U.S. Medical Device Excise Tax: Helping Medical Device Manufacturers with Implementation and Compliance

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Table of Contents

Introduction 4
What is the Medical Device Excise Tax? 4
Who is affected? 4
What can you expect? 5
What does the Excise Tax mean for medical device manufacturers? 5
Constructive Sales Price 7
QAD Enterprise Applications helps with compliance 8
QAD Tax Solutions 9
Conclusion 10

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Introduction

This white paper describes the U.S. Medical Device Excise Tax, outlines the implications that will affect a medical device manufacturer's business processes, and explains how QAD Enterprise Applications can help your company comply with the requirements of the tax.

What is the Medical Device Excise Tax?

On January 1, 2013, an excise tax of 2.3 percent on all taxable medical devices manufactured or imported for sale into the United States took effect. The tax affects U.S. medical device manufacturers and importers of medical devices into the U.S. and will pose operational challenges, particularly with respect to ensuring that enterprise applications support new mandated requirements. The new tax has a number of complex rules detailing items such as:

- Retail exemptions
- Reporting requirements
- Constructive pricing
- Discounts from sale price

Who is affected?

The mandate for the Medical Device Excise Tax is defined in the 2010 Patient Protection and Affordable Care Act (PPACA). It is estimated that the tax will generate as much as $20 billion over 10 years to help fund the implementation of the PPACA.

The new Internal Revenue Code section 4191 relies almost entirely on the Federal Food, Drug and Cosmetic Act (FFDCA) to determine which devices are taxable under the excise tax. Specifically the IRS defined a taxable medical device as:

> "…a device defined in section 201(h) of the FFDCA that is intended for humans means a device that is listed as a device with the FDA under section 510(j) of the FFDCA and 21 CFR Part 807, pursuant to FDA requirements."

The regulations go further by stating in the preamble section on what constitutes a taxable use of a taxable medical device that "the provision or use of taxable medical devises as a demonstration product may constitute a taxable use, depending on the facts and circumstances of the arrangement."

However, the excise tax provision in the PPACA does describe a few major exemption categories, which include:

- Devices which are for use by a purchaser for further manufacture, or for resale to a secondary purchaser for remanufacture, such as components of a kit
- Devices manufactured that are ultimately intended for export outside the U.S.

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- Devices that are "…determined by the Secretary to be of a type that is generally purchased by the general public at retail for general use (the retail exemption)." These include eyeglasses, contact lenses, hearing aids, any other device determined to fall into the retail exemption

The final IRS guidance has determined that since this is a "manufacturer's excise tax," governed under the existing excise tax rules in Chapter 32 of the Internal Revenue Code (IRC), which defines a taxable sale as the transfer of title or substantial incidence of ownership. In the medical device industry this generally occurs when title is passed to a distributor or independent wholesaler. Therefore, under Chapter 32, and the recently released IRS final regulations, medical device manufacturers will be held responsible for complying with the regulations as the tax will attach at the point of sale from the manufacturer to the distributor.

What can you expect?

To address the various rules governing the tax your organization needs to develop procedures that will impact your business transaction system. These processes include:

- Ensuring that your system is capable of managing and segregating the data needed to determine the taxable sales under the rules
- Identifying the medical devices intended for further manufacturer or for export at the end of manufacturing, both of which can be exempt from the excise tax
- Calculating the tax implications of installment or consignment sales or lease of medical devices and equipment
- Managing the tax implications of convenience kits or the complex rules for determining the constructive sales prices of medical devices
- Ensuring that your system is capable of capturing the data necessary to properly identify and calculate any necessary additions, rebates, discounts, etc. from sale price

Although the IRS has only recently issued final regulations on the Medical Device Excise Tax, it is important that device manufacturers be prepared to quickly and accurately comply with the new reporting and payment requirements. Flexibility will be a key factor in meeting the requirements; recent IRS guidance includes interim guidance on issues such as sales price determination and kitting.

What does the Excise Tax mean for medical device manufacturers?

As a medical device manufacturer, you face a number of challenges in understanding these new rules, defining procedures to comply and ensuring that your enterprise systems are able to comply with the requirements. This section covers some of the key issues and their potential impact on the typical medical device manufacturer's business and processes.

