# A Washington National Tax Services (WNTS) Publication



# **IRS Hot Topics**

IRS and Treasury issue interim guidance on the annual fee imposed on branded prescription pharmaceutical manufacturers and importers

The health care acts passed in 2010 impose an annual fee on any "covered entity" engaged in the business of manufacturing or importing branded prescription drugs beginning in calendar year 2011. On November 29, 2010, the IRS and Treasury issued Notice 2010-71 to provide guidance and to explain the background and purpose of new Form 8947 Report of Covered Pharmaceutical Manufacturers and Importers which was released by the IRS on November 24, 2010.

Form 8947 must be filed by January 20, 2011, with respect to the annual fee imposed for calendar year 2011.

## **Background**

The new annual fee is imposed by section 9008 of the Patient Protection and Affordable Care Act (P.L. 111-148) as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152) (the "Act") and is effective for calendar years beginning after December 31, 2010. The law requires that the IRS make notice and demand for payment of the fee no later than September 30 of each calendar year.

The annual fee is imposed on "covered entities" which are defined as entities engaged in the business of manufacturing or importing branded prescription drugs and that have gross receipts from branded prescription drug sales exceeding \$5 million. The terms "prescription drugs" and "branded prescription drugs" rely on the definitions provided in section 505(b) of the Federal Food,

Drug and Cosmetic Act and section 351(a) of the Public Health Service Act. Branded prescription drug sales are sales to specified government programs which include Medicare Part B and D Programs, the Medicaid Program, programs under which branded prescription drugs are procured by the Department of Veterans Affairs, and the TRICARE retail pharmacy program.

Each covered entity's annual fee will be determined by the IRS based upon the covered entity's market share for each calendar year. A covered entity's market share for a calendar year is equal to the covered entity's branded prescription drug sales "taken into account" during the preceding calendar year as a percentage of the aggregate branded prescription drug sales of all covered entities during the preceding calendar year. The resulting percentage is multiplied by the "applicable amount," \$2.5 billion for calendar year 2011, to determine the annual fee. In calculating the fee, the law requires the IRS to determine the covered entity's branded prescription drug sales (i) on the basis of reports submitted by the Secretaries of Health and Human Services, Veterans Affairs and Defense; and (ii) through the use of any other source of available information.

## The guidance

Notice 2010-71 addresses three significant points:

1. The Notice describes a proposed methodology for calculating the annual fee.

- 2. The Notice describes the use of the fee calculation methodology to provide a preliminary fee calculation for the 2011 calendar year.
- The Notice solicits public comments on all of its aspects.

#### Proposed fee calculation methodology

There are two calendar years relevant to the calculation of the annual fee. The first is the calendar year for which the fee must be paid (the "fee year"), and the second is the calendar year of the branded prescription drug sales which will be used to determine the amount of the fee (the "sales year"). The statute requires the IRS to use the immediately preceding calendar year as the sales year, for example, the 2010 calendar year for the calculation of the 2011 fee. However, the IRS proposes to use the second calendar year preceding the fee year as the sales year for purposes of calculating the annual fee.

The Notice notes that it has been determined that the Department of Defense and the Veterans Administration are expected to have complete data on prescription drug sales for the calendar year immediately preceding the fee year within the time frame necessary to administer the fee. However, it is also noted that the Department of Health and Human Services is not expected to have comparable data because it cannot complete its data processing within the necessary time frame. Accordingly, the IRS and the Treasury cite the regulatory authority provided under section 9008(i) of the Act and the ability to use any other source of available information as the basis for using a different sales year in the calculation of the fee. So, for example, the IRS will use the 2009 calendar year as the sales year for computation of the fee for the 2011 calendar year.

The annual fee for each covered entity is calculated by determining the ratio of (i) the covered entity's branded prescription drug sales taken into account during the preceding calendar year to (ii) the aggregate branded prescription drug sales taken into account for all covered entities during the same year, and applying this ratio to the applicable amount specified in the statute, \$2.5 billion for the 2011 calendar year. "Sales taken into account" is reduced by sales of orphan drugs for which a credit has been allowed under I.R.C. § 45C and after application of the percentage adjustment to sales specified in an adjustment table set forth in the statute. Rebates to

certain of the programs are also taken into account in arriving at the correct sales figure.

