Medical Device Tax News

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Final rules provide helpful guidance to the medical device industry – IRS and Treasury publish regulations notice and FAQs implementing Medical Device Excise Tax

Final regulations on the implementation of the Medical Device Excise Tax were released by the Federal Register on December 5, 2012. The Internal Revenue Service and the Department of the Treasury also released Notice 2012-77 addressing issues that were deferred in the final regulations as well as Frequently Asked Questions and answers. Though many questions remain unanswered, the IRS and Treasury have pledged to release further guidance in the future.

Background

The Statute

The Health Care and Education Reconciliation Act of 2010 ("Reconciliation Act") added new section 4191, captioned "Medical Devices," to the Code effective for sales of taxable medical devices after December 31, 2012. Pursuant to this new provision, an excise tax equal to 2.3 percent of the sale

price is imposed on the sale of any taxable medical device by the manufacturer, producer, or importer of such device. A taxable medical device is any device, defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act "FFDCA"), intended for humans.

The new provision does not apply to eyeglasses, contact lenses, hearing aids, and any other medical device determined by the Secretary to be of a type that is generally purchased by the general public at retail for individual use. The present law excise tax exemptions for further manufacture and for export also apply to the new tax imposed under section 4191 except that supplies for vessels or aircraft and for sales to state or local governments, nonprofit educational organizations, and qualified blood collector organizations are not exempted from the medical device tax.

The Proposed Regulations

The proposed rules were published on February 7, 2012, and addressed a number of issues that were raised by comments made in response to Notice 2010-89. These primarily focused on the definition of the term "taxable medical device" and the scope of the "Retail Exemption," but also dealt with other issue such as treatment of medical kits. The proposed rules generally deferred to the Food and Drug Administration's registration and listing rules for the definition of taxable medical devices and certain exemptions. A set of factors and a safe harbor were provided for implementation of the Retail Exemption.

Importantly, the proposed regulation made it clear that the final rules would track existing rules applicable to Chapter 32 manufacturers taxes. Thus, the existing section 4216(b) rules on constructive pricing for intercompany sales made other than at a fair market price would apply to determine the tax base rather than income tax transfer pricing principles.

THE FINAL REGULATIONS

The final regulations, T.D. 9604 (Dec. 7, 2012), primarily continued the focus of the proposed rules to address the definition of the term "taxable medical device." But, in responding to public comments on the proposed regulations, the preamble to the regulations provides additional insights.

Retail Exemption

The final regulations generally retain the "Safe Harbor" and "two-pronged facts and circumstances" test of the proposed rules' Retail Exemption. However, significant additions to the test and comments on the rules were made. Some of the most important follow:

1. Non-exclusivity of Factors - The regulation's facts and circumstances approach requires a balancing of the factors; no one factor is determinative. Thus, a device may qualify for the retail exemption without meeting all of the positive factors, and a device may qualify for the retail exemption even if there are one or more negative factors. Further, additional facts and circumstances not listed in the regulations may be pertinent in the determination of whether a device falls within the retail exemption. The final regulations include examples that illustrate the process for determining whether a device falls within the retail exemption, including the balancing of different factors.

2. Purchase at retail - The ability of a non-medical professional consumer to acquire a medical device at retail includes purchases in person, over the telephone, or internet, through retail businesses such as drug stores, supermarkets, or medical supply stores and retailers that primarily sell medical devices.

3. Cost - The cost factor for the retail exemption is a comparative one. It compares the costs of devices used in hospitals, doctors' offices and other medical institutions, such as x-ray machines or magnetic resonance imaging systems to those affordable by individual consumers. Large capital equipment would likely be prohibitively expensive for an average individual user.

