



**American Orthotic &
Prosthetic Association**

AOPA 2nd Quarter 2011 Staff Report

To: AOPA Membership

From: Thomas F. Fise, Executive Director

Date: July 15, 2011

Subject: New Threats Abound

Last year about this time concerns revolved around how the new health care law would be implemented and how O&P would be affected. One year later there are few answers and even more questions. The definition of “essential health benefits” awaits action from the Secretary of Health and Human Services who is charged with writing that definition and the push continues to make sure that O&P is included. Sen. Harkin (D-IA) gave reassuring comments at last year’s Policy Forum that O&P would be included – but that still remains to be seen. This year’s Policy Forum triggered interest from several legislators who were visited by AOPA members who explained the importance of O&P care being included in the definitions of “essential health benefits.” Some legislators followed up with letters to HHS Secretary Sebelius urging O&P inclusion in the definition.

One year ago we saw the tip of the iceberg on state Medicaid cuts with California and Arizona leading the parade in proposing beneficiary eligibility cuts that have frequently included O&P reductions. O&P dodged the bullet in California but Arizona passed a law prohibiting orthotic care and microprocessor prosthetics for those over age 21. The Arizona O&P community is pursuing a quiet strategy to try to overturn the law. On the heels of those threats came a proposal from the outgoing governor of Nevada proposing Medicaid cuts that would affect O&P patients. Nevada O&P professionals and AOPA moved quickly, and fortunately, the new governor wisely did not pursue making those cuts.

Minnesota saw a similar threat and also succeeded in stifling proposed cuts but Texas, where O&P and others are targeted for double-digit payment cuts, is now one of the most important battle fields with a rally of the O&P community on the capitol steps planned for July 12, the same day as hearings on the cuts. In all of these efforts, AOPA has been able to play a supporting role by providing guidance, specific advocacy materials such as testimony, billboards, print ads, editorial placement, and sample letters to patients and legislators.

The continued threat of broad scale Medicaid cuts prompted AOPA to fund development of a highly emotional and hard hitting 30 second Public Service Announcement that was sent to some 4,000 television stations in late June. The PSA, AOPA’s first-ever TV ad, depicts an amputee returning his prosthesis to a state Medicaid office in exchange for a crutch.

The viewer audience is expected to exceed 2 million and the Amputee Coalition joined with AOPA to sponsor distribution of the PSA. Go to www.LimbsAreEssential.org to view the commercial and then click on the "Take Action" button to generate letters to your local media, members of Congress, your Governor and Lt. Governor. It takes about two minutes for you, your employees and/or your patients to make this happen.

Another Threat Looms from the Food & Drug Administration

As if there weren't enough threats on the horizon from Medicaid cuts, O&P patient care facilities, including a few AOPA members, have selectively been singled out by investigators from the Food & Drug Administration (FDA) to ascertain whether they are considered manufacturers and must comply with the FDA's Good Manufacturing Practices regulations. Those facilities offering central fabrication services seem to be in the forefront of investigator interest.

All AOPA member companies, both patient care facilities and suppliers, have received in the mail a 52 page [FDA Compliance Manual](#) to provide a basic understanding of FDA's authority over medical devices, details on Good Manufacturing Practices regulation compliance and what to do if an FDA investigator appears on the premises to conduct an investigation and why AOPA believes FDA's rule does not apply to O&P patient care. The manual was prepared by AOPA staff and the contents were reviewed by FDA experts Paul Kim and Jim Flaherty, FDA counsel with the law firm of Foley Hoag. The firm also serves as legislative counsel to AOPA.

New Information Source on AOPA Issues and Services Important to You

A monthly letter from yours truly is a new, single-issue communications tool spotlighting a topic AOPA is working on that is important for the future of your business. The first in the series was an enclosure in the mailing with the FDA Compliance Manual and singled out O&P inclusion in the definition of "essential health benefits," why it is critically important and what AOPA is doing to make sure we're included. The next issue will deal with the state cuts in Medicaid and what AOPA is doing to combat that threat to patients and your reimbursements.

