American Orthotic & Prosthetic Association

AOPA 4th Quarter 2012 Staff Report

To: AOPA Membership
From: Thomas F. Fise, Executive Director
Date: January 28, 2013

Subject: The Line of Challenges Just Gets Longer

RAC Audit Update

No let up in sight for the time demanding, cash flow-killing RAC and CERT audits and now prepayment reviews are raising their ugly head and becoming a further disruption of patient care. Region B has started to experience pre-payment reviews on every claim resulting in an uproar among the O&P community. AOPA is surveying Region B members to document the scope of the problem.

AOPA was promised a "middle ground" solution in a meeting with CMS Administrator Tavenner October 15th. She said she would announce that solution by December 1st. Her response, although not official, obligated the Administrator to implement a Rulemaking Procedure that would enforce BIPA's 427 provisions limiting reimbursements to properly licensed or otherwise qualified providers. AOPA and others in O&P have been pushing for BIPA 427 enforcement since 2002 and the AOPA sponsored Medicare O&P Improvements Act which has been introduced in the last three sessions of Congress also mandates CMS enforcement of BIPA 427.

AOPA has indicated to the Administrator – that the rulemaking solution would be fine except it will take almost a year for the process to conclude – and AOPA members need relief now!

So AOPA has made a formal request that CMS suspend any new RAC audits as well as all prepayment reviews until the rulemaking process can take effect. To date, there has been no formal response from CMS.

The AOPA Board of Directors met January 13th and discussed a host of possible actions which included a long conversation with Attorney Tom Mills, one of the few legal experts who have successfully sued CMS on behalf of providers over unfair policy issues. Mr. Mills wrote a formal letter to the CMS Administrator which stated all of the perceived breaches of proper CMS procedures and policies. That letter has been shared

with all AOPA members (copy attached). All options are on the table in the quest to return some semblance of fairness and normalcy to Medicare O&P patient care in the face of this unwarranted CMS "dragnet" on O&P claims.

Huge $100 Million Win on Exempting O&P from 2.3% Medical Device Excise Tax

Treasury released the medical device excise tax final rule and we WON! Unique among virtually all industries, O&P folks--patient care facilities as well as manufacturers--are exempt from the 2.3% tax. If there is close to $4 billion in industry sales--a $92 million tax savings PER YEAR for our members and their patients--that's good value for AOPA members' dues dollars!

It may have been a long shot initially but as AOPA met with Treasury officials, IRS representatives, legal experts and Members of Congress it became increasingly clear that orthotics and prosthetics met the law's criteria and should qualify for the exemption.

Fortunately, wisdom prevailed and the proposed regulations issued for comment by Treasury did indeed exempt O&P. Subsequent appearances at formal hearings on the proposed regulations and statements submitted by AOPA sought further clarification to make sure both supplier and patient care providers would be eligible for the exemption.

AOPA applauded the final regulations published December 5, 2012 which confirmed the exemption and clarified that both manufacturers and patient care providers qualified for it

We need to be clear that this is not a universal exemption of any manufacturer's entire product line—it really depends on whether the component goes into a finished O&P device that qualifies for exemption. If every component a company makes is used in an exempt device, then all those products would be exempt from the tax. Other manufacturers may sell some components that meet the criteria for the retail exemption and other products (e.g., non-O&P devices) that do not qualify for the exemption. They will have to pay tax on the latter products, but not as to the former ones.

Survival Imperatives Take Center Stage With AOPA Board

The RAC, CERT and prepayment audits are just a few of the actions that threaten O&P. AOPA members must face the reality that over the next few months and years, draconian measures may very well be taken to achieve real deficit reduction. Policy makers may conclude that the only way those reductions can happen is to spend less and bring expenditures closer in line with incoming revenue, and that surely means entitlements like Medicare and Medicaid are going to feel pain. Without Congressional intervention sequestration which mandates automatic cuts across the board in almost every area – 10% for most, limited Medicare cuts to a more modest 2% will take effect March 2. But in the usual last minute band-aid solutions that Congress and the Administration are famous for now, there is the constant danger that O&P and other health care providers may be facing a reshifting of the rule to override the 2% Medicare boundary which would trigger much greater fee reductions.

