Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 47

[REG–115560–23]

RIN 1545–BQ92

Excise Tax on Designated Drugs

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations relating to the excise tax on certain sales of designated drugs by manufacturers, producers, and importers during statutorily defined periods. The proposed regulations would provide substantive rules that relate to the imposition and calculation of the tax. The proposed regulations would affect manufacturers, producers, and importers of designated drugs that sell such drugs during statutorily defined periods.

DATES: Written or electronic comments and requests for a public hearing must be received by March 3, 2025. Requests for a public hearing must be submitted as prescribed in the ''Comments and Requests for a Public Hearing'' section.

ADDRESSES: Commenters are strongly encouraged to submit public comments electronically via the Federal eRulemaking Portal at *https://www.regulations.gov* (indicate IRS and REG–115560–23) by following the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The Department of the Treasury (Treasury Department) and the IRS will publish for public availability any comments submitted to the IRS's public docket. Send paper submissions to: CC:PA:01:PR (REG–115560–23), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, contact James S. Williford or Jacob W. Peeples at (202) 317–6855 (not a toll-free number); concerning the submission of comments and requests for a public hearing, contact the Publications and Regulations Section of the Office of Associate Chief Counsel (Procedure and Administration) by phone at (202) 317–6901 (not a toll-free number) or by email at *publichearings@irs.gov* (preferred).

SUPPLEMENTARY INFORMATION:

Authority

This notice of proposed rulemaking contains proposed regulations that would amend 26 CFR part 47 (Designated Drugs Excise Tax Regulations) related to the excise tax imposed by section 5000D of the Internal Revenue Code (Code) on certain sales by manufacturers, producers, or importers of designated drugs (section 5000D tax). These proposed regulations are issued under the express delegation of authority granted to the Secretary of the Treasury or her delegate (Secretary) by section 5000D(h), which states: ''The Secretary shall prescribe such regulations and other guidance as may be necessary to carry out the provisions of this section.'' These proposed regulations are also issued under the express delegation of authority provided in section 7805(a), which authorizes the Secretary to prescribe all needful rules and regulations for the enforcement of the Code, including all rules and regulations as may be necessary by reason of any alteration of law in relation to internal revenue.

Background

Sections 1191 through 1198 of the Social Security Act (SSA) (42 U.S.C. 1320f to 1320f–7), added by sections 11001 and 11002 of Public Law 117–169, 136 Stat. 1818 (August 16, 2022), commonly known as the Inflation Reduction Act of 2022 (IRA), require the Secretary of Health and Human Services (HHS) to establish a Medicare prescription drug price negotiation program (Program) to negotiate maximum fair prices (MFPs) for certain high expenditure, single-source drugs covered by Medicare. Under the Program, the Secretary of HHS must, among other things: (1) publish a list of selected drugs in accordance with section 1192 of the SSA; (2) enter into agreements with willing manufacturers of selected drugs in accordance with section 1193 of the SSA; and (3) negotiate MFPs for such selected drugs in accordance with section 1194 of the SSA. Under section 1193(a)(3) of the SSA, manufacturers of selected drugs that choose to enter into agreements with the Secretary of HHS and that agree to an MFP commit to provide access to selected drugs at the negotiated prices to MFP-eligible individuals (as defined in section 1191(c)(2) of the SSA), as well as to pharmacies and other dispensers, hospitals, physicians, other providers of services, and suppliers with respect to MFP-eligible individuals.

Section 5000D was added to a new chapter 50A of the Code by section 11003 of the IRA and is effective for sales on and after August 16, 2022. Section 5000D(a) imposes the section 5000D tax on the sale by the manufacturer, producer, or importer of any designated drug during a day described in section 5000D(b), referred to herein as a ''statutory period,'' with respect to such designated drug. In the case of a sale of a designated drug timed for the purpose of avoiding the section 5000D tax, section 5000D(f)(2) authorizes the Secretary to treat such sale as occurring during a statutory period.

Section 5000D(e)(1) provides that a ''designated drug'' is any ''negotiation-eligible drug,'' as defined in section 1192(d) of the SSA, included on the list published under section 1192(a) of the SSA that is manufactured or produced in the United States, as defined in section 5000D(e)(2), or entered into the United States for consumption, use, or warehousing.

Under section 5000D(a), the amount of section 5000D tax imposed on the sale of a designated drug during a statutory period is the amount that causes the ratio of (1) the section 5000D tax, divided by (2) the sum of the section 5000D tax and the price for which the designated drug was sold, when such ratio is expressed as a percentage, to equal the ''applicable percentage'' (as defined in section 5000D(d)):

$$\text{Applicable Percentage} = \text{Tax}/(\text{Tax} + \text{Price})$$

The applicable percentage ranges from 65 percent to 95 percent, depending on the number of days a sale

is made after the start of a statutory period. Section 5000D(d).

As noted previously, section 5000D(h) authorizes the Secretary to prescribe such regulations and other guidance as may be necessary to carry out the provisions of section 5000D. On August 28, 2023, the Treasury Department and the IRS published Notice 2023–52, 2023–35 I.R.B. 650, announcing the Secretary's intent to issue proposed regulations addressing substantive and procedural issues related to section 5000D. Notice 2023–52 described certain rules that those proposed regulations would include and provided taxpayers with interim guidance.

On October 2, 2023, the Treasury Department and the IRS published a notice of proposed rulemaking (REG–115559–23) in the **Federal Register** (88 FR 67690) proposing amendments to the Excise Tax Procedural Regulations under 26 CFR part 40 to address tax return filing and other procedural requirements related to the section 5000D tax applicable to returns filed for calendar quarters beginning on or after October 1, 2023. On July 5, 2024, the Treasury Department and the IRS published a Treasury decision (T.D. 10003) in the **Federal Register** (89 FR 55507) finalizing, with minor modifications, the proposed amendments to 26 CFR part 40 and adding part 47 to 26 CFR.