Calculation of the annual fee is done in four steps:

 Calculation of each covered entity's branded prescription drug sales for each program by NDC.

After receiving information from the federal agencies mentioned above and the covered entities on Form 8947. the IRS will calculate relevant sales for each program. A covered entity's branded prescription drug sales for each program will equal (i) the sum of all the covered entity's branded prescription drug sales reported by the program. less (ii) the sum of all branded prescription drug sales reported by the program for each NDC for which the covered entity has appropriately claimed the orphan drug exclusion, less (iii) the sum of rebates reported by the covered entity on Form 8947 for the sales year. An NDC is an identifier of the manufacturer or importer assigned by the Food and Drug Administration to a branded prescription drug, as well as other drugs. Therefore, a covered entity within the statutory definition of that term is the person identified in the Labeler Code of the NDC with respect to such drug.

2. Calculation of each covered entity's branded prescription drug sales taken into account in determining the covered entity's market share.

After calculating the branded prescription drug sales for each program, the IRS will calculate each covered entity's branded prescription drug sales taken into account for purposes of determining that covered entities market share, or the ratio set forth in section 9008(b)(1) of the Act and described above. A covered entity's branded prescription drug sales taken into account for purposes of section 9008(b)(1)(A) of the Act will equal the sum of the covered entity's branded prescription drug sales for all programs reduced by the appropriate percentages set forth in section 9008(b)(2) of the Act.

3. Calculation of the aggregate branded prescription drug sales of all covered entities taken into account.

The IRS will then calculate the aggregate branded prescription drug sales of all covered entities taken into account for purposes of section 9008(b)(1)(B) of the Act, which is the sum of all the covered entities branded prescription drug sales taken into account for purposes of section 9008(b)(1)(A) of the Act.

# 4. Calculation of each covered entity's fee.

To determine each covered entity's fee, the IRS will divide each covered entity's branded prescription drug sales taken into account for purposes of section 9008(b)(1)(A) of the Act by the aggregate branded prescription drug sales of all covered entities taken into account for purposes of section 9008(b)(1)(B) of the Act and multiply that fraction by the applicable amount for the appropriate year as set forth in section 9008(b)(4) of the Act.

#### Adjustments

The Notice recognizes that the use of an earlier sales year is likely to cause distortions in the amount of the fee paid by a covered entity. Therefore, the annual fee due in future calendar years will include an "adjustment amount." The adjustment amount will be calculated for each person identified in the NDC and will be added or subtracted to the fee otherwise payable by the covered entity responsible for the NDC in the fee year in which the adjustment is calculated.

#### Preliminary fee calculation for the 2011 fee year

The IRS will use the proposed methodology described above to provide each covered entity with a preliminary 2011 fee calculation. To assist the IRS in calculating the preliminary 2011 calendar year fee calculation, the IRS asks that Form 8947 be submitted to the IRS by January 20, 2011. From the data on the Forms 8947, the IRS will compile a list of NDCs and provide that list to the federal agencies mentioned above by March 1, 2011. The IRS will use the data submitted on the Forms 8947 and the sales data provided by the federal agencies to calculate the preliminary fee and will send notification of its preliminary fee calculation to each covered entity by May 2, 2011.

The IRS will send the final fee calculation to each covered entity by August 15, 2011.

# Request for comments

The IRS and Treasury request comments on the procedures described in Notice 2010-71 for consideration in the promulgation of regulations setting forth procedures for 2011 and the following years. The deadline for submission of comments is June 2, 2011.

#### **Observations**

Several key points can be taken from the Notice. First, the modification of the sales year by the IRS and Treasury appears to depart from the expectation of the Congress in its definition of the fee amount in section 9008(b)(1)(A) and (B). The IRS and Treasury may be comfortable with the use of an earlier sales year thinking that such use is within the power granted to the Secretary and his delegate by the statute. Or, the IRS and Treasury may seek a retroactive technical correction which appears to be unlikely in the current political climate. In the absence of a technical correction, it remains to be seen whether this use of an earlier sales year will withstand judicial scrutiny.