On top of these threats, competitive bidding for all Orthotics and Prosthetics has been touted by the Center for American Progress (CAP) in a recent New England Journal of

Medicine article authored by a notable group of physicians. They claim Medicare can save $38 billion by shifting policy so that every medical device paid for by Medicare is acquired via competitive bidding. AOPA and the Amputee Coalition (AC) responded with a joint letter to all Members of Congress pointing out that custom O&P medical devices require so much customizing to the patient's individual needs by a provider they trust and who understands those needs that any expansion of competitive bidding for O&P would severely disrupt patient care. AOPA and AC pointed out to the legislators that this individual patient care is what would be lost if the CAP recommendations were adopted and prosthetics and custom orthotics were treated like a cane or a walker.

To meet these and other threats and to anticipate coming trends in private sector health plans, last July the AOPA Board identified several critical areas that pose the greatest risk for the O&P community and created specific responses to deal with each. Research or more specifically, the lack thereof, in some form runs through most of these survival challenges and it's this fluidity that spawned the "stream" concept to identify each needed response areas.

Stream 1 addresses the need to develop a longitudinal patient database, with collection of uniform patient intake data to track treatments and outcomes and then funnel the collection process through some of the large existing O&P database systems providers as well as other providers.

Stream 2 envisions the development of a series of best practices/practice guidelines and targeted two specific areas as a starting point. Awards to Chief Scientist/Principal Investigators have already been made to perform systematic literature reviews on (1) orthotic management of post-stroke patients; and (2) post-amputation care of transtibial amputees. The stroke topic was awarded to Marcus Besser, Ph.D of Thomas Jefferson University in Philadelphia and the post-amputation care of transtibial amputees went to M. Jason Highsmith, PT, DPT, PhD, CP, FAAOP of the University of South Florida in Tampa. These scientists will provide the tools, including evaluation of the levels of evidence in the literature, to facilitate the work of soon-to-be announced expert panels and reference groups who will be charged to write the best practice documents. This initial research will lay the foundation for tracking episodes of care and practice standards to support the evidence based practice care that payors are demanding. James Campbell, PhD, CO, who fills the newly created Clinical Director seat on the AOPA Board, and AOPA immediate past president, Tom DiBello, CO, FAAOP are co-chairs.

Stream 3 has the objective of identifying and prioritizing a range of important unanswered research questions and determining how to achieve valid, verifiable evidence on the questions. Potential options include securing retrospective data from the Medicare database and other sources, seeding new clinical studies or commissioning additional comparative effectiveness research studies. In this regard, this stream dovetails into the other streams, especially Stream 1 and 2 by gathering information in needed areas. The initial step undertaken has been to try to tweak meaningful information out of the Medicare database which is now being analyzed by consultant, Dobson DaVanzo, commissioned by the Amputee Coalition to conduct this research which is funded by AOPA. The firm obtained a database from Medicare that contains a four year tracking of 100% of Medicare O&P episodes of care. Preliminary data runs show early O&P

intervention paid off in reducing longer range patient care costs. Anita Liberman-Lampear, MA, AOPA's vice president-elect, is the stream leader for this survival imperative.

Stream 4 addresses the critical issues related to payor awareness of the contributions O&P makes to restoring mobility and ultimately lowering payor costs for many of their insureds or Medicare/Medicaid beneficiaries. As our research efforts bear fruit we need the channels to get this information to insurers and policy makers. A multi-pronged education effort will target key decision makers at major insurance companies and at the federal/state health care level. Scott Schneider, AOPA Supplier Board Member, heads up this imperative.

Stream 5 identifies the alliances O&P can develop and leverage to help understand and master the myriad of health care delivery models emerging under the Affordable Care Act as well as delivery models being introduced at the state level. Exploring potential alliances with similarly situated providers can help reduce the threats to smaller areas of health care, like O&P, if they can find common ground in how the care is delivered and reimbursed. The leaders of Stream 4 and 6 teamed up with Stream 5 leader, Michael Oros, CPO, to develop a survey instrument that will deliver information enabling each of these three streams to share a common data source in their efforts to fully develop their own survival imperatives.

