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Part III

Administrative, Procedural, and Miscellaneous

26 CFR 601.105: Examination of returns and claims for refund, credit, or abatement; determination of correct tax liability

Rev. Proc. 2011-24

Branded Prescription Drug Sales – Dispute Resolution Process for 2011 Preliminary Fee Calculation

SECTION 1. PURPOSE

This revenue procedure establishes a dispute resolution process for the preliminary fee calculation for the 2011 annual fee imposed on covered entities engaged in the business of manufacturing or importing branded prescription drugs. The fee was enacted by section 9008 of the Patient Protection and Affordable Care Act (ACA), Public Law 111-148 (124 Stat. 119 (2010)), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010 (HCERA), Public Law 111-152 (124 Stat. 1029 (2010)). All references in this revenue procedure to section 9008 are references to section 9008 of the ACA, as amended by section 1404 of HCERA.

SECTION 2. BACKGROUND

.01 Section 9008 imposes an annual fee on each covered entity with gross receipts of over $5 million from branded prescription drug sales to any specified government program or pursuant to coverage under such program (branded prescription drug sales). A covered entity is generally any manufacturer or importer with gross receipts from branded prescription drug sales. Multiple related manufacturers or importers may be treated as a single covered entity under certain circumstances. See §9008(d)(2) and Part 1 of Notice 2011-9. The specified government programs are the Medicare Part D program, the Medicare Part B program, the Medicaid program, and any program under which branded prescription drugs are procured by the Department of Veterans Affairs (VA), Department of Defense (DOD), and DOD's TRICARE retail pharmacy program (the Programs). Fees collected under section 9008 are credited to the Medicare Part B trust fund.

.02 Section 9008 sets the aggregate annual fee for all covered entities. For 2011, the aggregate fee is $2.5 billion. This aggregate fee is apportioned among the covered entities for each year based on each entity's proportionate share of branded prescription drug sales that are taken into account during the previous calendar year. The Secretary of the Treasury is to establish an annual payment date that is no later than September 30 of each year.

.03 Special rules in section 9008 exclude sales of certain orphan drugs from "branded prescription drug sales"; provide that an entity's branded prescription drug sales between $5 million and $400 million will only partially be taken into account in determining an entity's proportionate share of sales; and provide a controlled group rule so that all persons that are treated as a single employer under certain provisions of the Internal Revenue Code (Code) will be treated as a single covered entity.

.04 Section 9008 requires the Secretary of Health and Human Services, the Secretary of Veterans Affairs, and the Secretary of Defense (the Agencies) to report to the Secretary of the Treasury, at such time and in such manner as the Secretary of the Treasury prescribes, the total branded prescription drug sales under each Secretary's jurisdiction. The provision includes the detailed information to be included in the reports by the respective Secretaries for each specified government program.

.05 In Notice 2011-9, 2011-6 I.R.B. 459, the Treasury Department and the Internal Revenue Service (IRS) described a proposed methodology for calculating the section 9008 fee and the approach that the IRS will use to mail each covered entity a preliminary 2011 fee calculation by May 16, 2011. Under that methodology, each

covered entity's fee for 2011 is calculated using data from the 2009 sales year. As set forth in Notice 2011-9, each covered entity was asked to submit a Form 8947, Report of Branded Prescription Drug Information, to the IRS by February 11, 2011, to provide data on orphan drugs and rebates. In addition, any controlled group treated as a single covered entity under section 9008(d)(2) was asked to identify on Form 8947 a single person as the "designated entity" to act for the controlled group with respect to the section 9008 fee.

.06 From the data on the Forms 8947, the IRS compiled a list of National Drug Codes (NDCs) for branded prescription drugs sold to the Programs and, after appropriate due diligence, provided that list to the Agencies. The Agencies will provide sales data to the IRS on the branded prescription drug sales for the 2009 sales year by Program and NDC.