Second, the Act provides a controlled group rule under which all persons treated as a single employer under I.R.C. §§ 52(a), 52(b), 414(m), or 414(o) are treated as a single covered entity. For this purpose, a foreign entity subject to tax under section 881 is included within a controlled group under section 52(a) or 52(b). This controlled group rule will be applied as of the end of the day on December 31 of the sales year. All persons treated as a single employer under section 9008(d)(2) are jointly and severally liable for the fee. See section 9008(d)(3). Further, in the case of a controlled group that is treated as a single covered entity under the Act, the controlled group must identify a single person as the "designated entity" that may act for the controlled group with respect to the annual fee. If the controlled group, without regard to foreign corporations included under section 9008(d)(2)(B) of the Act, is also an affiliated group that filed a consolidated return for federal income tax purposes, the designated entity is the common parent of the affiliated group as identified on the tax return filed for the sales year. In all other situations, the controlled group must select a person as the designated entity on Form 8947, which is signed by the designated entity under penalties of perjury, stating that all the manufacturers or importers of branded prescription drugs who are members of the covered entity have consented to the selection of the designated entity.

Third, in order to facilitate the preliminary 2011 calendar year fee calculation, Form 8947 must be filed by a covered entity by January 20, 2011. The preliminary fee notification will be sent to each covered entity by May 2, 2011, and the final fee calculation will be sent by the IRS by August 15, 2011. While the Form is not required by law, completion of the Form may well benefit the covered entity. Information provided on this form may reduce the covered entity's fee, especially in cases in which the

covered entity has sales of branded prescription drugs within the orphan drug exception and rebates were made to the Medicare Part D program and the Medicaid program. The information requested on the Form is necessary to the IRS because the Department of Health and Human Services does not have rebate data for 2009 for by NDC. Further, data provided for the Medicaid Program will not include state supplemental rebate information.

Fourth, the Notice does not provide an appeals process if the covered entity does not agree with the calculation of the preliminary fee. Perhaps the IRS and Treasury believe that the opportunity to comment on the proposed methodology and to file Form 8947 provides the covered entity with an abundance of "due process" and that an administrative appeal process is not necessary. Or, perhaps an administrative appeals process will be included with the preliminary fee calculation sent to covered entities by May 2, 2011, for the 2011 fee year, before the final fee calculation is sent on August 15, 2011. Of course, the covered entity may ultimately file a complaint in federal district court, but an administrative appeals process appears to be the better course. Perhaps such a process will be left to Internal Revenue Manual provisions or forthcoming regulations.

Fifth, the Notice provides helpful guidance on when an I.R.C. § 45C credit is allowed for any taxable year for purposes of the orphan drug sales exclusion. The credit is considered to be "allowed" if the covered entity claimed the credit and there has not been a final assessment or a court order disallowing the full credit taken for the drug. The Instructions to Form 8947 embellish this concept by providing that, "Branded prescription drug sales do not include sales of orphan drugs if the covered entity claimed the section 45C credit for the orphan drugs on a return or claim for refund, and there has not been a final assessment or a court disallowance of the full section 45C credit taken for the drug."

Accordingly, covered entities and related NDCs should claim the section 45C credit for any year in which such entity could have, but did not, claim the credit, on an amended return, taking into account the limitations period on refund claims. While there is no date mandated for the filing of an amended return other than that prescribed by the limitations period on refund claims, it is wise to file the amended return on or before the date of the filing of Form 8947 which is due on January 20, 2011, for the 2011 fee year. In this manner, the orphan drug credit will be considered as allowed for purposes of the 2011 fee year fee calculation.

Sixth, it should be noted that the IRS does not intend to recalculate the fee allocations or the adjustment amounts based on data that becomes available after those amounts are assessed.

Finally, covered entities should be aware of the opportunity to comment on the procedures set forth in the Notice. If the IRS and Treasury Department subsequently promulgate regulations that modify the methodology for calculating each covered entity's fee, the modified methodology will be adopted in determining the final fee amount for each covered entity for 2011. Thus, if the methodology changes, the amount of the final fee for 2011 may vary from the preliminary fee calculation.

#### For more information

Please contact:

Lew Fernandez at (202) 312-7683 or lew.fernandez@us.pwc.com

Mike Swanick at (267) 330-6060 or michael.f.swanick@us.pwc.com

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