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Client Alert

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The Taxman Cometh: Are Your Medical Device Sales Subject to the New Excise Tax?

After consulting with the Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS) and taking public comments, the Internal Revenue Service (IRS) has proposed regulations implementing an excise tax on certain "taxable" medical devices.[1] The tax amounts to 2.3 percent of the sales price of "taxable medical devices" sold by manufacturers, importers and producers after December 31, 2012.

A "taxable medical device" is defined as any medical device as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (FDCA)[2] for human use and that is listed with the FDA as required under the FDCA. This includes devices that have medical and non-medical uses as long as they are listed with the FDA and human devices listed with FDA that are also used for veterinary purposes.

On the other hand, devices intended for use exclusively in veterinary medicine, devices subject to an Investigative Device Exemption (IDE) and devices used exclusively in research, teaching or analysis and not introduced into commercial distribution are not "taxable medical devices" as they need not be listed with the FDA. In addition, the tax does not apply to sales of product for export or for further manufacture, products that fall within a safe harbor provision under the regulations, and products that are generally purchased by the general public at retail for indication use.

The "Retail Exemption"

A medical device that is generally purchased for individual use by the general public at retail establishments such as drug stores, supermarkets and similar vendors and is designed in such a way as to demonstrate that it is not primarily intended for use in a medical institution or office or by a medical professional, is not a taxable medical device. For example, the "retail exemption"

1 77 Fed. Reg. 6028 (Feb. 7, 2012). The tax is imposed under the Health Care and Education Reconciliation Act of 2010 and the Patient Protection and Affordable Care Act (Section 4191 of the Internal Revenue Code).

2 Section 201(h) of the FDCA (21 U.S.C. §321(h)) provides generally that the term "device" means 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, 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 of any function of the body, and that does not achieve its primary intended purposes through chemical action within or on the body and that is not dependent upon being metabolized for the achievement of its primary intended purposes.

would include medical devices such as eyeglasses, contact lenses, hearing aids, certain bandages and tipped applicators, certain pregnancy test kits and diabetes testing supplies, and items such as certain denture adhesives and snake bite kits.

The fact that a device requires a prescription is not a factor in determining whether or not the device falls under the retail exemption. A non-exclusive list of factors to be considered include the following:

1. Whether the device is generally purchased by the public at retail for individual use;
2. Whether consumers who are not medical professionals can use the device safely and effectively for its intended medical purpose with minimal or no training from a medical professional; and
3. Whether the device is classified by the FDA as a Physical Medicine Device.

On the other hand, the proposed regulations indicate that the retail exemption may not apply if any of the following conditions apply:

1. The device generally must be implanted, inserted, operated, or otherwise administered by a medical professional;
2. The cost to acquire, maintain, and/or use the device requires a large initial investment and/or ongoing expenditure that is not affordable for the average consumer;
3. The device is a Class III device under the FDA system of classification; or
4. The device is classified in certain other product categories identified in the proposal.

The "Safe Harbor" Provision

Whether a device meets the "retail exception" is based upon all the relevant facts and circumstances and may not be immediately clear. Therefore, the IRS and Treasury Department have identified certain categories of taxable medical devices that they believe do meet the retail exemption. These include the following:

1. Devices identified in the FDA's IVD Home Use Lab Tests (Over-the-counter Tests) database, available by clicking here;[3]
2. Devices described as "over the counter" or "OTC" devices in the relevant FDA classification regulation heading;
3. Devices described as "over the counter" or "OTC" devices in the FDA's product code name, the FDA's device classification name or the "classification name" field in the FDA's device registration and listing database, available by clicking here;[4]
4. Devices that qualify as durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) for which payment is available on a purchase basis under Medicare Part B payment rules in accordance with the fee schedule published by CMS.

3 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfIVD/Search.cfm
4 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/rl.cfm

What is a Taxable Event?

Unless the medical device falls into the retail exemption or a safe harbor category, the tax applies to the sale of a medical device by a manufacturer, importer or producer of taxable medical device UNLESS the device is sold for the following reasons:

1. For use by the purchaser for further manufacture, or resold by that purchaser to a second buyer for further manufacture; or
2. For export.

It may still be difficult to decide whether a sale is subject to the tax. The IRS and Treasury proposal provides several examples to clarify further how the regulations may be applied. For example:

1. Sales of veterinary products are not subject to the tax, unless the devices are intended for human use and listed with the FDA;
2. Sales of devices exempt from the FDA's registration and listing requirements because they are used solely in research, teaching or analysis and are not introduced into commercial distribution are not taxable medical devices;
3. Sales of devices subject to investigational device exemptions (IDEs), which are exempt from the FDA listing requirements and that are not otherwise in commercial distribution, are likewise not taxed;
4. Sales of products that have both medical and non-medical uses are taxable because the product is listed for the medical use with the FDA.

On the other hand, unless exempted, kits that contain both taxable and non-taxable items would be taxed as a new taxable item. However, if a manufacturer sells a taxable item for a kit to a producer that assembles the final kit, the initial sale of the taxable item used in the kit may be a tax-free sale since it was intended for further manufacture (the kit assembly); the tax attaches however, upon the sale of the kit by the distributor. If a taxable article and a nontaxable article are sold by the manufacturer as a unit, unless exempted, the tax will attach to that portion of the unit that is properly allocated to the taxable article (i.e., the portion that is listed as a medical device with the FDA). Payments made under an installment plan for the sale of taxable medical devices will be taxed beginning January 1, 2013, even if the payment installment contract predates the tax. Sales of associated devices and components of devices fall under the excise tax if the device accessories and components are listed with the FDA and not otherwise exempted.

IRS Request for Comments

Because the implementation of the new tax rules is complicated and will be based upon all facts and circumstances, the IRS has asked for comments and information on factors, examples, or additional safe harbors that could be added to provide greater certainty for a larger number of devices. For example, the IRS has asked for suggestions about combination products (of prescription drugs and medical devices) that do not meet the retail or other exemptions and that can be taxed both as drugs and devices under the legislation.

The IRS also points out in the preamble to the proposed regulations that "inexpensive equipment," as defined in CMS regulations in 42 C.F.R. §414.220(a)(1), appears to meet the retail exception under an application of the facts and circumstances test. However, the IRS points out that the CMS fee schedule categorizes "inexpensive equipment" together with other medical devices that appear not to fall within the retail exception and the decision may not be self-evident.

Of special concern are medical devices that are sold primarily or exclusively through specialty medical retailers; whether the packaging and labeling of a taxable medical device or the terms and conditions of the manufacturer's warranty with respect to a device should be taken into consideration when considering that medical device is table; and whether substantial sales of a device over the internet would be meaningful factors for use in establishing whether a device qualifies for the retail exception. If so, how should such factors be described and applied?

Finally, the IRS is also soliciting comments on other types of DMEPOS that should be considered for safe harbor treatment and how those items can be consistently and specifically identified.

The IRS is accepting comments on the proposal until May 7, 2012, and a hearing to discuss the tax is scheduled for May 16, 2012, at the Internal Revenue Building in Washington DC.