



# IRS Hot Topics

## IRS and Treasury request comments on implementation of medical device excise tax

On December 3, 2010, the IRS and Treasury issued Notice 2010-89 concerning the new I.R.C. § 4191 excise tax on medical devices. The Notice announces establishment of a guidance project on the new excise tax and requests comments. Comments are specifically requested on medical devices that should be exempted from the excise tax.

Comments must be submitted by March 3, 2011.

### Background

Section 1405 of the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152) ("Reconciliation Act") adds new section 4191, captioned "Medical Devices," to the federal excise tax subtitle of the Internal Revenue Code effective for sales of taxable medical devices after December 31, 2012. Pursuant to this new provision, a 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, intended for humans. Section 201(h) defines the term "device" as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation,

treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

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 Secretary may determine that a specific medical device is exempt if the device is generally sold at retail establishments (including over the internet) to individuals for their personal use. The exemption for such items is not limited by device class as defined in section 513 of the Federal Food, Drug, and Cosmetic Act. For example, items purchased by the general public at retail for individual use could include Class I items such as certain bandages and tipped applicators, Class II items such as certain pregnancy test kits and diabetes testing supplies, and Class III items such as certain denture adhesives and snake bite kits. Such items would only be exempt if they are generally designed and sold for individual use. In this regard, the Congress anticipates that the Secretary will publish a list of medical device classifications that are of a type generally purchased by the general public at retail for individual use.

The present law excise tax exemptions for further manufacture and for export apply to the new tax imposed under section 4191. However exemptions for use as supplies for vessels or aircraft, and for sales to state or local governments, nonprofit educational organizations, and qualified blood collector organizations are not applicable.

### **Notice 2010-89**

The Notice invites public comments regarding issues that should be addressed in guidance implementing the new excise tax. Comments are specifically requested on the exemption for any medical device "determined by the Secretary to be of a type which is generally purchased by the general public at retail for individual use." In addition, comments are requested on issues pertaining to the application of existing Manufacturers Excise Tax rules to section 4191. Comments must be submitted by March 3, 2011.

### **Observations**

The Notice makes it clear that the IRS and Treasury have established a guidance project on the new section 4191 and that they are interested in determining the important issues prior to commencing the drafts. This is welcome news in advance of publication of the annual Priority Guidance Plan which will likely reflect the guidance project.

Clients should consider whether any medical devices they import or manufacture and sell are of a type that should be exempted from imposition of the tax. The IRS and Treasury may agree to exempt any device that is designed to be sold at retail to individuals for their personal use. Comments should be submitted on such devices so that the IRS and Treasury may consider its addition to a list of medical device classifications that the IRS and Treasury are expected to publish.

Clients may also request that the guidance contain a general statement that the rules normally applicable to manufacturers excise taxes are applicable to the excise tax on medical devices. For example, it is presumed that

the rules generally applicable to manufacturers excise taxes that allow separate statement of the tax on sales invoices will be applicable to sales of medical devices as well.

Clients may also request guidance on the registration requirements that will allow application of the exemptions for (1) sales for use of the purchaser for further manufacture or for resale to a second purchaser for further manufacture, and (2) sales for export or for resale to a second purchaser for export.

### **For more information**

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