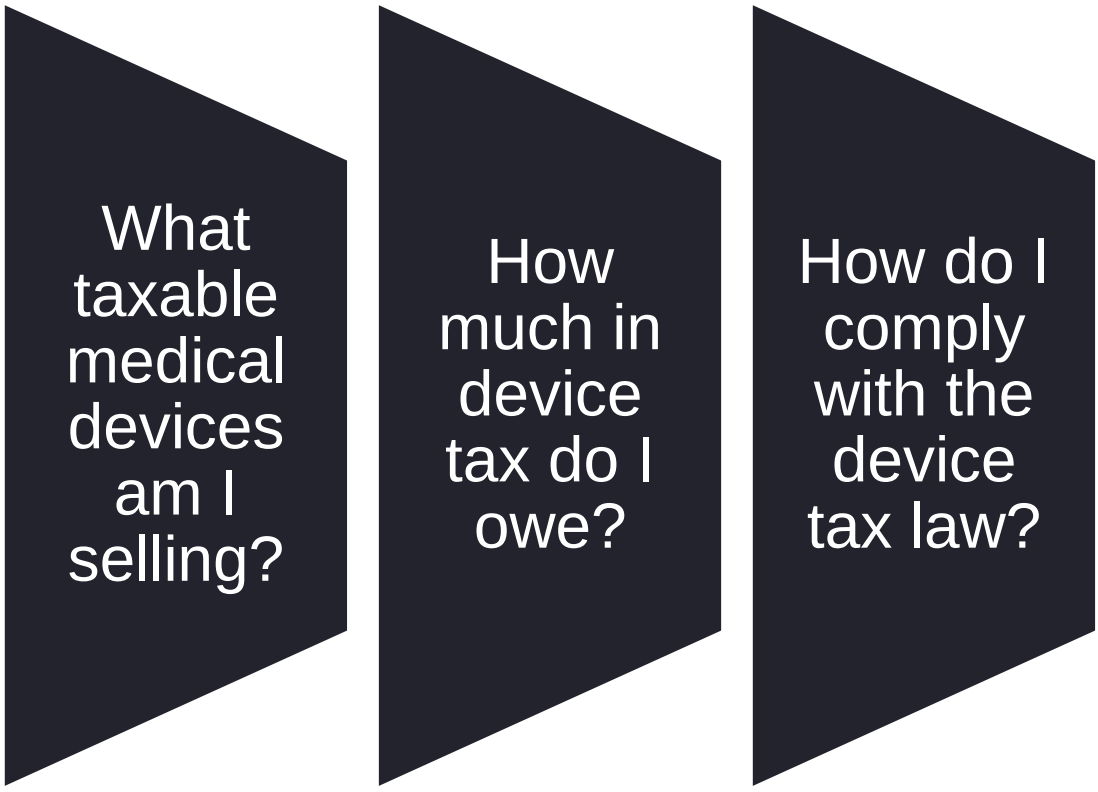
Medical Device Excise Tax: Minimization and Compliance

By John Monahan and Gary Purpura

TaxOps
Tax Intelligence

Path to compliance

The medical device excise tax of 2.3% takes effect Jan. 1, 2013, putting in motion significant tax challenges and operational infrastructure demands on the medical device industry. Manufacturers, producers, and importers of medical devices should be considering three main questions to prepare to comply with the new tax law.



Background

The 2012 Supreme Court decision to uphold the major tax laws of President Obama's signature health care law clears the path for a number of tax provisions to move forward on schedule. The Health Care and Education Reconciliation Act of 2010 (HCERA) in conjunction with the Patient Protection and Affordable Care Act (PPACA) enacted the Medical Devices Excise Tax at Sec. 1405(a) of the HCERA. Section 4191 of the Internal Revenue Code imposes a 2.3% excise tax on the sale of a broad range of medical devices after December 31, 2012.