.07 After receiving the sales data from the Agencies, the IRS will make adjustments for orphan drug sales and rebates, and then calculate each covered entity's branded prescription drug sales taken into account for purposes of the ratio set forth in section 9008(b)(1). The IRS will then provide each covered entity with a preliminary fee calculation for 2011 by dividing each covered entity's branded prescription drug sales taken into account under 9008(b)(2) by the aggregate branded prescription drug sales taken into account for all covered entities and multiplying that fraction by the applicable amount for the year as set forth in section 9008(b)(4). The IRS will mail each covered entity notification of its preliminary fee calculation for 2011 by May 16, 2011.

.08 The notification of the preliminary fee calculation for 2011 will include: (1) the covered entity's preliminary fee calculation; (2) the covered entity's branded prescription drug sales for 2009, by NDC, for each Program; (3) the covered entity's branded prescription drug sales for 2009 taken into account after application of section 9008(b)(2); and (4) the aggregate branded prescription drug sales for 2009 taken into account for all covered entities.

.09 The IRS will mail a final fee calculation for 2011 to each covered entity by August 15, 2011, and payment of the fee from each covered entity will be due no later than September 30, 2011.

SECTION 3. SCOPE

This revenue procedure provides the process a covered entity may use to dispute what it believes are errors in its 2011 preliminary fee calculation. This is the exclusive process available to dispute the preliminary fee calculation and obtain any change that would be reflected in the final fee calculation mailed by the IRS by August 15, 2011.

SECTION 4. PROCEDURES FOR DISPUTING A 2011 PRELIMINARY FEE CALCULATION

.01 Submission of claimed error(s) to the IRS

Upon receipt of the notification that contains its 2011 preliminary fee calculation from the IRS, a covered entity should review the data contained in the notification. If the covered entity believes that the notification contains one or more errors in the mathematical calculation of the fee, the orphan drug or rebate data, the drug sales, or

any other error, the covered entity must provide an error report, in writing, to the IRS postmarked by June 1, 2011, in order for a correction to the claimed error(s) to be considered by the IRS. If a designated entity filed a Form 8947 on behalf of the covered entity, the error report for the covered entity must be submitted by the designated entity that filed the Form 8947. An error report must include the following information with respect to a covered or designated entity:

(1) Entity name, entity number (if applicable, from Part I(a) of the Form 8947), address, and Employer Identification Number (EIN) as previously reported on the Form 8947.

(2) The name, telephone number, and e-mail address (if available) of one or more employees or representatives of the entity with whom the claimed errors may be discussed by the IRS and/or the Agencies. If the representative is not an employee of the entity, a Form 2848 Power of Attorney and Declaration of Representative, must be filed with the error report.

(3) For a mathematical calculation error, the specific calculation element(s) that the entity disputes and its proposed corrected calculation.

(4) For an orphan drug or rebate data error, a discussion of whether the data used in the preliminary fee calculation matches data reported on a previously filed Form 8947, and if the data does match what was previously reported, an explanation as to why the originally reported data was erroneous and why the proposed correction is appropriate..

(5) For a sales data error, the Program that reported the data, the NDC, drug

name, the specific amount disputed, an explanation of how the entity established that an error was made, and the proposed corrected amount.

(6) For any other claimed error, an explanation of the nature of the error, how the error affects the fee calculation, an explanation of how the entity established that an error was made, and the proposed correction to the error.

(7) If a covered entity is using data to establish the existence of an error and that data was not reported on Form 8947 or contained in the notification of the preliminary fee calculation, a description of what the data is, how it was acquired, and who maintains it.

(8) Documentation of any sales data, rebate and orphan drug data, or other information used to establish the existence of any errors.

.02 Format of submission

(1) In general. For each program, a covered entity must prepare separate error reports with corresponding narratives, data relating to mathematical calculations, orphan drugs or rebates, sales or other errors, and supporting documentation. In addition, one comprehensive error report must be prepared for the IRS. The following format must be used:

(a) The error reports and the supporting documentation must be submitted on a CD-ROM**;**

(b) Asserted errors in mathematical calculations, orphan drug or rebate data, sales data, or any other errors must be submitted on separate Microsoft Excel spreadsheets for each program (e.g., a spreadsheet with sales data errors for the

Medicaid program must be separate from a spreadsheet with sales data errors for the Medicare Part D program)

(c) Separate narratives for each spreadsheet must be in Microsoft Word format; and

(d) Supporting documentation for each spreadsheet must be in Adobe Portable Document Format, if not available in Microsoft Word or Excel format.

