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Medical Device Excise Tax: Minimization and Compliance

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

Path to compliance

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 impacts earnings and increases tax-compliance costs on the industry. Although repeal is being waged in Washington, it is not imminent. As such, manufacturers, producers, and importers must comply with the reporting and filing requirements of the excise tax.
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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 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

- 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.

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?

Tax saving opportunities

- Analyze the medical products and components to see which may be sold at retail further down the sales chain
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- 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.

What much do you 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.

Complying

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 must have processes, procedures and tax compliance systems capable of capturing 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?

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

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

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

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How can we help?

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