The Medical Device Excise Tax, Wrap Up, Audits and Refunds

Michael Cronin | SALT - Senior Manager - New England State and Local Indirect Tax and National Medical Device Excise Tax Leader

T +1 617 848 4999
C +1 617 797 8532
michael.cronin@us.gt.com
Topics

- Whether companies can expect a temporary MDET freeze for 2 years or something more permanent

- MDET IRS audits are still on-going, what are best practices to get ready and defend these audits

- Common errors/refund opportunities which may be available. **Any refunds for the 1st quarter of 2013 must be filed by the end of April 2016**

- Questions
Temporary MDET Freeze?

– Medical device excise tax in effect from 2013-2015

– Path Act suspends it for 2016-2017

– Scheduled to take affect again in 2018

– Will tax actually come back in 2018?
Temporary MDET Freeze Cont'd?

- Camel's nose is in the tent
- Now that it's been delayed once, very easy for Congress to come back and delay it again
- Only raises about $2 billion a year
- It's paired with delays of 2 other deeply unpopular ACA taxes
- 'Cadillac tax' least is likely to come back, but MDET also disliked by many in both parties
- Good chance we never see this tax again

**BUT. . .**

- No guarantees with legislative process: Need to prepare to comply in 2018 until and unless it actually is repealed or delayed again
MDET Audit: The Information Document Request (IDR)

- Copies of excise tax returns (Forms 720) for the audit period, and forms 637 registration statements (e.g. exports)
- Copies of income tax returns and financial statements (including income statements and balance sheets) for audit periods
- Charts of accounts, trial balances
- Excise tax payable ledger, detail sales account ledgers
- List of related entities (and descriptions) with EINs
- Work papers used in preparing the 720s
- Describe in detail the distribution chain(s) of all taxable medical devices; whether each device is manufactured or imported, and how each device is treated for MDET purposes, provide a schematic flow chart
- Please note the point when ownership of a device is first transferred from the manufacturer or importer to another entity (first taxable sale)
MDET Audit: The IDR Cont'd

- List/locations of all manufacturing facilities
- List all devices manufactured and devices imported including kits
- Provide a list of all of the above devices listed with the FDA
  - Provide your FDA registration number
- Provide the specific methodology for how the taxable medical devices are identified and reported for purposes of the MDET
- Did you sell any devices tax free? If yes please describe
- List any contract manufacturers, explain the contract manufacturer's responsibility and provide a sample contract
- Do you participate in a Group Purchasing Organization (GPO). If so please describe the arrangement. Provide expenses ledgers associated with the GPO.
Provide an overview of how the sale price is determined for each taxable device including a sample computation

• Whether the sales price is an actual or a constructive sales provide
• If a constructive sales price was used, did you use a safe harbor from IRS Notice 2012-77 or construct your own fair market price
• Describe in detail all that apply and to which devices
• How packaging, transportation, advertising, adjustments, rebates, discounts and other costs are handled

Provide a listing of all taxable devices that are exempted under the retail exemption and the analysis performed by the company in determining how the exempt conclusion was reached (if applicable)

Were any credits or adjustments taken on your return (such as on Form 720/Schedule C); 8849 or amended 720.
MDET Refunds

- 3 year statute of limitations
  - First quarter 2013 refunds must be filed by end of April 2016
  - Second quarter 2013 by end of July 2016 and so on.....
  - Best practice is to file refund claims for all periods if possible as should be assigned to one auditor; as opposed to different auditors if filing on a quarterly basis
  - File form 720X (amended form 720) for refund claims. Include as much supporting documentation as possible with refund claim.
  - Waiting time right now for refund claims to be assigned to IRS reviewer is about 3 – 4 months, could be more.
  - Expect IRS auditors/refund reviewers that are more comfortable with other excise taxes, not MDET. Could be a blessing or problematic.
Imposition of the MDET

- Tax imposed is based on:
  - The sales price that the manufacturer sells the medical device to a wholesale distributor; who then sells the taxable article to a retailer that makes a sale at retail.
  - **Wholesale distributors are uncommon in the industry.**

- Regulations provided that all sales to hospitals are considered sales at retail.
MDET Refunds Cont'd

– Constructive Price Rules: Safe Harbor
  • Sales at retail
  • 75% of actual selling price

– Unrelated Retailer
  • 90% of **lowest price** for which the articles are sold to unrelated retailers.

– Related Retailer
  • 75% of the product of 95% of the actual selling price.

* If you don't use these rules, you bear the burden of proof to demonstrate the fair market price.
MDET Refunds Cont'd

- Fair Market Value Price Methodology:
  
  "If a taxpayer does not apply the rules provided in this notice, and does not use the actual sale price of the article to calculate its medical device excise tax liability, then the taxpayer bears the burden of demonstrating that it used the fair market price of the article to calculate its tax liability. This approach is consistent with the general rule under which a manufacturer may rebut the constructive sale price if the manufacturer demonstrates that it sold the article at a fair market price". *Rev. Rul. 89-47, 1989-1 C.B. 295*. See IRS Notice 2012-77.

- GT Market Observations
  
  • Generally, companies are overpaying by at least 15% – 25% plus from using safe harbor percentages.
  
  • It appears IRS prescribed safe harbor pricing rules are erroneously based on “industry wide” percentages instead of medical device industry subsectors.
MDET Refunds Cont'd

– Retail Exemption (RE): Not just for over the counter products
  • Prescribed products, FDA Class 2 does not eliminate RE availability
  • Facts and circumstances test, but pay close attention to "can consumers who are not medical professionals safely and effectively use the device for its intended medical purpose with minimal or no training from a medical professional"

– Exclusions from MDET price
  • Tax itself
  • Transportation/delivery/insurance
  • Installation
  • Discounts, rebates
  • Warranty, if optional
MDET Refunds Cont'd

- Contract manufacturing
- Embedded services
- Free products (e.g. samples)
- Razor/razor blade sales
- Ancillary products/components that do not have FDA listings
- Exports, further manufacturing
Disclaimer

This Grant Thornton LLP presentation is not a comprehensive analysis of the subject matters covered and may include proposed guidance that is subject to change before it is issued in final form. All relevant facts and circumstances, including the pertinent authoritative literature, need to be considered to arrive at conclusions that comply with matters addressed in this presentation. The views and interpretations expressed in the presentation are those of the presenters and the presentation is not intended to provide accounting or other advice or guidance with respect to the matters covered.

For additional information on matters covered in this presentation, contact your Grant Thornton, LLP adviser.
Thank you for attending

Visit us online at:
• www.GrantThornton.com
• twitter.com/GrantThorntonUS
• linkd.in/GrantThorntonUS