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E-ALERT | Health Care

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HEALTH CARE REFORM: ANNUAL FEE ON PRESCRIPTION DRUG MANUFACTURERS AND EXCISE TAX ON MEDICAL DEVICE MANUFACTURERS

On March 23, 2010, President Obama signed into law Pub. L. No. 111-148, the Patient Protection and Affordable Care Act (PPACA). Shortly afterwards, on March 30, 2010, President Obama signed into law Pub. L. No. 111-152, the Health Care and Education Affordability Reconciliation Act of 2010 (the Reconciliation Amendments), amending PPACA. PPACA, as now amended by the Reconciliation Amendments (collectively the Act), will have far-reaching effects for the entire health care sector.

This alert, part of a series explaining the impact of the Act on life sciences companies, summarizes the provisions of the Act relating to the annual fee on branded prescription pharmaceutical manufacturers and importers and the excise tax on medical device manufacturers, producers, and importers. These provisions can be found in section 9008 of PPACA and sections 1404 and 1405 of the Reconciliation Amendments.

Executive Summary

- The Act provides for an annual fee on the branded prescription pharmaceutical industry. The amount of the fee ranges from $2.5 billion in 2011 to a peak of $4.1 billion in 2018, and then $2.8 billion thereafter. The fee is allocated among covered entities based on market share in the aggregate for specified government programs.
- The Act provides for an excise tax equal to 2.3% of the sale price on the sale of any "taxable medical device" by the manufacturer, producer, or importer.

Annual Fee on Branded Prescription Drug Manufacturers

ENTITIES SUBJECT TO THE TAX

- Any manufacturer or importer with gross receipts from branded prescription drug sales engaged in the business of manufacturing or importing branded prescription drugs is a "covered entity" subject to the fee.
- Under the Act, the annual fee is allocated among covered entities based on market share — the covered entity's aggregate sales of branded prescription drugs during the preceding calendar year as a percentage of the aggregate branded prescription drug sales of all covered entities during that year.

AMOUNT OF THE FEE

- The amount of the fee imposed on the branded prescription pharmaceutical industry as a whole varies by year as follows:

Year	Amount (in Billions)
2011	$2.5B
2012	$2.8B
2013	$2.8B
2014	$3.0B
2015	$3.0B
2016	$3.0B
2017	$4.0B
2018	$4.1B
2019 and thereafter	$2.8B

BRANDED PRESCRIPTION DRUG SALES

- The Act defines "branded prescription drug sales" as the sales of branded prescription drugs to any specified government program or pursuant to coverage under any such program. The specified government programs are Medicare Parts B and D, Medicaid, and any program under which branded prescription drugs are procured by the Department of Veterans Affairs, the Department of Defense, or the TRICARE retail pharmacy program.
- Under the Act, a "branded prescription drug" is any prescription drug (subject to section 503(b) of the Federal Food, Drug and Cosmetic Act (FDCA)) marketed under a new drug application under section 505(b) of the FDCA or any biologic licensed under section 351(a) of the Public Health Service Act.
- As defined by the Act, "branded prescription drugs sales" exclude the sales of any drug or biologic for which an orphan drug tax credit was allowed for any taxable year under section 45C of the Internal Revenue Code (IRC). An orphan drug or biologic loses the exclusion once it is approved by the Food and Drug Administration for any indication other than an orphan indication for which a 45C credit was allowed.
- The percentage of branded prescription drug sales taken into account in determining any specific covered entity's fee under the Act varies as follows:

Covered Entity's Aggregate Annual Branded Prescription Drug Sales (Millions)	Percentage Taken Into Account
≤ $5M	0
> $5M and ≤ $125M	10
> $125M and ≤ $225M	40
> $225M and ≤ $400M	75
> $400M	100

TAX TREATMENT OF FEES

- The Act provides that fee payments will not be deductible for federal income tax purposes.

MECHANICS

- The Act provides that the Secretary of the Treasury (Treasury) will determine each covered entity's branded prescription drug sales on the basis of reports submitted by the Secretary of Health and Human Services, the Secretary of Veterans Affairs, and the Secretary of Defense, and will calculate the fee payable by each covered entity.
- The Act requires that each covered entity pay the fee by the annual payment date set by Treasury, but no later than September 30 of that year. The fee payments will be credited to the Medicare Part B trust fund.

Excise Tax on Medical Device Manufacturers, Producers, and Importers

TAXABLE MEDICAL DEVICES

- For the purposes of the medical device excise tax provision, a "taxable medical device" is any device — as defined in section 201(h) of the FDCA — intended for humans.
- There is an exemption for eyeglasses, contact lenses, hearing aids, and any other medical device determined by Treasury to be of a type which is generally purchased by the general public at retail for individual use.

AMOUNT OF THE TAX

- The Act provides for an excise tax equal to 2.3% of the sale price on the sale of any "taxable medical device" by the manufacturer, producer, or importer.

TAX TREATMENT

- The Act amends Chapter 32 of the IRC to establish the excise tax on medical device manufacturers, producers, and importers. The Act also amends sections 4221(a) and 6416(b)(2) of the IRC to provide that certain exemptions and certain special cases in which tax payments are considered overpayments, respectively, shall not apply in the case of the medical device excise tax.

Effective Dates

Provision	Date
Annual fee on branded prescription drug manufacturers	First fee payments will be due in 2011 and will be based on branded prescription drug sales in 2010
Medical device excise tax	Applies to sales after December 31, 2012

Outstanding Issues and Implementation Challenges

- Under the Act, the Centers for Medicare & Medicaid Services must establish a process for determining the units and allocated price for branded prescription drugs that are not separately payable or for which National Drug Codes are not reported.
- As the branded prescription pharmaceutical industry fee for each covered entity is determined based on market share, it is not clear what will happen if market share reports are later found to be inaccurate.

- It is unclear what, if any, types of devices beyond those explicitly mentioned in the statute, Treasury will determine to be "generally purchased by the general public at retail for individual use" and therefore exempt from the medical device tax; nor is it clear what criteria Treasury will use to make such determinations.
- An earlier version of the legislation specifically excluded devices classified in class I under FDCA section 513. This language is not included in the Act, and it is not clear whether Treasury will issue guidance to exclude such devices.

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There are many detailed changes in the Act. We would be pleased to discuss these changes and their potential impact on your industry, company, or customers.

If you have any questions concerning the material discussed in this client alert, please contact the attorneys listed below:

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