Part III

Administrative, Procedural, and Miscellaneous

26 CFR 601.601: Rules and Regulations.
(Also Part I, Section 5000D; § 47.5000D-3.)

Rev. Proc. 2025-9

SECTION 1. PURPOSE

This revenue procedure provides a safe harbor and safe harbor percentage that a manufacturer, producer, or importer may use to identify applicable sales of a designated drug made during a day described in section 5000D(b) of the Internal Revenue Code.[1]

SECTION 2. BACKGROUND

.01 Section 5000D imposes an excise tax on the applicable sales of a designated drug made during a day described in section 5000D(b) (section 5000D tax). For additional background, *see* section 3.01 of Notice 2023-52, 2023-35 I.R.B. 650.

[1] Unless otherwise specified, all "Section" or "§" references are to sections of the Internal Revenue Code (26 U.S.C. 1, et seq.) or the Designated Drugs Excise Tax Regulations (26 CFR part 47).

.02 In conjunction with the publication of this revenue procedure, the Department of the Treasury and the Internal Revenue Service (IRS) are publishing a notice of proposed rulemaking that contains proposed regulations issued under section 5000D (REG-1115560-23) in the ***Federal Register***. The proposed regulations would provide definitions and proposed rules relating to the imposition and calculation of the section 5000D tax.

.03 Section 47.5000D-3(a)(4)(iv) of the proposed regulations would provide a safe harbor under which a manufacturer, producer, or importer may identify the applicable sales of a designated drug made during a day described in section 5000D(b) by using a safe harbor percentage provided in guidance published in the Internal Revenue Bulletin (IRB). This revenue procedure provides a similar safe harbor, including a safe harbor percentage, that a manufacturer, producer, or importer may use until the proposed regulations are finalized or other guidance is published in the IRB or the ***Federal Register***.

SECTION 3. DEFINITIONS

Terms used in this revenue procedure and not defined herein have the same meaning as in section 5000D and the proposed regulations.

SECTION 4. SCOPE

The safe harbor provided in section 5.01 of this revenue procedure and the safe harbor percentage provided in section 6.01 of this revenue procedure may be used by any manufacturer, producer, or importer of a designated drug that makes a sale of such designated drug during a day described in section 5000D(b).

SECTION 5. SAFE HARBOR

.01 *Overview*. A manufacturer, producer, or importer may identify the applicable sales of a designated drug made during a day described in section 5000D(b) by using the safe harbor percentage provided in section 6.01 of this revenue procedure, provided that the manufacturer, producer, or importer satisfies the requirements described in section 5.02 of this revenue procedure.

.02 *Requirements.*

(1) *Must use safe harbor for four consecutive calendar quarters*. Except as provided in section 6.02 of this revenue procedure, a manufacturer, producer, or importer that uses the safe harbor described in section 5.01 of this revenue procedure must use the safe harbor for a period of four consecutive calendar quarters, beginning with the calendar quarter in which the safe harbor is first used.

(2) *Uniform application required*. A manufacturer, producer, or importer that uses the safe harbor described in section 5.01 of this revenue procedure for sales of units of any designated drug made during any day described in section 5000D(b) falling within a calendar quarter must apply the safe harbor to all sales by such manufacturer, producer, or importer during all days described in section 5000D(b) falling within that calendar quarter. Thus, if a manufacturer, producer, or importer uses the safe harbor described in section 5.01 of this revenue procedure with respect to one sale of a designated drug during a day described in section 5000D(b), it must use the safe harbor for all sales of that designated drug and all sales of any other designated drug that occur in that calendar quarter during a day described in section 5000D(b).

.03 *Recalculation of liability not permitted*. Once a section 5000D tax liability is reported to the IRS for a particular calendar quarter using the safe harbor described in section 5.01 of this revenue procedure and the safe harbor percentage described in section 6.01 of this revenue procedure, the manufacturer, producer, or importer liable for the section 5000D tax may not later recalculate its section 5000D tax liability for that quarter using a different method to identify its applicable sales. Once a section 5000D tax liability is reported to the IRS for a particular calendar quarter using a method other than that described in section 5.01 of this revenue procedure and the safe harbor percentage described in section 6.01 of this revenue procedure, the manufacturer, producer, or importer may not later recalculate its section 5000D tax liability using the safe harbor described in section 5.01 of this revenue procedure and the safe harbor percentage described in section 6.01 of this revenue procedure.

.04 *No election required*. No election is required for a manufacturer, producer, or importer to use the safe harbor described in section 5.01 of this revenue procedure.

SECTION 6. SAFE HARBOR PERCENTAGE

.01 *Overview*. For purposes of this revenue procedure, the “safe harbor percentage” is 40 percent. The percentage represents the mean, rounded to the nearest 10 percent, of the quotient of the total units associated with Medicare Part D prescription drug fills (that is, the “quantity dispensed” field reported by plan sponsors in prescription drug event records) and the units of total retail pharmacy sales reported by manufacturers to the Centers for Medicare & Medicaid Services (CMS) through average manufacturer price (AMP) data for qualifying single-source drugs for the period from June 1, 2022,

through May 31, 2023, removing qualifying single source drugs with missing AMP units, zero AMP units reported, or with greater than 100 percent of Medicare units or sales as a proportion of AMP units or sales. A conversion factor was applied to the Medicare Part D prescription drug units when necessary to make them comparable to AMP units.

.02 *Updates to safe harbor percentage*. Any update to the safe harbor percentage described in section 6.01 of this revenue procedure will use a calculation methodology similar to that described in such section, use the most recent analysis that the IRS has received from CMS of data available to CMS, and relieve a manufacturer, producer, or importer from an existing obligation under section 5.02(1) of this revenue procedure to use the safe harbor described in section 5.01 of this revenue procedure as of the effective date of such updated safe harbor percentage. If a manufacturer, producer, or importer continues to use the safe harbor described in section 5.01 of this revenue procedure after the safe harbor percentage is updated, such manufacturer, producer, or importer must use the updated safe harbor percentage on and after the effective date of such updated safe harbor percentage and for the remainder of any period required by section 5.02(1) of this revenue procedure.

SECTION 7. EFFECTIVE DATE

This revenue procedure is effective for returns filed on or after December 31, 2024, and will remain in effect through the day before the effective date of superseding guidance published in the IRB or the ***Federal Register***.

SECTION 8. DRAFTING INFORMATION

The principal author of this revenue procedure is the Office of the Associate Chief

Counsel (Passthroughs & Special Industries). For further information regarding this revenue procedure, contact at (202) 317-6855 (not a toll-free call).