

PUBLICATION

Spotlight on Health Care Reform: New Tax on Pharmaceutical Manufacturers and Importers

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Under the recently enacted health care reform legislation, manufacturers and importers of "branded prescription drugs" will be assessed an annual fee by the U.S. Department of the Treasury. This fee will be characterized as an excise tax on gross receipts. The Patient Protection and Affordable Care Act of 2010 (PPACA), as amended by the Health Care and Education Reconciliation Act of 2010 (Reconciliation Act) (collectively, the "Health Care Reform Law"), contains a convoluted array of provisions implementing this new excise tax. Below is an overview of the main provisions.

Background

Under the Health Care Reform law, pharmaceutical manufacturers and importers will be assessed an annual fee on gross receipts from sales of "branded prescription drugs". The fee will apply to sales in calendar year 2011 and thereafter, with payments first due no later than September 30, 2012. "Branded prescription drugs" are defined as: (1) prescription drugs approved under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA); and (2) any biological product for which a license was submitted under section 351(a) of the Public Health Service Act. A "prescription drug" means any drug subject to Section 503(b) of the FFDCA. As a result, generic drug sales are excluded. In addition, "orphan" drug or biological product sales are excluded if they qualify for the § 45C tax credit under the Internal Revenue Code (IRC).

The annual fee will be treated as an excise tax and will not be deductible for purposes of determining federal taxable income.

The Internal Revenue Service is directed to publish guidance necessary to carry out the purposes of the new annual excise tax.

Calculation of the Excise Tax

The excise tax will not be self-reported or based on gross receipts from branded prescription drug sales reported to Treasury by the manufacturer or importer. Rather, the fee will be determined by Treasury from reports it receives from the federal government programs that purchase or provide coverage for branded prescription drugs (Medicare/Medicaid, Veterans Administration, and Department of Defense), as well as "any other source of information available to the Secretary of the Treasury." These programs will submit yearly reports to Treasury of the total branded prescription drug sales (or units of drugs dispensed and the corresponding payment amount) for each "covered entity." (As addressed below, the definition of a "covered entity" includes certain affiliated companies, and it is unclear how these programs will have sufficient information on corporate structure to know the scope of the "covered entity".)

The calculation of the annual excise tax is a complicated market share determination, and since it is done by Treasury based on reports from other government programs and sources of information, it lacks transparency for the taxpayer. Verification, at least under this reporting structure, will be problematic. From the Medicare/Medicaid, VA, and DOD reports, the Secretary of the Treasury will determine the annual fee using a three-step process, as follows:

Step 1: Treasury will first determine a covered entity's "sales taken into account." Under PPACA, Section 9008(b)(2), "sales taken into account" are based on a percentage of a covered entity's branded drug sales, as follows:

Covered entity with \$5 million of such sales or less:	0%
Covered entity with more than \$5 million, but not more than \$125 million:	10%
Covered entity with more than \$125 million, but not more than \$225 million:	40%
Covered entity with more than \$225 million, but not more than \$400 million:	75%
Covered entity with more than \$400 million:	100%

For example, if a covered entity has \$250 million of branded prescription drug sales during the 2011 calendar year, its branded prescription drug "sales taken into account" are \$168,750,000 or 75 percent of \$250 million.

Step 2: Treasury will then determine a covered entity's "fee ratio," which is (a) the covered entity's branded prescription drug sales taken into account under Step 1 to (b) the industry's aggregate branded prescription drug sales.

For example, using the Step 1 example, the covered entity's branded prescription drug sales taken into account are \$168,750,000; if the industry's aggregate branded prescription drug sales are \$25 billion, the covered entity's fee ratio is \$168,750,000 / \$25 billion or 0.00675.

Step 3: The covered entity's ratio is applied to the "applicable amount," which is an amount that increases annually, as follows:

2011	\$2.5 billion
2012	\$2.8 billion
2013	\$2.8 billion
2014	\$3 billion
2015	\$3 billion
2016	\$3 billion
2017	\$4 billion
2018	\$4.1 billion
2019 and thereafter	\$2.8 billion

Using the above examples, our covered entity's annual excise tax for 2011 (payable no later than September 30, 2012) would equal 0.00675 of \$2,500,000,000 or \$16,875,000. Note: assuming for sake of illustration that

the example's "sales taken into account," aggregate branded prescription drug sales, and "fee ratio" do not change, the covered entity's excise tax will increase in future years simply because the "applicable amount" increases, until 2019 and thereafter.

Covered Entity

A "covered entity" is "any manufacturer or importer with gross receipts from branded prescription drug sales."

However, a pharmaceutical manufacturer or importer could see its covered entity status significantly expanded. A "controlled group" is treated as a single covered entity. The term "controlled group" is defined to mean a "single employer" as defined under IRC § 52, or an "affiliated service group" as defined under IRC § 414(m). The "single employer" definition of IRC § 52 references the definition of a "controlled group of corporations" under IRC § 1563. The Health Care Reform law expands the "controlled group of corporations" definition for purposes of defining a "covered entity" subject to the annual excise tax in two significant respects. First, the 80 percent of vote or value stock ownership test of § 1563(a) is changed to 50 percent. Second, foreign corporations that have U.S. source income that is not connected with a U.S. trade or business conducted by it is included in the covered entity controlled group. Further, the Health Care Reform law provides that each group member is jointly and severally liable for the group's excise tax.

One result of these definitional changes is that a foreign corporation that is a member of a controlled group and that imports branded prescription drugs into the U.S. also will have its gross receipts included in the measure of excise tax. Because the percentage of branded drug sales taken into account for determining the excise tax increases as branded drug sales increase, the aggregate excise tax imposed on two affiliated covered entities may be more than would apply if the excise tax were calculated separately for each of them. For example, if "FS", a foreign subsidiary of a U.S. parent corporation, "P", has gross receipts from sales of \$150 million of branded prescription drugs that are covered by Medicare in a calendar year and P has \$300 million of gross receipts from sales of branded prescription drugs to the Veterans Administration in a calendar year, P and FS are treated as a single covered entity and have \$450 million of branded prescription drug sales subject to the annual excise tax determination. The P and FS covered entity controlled group would have 100% of their branded prescription drug sales taken into account. If only P was treated as a covered entity, it would have 75% of its branded prescription drug sales taken into account.

Summary

The new annual excise tax on pharmaceutical manufacturers and importers will likely have a range of consequences. From problems of verification of the amount of the tax to addressing joint and several liability for controlled group members, to effects on distribution and tax-sharing agreements, transfer pricing, and even state income tax reporting, the excise tax raises a number of questions.

If you would like to discuss the any of matters addressed in this Alert, please contact one of the members of our Tax or Health Departments.