PATTON BOGGS LLP

February 7, 2012

# Regulations on Medical Device Excise Tax Proposed; Opportunities for Comment

TAX POLICY CLIENT ALERT

*This Alert provides only general information and should not be relied upon as legal advice. We would be pleased to discuss our experience and the issues presented in this Alert with those contemplating investments in these markets. For more information, contact your Patton Boggs LLP attorney or the authors listed below.*


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On Friday, February 3, 2012 the Internal Revenue Service and Department of the Treasury (Treasury) released a Notice of Proposed Rulemaking (NPRM) on the excise tax imposed on the sale of certain medical devices under section 4191 of the Internal Revenue Code (Code). Code section 4191 imposes a 2.3 percent excise tax on the sale of taxable medical devices by a manufacturer or importer after December 31, 2012. Section 4191(b)(1) provides that a "taxable medical device" is any device, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FFDCA), intended for humans. Section 4191(b)(2) 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 NPRM includes proposed regulations addressing many, but not all, of the key issues raised by the medical device industry and other stakeholders. The preamble reviews the proposed regulations and describes how existing rules for manufacturers excise taxes apply to the sale of medical devices by manufacturers and importers.

The NPRM announces a public hearing to be held at 10 a.m. on May 16, 2012, and the NPRM seeks written or electronic comments on the NPRM, and presentation outlines to be discussed at the public hearing, by May 7, 2012 (90 days after publication of the NPRM in the Federal Register.)

The NPRM incorporates both Food and Drug Administration (FDA) and IRS concepts, and includes cross references to the FFDCA, FDA regulations, and manufacturers excise tax regulations.

## Definition of Taxable Medical Device

The Code and proposed regulations define a "taxable medical device" as any device, as defined in section 201(h) of the FFDCA, that is intended for humans. The proposed regulations state that this means "a device that is listed as a device with the FDA under section 510(j) of the FFDCA and 21 CFR Part 807." If the FDA determines that a device that is not listed should have been listed, the proposed regulations would treat the device as listed as of the date the FDA notifies the manufacturer or importer that corrective action is required.

The proposed regulations indicate that devices intended exclusively for use in veterinary medicine are not taxable medical devices, and that devices intended for both human and veterinary use are taxable medical devices.

**Retail Exemption**

Under the proposed regulations, a "facts and circumstances" test would be used to determine if a device would be considered to be of a type generally purchased at retail for individual use. Specifically, the NPRM provides that a device would be subject to 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."

Factors suggesting that a device would be subject to the retail exemption include the following:

- "Consumers who are not medical professionals can purchase the device through retail businesses that also sell items other than medical devices, such as drug stores, supermarkets and similar vendors."
- "Consumers who are not medical professionals can use the device safely and effectively for its intended medical purpose with minimal or no training from a medical professional."
- The device is classified by the FDA under Subpart D of 21 CFR Part 890 (physical medical devices).

Factors suggesting that a device is not exempt include the device being classified by FDA under certain regulatory classifications, the fact that the device "must be implanted, inserted, operated or other otherwise administered by a medical professional," and that the cost to acquire, maintain and/or use the device is not affordable to the average consumer.

Under the safe harbor, the following types of devices would fall within the retail exemption:

- 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

- Devices that are described as "OTC" or "over the counter" devices in the 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 durable medical equipment, prosthetics, orthotics, and supplies, as described in Subpart C of 42 CFR Part 414 (Parenteral and Enteral Nutrition) and Subpart D of 42 CFR Part 414 (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 CFR 414.202, that do not require implantation or insertion by a medical professional;
    - "Parenteral and enteral nutrients, equipment, and supplies" as defined in 42 CFR 411.351 and described in 42 CFR 414.102(b);
    - "Customized items" as described in 42 CFR 414.224;
    - "Therapeutic shoes," as described in 42 CFR 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 (Centers for Medicare and Medicaid Studies Publication 100-02).

The proposed regulations include examples illustrating the application of the facts and circumstances test.

The preamble indicates that the IRS and Treasury intend through the rulemaking process to identify easier mechanisms for applying the above exemptions. The NPRM seeks comments on additional factors, examples, and safe harbors. It also indicates that the IRS and Treasury are especially interested in comments on medical devices sold primarily or exclusively through special medical retailers and on whether packaging, labeling, warranty terms, and Internet sales are meaningful factors. The NPRM rejected a quantitative data approach (comparing retail sales to sales to doctors' offices and medical institutions) for determining whether the exemption applies.

