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From The Desk Of
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The Medical Device Tax: Stop Dreaming and Start Planning

The Senate's recent vote of 79-20 to end the medical device tax has many using their replacement knees to jump up and down. Unfortunately, the dream is over and the reality is still with us. The Senate vote was on a budget resolution – the U.S. Senate's answer to an air kiss.

While this feel-good vote might be used to build on (and certainly the margin of the vote is noteworthy) the reality is that this vote and a magic feather will get you a flying elephant. For those still dreaming that the medical device tax is going away is the cold water that the amendment required that the revenue loss (not an insignificant amount – over $10 billion dollars over 10 years) must be completely offset with new undetermined revenues. So the vote was in essence – "yes I'd like to replace this stupid tax by raising some unknown tax on unknown persons at an unknown time." Wow – who were the 20 who voted against that?

Is there a possibility of the medical device tax being removed (or modified) down the road? Yes there is – but that road is much more potholed and twisted then many medical device manufacturers think – if the phone calls I'm getting are any indication.

Why is that? First, getting an acceptable offset is not at all easy – the tax writing committees do not have $10 billion dollar plus offsets that no one opposes jingling in their pockets. Second, as I learned from years on the Finance Committee – if you want to move a tax provision you need to be on a tax train (ie a bigger tax bill). You need the locomotive of a bigger tax bill to move things forward. The only big tax bill in sight at the moment is tax reform and readers can take their own views on the likelihood of tax reform happening in the near future. In short – the outlook for tax legislation moving in the near future that would include a reform/repeal of the medical device tax is not great.

My worry is that medical device companies will be too busy chilling champagne and not doing the necessary planning to prevent overpaying the medical device tax.

As a reminder, the tax is a 2.3% excise tax on the sales price (that's gross sales, not profit) of taxable medical devices. The tax is extremely broad-based and applies to almost any FDA-registered device that is intended for human use – everything from MRIs to tongue depressors to ultrasounds to condoms. There are exceptions and exemptions if you know where to look, but this one-paragraph-long statute has already produced pages of perplexing regulations and an IRS Notice full of temporary guidelines.

Of particular concern is that there are a significant number of taxpayers who either don't realize the law applies to them or hope that it will be repealed (or they would be exempted). These taxpayers have been caught completely flatfooted, and I and my colleagues have had to pull oars registering these medical device companies with the IRS, coming into compliance, and even navigating some of those exceptions and exemptions mentioned earlier. Equally important though are steps that can be taken to ensure your company does not overpay (of which we see a good deal).

One of the best strategies to limit your exposure to the tax is to determine — what is the "price" of the medical device? The law wants to capture the cost of the device itself, but many times there are bundled services, warranties, and other items that can be separated out from the cost of the actual medical device. The results of this may be depending on the facts a reduction of the "price" and tax liability. The bundled items have to be genuinely optional, so sales contracts may have to change so that technical assistance, training, service updates, etc. are genuinely optional. As part of this, you need to have arms-length valuation that accurately accounts for these items.

Another area that we are seeing overlooked is the situation of the contract manufacturer – manufacturers who are making products using materials and intellectual property actually owned by the customer. A contract manufacturer escapes the tax entirely (it shifts to the customer), but it always depends on the facts and circumstances of the taxpayer. On top of these are a number of potential safe harbor price reductions that can vary from customer to customer.

The Service knows this tax is hitting a lot of people unawares, and to their credit the IRS is trying to work with taxpayers. The IRS has stated that taxpayers won't be hit with penalties for nonpayment through September, but there's a caveat – "unless due to willful neglect." If you aren't in compliance now because the tax is a maze and you need help, even the Government understands. But if you're sticking your head in the sand, hoping Congress will solve all your problems, the Service is likely to take a dim view of that, and you'll still be stuck with the bill – a big bill.

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