Stream 6 is exploring how O&P can explore some of the risk sharing tied to reimbursements and find ways that quality of care can be measured more reliably to predict the most patient/provider friendly care models. Michael Hamontree is providing the leadership for this stream.

AOPA Policy Forum – March 12-13, 2013 Is Your Last Chance Effort
Bring a Patient to Make the Case for O&P Care

Fears are rampant that pressure cooker Congressional/Administration negotiations over the deficit, budget authorizations , massive government spending cuts under sequestration and a host of other issues may produce some distasteful and bitter consequences for AOPA members and their patients. To try and quell some of the potentially most damaging consequences, AOPA has advanced the date of the 2013 O&P Policy Forum from the usual mid-April dates to mid-March. The advanced timetable anticipates that much harm could happen to O&P before the end of March. Despite some respite on the debt limit until May, there still remains a laundry list of issues that could adversely affect O&P patient care that might be acted on before the end of March. That's why all stops are being pulled to convince AOPA members that only patient/provider face-to-face meetings with legislators and their staff will provide an opportunity to make the case for O&P patient care. The irrational documentation requirements, the RAC, CERT and prepayment audits, competitive bidding and budget cuts represent more survival threats at any one time that O&P has ever witnessed before.

The AOPA Policy Forum is your best opportunity to weigh-in and try to impact these policy aberrations which are threatening the existence of your business -- you should consider attendance mandatory, not optional.

Make plans now to attend and bring a patient using the enclosed Policy Forum Registration form or go online to www.AOPAnet.org, select the Legislative and Regulatory menu and click on Policy Forum. Briefings by AOPA lobbyists and Members of Congress will occur on Tuesday, March 12th beginning at 1 p.m., followed by a dinner event. Appointments Wednesday, March 13th are all arranged by AOPA staff and lobbyists; talking points will help you educate your legislators; and leave behinds will encourage staff members to keep the issue front and center for their member. Real stories make the most effective impression and that's why AOPA so strongly encourages every member to bring a patient who can put a human face on the risks to care patients face by Congress tampering with O&P patient care. The registration fee for patients brought by members is only $25 compared to the regular registration fee of $125.

Just a reminder – these visits during the Policy Forum do make a difference. The O&P exemption from the 2.3 percent Medical Device Excise Tax is a case in point and might not have happened but for the efforts of AOPA members during the 2012 Policy Forum!

World Congress Makes Hoped for Global Impact

The list only grows longer of the global partners who have joined with AOPA in creating and sponsoring the O&P World Congress in Orlando, Florida, September 18-21, 2013 at the Gaylord Palms Resort. This event was inspired by the Orthopadiet Reha-Technik, the very successful Leipzig show sponsored by the German Association of Orthopaedic Technology. This event so impressed AOPA leadership four years ago that exploration began as to whether a counterpart event could be staged in the western hemisphere. Enthusiastic support soon emerged confirming the potential global impact. AOPA and the German sponsor of the Leipzig meeting, Con.Fair.Med, were soon joined as co-sponsors by the U. S. National Member Society of ISPO, the Amputee Coalition and the Canadian Association of Orthotics and Prosthetics. Several more global partners are expected to add their prestige to this event.

Members of the World Congress Planning Committee from more than twelve international organizations headed by David Boone, PhD, CP, MPH, have already mapped out a speaker's roster that reads like the Who's Who of global O&P.

Keynote speakers include Dr. Yshiyuki Sankai, an inventor, creator and driving force behind robotics. He serves as a professor of the Graduate School of Systems & Information Engineering at the University of Tsukuba, and as president and CEO of CYBERDYNE Inc. Another highlight will be the presentation from another world leader in the field, Jan Geertzen, MD, PhD, President of the International Society of Prosthetics and Orthotics. The World Congress will also inaugurate the first International Lifetime Achievement Award that will honor and recognize the accomplishments of a significant global personality who has helped shape the world of O&P.

Registration is now open by visiting AOPA's web site www.AOPAnet.org and selecting the education menu and clicking on the 2013 World Congress.

