



**American Orthotic &
Prosthetic Association**

AOPA in Advance

Breaking News for O&P Professionals

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Newsletter Feedback

We invite your comments and questions. Please contact Steven Rybicki at srybicki@AOPAnet.org or (571) 431-0835.

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O&P NEWS

AOPA's Advocacy for O&P Yields Positive Signal in Medical Device Excise Tax Proposed Rule Making

On Friday, February 3, **AOPA** received some very good news regarding O&P and the Medical Device Excise Tax. The Department of Treasury and the Internal Revenue Service (IRS) released their initial proposed rules on the Medical Device Excise Tax. From the text released, it appears that **AOPA's** early intervention about a year ago on behalf of O&P have borne some quality fruit.

The proposal includes pathways to exclude O&P from the tax under the retail exemption (which has been the focus of **AOPA's** research, presentation, and documentation submitted to both the Department of Treasury and the IRS), and they also provided even greater clarity by including O&P within the safe harbor provisions.

[Click here to read the proposed rule language released on February 3.](#)

[Click here to read the letter AOPA sent to the Department of the Treasury in 2011 explaining why O&P should be excluded from the Medical Device Excise Tax.](#)

[Click here to read the letter AOPA sent to the IRS in 2011 explaining why O&P should be excluded from the Medical Device Excise Tax.](#)

To be clear, the language released is only a proposal, so it is subject to change, but if this policy sticks, and there are no unseen gremlins included, it could save all industry members--both patient care facilities and manufacturers (since with O&P manufacturers positioned to claim component exemption, the tax could have been collected from either manufacturers or patient care facilities) will be spared a 2.3 percent across-the-board tax levy. Under the proposal, that levy will impact virtually all other components of the medical device field (some exemption pathways for DME are also referenced).

Questions? Contact Catherine Graf at cgraf@AOPAnet.org or (571) 431-0807.

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PDAC Rescinds Product Labeling Requirements

AOPA's effort to convince PDAC to avoid duplicating FDA authority on medical device labeling also bore fruit with a January 30 announcement rescinding the requirement, just two days before its February 1, 2012 effective date. The labeling requirement would have applied to all products submitted to PDAC after that date by O&P device manufacturers for LCode advice.

[Click here to see the announcement.](#)

The concern **AOPA** had with this issue was the possibility that O&P suppliers would be subject to two labeling mandates - one from PDAC and the other from the Food and Drug Administration. **AOPA** submitted two legal opinions by experts from the law firms of Williams and Connolly where Richard Cooper, Esquire, former chief counsel to FDA is associated, and Thomas Barker, Esquire, of Foley Hoag who was formerly the HHS General Counsel. Both legal opinions confirmed Congress has only given the FDA labeling authority over medical devices. FDA is in the process of producing a Unique Identification System for all medical devices. O&P suppliers could have been subject to labeling

requirements from CMS/PDAC and FDA going forward.

AOPA's December 22, 2011 letter to CMS requested withdrawal of the labeling requirement for all products submitted for coding advice provided the two legal opinions confirming only FDA has authority.

[Click here to read the December 22 letter sent to CMS/PDAC.](#)

[Click here to read the Foley Hoag memorandum to CMS.](#)

[Click here to read Richard Cooper's legal opinion on the matter.](#)

Questions? Contact Catherine Graf at cgraf@AOPAnet.org or (571) 431-0807.

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An FDA Inspector Knocks at Your Door Today...What Would You Do? Do Your Homework-Attend AOPA's First-Ever FDA Compliance Workshop

Join **AOPA** on February 24, 2012 in Baltimore, MD at the Sheraton Inner Harbor for an exclusive one-day seminar examining the compliance policies required of O&P by the US Food and Drug Administration (FDA). FDA regulatory compliance awareness is important to provide O&P manufacturers, suppliers, component manufacturers, and distributors with a basic understanding of FDA regulations that apply to the O&P industry. Regulatory compliance training is critical for ensuring your organization's understanding of applicable FDA regulations as it relates to manufacturing & distributing practices, medical devices & device classification, and forms, fees, and key contacts. Penalties are severe if your company is in non-compliance ranging from fines to product recall.

