Understanding the Medical Device Excise Tax (MDET)

May 9, 2012
Agenda

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    • Imports and Exports
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• Questions
Medical Device Excise Tax - Overview

- Health Care and Education Reconciliation Act of 2010
- Established a 2.3% excise tax imposed on the first sale in the US of taxable medical devices effective 1/1/13.
- Taxable medical device - any device defined in section 201(h) of the Federal Food, Drug and Cosmetic Act intended for humans
- Certain sales of taxable medical devices are exempt –
  1. For further manufacture
  2. For export
- Tax not imposed on items available for purchase by the general public (e.g., eyeglasses, contact lenses, hearing aids)
- Many open issues still exist, including significant complexities surrounding determination of taxable price issues surrounding product “kitting,” etc.
**Washington Update: MDET – Legislative Repeal Activities**

- Efforts continue to grow around legislative repeal of the tax.
- The Advanced Medical Technology Association (AdvaMed) is leading an initiative to repeal the tax.
- More than 400 companies signed a letter to leaders of Congress stating that the tax would “stifle innovation and US competitiveness.”
- The case for repeal:
  - Tax is having an adverse impact on R&D investment and job creation.
  - Cost cutting measures will lead to job losses (public announcements have already been made in this regard)
  - Tax will adversely impact patient access to new and innovative medical technologies.
- Repeal efforts continue to advance (*H.R. 436, the Protect Medical Innovation Act of 2011*, introduced by Representative Paulson.
- Likelihood of repeal in 2012?
**Washington Update: Supreme Court Challenge to Healthcare Reform**

- In March 2012, the Supreme Court heard three days of oral arguments on the constitutionality of the minimum coverage provision (e.g., individual mandate) of Healthcare Reform.
- **Severability** of the individual mandate is the most relevant issue for the medical device industry.
- If the individual mandate is considered severable, the MDET would continue to exist (even if the individual mandate is ruled unconstitutional).
- A ruling a) against the constitutionality of the individual mandate and b) that it cannot be severed from the rest law would bring down the entire act—and the device tax with it.
- The Supreme Court’s decision is expected in June 2012.
Washington Update – What is a Company to Do?

- Given the potential for repeal, why do I care right now??
- Good question... But keep listening...
- Do you consider your supply chain similar to that of a fishing lure manufacturer?
- Archaic IRS rules, thus... are you IT systems ready?? (More on that later...)
The Supply Chain from 10,000 feet ......

Supply Chain Considerations:
- Tax due on the first sale in the US.
- The relationship between suppliers/manufacturers/distributors and customers will dictate many aspects of the MDET.
- These relationships determine a) who is responsible for the tax b) the applicable computational tax base.

Is the customer the end user and will the device be exported?

Material/transaction flow
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Suppliers

- US or OUS Suppliers

- Purchase of devices from OEM/CM
  * Is this an OEM or CM relationship?
  * If imported, who is the importer of record?

US Mfg

- Devices further manufactured? Is the sale by the Manufacturer to a related company?

Regional/central/local warehousing

Finished goods transfer to US Mfg’s warehouse

Finished goods – SOLD by US Mfg

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Example 1 – US Contract Manufacturer Supplier

**US Mfg is the OEM (e.g., holds the IP and related product rights, etc).**

**US Mfg**

Finish goods transfer to US Seller’s warehouse

- **Device is not further manufactured or exported**

**Medical Devices**

**US Supplier**

**MDET Supply Chain Impacts:**
- Tax due on the first sale made by US Mfg to its customer
- Is the customer the end user of the device? (Answer to this question has a significant impact on the MDET taxable base).
- Will some or all of the tax be “passed through” to the customer via the invoice?

**Finished goods – SOLD by US Mfg**

Regional/central/local warehousing

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Example 2 – Imported from OUS Supplier

MDET Supply Chain Impacts:

- Tax due on the first sale made by US Mfg to its customer.

- What if US Seller is merely distributing the product of OUS supplier?

- What if OUS Supplier (or its US affiliate) imported the device?

• US Mfg is the importer of record

• Device is not further manufactured or exported

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**Example 3 – Sale for Further Manufacturing**

Supply Chain
- Sale to US Mfg #1 not taxed because of further manufacturing.
- What if US Mfg #2 is merely “kitting” products?
- How do contractual terms between US Mfg #1 and #2 impact who economically bears the tax?

**US Seller will further manufacturer the product purchased.**

Material/ transaction flow

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Example 4 – Sale for Export to OUS Customer

Supply Chain

- Sales for export are exempt for MDET purposes.
- Proper exemption documentation is needed.
- What if product is first sold to a US customer, who then exports the product for OUS use?

-Device will be exported to OUS customer

Device will be exported to OUS customer

Material/ transaction flow

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MDET – Compliance Challenges

• Why is it important to focus on this tax now?
• Taxable base computations are highly complex and frequently are not derived from the actual 3rd party sales price.
• Items such as rebates, discounts, leases, intercompany sales and numerous other factors must be addressed so that taxpayers are ready to comply with the new excise tax when it becomes effective on January 1, 2013.
• IT systems must be materially updated/modified in advance so that the correct amount of excise tax can be calculated, reported and paid.
Why isn’t this a straightforward calculation??

  e.g. Domestic sales $5B x 2.3% = $115M

What about sales for export or for further manufacturing? How do I systematically capture that data for exemption purposes?

What about sales where the supplier is the domestic manufacturer and subject to the tax? How do I make sure I don’t pay tax on these sales?

Also – the law allows reductions to the taxable base for: 1) rebates, 2) transportation costs incurred after title transfer – How do I capture this information?

Is the product sold by the manufacturer to the end user (e.g., a hospital)? If so, the law allows a taxable base reduction (via highly complex rules) to arrive at a wholesale (vs. retail) price. These highly complex rules often require accessing 3rd party sales data to determine a highest (or lowest) wholesale price.

Are sales made via a related party sales affiliate? If yes, a taxable base reduction (via highly complex rules) is also allowed.

Impractical?? Yes. Required – Yes. The above creates significant IT systems challenges.
MDET – Savings Opportunities

• Significant Tax Savings opportunities exist with proper planning

• Examples include:
  • Bundled products (sales of products that include non-taxable elements – e.g., services, software, etc).
  • Consideration of related party sales company impacts (related party sales often materially impact the amount of tax due and payable)
  • Incorporation of transfer pricing concepts (to derive a sale by manufacturer value), where appropriate
MDET – Current State of MDET at Medical Device Companies

• It’s quite varied...
• Companies are at various stages regarding the planning process.
• Some are taking more of a “wait and see” approach due to potential for repeal (Not recommended for any company where the MDET would have a material impact beginning 1/1/2013).
• Some have approached it from a more tax technical or academic level and have yet to consider a system-based solution
• Others are beginning to consider system requirements or are actively in the initial stages of a systems based implementation process.
MDET – Emerging Best Practices

1) Educate the organization to understand the tax.
2) Gauge the ability of your organization to pass the tax onto customers.
3) Approximate the financial impact of the tax for each business unit.
4) Perform a pre-implementation assessment of the information technology and business processes requirements in order to be compliant with the tax.
5) Implement a system-based solution that will allow compliance with the material aspects of the MDET.
Questions?

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Thank you!
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