These proposed regulations would amend the Designated Drugs Excise Tax Regulations by providing substantive rules related to the section 5000D tax, including rules consistent with the substantive rules described in Notice 2023–52. Specifically, these proposed regulations would provide definitions of certain terms, such as ''manufacturer, producer, or importer,'' ''sale,'' and ''price,'' and rules governing the imposition and calculation of the section 5000D tax. Concurrently with the filing for public inspection of these proposed regulations, the Treasury Department and the IRS are releasing Revenue Procedure 2025–9 to provide a safe harbor that taxpayers may use to identify the subset of each sale in units of a designated drug made during a statutory period that is subject to the section 5000D tax. After its release, Revenue Procedure 2025–9 will be published in the Internal Revenue Bulletin (*see* § 601.601(d) of the Statement of Procedural Rules (26 CFR part 601)).

Explanation of Provisions

These proposed regulations are organized into two sections: proposed § 47.5000D–2 (relating to definitions) and proposed § 47.5000D–3 (relating to the imposition and calculation of the section 5000D tax).

I. Definitions

Proposed § 47.5000D–2 would provide definitions necessary to clarify the application of section 5000D.

A. Applicable Percentage

Proposed § 47.5000D–2(b)(1) would incorporate the substance of the statutory definition of the term ''applicable percentage'' provided in section 5000D(d). Proposed § 47.5000D–2(b)(1) would also clarify that, to determine the appropriate applicable percentage for a specific applicable sale, days described in section 5000D(b) are cumulative regardless of whether such days are consecutive.

B. Applicable Sale

Proposed § 47.5000D–2(b)(2) would define the term ''applicable sale'' to mean the sale transaction that is the subset of each sale in units of a designated drug, as defined in section 5000D(e)(1), by the manufacturer, producer, or importer that will be dispensed, furnished, or administered to MFP-eligible individuals, as defined in section 1191(c)(2) of the Social Security Act (42 U.S.C. 1320f(c)(2)) and any regulations or guidance issued thereunder by the Secretary of HHS. As explained in part II.A of this Explanation of Provisions, the proposed definition of ''applicable sale'' would reflect the scope of the section 5000D tax provided by the statutory context of its enactment.

C. Manufacturer, Producer, or Importer

The section 5000D tax is imposed on the sale of a designated drug by the ''manufacturer, producer, or importer'' of that designated drug. While the statute does not define ''manufacturer, producer, or importer,'' the language of section 5000D(a) makes clear that these terms are not limited to the persons directly responsible for the conduct that gives rise to statutory periods. Proposed § 47.5000D–2(b)(3)(i) would define the term ''manufacturer, producer, or importer'' to mean the person that makes the first sale (the definition of ''sale'' is explained in part I.F of this Explanation of Provisions) of units of a designated drug or, in the case of imports, the person that makes the first sale of such units after they are entered into the United States for consumption, use, or warehousing. *See* section 5000D(e)(1). Under this proposed definition, the section 5000D tax would typically be imposed on persons colloquially considered drug makers (that is, persons that physically or chemically create units of a drug).

The proposed definition of ''manufacturer, producer, or importer'' would also clarify that a sale of units of a designated drug would be the ''first sale'' if that sale precedes in time all other sales of those units. The ''first sale'' of any units of a designated drug would not, therefore, generally be the sale of such units to an MFP-eligible individual or other sales of such units that typically occur ''down'' or ''later'' in the supply chain that begins with the maker of a drug and ends with its ultimate user. For example, sales of units of a designated drug by a wholesaler, relabeler, repackager,[1] retail pharmacy, healthcare provider, or other person that typically sells drugs or biological products ''down'' or ''later'' in the supply chain, would not, under most circumstances, be the first sale of those units and, consequently, such person would not be the manufacturer, producer, or importer with respect to such units for purposes of the section 5000D tax. That designation would, under most circumstances, fall to a person ''up'' or ''earlier'' in the supply chain. If, however, a wholesaler, relabeler, repackager, retail pharmacy, healthcare provider, or other person were to make the first sale of units of a designated drug after entry into the United States for consumption, use, or warehousing, such person would be the manufacturer, producer, or importer with respect to such units for purposes of the section 5000D tax.

The first sale concept is consistent with almost a century of case law regarding the imposition of excise taxes on first or initial sales by manufacturers, producers, or importers. *See, e.g., Indian Motorcycle Co.* v. *United States,* 283 U.S. 570, 574 (1931) (''[T]he requirement that the tax be paid by 'the manufacturer, producer, or importer' [. . .] is intended to be no more than a comprehensive and convenient mode of reaching all first or initial sales[.]''); *Smith* v. *United States,* 319 F.2d 776, 778–79 (5th Cir. 1963) (excise tax is designed ''to impose a tax on the initial sale made in the United States by a manufacturer, producer, or importer''); *Texas Truck Parts and Tire* v. *United States,* 118 F.4th 687, 697 (5th Cir. 2024) (''Our reading of the relevant law comports with this principle, providing

[1] The Treasury Department and the IRS understand that, for purposes of the SSA and regulations and guidance issued thereunder, relabelers and repackagers are considered ''manufacturers,'' and drugs, once relabeled or repackaged, new drugs. That regulatory regime is, however, nondeterminative with regard to the section 5000D tax.

that Texas Truck is liable for the excise tax upon the initial sale in the United States.'').

Proposed § 47.5000D–2(b)(3)(ii) would clarify that the proposed definition of ''manufacturer, producer, or importer'' would apply independently of whether the sale in question occurs during a statutory period, meaning that the person that makes the first sale of a unit of a designated drug is the manufacturer, producer, or importer of that unit, to the exclusion of others in the supply chain, even if such sale is not taxable. *See* the example provided in proposed § 47.5000D–2(c)(2).

D. Sale Prior to Publication of Selected Drug List

Under proposed § 47.5000D–2(b)(3)(iii), a person that would meet the definition of ''manufacturer, producer, or importer'' but for the timing of the publication of the list of selected drugs published under section 1192(a) of the SSA would be considered a manufacturer, producer, or importer for purposes of the section 5000D tax. As illustrated in the example provided in proposed § 47.5000D–2(c)(3), this proposed rule would ensure that subsequent sales by other persons, ''down'' or ''later'' in the supply chain, that take possession of a drug or biological product prior to the publication of that list are not subject to taxation if such drugs or biological products become designated drugs while in such persons' possession.

