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TAX, BENEFITS AND NONPROFIT ORGANIZATIONS CLIENT ALERT

TREASURY ISSUES BINDING GUIDANCE ON MEDICAL DEVICE EXCISE TAX

Overview

The Department of the Treasury and the Internal Revenue Service (IRS) published in the December 7, 2012 Federal Register final regulations and released other interim guidance on the implementation of the new excise tax on medical devices. The IRS also posted FAQs on the new excise tax. Effective January 1, 2013, section 4191 of the Internal Revenue Code imposes on manufacturers and importers of taxable medical devices a tax equal to 2.3 percent of the "price" at which a taxable medical device is sold. Congress provided exemptions for eyeglasses, hearing aids, contact lenses and "any other medical device determined … to be of a type which is generally purchased by the general public at retail for individual use" (the "retail exemption").

The new regulations make relatively few changes to the regulations that were proposed in February 2012 (the "proposed regulations"). The final regulations include additional guidance on the retail exemption and include 15 examples (including eight new examples) showing how the retail exemption rules apply.

The preamble to the final regulations responds to comments received by the IRS on the proposed regulations and explains the reasons the Treasury and IRS rejected positions advocated by commenters. The IRS and Treasury also used the preamble to clarify a variety of issues that are not specifically addressed in the final regulations.
In Notice 2012-77, the IRS provided interim guidance on key issues of concern to manufacturers and purchasers of medical devices, including rules on constructive sales price, the treatment of licenses, the application of the tax to donated articles and convenience kits, and provides relief from penalties for failures to make adequate deposits of tax.

Interim Guidance

Constructive Purchase Price

Section 4216 of the Code and regulations under section 4216 provide rules for determining "price" for purposes of manufacturers excise taxes. Those rules apply to sales of taxable medical devices. The section 4216 rules treat the price for which a manufacturer sells a taxable article to an independent wholesale distributor, subject to certain adjustments, as the applicable price for purposes of the tax. Generally, a constructive price needs to be determined when a manufacturer sells a taxable article to a purchaser other than an independent wholesale distributor. Notice 2012-77 provides safe harbors for determining price when manufacturers and importers sell through certain distribution chains. For example, if a manufacturer sells taxable medical devices to unrelated end-users and does not regularly sell the medical devices to independent wholesale distributors, the constructive sales price is 75 percent of the actual selling price after taking into account the adjustments provided in section 4216(a) (i.e., exclusion of amount of the tax and transportation, delivery, installation and other similar charges). If a manufacturer sells articles to unrelated retailers but not to independent wholesale distributors , the constructive sales price is 90 percent of the lowest price for which the articles are sold to unrelated retailers (as determined without adjustment for any exclusion other than for the tax). The notice also provides safe harbors for (i) sales to related retailers when the manufacturer does not sell to independent wholesalers, (ii) sales to related resellers that sell and lease the articles to unrelated end-users, and (iii) sales to related resellers that only lease if there are no regular sales to independent wholesale distributors.

Under the interim guidance, the IRS will treat the sale of a taxable article to a medical institution or office as a "sale at retail" for purposes of applying the sales price rules. Thus, for example, if a medical device manufacturer sells exclusively to hospitals, medical clinics and medical offices, the manufacturer can 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.

A taxpayer that does not follow the safe harbors and does not use the actual sales price of the article to calculate the tax bears the burden of demonstrating that it used the fair market value of the article to calculate the tax liability.

Licenses

The Notice states that the IRS will treat the license of a taxable medical device as a lease of that device as of the date both parties entered into the license agreement. In the case of a lease by a manufacturer or importer, the tax is imposed on rental payments. Therefore, in the case of a license of a taxable medical device by the manufacturer of the device, the tax will be imposed on the license payments.

Donations to Charity

The Notice treats the donation of a taxable medical device to a charity (other than for resale by the charity) as a nontaxable use. The charity would be subject to tax if it subsequently sells the device.

Convenience Kits

In a departure from the position taken by the Notice of Proposed Rulemaking in February, the Notice states that no tax will be imposed on the sale of a domestically produced kit that is listed as a medical device with the FDA. Instead, tax will be imposed on the sale of taxable medical devices that go into domestically produced kits.

The excise tax will be imposed on the sale of an imported kit that is a taxable medical device, but only on the portion of the price attributable to taxable medical devices included in the kit.

Deposit Penalty Relief

The Notice states that during the first three calendar quarters of 2013 the IRS will not impose a penalty for failure to make adequate, timely deposits of the excise tax if the taxpayer demonstrates a good faith attempt to comply with the deposit requirements and the failure was not due to willful neglect. The "good faith attempt" standard replaces the "reasonable cause" test that otherwise would apply. Tax law requires that the tax be deposited semi-monthly.

Temporary Status of Guidance

The interim guidance generally applies only until the IRS and Treasury issue further guidance. Notice 2012-77 invites comments on the interim guidance. The notice states that the deadline for submission of comments is March 29, 2013.