The excise tax is expected to have a negative impact on earnings and increase tax-compliance costs on the industry. According to the Wall Street Journal, the cost to Medtronic Inc., the nation's largest device maker, may be as much as $150 million in 2013; Stryker Corp. reported that it will owe $130 to $150 million next year, roughly one-third of its Research and Development budget.[1] Startups and small- to mid-size medical device manufacturers are likely to be affected the most by layoffs and additional cost reductions to offset the marginal tax compliance burden.

Although debate is being waged in Washington, the White House has promised to veto any legislation to repeal the device tax. This development significantly reduces the likelihood that the tax will be repealed before the date the first excise tax deposit is due **Jan. 29, 2013**; the first quarterly federal excise tax return is due **April 30, 2013**. As such, manufacturers, producers, and importers will want to take action early to prepare to comply with the reporting and filing requirements of the new tax.

---

[1] Christopher Weaver, *Excise Tax Remains for Medical Device Makers,* The Wall Street Journal, June 28, 2012, http://online.wsj.com/article/SB10001424052702304441404577480972664688712.html.

What taxable medical devices am I selling?

The single stage transaction tax is levied on the first segment of the supply chain, specifically the manufacturers, producers and importers. The IRS and the U.S. Treasury Department issued proposed regulations in February 2012 that generally defer to the Food and Drug Administration's registration rules for the definition of taxable medical devices and certain exemptions.[2] The term "medical device" is defined in Sec. 201(h) of the Federal Food, Drug, & Cosmetic Act. The law taxes medical devices such as implements, machines, implants, or other similar or related items intended for humans that are:

- Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them;
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease; or
- Intended to affect the structure or any function of the body, excluding products relying on a chemical reaction within or on the body or being metabolized to achieve their primary intended purposes.

The tax may also apply to the constructive sales price for intercompany sales made other than at a fair market price under existing 26 USC Sec. 4216(b). According to the proposed rules, "if a manufacturer sells a taxable article other than to a wholesale distributor or at less than a fair market arm's length price, the taxable sale price is determined on a constructive sale price rather than the actual sale price."

Companies that manufacture, produce, and import medical devices already register with the Food and Drug Administration. The IRS and FDA are expected to share information for compliance with the device tax law. The IRS is likely to use the FDA registration list to cross-check sellers and confirm that devices subject to the tax are being reported.

---

[2] Internal Revenue Service, REG-113770-10, **http://www.irs.gov/file_source/pub/newsroom/reg-113770-10.pdf**.

Exemptions

Four categories of devices are broadly exempt from the device tax.

- Products sold for resale, including devices sold at retail intended for use by the general public such as eyeglasses, contact lenses, hearing aids, and other retail devices.
- Products sold for export.
- Products sold for further manufacturing.
- Products sold for non-human use.

The proposed regulations establish a facts-and-circumstances test, as well as a safe harbor, for determining the retail exemption under the definition of a taxable medical device. Further guidance from the U.S. Treasury department on the scope of retail exemptions, along with regulations that may address internet sales and manufacturers' warranties, is expected and may be helpful in determining whether a device qualifies for the retail exemption.

Take Action

The tax leader responsible for providing tax functionality at your business – a controller; finance, accounting, or tax executive; or service provider -- should review existing devices to determine which in whole or part are taxable by applying the FDA definition and known exemptions. In analyzing which devices are taxable, consider the following questions.

- Which products are manufactured for individual use versus those to be provided for further manufacturing?
- Which manufactured products will ultimately be exported outside the U.S.?
- Which devices are intended for retail sale?

Opportunities to minimize tax obligations may be available.

- Analyze the medical products and components to see which may be sold at retail further down the sales chain.
- Determine whether individual components of a product qualify for an exemption even though the device as a whole does not.
- Look closely at the distribution chain to determine if there are opportunities to modify where sales take place. For example, manufacturers with a distribution company that does not have taxable sales may be able to transfer some medical device sales to that distribution company.

How much in device tax do I owe?