E. Price

Under section 5000D(a)(2), the section 5000D tax is calculated, in part, by reference to the price of the designated drug sold during a statutory period; however, section 5000D does not define the term ''price'' for this purpose. Proposed § 47.5000D–2(b)(4) would define ''price'' broadly,[2] capturing all amounts (other than the amount of the section 5000D tax) required by a manufacturer, producer, or importer to be paid as consideration for, or otherwise as a condition of, a sale of the subset of units of such sale that comprise an applicable sale. Because, as explained in part II.A of this Explanation of Provisions, section 5000D(a) imposes a tax only on sales of designated drugs dispensed, furnished, or administered to MFP-eligible individuals, the price charged by the manufacturer, producer, or importer for such units would generally be the relevant price for purposes of determining the section 5000D tax. For purposes of this proposed definition, it would be immaterial that any amount constituting the price may be paid to a person other than the manufacturer, producer, or importer, or that it may be separately billed to the buyer as an amount earmarked for expenses incurred or to be incurred on such buyer's behalf.

Rebates and other price adjustments are common in the prescription drug supply chain. To account for such adjustments, proposed § 47.5000D–2(b)(4)(ii) would allow a manufacturer, producer, or importer to adjust the amount charged in an applicable sale, for purposes of calculating the section 5000D tax, to reflect bona fide discounts, rebates, or allowances that are connected to that applicable sale and either paid to the buyer in such applicable sale, credited to the account of such buyer, or reimbursed to a third party for the benefit of such buyer by such manufacturer, producer, or importer. Under the proposed rule, a bona fide discount, rebate, or allowance would be made when the amount actually paid by, or charged against the account of, the buyer in the applicable sale is reduced by subsequent transactions between the parties. For example, a wholesaler chargeback paid by a manufacturer, producer, or importer to reflect a discounted sale of drugs ''downstream'' by the wholesaler would constitute a bona fide discount, rebate, or allowance, provided that such chargeback is connected to the applicable sale giving rise to the section 5000D tax liability (and not any other sale, ongoing sales generally, or any other goods or services) and reduces the amount paid by, or charged against the account of, the buyer in that applicable sale (and not any other sale).

Proposed § 47.5000D–2(b)(4)(iii) would provide that the amount of any bona fide discount, rebate, or allowance described in § 47.5000D–2(b)(4)(ii) that may be used to reduce the amount charged for an applicable sale is limited to the percentage of a sale that constitutes such applicable sale. *See* Identification of Applicable Sales in part II.C of this Explanation of Provisions.

Proposed § 47.5000D–2(b)(4)(ii) and (iii) are intended to reflect the amount charged for the applicable sale in light of industry practices related to bona fide discounts, rebates, and allowances. The Treasury Department and the IRS request comments on other types of discounts, rebates, or allowances, including discounts, rebates, and allowances occurring at other points in the supply chain, that should be considered or treated as price adjustments under proposed § 47.5000D–2(b)(4)(ii) and (iii).

Proposed § 47.5000D–2(b)(4)(iv) would provide the method for allocating the amount described in proposed § 47.5000D–2(b)(4)(iii)—that is, the amount by which any bona fide discount, rebate, or allowance reduces the amount charged in an applicable sale—between tax and price. This proposed rule would treat an applicable sale, including the extent to which the amount charged includes price and tax, as provided in § 47.5000D–3(b)(2)(i), as though such applicable sale was initially made at the adjusted price.

Proposed § 47.5000D–2(c)(6) would provide an example of a price adjustment under proposed § 47.5000D–2(b)(4)(ii) and (iii) and the allocation required under proposed § 47.5000D–2(b)(4)(iv).

F. Sale

Proposed § 47.5000D–2(b)(5) would define ''sale'' as any agreement by which substantial incidents of ownership in units of a designated drug serve, in whole or in part, as consideration.

II. Imposition and Calculation of Tax

Proposed § 47.5000D–3 would provide rules relating to the imposition and calculation of the section 5000D tax.

A. Imposition of Tax

Proposed § 47.5000D–3(a)(1) would provide that section 5000D imposes a tax on an applicable sale made by a manufacturer, producer, or importer during a day described in section 5000D(b). As described in part I.B of this Explanation of Provisions, the term ''applicable sale'' refers to the subset of a sale in units of a designated drug that will be dispensed, furnished, or administered to MFP-eligible individuals, as defined in section 1191(c)(2) of the SSA and any regulations or guidance issued thereunder by the Secretary of HHS.

The scope of sales potentially subject to the section 5000D tax, as expressed in this proposed rule, reflects the broader statutory context of the Program, which defines both the substance and operation of the tax. Among other things, the objects of the tax, ''designated drug[s],'' are defined by section 5000D(e)(1), in part, by reference to the ''negotiation-eligible drugs,'' as defined in section 1192(d) of the SSA, included on the list published under section 1192(a) of the SSA. Such negotiation-eligible drugs are identified, under the Program, on the basis of

[2] ''Price,'' as defined in proposed § 47.5000D–2(b)(4), does not apply beyond section 5000D.

historical Medicare expenditures (*see* section 1192(b) and (c) of the SSA) and for the sole purpose of affecting prices paid by Medicare beneficiaries (*see* section 1192(a)(3) of the SSA). Similarly, the statutory periods during which the section 5000D tax may arise are defined by reference to milestones of the Program. *See* section 5000D(b). And, more generally, the applicability of the section 5000D tax is expressly linked to whether the manufacturer of a designated drug has a statutorily defined agreement with Medicare in place. *See* section 5000D(c). Because the section 5000D tax depends substantively on, and operates only in relation to, the Program, the scope of the Program—which provides access to selected drugs at the negotiated prices only to Medicare beneficiaries and their pharmacies, mail order services, and other dispensers, as well as hospitals, physicians, and other providers of services and suppliers—is reflected in the scope of the tax.

