

IRS Extends Filing Date for Reporting 2009 Sales of Branded Prescription Drugs Under the Affordable Care Act, Clarifies Information Requested From Covered Entities

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On January 14, 2011, the Internal Revenue Service ("IRS") issued Notice 2011-9 (the "Notice"), which extended the filing date for reporting on Form 8947 a covered entity's 2009 sales of branded prescription drugs under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "Affordable Care Act" or the "ACA"). The filing date for Form 8947 with respect to 2009 sales of branded prescription drugs was extended from January 20, 2011 to February 11, 2011. In addition, in response to numerous comments received by the IRS, the Notice made certain changes to Notice 2010-71, 2010-50 IRB (the "Initial Notice"), primarily with respect to the information requested from covered entities.

Background

On November 29, 2010, the IRS issued the Initial Notice, which provided guidance on the calculation of the annual fee imposed on certain manufacturers and importers of branded prescription drugs for calendar years beginning after December 31, 2010. For a detailed description of the Initial Notice, including the definitions of "branded prescription drugs," "covered entity," "Sales Year" and "Fee Year," see Reed Smith's Tax Alert [2010-278](#).

The Initial Notice provided that all covered entities are required to file IRS Form 8947, Report of Branded Prescription Drug Information, with the IRS by December 15 of each year, setting forth data with respect to the immediately preceding Sales Year, unless an alternative date is prescribed in the form or instructions. The Initial Notice stated that, for the 2011 Fee Year, (i) the Form 8947 (which will provide data for the 2009 Sales Year) must be submitted to the IRS by

January 20, 2011; (ii) the IRS will calculate the preliminary fee and will send to each covered entity notification of its preliminary fee calculation by May 2, 2011; and (iii) the final fee calculation will be sent to each covered entity by August 15, 2011, with payment due no later than September 30, 2011.

Modifications Made to the Initial Notice

The Notice modifies, restates and supersedes the Initial Notice. Substantively, the Notice makes the following changes to the section of the Initial Notice entitled "Information Requested from Covered Entities":

- Clarifies that the information requested on Form 8947 is only for those members of a controlled group that are manufacturers and importers with gross receipts from the sale of branded prescription drugs to specified government programs (or sales due to coverage under the programs).
- Modifies which orphan drugs may be reported on Form 8947. These orphan drugs are excluded from branded prescription drug sales under section 9008(e)(3) of the ACA. The Notice states that, for purposes of section 9008(e)(3) of the ACA, the credit is considered "allowed" for a drug if any person claimed the orphan drug credit under section 45C of the Internal Revenue Code. Thus, the section 45C credit is considered allowed if any entity claimed the credit, even if that entity was not the covered entity (or a member of the covered entity's controlled group) at the time the credit was claimed. The IRS had received numerous comments that the restrictive interpretation of the section 9008(e)(3) exclusion for orphan drugs set forth in the Initial Notice (i.e., that a covered entity was only entitled to the exclusion if it had taken the section 45C credit) was contrary to the statute.
- Modifies which Medicare Part D rebates are to be reported. The Initial Notice provided for reporting of rebates for drug sales as taken into account on a covered entity's tax return. Commentators indicated that pharmaceutical manufacturers generally compile rebate information at an aggregate entity level for tax purposes, rather than at the drug product level. The Notice provides that rebates should be reported for drugs dispensed in the 2009 Sales Year if the rebates are paid before Form 8947 is filed.

- Modifies which Medicaid rebates are to be reported. The Notice requires reporting of rebates invoiced by states for drugs reimbursed by states in the 2009 Sales Year and paid by the covered entity before Form 8947 is filed.
- Clarifies that rebate information will be taken into account in calculating a covered entity's annual fee for 2011 only if it is reported on a timely filed Form 8947.

In addition, the Notice revises the time schedule set forth in the Initial Notice. The revised time schedule is as follows:

- The due date for filing Form 8947 for reporting sales of branded prescription drugs during the 2009 Sales Year is extended to February 11, 2011.
- The date the IRS will send to each covered entity notification of its preliminary fee calculation is extended to May 16, 2011.
- The deadline for submission of comments on the calculation procedures described in the Notice is extended to June 15, 2011. This date will give covered entities the opportunity to consider the information received in their preliminary fee calculation when providing comments.
- The date the IRS will send the final fee calculation to each covered entity remains August 15, 2011. The due date for payment of the fee remains September 30, 2011, as set forth in the statute.

Reed Smith's tax and government pricing lawyers are available to answer any questions clients may have with respect to their completion of Form 8947, and to assist clients who are interested in submitting written comments to the IRS on the calculation procedures set forth in the Notice.

This *Tax Alert* is intended only to provide a general summary of the Notice. We will continue to provide updates as appropriate upon the issuance of any future guidance (including regulations) with respect to the reporting requirements and the calculation of the fee under section 9008 of the ACA. If you have questions, would like additional information about any of the information discussed in this *Tax Alert*, or want to submit comments to the IRS with respect to the calculation procedures, please contact one of the authors or the Reed Smith attorney with whom you regularly work.

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