



## A TOPIC AOPA IS WORKING ON THAT IS IMPORTANT TO THE FUTURE OF YOUR BUSINESS

### Nipping CMS Overreach in the Bud Is What AOPA Is Here For OR Why Should Two Duplicative Labeling Regulations Apply to O&P?

#### The Core of the Issue

Give an inch – take a mile. It’s an old adage that’s been around forever. It too often applies to the government. A recent example of an AOPA suspected overreach by the PDAC Region 4 of CMS involves the announced February 1, 2012 effective date requiring permanent labeling of any devices submitted for the coding verification process. The label must have the manufacturer’s name, product name and model number affixed to all products that require a sample product to be submitted to the PDAC.

In the opinion of AOPA’s legal counsel, it is clear that Congress intended FDA to be the exclusive regulator of medical devices and the exclusive implementer of a unique device identifier (UDI) system. When Congress addressed federal regulatory authority over medical devices Congress understood and intended that FDA would exercise that authority. The Secretary of Health and Human Services (HHS) had already delegated to FDA the authority to administer the Food Drug and Cosmetic Act.

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It’s also the opinion of AOPA’s legal counsel that the PDAC requirement would frustrate the effort being developed by the Food and Drug Administration that there be a single national system of unique device identifiers. It would create unnecessary burdens on device manufacturers, medical providers, and government agencies and others that maintain device-related databases. It also would provide no information not provided by FDA’s system. In light of Congress’s grant of authority to FDA to regulate device labeling and the enactment of specific legislation in 2007 directing FDA to create a UDI system, PDAC should refrain from implementing its own separate device-identification requirement and, instead, defer to FDA’s UDI system. Once FDA’s system is in place, it will serve the purpose that PDAC seeks to serve and many additional important purposes as well.



#### Why Is It Important To You?

Almost every day another local, state or federal regulation targets the business community, especially health care providers. The new Affordable Care Act has a series of new regulation implementation dates all of its own that will impact O&P providers and suppliers. So at some point business has to say, “stop, we’re not going to take it any more.”

That’s AOPA’s job – to stand up to unnecessary regulation at the federal level so you can do your job in providing patient care or as supplier – providing the products and support that make quality care possible. The PDAC labeling mandate will affect both supplier members and patient care facilities as another recordkeeping, time wasting burden that is unnecessary and that will ultimately be duplicative of the unique device identifier system FDA will require.

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**What Is AOPA Doing About This?**

Upon learning of the September 22, 2011 PDAC device labeling announcement AOPA conducted a quick survey of manufacturer members and spoke by phone with several to get a sense of the impact and to gauge the significance of the issue. AOPA's Executive Committee met and agreed to a strategy that would first assess whether PDAC had authority to impose labeling requirements by seeking two separate legal opinions from FDA legal experts.

The Williams and Connolly law firm opinion authored by the former Chief Counsel to the Food and Drug Administration, Richard Cooper, and another authored by Foley Hoag partner, Thomas Barker, formerly general counsel to the Department of Health & Human Services related to CMS/Medicare issues, concurred that FDA has the sole authority to regulate medical device labeling.

The AOPA cover letter transmitting the legal opinions to Laurence Wilson of CMS stated, "Based on these two analyses it seems clear that CMS needs to withdraw the requirement

articulated by its PDAC contractor on September 22 of any statements mandated to be affixed to the specific medical devices, in advance of the originally stated effective date of February 1, 2012."

That's the first step. AOPA is awaiting a response from CMS to determine what further steps may be necessary. It may be wishful thinking to imagine AOPA can get CMS to alter a published policy on relatively short notice. But it's the old try, try and try again spirit that eventually bears success. If nothing else, AOPA may encourage CMS in the future to test the waters with industry knowledgeable experts before embarking on questionable activities.

Very truly yours,  
  
 Thomas F. Fise, JD  
 AOPA Executive Director

**Did You Miss Anything?** Here are the back titles of recent Executive Director Letters. If you missed one you'd like to know more about—request Executive Director letter and month at [info@AOPAnet.org](mailto:info@AOPAnet.org).



JUNE 2011  
**Making Sure that Orthotics and Prosthetics Are Included in the Essential Health Benefits Package Under Health Care Reform**



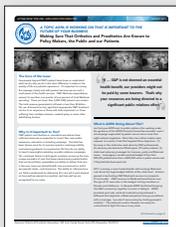
OCTOBER 2011  
**Joint Amputee Coalition/AOPA Cost Effectiveness Study Could Buttress O&P's Value Claims in an Adverse Health Care Environment**



JULY 2011  
**Aggressively Intervening in States to Counter Moves to Eliminate Coverage for Orthotics and/or Prosthetics to Medicaid Beneficiaries**



NOVEMBER 2011  
**Making Sure the IRS and the Department of Treasury Exempts O&P Patient Care Facilities and Manufacturers from the 2.3 percent Medical Device Excise Tax**



AUGUST 2011  
**Making Sure That Orthotics and Prosthetics Are Known to Policy Makers, the Public and our Patients**



DECEMBER 2011  
**Investing In Outcomes /Evidence-Based Research Is Not Only the Right Thing To Do—It Will Be Salvation for O&P Payments on New Technologies!**

\*The September Executive Director Letter was not published in lieu of National Assembly.