Notice 2014-42 (IRS NOT), 2014-34 I.R.B. 387, 2014 WL 3668343

Internal Revenue Service (I.R.S.)

IRS NOT
Notice

BRANDED PRESCRIPTION DRUG FEE; PROCEDURAL AND ADMINISTRATIVE GUIDANCE

Released: July 24, 2014
Published: August 18, 2014

This notice provides guidance on the branded prescription drug fee 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. Notice 2013-51, 2013-34 I.R.B. 153, which provides guidance for the 2014 fee year, is obsoleted as of October 1, 2014.

This notice provides guidance on the branded prescription drug fee for each 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 § 9008 of the Patient Protection and Affordable Care Act, Public Law 111-148 (124 Stat. 119 (2010)), as amended by § 1404 of the Health Care and Education Reconciliation Act of 2010, Public Law 111-152 (124 Stat. 1029 (2010)) (collectively the ACA).

The Branded Prescription Drug Fee Regulations in 26 C.F.R. Part 51, which were published on July 28, 2014, (TD 9684, 79 FR 43631) 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, § 51.2(g) defines *fee year* as the calendar year in which the fee for a particular sales year must be paid and § 51.2(m) defines *sales year* as the second calendar year preceding the fee year.

Section 51.3 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 51.6 provides that for each sales year the Internal Revenue Service (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 51.7 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. Section 51.7(b) sets out the information that a covered entity must submit to support each asserted error. Section 51.7(c) 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 51.8 provides that the IRS will send each covered entity its final fee calculation no later than August 31 of each fee year and also provides that covered entities must pay their fee by September 30 of the fee year.

Section 7503 of the Internal Revenue Code provides that if the last day for performing an act required under the authority of the internal revenue laws falls on a Saturday, Sunday, or legal holiday, the performance of the act is timely if the act is performed on the next succeeding day that is not a Saturday, Sunday, or legal holiday. Section 9008(f)(1) of the ACA and § 51.9(a) treat this annual fee as an excise tax for purposes of subtitle F of the Code. Therefore, § 7503 applies to acts required to be performed under § 9008. Accordingly, if a date prescribed in this notice falls on a Saturday, Sunday, or legal holiday, a covered entity's performance of an act by this date is timely if the covered entity performs the act on the next succeeding day that is not a Saturday, Sunday, or legal holiday.

Submission of Form 8947

For each fee year, a covered entity that chooses to submit Form 8947 reporting information for the sales year must file the form by November 1 of the preceding year. For example, for the 2015 fee year, a covered entity must submit its Form 8947 reporting information for the 2013 sales year by Monday, November 3, 2014 (after applying § 7503).

A covered entity may submit its Form 8947 by mail or using e-file. Before using e-file, a covered entity must first: (1) successfully register with IRS e-services; (2) successfully complete the e-file application; and (3) receive an e-file acceptance letter (5120C letter) that contains an Electronic Filing Identification Number (EFIN) and an Electronic Transmitter Identification Number (ETIN). A covered entity must also file Form 8453- R, Declaration and Signature for Electronic Filing of Forms 8947 and 8963. The IRS provides instructions regarding e-file on the dedicated ACA e-file webpage at http:// vvww.irs.gov/uac/ e-file-Affordable-Care-Act-Information-Reports. A covered entity may also contact the IRS e-Help Desk at 1-866-937-4130 (Monday-through Friday from 6:30 am to 6:00 pm (CST)).

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

The IRS will mail each covered entity a paper notice of its preliminary fee calculation by March 1 of each fee year. This mailing will include a National Drug Code attachment (NDC attachment) that lists the covered entity's National Drug Codes and the sales data reported to the IRS by each government program pursuant to § 51.4.

A covered entity may request that the IRS send an electronic copy of the NDC attachment on a separate CD-ROM in Microsoft Excel format or other electronic format the IRS may designate in the future. The covered entity must submit a request by February 15 of each fee year by telephone, email, or fax as indicated in the *Contact Information* section of this notice. If a covered entity makes this request timely, the IRS will mail the covered entity its notice of preliminary fee calculation and the NDC attachment on paper as well as send the electronic version of the NDC attachment by March 1 of each fee year.

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

A covered entity that chooses to submit an error report regarding its preliminary fee calculation must mail the error report by May 15 of each fee year.

When the IRS mails each covered entity a notice of its preliminary fee calculation by March 1 of each fee year, the IRS will also send each covered entity a template that the covered entity must use to prepare its error report. The IRS will send this template on a separate CD-ROM in Microsoft Excel format or other electronic format the IRS may designate in the future. All

completed templates and the supporting documentation must be submitted on a CD-ROM in Microsoft Excel format or other electronic format designated by the IRS and sent to:
Department of the Treasury

Internal Revenue Service - Branded

Prescription Drug Fee 1973 N. Rulon White Boulevard, Mail

Stop 4916 Ogden, UT 84404

Notice of Final Fee Calculation

In accordance with § 51.8(a), the IRS will notify each covered entity of its final fee calculation by August 31 of each fee year. The IRS will mail a notice of final fee calculation and a final NDC attachment on paper. If, for purposes of the preliminary fee notification, a covered entity timely requested that the IRS send an electronic copy of the NDC attachment on a separate CD-ROM or other electronic format, the IRS will also send an electronic copy of the final NDC attachment on a separate CD-ROM or other electronic format. In accordance with § 51.8(c), each covered entity must pay this fee by September 30 of each fee year.

Contact Information

A covered entity may contact the IRS regarding the branded prescription drug fee by: (1) leaving a voice mail message in the BPD Mailbox at (908) 301-2118 (not a toll free call): (2) sending an email to it.bpd.fee@irs.gov, or (3) sending a fax toll free to (877) 797-0234.

Effective/Applicability Date

This Notice is effective on August 11, 2014, and applies on October 1, 2014 and thereafter.

Effect on Other Documents

Notice 2013-51, 2013-34 I.R.B. 153, which provides guidance for the 2014 fee year, is obsoleted as of October 1, 2014.

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, please contact Celia Gabrysh at (202) 317-6855 (not a toll-free number).

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