Essential Benefits Definition Now Main Event

A lot of patient access and O&P business issues ride on the definition of "essential health benefits" in the implementation of the Affordable Care Act. That's why AOPA has been so aggressive in pursuing this issue including debunking a flawed Department of Labor report on the prevalence of O&P coverage in employer insurance programs.

The Secretary of Human Health and Services, Kathleen Sebelius, is responsible for defining what services are covered. The O&P community has a huge stake in who will have access and whether providers are paid under the health care reform law.

By way of history, the House of Representatives passed a version of the new health care law that specifically spelled out that O&P and several other services are an essential benefit. The Senate passed a version that was less clear, including "rehabilitative and habilitative services," delegating defining essential benefits to the Secretary of HHS and requiring the Department of Labor (DOL) to conduct a study on coverage offered in employer health plans to provide some guidance to the HHS Secretary as to what should be included in the definition. As required, the DOL presented a study to HHS but it did not conduct a new study, relying instead upon historical data it already possessed which in itself was suspect in the manner in which it was collected. The information on O&P was particularly surprising and potentially damaging. The DOL study found that less than 50 percent of the employers in their report offered O&P benefits.

That was contrary to a February 2011 independent study conducted by the Society of Human Resources Management (SHRM) which found that on average 75 percent of employer health plans offered O&P

benefits. That study also coincided with a seven major metropolitan area study of big employers conducted by AOPA which also found a 75 percent prevalence of O&P benefits.

AOPA delivered a letter and a packet of materials to Secretary Sebelius pointing out the flaws in the data and the methodology used by DOL and furnishing results of the SHRM study commissioned by AOPA along with AOPA's own study of the seven-city, large employer survey results.

AOPA and other O&P efforts resulted in a letter of support from Rep. Rob Andrews (D-NJ) and supporting statements in the Congressional Record by Rep. Pascrell (D-NJ) and Rep. Miller (D-CA) which were also included in the package sent Secretary Sebelius. In mid-July, AOPA is meeting with HHS officials who are writing this rule. The AOPA Policy Forum member visits to their legislators also paid off in triggering several letters from Members of Congress to the Secretary urging that O&P be included in the definition.

An Intensified Focus for AOPA

While the essential benefits issue may be the main event for the next few months, there will be a myriad of other regulations written to implement the Affordable Care Act. To make sure AOPA is ahead of the curve in how the regulations are written, AOPA's Board of Directors authorized adding a new staff position – the Director of Regulatory Affairs. Joining the staff in that role is Catherine Graf, JD, who brings solid CMS experience from her prior position in the HHS Office of General Counsel and before that as a law clerk with the U. S. Federal Court of Federal Claims. Catherine played a key role in producing the recently distributed FDA Compliance Manual.

Rumors of Orthotic Off-the-Shelf Products Included In Competitive Bidding

AOPA's Executive Committee and Board of Directors will be deeply involved in devising the appropriate strategy to respond to the possibility that a range of orthotic products may be included in the CMS Round II competitive bidding list. In fact, AOPA's lobbyists were provided a CMS report claiming that value of orthotic products under consideration of about \$200 million suggests CMS has gone far afield from Congress' definition of off-the-shelf orthotics as limited to devices usable by patients with "minimal self adjustment" to consider a much broader array of products. Under the DMEPOS competitive bidding program, the list that CMS publishes is final, with no opportunity for comment or to recommend changes. AOPA and the O&P Alliance have pulled out all stops to get the message to CMS that their "too broad a list" is not legal and would harm patients. All means of recourse, even to the extent of litigation, are being weighed.

What's even more troubling is the likelihood of "business opportunities" cropping up such as the one conveyed to several AOPA members by a non-O&P company which has experience with CMS in DMEPOS competitive bidding seeking to recruit practitioner talents to provide final adjustments to orthotic products the company sells over the Internet. An impression was also left that the company was selected in the Round II competitive bidding process which was erroneous as no Round II bidder selections have been made. Practitioners were offered a flat \$25 to provide the service and to provide the necessary paperwork offering evidence of service rendered, to assist the company in being paid.

