New Fee Assessed on Brand Pharmaceutical Manufacturers

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Section 9008 of the Patient Protection and Affordable Care Act (Pub. L. No. 111-148) imposes an annual fee on branded prescription pharmaceutical manufacturers and importers. This memorandum analyzes the structure and operation of the fee.[1]

The fee (treated as an excise tax for Internal Revenue Code purposes[2]) is payable at a date to be determined by the Secretary of the Health and Human Services (HHS) Department but no later than September 30 of years beginning after 2010 (i.e., the first payment of the fee will be due not later than September 30, 2011).[3] It is structured to raise a total of $2.5 billion in 2011, $2.8 billion in 2012 and 2013, $3 billion in 2014, 2015 and 2016, $4 billion in 2017, $4.1 billion in 2018, and $2.8 billion in both 2019 and years thereafter.[4] The fee is credited to the Supplementary Medical Insurance Trust Fund.

The aggregate fee is apportioned among the "covered entities" each year based on each entity's relative market share of "branded prescription drug sales" taken into account during the preceding calendar year. A "covered entity" is any manufacturer or importer with gross receipts attributable to branded prescription drug sales. Under the statute, the term "branded prescription drug sales" consists of two prongs. First, there must be a sale of branded prescription drugs (other than sales of orphan drugs). Branded prescription drugs are drugs for which an application for approval to the FDA was submitted under Section 505(b) of the Federal Food, Drug, and Cosmetic Act or Section 351(a) of the Public Health Service Act—this includes new drug applications and biological license applications.[5] Therefore, the sale or importation of generic drugs is not subject to the fee.

Second, the sale must be to a specified government program (or pursuant to coverage under such a program). Under the statute, the term "specified government programs" is defined as Medicare Parts B and D, Medicaid programs, Veterans Affairs programs, the Department of Defense programs or the TRICARE retail pharmacy program. Thus, a covered entity's sales in the private marketplace are not "branded prescription drug sales" and are excluded in determining the amount of the fee. The legislation requires the Secretary of HHS, the Secretary of Veterans Affairs and the Secretary of Defense each to report to the Secretary of the Treasury the total branded prescription drug sales for each covered entity with respect to each specified government program under its respective jurisdiction. The Treasury Department is required to publish necessary guidance but in general is tasked with calculating each covered entity's fee each year based on these reports as well as on information otherwise available. The statute does not contain any reporting requirement on manufacturers.

The information in these reports varies depending upon which federal program is filing the report. With respect to Medicare Part D, the Secretary will obtain information from Part D and Medicare Advantage plans. These plans would be required to report to the Secretary of HHS the per-unit ingredient cost of each branded prescription drug, less any rebate, discount, or other price concession provided by the payer of the fee. This per-unit cost would then be multiplied by the number of units of the branded prescription drug paid for by Part D.

With respect to Medicare Part B, the Secretary of HHS will obtain information based upon the separately-payable drug's reported per-unit average sales price (ASP) (or, in the case of a drug without a reported ASP, the Part B payment rate for the drug). This per-unit price would then be multiplied by the number of units paid for under Part B.

Regarding sales pursuant to coverage under the Medicaid program, HHS will obtain information based upon the per-unit ingredient cost of each branded prescription drug paid to pharmacies by State Medicaid plans minus the rebate paid by the manufacturer to the State (including supplemental rebates). This per-unit amount would then be multiplied by the number of units paid for by Medicaid.

The Department of Veterans Affairs would report the total amount of branded drugs procured by it. With respect to the Department of Defense, the Secretary would report the total amount paid for branded prescription drugs procured by the Department and the per-unit ingredient cost (less rebates) paid to TRICARE pharmacies, multiplied by the number of units paid.

A graduated structure determines the proportion of a covered entity's drug sales taken into account in determining the fee. Zero percent of an entity's sales up to $5 million for the preceding calendar year are included; 10 percent of sales over $5 million and up to $125 million; 40 percent of sales over $125 million and up to $225 million; 75 percent of sales over $225 million and up to $400 million; and 100 percent of a sales over $400 million.

The table that follows illustrates the graduated structure of the fee for a covered entity, "Q Pharmaceuticals," with $1 billion in total branded prescription branded drug sales in 2010 (under specified programs):

Statutory Scale: Total Branded Prescription Drug Sales	**Applicable Sales**	**Percentage of Sales Taken into Account**	**Covered Entity's Sales Taken into Account**
Up to $5m	$5m	0%	$0
More than $5m up to $125 m	$120m	10%	$12m

More than $125m up to $225m	$100m	40%	$40m
More than $225m up to $400m	$175m	75%	$131m
More than $400m	$600m	100%	$600m
Total Sales Taken into Account			**$783m**

To calculate a covered entity's share of the statutorily determined aggregate fee, the Treasury would multiply the fee by the ratio of the covered entity's total sales taken into account to the aggregate of all covered entities branded drug sales taken into account.

$$\text{Determined Fee} \times \frac{\text{Q Pharmaceuticals Sales Taken into Account}}{\text{Aggregate Industry Sales Taken into Account}}$$

Under the above scenario, where Q Pharmaceuticals total sales taken into account is $783 million in 2010, and where the aggregate sales taken into account for all covered entities is $10 billion, Q Pharmaceuticals fee would be:

$$\$2.5 \text{ billion} \times \frac{\$783 \text{ million}}{\$10 \text{ billion}} = \$195.75 \text{ million}$$

The statute also specifies that the fee is not deductible for federal income tax purposes. Like other areas of the income tax law, all entities within the same consolidated group of corporations are treated as a single covered entity for purposes of liability for the tax. Finally, if all covered entities are jointly and severally liable for the annual fee.

[1]This memorandum is written under the assumption that the reconciliation legislation (H.R. 4872, Health Care and Education Affordability Reconciliation Act) that passed the House of Representatives on March 21, 2010, will also be enacted into law. The reconciliation language, released on March 18, 2010, was itself revised by the Manager's Amendment accompanying the rule for consideration of the reconciliation legislation. This memorandum reflects the reconciliation legislation as passed

by the House – i.e., after adoption of the Manager's amendment. Where relevant, it will indicate differences between the enacted Public Law and the reconciliation legislation as passed by the House.

[2]The statute makes clear that the fee is not deductible, however. For purposes of procedure and administration under subtitle F of the Internal Revenue Code, any fee assessed under this provision is treated as an excise tax with respect to which only civil actions for refund under subtitle F apply. The Secretary of the Treasury also may re-adjust a covered entity's' fee for any calendar year for which the statute of limitations remains open.

[3]Under the enacted Public Law, the tax is first payable no later than September 30, 2010.

[4]As originally passed by the Senate, the tax was to raise $2.3 billion per year.

[5]H.R. 3590 also creates a pathway under PHSA 351(k) for follow-on biologic or biosimilar products. These products, even if deems interchangeable with the reference product, would not be subject to the fee.