B. Attachment of and Person Liable for the Tax

Proposed § 47.5000D–3(a)(2) would clarify that the section 5000D tax attaches when a manufacturer, producer, or importer of a designated drug makes an applicable sale of such designated drug during a statutory period. Under proposed § 47.5000D–3(a)(3), the manufacturer, producer, or importer of a designated drug that sells units of such designated drug during a statutory period would be liable for any section 5000D tax arising from that sale.

C. Identification of Applicable Sales

Consistent with Notice 2023–52, proposed § 47.5000D–3(a)(4) would require a manufacturer, producer, or importer to employ a reasonable method to identify any applicable sales it made during a statutory period. The proposed rule would require a manufacturer, producer, or importer's method of identifying such applicable sales to be based on recent transactions reflected in books, records, or other information pertaining to the drug or biological product selected under the Program. For this purpose, recent transactions would include those occurring no more than 24 months before the first day of the calendar quarter in which the applicable sales occurred.

For statutory periods that begin prior to March 1, 2026, proposed § 47.5000D–3(a)(4)(iii) would allow a manufacturer, producer, or importer to disregard sales of drugs or biological products furnished or administered by a hospital, physician, or other provider of services or supplier, where the recipient is an individual enrolled under Medicare part B of title XVIII of the SSA, including an individual enrolled in a Medicare Advantage plan under part C of title XVIII of the SSA, if payment may be made under part B for such units, consistent with section 1192(b)(2) of the SSA, which provides for the temporary exclusion of expenditures under part B of title XVIII of the SSA for purposes of ranking negotiation-eligible drugs.

The Treasury Department and the IRS are aware that identifying applicable sales made during a statutory period may be difficult or burdensome. To help a manufacturer, producer, or importer comply with this requirement, the Treasury Department and the IRS are proposing a safe harbor for identifying such applicable sales. Specifically, proposed § 47.5000D–3(a)(4)(iv) would provide that a manufacturer, producer, or importer may satisfy the requirement to identify applicable sales by using the safe harbor percentage provided in guidance published in the Internal Revenue Bulletin. A manufacturer, producer, or importer that uses the safe harbor provided in proposed § 47.5000D–3(a)(4)(iv) to identify the applicable sales made during a statutory period would be deemed to have complied with the requirements of proposed § 47.5000D–3(a)(4)(i) through (iii), as applicable.

To ensure consistent reporting and reduce the potential for abuse, proposed § 47.5000D–3(a)(4)(iv)(C) and (D) would require the safe harbor to be applied uniformly to all sales of a designated drug by a manufacturer, producer, or importer subject to the section 5000D tax during a calendar quarter and, unless the safe harbor percentage is changed by subsequent guidance, for a period of three consecutive calendar quarters thereafter.

Under proposed § 47.5000D–3(a)(4)(iv)(E), any update of to the safe harbor percentage described in proposed § 47.5000D–3(a)(4)(iv)(A) would use a calculation methodology similar to that described in proposed § 47.5000D–3(a)(4)(iv)(A), 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 proposed § 47.5000D–3(a)(4)(iv)(C) to use the safe harbor described in proposed § 47.5000D–3(a)(4)(iv) 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 proposed § 47.5000D–3(a)(4)(iv) after the safe harbor percentage is updated, such manufacturer, producer, or importer would be required to 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 proposed § 47.5000D–3(a)(4)(iv)(C).

Finally, proposed § 47.5000D–3(a)(4)(v) would provide that once a section 5000D tax liability is reported to the IRS for a particular calendar quarter, 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. However, the correction of a mathematical or clerical error or the use of corrected data from the same historical period used to identify the applicable sales originally would not alone constitute the recalculation of a section 5000D tax liability using a different method.

D. Calculation of Tax

Proposed § 47.5000D–3(b)(1) would provide the tax rate by restating the statutory formula for calculating the section 5000D tax. As described in the Background section of this preamble, section 5000D(a) provides a formula for calculating the section 5000D tax by which an applicable percentage, ranging from 65 to 95 percent, equals the tax divided by the sum of the tax and the price. The applicable percentage varies depending on the number of days that have passed since a statutory period began.

E. Effect of Invoicing Tax on Tax Calculation

Consistent with Notice 2023–52, proposed § 47.5000D–3(b)(2)(i) would provide that if a manufacturer, producer, or importer makes no separate charge on its invoice or similar document with respect to a sale, the amount charged is presumed to include the proper amount of the section 5000D tax. The price would, under those circumstances, exclude the portion of the amount charged that is allocable to the section 5000D tax; no section 5000D tax would be calculated on the amount allocated to the section 5000D tax. *see* the example provided in proposed § 47.5000D–3(b)(3).

If a manufacturer, producer, or importer includes the section 5000D tax as a separate line item on an invoice or similar document, proposed § 47.5000D–3(b)(2)(ii) would provide that the amount of section 5000D tax so charged is not included in the price; thus, no section 5000D tax would be due on the amount of section 5000D tax so charged.

Although this rule is modeled on a similar rule found in § 48.4216(a)–2(a) of the Manufacturers and Retailers Excise Tax Regulations, neither that rule nor any other found in 26 CFR part 48 would apply or provide any interpretive guidance with respect to any rule proposed or issued under section 5000D because the part 48 regulations apply to taxes imposed by chapters 31 and 32 of the Code, and section 5000D is in chapter 50A.

F. Anti-Abuse Rule

Pursuant to the authority provided in section 5000D(h), proposed § 47.5000D–3(c) would provide an anti-abuse rule under which a transaction or series of transactions, including transactions made other than at arm's length, may be adjusted, recharacterized, or otherwise recast by the IRS in circumstances in which the parties engaged in such transaction or series of transactions with a principal purpose of avoiding the section 5000D tax or substantially reducing the purported price on which the section 5000D tax is calculated.

