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Coming in 2013, the Medical Device Excise Tax

By Gregory J. Hartker

Now that the Supreme Court has upheld, at least in part, the Affordable Care Act, one of the additional taxes set to take effect in 2013 is the so-called Medical Device Excise Tax. Beginning in 2013, Section[1] 4191 imposes a 2.3% excise tax on the "sale" of certain medical devices intended for humans. Although many view the tax as a retail sales tax, at the last moment, Congress changed the application of the tax from a retail sales or excise tax to a manufacturer's excise tax. Thus, the tax can apply even to certain transfers or uses of a device in situations that one might not normally think of as constituting a sale.

As of the date of this alert, only proposed regulations have been issued implementing Section 4191, although final regulations are expected shortly. In order to help resolve uncertainty as to what types or categories of devices are subject to the tax, the proposed regulations provide that a taxable medical device is a device that is listed as a device with the FDA under Section 510(j) of the Federal Food, Drug, and Cosmetic Act and 21 CFR part 807, pursuant to FDA requirements. In other words, a medical device that has a three-letter FDA product code and is intended for humans will generally be subject to the tax.

There are two main categories of devices exempt from the tax. First, eyeglasses, contact lenses and hearing aids are specifically listed as being exempt. The second and broader category, commonly referred to as the "Retail Exception," exempts a device which is "of a type which is generally purchased by the general public at retail for individual use."[2] The proposed regulations expand on the Retail Exception by providing a two-part test which states that such exception applies if the medical device is regularly available for purchase and use by individual consumers who are not medical professionals and if the design of the device demonstrates that it is not primarily intended for use in a medical institution or office by a medical professional. Stated differently, the device will be exempt if it can be purchased at drug stores, supermarkets and other similar establishments and it can be used for its intended use without training from a medical professional. The proposed regulations provide, as an example, adhesive bandages.

Generally, the excise tax attaches when title to the taxable device passes from the manufacturer (or importer) to a purchaser. A sale may also include certain uses of the product such as for demonstration purposes or certain transfers free of charge for promotional purposes.

As for the base amount off of which the 2.3% tax is calculated, it is generally determined by the price for which the item is sold. While seemingly straightforward at first glance, additional charges may also be included in such price or base. For example, charges for required warranties and for containers and packaging are also generally included. For some devices, these additional amounts, especially containers and packaging, could be meaningful.

[1] Unless otherwise indicated, all Section references are to the Internal Revenue Code of 1986, as amended.

[2] Section 4191(b)(2)(D).

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Those in the medical device industry, especially manufacturers, need to carefully review their business models and products to determine whether and to what extent the medical device excise tax applies to their products.

Highlights

- If a medical device has a three-letter FDA product code and is intended for humans, unless an exemption applies, the 2.3% excise tax will generally apply.
- Consideration should be given to whether a taxpayer is a "manufacturer" for these purposes. For example, certain kitting activities could constitute manufacturing for purposes of these rules. In addition, to avoid cascading of the tax when "kitting" activities constitute manufacturing of devices, the proposed regulations clarify that the kitting activities constitute further manufacture of the device included in the kit (and thus the initial sale of the separate device should not attract the tax) and, in the event tax was paid or included in the price, the current credit and refund provisions otherwise applicable to excise taxes would be applicable.
- Manufacturers must take care to understand how all of their devices are used in commerce as some "uses" may constitute sales under the applicable rules.
- Consideration should be given as to whether a related party distributor relationship could be beneficial. Although certain previously existing constructive price provisions (for such things as bows and arrows) that apply to non arm's-length sales may apply in such cases, manufacturers should consider whether Section 482 theories and pricing may be beneficial in this context.
- Although taxpayers may be of the view that the excise tax will simply be passed down the line, additional consideration should given to those devices that are generally subject to reimbursement by Medicare. We would not expect the tax "buck" to be easily passed on to the government as the revenue raising purpose of the tax would be undermined if the government were to pay the tax directly or indirectly.

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