**Other Device Issues**

The NPRM indicates that **dual use devices** (ones that may be used for both medical and nonmedical purposes) are taxable medical devices if they fall within the definition of taxable medical devices and the retail exemption does not apply.

The NPRM also indicates that a **combination product** (therapeutic or diagnostic products that combine drugs and devices) is subject to the tax if it meets the definition of a taxable medical device and no exemption applies. The regulatory preamble states that IRS and Treasury anticipate that few, if any, products will be subject to both the branded prescription drug fee and medical device excise tax, but seek comments on potential overlap and mechanisms by which the impact can be divided.

The NPRM states that devices that are subject to an FDA **Investigational Device Exemption** are not taxable medical devices because they are exempt from FDA's listing requirements.

The NPRM rejected a blanket exclusion for **dental instruments and equipment**.

The proposed regulations treat a **"kit"** as a taxable medical device if the kit itself is listed as a device with the FDA. If the kit is not a taxable medical device, the manufacturer of taxable medical devices included in the kit will be liable for the tax (unless an exemption applies) on the sale of the device to the kit manufacturer or upon the sale of the kit if the taxable medical device manufacturer is the seller of the kit.

**Manufacturers Excise Tax**

The preamble to the proposed regulations indicates that statutory provisions, regulations, rules, cases, and other published guidance applicable to manufacturers excise taxes are applicable to the medical device excise tax. The preamble provides a useful summary of the rules. Highlights include the following:

- If **more than one person is involved in the manufacture** or importation of an item, such as in a contract manufacturing arrangement, the determination of which person is the manufacturer is based on the facts and circumstances of the arrangement

- The manufacturer's excise tax **attaches when the title to the taxable article passes** from manufacturer to purchaser. In the case of a conditional or installment sale, the tax attaches to each partial payment

- The provision or use of a taxable medical device as a **demonstration product** may constitute a taxable use or sale

- A **lease** is considered a sale. The tax attaches to each lease payment. If the manufacturer sells the same product, the tax is capped when the cumulative total of tax payments equals the total tax if the product had been sold

- The **taxable sales price** includes charges for coverings or containers and charges incident to placing the article in a condition to be packed and ready for shipment, but excludes:

    - The manufacturers excise tax, whether or not it is stated as a separate charge
    - The cost of transportation, delivery, insurance, and installation
    - Discounts, rebates, and similar allowances
    - Charges for a warranty paid at purchaser's option

- The tax does not apply to sales for further manufacture. To make a tax-free sale for further manufacture of export, the manufacturer; the first purchasers; and in some cases, the second purchaser must be registered by the IRS by filing Form 637. Generally, the purchaser must provide the purchaser's registration number and certify the exempt purpose for which the article will be used.

- If **taxable and nontaxable articles are sold** by the manufacturer as a unit, the tax attaches to the portion of the unit allocable to the taxable article.

**Other Issues**

The preamble and/or proposed regulations appear to address most, but not all, of the issues raised in prior comments to the IRS. In particular, the regulations do not address issues that arise because the excise tax is based on purchase price, whereas most current manufacturers' excise taxes are based on quantities or measures other than price. For example, does a vertically integrated company pay the tax based on the sales price to the final consumer while a nonvertically integrated manufacturer pays the tax based on the sales price to the distributor? The NPRM also does not specifically address the deductibility of the tax. Presumably, principles applicable to other manufacturers' excise taxes would apply.

**Next Steps**

Companies should consider submitting formal comments in response to the NPRM. The preamble and proposed regulations, while not binding until adopted as final or temporary regulations, provide sufficient guidance for manufacturers to begin work on internal processes for implementing the tax. These may include:

- Determination as to which products are potentially taxable

- Determination of which products are eligible for the retail exemption

- If the manufacturer sells devices for further manufacture, taking steps to make sure that purchasers are registered and will be providing exemption certificates

- Establishing internal procedures for recordation and reporting of taxable sales and payment of the tax, and for the invoicing of the tax (if desired)

**Patton Boggs**

Patton Boggs' team of tax, FDA, and public policy lawyers can assist clients in interpreting and applying the excise tax rules and in seeking modifications to the NPRM.

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