

Part III – Administrative, Procedural, and Miscellaneous

Branded Prescription Drugs

Notice 2011-46

Deferral of Dates Related to the 2011 Branded Prescription Drug Fee

Purpose

This notice defers two dates by which certain actions are to be taken for purposes of the branded prescription drug fee.

Background

An annual fee on covered entities engaged in the business of manufacturing or importing branded prescription drugs 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)).

Notice 2011-9, 2011-6 I.R.B. 459, provides guidance for implementing this fee in 2011. Among other things, Notice 2011-9 states that the IRS will provide each covered

entity with a preliminary fee calculation by May 16, 2011, and a final fee calculation by August 15, 2011.

Rev. Proc. 2011-24, 2011-20 I.R.B. 787, provides a dispute resolution process by which a covered entity may dispute its preliminary fee calculation before the IRS sends it a final fee calculation. Section 4.01 of the Rev. Proc. provides that a covered entity must provide a written error report to the IRS, postmarked by June 1, 2011, in order for a correction to any claimed error to be considered by the IRS. Section 5.02(1) of the Rev. Proc. provides that 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.

Reason for change and deferral of dates

The IRS has been told that certain covered entities may have difficulty meeting the June 1 deadline for submitting these error reports because of the volume of data they need to review. Accordingly, this notice defers until June 10, 2011, the date by which error reports under Rev. Proc. 2011-24 must be postmarked in order to receive IRS consideration.

To preserve the time needed to give appropriate consideration to the error reports, the IRS will send covered entities their 2011 final fee calculation and, if applicable, notification of the final determination with respect to error reports by August 24, 2011, instead of August 15, 2011.

Effect on Other Documents

Notice 2011-9 and Rev. Proc. 2011-24 are modified.

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 on (202) 622-3130 (not a toll-free call).