Cost Effectiveness Research Commissioned

Patient outcomes and what treatment is most cost effective has been the vexing question facing the O&P community. Most everyone realizes as the health care system undergoes major changes – most changes will be tied to government and other payers believing they are getting their biggest bang for the buck. The absence of solid evidence will be cited as a rationale to deny reimbursement.

An RFP was issued earlier this year to retain the services of a consultant to review all available data, including Medicare payment data, to compare longer term costs for patients receiving appropriate O&P treatment versus patients with a similar diagnosis who did not receive appropriate O&P care. The group

that went without appropriate care will then be tracked as to what co-morbid conditions may have developed and the associated costs. This study should provide a basic platform to evaluate a series of diagnoses in a care versus non-care setting to determine how cost effective proper and timely O&P treatment is for patients and payers.

AOPA is funding the research which has been commissioned by the Amputee Coalition (AC) as the primary sponsor on behalf of the patient population.

An organizational meeting with Dobson/DaVanzo, the research consultant, AOPA and AC members and two physician experts on June 9th set the basic parameters and methodology of the project which is expected to be completed in about six months.

Comparative Foot Research Grant Awarded

The British Columbia Institute of Technology was recommended by the Board of the Center for O&P Learning to receive the \$150,000 research grant to measure the comparative effectiveness of dynamic response versus non-dynamic response prosthetic feet. The research is jointly funded by AOPA and five manufacturers: Endolite, Freedom Innovations LLC, Össur Americas, Otto Bock and Willow Wood.

New Version of Parity Legislation

The Insurance Fairness to Amputees Act (S.773) has been introduced in the U. S. Senate by Sen. Harkin (D-IA) and Sen. Snowe (R-ME) and similar legislation is expected in the House by Rep. Rob Andrews (D-NJ) and other bi-partisan co-sponsors. The new title of the bill reflects the concerns about the word parity being part of the title which conveyed the suggestion of a mandate.

O&P Medicare Improvement Act Introduced

The O&P Medicare Improvements Act (H.R. 1958) was introduced in the U. S. House of Representatives May 24, 2011 by Rep. Berkley (D-NV), Rep. Glenn Thompson (R-PA) and four other bi-partisan co-sponsors to fight fraud and abuse and improve the quality of patient care. A similar bill is expected to be introduced in the Senate by Sen. Rockefeller (D-WV).

Manufacturer Coding Training Seminar July 21, 2011

How to get the right L Code for a product is a key ingredient of market success but more than one AOPA supplier member has expressed frustration as to the “how.” A CMS representative will join with AOPA experts on staff and from the Coding and Reimbursement Committee to explain the in’s and out’s of the coding application process. This first ever of its kind seminar designed especially for AOPA supplier members is at the DoubleTree by Hilton at Baltimore Washington International Airport.

Device Tax Exemption for O&P Sought

AOPA continues efforts to convince the U. S. Department of Treasury and the Internal Revenue Service that O&P patient care facilities and manufacturers should be exempt from the 2.3 percent tax mandated in the Affordable Care Act. Several other exempt product areas resemble activities of the O&P field. AOPA’s request is based on the exemption for hearing aids, eyeglasses and other similar products which are exempt and for use by a single retail customer.

2011 National Assembly at Las Vegas Mirage Resort & Casino - \$135 Per Night!

It’s been a long time since members attending the National Assembly have seen a \$135 room rate in a Four Diamond rated hotel. But the rock bottom room rate is just one of several WOW experiences that makes the September 19-22, 2011 event “The Place to Be.” The new Business Certificate Program will be launched enabling members of the O&P community to follow a carefully devised curriculum teaching key management skills to achieve the certificate. And that’s just the beginning of an education packed four days with serious networking, entertainment and all the rush and excitement of Las Vegas

at its best. Register and reserve your room early while the AOPA room block can still offer these rates. Go to www.AOPAnet.org and click on the AOPA National Assembly icon.

It's always good news to report exhibit space is sold out as has happened with our original floor plan. AOPA is seeking approval from the Fire Marshall and the Mirage to add additional booths to accommodate demand. Early-bird registration has taken off running ahead of last year at this time so all indicators are pointing toward a record event in every way.

We've included a copy of the preliminary program with this report – take a look and let us know if you have questions. We look forward to seeing you in Las Vegas!

