# IRS Issues Final Regulations for Medical Device Excise Tax Effective January 1, 2013: Industry Continues to Seek Delay or Repeal

The IRS recently published final regulations to implement the 2.3 percent medical device excise tax scheduled to go into effect on January 1, 2013. The final rule makes no major changes from the proposed rule issued earlier this year. The tax was included in the Patient Protection and Affordable Care Act, enacted in 2010. The IRS also issued an interim guidance document to clarify issues not covered in the final regulations. The medical device industry has strongly opposed this tax, and efforts to delay or repeal the tax are ongoing.

## Medical Devices Covered

The final regulations confirm that the tax covers any device, as defined in section 201(h) of the Federal Food, Drug & Cosmetic Act (FFDCA), intended for human use and required to be listed with the Food and Drug Administration (FDA) under section 510(j) of the FFDCA. FDA's drug listing regulations require manufacturers, repackagers or relabelers, and initial importers of medical devices to submit device listing information to FDA for devices in commercial distribution. An entity that contract manufactures a device for another party is not required to list that device.

Among other things, the final rule:

- Provides that so-called "dual use" devices that have both medical and non-medical uses are subject to the tax regardless of their end use.
- Provides that demonstration products may be taxable based on the "facts and circumstances" of the arrangement. The IRS declined commenters' suggestions to specifically exclude demonstration, evaluation, testing and development, and loaned products from the tax.
- States that medical devices covered under the FDA's humanitarian device exemption are not exempt from this tax.
- Provides relief for payments made after January 1, 2013 as part of medical device leasing or sales agreement entered into before March 30, 2010. These payments will not be taxable.

Under the interim guidance, the IRS interprets the statute and regulations as meaning that:

- Donated devices are not taxable unless the manufacturer has reason to believe the donation will be resold.
- Convenience kits are taxed based on the individual medical devices within the kit; only the proportion of the kit price that is allocated to taxable medical devices is taxable.

## The Retail Exemption

Devices generally purchased by the public at retail for individual use are not subject to the tax (the "retail exemption"). Devices are considered to fall under this exemption if two conditions are met:

- the device is regularly available for purchase and use by individual consumers who are not medical professionals, and
- the device's design demonstrates that it is not primarily intended for use in a medical institution or office, or by medical professionals.

The final rule retains the "facts and circumstances" approach of the proposed rule to determine whether a device falls within the exemption. The regulations list non-exclusive factors that will be used in this determination; packaging and labeling are not considered.

Eyeglasses, contacts, and hearing aids are specifically exempted from the tax. The final rule, consistent with the proposed rule, also provides a "safe harbor" for certain devices, which will be considered to fall under this exemption. Examples include devices described as over the counter by the FDA and certain durable medical equipment, prosthetics, orthotics, and supplies covered by Medicare.

## Determining Sale Price

Generally, manufacturers' excise taxes are based on the sale price to an independent wholesale distributor. This rule applies to medical device manufacturers as well. In other cases, a constructive price is determined. The interim guidance replaces the tax code's general rules for calculating this constructive price with rules specific to medical device manufacturers who use one of five enumerated distribution channels.

For example, if a medical device manufacturer sells taxable medical devices directly to end users, the constructive sale price is 75 percent of the actual selling price. If a medical device manufacturer sells taxable medical devices to an unrelated retailer, the constructive sale price is 90 percent of the lowest sale price. The interim guidance document states that sales to medical institutions or offices are considered retail, not wholesale, sales until further notice.

If a manufacturer's supply chain does not fall into one of the five enumerated ones, and the manufacturer does not use actual sale price to calculate the tax, the manufacturer bears the burden of demonstrating that it used a fair market price.

## Industry Opposition

The medical device industry has opposed the tax on the grounds that it would stifle innovation and cause layoffs. Representative Erik Paulsen (R-MN) has sponsored a bill to repeal the tax. There is also growing bipartisan support to delay implementation as part of the "fiscal cliff" negotiations, particularly given that the final rule was issued less than a month before the tax is scheduled to go into effect.

If you would like to discuss the foregoing or any other related matter, please contact your usual Ropes & Gray advisor.