(2) Alternative formats. Formats for submission other than Microsoft Word or Excel, or Adobe Portable Document format may be arranged on a case-by-case basis, if necessary, by contacting the IRS representative listed in Section 6 of this revenue procedure).

.03 Address for submission

Error reports and all supporting documentation must be mailed to:

Department of the Treasury
Internal Revenue Service
1973 Rulon White Boulevard, Mail Stop 4916
Ogden, UT 84404

SECTION 5. REVIEW OF CLAIMED ERROR(S)

.01 In general

If a claimed error involves a mathematical calculation or a correction to orphan drug or rebate data, the IRS will review the information and determine whether to make a correction. If a claimed error involves sales data provided by a Program, the IRS will provide the information sent by the covered entity to the Agency with jurisdiction over the appropriate Program to determine whether to make a correction. For any other claimed error, the IRS will review the information and determine whether the IRS or an

Agency should determine whether to make a correction.

.02 Period of review of error reports and notification of final determinations.

(1) The IRS and the Agencies will review the error reports. If the IRS or an Agency disagrees with a covered entity's proposed correction, the IRS or the Agency will contact the entity to discuss the disagreement. By July 15, 2011, the IRS or the Agency will make a final determination as to whether to make the proposed corrections to the entity's preliminary fee calculation for 2011. The IRS will notify the entity of the final determination with respect to error reports in writing before the IRS sends the covered entity the August 15, 2011 final fee calculation.

(2) A covered entity's final fee determination will be based solely on the data used for the preliminary fee calculation along with any adjustments made as a result of the dispute resolution process described in this revenue procedure. To the extent any covered entity's preliminary fee calculation is changed as a result of the dispute resolution process, the final fee calculation for all covered entities may differ from the preliminary fee calculations previously received. Any such changes will be reflected in the covered entity's final fee calculation for 2011.

SECTION 6. CONTACT INFORMATION

For questions about a notification of a preliminary fee calculation other than questions with respect to the branded prescription sales data contained in the notification, contact:

Internal Revenue Service
Lou Milano
(908) 301-2118 (not a toll-free call)

For questions about branded prescription sales data contained in the notification, contact:

Medicaid
[NAME, TELEPHONE #]

Medicare Part B
[NAME, TELEPHONE #]

Medicare Part D
[NAME, TELEPHONE #]

Department of Defense
[NAME, TELEPHONE #]

TRICARE
[NAME, TELEPHONE #]

Department of Veterans Affairs
[NAME, TELEPHONE #]

SECTION 7. EFFECTIVE DATE

This revenue procedure is effective **[INSERT DATE REV PROC IS RELEASED TO THE PUBLIC]**.

SECTION 8. PAPERWORK REDUCTION ACT

The collections of information contained in this revenue procedure have been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act (44 U.S.C. § 3507) under control number 1545-XXXX.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

The collections of information in this revenue procedure are in section 4.01.

This information is required to evaluate whether an error report regarding a

preliminary fee calculation is valid and justifies an adjustment to the preliminary fee calculation. The likely respondents are businesses.

The estimated total annual reporting and/or recordkeeping burden of this revenue procedure, and Rev. Proc. 2011-1, is X,XXX hours.

The estimated annual burden per respondent/recordkeeper varies from X hours to XX hours, depending on individual circumstances, with an estimated average burden of XX hours. The estimated number of respondents and/or record keepers is XXX.

The estimated frequency of responses is annual.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of the branded prescription drug fee and any related internal revenue law. Generally, this information is confidential, as required by 26 U.S.C. § 6103.

SECTION 9. DRAFTING INFORMATION

The principal author of this revenue procedure is [Author's Name] of the Office of Associate Chief Counsel ([ACC Office Name]). For further information regarding this revenue procedure contact [Contact name] on [(XXX) XXX-XXXX] (not a toll free call).