

Medical Device Excise Tax

On Dec. 5, 2012, the IRS issued [final regulations](#) on the new 2.3 percent medical device excise tax that manufacturers and importers will pay on sales of certain medical devices beginning January 1, 2013. In addition, the IRS issued

[Notice 2012-77](#)

, which provides interim guidance regarding the determination of sale price and other issues related to the tax.

The IRS developed the final regulations in consultation with technical experts at the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services, and after carefully reviewing numerous public comments.

Generally, under the final regulations, a “taxable medical device” is a device that is listed as a device with the FDA under section 510(j) of the Federal Food, Drug and Cosmetic Act, and 21 CFR part 807, pursuant to FDA requirements. If a device is not listed as a device with the FDA but the FDA determines that the device should have been listed as a device, the device will be deemed to be listed as a device with the FDA as of the date the FDA notifies the manufacturer or importer in writing that corrective action with respect to listing is required.

The new tax does not apply to sales of eyeglasses, contact lenses, and hearing aids. The new tax also does not apply to the sale of any other devices that are of a type generally purchased by the general public at retail for individual use (the retail exemption).

In general, the final regulations provide a facts-and-circumstances approach to evaluating whether a type of device qualifies for the retail exemption. Specifically, the final regulations suggest factors to consider in evaluating whether a particular type of device qualifies for the retail exemption. The factors enumerated in the final regulations are non-exclusive; additional factors may be relevant to determining whether a given type of device qualifies for the retail exemption.

The final regulations also identify several categories of medical devices that qualify for the retail exemption (the retail exemption safe harbor). The retail exemption safe harbor includes devices in the FDA’s online in vitro diagnostics (IVD) Home Use Lab Tests (Over-the-Counter Tests)

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database, devices that the FDA describes as “OTC” or “over the counter” in certain official FDA classification or product code headings or descriptors, and a number of devices that qualify as durable medical equipment, prosthetics, orthotics or supplies for which payment is available on a purchase basis under the Medicare Part B payment rules.

The medical device excise tax applies to manufacturers and importers and generally does not apply to individual consumers.

Sales of taxable medical devices for further manufacture or export may be made tax free if certain registration and other requirements are met. Click on the [Form 637 Registration Program](#) link below for more information.

The medical device excise tax is reported on [Form 720, Quarterly Federal Excise Tax Return](#) . Payment is due with the return. The first quarterly return for the medical device excise tax is due April 30, 2013, for the months of January, February, and March 2013. Form 720 may be filed electronically or on paper.

Manufacturers and importers of taxable medical devices may also pay the tax via the free, secure Electronic Federal Tax Payment System (EFTPS). Visit [EFTPS](#) to enroll or call 800-555-4477 for information.

To pay the tax with a paper Form 720, use EFTPS or enclose a check or money order (made payable to “United States Treasury”) and Form 720-V, Payment Voucher, with the timely filed Form 720. The payment voucher and instructions are on the final page of Form 720.

Manufacturers and importers of taxable medical devices are generally required to make semi-monthly deposits of tax. The first semimonthly deposit for the medical device excise tax, which covers the first 15 days of January, is due January 29, 2012. In general, manufacturers and importers must use electronic funds transfer to make excise tax deposits through EFTPS.

[Notice 2012-77](#)

provides transition relief from deposit penalties during the first three calendar quarters of 2013.

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For more information, call the toll-free Business and Specialty Tax Line (800-829-4933), available Monday – Friday from 7 a.m. to 10 p.m. local time, or visit the resources shown below.

References/Related Topics

- [Questions and answers](#) about the medical device excise tax
- Manufacturers taxes ([Chapter 5](#) of [Pub. 510, Excise Taxes](#))
- Filing Form 720 ([Chapter 11](#) of Pub. 510, Excise Taxes)
- Payment of Tax; Deposits ([Chapter 12](#) of Pub. 510, Excise Taxes)
- [Form 637 Registration Program](#)