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Posted at 5:03 AM on December 15, 2010 by Sheppard Mullin

IRS Guidance On New Excise Tax On Branded Pharmaceutical Companies: Filing Due January 21, 2011

By Peter S. Reichertz

In a prior article dated May 25, 2010, we advised of a new excise tax on branded pharmaceutical manufacturers. We indicated that the Patient Protection and Affordable Care Act ("PPACA") required the Internal Revenue Service ("IRS") to publish guidance "necessary to carry out the purpose" of the section in which the tax is included. The IRS has now issued that guidance ("the Guidance").

The Guidance sets forth a proposed methodology for calculating the fee, as well as the requirements for pharmaceutical manufacturers subject to the tax. The fee is to be calculated by the IRS based on information obtained from government agencies which either reimburse for, or procure, branded prescription drugs, including those reimbursed under or purchased by Medicare Parts B and D, Medicaid, the VA, DOD and TRICARE. A description of the methodology for calculation of the fee is found on pages 2-7 of the Guidance.

What is required of pharmaceutical companies? Companies do not calculate the fees; they just provide certain information to the IRS. IRS then obtains information from the appropriate government agencies. Under the Guidance, pharmaceutical companies subject to the tax would have to file a Form 8947 annually, by December 15th of each year except that the initial submission must be made by **January 21, 2011**.

Form 8947 solicits the following information from each "covered entity":[1]

1. For a single-person covered entity, the covered entity's name, address, and employer identification number. For a covered entity which is a controlled group, the name, address, and employer identification number of the designated entity and each manufacturer or importer with gross receipts from the sale of branded prescription drugs that was included in the covered entity as of the end of the day on December 31 of the sales year.

2. All of the NDCs for branded prescription drugs in which the covered entity is identified in the labeler code as of the end of the day on December 31 of the sales year. For a covered entity which is a controlled group, this includes all NDCs in which a member of the covered entity is identified in the Labeler Code as of the end of the day on December 31 of the sales year.

3. The brand name and NDC for each orphan drug for which the covered entity was allowed a section 45C credit. A credit was "allowed" for any particular drug 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. In addition, even if the credit has been allowed, a covered entity must not report an NDC for an orphan drug for any sales year following the calendar year in which the FDA approved the drug for marketing for any indication other than the treatment of the rare disease or condition for which the section 45C credit was allowed.

4. The rebates for each NDC paid in the sales year by the covered entity to Medicare Part D with respect to sales occurring in that sales year. Section 9008(d)(1) of PPACA defines covered entity as "any manufacturer or importer with gross receipts from branded prescription drug sales." For purposes of section 9008(a), a manufacturer or importer is the person identified in the Labeler Code of the National Drug Code (NDC) for a branded prescription drug.

   Rebate is considered paid in the sales year if it is taken into account on the covered entity's tax return(s) for the sales year. This information is needed for the 2009 sales year because, at this time, CMS does not have rebate data on branded prescription drug sales by NDC. However, starting in 2011, CMS is planning to collect this rebate information by NDC for the 2010 and subsequent sales years. It is therefore possible that covered entities will not report this rebate information for years following 2009.

5. The state supplemental rebates for each NDC paid in the sales year by the covered entity with respect to sales under Medicaid occurring in that sales year. For this purpose, a rebate is considered paid in the sales year if it is taken into account on the covered entity's tax return(s) for the sales year. This information is needed because Medicaid data will not include state supplemental rebates.

The IRS will provide each "covered entity" with a preliminary fee calculation by **May 2, 2011** setting forth the covered entity's:

- fee
- branded Rx drug sales by NDC, by government program|
- drug sales taken into account
- aggregate drug sales taken into account for all entities.

A final fee calculation will be sent on **August 15, 2011**.

Part III – Requests for comments

The IRS has requested comments on the procedures described for consideration when promulgating regulations setting forth procedures for 2011 and the following years. The deadline for submission of comments is **June 2, 2011**. Written comments should be submitted to: Internal Revenue Service, CC:PA:LPD:PR (Notice 2010-71), Room 5203, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (Notice 2010-71), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC.: Comments may be transmitted electronically via the following e-mail address: Notice.Comments@irscounsel.treas.dov. "Notice 2010-71" should be in the subject line of any electronic communications.

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[1] Section 9008(d)(1) of PPACA defines a covered entity as "any manufacturer or importer with gross receipts from branded prescription drug sales." A manufacturer or importer is the person identified in the Labeler Code of the National Drug Code (NDC) for a branded prescription drug.

Section 9008(d)(2) of PPACA provides a controlled group rule under which all persons treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code (Code) shall be 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. In the case of a controlled group that is treated as a single covered entity under section 9008(d)(2), the controlled group must identify a single person as the "designated entity" that may act for the controlled group with respect to the section 9008 fee. If the controlled group, without regard to foreign corporations included under section 9008(d)(2)(B), 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, Report of Branded Prescription Drug Information 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.