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Medical Device Excise Tax Set to Become Effective January 1, 2013

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Beginning January 1, 2013, a 2.3 percent excise tax will be imposed on sales of "taxable medical devices" by manufacturers and importers. This tax, known as the "Medical Device Excise Tax" (MDET), was enacted as part of The Health Care and Education Reconciliation Act of 2010.

On December 5, 2012, the Internal Revenue Service (IRS) released Final Regulations on the MDET and also issued Notice 2012-77 (the Notice), which provides interim guidance on certain issues not addressed in the Final Regulations that the IRS is continuing to study.

Exemptions From Definition of Taxable Medical Device

In general, a taxable medical device is a device required to be listed as a device with the Food and Drug Administration (FDA) under section 510(j) of the Federal Food, Drug, and Cosmetic Act and its regulations. The MDET, however, does not apply to sales of eyeglasses, contact lenses, hearing aids, or any other devices that are generally purchased by the general public at retail for individual use (the Retail Exemption).

The Final Regulations provide a list of non-exclusive factors to be

considered in determining whether a device qualifies for the Retail Exemption, including whether consumers can regularly purchase the device at retail and use it safely and effectively for its intended medical purpose. Certain devices will automatically qualify for the Retail Exemption under a safe harbor in the Final Regulations, such as "over-the-counter" devices, devices included in the FDA's online IVD Home Use Lab Tests database, and certain durable medical equipment, prosthetics and orthotics.

Exempt Sales

In addition to the Retail Exemption, certain sales may qualify for tax-free sale treatment under the MDET. Sales that may qualify include sales of devices to purchasers for further manufacture and sales for export. To qualify for tax-free sale treatment, among other requirements, device manufacturers and purchasers, other than foreign purchasers, must register with the IRS by filing a Form 637 and obtain a "Letter of Registration." A device manufacturer will be liable for the MDET for sales that would qualify as exempt after December 31, 2012 while it awaits receipt of its Letter of Registration.

Notice 2012-77

The Notice provides interim guidance that device manufacturers can rely on until additional guidance is published regarding constructive sale price, licensing of taxable medical devices, donations of taxable medical devices, and convenience kits.

The MDET is imposed on the price at which a manufacturer sells or would sell taxable medical devices to independent wholesalers. The Notice provides rules for determining a constructive sale price that approximates the price of

sales to an independent wholesaler in situations where a manufacturer does not sell devices to independent wholesalers. The Notice discusses five different model distribution chains commonly used by device manufacturers.

The Notice also provides that the sale of domestically produced convenience kits will not be subject to the MDET, but the sale of taxable medical devices to kit producers will be subject to the MDET. Importers of kits, however, will be taxed on that portion of the sales price of a kit that is allocable to the individual taxable medical devices included within the kit.

Reporting the Medical Device Excise Tax

Manufacturers and importers must report their MDET tax liability quarterly on IRS Form 720 (Quarterly Federal Excise Tax Return). Manufacturers and importers liable for the MDET will also be required to make semimonthly tax deposits. Penalties for failure to deposit may apply where deposits are not made. The Notice provides transitional relief from the penalties for the first three quarters of 2013, so long as the manufacturer or importer makes good faith efforts to comply with the deposit requirements

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