Update on the Legislation and Regulatory Scene

A new 113th Congress means all legislation goes back to "go" and new bills must be introduced in this Congress. AOPA is lining up support for re-introduction of the O&P Medicare Improvements Act which has been a mainstay of AOPA legislative efforts since 2008 when first introduced by former Representative Shelley Berkley who lost her bid for a Nevada Senate seat in the last election. The bill would save Medicare hundreds of millions of dollars by reducing fraud and waste while simultaneously improving the quality of patient care. The Insurance Fairness for Amputees Act will be another priority and the effort is on to secure a Republican Senate co-sponsor to join with Sen. Harkin (D-IA) replacing retired Sen. Snowe as the bill's other bi-partisan co-sponsor. The Injured and Amputee Veterans Bill of Rights is another candidate for re-introduction.

AOPA met with Dr. Lucille Beck, Chief Consultant (Acting) Prosthetic and Sensory Aids Service, Dr. Joseph Webster, National Director of Amputation System of Care and Dr. Joe Miller, National Program Director for Orthotic and Prosthetic Care, of the Veterans Administration October 9th to clarify the patient choice issue and other areas of potential collaboration. A significant source of contention has arisen with the assertion by some VA officials claiming a 1985 legislative provision directs care to be delivered at a VA facility unless outside providers are specifically authorized by the VA. This policy claim contradicts other understandings of patient choice in the O&P community and the House Veterans Affairs Health Subcommittee is raising questions on the VA interpretation.

To further document the October 15th meeting with CMS Acting Administrator, Marilyn Tavenner, AOPA presented three recommendations: (1) stop denying the entire claim and instead deny only items within a claim which are being questioned; (2) stop prepayment audits; and (3) recognize that the referring physician is not the likely "go to" provider for an amputee who has a problem or needs a replacement prosthesis. The referring physician is very often the surgeon who performed the amputation who very likely has little working knowledge of the elements of prosthetic patient care after the amputation. As noted earlier in this report, CMS did promise a rule making process to implement provisions of BIPA 427, an action long overdue, which is something the proposed O&P Medicare Improvements Act would mandate.

AOPA also filed a statement of comments under the essential health benefit regulations with the Department of Health and Human Services expressing concerns about state efforts to implement health care insurance plans again urging that plans selected include O&P coverage. The statement emphasized Congressional intent that O&P benefits be included. Two statements filed with the Food and Drug Administration related to (1) the Unique Device Identifier System, and (2) requesting amplification of the custom device rule exemption in the statute as applying to O&P devices.

New Research Center May Offer Opportunities for O&P Research Funding

The Patient Centered Outcomes Research Institute is a new private entity created by Congress in the Affordable Care Act and funded by payments from insurance companies. PCORI held a meeting December 4th to which AOPA was invited as one of three O&P stakeholders that sought to identify issues to study and fund. AOPA held a follow up

meeting December 20th with the PCORI Deputy Director and other officials to further explore any common research interests and opportunities.

Further AOPA Research Projects Advance the Agenda

The final report on the comparative effectiveness study involving dynamic and non-dynamic prosthetic feet conducted by the British Columbia Institute of Technology (BCIT) has been completed but results won't be released until the researcher has published results in a peer review journal. AOPA has requested an abstract summarizing the research findings.

Another research project on microprocessor controlled and non-microprocessor controlled knees has experienced some delays but continues to move forward.

Both studies are jointly funded by manufacturers and AOPA.

Northwestern University was awarded a grant to evaluate and validate the methodology of the Manufacturers' Foot Research Project which was presented to CMS more than two years ago and recommended L Codes for prosthetic feet based on product characteristics.

