MEDICAL DEVICE EXCISE TAX TAKES EFFECT ON JANUARY 1, 2013 AND CAN BE PASSED ON TO CUSTOMERS

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On December 7, 2012, the Internal Revenue Service (IRS) issued final regulations[1] concerning the implementation of the 2.3% medical device excise tax, which was put into law in section 4191 of the Internal Revenue Code as part of the Affordable Care Act.[2] The new medical device tax takes effect on January 1, 2013, with the first payments due on January 29, 2013. The IRS also issued Notice 2012-77 (the Notice)[3], which provides interim guidance until final regulations are issued.

The 2.3% Medical Device Excise Tax

Section 4191, which created the device tax, was added to existing laws governing other "manufacturers excise taxes" in Chapter 32 of the Internal Revenue Code. The implementation of the medical device tax therefore depends in part on already existing laws and regulations that govern the application of manufacturers excise taxes generally.

The 2.3% medical device excise tax is based on the medical device's price and is imposed on the manufacturer or importer when the taxable device is first sold, leased, rented or used by the manufacturer or importer. A taxable device is considered sold when title passes from the manufacturer to the purchaser.

The final regulations state that the manufacturer "making the sale of the taxable medical device is liable for the tax . . . ."[4] Manufacturers, however, are not prohibited from passing along the actual cost of the device tax to their customers. Manufacturers therefore will likely attempt to recover at least part of the cost of the tax from the purchasers to recoup some portion of their ultimate tax liability, although customers are likely to strongly resist such price increases and surcharges when it is Medicare, Medicaid, the Veterans Administration, or the Department of Defense that is ultimately responsible for payment.

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[1] Taxable Medical Devices, 77 Fed. Reg. 72,924 (Dec. 7, 2012) (to be codified at 26 CFR Part 48), available at http://www.gpo.gov/fdsys/pkg/FR-2012-12-07/pdf/2012-29628.pdf (last visited Dec. 17, 2012).

[2] The "Affordable Care Act" means 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.

[3] Available at http://www.irs.gov/file_source/pub/irs-drop/n-12-77.pdf (last visited Dec. 17, 2012).

[4] 26 CFR § 48.4191.1(c).

During the comment period on the regulations, the Federation of American Hospitals, American Hospital Association, Catholic Health Association of the United States, and the Health Industry Group Purchasing Association submitted a lengthy letter specifically requesting that "device companies should be prohibited from passing through the tax to their customers, including hospitals."[5]

While many medical device distributors and manufacturers initially believed that the regulations would prevent manufacturers from passing on the tax to its customers, that did not happen. The IRS and Treasury Department declined to include such a prohibition in the final regulations. The interim guidance included in Notice 2012-77 includes a section relating to sales to hospitals or doctors' offices and classifies such sales as "sales at retail," until the IRS and the Treasury Department issue further guidance.[6] The practical effect of this classification is that, for the time being, if a manufacturer sells exclusively to hospitals, medical clinics and medical offices, the manufacturer may use the 75-percent-of-actual-price safe harbor applicable to sales to ultimate users rather than the 90-percent-of-lowest-price safe harbor applicable to manufacturers that sell to retailers but not to wholesale distributors even if the hospital or office charges the patient for the device and the patient leaves the office with the device.[7]

Convenience Kits

Notice 2012-77 also provides interim guidance regarding the tax treatment of convenience kits.[8] The Notice acknowledges that finished taxable medical devices are oftentimes packaged together into kits for the convenience of a healthcare provider in the performance of a medical procedure. The Notice also states that convenience kits that are listed with the FDA under section 510(j) of the Federal Food Drug and Cosmetic Act (FFDCA) and 21 CFR Part 807 are "taxable medical devices" under the regulations unless they fall within an exemption under § 4191(b) or § 48.4191-2(b) of the regulations.[9]

As used in the Notice, a "convenience kit" is defined as a set of two or more devices that is enclosed in a single package, such as a bag, tray, or box, for the convenience of a health care professional or the end user. A convenience kit may contain a combination of devices and other articles.

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[5] http://www.aha.org/advocacy-issues/letter/2011/110328-cl-devexcisetax.pdf (last visited Dec. 13, 2012).
[6] Notice 2012-77, at § 4(a).
[7] Notice 2012-77, at § 3(b).
[8] Notice 2012-77, at § 5.
[9] Pursuant to § 4191(b) and 26 CFR 48.4191-2(b), the term "taxable medical device" does not include eyeglasses, contact lenses, hearing aids, and any other device of a type that is generally purchased by the general public at retail for individual use. This is known as the retail exemption.

Pursuant to the interim rules provided in the Notice:

> Until the IRS and the Treasury Department issue further guidance, no tax will be imposed upon the sale of a domestically-produced convenience kit that is a 'taxable medical device' under § 4191 of the Code and § 48.4191-2(b) of the regulations. During this interim period, the sale of a taxable medical device that goes into a domestically-produced convenience kit will be subject to tax upon its sale by the manufacturer or importer, pursuant to the normal rules of § 4191 and the regulations thereunder; however, *the sale of the convenience kit by the kit producer will not be subject to tax*.

Notice 2012-77, at § 5(c) (emphasis added).

Different rules apply, however, for imported convenience kits. Until further guidance is issued, imported convenience kits will be subject to the medical device excise tax, "but only on that portion of the importer's sale price of the convenience kit that is properly allocable to the individual taxable medical devices included in the convenience kit."[10]

How The Tax Is Calculated

According to already existing regulations, the inclusion of the tax as part of the cost of the taxable device is allowed, although the tax itself is not considered part of the sale price. So a manufacturer may compute the tax on the sale price and charge the proper tax as a separate item, which will not become part of the taxable sale price and no tax will be due on the excise tax itself.[11] If the manufacturer makes no separate charge for the tax, it will be presumed that the price includes the tax and the appropriate percentage of the charged price will be allocated to the tax.[12]

The regulations provide the following sample manufacturers excise tax calculation:

> (2) *Computation of tax.* If an article subject to tax at the rate of 10 percent is sold for $100 and an additional item of $10 is billed as tax, $100 is the taxable selling price and $10 is the amount of tax due thereon. However, if the article is sold for $100 with no separate billing or indication of the amount of the tax, it will be presumed that the tax is included in the $100, and a computation will be necessary to determine what portion of the total amount represents the sale price of the article and what portion represents the tax. The computation is as follows:
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> Taxable sale price = sale price including tax/100+rate of tax.
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> Thus, if the tax rate is 10 percent and the sale price including tax is $100, the

[10] Notice 2012-77, at § 5(d).
[11] 26 CFR § 48.4216(a)-2(a)(1).
[12] *Id.*

> taxable sale price is $90.91 (that is, $100 divided by (100+10)), and the tax is 10 percent of $90.91, or $9.09.

26 CFR § 48.4216(a)-2(a)(2).

The interim guidance provided in the Notice provides that during the first three quarters of 2013, the IRS will not impose penalties under section 6656 of the Internal Revenue Code for failure to make the semimonthly deposits of the excise taxes. The taxpayer will have to demonstrate, however, that it attempted in good faith to comply with the tax requirements and that its failure was not due to willful neglect.[13]

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[13] Notice 2012-77, at § 6(b).