

The Medical Device Excise Tax: Frequently-Suspended Tax May Take Effect on January 1, 2020

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Highlights:

- Unless Congress acts in the next three weeks, effective as of January 1, 2020, a 2.3% excise tax (the “Medical Device Tax”) generally will be imposed on the price at which a “taxable medical device” is sold (or leased) by its manufacturer or importer. Some medical device manufacturers and importers may be unaware of, or unprepared for, their tax deposit and reporting obligations that could take effect almost immediately.
- Over the years, Congress has repeatedly suspended the implementation of the Medical Device Tax.
 - ▶ The most recent suspension expires on December 31, 2019, and it appears that Congress may not extend the suspension before adjourning for 2019. It is possible, however, that Congress could enact a suspension at a later date, with retroactive effect to January 1, 2020.
- Although the law provides for some exemptions, many medical devices would be subject to the Medical Device Tax if it goes into effect.
 - ▶ In addition, there have been new classes of medical devices approved by the Food and Drug Administration (the “FDA”) since the original enactment of the Medical Device Tax, such as software-driven prescription digital therapeutics. These new classes of devices – not even contemplated by Congress or the Internal Revenue Service (“IRS”) at the time of enactment of the Medical Device Tax – also may now be subject to the tax.
- Manufacturers and importers generally must make semi-monthly deposits of the Medical Device Tax and file quarterly reports with the IRS. Penalties and interest apply if these deposits are not paid and reports are not filed.

The Medical Device Tax

In this Client Alert, Foley Hoag healthcare and tax attorneys provide some background on the Medical Device Tax, an explanation of the “retail exemption” from the tax and certain operational considerations relating to the tax.

Background

The Patient Protection and Affordable Care Act of 2010 contained a series of healthcare-related taxes, including the Medical Device Tax, that were intended to help pay for the medical insurance coverage expansions included as part of the new law.

The Medical Device Tax was codified in Section 4191 of the Internal Revenue Code. It imposes a tax equal to 2.3% of the sales price of any “taxable medical device.” Note that this tax is imposed on the **sales price** of the medical device – without any corresponding deduction for cost of goods sold. As a result, manufacturers or importers with low profit margins face the potential for negative cash flow when paying the tax.

The law generally defines a “taxable medical device” as any medical device approved by the Food and Drug Administration (the “FDA”) intended for human use. A medical device is generally an instrument or other similar or related article intended for use in the diagnosis or treatment of disease that does not achieve its primary intended purpose through chemical or biological action.

The Retail Exemption

Not all FDA-approved or cleared medical devices are subject to the Medical Device Tax. For example, eyeglasses, contact lenses and hearing aids are specifically exempt from the tax. The Medical Device Tax also does not apply to the sale of any other devices that are of a type generally purchased by the general public at retail for individual use (the “Retail Exemption”).

Regulations promulgated by the IRS in 2012 provided additional detail on the scope of the Retail Exemption. In general, the policy adopted in the IRS regulations is that a medical device is eligible for the Retail Exemption if (1) it is regularly available for purchase and use by individual consumers who are not medical professionals and (2) the design of the device demonstrates that it is not for use in a medical institution or office by a medical professional. For example, a toothbrush is a medical device that is eligible for the Retail Exemption; a heart-lung bypass machine is a medical device that is not eligible for the Retail Exemption. The IRS regulations flesh these concepts out in much greater detail by providing a safe harbor, as well as a non-exclusive list of positive and negative factors that are relevant to the determination of whether a particular medical device is subject to the Medical Device Tax.

Software Approved or Cleared as a Medical Device

Since the passage of the Patient Protection and Affordable Care Act and issuance of the IRS regulations, the FDA has approved or cleared some software applications and software technology products as medical devices. The IRS regulations address the issue of software sold as part of a bundle, and also indirectly make clear that software that is approved or cleared as a medical device may be subject to the Medical Device Tax. But, in many cases, technology has outpaced the guidance provided in the existing IRS regulations. Accordingly, some manufacturers and importers of digital therapeutics may not be aware of the Medical Device Tax or their possible obligation to pay it (subject to whether the Retail Exemption or other exemption under the applicable rules may be available).

Operational Considerations

The Medical Device Tax was codified in the subtitle of the Internal Revenue Code that governs manufacturer excise taxes; as such, the IRS has clarified that the operational and procedural rules applicable to those excise taxes also apply to the Medical Device Tax. Some relevant considerations include:

- A “sale” of a medical device occurs when a manufacturer or importer of a medical device agrees to transfer a taxable medical device in exchange for some form of consideration (typically, but not necessarily, cash). For example, a lease and an installment sale constitute a “sale” under the excise tax rules. Generally, the use of a demonstration or evaluation product, testing and development products and donations of a medical device can constitute a taxable sale, depending specifically on the facts and circumstances of the use of the product.
- There are a number of exemptions in addition to the Retail Exemption. For example, a sale of a taxable medical device by a manufacturer or importer may, in certain circumstances, be exempt from the Medical Device Tax if the device is sold for use by the purchaser for further manufacture (or for resale by the purchaser to a second purchaser for further manufacture), or for export (or for resale for export). To make a tax-free sale for further manufacture or export, both parties to the sale must be registered with the IRS.
- As noted above, the tax applies to the sales price of a medical device without a deduction for cost of goods sold. The IRS rejected suggestions that the “sales price” of a medical device could be based on a sales price of 75% of the retail price, with deductions for containers, transportation and packaging costs. A 1980 Revenue Ruling (Rev. Rul. 80-273, 1980-2 CB 315) held that such a sales price calculation was permissible in certain instances. However, because that Revenue Ruling only applies to explicitly-listed Internal Revenue Code sections, and Section 4191 is not one of those sections, the IRS concluded that it could not apply this policy. In addition, the IRS rejected a suggestion that a manufacturer or importer could use transfer pricing to calculate the sales price.
- The IRS regulations also address issues related to the treatment of rebates associated with the sales of medical devices, especially where rebates are granted after the sale of the device.
- Finally, the IRS regulations explain how payment and reporting of the Medical Device Tax will work. In general, manufacturer excise taxes are reported on IRS Form 720, which is filed quarterly with the IRS. A consolidated return option for reporting and payment of the tax is not available for medical device manufacturers or importers that are part of a consolidated group. In addition, manufacturers and importers must make semi-monthly deposits unless the net tax liability does not exceed \$2,500 for the quarter.

Penalties are applicable to manufacturers or importers that do not timely make the required deposits.

Conclusion

Because Congress has, over the years, repeatedly delayed the imposition of the Medical Device Tax, many manufacturers and importers may not realize that Congress has not yet extended the suspension of the tax beyond 2019. If Congress does not act, the Medical Device Tax may well go into effect in a few short weeks. Foley Hoag healthcare and tax attorneys are available to counsel clients who may have questions about the applicability of the Medical Device Tax to their medical device products and their related tax compliance and reporting obligations.

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