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IRS Issues Guidance on Calculation of the Annual Fee Imposed on Manufacturers and Importers of Branded Prescription Drugs Under the Affordable Care Act

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On November 29, 2010, the Internal Revenue Service (the "IRS") issued Notice 2010-71, 2010-50 IRB (the "Notice"), which provides 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, pursuant to 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 following provides background on the annual fee and a summary of the information contained in the Notice.

Background

Section 9008 of the ACA imposes an annual fee (the "Fee") on each "covered entity" engaged in the business of manufacturing or importing "branded prescription drugs." The Fee applies to calendar years after 2010.

A "covered entity" is any "manufacturer or importer" with gross receipts from "branded prescription drug sales." Certain controlled groups of corporations (including foreign corporations that are part of such a controlled group) are treated as a single covered entity for purposes of determining and assessing the Fee.[1] A "manufacturer or importer" is the person identified in the labeler code segment of the National Drug Code ("NDC") for a particular "branded prescription drug." The term "branded prescription drug sales" means sales of "branded prescription drugs" to any "specified government program" or pursuant to coverage under any such program. "Branded prescription drugs" generally are (i) "prescription drugs" for which a new drug application was submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act

(the "FDC Act"), and (ii) biological products for which a license was submitted under section 351(a) of the Public Health Service Act. A "prescription drug" generally is any drug subject to section 503(b) of the FDC Act. The term "specified government program" means (i) Medicare Part D, (ii) Medicare Part B, (iii) Medicaid, (iv) any program under which branded prescription drugs are procured by the Department of Veteran Affairs, (v) any program under which branded prescription drugs are procured by the Department of Defense, and (vi) the TRICARE retail pharmacy program (each, a "Program," and collectively, the "Programs").

The Fee is due by the date determined by the Secretary of the Treasury, but in no event later than September 30 of each Fee Year (as defined below). The Fee for a calendar year generally is not imposed on any covered entity with branded prescription drug sales of $5 million or less during the preceding calendar year. The amount of the Fee payable by a covered entity with branded prescription drug sales in excess of $5 million is calculated annually by the Secretary of Treasury based on the ratio of the covered entity's branded prescription drug sales taken into account for the year (as described further below) to the aggregate branded prescription drug sales taken into account for all covered entities during the same year. In other words, the amount of a covered entity's Fee generally depends on what could be described as such covered entity's "federal market share" of government drug spending.

The Notice

General

The Notice is broken down into three parts: (i) a discussion of the IRS' proposed methodology for calculating the Fee; (ii) a discussion of how the Fee will be calculated for 2011; and (iii) a request for comments.

Proposed Methodology for Calculating the Fee

The Notice indicates that two years are relevant to the calculation of the Fee: (i) the calendar year in which the Fee must be paid (the "Fee Year"), and (ii) the calendar year of the branded prescription drug sales (the "Sales Year"). The amount of the Fee with respect to a particular covered entity for any given Fee Year is calculated by determining the ratio of (A) the covered entity's "branded prescription drug sales taken into account" during the second Sales Year preceding the Fee Year to (B) the aggregate "branded prescription drug sales taken into account" for all covered entities during the same Sales Year, and applying this ratio to the

"applicable amount" set forth in section 9008(a)(4) of the ACA (the "Applicable Amount"). Thus, for example, the amount of the Fee for 2011 will be determined based on 2009 sales data (subject to adjustment to the amount of the Fee in 2012, as described further below). Each covered entity's "branded prescription drug sales taken into account" is a specified percentage of the covered entity's aggregate branded prescription drug sales for the applicable Sales Year. In general, the greater the covered entity's aggregate branded prescription drug sales for the applicable Sales Year, the greater the percentage (and such percentage equals 100 percent for covered entities with aggregate branded prescription drug sales for the applicable Sales Year in excess of $400 million). The "Applicable Amount" is: (i) $2.5 billion for 2011; (ii) $2.8 billion for 2012 and 2013; (iii) $3 billion for 2014, 2015, and 2016; (iv) $4 billion for 2017; (v) $4.1 billion for 2018; and (vi) $2.8 billion for 2019 and thereafter.

