Medical Device Tax Provisions in Health Care Reform Legislation

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The Patient Protection and Affordable Care Act of 2009 (Pub. L. No. 111-148),[1] which President Obama signed into law on March 23, 2010 imposes an annual fee on medical device manufacturers and importers. The "Health Care and Education Affordability Reconciliation Act of 2010" (H.R. 4872, or the "Reconciliation Package") [2], as revised by the amendment reported to the Reconciliation Package on March 20, 2010, and passed by the House of Representatives on March 21, 2010,[3] would impose an excise tax on medical device manufacturers. Below we provide an overview of these provisions, which are found in Section 9009 of Pub. L. No. 111-148 and Section 1405 of the Reconciliation Package, and how the two provisions differ.

Patient Protection and Affordable Care Act of 2009
(Pub. L. No. 111-148)

Section 9009 of the Patient Protection and Affordable Care Act is uncodified in the Internal Revenue Code and is structured as a "fee" on medical device manufacturers and importers, first payable on September 30 of each year beginning on or after 2011. Under Pub. Law. No. 111-148, the fee applicable to a "covered entity" is equal to the ratio of that covered entity's gross receipts from medical device sales for the preceding taxable year to the aggregate gross receipts of all covered entities attributable to medical device sales in that year, multiplied by $2 billion (increasing to $3 billion in 2017). The fee is not deductible by the payer. Thus, in order for the seller of a medical device to know whether it is subject to the tax with respect to the sale of the device, the seller must know (a) whether it is a covered entity; and (b) its gross receipts attributable to medical device sales and (c) the total gross receipts in the United States attributable to medical device sales.

Under Pub. Law. No. 111-148, a "covered entity" is defined as any manufacturer or importer with gross receipts from medical device sales. Section 9009(e)(2). As with other aggregation rules applicable under the tax laws, all members of a controlled group of corporations are treated as a single covered entity. In determining whether there has been a sale of a medical device for purpose of determining gross receipts from medical device sales, sales of class I medical devices and class II medical devices that retail for $100 or less are not taken into account nor are the first $5 million of receipts from medical device sales. Section 9009(c)(1). Further, only 50% of gross receipts between $5 million and $25 million are taken into account. Section 9009(b)(2). Finally, all receipts above $25 million are taken into account.

The Secretary of the Treasury (likely acting through the Internal Revenue Service) will determine the amount of a covered entity's fee, based on reports filed by the entity with the IRS regarding its gross receipts from medical device sales. Section

9009(b)(3). In addition to these reports, the Secretary can derive data from "any other source of information available to the Secretary."

Reconciliation Package (H.R. 3692)

Section 1405 of the Reconciliation Package repeals and replaces the provision in Pub. L. 111-148 that would impose an annual fee on medical device manufacturers. Starting in 2013, a new section 4191 of the Internal Revenue Code of 1986, as added by section 1405 of the Reconciliation Package, establishes an excise tax on the sale of a "taxable medical device" equal to 2.3% [4] of the price of the device. This excise tax is deductible.[5]

Under the Reconciliation Package, a "taxable medical device" is any medical device as defined in section 201(h) of the Federal Food, Drug and Cosmetic Act (FFDCA).[6] Certain types of devices, however, are exempt from the tax, including eyeglasses, contact lenses, hearing aids, and other devices that are "generally purchased by the general public at retail for individual use" as determined by the Secretary of the Treasury. Under the original version of the Reconciliation Package released on March 18, Class I medical devices were also exempt from the tax. The House Rules Committee amendments to the Reconciliation Package removed this exemption.

Our initial impression is that one major area of interest in the Reconciliation Package is the retail exemption. In order to be exempt from the tax, the Secretary of Treasury must determine that the device (a) is generally purchased by the general public; (b) at retail; (c) for individual use. We would note that with respect to the second prong of the test, purchased "at retail," the term "retail" relates more to the end purchaser than to the location of the sale. Black's Law Dictionary defines "retail" as "[t]he sale of goods or commodities to ultimate consumers, as opposed to the sale for further distribution or processing." (Emphasis added).

Depending on what occurs the week of March 22 in terms of debate and votes on the Reconciliation Package, the Reconciliation Package, which modifies Pub. L. 111-148, may also be signed into law later this week.

[1]The "Patient Protection and Affordable Care Act" (H.R. 3590), was passed by the Senate on Dec. 24, 2009, and by the House of Representatives on March 21, 2010, and signed into law on March 23, 2010.

[2]The "Health Care and Education Affordability Reconciliation Act of 2010" (H.R. 4872, or the "Reconciliation Package"), as passed on March 21, 2010, available at http://docs.house.gov/rules/hr4872/111_hr4872_amndsub.pdf.

[3]Those revisions are available at http://docs.house.gov/rules/hr4872/111_managers_hr4872.pdf.

[4]The Rules Committee amendments to the Reconciliation Package reduced the excise tax from 2.9% (the level in the Reconciliation Package released on March 18, 2010) to 2.3%.

[5]Note: Department of Treasury Regulations (Treas Reg. 1.164-2(f)), state that excise taxes are not deductible, however, "The fact that any such tax is not deductible as a tax under section 164 does not prevent (1) its deduction under section 162 or section 212, provided it represents an ordinary and necessary expense paid or incurred during the taxable year by a corporation or an individual in the conduct of any trade or business or, in the case of an individual for the production or collection of income, for the management, conservation, or maintenance of property held for the production of income, or in connection with the determination, collection, or refund of any tax, or (2) its being taken into account during the taxable year by a corporation or an individual as a part of the cost of acquiring or producing property in the trade or business or, in the case of an individual, as a part of the cost of property held for the production of income with respect to which it relates."

[6]The FFDCA defines “device” as any “instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article” that meets any of the following three tests: (1) is recognized in the National Formulary or the United States Pharmacopeia (or a supplement); (2) is used for the diagnosis, cure, mitigation, treatment, or prevention of disease; or (3) is intended to affect the structure or any function of the body through other than chemical means (or is not dependent upon being metabolized to achieve its primary intended purpose).