

Part III – Administrative, Procedural, and Miscellaneous

Branded Prescription Drugs

Notice 2011-92

Branded Prescription Drug Fee; Guidance for the 2012 Fee Year

Purpose

This notice provides guidance on the branded prescription drug fee for the 2012 fee year related to (1) the submission of Form 8947, “Report of Branded Prescription Drug Information,” (2) the time and manner for notifying covered entities of their preliminary fee calculation, (3) the time and manner for submitting error reports for the dispute resolution process, and (4) the time for notifying covered entities of their final fee calculation.

Background

An annual fee on covered entities engaged in the business of manufacturing or importing branded prescription drugs is imposed by section 9008 of the Patient Protection and Affordable Care Act, Public Law 111-148 (124 Stat. 119 (2010)), as

amended by section 1404 of the Health Care and Education Reconciliation Act of 2010, Public Law 111-152 (124 Stat. 1029 (2010)).

The Branded Prescription Drug Fee Regulations in 26 C.F.R. Part 51, which were published on August 18, 2011 (76 FR 51245), provide the method by which each covered entity's annual fee is calculated. These regulations also define terms for the administration of the fee. As relevant for this notice, § 51.2T(g) defines fee year as the calendar year in which the fee for a particular sales year must be paid and § 51.2T(m) defines sales year as the second calendar year preceding the fee year.

Section 51.3T provides that annually, each covered entity may submit a completed Form 8947, "Report of Branded Prescription Drug Information," in accordance with the instructions for the form. Generally, the form solicits information from covered entities on National Drug Codes, orphan drugs, designated entities, rebates, and other information specified by the form or its instructions. The form is to be filed by the date prescribed in guidance published in the Internal Revenue Bulletin.

Section 51.6T provides that for each sales year the IRS will make a preliminary fee calculation for each covered entity and will notify each covered entity of this calculation by the date prescribed in guidance published in the Internal Revenue Bulletin. This notification will also include additional prescribed information. As used in this notice, "notice of preliminary fee calculation" includes the additional prescribed information.

Section 51.7T provides that upon receipt of its preliminary fee calculation, each covered entity will have an opportunity to dispute this calculation by submitting to the

IRS an error report with prescribed information. Sections 51.7T(b) and (c) set out the information that a covered entity must submit to support each asserted error. Section 51.7T(d) provides that each covered entity must submit its error report(s) in the form and manner that is prescribed in guidance published in the Internal Revenue Bulletin. This guidance will also prescribe the date by which each covered entity must submit its report(s).

Section 51.8T provides that the IRS will send each covered entity its final fee calculation no later than August 31st of each fee year and also provides that covered entities must pay their fee by September 30th of the fee year.

Submission of Form 8947

For the 2012 fee year, a covered entity that chooses to submit Form 8947 must file the form by December 15, 2011.

Time and manner for notifying covered entities of their preliminary fee calculation

For the 2012 fee year, the IRS will mail each covered entity a paper notice of its preliminary fee calculation by April 2, 2012. This mailing will include a National Drug Code (NDC) attachment (NDC attachment) that lists the covered entity's NDCs and the sales data reported to the IRS by each government program pursuant to § 51.4T.

A covered entity may request that the IRS send a CD-ROM with the NDC attachment in Microsoft Excel format. The covered entity must make this request by March 1, 2012. This request must be made either by telephone to Lou Milano at (908) 301-2118 or Mi Lim at (312) 566-3775 (not toll-free calls) or by email to mits.bpd.fee@irs.gov. If a covered entity makes this request timely, the IRS will mail

the covered entity its notice of preliminary fee calculation on paper and the NDC attachment on paper and CD-ROM by April 2, 2012.

Time and manner for submitting error reports for the dispute resolution process

For the 2012 fee year, a covered entity that chooses to submit an error report regarding its preliminary fee calculation must mail the error report by May 16, 2012.

When the IRS mails each covered entity a notice of its preliminary fee calculation by April 2, 2012, the IRS will also send each covered entity a template on a CD-ROM that the covered entity must use to prepare its error report. All completed templates and the supporting documentation must be submitted on a CD-ROM and sent by mail to:

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

Notification of Final Fee Calculation

In accordance with § 51.8T(a), the IRS will notify each covered entity of its final fee calculation for 2012 by August 31, 2012. In accordance with §51.8T(c), each covered entity must pay this fee by September 30, 2012.

Effect on Other Documents

Rev. Proc 2011-24 is obsolete.

Drafting Information

The principal author of this notice is Celia Gabrysh of the Office of Associate Chief Counsel (Passthroughs & Special Industries). For further information regarding this notice contact Celia Gabrysh at (202) 622-3130 (not a toll-free call).