The Notice states that the IRS will determine the Fee for any given Fee Year based on the second preceding Sales Year, and not the immediately preceding Sales Year, because the Centers for Medicare & Medicaid Services of the Department of Health and Human Services ("CMS") is not expected to have complete data on branded prescription drug sales for the immediately preceding year within the necessary time frame. Because the IRS will use the second preceding year rather than the immediately preceding year as the Sales Year, the Fee due in every year other than 2011 will include an adjustment to the preceding year's Fee. This adjustment amount generally will equal the difference between (i) the amount of the Fee determined for such immediately preceding Fee Year (based on data from the second Sales Year preceding such Fee Year) and (ii) the amount the Fee would have been for the immediately preceding Fee Year if determined based on the Sales Year immediately preceding such Fee Year. For example, the Fee for 2012 would include an adjustment amount equal to the difference between the Fee for 2011 (determined using 2009 data) and what the Fee for 2011 would have been if 2010 data were utilized. The Fee otherwise payable in 2012 by a covered entity would be increased or decreased, as appropriate, to true-up the Fee due in 2011, by the adjustment amount.

To permit the IRS to calculate and assess the Fee, all covered entities are required to file Form 8947 (available at www.irs.gov) 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 (e.g., the Form 8947 for the 2011 Fee Year, providing data for the 2009 Sales Year, is required to be filed by January 20, 2011). Form 8947 generally requires a

covered entity to disclose the following information: (i) identifying information about the covered entity (or, if applicable, the controlled group members that comprise a single covered entity as of December 31 of the immediately preceding Sales Year); (ii) all of the NDCs for branded prescription drugs (i.e., each 11-digit NDC) in which the covered entity is identified in the labeler code as of December 31 of the Sales Year; (iii) the brand name and NDC for each orphan drug for which the covered entity was allowed a section 45C tax credit and the latest year the section 45C orphan drug credit was allowed; (iv) all 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; and (v) all state supplemental rebates for each 11-digit NDC paid in the Sales Year by the covered entity with respect to sales under Medicaid occurring in that Sales Year. For purposes of Form 8947, rebates are taken into account using the method of accounting utilized by a covered entity in preparing its tax return(s).

The IRS will use the data submitted on Forms 8947 to compile a list of branded prescription drugs by NDC and will share this information with CMS, the Department of Veterans Affairs and the Department of Defense (collectively, the "Agencies"). The Agencies will, in turn, provide data to the IRS on the branded prescription drug sales during the Sales Year by Program and NDC. The Notice sets forth the calculation methodology for each Program that the Agencies expect to use in compiling such data and that the IRS will use to determine each covered entity's branded prescription drug sales. In general, the IRS proposes to use the data to estimate net federal expenditures for each drug product based on the data unique to each Program.[2]

Following the IRS' receipt of this information, it will calculate each covered entity's branded prescription drug sales for each Program for the Sales Year, which 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 which the covered entity has claimed the orphan drug exclusion, less (iii) the sum of rebates reported by the covered entity on Form 8947 for the Sales Year. To arrive at a covered entity's branded prescription drug sales "taken into account," a covered entity's branded prescription drug sales are then multiplied by the appropriate percentage listed in section 9008(b)(2) of the ACA. The appropriate percentage depends on the level of the covered entity's aggregate branded prescription drug sales for the Sales Year. In general, the percentage for sales made by large manufacturers and importers (defined as those with branded prescription drug sales during the applicable Sales Year in excess of $400 million) is 100 percent, while a reduced percentage (between 10 percent and 75

percent) is applied to sales made by smaller manufacturers and importers (defined as those with branded prescription drug sales in excess of $5 million but not more than $400 million during the applicable Sales Year).

To determine each covered entity's Fee for a Fee Year, the IRS will divide each covered entity's branded prescription drug sales taken into account by the aggregate branded prescription drug sales taken into account for all covered entities, and multiply that fraction by the Applicable Amount for such Fee Year.

