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Client Alert

FDA & Life Sciences, Tax, and Government Advocacy & Public Policy Practice Groups

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IRS Issues Final Regulations Implementing the Affordable Care Act's Medical Device Excise Tax

On December 5, 2012, the Internal Revenue Service (IRS) published final regulations regarding the implementation of the excise tax applicable to the sale of certain medical devices, enacted by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), and codified under section 4191 of the Internal Revenue Code (Code). The IRS developed the final regulations in consultation with the Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS). The final regulations provide additional guidance regarding which devices are subject to the tax, address comments submitted to the IRS in response to proposed regulations issued in February 2012 and during a May 2012 public hearing, and seek further comment on certain issues.

The ACA imposed an excise tax on the sale of certain medical devices by the manufacturer, producer or importer of the device in an amount equal to 2.3% of the sale price, effective January 1, 2013. Excluded from the tax are eyeglasses, contact lenses, hearing aids and "any other medical device determined by the Secretary [of the Treasury] to be of a type that is generally purchased by the general public at retail for individual use."

Although efforts are underway to legislatively repeal the excise tax or, at a minimum, delay its effective date, if such efforts are unsuccessful, many medical device manufacturers will be subject to the tax effective January 1, 2013. The medical device excise tax is reported on Form 720 (Quarterly Federal Excise Tax Return) on a quarterly basis, and most taxpayers subject to the tax will be required to make semi-monthly deposits to the IRS. The first semi-monthly deposit for the medical device excise tax, which covers the first 15 days of January 2013, is due on January 29, 2013. The IRS has stated that it will not impose penalties for the first three calendar quarters of 2013 on taxpayers who make good faith efforts to comply with the medical device excise tax filing requirements.

Definition of a "Taxable Medical Device"

The medical device excise tax will be imposed on "taxable medical devices." Section 4191(b)(1) of the Code defines a "taxable medical device" as a device defined in section 201(h) of the federal Food, Drug and Cosmetic Act (FDCA) that is intended for humans. The IRS final regulations further define

For more information, contact:

Seth H. Lundy
+1 202 626 2924
slundy@kslaw.com

Marian J. Lee
+1 202 661 7955
mlee@kslaw.com

Hap Shashy
+1 202 626 5614
hshashy@kslaw.com

Preeya Noronha Pinto
+1 202 626 5547
ppinto@kslaw.com

Michael A. Andrews
+1 202 626 5609
mandrews@kslaw.com

Sara Silverstein
+1 202 626 2646
ssilverstein@kslaw.com

King & Spalding
Washington, D.C.
1700 Pennsylvania Avenue, NW
Washington, D.C. 20006-4707
Tel: +1 202 737 0500
Fax: +1 202 626 3737

www.kslaw.com

the term to mean that the device must be listed as a device with the FDA under section 510(j) of the FDCA and 21 C.F.R. Part 807. If a device is not listed with the FDA, but the FDA later determines that the device should have been listed as a device, the device will be deemed to have been listed as a device with the FDA as of the date the FDA notifies the manufacturer or importer in writing that corrective action with respect to listing is required. Conversely, if a manufacturer lists a device with the FDA but the device was not required to be listed, a credit or refund may be available for tax paid on sales of the device once the device has been de-listed.

The final regulations clarify that section 4191 does not limit the definition of a taxable medical device to a device that is intended exclusively for medical purposes. Dual-use devices, that is, devices that may have medical and non-medical purposes, meet the definition of a taxable medical device as long as they are devices under section 201(h) of the FDCA and are listed with the FDA under section 510(j) of the FDCA and 21 C.F.R. Part 807. Further, devices that are not used in the direct treatment, diagnosis or monitoring of a patient (*e.g.*, sterilization process indicators, software and containers used to hold or transport medical products) are also considered to be taxable medical devices if they meet the FDA listing requirements.

Similarly, devices that have both human and veterinary applications would be considered taxable medical devices if they meet the FDA listing requirements. If a device is listed for use exclusively in veterinary medicine, however, then it would not meet the definition of a "taxable medical device."

