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Medical Device Final Regulations Published

On Wednesday, December 5, 2012, the Internal Revenue Service ("IRS") released an advanced copy of the final regulations, which were officially issued Friday, December 7, 2012 and which provide guidance on the 2.3% excise tax imposed on the sale of certain medical devices that will go into effect on January 1, 2013. While the final regulations provide some helpful guidance and additional clarification, but for the examples included in the regulations both the discussion in the preamble and the regulations themselves repeat much of what was already known based on the statutory language in the Internal Revenue Code ("IRC"), the legislative history behind the provisions enacted as part of the Health Care and Education Reconciliation Act of 2010, and the proposed regulations issued on February 7, 2012, as the IRS generally rejected most of the comments and suggestions provided by the public. However, the IRS also issued an advance copy of Notice 2012-77, which provides much more helpful guidance and interim relief measures with respect to the determination of the price of a taxable medical device that is actually subjected to the medical device excise tax (the "MDET"), certain relief for a limited period from penalties related to compliance with the MDET, and other aspects of the MDET .

The MDET is imposed on the sale of any "taxable medical device" by the manufacturer, producer, or importer of the device. The tax is imposed at the rate of 2.3% of the price (but not including the MDET itself, whether separately stated or included in the price) for which the device is sold. A taxable medical device is any device that is intended for humans and is defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"). The regulations go on to state that a device defined in 201(h) of the FFDCA that is intended for humans is a device that is (should have been) listed as a device with the Food and Drug Administration ("FDA") under section 510(j) of the FFDCA and 21 CFR part 807, pursuant to FDA requirements.

DEFINITION OF DEVICE UNDER THE FINAL REGULATIONS

The preamble to the regulations makes clear that if an item is not separately listed as a device with the FDA under section 510(j), then the item does not meet the definition of a taxable medical device. The specific example in the preamble pertains to software and/or software upgrades that are not separately listed under section 510(j) as a device and are not considered taxable medical devices subject to the MDET when such software or software upgrades are sold. Presumably, this would extend to the manufacturer or producer of components who supplies such components to the manufacturer or producer of a medical device. For example, assume that a manufacturer makes syringes for the commercial food industry (e.g., for injecting liquids into foods or in making candy) and the manufacturer is approached by a third party to make both the plunger and glass tubing needed to make a syringe for use in connection with the medical treatment of humans. Assume further that the

manufacturer only sells the plungers and glass tubing to the third party who, along with other parts that the third party either purchases or manufactures itself, assembles the syringes, which it then sells to hospitals, doctors and other medical professionals. Assuming only the syringe is listed under section 510(j) as a device and neither the plungers nor the glass tubing are separately listed under section 510(j), then the separate sales of the plungers and glass tubing by the manufacturer would not be sales of taxable medical devices subject to the MDET. Assuming the manufacturer is not engaged in any other activities related to the medical device industry beyond the supplying of the plungers and glass tubing, the manufacturer would not otherwise be required to be register (by filing a Form 637, Application for Registration for Certain Excise Tax Activities) nor file quarterly MDET returns (Form 720, Quarterly Excise Tax Return).

This strict approach to listing under 510(j) was a consistent theme in the regulations and the preamble. For example, the IRS rejected several suggestions that devices reviewed by the FDA Center for Biologics Evaluation and Research ("CBER) be granted a blanket exclusion from the definition of taxable medical device. In response the preamble stated that devices that CBER regulates will be considered taxable medical devices if listed under section 510(j) and will be exempt from the MDET if not so listed.

MULTIPLE-USE DEVICES

The most troubling aspect of the regulations is the guidance with respect to devices that are dual use devices (either devices that can be used for human and veterinary applications or devices that have medical and non-medical applications) and devices that qualify for an exemption from the MDET. The preamble to the final regulations notes that only devices having both human and veterinary application are required by the FDA to be listed under section 510(j) and, further, devices having only veterinary application are not listed as devices under section 510(j). Accordingly, only medical devices that solely have veterinary application are not taxable medical devices subject to the MDET. Thus, according to the preamble, any device listed under section 510(j), even if the device can be used in the practice of veterinary medicine, is a taxable medical device subject to the MDET. The preamble goes on to note that section 4191 of the IRC does not provide that a taxable medical device has to be intended exclusively for use in treating humans. Thus, although not specifically stated, the discussion in the preamble clearly implies that any sale by a manufacturer of a device listed under section 510(j), even if that device is clearly intended for use in the practice of veterinary medicine, is subject to the MDET when it is sold by the manufacturer.

