



What's News in Tax

New Excise Tax on Medical Devices

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New section 4191 imposes an excise tax on the sale of certain medical devices by their manufacturer or importer. The tax applies to sales after December 31, 2012. This article provides background on manufacturers excise taxes in general, describes the new tax on medical devices, and answers some frequently asked questions regarding the new tax.

Background

A basic understanding of manufacturers excise taxes helps in understanding the new medical devices tax. Manufacturers excise taxes are codified in chapter 32 of subtitle D of the Code. The substantive regulations for manufacturers taxes are contained in part 48 (Manufacturers and Retailers Excise Taxes) of the *Code of Federal Regulations* and the procedural regulations for manufacturers excise taxes are contained in part 40 (Excise Tax Procedural Regulations). The new tax on medical devices was added to chapter 32 of the Code; accordingly, the rules contained in these regulations generally will apply to this new tax.

Chapter 32 also provides rules relating to the definition of price (section 4216), leases (section 4217), use by a manufacturer or importer considered a sale (section 4218), and registration (section 4222). In addition, under chapter 32, section 4221 generally provides for exemptions from tax for use in further manufacture, export, use as supplies for vessels and aircraft, use by a state or local government, use by a nonprofit educational organization, and use by a qualified blood donor organization. Section 6416(b)(2) generally provides a credit or refund of tax with respect to those uses if tax was imposed.

The manufacturers excise tax regulations define the terms manufacturer, importer, sale, sale price, purchaser, exporter, and exportation. The procedural regulations set forth administrative provisions relating to certain excise taxes, including those imposed under chapter 32. Those regulations include rules for filing returns, paying tax, and making deposits of tax.

Under the manufacturers excise tax regulations, tax generally attaches when the title to the article sold passes from the manufacturer to a purchaser. Under the procedural regulations, tax is reported on Form 720, *Quarterly Federal Excise Tax Return*. Additionally, the procedural rules require each person that files Form 720 to make a deposit of tax for each semimonthly period in which tax liability is incurred; however, no deposits are required if the net tax liability for the calendar quarter does not exceed \$2,500. For excise tax purposes, there are no disregarded entities and no consolidated returns. Each entity with an employer identification number must file its own Form 720. Manufacturers excise taxes (along with the other excise taxes reported on Form 720) are under the jurisdiction of the Excise Tax section of the IRS Small Business/Self-Employed Division, Specialty Taxes.

New Excise Tax on Medical Devices

The Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, § 1405 (“Reconciliation Act”) added section 4191 to the Code, imposing a new excise tax on the sale of taxable medical devices by the manufacturer or importer. The amount of tax is 2.3 percent of the sale price of the medical device. The statute defines “taxable medical device” and provides some exemptions to the tax.

The Reconciliation Act also amended sections 4221(a) and 6416(b)(2) of the Code. Under these amendments, the following exemptions from the tax and credits or refunds of tax do not apply with respect to the medical device tax: (1) use by the purchaser for supplies for vessels and aircraft; (2) use by a state or local government; (3) use by a nonprofit education organization; and (4) use by a qualified blood collector organization.

Frequently Asked Questions

With the enactment of section 4191, manufacturers and importers of taxable medical devices may be evaluating how to develop a program to implement the tax. The new tax raises a number of questions. Below are the most frequently asked questions:

Q.1. Which medical devices are taxable?

A.1. The new law, section 4191(b)(1), defines the term “taxable medical device” to mean any device—as defined in the Federal Food, Drug, and Cosmetic Act—intended for humans. Section 201(h) of the Federal Food, Drug, and Cosmetic Act (codified at 21 U.S.C. § 321(h)) defines the term “device” to mean (with certain exceptions) an instrument, apparatus, implement, machine, contrivance, implant,

in vitro reagent, or other similar or related article, including any component, part, or accessory, that is:

- Recognized in the official National Formulary, or the U.S. 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, in man; or
- Intended to affect the structure or any function of the body of man, and does not achieve its primary intended purposes through chemical action within or on the body of man and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Section 4191(b)(2) excludes certain medical devices from the new tax. 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 is not a “taxable medical device.”

Q.2. Who is liable for the tax on medical devices?

A.2. The manufacturer or importer is liable for the tax. *See Gurley v. Rhoden*, 421 U.S. 200 (1975). The manufacturers excise tax regulations define the term “manufacturer” generally to include any person that produces a taxable article from scrap, salvage, or junk material, or from new or raw material, by processing, manipulating, or changing the form of an article or by combining or assembling two or more articles. The term also includes a “producer” and an “importer.” An importer of a taxable article is any person that brings the article into the United States from a source outside the United States or that withdraws the article from a customs bonded warehouse for sale or use in the United States. If the nominal importer of a taxable article is not its beneficial owner (for example, the nominal importer is a customs broker engaged by the beneficial owner), the beneficial owner is the importer of the article for purposes of chapter 32 of the Code and is liable for tax on its sale or use of the article in the United States.

Q.3. Does the tax apply to medical devices exported or sold for export?

A.3. No. For manufacturers taxes generally, section 4221(a)(2) allows tax-free sales for export or for resale for export. Section 4222(a) requires the seller and purchaser to be registered by the IRS in order for an exemption to apply. However, the manufacturers excise tax regulations generally exempt foreign purchasers from the registration requirement. Instead the seller must obtain

specified paperwork from the purchaser to document the tax-free nature of the sale. This means that the manufacturer must be registered by the IRS to effectuate tax-free sales and domestic purchasers for export must be registered by the IRS to purchase tax free for export, but foreign purchasers need only furnish the required documentation.

In situations when the registration requirements are not met and if specified conditions are met, section 6416(b)(2)(A) may allow a credit or refund to the manufacturer if a taxed medical device is exported.

Q.4. Is the tax on medical devices deductible for income tax purposes?

A.4. No. Manufacturers excise taxes are not deductible taxes under section 164. However, the sale price to the purchaser generally would include an amount representing the medical device tax and the tax would be one of the costs of the device sold. Consequently, to the extent that any costs of the manufacturer or importer selling the device would be deductible, the amount of the tax would be deductible by the manufacturer or importer as a cost of the device sold.

Q.5. Has the Treasury Department or IRS provided guidance on the tax on medical devices?

A.5. As of the date of this article, no guidance has been issued on the new tax; however, it is the authors' understanding that attorneys in the Excise Tax Branch of the IRS Office of Chief Counsel, Associate Chief Counsel (Passthroughs and Special Industries) are working on guidance. Additionally, it is anticipated that Form 720 will be updated for the medical devices tax. Accordingly, taxpayers may want to discuss the effect of this new tax with their tax advisors. Also, affected taxpayers may wish to provide comments to the Office of Chief Counsel, Excise Tax Branch on the implementation of the medical devices tax, including issues such as the types of medical devices that are generally purchased by the general public at retail for individual use.

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