Humanitarian Use Devices marketed under a Humanitarian Device Exemption are not exempt from the FDA listing requirements and, therefore, are also considered to be "taxable medical devices" unless they are otherwise exempt from the definition. Software and software updates that are not required to be separately listed with the FDA, however, do not fall within the definition of a "taxable medical device."

Combination products (therapeutic or diagnostic products that combine devices with drugs and/or biological products) that meet the FDA listing requirements are taxable medical devices unless they are otherwise exempt from the definition. This determination is made regardless of whether the annual fee for branded prescription drugs set forth in section 9008 of the ACA is also applicable to the product.

With regard to particular uses by a manufacturer, the IRS declined to issue a blanket exemption for medical devices used for demonstration, evaluation or testing purposes. Generally, existing IRS rules provide that, if a manufacturer of a taxable article uses the article for any purpose other than in the manufacture of another taxable article, then the manufacturer is liable for tax on the article as if the manufacturer had sold it. Nevertheless, IRS rules may limit the taxability of particular medical devices used as demonstration products, and also provide that, if a manufacturer uses a taxable article in the testing of another article of its own manufacture, the use of the taxable article is not a taxable use.

If a manufacturer refurbishes or remanufactures a medical device into a new and different taxable article, then that article can be considered a taxable medical device if it meets the FDA listing requirements and is not otherwise subject to an exemption to the definition. Also, if a manufacturer provides a replacement device (or replacement part) to a purchaser, tax liability is assessed on the actual amount, if any, paid for the replacement item, whether under warranty or not.

Sales of taxable medical devices for further manufacture or export may be made tax free if certain registration and other requirements are met.

The Retail Exemption's Facts and Circumstances Test

Section 4191(b)(2) of the Code provides that the term "taxable medical device" does not include eyeglasses, contact lenses, hearing aids and any other medical device determined by the Secretary of the Treasury to be of a type that is generally purchased by the general public at retail for individual use. The final rule has set forth a "facts and circumstances" test to determine whether a particular device qualifies for the "retail exemption" to the medical device excise tax. The test begins with a two-pronged analysis—a device will be considered of a type generally purchased by the general public at retail for individual use if: (1) it is regularly available for purchase and use by individual consumers who are not medical professionals, and (2) 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. Each prong is analyzed through consideration of a number of factors. No one factor is determinative to the analysis, and other factors not specifically listed by the IRS in the final regulations may also be considered. The determination of whether a device qualifies for the retail exemption is made based on the overall balance of positive and negative factors relevant to the particular type of device.

The following factors suggest that a device is of a type that is regularly available for purchase and use by individual consumers who are not medical professionals (the "positive factors"):

- Consumers who are not medical professionals can purchase the device in person, over the telephone, or over the internet, through retail businesses such as drug stores, supermarkets, or medical supply stores and retailers that primarily sell devices (for example, specialty medical stores, durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers and similar vendors)[1];

- Consumers who are not medical professionals can use the device safely and effectively for its intended purpose with minimal or no training from a medical professional; and

- The device is classified by the FDA under Subpart D of 21 C.F.R. Part 890 (Physical Medicine Devices).

The following factors suggest that a device is designed primarily for use in a medical institution or office or by a medical professional (the "negative factors"):

- The device generally must be implanted, inserted, operated, or otherwise administered by a medical professional;

- 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;

- The device is a Class III device under the FDA system of classification;

[1] The final regulations broadened the scope of this factor, which in the proposed regulations, referred only to "drug stores, supermarkets and similar vendors." *See* 77 Fed. Reg. 6028 at 6036 (Feb. 7, 2012).