PAC Donors Making the Difference in O&P Advocacy

President's Circle ($1,000-$5,000) Michael J. Allen, CPO, FAAOP; Robert E. Arbogast; Kel M. Bergmann, CPO; Maynard Carkhuff; Ronald Cheney; Thomas V. DiBello, CO, LO, FAAOP; Mike Fenner, CP, BOCO, BOCP; Rick Fleetwood, MPA; Michael Gozola, CP; Russell J. Hornfisher, MBA, MSOD; Harry W. Layton, CPO, LPO; Jon P. Leimkuehler, CPO, FAAOP; Robert V. Leimkuehler, CPO; Mark T. Maguire, CPO; Gary Mahler; Patricia Petersen; Walter Racette, CPO; John A. Roberts, Jr., CPO; Scott Schneider; Gordon Stevens, CPO, LPO; Paulette Vaughn; Bernie Veldman, CO; Frank Vero, CPO; James Weber MBA; James O. Young, Jr., CP, LP, FAAOP.

Senator's Table ($500-$999) J. Martin Carlson, CPO, FAAOP; Glenn Crumpton, CPO, C.Ped.; Edward De LaTorre; Ed H. Gildehaus, III, C.Ped., CPO, FAAOP; Michael E. Hamontree; Alfred E. Kritter, CPO, FAAOP; Ellen Leimkuehler; William J. Leimkuehler, CPO, LPO; Marlon Moore, CO; Ted Muilenburg, CP, LP; Rodney M Pang, CPO, Gerri Price, CFom, C.Ped.; Ashlie White; Jeffrey J. Yakovich, CO.

Chairman's Table ($100 - $499) Rudy Becker, Sr.; Robert Biaggi, CPO; Jeffrey M. Brandt, CPO; George Breece; Terri Bukacheski, CP, LP; Alan R. Burke, BOCO; Erin Cammarata, RTO; Kenneth Cornell, CO; Charles H. Dankmeyer, CPO; Don J. DeBolt; William A. DeToro, CPO; Mark F. Devens, CPO; Martin Diaz, BOCO, C.Ped.; Ted Drygas, CPO; David Falk, CPO; James Fenton, CPO; Michael Hall, CPO, C.Ped.; Joseph Huntsman, MBA, MA; Fran Varner Jenkins; Marc N. Karn, CP; John M. Kenney, CPO, FAAOP; Thomas Kirk, Ph.D.; Eileen Levis; Pam Lupo, CO; Ann Mantelmacher; Lee Mantelmacher, CPO; Clyde Newton Massey, CPO; Brad Mattear, CPA, CFo; Steve McNamee, CP, BOCO, FAAOP; Steven A. Mirones, CO, C.Ped., FAAOP; Michael Oros, CPO, LPO; James Price, Jr., Ph.D., CPO, C.Ped., FAAOP; John Ruzich, CP, LP; Mark Smith, CP; Chris Snell; Peter Thomas, Esq. Joan Weintrob, CPO; Steve Whiteside, CO, FAAOP; Jon D. Wilson, CPO; Claudia Zacharias, MBA, CAE.

1917 Club (Up to $99) J. Laurence Allen, CPO; David Bow, CPO; Jim Campbell, Ph.D., CO, FAAOP; Maureen Canter; Frank Caruso, CO; Melvin Cunningham; Joe Davant; Jason Eddy; Jeff Erenstone, CPO; Troy Fink; John Galonek, CO; Carey Glass, CPO, FAAOP; Eddy Gosschalk, CPO; Garrett Griffith; April Groves, CO; Rita Hammer; David A. Johnson, CO; Rahul Kaliki, Phd; Paul Macy, CPO; Salvatore Martella, CPO; Kathy Mascola, CPO, BOCO; Kevin Matthews, CO, LO; Sean McKale, CO; Nina Miller; George Newton, CPO; Daryl Reuter; Eric Schopmeyer, CO; Anthony J. Squicciarini, CPO, C.Ped.; Jeff Wensman CPO.