4. FDA classification categories - Under the proposed regulations, the inclusion of a medical device in certain FDA regulatory classifications could be read as a fatal characteristic causing the device to fall outside the Retail Exemption. The final regulations ameliorate that fear somewhat. The final regulations do not remove any FDA classification categories from the test because the government continues to believe that the overwhelming majority of devices that fall within these regulatory categories do not fall within the Retail Exemption. However, under the final rules, such a characteristic is

simply one factor in applying the test. Devices in these categories must be evaluated in light of all relevant facts and circumstances. An example makes this point by providing that a portable oxygen concentrator, while classified by the FDA in 21 CFR Part 868, falls within the Retail Exemption under the facts and circumstances analysis.

Sale Price

The substantive provisions of the final regulations do not address specific issues concerning the determination of the sales price upon which the tax is applied. However, the preamble to the regulations addresses several points concerning the computation of the taxable sales price and the constructive price rules:

1. Rev. Rul. 80-273 - The IRS and Treasury specifically addressed requests that the final regulations extend the principle of Rev. Rul. 80-273 to taxable medical devices. Rev. Rul. 80-273 concludes that when a manufacturer or importer sells a taxable article directly to an unrelated end user at retail, the excise tax may be based on a sale price of 75 percent of the retail sale price, after certain adjustments. The government did not adopt that principle in the regulation, but, as discussed below, the IRS and Treasury extended the principles of Rev. Rul. 80-273 to certain distribution chains in interim guidance.

2. Patient or Hospital as End User - Commenters requested that the final regulations clarify that sales "at retail" in the medical device context include sales to hospitals and other medical service providers despite the fact that certain medical devices can be characterized as being on-sold to patients. This suggestion was not adopted, but the IRS and Treasury also applied this concept in interim guidance.

3. Transfer Price as Taxable Sales Price - A commenter requested that the final regulations provide that taxpayers can use transfer pricing under section 482 to determine the taxable sale price of a taxable medical device. The government responded that the standards are not identical under the section 482 regulations and section 4216. Therefore, an arm's length result determined under section 482 is not an appropriate proxy for the constructive sale price or fair market price under section 4216. In certain

circumstances, facts used to support a transfer price for purposes of section 482 may be relevant to determining the sale price under section 4216, but transfer pricing documentation or studies developed for purposes of section 482 or section 6662(e) will not be conclusive of the sales price.

4. Rebates - Several commenters requested that the final regulations provide manufacturers with the option of excluding from the sale price a reasonable estimate of purchase price adjustments for rebates, with a later true-up based on the actual rebate amounts. The regulations instead provide that a manufacturer may take a rebate into account in determining sale price only to the extent the rebate is made prior to the close of the quarter during which the sale associated with the rebate is made. Later price adjustments may result in refund claims.

Kits

A "kit" generally is a set of two or more articles packaged in a single bag, tray, or box for the convenience of the end user. The proposed regulations provided that a kit listed with the FDA is itself a taxable medical device, and the inclusion of other taxable medical devices in the assembly of the kit constituted "further manufacture" by the person that produced the kit.

The final regulations are silent regarding whether kit assembly is further manufacture. However, in interim guidance discussed below, the IRS and Treasury set forth temporary rules for kits produced domestically and for kits that are imported.

Several commenters also requested that the final regulations confirm that the assembly of a kit by a hospital or medical institution for its own use would not be taxable. Hospitals or medical institutions that produce kits for their own use are exempt from the FDA's registration and listing requirements. Therefore, such kits are not taxable medical devices and the use of the self-produced kits by the hospital or medical institution would not be a taxable use.

Installment sales, leases, and long-term contracts

Several commenters requested transition relief for installment sales and leases of taxable medical devices where the contract is entered into prior to the effective date of the tax on January 1, 2013. The final rules provide transition relief for contracts entered into prior to March 30, 2010, the date the ACA was enacted.

Specifically, the final regulations provide that payments made on or after January 1, 2013, pursuant to a written binding contract for the lease, installment sale, or sale on credit of a taxable medical device that was in effect prior to March 30, 2010, are not subject to tax unless the contract is materially modified on or after March 30, 2010.