A similar conclusion can be reached on sales of devices listed under section 510(j) that also have non-medical applications. For example, a syringe that is listed as a device under section 510(j) that is sold by the manufacturer of the syringe to a college or university to be used in its science research laboratories would be subject to the MDET unless the device qualified under a specifically enumerated exemption such as the retail exemption.

RETAIL EXEMPTION

IRC section 4191 provides exemptions for eyeglasses, contact lenses, hearing aids and any other medical device determined by the Secretary to be of a type which is generally purchased by the general public for individual use (the "Retail Exemption"). First, the final regulations retained, mostly without change, the safe harbors set forth in the proposed regulations providing that the Retail Exemption requirements will be met with respect to a device if the device: (i) is included in the FDA's online IVD Home Use Lab Tests (Over-the-Counter Tests) database (available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfIVD/Search.cfm); (ii) is described as an "OTC" or an "over the counter" device in the relevant FDA classification regulation heading; (iii) is described as "OTC" or an "over the counter" device in the FDA's product code name, the FDA's device classification name, or the "classification name" filed in the FDA's device registration and listing

database (available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/rl.cfm); (iv) qualifies as durable medical equipment ("DME"), a prosthetic, an orthotic, and supplies (collectively "DMEPOS"), for which payment is available on a purchase basis under the Medicare Part B payment rules. The definition is further limited by providing that only (I) a prosthetic or orthotic device that is defined in 42 CFR 414.202 and does not require implantation or insertion by a medical professional, (II) parenteral and enteral equipment and supplies as defined in 42 CFR 411.351 and in 42 CFR 414.102(b), (III) customized items as described in 42 CFR 414.224, (IV) therapeutic shoes as described in 42 CFR 414.228, or (V) supplies necessary for the effective use of DME as described in section 110.3 of Chapter 15 of the Medicare Benefit Policy Manual (Centers for Medicare and Medicaid Studies Publication 100-02), fall within the meaning of DEMPOS.

Second, a device will qualify for the Retail Exemption and, thus, be exempt from the MDET, if it is (A) regularly available for purchase and use by individual consumers who are not medical professionals and (B) if the design of the device demonstrates that it is not primarily intended for use in a medical institution or office, or by a medical professional. The final regulations retain the facts and circumstances approach to determining whether a particular device falls within the Retail Exemption that was set forth in the proposed regulations with some modification. The facts and circumstances approach requires a weighing of a non-exclusive list of positive and negative factors in determining if a device satisfies the requirements for exemption from the MDET under the Retain Exemption. The positive factors are whether (1) consumers who are not medical professionals can purchase the device in person, over the telephone, over the internet, at retail outlets, such as drug stores, supermarkets, or medical supply stores and retailers that primarily sell devices (for example, specialty medical stores, DEMPOS suppliers and vendors) to consumers; (2) consumers who are not medical professionals can use the device safely and effectively for its intended medical purpose with minimal or no training from a medical professional; and (3) the device is classified by the FDA under Subpart D of 21 CFR part 890 (Physical Medical Devices). The negative factors are whether the (1) device generally must be implanted, inserted, operated, or otherwise administered by a medical professional; (2) cost to acquire, maintain, and/or use the device requires a large initial investment and/or onging expenditure that is not affordable for the average consumer; (3) device is a Class III device under the FDA system of classification; (4) device is classified by the FDA under certain enumerated parts of subparts of 21 CFR; and (5) device qualifies as DMEPOS for which payment is available exclusively on a rental basis under the Medicare Part B payment rules and is an "item requiring frequent and substantial servicing" as defined in 42 CFR 414.222. The final regulations clarify that the factors listed above are non-exclusive and that the presence of a negative factor does not automatically prevent a device from meeting the requirements for the Retail Exemption. Instead, the approach requires a balancing of the factors.

BUNDLING OR KITS

The final regulations and the preamble thereto addressed some of the issues related to bundled items, some or all of which may be considered to be taxable medical devices. If an item that is bundled contains both a device listed under section 510(j) of the FFDCA and an unlisted device (in other words, the entire bundle is not a taxable medical device), the MDET attaches only to the sale of the taxable medical device. The preamble provides an example of software and services that are bundled with other taxable medical devices in a single sale. The example holds that the MDET attaches only to the taxable medical devices and not the portion of the sales price that attaches to the software and service items.

