January 8, 2013

The Patient Protection and Affordable Care Act ("PPACA") imposed a 2.3% tax on the sale of certain medical devices in the United States. The tax went into effect as of January 1, 2013, despite efforts from opponents of the tax to repeal the tax or delay its implementation. The PPACA-imposed tax, codified at Section 4191 of the Internal Revenue Code ("IRC"), applies to U.S. sales of "taxable medical devices" by their manufacturer, importer, or producer after December 31, 2012. On December 7, 2012, the U.S. Internal Revenue Service ("IRS") and Department of Treasury issued final regulations providing guidance on the tax (the "Final Regulations").

The Final Regulations define a "taxable medical device" to include, subject to certain exemptions, any "device that is listed as a device with the FDA under section 510(j) of the [Federal Food, Drug & Cosmetic Act] and 21 CFR part 807." The Final Regulations reference rules for tax-free sales of taxable medical devices for further manufacture or export at Section 4221 of the IRC and 26 C.F.R. §48.4221-1 through §48.4221-3. In addition, Section 4191(b)(2) of the IRC lists various exemptions which are not taxable medical devices including eyeglasses, contact lenses, hearing aids, and, most notably, a broad "retail exemption" for a "medical device determined by the Secretary to be of a type which is generally purchased by the general public at retail for individual use." To evaluate whether a device qualifies for this retail exemption, the Final Regulations utilize: (1) a "facts and circumstances" approach including factors such as "whether consumers who are not medical professionals can purchase the device through retail businesses that also sell items other than medical devices, including drug stores, supermarkets, and similar vendors" and "whether consumers who are not medical professionals can safely and effectively use the device for its intended medical purpose with minimal or no training from a medical professional" as well as (2) a "safe harbor" for certain categories of medical devices that automatically fall within the retail exemption. Notably, among the safe harbored devices are FDA-classified "over-the-counter" devices and "'prosthetic and orthotic devices,' as defined in 42 CFR 414.202, that do not require implantation or insertion by a medical professional" and that are eligible for payment under Medicare Part B. Devices that are not in the safe harbor may still qualify for the retail exemption based on an application of the facts and circumstances test.

The Final Regulations explain that to comply with the medical device excise tax a manufacturer, importer, or producer of a taxable medical device must report taxes owed using IRS Form 720, Quarterly Federal Excise Tax Return and make semi-monthly deposits of such taxes or face penalties for failure to file required returns, pay taxes owed, or report accurately due to negligence or disregard of the rules or regulations. The IRS and the Treasury Department will issue separate interim guidance addressing penalties, as well as interim guidance addressing the following other topics: whether the licensing of a taxable article is a taxable event; whether to treat "kits" as medical devices; the determination of sale prices; and whether a donation of a taxable article to charity constitutes a taxable use.

For questions about the implications of the medical device excise tax for your organization, please contact one of the attorneys listed above.

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