Special Support Group – ***Each year, the O&P PAC organizes fundraising events for members of Congress who have been supportive of O&P. For each event AOPA members make a personal contribution to the member's campaign and spend time with the member talking about a variety of issues including health care and the provision of O&P. These events are a unique way to share O&P concerns, get to know a member of Congress and get a congressional update, and have been very successful in getting Congress to understand O&P concerns. Also, each year the O&P PAC sponsors events which allow AOPA members to learn more about the activities of the PAC, and provides them with the opportunity to get involved. We would also like to thank those individuals who have donated directly to a candidate's fundraiser or to an O&P PAC sponsored event are valuable supporters in achieving the legislative goals of AOPA and the O&P PAC.***

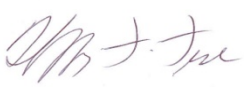
Rudy Becker, Sr.; Kel M. Bergmann, CPO, Frank Bostock, CO; Brightree, LLC; Kendra Calhoun; Jim Campbell, PhD, CO, FAAOP; Luis Carbajal; Maynard Carkuff; Thomas J. Costin; Don DeBolt; Thomas V. DiBello, CO, LO, FAAOP; Thomas F. Fise, Esq.; Rick Fleetwood, MPA; Nancy Gagne; Richard & Marbee Gingras; Eddy Gosschalk; Catherine Graf, Esq.; Paul Gudonis; Darlene Hall, C.Ped.; Michael Hamontree; Hanger PAC; Russell Hornfisher, MPA, MSOP; Joe Huntsman, MBA, MA; James Kaiser, CP, LP; Marc Karn, CP; Patricia Kaviani; Steve Kelly; Mark Kenney, CPO; Tonya Kettering; Tom Kirk, Ph.D; Anthony Korjagin, CP; Alfred E. Kritter, CPO, FAAOP; Terri Kuffel, Esq.; Scott Langston; Robert V. Leimkuehler, CPO; Jon P. Leimkuehler, CPO, FAAOP; Eileen Levis; Anita Liberman-Lampear, MA; Pedro Llanes, CPO; Ronald Longo, CP; Pam Lupo, CO; Alexander Lyons, CPO; Catriona Macdonald; Ron Manganiello; Ann Mantelmacher; Mollie Matthews; Megan Matjevich; Doug McCormack; Joe McTernan; Steven A. Mirones, CO, C.Ped.; Tina Moran; Dominique Mungo; Michael Oros, CPO; Ed Peguero, BOCO; Patricia Petersen; Anthony Potter; Proteor; Walter Racette, CPO; Rick Ramos, CP, LP, C.Ped.; John Roberts, Jr., CPO; Luke Rogers, CO, BOCP; Rick Riley; Bradley N. Ruhl; Joyce Schlemmer; Scott Schneider; Brian Smith, BOCO; Chris Snell; William C. Snell, CPO; Jan Stokosa, CP, FAAOP; Peter Thomas, Esq., Randall Valverde; Frank Vero, CPO; Ben Walker, BOCPO, LPO; James Weber, MBA; Ashlie White; Daryl Williams; Connie Withers; James O. Young, Jr., CP, LP, FAAOP; and Claudia Zacharias, MBA, CAE.

And In Conclusion

We made such a strong pitch for you and a patient to attend the 2013 Policy Forum because we are convinced that much mischief can happen that can have an incredibly adverse impact on your business and the health and welfare of your patients. Please, if you can do anything to advance your prospects for survival this year, put your Policy Forum attendance at the top of the list.

The rest of the AOPA staff joins me in extending the deepest thanks and appreciation for the tremendous loyalty you and our other members confirm every year through their renewal. Few associations in any field enjoy a consistent 95 percent renewal rate and that's why it is so special for all of us to serve you and your patients. We know you care.

Sincerely,



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Dear Administrator Tavenner:

I write on behalf of The American Orthotic & Prosthetic Association (AOPA) to follow up on the several meetings they had with you and your staff this past year. AOPA is writing on behalf of its approximately 1,900 -- member/patient care facilities who are licensed and certified suppliers of orthotics and prosthetics to Medicare beneficiaries. Most recently AOPA met with you on October 15. Before that, AOPA met with you on April 16, 2012.

In the meetings and correspondence AOPA has brought to your attention the unlawful and unfair requirements which have been used by CMS, DME MAC's and RAC auditors to delay and deny or recoup payments (and interest) for prosthetics provided to Medicare beneficiaries. The requirements have caused serious harm to its members and Medicare beneficiaries who are amputees.