- The device is classified by the FDA under—
    - 21 C.F.R. Part 862 (Clinical Chemistry and Clinical Toxicology Devices), 21 C.F.R. Part 864 (Hematology and Pathology Devices), 21 C.F.R. Part 866 (Immunology and Microbiology Devices), 21 C.F.R. Part 868 (Anesthesiology Devices), 21 C.F.R. Part 870 (Cardiovascular Devices), 21 C.F.R. Part 874 (Ear, Nose and Throat Devices), 21 C.F.R. Part 876 (Gastroenterology – Urology Devices), 21 C.F.R. Part 878 (General and Plastic Surgery Devices), 21 C.F.R. Part 882 (Neurological Devices), 21 C.F.R. Part 886 (Ophthalmic Devices), 21 C.F.R. Part 888 (Orthopedic Devices) and 21 C.F.R. Part 892 (Radiology Devices);
    - Subpart B, Subpart D or Subpart E of 21 C.F.R. Part 872 (Dental Devices);
    - Subpart B, Subpart C, Subpart D, Subpart E or Subpart G of 21 C.F.R. Part 884 (Obstetrical and Gynecological Devices); or
    - Subpart B of 21 C.F.R. Part 890 (Physical Medicine Devices); and
- The device is a DMEPOS item 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" as defined in 42 C.F.R. § 414.222.

The final regulations clarified that the fact that a device requires a prescription, or the contents of a device's packaging and labeling, are not instructive as to whether a device is generally purchased by the general public at retail for individual use. Further, the IRS stated that documents submitted to the FDA, such as those in support of a PMA application or 510(k) clearance, are not consistently reliable indicators of whether a device falls within the retail exemption.

The IRS provided a number of examples of devices that, through application of the above facts and circumstances test, fall within the retail exemption. These include: (1) non-sterile absorbent tipped applicators; (2) adhesive bandages; (3) snake bite suction kits; (4) denture adhesives; (5) mechanical and powered wheelchairs; (6) portable oxygen concentrators; and (7) therapeutic AC-powered adjustable home use beds. In addition, the IRS provided examples of devices that are not subject to the retail exemption, including: (1) mobile x-ray systems; (2) nonabsorbable silk sutures; (3) nuclear magnetic resonance imaging systems; and (4) powered flotation therapy beds.

The Retail Exemption's Safe Harbor Provision

The final regulations also set forth a safe harbor provision, under which certain medical devices are always subject to the retail exemption regardless of the application of the facts and circumstances analysis. The following devices are subject to the safe harbor and, therefore, will be considered to be of a type generally purchased by the general public at retail for individual use (and sales of these devices will not be subject to the medical device excise tax):

- Devices that are included in the FDA's online IVD Home Use Lab Tests (Over-the-Counter Tests) database;

- Devices that are described as "OTC" or "over the counter" devices in the relevant FDA classification regulation heading, FDA's product code name, the FDA's device classification name, or the "classification name" field in the FDA's device registration and listing database;

- Devices that qualify as DMEPOS, as described in Subpart C of 42 C.F.R. Part 414 (Parenteral and Enteral Nutrition) and Subpart D of 42 C.F.R. Part 424 (Durable Medical Equipment and Prosthetic and Orthotic Devices), for which payment is available on a purchase basis under Medicare Part B payment rules and are—

    - "Prosthetic and orthotic devices" as defined in 42 C.F.R. § 414.202 that do not require implantation or insertion by a medical professional;
    - "Parenteral and enteral nutrients, equipment and supplies" as defined in 42 C.F.R. § 411.351 and described in 42 C.F.R. § 414.102(b);
    - "Customized items" as described in 42 C.F.R. § 414.224;
    - "Therapeutic shoes," as described in 42 C.F.R. § 414.228(c); or
    - Supplies necessary for the effective use of DME as described in Section 110.3 of Chapter 15 of the Medicare Benefit Policy Manual published by CMS.

The IRS rejected comments that all DMEPOS items, all capped rental DMEPOS items, or all dental devices should fall within the retail exemption safe harbor. The IRS further provided examples of items that fall within the safe harbor, including: (1) over-the-counter pregnancy test kits; (2) blood glucose monitors, test strips and lancets; (3) single axis endoskeletal knee skin systems and prosthetic legs; and (4) urinary ileostomy bags.

