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Revising Regulations For Medical Device Excise Tax

Law360, New York (September 21, 2012, 2:25 PM ET) -- The highly publicized Medical Device Excise Tax (MDET), a part of the Health Care and Education Reconciliation Act of 2010, applies to sales of taxable medical devices beginning on Jan. 1, 2013. While much has been written about the MDET, this article discusses the less publicized interaction between proposed Internal Revenue Service regulations implementing this new tax and recent amendments to the U.S.Food and Drug Administration device-listing regulations.

Taken together, these regulations could have the effect of broadening the category of "taxable medical devices" to include device components and finished devices manufactured by contract manufacturers on behalf of other entities. We believe this result was not intended by MDET.

Health Care and Education Reconciliation Act — Medical Device Excise Tax

The statutory provision enacting the MDET is short and seemingly clear. Section 1405 of the act imposes a 2.3-percent excise tax on the sale of "any taxable medical device" by manufacturers, producers and importers (manufacturers).

According to Section 1405, the term "taxable medical device" means any device intended for humans as defined in Section 201(h) of the Federal Food, Drug and Cosmetic Act (FDCA). Section 1405 specifically excludes from the "taxable medical device" category certain products that are considered devices for human use under the FDCA, including eyeglasses, contact lenses, hearing aids and other devices which are "generally purchased by the general public at retail for individual use."

The IRS's Proposed Regulations

The implementing regulations proposed by the IRS in February of this year (see 77 Fed. Reg. 6028) adopt and refine the definition of a "taxable medical device" contained in Section 1405.

According to proposed 26 CFR § 48.4191-2(a), a taxable medical device is any device intended for humans as defined in section 201(h) of the FDCA, that is listed as a device under section 510(j) of the FDCA and 21 CFR Part 807, pursuant to the FDA requirements. This refinement was proposed to help device manufacturers know whether their devices are taxable medical devices.

According to the preamble to the proposed rule:

"The FDA listing requirements are longstanding. Further, device manufacturers must comply with these requirements as part of the FDA's device regulation process. Therefore, device manufacturers can be expected to know which devices fall within the definition."

At this time, final IRS regulations have not been published. The comment period for the proposed regulations ended on May 7, 2012, and we anticipate final rules and regulations by the end of 2012.

Recent Amendment of the FDA's Listing Regulations

The definition of a device under Section 201(h) of the FDCA includes components of devices as well as finished devices. Therefore, components of devices and finished devices would be considered "taxable medical devices" under Section 1405.

However, until very recently, under the FDA regulations, contract manufacturers of device components and finished devices (that is, as described in the FDA regulations, manufacturers of products according to another person's specifications for distribution by that other person) were not required to list their products. Because the FDA regulations did not require them to list their products, contract manufacturers of device components and finished devices would not have been considered manufacturers of "taxable medical devices" when the IRS proposed its regulations in February 2012.

However, in August of this year, the FDA amended its listing regulations (see 77 Fed. Reg. 45927) to broaden the group of manufacturers who must list the devices they manufacture. The amended 21 CFR § 807.20(a)(2), which is effective on Oct. 1, 2012, effectively requires all manufacturers of devices to list the products they manufacture, even contract manufacturers of device components and finished devices.

The FDA's expansion of the category of manufacturers who must list their products implements amendments to the FDCA made in 2007, well before the enactment of Section 1405. The FDA explained the purpose of requiring additional manufacturers to list their products in the preamble to its final regulation.

For example, listing all devices will enable FDA to know where they are manufactured, which will be helpful if manufacturing problems arise or if a recall is necessary. Additionally, according to FDA, information on manufacturing sites would be critical information when a device is in short supply or needed in the event of a national emergency.

Regardless of the FDA's reasons for broadening the group of device manufacturers who must list their devices, because this FDA action increases the range of devices that must be listed, it also appears to inadvertently increase the products considered "taxable medical devices" under the proposed IRS regulations implementing the MDET.

Conclusion

The political fate of the MDET is yet to be determined. However, in light of the U.S. Supreme Court's decision in National Federation of Independent Business v. Sebelius, medical device companies have begun bracing themselves for the impact of the MDET.

When IRS final regulations are released, we hope that the interaction between the IRS rules and new FDA device listing rules will be clarified. Moreover, it is important to note that some sales of "taxable medical devices" may be tax exempt, such as sales for use in further manufacture. We recommend that contract manufacturers and entities purchasing finished devices or device components from them consult tax and FDA regulatory professionals to assess the applicability of the MDET to their particular situation.

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