Products that fall under the FDA definition of a medical device and are not eligible for an exemption are taxable. The 2.3% excise tax is a tax on total revenues a company receives from taxable medical devices *regardless of whether the company is profitable or generating income tax losses.* The tax is not deductible against other items.

Take Action

As we wait for final regulations from the IRS and U.S. Treasury, covered businesses should update their tax estimates for 2013 to include projected tax obligations from the device tax. The estimated liability per company should be calculated prior to year-end 2012 for inclusion in financial statements and management projections.

How do I comply with the device tax law?

The manufacturer, producer, or importer of a taxable medical device is responsible for reporting and paying the tax on Form 720, Quarterly Federal Excise Tax Return. IRS Publication 510, Excise Taxes, includes detailed information on filing, deposits, and payments.[3] The IRS also has a process for claiming a refund for companies that pay excise taxes on devices that are not subject to the tax.

Take Action

Covered businesses should redesign or refine processes, procedures and their tax compliance systems to capture the information needed to meet filing deadlines and fully comply with the tax law. All system updates, compliance processes, and procedures should be tested well in advance of filing deadlines to confirm that pricing, purchase tracking, tax codes and adjustments to the taxable base are accurate and accessible for calculating tax for the period. A number of questions should be considered in developing a plan for tax compliance, including the following.

- Do I have a system that accurately determines what is taxable?
- Do I have a system that pays the correct amount of tax not only for quarterly filings but for any required estimated taxes as a deposit before quarterly tax payments are due?
- Do I have a system that reports the tax on a timely basis?

---

[3] Chapters 11 and 12, Internal Revenue Service Publication 510, Excise Taxes, http://www.irs.gov/file_source/pub/irs-pdf/p510.pdf.

TaxOps
Tax Intelligence

John Monahan
Partner
215 Union Blvd.
Suite 325
Lakewood, CO
80228

O 720.227.0060
jmonahan@taxops.com

John's professional emphasis is on designing efficient tax solutions that maximize tax opportunities and minimize tax risk for companies of all sizes. His broad-based approach to tax solutions is founded in his experience building and running large tax functions for private businesses and public accounting firms. In addition, John has deep technical knowledge of ASC-740, income tax compliance, and international tax matters.

Gary Purpura
Partner
1177 Summer St.
Suite 301B
Stamford, CT
06905

O 203.307.2820
gpurpura@taxops.com

Gary brings more than 20-years of diverse tax consulting and compliance experience to his role as managing partner of the Stamford, Connecticut office. He specializes in helping partnerships and corporations develop tax strategies and deal with complex compliance and financial reporting needs. He has significant experience in a variety of industries including real estate, media, communications, biotechnology, professional services firms, private equity and venture capital. His legal background lends depth to his understanding of the tax rules and complex business agreements that dictate the tax treatment of these specialized industries. He is uniquely experienced in handling complex tax issues including accounting methods, tax deferrals, debt workouts, and business acquisition, spin-off, liquidation, and exit strategies. In addition, he has represented several clients in IRS and state and local tax controversies.

About TaxOps

TaxOps is a business tax outsourcing and advisory firm founded by former Big Four tax executives committed to delivering high-quality, value-driven solutions. TaxOps business model is based on flat-fee, value-based pricing and year-round delivery, which offers the best results and the best working environment for our clients, employees and partners. TaxOps has experienced significant growth in recent years, and its client retention rate is among the highest in the industry. *TaxOps is the #1 ranked small firm on the 2012 Accounting Today's Top 100 Best Accounting Firms to Work For and listed on the Inc. 5000 as one of the Fastest Growing Private Companies in America.*

Englewood Office
9777 Pyramid Court, Suite 130
Englewood, CO 80112
Phone: 720.227.0070

Colorado Springs Office
30 E. Kiowa St., Suite 100
Colorado Springs, CO 80903
Phone: 720.227.0070

Lakewood Office
215 Union Blvd., Suite 325
Lakewood, CO 80228
Phone: 720.227.0070

Stamford Office
1177 Summer St., Suite 301B
Stamford, CT 06905
Phone: 203.307.2820