Final Regulations

The final regulations make relatively few changes in the proposed regulations discussed in our client alert dated February 7, 2012, but they do significantly expand the discussion of the application of the retail exemption. We discuss below places in which the final regulations expand on or make changes from the proposed regulations.

Retail Exemption

The final regulations state, "A device will considered to be of a type generally purchased by the general public at retail for individual use [and, therefore eligible for the retail exemption] if it is regularly available for purchase and use by individual consumers who are not medical professionals, and if 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." Like the proposed regulations, the final regulations provide a facts-and-circumstances test and certain safe harbors for determining whether a device qualifies for the retail exemption. The final regulations make clear that the final regulation's list of factors to be considered in applying the facts-and-circumstances test is not exclusive. The preamble reiterates that no one factor is determinative and that a device may qualify even it meets a negative factor. The fact that a device can be purchased only with a prescription is not a factor in determining whether the device falls under the retail exemption.

The final regulations identify three factors that are relevant in determining whether a device is of a type regularly available for purchase and use by individual consumers:

- Whether consumers who are not medical professionals can purchase the device in person, over the telephone, or over the Internet, through retail businesses or medical supply stores and retailers that primarily sell devices, including durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers;

- Whether consumers who are not medical professionals can use the device safely and effectively for its intended medical use with minimal or no training from a medical professional; and
- Whether the device is classified by the FDA under Subpart D of 21 CFR part 890 (Physical Medicine Devices).

The following factors are relevant in determining whether is device is designed primarily for use in a medical institution or office:

- Whether the device generally must be implanted, inserted, operated , or otherwise administered by a medical professional;
- Whether the cost to acquire, maintain, and/or use the device requires a large initial investment and/or ongoing expenditure that is not affordable for the average individual consumer;
- Whether the device is a Class III device under the FDA system of classification;
- Whether the device is classified under certain listed parts or subparts of the FDA regulations; and
- Whether the device qualifies as DMEPOS for which payment is available exclusively on a rental basis under the Medicare Part B payment rules, and is an item requiring frequent and substantial servicing.

Under the safe-harbor rules of the final regulations, certain types of devices will automatically be eligible for the retail exemption. These include, among others, devices included in the FDA's online IVD Home Use Lab Tests database; devices described as OTC or over-the-counter in the relevant FDA classification regulation heading; devices described as OTC or over-the-counter in the FDA's product code name or device classification name; certain types of devices that qualify as durable medical equipment, prosthetics, orthotics and supplies and that meet other listed requirements; and supplies necessary for the effective use of durable medical equipment.

The final regulations include 15 detailed examples illustrating the application of the rules for determining whether the retail exemption applies to a type of device. Examples indicate that portable oxygen concentrators, urinary ileostomy bags, mechanical and powered wheelchairs, absorbent tip applicators, adhesive bandages, snake bite suction kits, denture adhesives, pregnancy kits, blood glucose monitors, blood glucose test strips, single axis endoskeletal knee shin systems, certain prosthetic legs, and therapeutic AC powered adjustable home use beds qualify for the retail exemption The examples illustrates that device can qualify for the retail exemption even if it is in an FDA classification category that suggests that the device is primarily for use in a medical institution or office by a medical professional. Other examples indicate that powered flotation therapy beds, nonabsorbable silk sutures, magnetic resonance imaging systems, and mobile x-ray systems do not qualify for the retail exemption.

Pre-2013 Leases and Installment Sales

The final regulations state that the excise tax will apply to payments made on or after January 1, 2013, "pursuant to a contract for the lease, installment sale, or sale on credit of a taxable medical device that was entered into on or after March 30, 2010." The tax does not apply to "payments made pursuant to a binding contract for a lease, installment sale, or sale on credit … that was in effect before March 30, 2010," unless there was a material modification on or after March 30, 2010.

This provision is likely to generate controversy and challenge. The medical device excise tax applies to sales after December 31, 2012. Section 4217 of the Code treats the lease by a manufacturer as a sale for purposes of manufacturers excise taxes. In the case of a lease treated as a sale, section 4217(b) imposes the excise tax on each lease payment until the total tax on the lease payments under the lease and any prior lease to which the subsection applies equals the "total tax" as defined in section 4217(c). As a general rule, the total tax is the tax computed on the

constructive sale price for an article which would be determined under section 4216(b) if the article were sold at retail on the date of the first lease to which subsection (b) applies. Some argue that it takes a tortured reading of section 4217 to conclude that payments on a lease commenced before 2013 are subject to tax.

Guidance in Preamble

The Treasury and the IRS used the preamble to the final regulations to provide additional informal guidance on the IRS's position on matters on which commenters had made comments or inquiries. Some of the guidance from the IRS and Treasury follows:

- Devices that the FDA Center for Biologics Evaluation and Research (CBER) regulates and that are not listed with the FDA under section 510(j) of the FFDCA or 21 CFR part 807 are not taxable medical devices. Thus, biologics, such as in vitro diagnostic tests for blood screening, that are listed under 21 CFR part 607 are not taxable medical devices.
- Software updates that do not have to be separately listed with the FDA are not taxable.
- If a manufacturer lists a device with the FDA that does not have to be listed and the device is subsequently delisted, the manufacturer may be able to obtain a refund or credit for the tax paid.
- The tax is excluded from the price for purposes of determining the tax even if the tax is not stated as a separate charge.
- If an entire software and service bundle is not listed with the FDA, the tax only attaches to the components of the bundle that are listed with the FDA.
- If a product falls within a safe harbor for devices eligible for the retail exemption, the factors in the facts and circumstances are not relevant.

