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E-ALERT | Health Care

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IRS ISSUES GUIDANCE ON CALCULATION OF BRANDED PRESCRIPTION DRUG FEE

On November 30, 2010, the IRS issued Notice 2010-71, which outlines the proposed method for calculating the annual fee imposed on manufacturers and importers of branded prescription drugs ("covered entities") under the Patient Protection and Affordable Care Act (the "Affordable Care Act"). For additional background on the fee, please see our previous client alert, available here.

Executive Summary

- The IRS proposes to use sales numbers from the second sales year preceding the fee year to calculate the fee and will adjust subsequent fees according to the sales numbers for the preceding sales year.
- Only sales of orphan drugs for which a 45C credit is claimed would be excluded from total sales.
- Covered entities should submit their first Form 8947 by **January 20, 2011**.

Proposed Fee Calculation Methodology

All covered entities with aggregate branded prescription drug sales of over $5 million to specified government programs — Medicare Part D and Part B, Medicaid, the Department of Veterans Affairs (VA), the Department of Defense (DOD), and the TRICARE retail pharmacy program — must pay the fee. A covered entity's fee amount in a "fee year" is calculated based on its share of the total sales of branded prescription drugs by all covered entities during the "sales year."

The IRS proposes to use the second year preceding the fee year as the sales year for purposes of calculating the fee (e.g., 2009 will be the sales year for the 2011 fee year) because the Centers for Medicare & Medicaid Services ("CMS"), which provide data on Medicare Part D and Part B sales, are not expected to have data for the year immediately preceding the fee year in time for the fee calculation. The fee due in every year after 2011 will include an adjustment to the previous year's fee to reflect the sales figures for the year immediately preceding the fee year.

The IRS will calculate each covered entity's branded prescription drug sales ("Entity's Government Sales") for the purposes of the fee calculation as follows: (1) the sum of all the covered entity's branded prescription drug sales to the specified government programs, less (2) the sum of all branded prescription drug sales to the specified government programs for which the covered entity has appropriately claimed the orphan drug tax credit (see below), less (3) the sum of rebates reported by the covered entity on Form 8947. The Entity's Government Sales will be divided by the total of the similarly calculated government sales for all covered entities and then multiplied by the applicable total fee for that year as set forth in the statute to arrive at the fee for the covered entity. For 2011, the total fee to be paid by all covered entities combined is $2.5 billion.

For purposes of the fee, the IRS will treat as a single covered entity all entities that are treated as a single employer for other tax purposes. Each entity that is part of the covered entity will be jointly and severally liable for the fee.

Information Collected by IRS for Fee Calculation

Each covered entity must submit an IRS Form 8947, on which it will provide information on: all of the NDCs for branded prescription drugs under its labeler code(s), the brand name and NDC for each orphan drug for which the covered entity was allowed a section 45C credit (see below), and (for each NDC) the rebates paid to Medicare Part D plans and to the states under the Medicaid program.

For each fee year, the specified government programs will provide data to the IRS on the branded prescription drug purchases during the sales year by NDC. For the *Medicare Part D Program*, CMS will report the product of the per-unit ingredient cost reported by Part D sponsors and the number of units for each branded prescription drug, based on Prescription Drug Event reports. For the *Medicare Part B Program*, CMS will use HCPCS codes to estimate Program spending on prescription drugs attributable to each manufacturer as follows:

- For HCPCS codes that consist solely and exclusively of branded drugs manufactured by a single entity, CMS will provide the total Medicare charges for that code.
- For HCPCS codes consisting of a mixture of branded and generic drugs, or branded drugs from different manufacturers, CMS will determine: (1) the total Medicare charges for that code, (2) the entities manufacturing each NDC assigned to that code, and (3) those entities that are manufacturing branded drugs. CMS will then apportion the total Medicare charges for that HCPCS code among the manufacturers based on their utilization percentage.
- For HCPCS consisting of multiple branded prescription drugs for which neither of those methods is sufficient, CMS will determine which entities manufacture each NDC under that HCPCS code and which entities manufacture branded prescription drugs. It will then multiply the utilization percentage attributed to each branded prescription drug manufacturer under the Medicare Part D program by the total charges for that HCPCS code to arrive at the charges attributed to those manufacturers under Medicare Part B.

The sum of charges calculated using each methodology will be attributed to each covered entity. The *Medicaid program* will determine the price for branded prescription drugs as the per-unit Average Manufacturer Price less the Unit Rebate Amount for each NDC. The VA, DOD, and TRICARE will provide the total amount paid for each branded prescription drug.

Schedule for 2011 Fee Calculation

The IRS will provide each covered entity with a preliminary 2011 fee calculation which will be calculated as described above and include: (1) the covered entity's fee, (2) the covered entity's branded prescription drug sales by NDC for each government agency, (3) the covered entity's branded prescription drug sales after rebates are accounted for, and (4) the total branded prescription drug sales for all covered entities.

Covered entities should submit Form 8947 by **January 20, 2011**. (In subsequent years, covered entities must file their Form 8947 by December 15 of the preceding year.) Data submitted will be used to compile a list of NDCs that will be submitted to the relevant government agencies by March 1, 2011. The agencies will provide data that the IRS will then use to notify covered entities of their preliminary fee calculation by May 2, 2011. The Notice provides no information on how to challenge or dispute the preliminary or final fee calculation. The final fee calculation will be sent to each

covered entity on August 15, 2011. According to § 9008(a)(2) of the Affordable Care Act, the fee will be due on the date set by the IRS, but no later than September 30 of the fee year.

Orphan Drugs

The Affordable Care Act provides that all sales of orphan drugs, which are drugs developed to treat rare conditions and serve small patient populations, will be excluded from the calculation of branded prescription drug sales. However, the proposed IRS guidelines provide only for the exclusion of orphan drugs for which a covered entity was "allowed a section 45C credit," defined as a claimed credit that has not been disallowed. The 45C credit is a tax credit for research conducted in the clinical testing of orphan drugs. Thus, manufacturers who did not claim a 45C credit for an orphan drug will not get the benefit of excluding it from their total drug sales for purposes of the Affordable Care Act fee. In addition, the orphan drug will not be excluded from an Entity's Government Sales if the FDA has approved the drug for any indication other than an orphan indication. Manufacturers whose products include orphan drugs should carefully examine how those products will affect their liability for the prescription drug fee.

Public Comments

The IRS is accepting public comments on the Notice until **June 2, 2011**. The IRS will take the comments into consideration when promulgating regulations.

Steps Manufacturers Can Take Now

- Become familiar with Form 8947, available on the IRS website at http://www.irs.gov/pub/irs-pdf/f8947.pdf, and begin filling it out with what information is currently available.
- Assemble and review information already available (e.g., TRICARE utilization and government direct sale and chargeback information), and begin estimating information that is not yet available.
- Use the proposed calculation guidelines and available information to estimate sales numbers and the associated fee, to compare to the information and preliminary fee to be supplied by the IRS on May 2.
- Submit comments to the IRS regarding aspects of the process that are open or ambiguous (e.g., how to challenge or dispute a preliminary fee calculation) or that may be unduly burdensome.

We would be pleased to discuss this notice and these procedures 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 following members of our firm:

Anna Kraus	202.662.5320	akraus@cov.com
Demetrios Kouzoukas	202.662.5057	dkouzoukas@cov.com
Jennifer Plitsch	202.662.5611	jplitsch@cov.com
Marie Boyd	202.662.5781	mboyd@cov.com