Proposed Applicability Date

These regulations are proposed to apply to sales of designated drugs on and after the date the Treasury decision adopting these rules as final regulations is published in the **Federal Register**.

Effect on Other Documents

Taxpayers may continue to rely on sections 3.01 and 3.02 of Notice 2023–52 until these proposed regulations are finalized.

Special Analyses

I. Regulatory Planning and Review—Economic Analysis

Pursuant to the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the IRS are not subject to the requirements of section 6 of Executive Order 12866, as amended. Therefore, a regulatory impact assessment is not required.

II. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) generally requires that a Federal agency obtain the approval of the Office of Management and Budget (OMB) before collecting information from the public, whether such collection of information is mandatory, voluntary, or required to obtain or retain a benefit. 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.

Any collection burden associated with rules described in these proposed regulations is previously accounted for in OMB Control Number 1545–0023, which covers Form 720, *Quarterly Federal Excise Tax Return.* The recordkeeping requirements associated with Form 720 have already been approved by OMB. Moreover, a taxpayer may avail itself of the safe harbor proposed in these proposed regulations without filing any formal election or statement or performing any other affirmative act. These proposed regulations do not, therefore, alter previously accounted for information collection requirements or create new collection requirements. For PRA burden estimated for procedural rules related to the section 5000D tax, see the preamble to TD 10003.

III. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6) (RFA), the Secretary of the Treasury hereby certifies that these proposed regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the section 5000D tax is imposed only when certain drug manufacturers, producers, or importers sell certain designated drugs during periods described in section 5000D(b). The periods described in section 5000D(b) relate to milestones in the Program, the scope of which is limited to a subset of drugs with high Medicare expenditures. To the extent any section 5000D tax liability arises, taxpayers will be few and unlikely to meet the relevant definitions of small entities under the RFA and regulations thereunder. These proposed regulations will not, therefore, create additional obligations for, or have a significant economic impact on, a substantial number of small entities, and analysis under the RFA is not required. Notwithstanding this certification, the Treasury Department and the IRS welcome comments on the impact of these proposed regulations on small entities.

IV. Section 7805(f)

Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking has been submitted to the Chief Counsel for the Office of Advocacy of the Small Business Administration for comment on its impact on small business.

V. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a State, local, or Tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. These proposed regulations do not include any Federal mandate that may result in expenditures by State, local, or Tribal governments, or by the private sector, in excess of that threshold.

VI. Executive Order 13132: Federalism

Executive Order 13132 (Federalism) prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on State and local governments, and is not required by statute, or preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. These proposed regulations do not have federalism implications, do not impose substantial direct compliance costs on State and local governments, and do not preempt State law within the meaning of the Executive order.

Comments and Requests for a Public Hearing

Before these proposed amendments to the regulations are adopted as final regulations, consideration will be given to comments that are submitted timely to the IRS as prescribed in the preamble under the **ADDRESSES** section. The Treasury Department and the IRS request comments on all aspects of the proposed regulations. All commenters are strongly encouraged to submit comments electronically. The Treasury Department and the IRS will publish for public availability any comment submitted electronically or on paper to its public docket on *https://www.regulations.gov.*

A public hearing will be scheduled if requested in writing by any person who timely submits electronic or written comments. Requests for a public hearing are also encouraged to be made electronically. If a public hearing is scheduled, notice of the date and time for the public hearing will be published in the **Federal Register**.

Statement of Availability of IRS Documents

The IRS notice cited in this preamble is published in the Internal Revenue Bulletin and is available from the Superintendent of Documents, U.S. Government Publishing Office,

Washington, DC 20402, or by visiting the IRS website at *https://www.irs.gov.*

Drafting Information

The principal author of these regulations is the Office of the Associate Chief Counsel (Passthroughs & Special Industries). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 47

Excise taxes.

Proposed Amendments to the Regulations

Accordingly, the Treasury Department and the IRS propose to amend 26 CFR part 47 as follows:

PART 47—DESIGNATED DRUGS EXCISE TAX REGULATIONS

■ **Paragraph 1.** The authority citation for part 47 is amended by adding entries in numerical order for §§ 47.5000D–2 and 47.5000D–3 to read in part as follows:

Authority: 26 U.S.C. 7805.

* * * * *

Section 47.5000D–2 also issued under 26 U.S.C. 5000D(h). Section 47.5000D–3 also issued under 26 U.S.C. 5000D(h).

■ **Par. 2.** Section 47.5000D–0 is amended by:

■ a. Removing the entry ''§§ 47.5000D–2—47.5000D–4 [Reserved]''.

■ b. Adding entries for §§ 47.5000D–2 and 47.5000D–3 and the entry ''§ 47.5000D–4 [Reserved]'' in numerical order.

The additions read as follows:

§ 47.5000D–0 Table of contents.

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■ **Par. 3.** Sections 47.5000D–2 and 47.5000D–3 are added to read as follows:

§ 47.5000D–2 Definitions.

(a) *Overview.* This section provides definitions for purposes of section 5000D of the Internal Revenue Code (Code) and the Designated Drugs Excise Tax Regulations in this part.

(b) *Definitions*—(1) *Applicable percentage.* The term *applicable percentage* has the meaning provided in section 5000D(d). To determine the applicable percentage with respect to a specific applicable sale, days described in section 5000D(b) are cumulative regardless of whether such days are consecutive.

(2) *Applicable sale.* The term *applicable sale* means the sale transaction that is the subset of each sale in units of a designated drug, as defined in section 5000D(e)(1), made by the manufacturer, producer, or importer that will be dispensed, furnished, or administered to maximum fair price-eligible individuals, as defined in section 1191(c)(2) of the Social Security Act (42 U.S.C. 1320f(c)(2)) and any regulations (in title 42 of the Code of Federal Regulations) or guidance issued thereunder by the Secretary of Health and Human Services. *See* § 47.5000D–3(a)(4) for methods of identifying applicable sales.