The IRS also deferred the issuance of final regulations applicable to kitters, i.e., a taxpayer that bundles two or more taxable devices in a bag, tray, or box for the convenience of an end user, other than self-kitters, which are hospitals or medical institutions that produce kits for their own use. Self-kitters are exempt from FDA registration and listing requirements. Accordingly, self-kitters are not subject to the MDET on the kits they produce for their own use. The IRS also deferred whether assembly of the kit constitutes further manufacture for purposes of whether the kit is subject to the

MDET. The IRS did provide, however, interim guidance in Notice 2012-77 as to the application of the MDET to "convenience kits" (i.e., a single package, such as a bag, tray, or box containing two or more devices). The interim guidance provides that the MDET will not be imposed upon the sale of a domestically-produced convenience kit that is a "taxable medical device" until additional guidance is issued. During this interim period, however, the sale of a taxable medical device that goes into a domestically-produced convenience kit will be subject to the MDET tax upon its sale by the manufacturer or importer, but the further sale of the convenience kit by the kit producer will not be subject to the MDET. Conversely, the IRS provided in the same interim guidance that the sale by an importer of a convenience kit is taxable as a medical device, but only on the value of the taxable products in the kit.

CONSTRUCTIVE SALES PRICE

The IRS also acknowledged in the preamble the concern expressed by numerous commenters in applying the constructive sales price, and various rules concerning price, in determining the amount of the MDET due with respect to a taxable medical device and indicated a willingness to work with stakeholders on compliance-related issues. To that end, the IRS rejected several commenters' requests to temporarily waive all compliance penalties relating to the failure to file the MDET returns and/or timely pay any the MDET due, noting in the preamble that an affirmative showing of reasonable cause (the exercise of ordinary business care and prudence) is available to abate any the MDET penalties that might otherwise apply and that taxpayers are encouraged to call the telephone number on the penalty notice to discuss abatement options. However, interim guidance and certain safe harbors as to price were provided by the IRS in Notice 2012-77, as well as certain interim penalty relief.

IRC section 4216 provides rules for determining the price on which the 2.3% the MDET is imposed at the time of sale of the taxable medical device by the manufacturer or producer. These rules generally equate the price to what a manufacturer or producer would sell the taxable medical device for to an independent wholesaler of such a device. When a manufacturer or producer of a taxable medical device sells the device to an end user, for example, IRC section 4216 and the regulations thereunder prescribe rules for determining the price that the independent wholesale distributor would have paid for the device, upon which the 2.3% the MDET is then computed. The IRS recognizes that the medical device industry is a diverse group of manufacturers that produce a broad range of articles utilizing a number of distribution chains, and that many of the manufacturers do not sell to independent wholesale distributors. Accordingly, the IRS provided "safe harbor" constructive sales price rules in the Notice that generally apply various percentages (determined by the type of distribution chain used by the manufacturer to sell the taxable medical device) times either the actual or lowest selling price for such device (once again determined by the type of distribution chain used by the manufacturer to sell such taxable medical device). If a taxpayer chooses not to apply the "safe harbor" rules provided in the Notice in determining the "sales price" of a taxable medical device subject to the MDET, then the taxpayer bears the burden of demonstrating that the price its uses to compute the MDET is the fair market price as determined under IRC 4216 and the regulations thereunder. The "safe harbor" rules may be used until further guidance is published.

PENALTIES AND OTHER RELIEF PROVIDED IN NOTICE 2012-77

Notice 2012-77 also provides a blanket waiver for certain failures under the deposit penalty rules for the first three calendar quarters of 2013. Generally, taxpayers subject to the MDET are required to deposit not less than 95% of the amount of net the MDET due for each semimonthly period that the tax applies. Alternatively, taxpayers can avoid the failure to deposit penalty if certain lesser amounts are timely deposited and any underpayment is paid by the due date for the filing of the quarterly the MDET return. The first deposit of the MDET, which will cover sales of taxable medical devices by a manufacturer or producer made during the first 15 days of January 2013, is due by January 29, 2013.

The Notice provides that any penalties due to a taxpayer's failure to make timely deposits (presumably, only deposits that are not sufficient to satisfy the 95% or alternative test for relief) will be waived for deposits required during the first three quarters of 2013 if the failure is not due to willful neglect. After that, the regular existing failure to deposit penalty rules will apply.

Notice 2012-77 also contains interim rules and guidance regarding the MDET treatment of medical software licenses and the taxability of donated medical devices. The IRS and the Treasury Department requested that any one desiring to submit comments on the interim rules and guidance set forth in the Notice should do so by March 29, 2013.

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The rules for determining what items are subject to the MDET, when an item may become subject to the MDET (e.g., at the time of importation of certain products or items), and the timely deposit and filing of the MDET returns are all quite complex. We have had considerable experience assisting clients on the regulatory side (assisting trade associations with comments to the IRS regarding regulations) and in assisting manufacturing clients with establishing a system for compiling the information needed to prepare and file the MDET returns beginning January 1, 2013. We would be happy to discuss with you your needs as they relate tocompliance with the MDET. For more information regarding the Medical Device Excise Tax, please contact any of the following Bryan Cave professionals:

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