Wine Tasting and Auction Event – Raises Money for a Good Cause!

And that good cause is the future of your business. Proceeds from the wine auction benefit AOPA's Government Relations Outreach—support for the O&P PAC, and AOPA's Capitol Connection. Quickly becoming one of the most anticipated Assembly events, the auction offers a chance to learn about and taste a variety of wines, including some made by your fellow members.

Mark your calendar for 6:30 p.m., Tuesday, September 20, 2011 to join the fun and help make a difference.

AOPAversity O&P Business Management Certificate

Our member survey of last December pointed to the ongoing need for more management skills education opportunities. To respond to that need a dedicated group of AOPA volunteers is creating a new Business Certificate program that will be unveiled at the 2011 National Assembly. The AOPAversity O&P Business Management Certificate is a comprehensive certificate program that will offer a series of business and management seminars (12 Modules) providing business owners, managers and practitioners of O&P practices, O&P Manufacturers and Distributors an opportunity to explore crucial business challenges – from finance, sales and marketing to business operations and management. The AOPA Business Management Certificate Program will be similar to non-degree continuing education programs that universities offer in conjunction with their business colleges. These programs will be offered at the AOPA Assembly each year, Online at AOPA's Website and at targeted seminars throughout the country (such as the Coding Seminar). The AOPA Business Certificate Program addresses skills that are fundamental to the success of an O&P business. This unique leadership learning experience will provide business owners and their employees an opportunity to experience fresh insights, new tools and proven techniques as a pathway for developing better business practices, in addition to creating ongoing returns for your company.

The AOPA Business Certificate Program will focus on four subject areas: Management, Sales and Marketing, Finance and Operations, with designated required and elective Modules within each of the four subject areas. The participants of the program will receive a certificate of completion once they have completed eight of the Business Program Modules and passed a Module specific quiz.

Don't miss the opportunity to be the first to participate in AOPA's new Business Certificate Program. Take the first step in earning your business certificate by attending the extensive 2-hour course "Financial Management Profitability Tools— Using Cost Accounting to Maximize Your Practice's Profitability" at the AOPA National Assembly. Benefits to attending this course at the Assembly include:

- No extra charge for Assembly attendees
- Free comprehensive workbook
- Your first step in earning a certificate in O&P Business Management
- Learning to develop an operations and financial budget
- Learning to determine the financial impact of a proposed discount

- Learning to create payer presentation strategies
- Learning what operational strategies you should consider
- And much more!

2011 Thranhardt Golf Classic

Two Great Causes and one great course make it not just golf, but a golf experience. For the third year in a row AOPA's Capitol Connection and OPAF have joined forces to co-sponsor this great event to benefit the inspiring efforts of OPAF and the legislative, research and education efforts of the Capitol Connection to further the O&P policy agenda.

Missed your invitation to play in the British Open? Not to worry. You can still play 18 of the best holes from 11 different British Open rotation courses, including two holes from this year's British Open. Better still, they are all on one golf course located less than 9 miles from the heart of the Las Vegas Strip. This is not your typical round of golf, and whether you are into the history of the game or just want a shot at Tiger Woods course record of 67 (Feb., 2001), Royal Links and your O&P friends will provide you with some great golfing memories.

Monday, September 19

Royal Links Golf Club, Las Vegas, NV

Tournament to be held in conjunction with the AOPA National Assembly

Star-Spangled Savings for the Month of July

AOPA in introducing the new AOPA online bookstore has created a special offer for all AOPA members. For the month of July, members can take 10% off all purchases at the new online AOPA bookstore. The discount is good for all educational and coding items, as well as our monthly audio conferences. If you've been waiting for the perfect time to stock your office's library, now is it!

Visit www.AOPAnet.org. To log in you will need your membership number and zip code. Enter **HOT** as the promotional code at checkout.

AOPA Recommendation on Supplier Standards Clarification Accepted by CMS

AOPA's letter to CMS seeking clarification of the CMS Supplier Standards on two basic issues proved successful when CMS agreed with the AOPA position. CMS clarified that contracting is now considered acceptable unless providers are located in a state that specifically prohibits contracting and also that an O&P facility can co-locate with a physician as long as the physician does not have a DMEPOS supplier number.

