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IRS Issues Guidance on the Dispute Resolution Process for the Preliminary Fee Calculation of the 2011 Fee Imposed on Manufacturers and Importers of Branded Prescription Drugs

Publication Date: May 03, 2011

On May 2, 2011, the Internal Revenue Service (the "IRS") issued Revenue Procedure 2011-24 (the "Revenue Procedure"), which establishes a dispute resolution process for the preliminary fee calculation for the 2011 fee imposed on certain manufacturers and importers of branded prescription drugs pursuant to the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"). As further explained below, in order to participate in the dispute resolution process, a "covered entity" must submit a written error report to the IRS that is postmarked no later than June 1, 2011. This *Tax Alert* provides background on the annual fee and a summary of the dispute resolution process established by the Revenue Procedure.

Background

Section 9008 of the ACA imposes an annual fee (the "Fee") on each "covered entity" (*i.e.*, any manufacturer or importer with gross receipts from sales of branded prescription drugs) with gross receipts of more than $5 million from certain sales of branded prescription drugs. In Notice 2010-71 (the "Initial Notice"), the IRS provided guidance on the calculation of the Fee. For 2011, the aggregate Fee to be paid by all covered entities is $2.5 billion. The IRS will apportion this Fee among the covered entities based on each covered entity's proportionate share of branded prescription drug sales that are taken into account during the applicable Sales Year. For a detailed description of the Initial Notice, including definitions of these terms and the methodology for calculating the Fee, see Reed Smith's *Tax Alert* 10-278.

In Notice 2011-9 (the "Second Notice"), the IRS described the approach that the IRS will use to perform a preliminary 2011 Fee calculation for each covered entity. The Second Notice provided that the IRS will mail each covered entity notification of its preliminary Fee calculation for 2011 by May 16, 2011.[1] For a detailed description of the Second Notice, see Reed Smith's *Tax Alert* 11-014. Each covered entity was required to file Form 8947, Report of Branded Prescription

Drug Information, with the IRS by February 11, 2011, to provide data on branded prescription drugs, orphan drugs and rebates. From the data on the Forms 8947, the IRS compiled a list of National Drug Codes ("NDCs") for branded prescription drugs sold to the Medicare Part D program, the Medicare Part B program, the Medicaid program, and any program under which branded prescription drugs are procured by the Department of Veterans Affairs, Department of Defense ("DOD") and the DOD's TRICARE retail pharmacy program (collectively, the "Programs"). After appropriate due diligence, the IRS provided that list to the Centers for Medicare & Medicaid Services of the Department of Health & Human Services ("CMS"), the Department of Veterans Affairs and the DOD (collectively, the "Agencies"). The Agencies provided sales data to the IRS on the branded prescription drug sales for the 2009 Sales Year by Program and NDC.

The Revenue Procedure

The Revenue Procedure states that the notification of the preliminary Fee calculation for 2011, which the IRS will mail to each covered entity by May 16, 2011, will include: (1) the covered entity's preliminary Fee calculation; (2) the covered entity's branded prescription drug sales for 2009, by NDC, for each Program; (3) the covered entity's branded prescription drug sales for 2009 taken into account after applying the specified percentage;[2] and (4) the aggregate branded prescription drug sales for 2009 taken into account for all covered entities.

The Revenue Procedure provides the exclusive process available to covered entities to dispute a preliminary Fee calculation and obtain any change to data that would be reflected in the final Fee calculation, which will be mailed by the IRS to each covered entity by August 15, 2011.

If, after reviewing the data contained in the notification, a covered entity believes that there are one or more errors in the mathematical calculation of the Fee, the orphan drug or rebate data, the Program drug sales data, or any other error, the covered entity must provide one or more written error reports to the IRS that are postmarked by June 1, 2011. Otherwise, the IRS will not consider a request for correction of the claimed error. The Revenue Procedure sets forth a list of the information that must be included in a written error report if the errors are in the mathematical calculation of the Fee, the rebate data, the listing of an NDC for an orphan drug, or

any other error other than Program drug sales data errors. If a covered entity asserts that there have been one or more errors in Program drug sales data, the entity must submit a separate error report for each Program. There is a separate list of the information that must be included in each written error report if the covered entity is asserting errors in drug sales data. The Revenue Procedure also sets forth the form and manner for submitting the error reports.

If a claimed error involves a mathematical calculation or a correction to orphan drug or rebate data, the IRS will review the information and determine whether to make a correction. If a claimed error involves drug sales data provided by a Program, the IRS will forward the error report to the Agency with jurisdiction over the appropriate Program to determine whether to make a correction. The IRS will rely exclusively on the Agencies to make determinations with respect to any proposed corrections to the Program drug sales data. For any other claimed error, the IRS will review the information and determine whether the IRS or an Agency should determine whether to make a correction.

The IRS will notify the covered entity in writing of the final determination with respect to error reports when it sends the covered entity the final Fee calculation no later than August 15, 2011. The IRS will base a covered entity's final Fee determination solely on the data used for the preliminary Fee calculation together with any adjustments to such data made as a result of the dispute resolution process.

It should be noted that, even if a covered entity does not submit an error report, its preliminary Fee calculation may be changed as a result of the dispute resolution process utilized by other covered entities. This is because the Fee calculation for each covered entity consists of an allocation of the $2.5 billion aggregate Fee for 2011. If a change is made to the total amount of all branded prescription drug sales that are taken into account during the applicable Sales Year, then the fraction applied to determine each covered entity's allocable share of the Fee will change.

Reed Smith's tax and government pricing lawyers are ready to assist clients who wish to submit error reports with respect to their preliminary Fee calculations.

This *Tax Alert* is intended only to offer a general summary of the information contained in the Revenue Procedure. We will provide updates as appropriate upon the issuance of any future guidance with respect to the Fee. If you have questions, would like additional information about the Revenue Procedure, or want to submit one or more error reports regarding your company's preliminary Fee calculation, please contact one of the authors or the Reed Smith attorney with whom you regularly work.

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1. In the Second Notice, the IRS also requested that comments on the methodology set forth in the Second Notice be submitted by June 15, 2011.

2. In general, the greater the covered entity's aggregate branded prescription drugs sales for the applicable Sales Year, the greater the percentage (and such percentage equals 100 percent for covered entities with aggregate branded prescription drug sales in excess of $400 million).