

Part III - Administrative, Procedural, and Miscellaneous

REQUEST FOR COMMENTS REGARDING THE EXCISE TAX ON MEDICAL DEVICES

Notice 2010-89

PURPOSE

This notice invites public comments regarding issues that should be addressed in guidance implementing the new excise tax on medical devices imposed by section 4191 of the Internal Revenue Code (Code). Section 4191 was added by section 1405 of the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029, 1064-1065 (the Act), in conjunction with the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119. The new excise tax applies to sales of taxable medical devices after December 31, 2012.

BACKGROUND

Under Chapter 32 (Manufacturers Excise Taxes) of Subtitle D of the Code, excise taxes are imposed on the sales of certain products by the manufacturer, producer, or importer. The Act amended Chapter 32 to add section 4191, which imposes an excise tax on the sale of any “taxable medical device” by the manufacturer, producer, or importer of the device in an amount equal to 2.3 percent of the sale price.

Section 4191(b)(1) provides that, in general, a “taxable medical device” is any device, as defined in section 201(h) of the Federal Food, Drug, & Cosmetic Act (FFDCA), that is intended for humans. Section 201(h) of the FFDCA defines “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, or (3) intended to affect the structure or any function of the body, and which does not achieve its primary intended purposes through chemical action within or on the body and which is

not dependent upon being metabolized for the achievement of its primary intended purposes.

Section 4191(b)(2) provides that the term “taxable medical device” does not include eyeglasses, contact lenses, hearing aids, or “any other medical device determined by the Secretary to be of a type which is generally purchased by the general public at retail for individual use.”

Section 4221 exempts certain sales from tax imposed under Chapter 32. The Act amended section 4221 to limit the exemptions for taxable medical device sales to sales by the manufacturer, producer, or importer (1) for use by the purchaser for further manufacture, or for resale by the purchaser to a second purchaser for use by such second purchaser in further manufacture; or (2) for export, or for resale by the purchaser to a second purchaser for export.

REQUEST FOR COMMENTS

The Internal Revenue Service and Treasury Department request comments on issues that should be addressed in guidance implementing the excise tax on medical devices. Comments are specifically requested on the exemption in section 4191(b)(2)(D) 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 Chapter 32 rules to section 4191. Comments must be submitted by March 3, 2011. Comments, identified by Notice 2010-89, may be sent by one of the following methods:

- o Mail:
Internal Revenue Service
CC:PA:LPD:PR (Notice 2010-89)
Room 5203
P.O. Box 7604
Ben Franklin Station
Washington, DC 20044
- o Hand or courier delivery:
Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to:
Courier's Desk
Internal Revenue Service
1111 Constitution Ave., N.W.
Washington, DC 20224
Attn: CC:PA:LPD:PR
(Notice 2010-89)
- o Electronic:
Alternatively, taxpayers may submit comments electronically to
Notice.Comments@irs.counsel.treas.gov. Please include “Notice 2010-89” in the subject line of any electronic communications.

All submissions will be available for public inspection and copying in room 1621, 1111 Constitution Avenue, NW, Washington, DC, from 9 a.m. to 4 p.m.

DRAFTING INFORMATION

The principal author of this notice is Natalie A. Payne of the Office of Associate Chief Counsel (Passthroughs & Special Industries Division). For further information regarding this notice, please contact Ms. Payne or Stephanie Bland at (202) 622-3130 (not a toll-free call).