(3) *Manufacturer, producer, or importer*—(i) *In general.* With respect to any units of a designated drug, the term *manufacturer, producer, or importer* means the person that makes the first sale of such units or, in the case of imports, the person that makes the first sale of such units after such units are entered into the United States for consumption, use, or warehousing. A sale is the first sale if it precedes in time any other sale of the same units. Each unit of a designated drug, therefore, has only one manufacturer, producer, or importer.

(ii) *Sale made other than on a day described in section 5000D(b).* A person that meets the criteria of paragraph (b)(3)(i) of this section is a manufacturer, producer, or importer regardless of whether the sale described in paragraph (b)(3)(i) is made during a day described in section 5000D(b). *See Example 2* provided in paragraph (c)(2) of this section.

(iii) *Sale made prior to publication of the list of selected drugs under section 1192(a) of the Social Security Act.* With respect to particular units of a drug or biological product, if a person would be described in paragraph (b)(3)(i) of this section but for the timing of the publication of the list of selected drugs under section 1192(a) of the Social Security Act, such person will nevertheless be considered the manufacturer, producer, or importer of such units. Subsequent sellers of such units would not, therefore, be the manufacturer, producer, or importer of such units. *See Example 3* provided in paragraph (c)(3) of this section.

(4) *Price*—(i) *In general.* Except as provided in § 47.5000D–3(b)(2)(i) and (ii), the term *price* means, with respect to an applicable sale of units of a designated drug sold during a day

described in section 5000D(b), any amount (whether in cash or in kind) that is required by a manufacturer, producer, or importer to be paid as a condition of such applicable sale. It is immaterial, for purposes of this paragraph (b)(4), that such amount may be paid to a person other than the manufacturer, producer, or importer, or that it may be separately billed to the buyer as an amount earmarked for expenses incurred or to be incurred on such buyer's behalf.

(ii) *Adjustment to amount charged.* A manufacturer, producer, or importer may adjust the amount charged in an applicable sale to reflect a bona fide discount, rebate, or allowance that is connected to such applicable sale and paid or credited by such manufacturer, producer, or importer against such amount. The basic consideration in determining, for purposes of this section, whether a bona fide discount, rebate, or allowance has been made is whether the amount actually paid by, or charged against the account of, the buyer in the applicable sale has been reduced. Such amount will be considered reduced by reason of a bona fide discount, rebate, or allowance only if the manufacturer, producer, or importer repays part or all of the amount charged to the buyer, credits the buyer's account, or reimburses a third party for part or all of the amount charged for the benefit of the buyer.

(iii) *Amount of adjustment.* The amount of any bona fide discount, rebate, or allowance described in paragraph (b)(4)(ii) of this section that may be used to reduce the amount charged for an applicable sale is limited by the percentage of a sale that constitutes such applicable sale.

(iv) *Allocation between price and tax.* The amount described in paragraph (b)(4)(iii) of this section must be allocated between price and the tax imposed by section 5000D(a) (section 5000D tax) in the same manner as the amount charged for the applicable sale absent such adjustment. *See Example 6* provided in paragraph (c)(6) of this section.

(5) *Sale.* The term *sale* means any agreement by which substantial incidents of ownership in units of a designated drug serve as consideration.

(c) *Examples.* The following examples illustrate the application of the definitions provided in this section and the rules provided in § 47.5000D–3. For purposes of this paragraph (c), all sales are applicable sales (*see* paragraph (b)(2) of this section and § 47.5000D–3(a)(4)) and, unless otherwise provided, all designated drugs are manufactured or produced in the United States.

(1) *Example 1: First sale of units of a designated drug*—(i) *Facts.* Manufacturer D is a manufacturer of Designated Drug Y. During the fourth quarter of 2024, Manufacturer D sells 1,000,000 units of Designated Drug Y to Wholesaler E, a drug wholesaler. With respect to Designated Drug Y, every day of the fourth quarter of 2024 is a day described in section 5000D(b).

(ii) *Analysis.* Manufacturer D incurs liability under section 5000D(a) and § 47.5000D–3(a) for its sale of the 1,000,000 units of Designated Drug Y to Wholesaler E. No other person incurs liability under section 5000D(a) and § 47.5000D–3(a) with respect to those units. Under paragraph (b)(3)(i) of this section, Manufacturer D's sale of the 1,000,000 units of Designated Drug Y to Wholesaler E is the first sale of such units of the designated drug. As a result, Manufacturer D is the manufacturer, producer, or importer with respect to such units of Designated Drug Y. Because Manufacturer D's sale of the 1,000,000 units of Designated Drug Y is made during a day described in section 5000D(b), that sale is subject to taxation under section 5000D(a) and § 47.5000D–3(a). No tax liability under section 5000D arises with respect to any subsequent sale of the 1,000,000 units of Designated Drug Y because no subsequent sale would qualify as the first sale of such units; therefore, no other person is the manufacturer, producer, or importer with respect to such units.

(2) *Example 2: Manufacturer sale prior to day described in section 5000D(b)*—(i) *Facts.* The facts are the same as those described in paragraph (c)(1)(i) of this section (*Example 1*), except that Manufacturer D's sale of the 1,000,000 units of Designated Drug Y is made after it is included on the list published under section 1192(a) of the Social Security Act, but before a day described in section 5000D(b).

(ii) *Analysis.* Manufacturer D incurs no liability under section 5000D(a) and § 47.5000D–3(a) for its sale of the 1,000,000 units of Designated Drug Y to Wholesaler E. In addition, no other person incurs liability under section 5000D(a) and § 47.5000D–3(a) with respect to those units. Under paragraph (b)(3)(i) of this section, Manufacturer D's sale of the 1,000,000 units of Designated Drug Y to Wholesaler E is the first sale of such units of the designated drug. As a result, Manufacturer D is the manufacturer, producer, or importer with respect to such units of Designated Drug Y. No tax liability under section 5000D, however, arises in relation to that sale because it was not made during a day described in section 5000D(b). Moreover, no tax liability under section 5000D arises with respect to any subsequent sale of the 1,000,000 units of Designated Drug Y because no subsequent sale would qualify as the first sale of such units, and therefore no other person is the manufacturer, producer, or importer with respect to such units.

