

## IRS Extends to June 10 the Deadline for Submitting Error Reports on Branded Prescription Drug Sales

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On Friday, May 27, 2011, the Internal Revenue Service ("IRS") issued Notice 2011-46 (the "New Notice"), which extended to **June 10, 2011** the deadline to submit error reports in accordance with the dispute resolution process established with respect to the preliminary fee calculation of the 2011 fee imposed on certain manufacturers and importers of branded prescription drugs.

### Background

Section 9008 of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, 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 it would use to perform a preliminary 2011 Fee calculation for each covered entity. It provided that the IRS would mail each covered entity notification of its preliminary Fee calculation for 2011 by May 16, 2011 which would be based on sales data received from Centers for Medicare & Medicaid Services of the Department of Health & Human Services ("CMS"), the Department of Veterans Affairs ("VA") and the Department of Defense ("DOD") with respect to each covered entity's

branded prescription drug sales 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 VA, DOD and DOD's TRICARE retail pharmacy program. 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. For a detailed description of the Second Notice, see [Reed Smith's Tax Alert 11-014](#).

In Revenue Procedure 2011-24 (the "Procedure"), the IRS established a dispute resolution process with respect to the preliminary 2011 Fee calculation. The Procedure provides the exclusive process available to covered entities to dispute a preliminary Fee calculation and obtain any change to the data that will be reflected in the final Fee calculation. Under the Procedure, the covered entity must provide one or more written error reports to the IRS that are postmarked by June 1, 2011, and the IRS will notify the covered entity in writing of the final determination when it sends the covered entity's final Fee calculation no later than August 15, 2011. Under section 9008 of the ACA, a covered entity must pay the final Fee amount by September 30, 2011. For a detailed description of the Procedure, see [Reed Smith's Tax Alert 11-111](#).

## **The New Notice**

The New Notice states that the IRS has been told that certain covered entities may have difficulty meeting the June 1 deadline for submitting error reports because of the volume of data they need to review. Therefore, the New Notice "defers" the deadlines as follows:

- The date by which error reports under the Procedure must be postmarked in order to receive IRS consideration is extended from June 1, 2011 to June 10, 2011; and
- The date by which the IRS will send covered entities their 2011 final Fee calculation and, if applicable, notification of the final determination with respect to error reports, is extended from August 15, 2011 to August 24, 2011.

While many prescription drug manufacturers will be focused for the next two weeks on preparing their error reports for submission to the IRS, they should not forget that June 15th is the deadline for submitting their comments to the IRS on the methodology for calculating the Fee set forth in the Second Notice.



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 provide a general summary of the information contained in the New Notice. 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 New Notice, or want to submit an error report with respect to 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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