The primary cause, but certainly not the only cause, of the harm to AOPA's members and their Medicare beneficiary clients, is the unlawful imposition of conditions to payments for prosthetics by the DME MAC's. These conditions are set forth in the attached "Dear Physician Letter" issued August 11, 2011 by the DME Medicare Administrative Contractors for the Centers for Medicare & Medicaid Services.

By its terms the "Dear Physician Letter" adopts a detailed ladder of "functional capabilities…crucial to establishing the medical necessity for a prosthetic device" and, for the first time, adopts the requirement that the physician referring the patient amputee to the prosthetist have, in the physician's medical record, extensive information previously supplied by the prosthetist and occasionally

supplemented by the prosthetic device supplier. As explained in the several meetings, the "referring physician" is generally the surgeon who performed the amputation. That surgeon is not the amputee's primary care physician, typically has no continuing physician-patient relationship, and no particular expertise in the highly technologically complex workings and mechanics of fitting, fabricating or repairing modern prostheses.

Therefore, the surgeon would not generally have the plethora of detailed information now required by the RAC's in their patient record. The prosthetist and the prosthetic device supplier have the expertise and are in better position than either the surgeon or primary care physician to document medical necessity. By adopting these detailed conditions purporting to define "medical necessity", the DME MACs foreclosed payments, and/or provided a basis for attempts undertaken and completed by CMS' contractor audit personnel to secure recovery of payments already made, without lawful authority.

The K-0 to K-4 functional capability ladder has never been the subject of notice and comment or any other requirement of the Administrative Procedure Act (APA). DME MACs cannot be delegated rule-making authority by CMS. However, even if they could, they cannot, as CMS cannot, lawfully avoid the mandate of the APA which commands that any rules promulgated by an agency be published in the Federal Register in advance of their effective date and be subject to comments by the interested public. When Congress delegates to the Executive the authority to implement parts of the Medicare program the law requires that the rules adopted be reasonably tailored to effect the lawful purpose for which intended. *Manhattan General Equipment Co. v. Commission of Internal Revenue, 297 U.S. 192, 134-135 (1936); Bowen v. Georgetown University Hosp., 488 U.S. 204, 208 (1988).* The notice and comment requirements of the APA are integral to that purpose.

These "rules" purportedly adopted by the DME MAC's are arbitrary, capricious, unreasonable, adopted without lawful authority, not tested by the provider and beneficiary public whom they affect, and therefore unlawful.

Worse, the RAC auditors have, as you have been told, imposed these unlawful requirements even with respect to goods and services provided before the issuance of the "Dear Physician Letter", i.e. those requirements have been given retroactive effect. Attached hereto are four files (for example only) where RAC auditors have given retroactive effect to the changes adopted by the "Dear Physician" letter. Moreover, even despite giving retroactive effect to vague and unclear rules governing adequate documentation of medical necessity, the RAC denial is exacerbated by its failure even to tell the beneficiary or supplier <u>in what manner</u> the documentation falls short. The law is clear in the United States that no regulation may be given retroactive effect to deny a claim, lawful when submitted. *Bowen, supra.* That the "regulation" is not even arguably lawful to begin with, because of its utter noncompliance with the APA, makes the harm all the more egregious.

CMS should develop a process - - perhaps penalties for recurrent wrongful disallowances - - by which it reviews the RACs to assure that their own financial interests do not

corrupt the objectivity and accuracy of their audits. The Recovery Audit Contractors are paid based upon a percentage (reportedly as high as 12%) of the claims denied during the audit process. Accordingly, the RACs have a financial incentive to deny lawful claims on even the most specious grounds because they benefit financially in doing so. I call your attention to the HHS Office of the Inspector General Compliance Program Guidance for Third-Party Medical Billing Companies, published in the Federal Register on December 18, 1987, which condemns contingency fees for companies who bill Medicare on behalf of Medicare Providers and Suppliers, 63 Fed Reg 70143 et seq. Those concerns were repeated and reinforced in two OIG Advisory Opinions, 98-1 and 98-4. "This Office has a longstanding concern that percentage billing arrangements may increase the risk of upcoding and similar abusive billing practices." Accordingly, while RACs may lawfully be paid contingency fees, CMS' failure to supervise the RAC, knowing of the inherent incentive to generate their own fees to the detriment of the provider supplier and Medicare beneficiary community, is unacceptable.