(3) *Example 3: Sale made prior to publication of the list of selected drugs*—(i) *Facts.* Manufacturer B, a drug manufacturer, sells 1,000,000 units of Drug J to Wholesaler V, a drug wholesaler. After such sale and before Wholesaler V resells those 1,000,000 units, Drug J is identified as a selected drug on the list published under section 1192(a) of the Social Security Act, making it a designated drug (Designated Drug J), as defined in section 5000D(e)(1). Wholesaler V subsequently sells the 1,000,000 units of Designated Drug J to pharmacies; these sales occur on a day described in section 5000D(b).

(ii) *Analysis.* Manufacturer B incurs no liability under section 5000D(a) and § 47.5000D–3(a) for its sale of the 1,000,000 units of Designated Drug J to Wholesaler V. In addition, no other person incurs liability under section 5000D(a) and § 47.5000D–3(a) with respect to those units. At the time of Manufacturer B's sale to Wholesaler V, Drug J had not been included on the list of selected drugs published under section 1192(a) of the Social Security Act and, therefore, was not a designated drug as defined in section 5000D(e)(1). Under paragraph (b)(3)(iii) of this section, Manufacturer B would nevertheless be considered the manufacturer, producer, or importer with respect to the sale to Wholesaler V. No tax liability under section 5000D(a) and § 47.5000D–3(a) would arise with respect to Manufacturer B's sale because that sale did not occur (and could not have occurred) during a day described in section 5000D(b). Moreover, no tax liability under section 5000D would arise with respect to Wholesaler V's sale of the 1,000,000 units of Designated Drug J, even though such sale occurred during a day described in section 5000D(b), because, as a function of the rule provided in paragraph (b)(3)(iii) of this section, Wholesaler V did not make the first sale of such units. Wholesaler V is not, therefore, the manufacturer, producer, or importer under paragraph (b)(3)(i) of this section with respect to such units of Designated Drug J, and is not subject to tax under section 5000D and § 47.5000D–3(a).

(4) *Example 4: Subsequent sale to relabeler*—(i) *Facts.* The facts are the same as those described in paragraph (c)(1)(i) of this section (*Example 1*),

except that during the fourth quarter of 2024, Wholesaler E sells the same 1,000,000 units to Relabeler F, a drug relabeler. Relabeler F then relabels the 1,000,000 units of Designated Drug Y and, before the end of the fourth quarter of 2024, sells all 1,000,000 units to pharmacies.

(ii) *Analysis.* Manufacturer D incurs liability under section 5000D(a) and § 47.5000D–3(a) for its sale of the 1,000,000 units of Designated Drug Y to Wholesaler E. No other person incurs liability under section 5000D(a) and § 47.5000D–3(a) with respect to those units. Relabeler F's relabeling of the 1,000,000 units of Designated Drug Y does not affect this outcome, regardless of whether such relabeling involves affixing a new National Drug Code or Codes to the units of Designated Drug Y prior to those units of Designated Drug Y being furnished to a maximum fair price-eligible individual. Relabeler F's sales of the 1,000,000 units of Designated Drug Y to pharmacies are the third sales of such units, not the first. As a result, Manufacturer D is the manufacturer, producer, or importer with respect to such units under paragraph (b)(3)(i) of this section, not Relabeler F. Thus, Relabeler F's sale of such units is not subject to taxation under section 5000D(a) and § 47.5000D–3(a), but Manufacturer D's sale of such units to Wholesaler E is subject to the tax.

(5) *Example 5: Importation*—(i) *Facts.* With respect to Designated Drug Y, every day of the fourth quarter of 2024 is a day described in section 5000D(b). Manufacturer R is a manufacturer of Drug Y. During the fourth quarter of 2024, Manufacturer R sells 1,000,000 units of Drug Y to Wholesaler Q, a drug wholesaler, before such units are entered into the United States for consumption, use, or warehousing. Before the end of the fourth quarter of 2024, Wholesaler Q enters the 1,000,000 units of Drug Y into the United States for consumption, use or warehousing, rendering them units of a designated drug (Designated Drug Y), as defined in section 5000D(e)(1), and sells all 1,000,000 units to pharmacies.

(ii) *Analysis.* Wholesaler Q incurs liability under section 5000D(a) and § 47.5000D–3(a) for its sale of the 1,000,000 units of Designated Drug Y to the pharmacies. No other person incurs liability under section 5000D(a) and § 47.5000D–3(a) with respect to those units. Under paragraph (b)(3)(i) of this section, Manufacturer R is not the manufacturer, producer, or importer with respect to the 1,000,000 units of Drug Y that Manufacturer R sold to Wholesaler Q during the fourth quarter of 2024 because Manufacturer R's sale occurred before such units were entered into the United States for consumption, use, or warehousing. As a result, Manufacturer R's sale to Wholesaler Q is not subject to taxation under section 5000D(a) and § 47.5000D–3(a). Wholesaler Q's sales of the same 1,000,000 units of Designated Drug Y to pharmacies in the fourth quarter of 2024, however, are subject to taxation under section 5000D(a) and § 47.5000D–3(a). Wholesaler Q's sales to such pharmacies are the first sales of those units after they were entered into the United States for consumption, use, or warehousing. As a result, Wholesaler Q is the manufacturer, producer, or importer under paragraph (b)(3)(i) of this section with respect to such units of Designated Drug Y, and its sales thereof are subject to taxation under section 5000D(a) and § 47.5000D–3(a).

(6) *Example 6: Chargeback reimbursement and allocation*—(i) *Facts*—(A) *Manufacturer sale.* Manufacturer P is the manufacturer, producer, or importer of 100,000 units of Designated Drug Q. During a day described in section 5000D(b), and no more than 90 days since the first such day, Manufacturer P sells 100,000 units of Designated Drug Q to Wholesaler V at $1.00 per unit ($100,000). Manufacturer P reasonably determines that 40 percent of the sale is the applicable sale. *See* paragraph (b)(2) of this section and § 47.5000D–3(a)(4). Manufacturer P does not separately invoice any section 5000D tax to Wholesaler V. *See* § 47.5000D–3(b)(2)(i). Manufacturer P's sale to Wholesaler V would, therefore, have resulted in a section 5000D tax liability of $26,000 ($26,000 ÷ $40,000 = 65 percent).

