, shifting payments to only certified providers could result in better care for beneficiaries and lower Medicare payments."

RAC Audits and the ALJ Appeals Backlog

Instead of using tools to keep bad actors from participating in the O&P sector, CMS has ramped up the Recovery Audit Contractor (RAC) program, which has had the effect of punishing legitimate providers.

While CMS makes payments to unlicensed and unaccredited providers, contravening Congress's intention, legitimate suppliers have been subject to RAC and prepayment audits conducted by contractors who appear to play by their own set of rules. It also appears that RAC audits penalize suppliers for paperwork or documentation errors as often, or more often, than they catch those perpetrating fraud. This sometimes results in legitimate providers, especially those who are small businesses, suffering cash flow problems or going out of business. AOPA estimates that roughly 100 O&P suppliers have gone out of business within the past eighteen months, at least in part due to these audit/recoupment related cash flow problems. The impact of these closings extends beyond economics and business—it directly and negatively affects individuals with limb

loss, as they have been deprived of long-standing, clinically-beneficial relationships with their health care providers. (We note that AOPA has sued the U.S. Department of Health and Human Services (HHS) over RAC audits and how they are being applied to O&P suppliers.)

We feel that certain actions by CMS have compromised the due process rights of O&P suppliers. For example, CMS issued a "Dear Physician" letter on its website in August, 2011 that had the effect of establishing new policy for payment for artificial limbs, and it applied the new policy retroactively in RAC and prepayment audits as to claims for dates of service as much as two years before the policy was issued in the letter.

There has been an explosion in the number of RAC audit claims under Medicare Part B for artificial limbs that are appealed to the Administrative Law Judge (ALJ) level. Congress and CMS have provided some modest relief for Medicare Part A providers, but none of this relief has been extended to Part B claims for artificial limbs. While we appreciate the difficult task facing the Office of Medicare Hearings and Appeals (OMHA), timely redress of improperly denied payments is critical. Many suppliers, particularly in the O&P field, are small businesses that do not have the luxury of waiting months for payment of services legitimately furnished. In fact, just last year, 35 Members of Congress wrote to HHS Secretary Kathleen Sebelius that well-intentioned efforts to reduce fraud and abuse in Medicare may be harming access for vulnerable Medicare beneficiaries and placing undue burdens on legitimate O&P providers. In a context of increasingly aggressive CMS audits, OMHA's decision to suspend ALJ review of provider and supplier claims is devastating to suppliers who deliver Medicare services to over 40 million beneficiaries.

Congress showed that it understood the importance of timely processing of Medicare appeals when it included in BIPA a requirement that an ALJ issue a decision about a case within 90 days of the date when the appeal request was filed. However, by OMHA's own admission, the current wait time for a hearing before an ALJ has increased to 16 months. In some areas that wait is as long as 26 months, which is unacceptable.

At the February 12, 2014 OMHA public hearing on this issue, Judge Griswold gave an explanation of OMHA's position, but offered few if any short-term remedies that would restore the right of a timely ALJ hearing to providers. With ALJs siding fully with appellants in over half of all decisions, ALJ hearings amount to a provider's primary means of challenging costly and often prejudicial CMS auditor decisions. As OMHA is leaving Medicare providers without an avenue of redress against auditors' payment denials, we believe it is only fair that CMS suspend these audits until an appropriate, timely, and statutorily required system providing due process to providers is restored.

Surety Bonds Are Not an Answer to Fraud—They Punish All Legitimate Medicare Providers, Without Posing Any Significant Impediment to Unscrupulous Actors Who Perpetrate Medicare Fraud

Effectively fighting Medicare fraud requires implementing truly effective measures aimed at stopping unscrupulous actors and saving Medicare dollars. CMS's imposition of surety bond

requirements on all providers has been misdirected because it has little relationship to preventing fraud. These bonds burden all O&P suppliers, disproportionately affecting small O&P suppliers, but they do nothing to distinguish legitimate supplier from fraudulent suppliers. Surety bond requirements are ineffective at preventing Medicare fraud and unnecessarily penalize legitimate providers.

Legislative Efforts Relating to Limiting the In-Office Ancillary Care Exception to Stark Self-Referral Rules

AOPA has noted that the Committee on Ways and Means Subcommittee on Health Ranking Minority Member, Rep. McDermott, has introduced a bill aimed at eliminating the exception to the Stark self-referral provisions for in-office ancillary services. AOPA supports this new legislation in principle. The Orthotic & Prosthetic Alliance in recent months has communicated concerns to OIG about how, in the context of physician-owned distributorships (PODs), the in-office ancillary services rule sometimes operates and results in an increase in the number and value of services that patients do not need. However, no substantive action was taken. This provision has also prompted state legislative issues in states like Texas where it has been used by special interests to try to expand the prospects for payments to unqualified or under-qualified providers.

