

Publications

Health Care Alert: IRS Issues Final Regulations on ACA Medical Device Excise Tax

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The Internal Revenue Service (IRS) has released final regulations on the excise tax imposed on the sale of certain medical devices (the Device Tax) under the Affordable Care Act. The Device Tax will impact the sale of any taxable medical device by the manufacturer, producer, or importer of the device, at a rate of two-point-three percent (2.3%) of the sale price. All medical devices listed with the Food and Drug Administration (FDA) and intended for human use are subject to the Device Tax. The Device Tax is effective for sales of taxable medical devices on or after January 1, 2013.

Exemptions to the Excise Tax

The regulations incorporate a statutory exemption for eyeglasses, contact lenses, hearing aids, and any other medical device that the IRS determines is of a type "generally purchased by the general public at retail for individual use" (the Retail Exemption). The Retail Exemption, generally, will apply to those devices that are broadly available for sale and use by the general public, and which need minimal or no involvement of a healthcare professional to be effective for their intended purpose. Although the IRS will evaluate a device's eligibility for the Retail Exemption based on all relevant facts and circumstances, the regulation provides a list of non-exclusive factors that will be balanced by the IRS in making this determination, including:

- *Whether the device is regularly available for purchase and use by individual consumers.* This includes whether consumers who are not medical professionals can purchase the device and use it safely and effectively for its intended purpose with minimal or no training from a medical professional and whether the device is classified by the FDA as a physical medicine device.
- *Whether the device is primarily for use in a medical institution or office or by a medical professional.* This factor includes whether the device generally must be implanted, inserted, operated, or otherwise administered by a medical professional; whether the cost of the device is affordable for the average individual consumer;

classification of the device by the FDA; and whether the device qualifies as durable medical equipment (DME), prosthetics, orthotics, and supplies for which payment is available exclusively on a rental basis under Medicare Part B.

The regulations also create a safe harbor under which the Retail Exemption will apply to:

- Devices included in the FDA's online In Vitro Diagnostics Home Use Lab Tests database
- Devices described as "over the counter" or "OTC" in certain FDA classifications
- Certain devices that qualify as DME, prosthetics, orthotics, and supplies for which Medicare Part B pays on a purchase basis

The regulation includes examples that illustrate how the IRS will apply the Retail Exemption factors and safe harbor.

Application to Leases and Installment Sales

The regulations also specify how the tax will be applied to payments made under a contract for the lease, installment sale, or sale on credit of a taxable medical device. Treatment of the payment will depend on whether the contract was entered into prior to enactment of the ACA on March 30, 2010. Payments made on or after January 1, 2013, under a written, binding contract entered into before March 30, 2010, are not subject to the tax. If the contract was entered into or materially modified on or after March 30, 2010, the payment would be subject to the tax.

This client alert is for general information purposes and should not be regarded as legal advice. As always, please let us know if you want more information or have questions about how these developments apply to your situation.

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