The OIG, in its 2012 Work Plan, and its August 2011 report titled "Questionable Billing by Suppliers by Lower Limb Prostheses" concluded that there were a high number of questionable billing practices by O & P Suppliers based largely upon failure to fulfill the physician documentation requirements. It did not, to our knowledge, examine the lawfulness of those requirements, the retroactive application of those requirements, nor the financial interests in the RACs seeking to recover claims for non-compliance with requirements which were not even published at the time many of the claims were submitted. Nor, to our knowledge, did OIG find actual abuse in the form of unnecessary prescriptions. It instead found only, statistically higher cost for prostheses, which it equated with abuse, even though the higher cost is likely attributable to the increased sophistication of prostheses. That led OIG to conclude that the long-standing practice of the physician signing a written prescription for the device (no different than a written prescription for, say, narcotic medications) was itself now deigned insufficient, and that it needed to be supplemented by additional extensive records, burdensome for the prosthetist or the patient to secure or supply, to provide still further evidence that the amputee Medicare beneficiary needs the device.

Thus, as AOPA has shown, the documentation requirements seem designed to assure they cannot be met, rather than to provide a practical and reliable basis to prove medical necessity and additional validation of the already existing written prescription. Of course these points would have been made had there been a notice and comment rule-making in accordance with the APA and likely would have resulted in different rules which would have both satisfied CMS' concerns for medical necessity and adequate documentation, while not devastating the industry.

Unfortunately, this is one episode in a pattern of abuses in which the agency, through its contractors, has initiated actions that are without statutory authority, in violation of the APA, or in violation of due process rights of providers, patients and other interested parties. (A) Jurisdiction B has invoked broad-based, virtually universal pre-payment audit policies as to orthotic and prosthetic devices interdicting payment entirely providing neither a single dollar as fair compensation for devices and services provided, nor

promulgating standards of such review. (B) These same DME MACs have ventured into setting product design specifications for ankle-foot orthoses (AFOs) setting required heights and measures—they have statutory authority **only** to define the device for coverage purposes, but **no statutory authority to announce, ab initio, what amount to design standards** which confine current and future scientific and medical advances (FDA, which has greater statutory authority over medical devices than CMS, itself wisely refrains in 21 CFR 890.3475 where it defines "limb orthosis" (and AFO would fall under that definition) from setting any design/dimensional product markers for AFOs). (C) CMS continues to operate the process for securing/setting new HCPCS codes each year via a mechanism completely absent either fair, valid APA protections and without even the most minimal due process protections, despite multiple meetings and requests for such protections.

In its meeting with you in October 15, AOPA again requested direct and immediate remedial action to stop the devastating harm (not the least being extraordinarily serious cash flow interruption and reversals which have and continue to force long-standing and legitimate Medicare prosthetic providers to go out of business for economic reasons) being done to its members by the series of unlawful and unfair acts outlined above. This letter then memorializes and restates the claims of AOPA and its members and requests that CMS immediately declare the purported requirements of the "Dear Physician Letter" be of no effect, halt the series of pre-payment audits which have been instituted by the DME MACs in some, but not all jurisdictions, direct the RAC's to cease using those requirements in assessing the sufficiency of physician documentation for claims submission purposes, to direct that all proceeds from all RAC and pre-payment audits conducted under there invalid standards articulated in the Dear Physician letter, i.e., each and every audit of prosthetic providers initiated since August 28, 2011 be returned in full to the prosthetic provider to whom those Medicare funds were originally paid, and to undertake a lawful rulemaking providing notice and comment to the affected public which would result in lawful rules with prospective and not retroactive effect. And further that CMS establish due process rights as to code decision/assignment and related processes, and that the agency reverse DME MAC actions to invoke product specifications for AFOs or other types of orthotic and/or prosthetic devices (as to which neither CMS nor its contractors has any statutory authority) under the guise of defining devices for coverage/payment.

Sincerely,

Thomas L. Mills
Attorney for AOPA