Healthcare Products Coalition

May 7, 2012

Douglas H. Shulman, Commissioner
Internal Revenue Service
CC:PA:LPD:PR (REG-113770-10)
Room 5203
P.O. Box 7604
Ben Franklin Station
Washington, D.C. 20044

Re: Notice of Proposed Rule Making to Implement Manufacturer Excise Tax on Medical Devices

Dear Commissioner Shulman:

As members of the Healthcare Products Coalition we write in response to the Internal Revenue Service (IRS) *Proposed Taxable Medical Device Excise Tax Regulations.* The Healthcare Products Coalition is comprised of manufacturers and distributors that are committed to ensuring the fair treatment of low-cost, non-invasive medical products by legislators and regulators. Our products are used by almost every provider throughout the continuum of care and are desperately needed in the marketplace. We are dedicated to a safe, efficient and cost-effective medical products supply chain that will benefit patient care.

The 2.3% excise tax on medical device manufacturers places a tremendous burden on the medical products supply chain. Therefore, the Healthcare Products Coalition urges the IRS to make the following changes in its final rule to ensure the tax is implemented as Congress intended, clarifies the retail definition and does not create undue administrative burden on the supply chain. Specifically, the Healthcare Products Coalition strongly recommends that the:

1. IRS specifically include internet retailers within the definition of retail;
2. IRS should allow for a voluntary, predetermination from the IRS for manufacturers seeking clarity for devices meeting retail exemption criteria;
3. IRS explicitly define the phrase “of a type” as devices within the same FDA product code; and
4. IRS accepts the 12 calendar quarter blanket exemption process for purposes of meeting the substantiation requirements of the further manufacture exemption.

Retail Exemption

We appreciate the agency’s effort to stay broad in its effort to define what it means for a device “to be of a type which is generally purchased by the general public at retail for individual use.” The safe harbors specifically spelled out in the proposed rule are useful and offer needed protections. We also appreciate the fact and circumstance criteria listed to assist in

determining whether a device falls under the retail exemption. The Healthcare Products Coalition has three specific recommendations regarding the retail exemption to ensure clarity.

1. Specifically include internet retailers within the definition of retail;
2. Allow for a voluntary, predetermination from the IRS for manufacturers seeking clarity for devices meeting retail exemption criteria; and
3. Explicitly define the phrase "of a type" as devices within the same FDA product code.

First, we urge the IRS to specifically include internet retailers within the definition of "retail businesses that also sell items other than medical devices" whether they be associated with bricks and mortar stores or not. More and more, individuals are purchasing medical products through the internet rather than at a physical store, both for convenience and for additional selection. If an individual can purchase a medical device through an internet site that sells items other than medical devices, those devices should be considered exempt from the tax.

Second, we urge the IRS to develop a voluntary pre-approval process. The determination of whether a device meets the retail exemption is not something that manufacturers will want to get wrong. Manufacturers should have the ability to (but not be required to) get pre-clearance from the IRS so it is not paying an unnecessary tax but also does not have to take the risk of not paying a required tax. This additional certainty will be useful for all involved.

Finally, the Healthcare Products Coalition agrees with the agency's approach to interpreting "of a type" broadly in the proposed rule and believes it is what Congress intended. Many of the examples refer to a general product category and its corresponding FDA category and we support that "of a type" refer to all of the different products within an FDA code.

For example, the FDA has a code for adhesive bandages. Our understanding of the proposed regulations is that if there are some bandages within a code that are purchased by individuals at retail, all bandages fit into the retail exception regardless of whether they are actually sold to a retail business or institutional provider. To improve the certainty and consistency of applying the retail exemption across the industry and to facilitate its administration, the Healthcare Products Coalition recommends that guidance explicitly define the phrase "of a type" as devices within the same FDA product code. Notwithstanding the FDA product code, however, other documentation should be received and considered from manufacturers to demonstrate a product or product code qualifies for the exemption.

Substantiation Required for Further Manufacturing Exemption

Section 4221(a)(1) of the Internal Revenue Code allows an exemption on the sale of a medical device that is used by the purchaser in further manufacture. In order to qualify for this

exemption, the manufacturer must comply with the requirements in Treas. section 48.4221-1(c). Under these rules, the Purchaser must indicate the exempt purpose for which the article is being purchased, in writing, to the manufacturer for each sale.

With the frequency and recurring nature of sales for further manufacture, the substantiation process outlined in the regulations places a significant compliance burden on both the manufacturer and the purchaser of devices used in further manufacture. The documentation requirements have been eased for other sales exempt under section 4221, allowing blanket exemptions covering sales within a period of up to 12 calendar quarters of sales. Treas. Reg. section 48.4221-4(d)(2)(iii) permits a blanket exemption certificate for purchases used as supplies for vessels or aircraft for sales within a period of up to 12 calendar quarters. Treas. Reg. section 48.4221-5(c) states that "If it is impracticable to furnish a separate certificate for each order or contract because of frequency of purchases, a certificate covering all orders between given dates (such period not to exceed 12 calendar quarters) will be acceptable". Treas. Reg. section 48.4221-6(c) also allows a single notification "to cover all sales to a non-profit organization made during a designated period not to exceed 12 successive calendar quarters."

Consistent with this precedence for other exempt sales and in the interest of reducing the administrative burden associated with this tax, the Healthcare Products Coalition recommends that the 12 calendar quarter blanket exemption process be accepted for purposes of meeting the substantiation requirements of the further manufacture exemption.

In closing, we thank you for the opportunity to comment and look forward to continuing to work with the agency to ensure the medical device tax is implemented fairly and as Congress intended.

Sincerely,

The Healthcare Products Coalition