A Flourishing Partnership Recognized

AOPA's close working relationship with the Amputee Coalition was recognized at the recent AC national convention when the AC presented the "Spirit of Collaboration Award" to AOPA. Among the collaborations have been support of the Insurance Fairness for Amputees Act (S. 773) formerly called the Prosthetic and Custom Orthotic Parity Act; advertising and media campaigns including the poster series with joint AOPA and AC logos, opposition to state Medicaid cuts, the recent 30 second Public Service Announcements and commissioning the Cost Effectiveness study funded by AOPA.

More on the O&P Community's Advocacy Lifeline

The O&P PAC advocates for legislative and political interests at the federal level which have an impact on the orthotic and prosthetic community. The O&P PAC achieves this goal by working closely with members of the House and Senate to educate them about the issues and help elect those individuals who share our concerns and support our issues.

As of July 6, 2011* the O&P PAC has raised \$40,066 from the following AOPA members:

Michael J. Allen, CPO, FAAOP; Rick Allen, CO; Sherrie Anderson, CP; Robert Arbogast; Dale Baeten, CPA; Stephen A. Blackwell, CPO, LPO; George Breece; Maynard Carkhuff; Marty Carlson, CPO; Mary Charton; Ronald Cheney, CPO; James Claiborne, CPO; Fred Crawford; Glenn Crumpton, CPO, C.Ped.; Heather Davidson, CO; Edward DeLatorre; Thomas DiBello, CO, LO, FAAOP; Kathy Dodson; Kathleen Easterbrooks; Robert Easterbrooks, CPO; David Edwards, CPO, FAAOP; David Falk, CPO; Rick Fleetwood, MPA; Ed Gildehaus III, CPO, C.Ped., FAAOP; Kevin Gilg, CP; Steve Hamontree, CPO; Sam E. Hamontree, CP; Daniel Hasso, CPO, LPO; M. Kale Hinnant, CP, FAAOP; James Hughes, CP, LP; James Kaiser, CP; Mo Kenney, CPO, FAAOP; Ronald G. Lanquist, CO; Jon Leimkuehler, CPO, FAAOP; Robert V. Leimkuehler, CPO; William Leimkuehler, CPO; Eileen Levis; Anita Liberman-Lamphear, MA; Randall L. Ludolph, CP; Mark Maguire, CPO; Clyde Newton Massey, CPO; Brad Mattear, CFO; Tina Moran; Eric Neufeld, CPO; Ronald W. Pawlowski, CPO; Mark A. Porth, CPO, FAAOP; Tom Rankin; Eduardo Reyes, LPO; Stephen Rinko, BS, CPO; Brad Ruhl; Joshua Schenkman; Terry Lee Shaw, BOCPO, CPO, FAAOP; Mark W. Smith, CP; Frank Eugene Snell, CPO, LPO, FAAOP; Rick Stapleton, CPO; H.E. Thranhardt, CPO(E); Loretta Thranhardt; Bernie Veldman, CO; Donald Virostek, CPO, LPO; Thomas H. Watson, CP; Ashlie White; Eddie White, CP; Jeffrey Yakovich, CO; James Young, CP, LP, FAAOP and Claudia Zacharias, MBA, CAE

AOPA would like to thank the following individuals who have generously contributed* directly to a political candidate's fundraiser, and/or have donated to an O&P PAC sponsored event:

Ryan Arbogast; Kel Bergmann, CPO; Stephen Blackwell, CPO, FAAOP; Frank Bostock, CO, FAAOP; Maynard Carkhuff; Fred Crawford; Glenn Crumpton, CPO, C.Ped.; Charles Dankmeyer, Jr., CPO; Thomas V. DiBello, CO, FAAOP; Deane Doty, CPO; Robert Easterbrooks, Jr., CPO; David Edwards, CPO, FAAOP; Rick Fleetwood, MPA; Richard Gingras, CPO, BOCOP; Bert Harman; James A. Kaiser, CP; Marc Karn, CP; Michelle Koehler, CO; Thomas Kirk, Ph.D; Mark Kirchner, CPO; Al Kritter, Jr., CPO, FAAOP; Jon Leimkuehler, CPO; Anita Liberman-Lamphear, MA ; Robert Morgan; Ralph Nobbe, CPO; Michael Oros, CPO, LPO; Jeff Parsons, LO, CO; Scott Schneider; Chris Snell; Clint Snell, CP; Rick Stapleton, CPO; Brian Steinberg, CO; Frank Vero, CPO; James Weber, MBA; James O. Young, CP, FAAOP and Claudia Zacharias, MBA, CAE.