Other Rules

The government also declined to adopt in the final regulations many significant comments on the proposed regulations. The most significant of these include:

1. Packaging and Labeling - The IRS and Treasury determined that a device's packaging and labeling are not instructive in determining whether a device falls into the Retail Exemption.

2. Documents submitted for FDA notification or approval - A commenter requested that the final regulations include a factor that considered whether documents submitted to the FDA included a statement that the device is intended for individual use. The government noted that such documents are not consistently reliable indicators of whether a device is of a type that is generally purchased by the general public for individual use and therefore may not be relevant for this test.

3. Safe Harbor; Durable Medical Equipment, Prosthetics, Orthotics and Supplies ("DMEPOS") - A commenter suggested that the Retail Exemption safe harbor be expanded to include all devices that fall under the definition of DMEPOS in 42 CFR 414.202. The regulations provide that devices that fall within the definition of DMEPOS that are not included in the retail exemption safe harbor, such as oxygen equipment and other rental durable medical

equipment devices, may qualify for the retail exemption by application of the facts and circumstances test.

4. Safe Harbor; Capped Rental Devices - A commenter suggested that the safe harbor be expanded to include "capped rental" devices which are devices for which title transfers to the individual Medicare beneficiary at the end of the rental term.

The government determined that information on the capped rental devices does not suggest a pattern of title transfer for specific types of devices. Accordingly, devices cannot categorically be said to fall within the Retail Exemption. However, such devices may qualify for the Retail Exemption by an application of the facts and circumstances test.

5. Other Requested Exceptions - Commenters suggested that a number of specific exclusions be contained in the regulations for certain devices or uses. Finding no statutory authority to do so, the government has declined to provide exemptions for.

> Dental devices such as crowns, bridges, and braces;
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> Combination products that are taken into account in computing the separate branded prescription drug fee;
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> Dual Use Devices, i.e., a listed medical device that can also be used for a non-medical purpose; and
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> Humanitarian Use Devices for which the FDA has approved a Humanitarian Device Exemption.

Request for Additional Comments

The preamble to the final regulations requests additional comments on a single issue. The IRS and the Treasury Department request public comments to help identify listed components of exempt devices, but which components are not included in a safe harbor or do not otherwise fall within the retail exemption by an application of the facts and circumstances test.

NOTICE 2012-77

The IRS and Treasury also issued interim guidance providing temporary rules to be followed until final rules are issued. The Notice provides guidance in six areas not explicitly covered by the final regulations:

1. Determination of Price under Section 4216(b) - The principles of Rev. Rul. 80-273, other published guidance and statutory constructive pricing rules are applied to various distribution chains in arriving at a constructive sales price when there are no sales of the identical articles to independent wholesale distributors. The distribution chains include: (i) Sales at retail; (ii) Sales to unrelated retailers; (iii) Sales to related retailer; (iv) Sales to related reseller that leases and sells at retail; (v) Sales to related reseller that leases and sells at retail; and (vi) Sales to related reseller that only leases at retail.

2. Status of Health Care Provider as End User - Sales of taxable medical devices to medical institutions or offices will be treated as sales at retail.

3. Licenses - A license of a taxable medical device is to be treated as a lease of that taxable medical device as of the date both parties entered into the license agreement.

4. Donated Taxable Medical Devices - The donation of a taxable medical device by the manufacturer of the device to an *eligible donee* will not constitute a taxable use as defined in section 4218. However, if at the time of donation, the manufacturer has reason to believe that the donation is not being made to an *eligible donee* or that the article donated will be resold by the *eligible donee*, the manufacturer is not relieved from the liability for the tax imposed. An *eligible donee* is an entity described in section 170(c). The rules of section 4219 (related to the application of tax in case of sales by other than the manufacturer) apply to an *eligible donee* that receives a donated taxable medical device and subsequently sells the taxable medical device.