The preamble states that the IRS and Treasury request public comments to help identify listed components of devices that are exempt under the retail exemption that are not included in the safe harbor or that do not otherwise fall within the retail exemption by application of the facts-and-circumstances test.

Rejected Positions in Preamble

The Treasury and IRS used the preamble to reject suggestions and proposals from taxpayers. Some of the positions that the Treasury and IRS rejected are:

- The tax should not apply to combination products (products regulated as drugs and medical devices), products listed as medical devices when sold for nonmedical uses, or Humanitarian Use Devices.
- The tax should not apply to otherwise taxable devices if labeled "veterinary use only" or "not for human use."
- The tax should not apply to products such as sterilization processor indicators, software, and containers used to hold or transfer medical devices because the devices are not "intended for humans."
- The regulations should include a presumption that the party that lists a device with the FDA is the manufacturer.
- Manufacturers may exclude from the sales price a reasonable estimate of future purchase price adjustments for rebates.
- The refurbishing or rebuilding of an already taxed medical device never creates a new taxable medical device.
- Replacement parts should never be subject to tax even if they are separately listed with the FDA. (Instead the provisions of existing law apply. Replacements under a warranty are generally taxable only to the extent that the customer pays an additional amount.)

- Using a product in any of following ways is not a taxable use per se (but in some cases may be a nontaxable use under prior rulings and other guidance):

    - As a demonstration product for health care professionals and product awareness;
    - As evaluation products provided to help health care professionals determine whether and when to use, order, purchase or recommend the device;
    - As a loaned device to facilitate procedures utilizing a sold taxable medical device; and
    - As a testing and development product.

- Members of an affiliated group should be able to file a joint Form 720 Excise Tax Return.
- Small medical device manufacturers should be able to report annually rather than quarterly.
- Entities that are "disregarded entities" for income tax purposes should also be disregarded for excise tax purposes. (The IRS reaffirmed that disregarded entities and corporate affiliates must file separate returns and, if required to register to obtain tax exemptions, must register separately.)

- The following factors should be removed from the factors for the facts-and-circumstances test for determining whether the retail exemption applies:

    - The "cost" of a product.
    - The classification of a device as a Class III device.

- Packaging and labeling should be added to the factors for the facts-and-circumstances test.
- The retail exemption safe harbor should be expanded to include all devices that fall under the definition of DMEPOS in 42 CFR 414.202.
- The retail exemption safe harbor should be expanded to include "capped rental" devices.

Scope of Guidance

The final regulations and interim guidance do not come close to answering all of the questions that device manufacturers and importers have about the application of the tax. Manufacturers excise taxes, including the excise tax on medical devices, are governed by a series of Code provisions and regulations that address items such as "price," taxable uses by the manufacturer, leases, exemptions for use in further manufacture or for export, timing for depositing the tax, tax refunds and credits, and tax returns. The answers to some questions will have to be derived from old cases and rulings on other manufacturers excise taxes. In addition, companies are likely to use the opportunity to comment on the interim guidance to seek additional guidance from the IRS on unrelated issues or to challenge some of the provisions in Notice 2012-77.

OUR TEAM

- George J. Schutzer, Partner and Chair of Patton Boggs' Tax, Benefits and Nonprofit Organization Practice Group.
- Rosemary Becchi, Partner. Tax and Public Policy.
- Martha Kendrick, Partner. Health Care Law and Public Policy.
- Michael Anderson, Associate. Tax.
- Anne Spiggle, Counsel. Food, Drug and Medical Device Law.
- Carey Nuttall, Associate. Food, Drug and Medical Device Law.
- Darryl Nirenberg, Partner. Public Policy.

OUR PUBLICATIONS

- Tax Policy Client Alert, "Regulations on Medical Device Excise Tax Proposed; Opportunities for Comment," February 7, 2012. Posted on our website here.
- Tax Policy Client Alert, "Medical Excise Tax: Avoid Surprises, Seek Answers Now," June 3, 2011. Posted on our website here.

OUR PRESENTATIONS

- Annual Meeting of AdvaMed, Tax Panel, October 3, 2012
- AdvaMed Device Tax Working Group webinar, "Preparation of Form 637 – Application for Registration (for Certain Excise Tax Activities), September 28, 2012.
- AdvaMed Medical Device Tax Workshop, Arlington, VA, September 19, 2012.
- AdvaMed Medical Device Tax Workshop, Irvine, CA, April 17-18, 2012.
- AdvaMed Webinar, "The Medical Device Excise Tax: What You Don't Know Could Cost You," July 15, 2010.

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