AOPA is offering this compliance training in the wake of reports from patient care and supplier members of increased FDA activity. A major interest is whether FDA good manufacturing practices (GMP) applies to O&P Patient Care Facilities, especially those with central fabrication companies.

[Click here to register.](#)

Questions? Catherine Graf at cgraf@AOPAnet.org or (571) 431-0807 with content questions. And contact Steve Custer at scuster@AOPAnet.org or 571/431-0876 with registration questions.

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Congressional Leaders Send Letter to HHS Expressing Concern about State-Level Definitions of Essential Health Benefits

On February 6, seven members of the House of Representatives sent a joint letter to Kathleen Sebelius, Secretary of the Department of Health and Human Services (HHS). The letter expressed concerns about the December 16 Essential Health Benefits Bulletin that offered guidance about how the HHS was proceeding with the definition of "essential health benefits."

[Click here to read the full text of the letter.](#)

The letter stressed that it was the intent of Congress when passing the Patient Protection and Affordable Care Act (ACA) to provide a basic level of coverage as it "included ten benefit categories defined in the ACA so that families would be guaranteed access to a defined benefit package that they can understand and which provides meaningful coverage." By HHS delegating the definition of the essential health benefits package to states the authors noted that this decision might undermine the ability for that federal decision to be implemented. The letter noted, however, HHS's current decisions on these issues surrounding the implementation of the essential health benefits package are too

vague to comment upon rigorously and that more information from HHS will be appreciated.

The letter's concerns and arguments mirror **AOPA's** own concerns about these elements of the essential health benefit decision from HHS as it has been hard to determine how O&P might be affected on a state-by-state basis and to respond to each of those decisions adequately.

[Click here to read AOPA's comments submitted to HHS regarding the December 16 Essential Health Benefits Bulletin.](#)

AOPA will continue to keep members updated as to any decisions or clarifications made by HHS on the essential health benefits issue.

Questions? Contact Catherine Graf at cgraf@AOPAnet.org or (571) 431-0807.

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2012 Bookstore Products Arriving, AOPA Products and Services Catalogue Now Available

AOPA's 2012 Products and Services Catalogue contains a comprehensive index of all events, resources, business solutions and products that **AOPA** provides. Make sure that your practice is taking advantage of all **AOPA** services that are provided at either no cost or reduced cost to members including **AOPA's** newsletters, the O&P Almanac magazine, business management monographs, meetings, webcasts, audio conferences, and reference manuals.

[Click here to see AOPA's 2012 Products and Services Catalogue.](#)

Of particular relevance to members, the 2012 Quick Coders have arrived and are now available for purchase and shipping.

Questions? Contact Michael Chapman at mchapman@AOPAnet.org or (571) 431-0845.

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Last Chance to Register for AOPA's February 8 Audio Conference: "Resources for O&P Patient Care Facilities"

Have you wondered where to find an answer to a question when the **AOPA** offices are closed? Ever have trouble navigating the CMS website? If you have ever faced this challenges, attend this month's **AOPA**iversity audio conference. This conference will provide you with the tools to help answer most of your O&P coding and billing questions, or at least get you pointed in the right direction.

- **AOPA's** LCodeSearch.com member benefit;
- Quickly find information on the CMS website;
- How to use your DME MAC websites as a resource;
- What type of information can be found on the PDAC website

The audio conference beings at 1 PM (EDT), the cost of participating is \$99 per line for **AOPA** members (\$199 for non-members), and any number of employees may listen on a given line. Listeners can earn 1.5 continuing education credits by returning the provided quiz within 30 days and scoring at least 80 percent. Contact Devon Bernard at dbernard@AOPAnet.org or (571) 431-0854 with content questions.

[Click here to register for the audio conference.](#)

Questions? Contact Stephen Custer at scuster@AOPAnet.org (571) 431-0876.