5. Medical Convenience Kits - A convenience kit is defined as a set of two or more devices within the meaning of section 201(h) of the FFDCA 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, within the meaning of section 201(h) of the FFDCA,

and other articles. The Notice provides that no tax will be imposed upon the sale of a domestically-produced convenience kit that would be a "taxable medical device." However, 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. Tax will be imposed on the sale by an importer of a convenience kit that is a taxable medical device, 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. When an importer sells a convenience kit that is a taxable medical device, the taxable portion of the sale price of such convenience kit may be determined by allocating the aggregate sale price between that of the taxable medical devices and nontaxable articles in the convenience kit.

6. Deposit Penalty Relief - During the first three calendar quarters of 2013, the IRS will not impose the penalty provided in section 6656 on a taxpayer that is liable for the medical device excise tax that fails to make timely deposits of the medical device excise tax as required by Treas. Reg. §§ 40.6302(c)-1 and 40.6302(c)-2 (relating to special deposits required in September), provided that the taxpayer demonstrates a good faith attempt to comply with requirements of Treas. Reg. §§ 40.6302(c)-1 and 40.6302(c)-2 and that the failure was not due to willful neglect.

Thereafter, a taxpayer may avoid penalties if it makes an affirmative showing that the failure to deposit is due to reasonable cause and not due to willful neglect. In addition, during the third and fourth calendar quarters of 2013, the IRS will not exercise its authority under Treas. Reg. § 40.6302(c)-1(b)(2)(v) to withdraw the taxpayer's right to use the deposit safe harbor rules of Treas. Reg. § 40.6302(c)-1(b)(2)(ii).

Comments on the interim guidance are requested by March 29, 2013.

FAQs were also published that restate the rules provided in the guidance discussed above.

PwC OBSERVATIONS

The publication of the final regulations and the adherence to the FDA listing requirements allows taxpayers to make final determinations concerning whether medical devices that they manufacture or export are subject to tax or

whether the devices fall into an exemption. It is expected the IRS Office of Chief Counsel will entertain private letter ruling requests. Medical device companies should consider requesting letter rulings to clarify any ambiguities concerning the status of their devices.

With respect to the determination of the taxable sales price, the IRS has signaled its intention to work with medical device companies and their representatives. Indeed, a private letter ruling or other IRS arrangement may provide a constructive price rule with respect to a company's particular fact pattern. Alternatively, the interim guidance may be followed. It is likely, however, that medical device companies may be able to provide data to the IRS that will support a more favorable discount from retail sales prices than is offered by the rules of Notice 2012-77.

Medical device companies should also consider submitting comments requested by the preamble to the final regulations and the interim rules in Notice 2012-77. With respect to the interim rules, the IRS and Treasury request comments on distribution chains not described in the Notice. In addition, the IRS and Treasury recognize that different segments of the industry use different distribution chains for different devices and that the determination of the price at which a manufacturer would sell its devices to a hypothetical independent wholesale distributor may vary across those segments. Therefore comments are requested on the manner in which the constructive sale price rules might address this segmentation, including comments on a reasonable percentage of the applicable sale price for determining the constructive sale price for each segment or product. Further, the IRS and Treasury request comments regarding alternative methods for determining the price for the distribution chain concerning sales to a related distributor that only leases and where there are no sales of the identical article to independent wholesale distributors.

Interestingly, the IRS and Treasury did not address several issues that widely affect the medical device industry. Specifically, the final regulation and Notice are silent regarding the treatment of group purchasing organization (GPO) fees as section 4216(a) exclusions. In addition, the guidance, in rejecting an approach for estimating future rebates, does not provide a solution to the industry limitation when "charge backs" and end customer rebates can rarely be tied back to original sales transaction.

Below are links to the new guidance.

http://www.ofr.gov/OFRUpload/OFRData/2012-29628_PI.pdf

For more information, please do not hesitate to contact:

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