Reinstatement of the medical device excise tax

The moratorium suspending medical device excise tax (MDET) is set to expire. Absent congressional action, effective January 1, 2020, MDET will be imposed on sales of taxable medical devices by manufacturers and importers. The first semimonthly deposit of MDET will be due January 29, 2020, and the first MDET return—filed on Form 720, Quarterly Federal Excise Tax Return—will be due April 30, 2020.

**Background**
Section 4191 imposes MDET on the sale, use, or lease of a “taxable medical device” by its manufacturer or importer at a rate of 2.3 percent of the price for which each device was sold. Certain adjustments to the sale price are allowed, and in some situations, a constructive sale price may be used to determine the tax base. In addition, export sales are generally not subject to the tax, subject to certain registration requirements.

The definition of a “taxable medical device” is any device listed with the Food and Drug Administration (FDA) under section 510(j) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. Part 807, pursuant to FDA requirements. There are exemptions provided for eyeglasses, contact lenses, and hearing aids, and devices of a type generally purchased by the general public at retail for individual use (the “retail exemption”).

In January 2018, Congress extended a two-year moratorium on application of the medical device excise tax on taxable medical devices sold, used, or leased between January 1, 2018, and December 31, 2019. Thus, manufacturers and importers of devices were not required to make semimonthly deposits of the excise tax or to file Forms 720 relating to those sales.

Absent congressional action, the MDET will be effective January 1, 2020 with respect to sales, uses, and leases of taxable medical devices by manufacturers and importers. Affected companies will need to begin making semimonthly deposits of tax and filing excise tax returns.

**Action items**
Manufacturers and importers of taxable medical devices should consider taking the following steps:

— Review existing MDET processes and procedures
— Review tax base calculations
— Consider constructive sale price methods to potentially reduce tax base
— Identify new products and SKUs that may be subject to MDET
— Communicate with customers to obtain required paperwork to make tax-free sales or claim refunds for nontaxable transactions
— Consider adjustments to contracts and invoices to take into account MDET
— Analyze technology solutions to minimize burden of tax compliance.

Our goal is to help companies meet their MDET tax compliance responsibilities and account for what devices are taxed under this law which, in turn, can help reduce demands on internal resources.

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How we can help

Computing MDET and documenting positions can be a complex undertaking. Many taxpayers have yet to develop the necessary compliance processes—such as calculating and supporting the tax base, including discounts, rebates, refunds, and allowances; determining and supporting exemption eligibility; and providing proof of further manufacture and proof of exportation. In addition, companies may need to update their IT systems to handle frequent tax computations and track purchases.

KPMG LLP’s (KPMG) cross-disciplinary team can help with your MDET challenges—from the complex substantive issues of the tax to the use of technology resources. Our skilled tax professionals, many with backgrounds at the IRS, can:

— Perform a current-state MDET assessment your risks and opportunities
— Review your existing positions and documentation and help remediate areas of risk

KPMG’s MDET Processing Tool, our proprietary web-based technology, can help you accurately calculate and manage your potential tax liabilities.

In addition, KPMG has several technology options to complete granular analysis of your high-volume transaction data, ensuring timely and accurate calculations.

Contact us

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