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Invoicing

One of the major business impacts will revolve around whether or not manufacturers choose to pass on the cost of the excise tax or absorb the tax as a cost of doing business. This means that business leaders will need to make decisions regarding how to adapt their pricing models. Depending upon which direction a manufacturer decides to proceed, companies will have to factor this into their pricing models in sales price negotiations with distributors and other buyers (e.g., GPOs, etc.).

If manufacturers decide to pass the tax on, a buyer may not be willing to adjust their purchase price or accept the additional burden of the excise tax. Conversely, should manufacturers choose to absorb the excise tax then this directly reduces their margins and complicates the business processes used to manage the excise tax.

What complicates this even further is that manufacturers will have to pay tax on the inventory on hand December 31, 2012 that is not sold until January 1, 2013 or later. Again, this adds complexity to the pricing models used for business plans and contracting as well as modifying business processes.

Compliance

Compliance issues are another area where a company's business process will be affected. For example, companies may need to register with the IRS using IRS Form 637, especially if they wish to qualify for exemptions from the tax due to further manufacture or export. Now that the tax has taken effect, it seems reasonable that the IRS would compare the FDA's list of registered companies with their listing to ensure that all U.S. device manufacturers comply with the requirement.

Manufacturers also must report the tax on a quarterly IRS Form 720, but make deposits twice a month if the liability exceeds $2,500 for the quarter. There are also additional rules regarding minimum amounts of the deposit, etc., which require documentation and adjustments to their business processes. Ultimately all of these requirements will require companies to adjust their ERP and accounting systems to track the data and put controls in place to comply with reporting and payment requirements.

Rebates

The medical device industry is dependent upon distributors and wholesalers to distribute their products for further sale leveraging volume or promotional pricing or negotiated pricing. Both of these scenarios entail the need for management of rebates and chargebacks as the regulations only allow companies to take the rebates into account in determining the taxable sales price "…only to the extent the rebate is made prior to the close of the quarter in which the sale associated with the rebate is made."

If appropriate discount, rebate, etc. data is not available in the quarter of sale, the manufacturer must make a refund or tax credit claim for the tax that is proportionate to

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the part of the price that is rebated at a later date. Again, this highlights the need for processes and systems to accurately manage this additional complexity.

Kitting

The medical device industry makes extensive use of kits made up of taxable medical devices as well as items not considered listed medical devices (and therefore non-taxable) as a convenience for end users. Many of these kits are listed by the FDA as medical devices and therefore were originally considered taxable at the full price of the kit.

However, IRS Notice 2012-77 provides interim guidance that the sale of a kit containing domestically manufactured taxable medical devices is not taxable even if it is a listed device. While the interim guidance is applicable, the sale of a taxable medical device that goes into a domestically-produced convenience kit will be subject to tax upon its sale by its manufacturer, producer or importer. As this will add complexity since companies must be able to track taxable vs. non-taxable components and assembly costs of a kit.

Constructive Sales Price

The medical device industry is composed of a diverse group of manufacturers that produce a broad range of devices. Many manufacturers employ more than one distribution chain related to a specific product or they may not use independent wholesale distributors at all. Setting a constructive sales price for these transactions is generally managed under the manufacturers excise tax rules, which set a sales price that approximates the price that an independent wholesale distributor would pay to the manufacturer of an identical article. However, due to the nature of the distribution system in the medical device industry, the IRS has recognized that they face difficult implementation issues as many of the rules don't address the all various distribution chains used in the healthcare industry.

Therefore, IRS Notice 2012-77 also provides interim guidance, in supplement to existing manufacturers excise tax guidance, on setting constructive prices, for excise tax purposes, for certain distribution chains. In addition to considering direct sales to medical institutions, hospitals or doctor's offices to be "at retail", these rules are summarized as:

- Sales at retail and no regular sales to independent wholesale distributors: 75% of actual selling price after section 4216(a) adjustments
- Sales to unrelated retailers and no regular sales to independent wholesale distributors: 90% of the lowest price for which the articles are sold to unrelated retailers without adjustment for any exclusion (except for the tax imposed on such article) and (e) .
- Sales to related retailer and no regular sales to independent wholesale distributors: 75% of the product of 95% of the actual selling price (that is, the price

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at which the article is sold to a person that is not a member of the group of companies that are related to the manufacturer). The 5% (100% - 95%) is the allowance for the section 4216(a) adjustments and no further section 4216(a) adjustments are allowed.

