

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, 2011-6 I.R.B. 459. 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 covered 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 a covered entity's branded prescription drug sales between \$5 million and \$400 million will only partially be taken into account

in determining a covered 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, 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 perform a preliminary 2011 fee calculation for each covered entity. The IRS will mail each covered entity notification of its preliminary fee calculation for 2011 by May 16, 2011. (The IRS requested that comments on this Notice be submitted by June 15, 2011.) Under that methodology, the IRS will calculate each covered entity's fee for 2011 using data from the 2009 sales year. As set forth in Notice 2011-9, the IRS asked covered entities to submit a Form 8947, Report of Branded Prescription Drug Information, to the IRS by February 11, 2011, to provide data on branded prescription drugs, 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 provided 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 a preliminary fee calculation for 2011 for each covered entity by dividing each covered entity's branded prescription drug sales taken into account under section 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. Covered entities will be able to review this information

before the June 15, 2011, deadline for commenting on the methodology proposal in Notice 2011-9.

.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 covered entities to dispute the preliminary fee calculation and obtain any change to data 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 Program drug sales data, or any other error, the covered entity must provide a written error report 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 designated entity must also file any error report for the covered

entity.

.02 Program drug sales data errors

If a covered entity asserts that there has been one or more errors in drug sales data, the entity must submit a separate error report for each Program with its asserted errors. Each report must include the following information:

(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 Agencies may discuss the claimed errors. 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) The name of the Program that reported the data, the NDC, the specific amount of sales data disputed, the proposed corrected amount, an explanation of why the Agency should use the proposed corrected data instead, and documentation of any Program drug sales data or other information used to establish the existence of any errors.

.03 Errors other than Program drug sales errors

If a covered entity asserts that there has been one or more errors in the mathematical calculation of the fee, the rebate data, the listing of an NDC for an orphan drug, or any other error (other than Program drug sales data errors), the entity must submit one error report, separated into sections by type of error, and must include the

following information:

(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 IRS and/or the Agencies may discuss the claimed errors. 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 a rebate data error, the NDC for the drug to which it relates; a discussion of whether the data used in the preliminary fee calculation matches previously reported Form 8947 data on rebates; and if the data used in the preliminary fee calculation does match the Form 8947 data, an explanation of why the Form 8947 data was erroneous and why the IRS should use the proposed corrected data instead.

(5) For the listing of an NDC for an orphan drug, the name and NDC of the orphan drug; a discussion of whether the data used in the preliminary fee calculation matches previously reported Form 8947 data on orphan drugs; and if the data used in the preliminary fee calculation does match the Form 8947 data, an explanation of why the Form 8947 data was erroneous and why the IRS should use the proposed corrected data instead.

(6) For any other asserted 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 occurred, the proposed correction to the error, and an explanation of why the IRS or Agency should use the proposed corrected data instead.

(7) If an 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 the entity acquired the data, and who maintains it.

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

.04 Form and manner of submission

(1) Each covered entity must submit its error report(s) in the following format and manner:

(a) All error reports and the supporting documentation must be submitted on a single CD-ROM.

(b) A separate folder must be created for each Program with asserted drug sales data errors and the corresponding files for each Program placed in the Program folder. (For example, a Microsoft Excel spreadsheet file with drug sales data errors for the Medicaid program must be separate from a Microsoft Excel spreadsheet file with drug sales data errors for the Medicare Part D program). The folder and file names of the Microsoft Excel, Word, or Adobe files must include the name of the Program to which the asserted errors will be communicated. Asserted errors in Program drug sales data

must be presented in a Microsoft Excel spreadsheet file (no version newer than 2007) in a format consistent with the data format from Attachment 2 of the Preliminary Fee Calculation Letter (the IRS will mail these letters (Letter 4657) by May 16, 2011) showing the amount reported by the Program and the corresponding amount asserted by the covered entity, with the difference between the two.

(c) Asserted errors in mathematical calculations, rebate data, an NDC listing for an orphan drug, or any other asserted errors must be submitted on a separate Microsoft Excel spreadsheet file (no version newer than 2007). This spreadsheet file must be placed in a folder separate from the Program sales data folder(s). The folder and file names must distinguish these items from the Program sales data folder and files. These folders must also contain the corresponding files for the asserted errors.

(d) A separate narrative for each Microsoft Excel spreadsheet file must be submitted and must be in Microsoft Word format (no version newer than 2007).

(e) Supporting documentation for each Microsoft Excel spreadsheet file must be in Adobe Portable Document Format (no version newer than 8.0), if not available in Microsoft Word or Excel format.

(2) A covered entity must also provide an additional copy of its error report(s) and supporting documentation in a separate folder labeled "IRS Comprehensive Error Report."

.05 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 first IRS representative listed in Section 6 of this revenue procedure.

.06 Address for submission

Error reports and all supporting documentation must be mailed to:

Department of the Treasury
Internal Revenue Service
1973 N. 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 drug 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 to determine whether to make the proposed corrections to the covered entity's preliminary fee calculation for 2011. The IRS will rely exclusively on the Agencies to make determinations with respect to any proposed corrections to the Program drug sales data. The IRS will notify the covered entity in writing of the final determination with respect to error reports when the IRS sends the covered entity the final fee calculation no later than August 15, 2011.

(2) The IRS will base a covered entity's final fee determination solely on the data used for the preliminary fee calculation together with any adjustments to that data 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 one or more covered entities may differ from the preliminary fee calculations those entities previously received. Any such changes will be reflected in the covered entity's final fee calculation for 2011.

SECTION 6. CONTACT INFORMATION

For questions regarding this dispute resolution process, contact Lou Milano on (908) 301-2118 (not a toll-free call). For all other questions regarding this revenue procedure, contact Celia Gabrysh on (202) 622-3130 (not a toll-free call).

SECTION 7. EFFECTIVE DATE

This revenue procedure is effective May 2, 2011.

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 1545-2209.

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.

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 is 4,760 hours.

The estimated annual burden per respondent/recordkeeper varies from 8 hours to 64 hours, depending on individual circumstances, with an estimated average burden of 40 hours. The estimated number of respondents and/or record keepers is 119.

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.