The O&P PAC has made donations* to the following members of Congress:

- Representative Bill Cassidy (R-LA, 6th District), Member of the Energy & Commerce Committee and its subcommittees on Health; Commerce, Manufacturing, and Trade; and Environment and the Economy
- Representative Brett Guthrie (R- KY, 2nd District), Member of the Energy and Commerce Subcommittee on Health
- Representative Wally Herger (R-CA, 2nd District), Chair of the Health Subcommittee of the House Ways and Means Committee
- Representative Joseph Pitts (R-PA, 16th District), Member of the House Energy and Commerce Committee, Chairman: Subcommittee on Health
- Representative Hal Rogers (R- KY, 5th District), Chair of the House Appropriations Committee
- Representative Dutch Ruppersberger (D-MD, 2nd District), Ranking Member of the House Select Committee on Intelligence
- Representative Glenn Thompson (R-PA, 5th District), Co-Chairman of the Congressional Healthcare Caucus
- Representative Fred Upton (R-MI, 6th District), Chairman: House Energy and Commerce Committee
- Representative Ed Whitfield (R- KY, 1st District), Member of the Energy and Commerce Subcommittee on Health

- Senator Orrin Hatch (R-UT), Senior Member of Senate Committee on Finance; Member of Health, Education, Labor and Pensions (HELP) Committee, Committee on the Judiciary, the Joint Committee on Taxation; Member of the Special Committee on Aging
- Senator Mitch McConnell (R-KY) Senate Republican Leader
- Senator Ben Nelson (D-NB), Member: Agriculture, Nutrition & Forestry; Appropriations; Armed Services; Rules & Administration Committees
- Senator Olympia Snowe (R-ME), Ranking Member of the Committee on Small Business & Entrepreneurship, Member of the Committee on Finance
- Senator Debbie Stabenow (D-MI), Chairwoman: Committee on Agriculture, Nutrition & Forestry; Member of the Budget Committee, the Energy & Natural Resources Committee, and the Finance Committee

*All contributions and donations were made/received between January 01, 2011 and July 06, 2011. Any contribution and or donation received/made after July 06, 2011 will be included in the next quarterly staff report.

In order to participate in and receive information about the O&P PAC, federal law mandates that you must first sign an authorization form. To review and sign a PAC authorization form visit www.AOPAnet.org.

A Great Contributor Winds Down

AOPA has benefited from the wisdom of Kathy Dodson for twenty-two years and July 1, 2011 marked Kathy's official retirement. However, that does not end the opportunity for AOPA to continue tapping Kathy's reservoir of knowledge and experience gained as one of the foremost experts on coding and reimbursement in the entire O&P community. Her service to members and special talent in explaining the most complex rules and regulations earned her the well deserved "face of AOPA" recognition. Over the past two decades she has indeed been the most visible and consistent response to member needs.

Kathy has agreed to continue on as a consultant through December 31, 2012. I'm sure you all join me in expressing heartfelt thanks and congratulations as she moves from our day to day experience dominating her life to her balancing a part time AOPA consulting role with her many other retirement plans.

A Huge Thank You

Special thanks go to a large number of AOPA members who have volunteered their time for so many good causes on behalf of the O&P community. We can't list them all but we know who they are and on behalf the AOPA Board and Officers, it's a pleasure to convey this heartfelt appreciation. Your staff is here to serve but our ability to do so really depends on the leadership and volunteerism within the membership who initiate, support and monitor the programs your resources make possible.

Sincerely,



Thomas F. Fise, JD
Executive Director