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You Can Make a Difference in 2012 by Attending AOPA's Policy Forum

An election year offers special opportunities for building relationships with members of Congress. They need your support and the Congressional offices will be more interested in your issues. That's just one more reason why you should attend the 2012 **AOPA** Policy Forum, scheduled for April 17-18.

Additionally, as Health Care Reform regulations continue to be developed, it is critical that the O&P field ensure its voice is heard during this process. The government is dealing with a budget deficit and is looking for ways to make cuts so it is more important than ever to educate members of Congress on how orthotics and prosthetics restore lives and are an essential part of the healthcare system. Legislators need to understand how continuing coverage of these benefits for your patients pays off in the long term. Only you and your patients can carry that message.

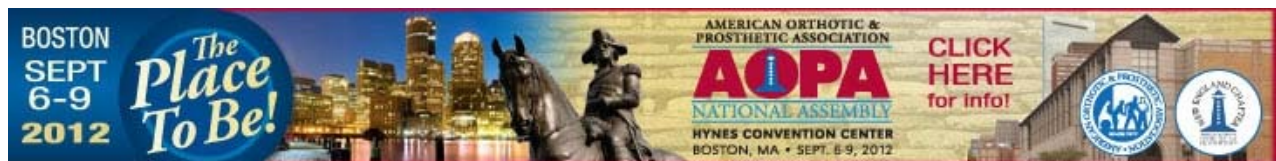
The 2012 **AOPA** Policy Forum is being held close to Capitol Hill, which is an ideal location for visiting the Nation's Capital and visiting your legislators. Make a difference for the entire profession and enjoy our historic city, with easy access to all the attractions of our nation's capital from this ideal location. All this for a low registration fee of only \$125!

[Click here for more information about the 2012 AOPA Policy Forum.](#)

[Click here to register for the 2012 AOPA Policy Forum.](#)

Questions? Contact Catherine Graf at cgraf@AOPAnet.org or (571) 431-0807.

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O&P RESOURCES FROM AOPA

Check Out the AOPA Job Board for New Opportunities in O&P

If you need a position filled at your business or are interested in looking at other job possibilities within the O&P field, check out the [AOPA Online Job Board](#). The online job board sports a freshly updated look and an easy-to-navigate profile creation system.

And remember: if you advertise on the Online Job Board and decide to also advertise in the *O&P Almanac*, then you'll receive a 5 percent discount on the cost of advertising in the *Almanac* and on the Job Board.

Questions? Contact Steven Rybicki at srybicki@AOPAnet.org or (571) 431-0835.

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O&P INSIDER'S TRACK

The Only Up-to-the Minute O&P Newsline

People in the News

[Hanger's](#) Vice President of Prosthetics **Kevin Carroll, MS, CP, FAAOP** was honored with the

Roscrea People of the Year International Award by *Roscrea People*, a community publication of Roscrea Co. Tipperary, Ireland.

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Businesses in the News

Color Me Yoga announced that it will be begin to teach a special "Yoga for Amputees Workshop" in [Orlando, Florida](#) on April 20 and [Oklahoma City, OK](#) on April 27.

Hanger announced that it will be changing the name of Hanger Orthopedic Group, Inc. to **Hanger** and Hanger Prosthetics & Orthotics will be renamed **Hanger Clinic**.

OPAF & The First Clinics announced that its Spring 2012 Thranhardt Golf Classic will be held on Wednesday, March 21 at Stone Mountain Golf Club. [Click here to register](#).

Össur announced that **Nike** is introducing a new sole utilizing state-of-the art design methods and technologies to create a lightweight, durable composite sole that can be used with Össur's Flex-Run prosthetic blade for amputee athletes.

Otto Bock announced it will be Gold Level sponsor in 2012 of **OPAF** & The First Clinics.

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Send Us Your News!

The next **AOPA in Advance** will arrive in your inbox on February 21. So if you have a new employee or a new office, tell us! Share your news with the over 15,000 readers of the *O&P Almanac* and **AOPA In Advance** newsletter. Contact Steven Rybicki at srybicki@AOPAnet.org.

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