According to the interim IRS guidance, manufacturers don't have to apply these rules. However, if they don't they must demonstrate that they have used the fair market price to calculate the tax accurately. The preamble to the final regulations also make it clear that an arm's length result determined under section 482 is not an approximate proxy for the constructive price or fair market price under section 4216.

Once again, applying these rules to the day-to-day business processes of a medical device manufacturing company introduces new complexity and the need to ensure that your underlying data systems can manage the requirements of the tax.

QAD Enterprise Applications helps with compliance

Complying with the U.S. Medical Device Excise Tax impacts a number of company functions from sales and pricing strategy to distribution. Developing, automating and implementing the appropriate modifications to your business processes will be critical to successful compliance while minimizing the negative impact to the business.

QAD Enterprise Applications has many features, functions and built-in automated controls to help companies comply with the requirements of the tax. QAD Enterprise Financials drives efficient financial processes for global companies supporting both shared financial services and localization in taxes, reporting, and compliance. Some of the functionality to support the excise tax includes:

- **Sales Quotes and Order Processing** – Various kit configurations can be set up in the sales quote and converted to sales orders automatically while allowing modifications if needed. Medical device tax status of each line item in the order is then determined by the settings in the Global Tax Management.
- **Global Tax Management (GTM)** – GTM determines line item tax status based on ship-to location and item number and provides ability to configure whether the tax is displayed on invoice or processed off invoice. In addition, GTM offers precise tax calculations and flexible setup for calculating other taxes for multiple countries within the same database.
- **Business Process Integration** – The complexity of the excise tax requires your software to integrate and utilize the information from a variety of your business processes. QAD Enterprise Financials fully integrates with the major processes dealing with customers, suppliers, sales and purchase orders across all aspects of your company's business relationships to accurately capture, and utilize, the information needed to comply with the tax's requirements.
- **Planning** – Software alone does not guarantee compliance as your company will need to understand the process changes resulting from the excise tax and the potential impact to your business. A thorough impact analysis led by a team

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of auditors, accountants and business process experts should be performed to help your organization define the proper policies and procedures appropriate for the operation of your business.

Once your organization understands the options and process changes required to meet the excise tax requirements, then you'll need to understand the implications to your ERP/SCM software. The QAD services team has the right expertise and experience to help you understand the implications of the tax on your software and help configure QAD applications so that your organization meets the requirements of the Medical Device Excise Tax.

QAD Tax Solutions

Scenario	Description	QAD Solution
Process integration	Integration with standard business processes and financials (e.g., tax class, tax environment, tax class, tax usage, tax type, accrual, etc.)	Supported by QAD Enterprise Applications
Global tax control	Management of tax across the global enterprise (e.g., country and region-specific taxes)	Supported by QAD Enterprise Applications
Convenience Kits	Determining the taxable components of a convenience kit	Supported by QAD Enterprise Applications and QAD Global Services engagement
Reporting Compliance	Generating quarterly IRS Form 720	Supported by Report Framework
Installment sales, leases, long term contracts	Supporting taxability of installment sales	Supported by QAD Global Services engagement using QAD Service and Support Management and Global Tax Management
Items for further manufacture	Supporting tax exempt sales of product for further manufacture	Supported by Global Tax Management
Tax services providers	Integration with common tax services providers	Supported by Global Tax Management

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Conclusion

Compliance with the Medical Device Excise Tax is a responsibility of all medical device manufacturers, producers and importers. The rules and exemptions governing the excise tax have implications with respect to a medical device manufacturer's processes and information systems. After your company has decided upon the options and process changes required, a critical success factor in compliance will be the readiness of the information system to meet the needs of the excise tax. QAD's Enterprise Application and consulting services can help your organization implement these requirements.

For more information, contact QAD for an evaluation.

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