Fee Calculation for 2011

Covered entities are required to submit Form 8947 for the 2011 Fee Year (listing information for calendar year 2009) by January 20, 2011. The IRS will utilize this data to compile a list of NDCs and will provide that list to the Agencies by March 1, 2011. The Agencies will provide the IRS with sales data for 2009. The IRS will use the data submitted on the Forms 8947 and the sales data provided by the Agencies to calculate a preliminary Fee for each covered entity, which will be sent to each such covered entity by May 2, 2011. Such preliminary Fee notification will include: (i) the covered entity's Fee for 2011; (ii) the covered entity's branded prescription drug sales, by NDC, for each Program; (iii) the covered entity's branded prescription drug sales taken into account; and (iv) the aggregate branded prescription drug sales taken into account for all covered entities.

If the IRS promulgates regulations that modify the methodology for calculating each covered entity's Fee, the amount of the final Fee for 2011 may vary from the preliminary Fee communicated to a covered entity. This final Fee calculation will be sent to each covered entity by August 15, 2011, with payment due no later than September 30, 2011.

Practical Considerations and Request for Comments

As a practical matter, company tax professionals will need to work closely with government pricing and regulatory affairs colleagues in order to comply with their reporting obligations, and to evaluate whether the company's Fee liability has been determined appropriately. While the Notice provides a solid starting point for IRS guidance, there are nevertheless areas of ambiguity that companies will need to evaluate, and about which they may wish to submit comments to the IRS. Some of these include:

- Whether reported data may be adjusted to take into account mid-year transactions in which a product is sold to another manufacturer, who in turn sells remaining inventory bearing the original manufacturer's NDC labeler code;
- How Part D and Medicaid supplemental rebate data should be allocated and reported among multiple 11-digit NDCs, where that data is only available at a 9-digit NDC level;
- Whether Medicare Part D "coverage gap" rebates payable in 2011 will need to be reported by manufacturers, or whether this information will be collected directly from CMS;
- Whether the IRS' proposed expenditure proxies (AMP, Medicare allowed charges) reflect fair metrics for evaluating federal expenditures that are comparable across programs (e.g., where Medicaid is only paying a minimal secondary payor amount for a Part B product);
- Whether Medicare allowed charges are to be considered net of patient copayments; and
- Whether the IRS will make any adjustment to the data to avoid "double counting" of sales for patients whose primary coverage for a product is Medicare Part B, but for whom Medicaid is a secondary payor.

These questions suggest that manufacturers and importers should carefully consider the proposed methods set forth in the Notice in light of the particular coverage and payor profiles of their products.

The IRS and the Treasury Department have requested comments on the calculation procedures described in the Notice for consideration when promulgating regulations setting forth procedures for 2011 and subsequent years. Interested persons may submit comments through June 2, 2011. Reed Smith's tax and government pricing lawyers are ready to assist clients who are interested in submitting comments to the IRS on the calculation procedures set forth in the Notice or who have questions with respect to their completion of Form 8947.

This *Tax Alert* is intended only to provide a general summary of the Fee and the information contained in the Notice. We will provide updates as appropriate upon the issuance of any future guidance with respect to these provisions. If you have questions, would like additional information about any of the information discussed above, 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.

To ensure compliance with Treasury Department regulations, we inform you that any federal tax advice contained in this communication is not intended or written to be used, and cannot be used, for the purpose of (i) avoiding penalties under the Internal Revenue Code or (ii) promoting, marketing, or recommending to another party any tax-related matters addressed herein.

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1. Generally, all entities treated as a single employer under section 52(a) or (b) (based upon certain ownership tests) or under section 414(m) or (o) (based upon the "affiliated service group" rules applicable to pension plans) of the Internal Revenue Code are treated as a single covered entity under section 9008 of the ACA.

2. For example, the IRS proposes to estimate Medicaid expenditures by assuming that the Medicaid average manufacturer price represents gross expenditures, and then subtracting Medicaid and supplemental rebates. Medicare Part B expenditures will be estimated based on total allowed Medicare charges (or a manufacturer's estimated share of total allowed charges where multiple products are billed using the same HCPCS code).