Prior Authorization is Not an Answer for Massive Non-Fraud RAC and Prepayment Audits That Have Hit Part B Medicare Claims for Artificial Limbs

The topic of prior authorization in terms of Medicare is a complex one. The BIG hitch is that Medicare Prior Authorization is NOT a promise of payment, and therefore AOPA and the vast majority of its patient care facility members oppose it as any kind of 'solution' to audits. CMS would be severely challenged to implement prior authorization.

CMS has unfortunately seen cookie-cutter solutions for RAC audits. Therefore, two years ago CMS said—"If a demonstration project in prior authorization was acceptable for power wheelchairs (PME) in DME, let's solve the O&P audit issues the same way." A major problem is that, in reality, the PME demo project resulted in longer delays for patients. CMS insists the numbers are shorter, but reliable reports estimate that it takes between 70-100 days from the date the physician orders a power wheelchair until the prior authorization goes through and the power wheelchair reaches the beneficiary. That kind of delay simply doesn't work for the care of amputees--who, even in the delays of the RAC environment, get their replacement limbs much faster. Prior authorization may have worked for a few limited cases in the private sector if, and only if, it is an absolute guarantee of payment (otherwise, it creates its own cash flow problems). That is not true in Medicare.

Recommendations for Reasonable Reforms of RAC and Pre-Payment Audits of Claims for Artificial Limbs for Beneficiaries under Medicare Part B

Following are proposals from the Orthotic & Prosthetic Alliance to reform RAC and prepayment audits of Part B claims for artificial limbs. These are steps that definitely would assist in restoring fairness, transparency and due process as well as greatly reducing the devastation RAC

and prepayment audits by CMS contractors has caused Part B claims for artificial limbs for Medicare amputees. They include:

a. Establish the prosthetist/orthotist's notes as a legitimate component of the patient medical record, comparable to a therapist;

b. Establish the prosthetist/orthotist as a recognized Medicare provider of care, distinguished from treatment as a DME supplier—the distinction between O&P and DME is clear both as O&P providers assume the role of lifetime mobility health professionals as well as being reflected in the much higher success rate when O&P appeals are decided at the ALJ level;

c. Remove the Qualified Independent Contractor (QIC) stage of the appeals process, since it takes time and virtually never results in a favorable decision for the O&P provider;

d. Advance the appeal more expeditiously to the ALJ for final action;

e. Mandate that CMS compile data on audit appeals for O&P only, separate from DME which is needed to track both the very high rate O&P RACs audit appeals and high overturn rate on appeal (CMS has consistently refused to track such data)*;

f. Establish financial penalties for RACs if an established percentage of appeal overturns occur, e.g. double interest penalties assessed against RAC, which funds along with savings from item C. above could be used to fund an increase in the number of ALJs; and

g. Address the need for more ALJs to mitigate the current backlog, either by direction to the Office of Medicare Hearings and Appeals (OMHA), which as an arm of HHS is responsible for funding for ALJs, or a statutory change to instruct CMS to fund ALJ appeals for RAC determinations.

* It was underscored in the May 20 hearing before the Oversight and Government Reform Committee that overturn rates at the ALJ level run between 56% to 74% provider success in overturning RAC audit conclusions.

CMS Should Issue a Moratorium on Part B RAC Audits

CMS should give serious consideration to halting RAC audits of Part B providers, especially for O&P providers. Many suppliers affected by RAC audits are small businesses like our members. They do not have the financial wherewithal to sustain their business when RAC audits and other questionable tactics to fight fraud and abuse continue unabated. We hope that this hearing shines the light also on the serious challenges faced by small providers without relief from RAC audits.

Many, including members of Congress, believe that the moratorium on RAC audits of short inpatient stays extends in some way to Part B claims for O&P. The truth is that there has been no relief whatsoever from RAC audits for Part B providers. We urge CMS to implement a similar "pause" so that it can explore fully the effect on legitimate Part B providers.

Conclusion

In conclusion, AOPA will continue to work with Congress and CMS to ensure that those who prey on Medicare beneficiaries do not find the O&P sector an easy place to establish and operate a fraud scheme. We offer our support for developing more effective means to fight Medicare fraud that does not punish legitimate suppliers who are playing by the rules. We believe that the fairest and most effective system is one that prevents fraud before it starts, and we hope that Congress will direct CMS to implement relevant provisions contained in Section 427 of BIPA and that it will pass H.R. 3112.

AOPA appreciates the Committee's efforts to work with us to find ways to better regulate our payments. We hope to continue to work with you to improve the quality of care we deliver to patients who need O&P services, and to protect the integrity of the Medicare program.