

IRS Requests Comments on New Medical Device Excise Tax

December 3, 2010

The Internal Revenue Service (IRS) issued a notice today inviting public comments on issues that the IRS should address in its guidance for the implementation of the new medical device excise tax imposed under the Health Care and Education Reconciliation Act of 2010 (Pub. L. No. 111-152). The law imposes a 2.3% excise tax on device sales (which, through the application of existing tax law, currently includes leases) starting in 2013.

Because the new tax provisions rely on the definition of a “device” under Section 201(h) of the Federal Food, Drug, and Cosmetic Act, the new tax may serve to highlight areas where the Food and Drug Administration’s (FDA’s) device jurisdiction is unclear, including, for example, with respect to health IT products. The new tax also may exacerbate inequities between companies that comply with FDA’s device requirements (including its registration and listing requirements) and those that do not or that rely on FDA’s enforcement discretion. In addition, several implementation questions have yet to be answered, such as the following:

- How will the IRS apply the tax for sales of combination products (e.g., device/drug or device/biologic combination products)?
- How will the IRS determine which devices and device manufacturers are subject to the tax?
- Will the tax apply to products that are subject to FDA enforcement discretion (and thus, may not be registered and listed with FDA)?
- How will the IRS apply the tax in situations where a company markets the same product for both device and nondevice uses (e.g., general industrial uses)?

The IRS is asking for specific comments on the statutory exemption for devices “determined by the Secretary to be of a type which is generally purchased by the general public at retail for individual use.” Although this provision appears to be aimed at over-the-counter devices, the language is somewhat unclear. The IRS is also requesting specific comments on issues pertaining to the application of existing manufacturers excise tax laws to the new medical device excise tax. The existing manufacturers excise tax laws include provisions that treat a lease as a sale and that determine the sales price of a medical device.

Manufacturers potentially affected by the new device tax should submit comments to the IRS by **March 3, 2011**, as described in IRS Notice 2010-89, available online at <http://www.irs.gov/pub/irs-drop/n-10-89.pdf>.

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact the authors of this LawFlash, **M. Elizabeth Bierman** (202.739.5206; mebierman@morganlewis.com), **Gary B. Wilcox** (202.739.5509; gwilcox@morganlewis.com), **Michele Buenafe** (202.739.6326; mbuenafe@morganlewis.com), or **Emmeline Babb** (215.963.5001; ebabb@morganlewis.com).

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