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IRS Issues Device Tax Regulations; Industry Braces for 2013 Implementation

Pending the January 1 effective date, final regulations and interim guidance on the medical device excise tax provide some clarity but leave many questions unanswered.

On December 7, the Internal Revenue Service (IRS) issued final regulations[1] providing guidance on the implementation of the "medical device excise tax," which was imposed in section 4191 of the Internal Revenue Code (Code), as enacted under the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, in conjunction with the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (together, the ACA). Device companies should review the devices they market in the United States to assess their potential tax liability and consider whether there are strategies to potentially reduce this tax liability. Significantly, tax payments must be made semimonthly, and the first payment will be due January 29, 2013.

Overview of the Regulations

Subsection 4191(a), which becomes effective January 1, 2013, imposes on the sale of any taxable medical device by the manufacturer, producer, or importer an excise tax of 2.3% of the price for which the device was sold. Subsection 4191(b) defines a "taxable medical device" as any "device" (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act) intended for humans; there are, however, carve-outs for eyeglasses, contact lenses, heading aids, and "any other medical device" determined by the IRS to be "of a type" that is "generally purchased by the general public at retail for individual use" (the retail exemption).

The ACA added section 4191 to an existing framework of "manufacturers excise taxes" in chapter 32 of the Code. The medical device excise tax thus depends on existing statutes, regulations, case law, and IRS pronouncements (as modified by the ACA) that define "manufacturer," "importer," "sale," and "price" and provide working rules for applying all manufacturers excise taxes. Critically, for taxable medical devices made under a contract manufacturing arrangement, a facts-and-circumstances dependent legal conclusion must be made as to whether the principal or the contract manufacturer is the "manufacturer" (thus bearing the medical device excise tax). Manufacturers excise taxes are also imposed on leases or uses of articles by a manufacturer, producer, or importer.

The final regulations were issued after a two-year comment period, during which industry stakeholders made tremendous efforts to seek repeal of the medical device excise tax. While these efforts continue, many believe that if a repeal occurs, it will not take place until after the medical device excise tax becomes effective in 2013.

The regulations also recast the statutory definition of a "taxable medical device" as a device listed with the U.S. Food and Drug Administration (FDA) under section 510(j) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. part 807. This definition sparked a number of comments from stakeholders regarding the applicability of

1. Taxable Medical Devices, 77 Fed. Reg. 72,924 (Dec. 7, 2012) (to be codified at 26 C.F.R. pt. 48), *available at* http://www.gpo.gov/fdsys/pkg/FR-2012-12-07/pdf/2012-29628.pdf.

the tax to certain products. The final regulations respond to these comments, but it is clear that many questions will remain unresolved until after the tax becomes effective. In conjunction with the final regulations, the IRS issued Notice 2012-77 (the Notice),[2] which provides separate interim guidance on four areas of concern mentioned in the preamble to the final regulations.

Issues Addressed in the Final Regulations

- Application of the definition of "taxable medical device" to biologic devices, veterinary devices, devices with medical and nonmedical applications, humanitarian use devices, and devices that are required to be, but are not, listed with the FDA
- Scope of the retail exemption
  - The final regulations mirror the proposed regulations by rephrasing the retail exemption, stating that the exemption applies to a device if (i) it is regularly available for purchase and use by individual consumers who are not medical professionals, and (ii) the design of the device demonstrates that it is not primarily intended for use in a medical institution or office or by a medical professional.
  - The final regulations also mirror the proposed regulations by using a facts-and-circumstances approach to determine if a device meets requirements (i) and (ii), providing lists of nonexclusive factors relevant for making determinations under these requirements.
  - The final regulations helpfully augment eight examples from the proposed regulations with seven new examples illustrating the determination of whether a device falls within the retail exemption.
- Application of the tax to combination products (i.e., products that combine drugs, devices, and/or biological products)
- Application of the tax to installment sales, leases, and long-term contracts

Issues Addressed in the Notice

- Application of the constructive sale price rules to the medical device industry
  - The Notice provides interim rules for how to apply the constructive sale price rules of chapter 32 of the Code to certain representative model distribution chains used by some manufacturers in the medical device industry.
  - The Notice also provides, as an interim rule, that the IRS will treat the sale of a taxable article to a medical institution or office as a "sale at retail" for purposes of the manufacturers excise tax.
- Treatment of a donation of a taxable medical device by a device manufacturer to an "eligible donee" (an entity defined in section 170(c) of the Code) as a nontaxable use
- Application of the tax to software sold together with services, licensing of software, refurbished and remanufactured medical devices, replacement parts, and convenience kits
  - For purposes of the manufacturers excise tax, the IRS will treat a license of a taxable medical device as a lease of that device.
  - For "convenience kits"—sets of two or more devices (perhaps with other articles) enclosed in a single bag, tray, box, or other package for the convenience of a healthcare professional or end user—the IRS (i) will not impose the medical device excise tax on the sale of a domestically produced convenience kit by a manufacturer or importer[3] but (ii) will impose the medical device excise tax on the sale by an importer of a convenience kit that is a taxable medical device.[4]
- Deposit penalty relief

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2. View the Notice at http://www.irs.gov/pub/irs-drop/n-12-77.pdf.

3. The sale of a taxable medical device going **into** such a convenience kit **will** be subject to the excise tax.

4. The medical device excise tax is only imposed on that portion of the importer's sale price of the convenience kit that is "properly allocable" to separate taxable medical devices included in such kit.

- During the first three calendar quarters of 2013, the IRS will not impose the penalty under section 6656 of the Code for failure to make the semimonthly deposits of excise taxes under section 6032 of the Code, provided the taxpayer demonstrates a good-faith attempt to comply with regulatory requirements and that the failure was not due to willful neglect.

Implications

Effective January 1, 2013, device companies will be subject to a 2.3% excise tax on all devices listed with the FDA and will need to make payments semimonthly, with the first payment due January 29, 2013. Device manufacturers, therefore, should review the devices they have listed with the FDA to assess their potential tax liability and consider whether there are strategies to reduce this liability.

The Notice is only interim guidance, and the IRS is requesting comments for the issues addressed in the Notice before the guidance is finalized. Thus, device companies still have the opportunity to provide insight to the IRS on these particular issues and should submit comments by March 29, 2013.

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