Other Issues and Areas for Further Comment

The final regulations clarify that, in determining the sale price for which a device is sold, the amount of the tax imposed (whether or not it is stated as a separate charge) should be excluded. The IRS rejected the use of transfer pricing under section 482 of the Code as a method to determine constructive sale price or fair market price for purposes of the medical device excise tax. The IRS also stated that a rebate may be taken into account in determining sale price only to the extent that the rebate is made prior to the close of the quarter during which the sale associated with the rebate is made. If a manufacturer subsequently allows a rebate for taxable articles on which tax has been paid, the manufacturer may make a claim for credit or refund of that portion of the tax that is proportionate to the part of the price that is rebated.

The IRS also stated that, in cases where a taxable article and a nontaxable article are sold together by the manufacturer as a unit (*e.g.*, software that is sold together with services and/or maintenance contracts and the entire software-services bundle is not FDA-listed), then the medical device excise tax attaches only to the sale of the devices within the bundle that are listed with the FDA.

In addition, any payments made pursuant to contracts for installment sales and leases entered into prior to March 30, 2010 (the date that the ACA was enacted) are not subject to liability under the medical device excise tax unless the contact is materially modified on or after that date. For this purpose, a "material modification" is only a modification that materially affects the property to be provided under the contract, the terms of payment under the contract, or the

amount payable under the contract. Payments made after January 1, 2013 pursuant to contracts for installment sales and leases entered into on or after March 30, 2012 are subject to liability under the medical device excise tax.

In Notice 2012-77, issued in conjunction with the final regulations, the IRS requested comments on a number of issues that were not resolved in the final regulations. Comments are due to the IRS by March 29, 2013. Pending the issuance of guidance on these issues, the IRS provided the following interim guidance:

- *Applicability of constructive sale price rules.* The IRS provided interim guidance regarding how taxpayers may apply the constructive pricing rules in section 4216 of the Code to certain model distribution chains employed by manufacturers in the medical device industry, for example, when manufacturers sell a taxable medical device to an independent wholesale distributor, or to a reseller that only leases the device at retail.

- *Convenience kits.* Convenience kits are finished taxable medical devices that are sometimes packaged together for convenience of a healthcare provider in the performance of a medical procedure. Although the kits are listed with the FDA under section 510(j) of the FDCA and 21 C.F.R. Part 807, the IRS is still considering whether they should be exempt from the definition of "taxable medical device." In the interim, no tax will be imposed upon the sale of a domestically-produced convenience kit, although the sale of a taxable medical device that goes into a domestically-produced convenience kit will be taxable. For imported convenience kits, a tax will be imposed, but only on the portion of the importer's sale price that is properly allocable to the individual taxable medical devices included in the convenience kit. Alternatively, an importer of a convenience kit that is a taxable medical device may pay tax on the entire price for which the importer sells the convenience kit. Further, because self-kits (*i.e.*, kits produced by hospitals or medical institutions for their own use) are exempt from the FDA's registration and listing requirements, they do not fall within the definition of a taxable medical device and, therefore, their use is not subject to tax liability.

- *Sales to medical institutions or medical offices.* The IRS will treat the sale of a taxable medical device to a medical institution or medical office as a "sale at retail" for purposes of calculating tax liability, whether the device is used solely in the medical institution or office, or it is sent home with the patient.

- *Licenses of medical devices.* The IRS will treat a license of a taxable medical device as a lease of that device as of the date that both parties entered into the license agreement. Section 4217(a) of the Code provides that the lease of a taxable item by the manufacturer is considered a sale for purposes of calculating tax liability.

- *Donations of medical devices.* The donation of a taxable medical device by the manufacturer to an eligible donee (as described in section 170(c) of the Code) will not constitute a taxable use. 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 tax liability.

In addition, in the final regulations, the IRS requested further comment regarding identification of listed components of devices that are exempt from the definition of taxable medical device under section 4191(b) of the Code and that are not yet included in a safe harbor or that do not otherwise fall within the retail exemption by an application of the facts and circumstances test.

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The final regulations, Notice 2012-77, FAQs and other guidance regarding the medical device excise tax may be found on the IRS website at: http://www.irs.gov/uac/Newsroom/Medical-Device-Excise-Tax.

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