

IRS Hot Topics

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*IRS issues Notice 2011-92
providing guidance on branded
prescription drug fee for 2012
fee year - Form 8947 due
December 15, 2011*

The Internal Revenue Service (IRS) recently issued Notice 2011-92, which provides guidance on the branded prescription drug fee for the 2012 fee year relating to (1) the submission of Form 8947, "Report of Branded Prescription Drug Information," (2) the time and manner for notifying covered entities of their preliminary fee calculation, (3) the time and manner for submitting error reports for the dispute resolution process, and (4) the time for notifying covered entities of their final fee calculation.

As background, section 9008 of the Patient Protection and Affordable Care Act, Public Law 111-148 (124 Stat.

119 (2010)), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010, Public Law 111-152 (124 Stat. 1029 (2010)), imposed an annual fee on covered entities engaged in the business of manufacturing or importing branded prescription drugs. Published on August 18, 2011 (76 FR 51245), the temporary regulations provide the method for calculating each covered entity's annual fee and also define certain terms. The regulations define "fee year" to be the calendar year in which the fee for a particular sales year must be paid and "sales year" as the second calendar



year preceding the fee year. Treas. Reg. §§ 51.2T(g), (m).

Submitting Form 8947, Report of Branded Prescription Drug Information

The regulations provide the opportunity to each covered entity to submit a completed Form 8947, "Report of Branded Prescription Drug Information." If a covered entity chooses to complete and file the Form, the Notice indicates that such form must be submitted by December 15, 2011, for the 2012 fee year. Form 8947 requests certain information from the covered entity regarding National Drug Codes, orphan drugs, designated entities, rebates, and other information specified by the form or its instructions.

Notice of preliminary fee calculation

After computation of a preliminary fee based upon data received from the specified government programs and from covered entities on Forms 8947, the IRS will mail to each covered entity a paper notice of its preliminary fee calculation by April 2, 2012. The preliminary fee calculation will include a National Drug Code (NDC) attachment (NDC attachment) that lists the covered entity's NDCs and the sales data reported to the IRS by each specified government program pursuant to Treas. Reg. § 51.4T. If a covered entity would prefer to receive this information in the form of a CD-ROM, it must make this request no later than March 1, 2012 by the means detailed in the Notice.

Submitting an error report

If a covered entity disputes the preliminary fee calculation, it must submit an error report by May 16, 2012 on the template provided by the IRS when the covered entity received the preliminary fee calculation, to the address indicated in the Notice.

The IRS will notify each covered entity of its final fee calculation for 2012 by August 31, 2012 and each covered entity must pay this fee by September 30, 2012.

This notice makes obsolete Rev. Proc 2011-24. That revenue procedure had instituted a dispute resolution process for the 2011 fee year preliminary fee calculation.

Observations

Publication of Notice 2011-92 fulfills pledges made by the IRS and Treasury in the temporary regulations to provide further guidance for each fee year.

Most important, clients should note that the Form 8947 for the 2012 fee year is due on December 15, 2011. Although filing of the Form is not mandatory, it is often in the best interests of a covered entity to provide the requested information to ensure that the IRS receives all of the information it needs to exclude from a covered entity's computation of branded prescription drug sales, those sales covered by the orphan drug exclusion, and rebates made to the Medicaid and Medicare programs. In accordance with the temporary regulations, sales data for the 2010 year should be taken into account for the 2012 fee year.

With respect to the notification of the preliminary fee calculation, the IRS has decided to accelerate the date of mailing. The 2011 fee year preliminary fee calculation was sent on May 16, 2011. The preliminary fee calculation for the 2012 fee year is expected to be sent on April 2, 2012. Care should be taken in filing error reports for, short of filing a refund claim, there will be no opportunity to

dispute the final fee calculation prior to payment.

As with the 2011 final fee, and all subsequent years, payment will be required by September 30 of the fee year.

It is expected that IRS and Treasury will continue to issue guidance on a fee year by fee year basis.

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