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

# 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

### The Core of the Issue

The Affordable Care Act imposes a 2.3 percent excise tax on the value of medical devices to help pay the costs of the new healthcare reform law. Unclear is whether it applies to manufacturers, patient care facilities, both or neither. If it applies only to manufacturers, then prices of devices will increase so manufacturers can recoup their cost. If it applies only to providers, then a mountain of paperwork will be imposed on patient care facilities. Reimbursements would shrink, attributable to this, as well as to a completely separate component of the Affordable Care Act which will operate to reduce your annual CPI increases by 1% or so in the name of so-called productivity adjustments each year – it will most certainly add new costs that are not reimbursed. If it applies to both, then the nightmare expands dramatically.

### Why Is It Important To You?

This tax carries the threat of increasing the costs of traditional manufacturers, patient care facilities, or both by 2.3 percent starting in January, 2013. That's a very formidable chunk of your bottom line, and in today's environment, there is no assurance that you'll be able to simply load this added cost onto the price of your products.

According to the Department of Treasury and IRS, which are enforcing the tax: "Under the provision, a tax equal to 2.3 percent of the sale price is imposed on the sale of any taxable medical device by the manufacturer, producer, or importer of such device. A taxable medical device is any device, defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, intended for humans. The excise tax does not apply to eyeglasses, contact lenses, hearing aids, and any other medical device determined by the Secretary to be of a type that is generally purchased by the general public at retail for individual use. The Secretary may determine that a specific medical device is exempt under the provision "if the device is generally sold at retail establishments (including over the internet) to individuals for their personal use."

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### What Is AOPA Doing About This?

The devil is always in the details and the language of the new law is vague as to whether O&P devices will be exempt or subject to the tax. There are two general categories of potential exemptions: (1) devices sold directly to a purchaser who uses the device for "further manufacture," i.e. Treasury will wait to collect the tax until farther down the "manufacturing chain" when the total value of the device, and therefore the total tax, will be higher; and (2) the so-called retail exemption, i.e., "…any other medical device determined by the Secretary to be of a type that is generally purchased by the general public at retail for individual use." AOPA has studied the law carefully and believes that O&P suppliers, manufacturers and patient care facilities qualify for the same exemption that applies to opticians and hearing aid dispensers. These providers supply eyeglass/contact lenses and hearing aids respectively directly to consumers at retail for their individual use. The fact that O&P devices are external medical devices used to improve or maintain the function of a part of an individual's body in accordance with a physician's prescription further supports AOPA's claim for exemption.

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AOPA wrote a detailed explanation to Secretary Geithner and to the Chief Counsel of the IRS on January 4, 2011, explaining why both O&P manufacturers and patient care facilities should be excluded from tax by virtue of the retail exemption. On February 10, AOPA staff, outside legal counsel and two AOPA members, Charles Dankmeyer, CPO and Scott Schneider had an extensive meeting with IRS and Treasury officials where we explained a range of issues relating to the use, fabrication and sale of O&P devices, again to explain our eligibility for the retail exemption. The face-to-face meeting was encouraging. Key points were made and explained, but the final issue will be how IRS/Treasury deal with this issue when they issue proposed rules on this topic, probably early in 2012.

## The Bottom Line

Recognizing the importance of this topic to the financial health of our members, AOPA has gotten out early on this issue, and presented a thorough case, with solid references to the regulations.

This tax is a pretty complex issue for O&P. The core of this issue is that we walk a very delicate balance. Manufacturers might like to assert the component exemption. But Treasury sees that as deferring the tax farther down the distribution line—not as a true elimination of the tax. So, if we made the component argument, and won—we'd be pushing the Treasury into trying to treat practitioners as if THEY were the final manufacturer. That would mean more dollars of total tax if collected at the practitioner level. Additionally, if Treasury were to treat practitioners as the final manufacturer where tax is collected, it could help tip the balance in the current fencing with FDA, and our contention that patient care facilities are NOT subject to FDA rules for manufacturers.

We understand that our members generally do not think of themselves, as providers in the health care field, as selling at retail. Yet, there are remarkable parallels to eyeglasses and hearing aids—in each case there is a prescription, and the device is fabricated for delivery to the ultimate consumer/patient for their unique personal use. Most importantly, this approach is the only one that offers the prospect for exemption of the O&P field at both the component manufacturer and the patient care facility levels. Here's what we have told Treasury on this:

"The exception for items sold at retail would not have full effect if component parts that make up an excepted device were subject to tax. For example, suppose that a business that makes wheelchairs (W) purchases cushions for the chairs from another manufacturer (C). This directly parallels the sale of component parts by manufacturers in O&P. For purposes of the example, assume that both the cushion and the wheelchair are medical devices that would be subject to the tax, and that a finished wheelchair is exempt from tax under the retail sale exemption.

"If the sale of the cushion by C to W is subject to tax, then the sale of the wheelchair will not be fully exempt from the tax. That is, C can be expected to pass the tax on to W, who will recoup the tax by adding it to the purchase price of the wheelchair. Thus, tax will be imposed with respect to the wheelchair. In order for the wheelchair to be sold without imposition of tax, sales of component parts for the wheelchair should also be exempt from tax. That is, no tax should be imposed on the sale of the cushion by C to W, nor to the O&P components secured by patient care facilities to fabricate the finished device to meet the prescription and for delivery to the final O&P patient/retail consumer."

All of this is to say that we want to make our strongest pitch around the "retail" exemption. That most likely would mean that NOBODY would pay the tax. So, while it might not seem like a perfect fit for what we do, it is very close to contact lenses, eyeglasses and hearing aids, and it is probably where we need to be.

There have been several efforts set in motion to completely repeal the medical device excise tax, and AOPA supports those efforts—but they face an uphill battle because under Congressional rules, they need to identify "offsets," in short another way to raise the same amount of money that would be derived from the medical device excise tax. Once IRS/Treasury issue their proposed regulations, we will be informing all AOPA members, and will be actively participating in providing comments on those regs, and encouraging all AOPA component manufacturer and patient care facility members to do the same.

Very truly yours,

Thomas F. Fise, JD
AOPA Executive Director