

AN ALERT FROM THE BDO TECHNOLOGY & LIFE SCIENCES PRACTICE

BDO KNOWS:

TECHNOLOGY & LIFE SCIENCES



► SUBJECT

THE AFFORDABLE CARE ACT AND MEDICAL DEVICES: WHAT YOU NEED TO KNOW

► DETAILS

The U.S. Supreme Court decision to uphold nearly all of the provisions of the landmark healthcare reform legislation means that medical device manufacturers will begin paying a 2.3 percent excise tax based on the sale price of certain medical devices sold in the U.S. by the manufacturer, producer or importer of the device. The tax goes into effect on sales made after December 31, 2012, and revenues from the tax will be used to help finance the Affordable Care Act.

This new piece of legislation raises a number of questions for manufacturers and importers of medical devices, some of which are answered below:

What is considered a medical device?

Medical device is defined as an instrument, apparatus, implant, in vitro reagent, or other similar or related article, which is 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 and which does not achieve any of its primary intended purposes through chemical action within or on the body.

How do you determine if a medical device is "taxable"?

The term "medical device" means any device intended for humans (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act), with the exception of eyeglasses, contact lenses, hearing aids, and any other medical device determined by the Service to be of a type that is generally purchased by the general public at retail locations for individual use. The manufacturers excise tax attaches to a product when the title to the taxable article passes from the manufacturer to the purchaser.

What is the rate of tax on medical devices and who is liable?

The new medical device excise tax is imposed at the rate of 2.3 percent of the price for which a taxable medical device is sold by a manufacturer, producer, or importer.

CONTACT:

TANYA ERBE-GERMAN

Senior Director, State and Local
Tax Practice
310-203-1259
terbe-german@bdo.com

BDO Technology & Life Sciences Practice

BDO is a national professional services firm providing assurance, tax, financial advisory and consulting services to a wide range of publicly traded and privately held companies. Guided by core values including competence, honesty and integrity, professionalism, dedication, responsibility and accountability for 100 years, we have provided quality service and leadership through the active involvement of our most experienced and committed professionals.

BDO works with a wide variety of technology clients, ranging from multinational Fortune 500 corporations to more entrepreneurial businesses, on myriad accounting, tax and other financial issues.

► Read more

How is sales price determined?

Sales price includes the total consideration paid for the device, whether in the form of money, services, or other type of payment. Sales price, however, does exclude the following: manufacturers excise tax, the actual cost of transportation (with the exception of goods to a warehouse), delivery, insurance, installation, and other expenses incurred by the manufacturer or importer, including discounts, rebates and similar allowances, local advertising charges, and charges for warranties paid at the purchaser's option.

Are there any exemptions?

Yes, there are a few. Exported medical devices are exempt from the excise tax, but companies must register and support exportation prior to use. Additionally, sales for further manufacture are exempt, but there are certification requirements. The responsibility for complying with the certification requirements is imposed on the seller, which must be obtained from the party acquiring the device certification for further manufacture. Additionally, the manufacturer must receive proof that the device was sold for further manufacture within six months of the date of sale.

Affected taxpayers should also be aware of an available retail exemption. In order for a device to fall under the retail exemption, it must pass the following two-prong test:

- The device must be regularly available for purchase and use by individual consumers who are not medical professionals; and
- The design of the device must demonstrate that it is not primarily intended for use in a medical institution or office or by a medical professional.

The fact that a device is of a type that requires a prescription is not a factor in determining if it falls under the retail exemption.

Also, devices used exclusively in veterinary medicine, as well as devices sold for use solely in research that are not listed because they satisfy the requirements of 21 CFR 807.65, are both excluded from the excise tax.

Additionally, devices under an investigational device are exempt, which include devices used in a clinical study in order to collect safety and effectiveness data required to support a premarket approval (PMA) application or a premarket notification submission to the Food and Drug Administration. Clinical studies are most often conducted to support a PMA.

What are the filing requirements?

The taxpayer incurring liability for federal excise taxes must file the required returns, with liability incurring when the title to a taxable medical device passes from manufacturer to purchaser. Semi-monthly deposits of estimated excise tax are required unless a taxpayer's quarterly liability for the excise tax is less than \$2,500. Taxpayers must transfer the funds electronically and the estimated amount is due on the 29th of the month for the first semi-monthly period and the 14th day of the following month (for the second semi-monthly period). Taxpayers should note that the first deposit is due January 29, 2013. In order to make the deposits timely and properly, taxpayers must use electronic funds transfers and the transaction must be initiated one day before the deposit is due.

Has any guidance been issued by the Internal Revenue Service (IRS)?

Comprehensive regulations were proposed on February 3, 2012, and a public hearing was held on May 16, 2012. However, as of July 25, 2012, no final regulations have been issued. Furthermore, although the statute does not state, and legislative history does not specify, whether the excise tax is deductible, existing general authority supports its deductibility for federal income tax purposes. The IRS has stated it will provide private letter rulings on issues arising under the excise tax; however it is unlikely their overall positions on certain issues will be known for at least three years from the time the tax goes into effect based on a typical audit cycle.

How BDO can help

There are many different elements to the medical device tax. We can help you understand all of the basics of the legislation and the issues that may become more apparent as companies begin to file. Additionally, our BDO tax professionals can identify if you are part of the manufacturing cycle that will have the burden of filing, and if so, assist you in determining which items, if any, will be subject to the tax. Moreover, we can identify if any of the exemptions exist and apply any reductions, including discounts, rebates, insurance, and transportation charges.

ABOUT BDO

BDO is the brand name for BDO USA, LLP, a U.S. professional services firm providing assurance, tax, financial advisory and consulting services to a wide range of publicly traded and privately held companies. For more than 100 years, BDO has provided quality service through the active involvement of experienced and committed professionals. The firm serves clients through more than 40 offices and more than 400 independent alliance firm locations nationwide. As an independent Member Firm of BDO International Limited, BDO serves multinational clients through a global network of 1,118 offices in 135 countries.

BDO USA, LLP, a Delaware limited liability partnership, is the U.S. member of BDO International Limited, a UK company limited by guarantee, and forms part of the international BDO network of independent member firms. BDO is the brand name for the BDO network and for each of the BDO Member Firms. For more information, please visit: www.bdo.com.

To ensure compliance with Treasury Department regulations, we wish to inform you that any tax advice that may be contained in this communication (including any attachments) is not intended or written to be used, and cannot be used, for the purpose of (i) avoiding tax-related penalties under the Internal Revenue Code or applicable state or local tax law provisions or (ii) promoting, marketing or recommending to another party any tax-related matters addressed herein.

Material discussed in this tax alert is meant to provide general information and should not be acted on without professional advice tailored to your firm's individual needs.