(B) *Wholesaler sale and chargeback.* Pharmacy G purchases the 100,000 units of Designated Drug Q from Wholesaler V at a discount. Wholesaler V issues a $30,000 chargeback invoice to Manufacturer P related to the amount of the discount. Manufacturer P pays Wholesaler V the full amount of the chargeback.

(ii) *Analysis*—(A) *Bona fide discount, rebate, or allowance.* Manufacturer P's reimbursement for Wholesaler V's chargeback is a bona fide discount, rebate, or allowance against the price of the applicable sale because it is for the sale of the 100,000 units (and no other sale, goods, or services). Of the 100,000 units sold, 40 percent, or 40,000, constitute the applicable sale and are therefore subject to the section 5000D tax. Manufacturer P's reimbursement to Wholesaler V reduces the amount charged in that applicable sale, such that the amount charged per unit is $0.70 and the total amount charged in the applicable sale is $28,000 ($0.70 per unit × 40,000 units). The reimbursement proportionally attributable to the applicable sale is, therefore, $12,000 ($0.30 per unit × 40,000 units).

(B) *Allocation of chargeback reimbursement between tax and price.* (*1*) The amount by which the chargeback reimbursement reduces the price and tax, for purposes of section 5000D, is determined by allocating the reimbursement according to the same price-tax ratio that initially applied to the applicable sale:

Equation 1 to Paragraph (c)(6)(ii)(B)(*1*)

$$\frac{\textit{Tax Inclusive Price Adjustment}}{\textit{Tax Inclusive Sale Price}} \times \textit{Tax Exclusive Sale Price} = \textit{Price Adjustment}$$

(*2*) The quotient of the tax-inclusive price adjustment ($12,000) and the tax-inclusive sale price (the $40,000 amount charged) multiplied by the initial tax-exclusive sale price of the applicable sale (($1.00 − $0.65) × $40,000, or $14,000) results in a price adjustment of $4,200, meaning that, of the $12,000 reimbursement, $7,800 is allocated to tax and $4,200 is allocated to price. Thus, Manufacturer P's liability under section 5000D for the applicable sale is $18,200 (the $26,000 tax liability arising from the sale as originally made less the $7,800 of the reimbursement allocated to the tax). In other words, Manufacturer P's liability under section 5000D after the price adjustment is identical to the liability that Manufacturer P would have incurred under section 5000D had Manufacturer P originally sold the 100,000 units of Designated Drug Q to Wholesaler V at the adjusted amount ($18,200 ÷ $28,000 = 65 percent).

(d) *Severability.* The provisions of this section are separate and severable from one another and any other section in this part. If any provision of this section is stayed or determined to be invalid, it is the intention of the Department of the Treasury and the Internal Revenue Service that the remaining provisions

and sections of this part shall continue in effect.

(e) *Applicability date.* This section applies to sales of designated drugs on or after [date of publication of final regulations in the **Federal Register**].

§ 47.5000D–3 Imposition of section 5000D tax.

(a) *Imposition of tax*—(1) *In general.* Section 5000D(a) of the Internal Revenue Code (Code) imposes a tax (section 5000D tax) on applicable sales made by a manufacturer, producer, or importer during a day described in section 5000D(b).

(2) *Attachment of tax.* The section 5000D tax attaches when a manufacturer, producer, or importer of units of a designated drug makes an applicable sale of such units during a day described in section 5000D(b).

(3) *Person liable for tax.* A manufacturer, producer, or importer of units of a designated drug that makes an applicable sale of such units during a day described in section 5000D(b) is liable for the section 5000D tax imposed on such sale.

(4) *Identification of applicable sales*—(i) *In general.* A manufacturer, producer, or importer of units of a designated drug must employ a reasonable method to identify the applicable sales of such units, if any, that it makes during a day described in section 5000D(b). A manufacturer, producer, or importer's method of identifying such applicable sales must be based on its books, records, or other information. For example, a subsidiary may rely on historical sales data collected and analyzed by its parent, provided that such data and analysis meet the requirements of paragraph (a)(4)(ii) of this section and are otherwise reasonable.

(ii) *Books, records, and other information.* Books, records, and other information used to identify applicable sales must reflect transactions pertaining to the drug or biological product selected for inclusion on the list of selected drugs published under section 1192(a) of the Social Security Act that predate the first day of the calendar quarter in which the applicable sales occurred by no more than 24 months.

(iii) *Disregard of Medicare part B sales permissible prior to March 1, 2026.* For periods described in section 5000D(b) that begin prior to March 1, 2026, a manufacturer, producer, or importer's method may disregard sales of drugs or biological products furnished or administered by a hospital, physician, or other provider of services or supplier, the recipient of which is an individual enrolled under Medicare part B of title XVIII of the Social Security Act, including an individual enrolled in a Medicare Advantage plan under part C of such title, if payment may be made under part B for such units. *See* section 1192(b)(2) of the Social Security Act.

(iv) *Safe harbor*—(A) *In general.* A manufacturer, producer, or importer may satisfy the requirements of this paragraph (a)(4) by using the safe harbor percentage provided in guidance published in the Internal Revenue Bulletin (see § 601.601 of this chapter), as applicable to the relevant calendar quarter, to identify its applicable sales. Such safe harbor percentage is a rounded average of the percentage of all sales that are applicable sales of a sample of qualifying single-source drugs (as defined in section 1192(e) of the Social Security Act) that is large enough to yield meaningful results, as determined by the analysis of certain manufacturer- and patient-level data conducted by the Centers for Medicare and Medicaid Services (CMS).

(B) *No election required.* No election is required for a manufacturer, producer, or importer to use the safe harbor described in paragraph (a)(4)(iv)(A) of this section.

(C) *Must use safe harbor for four consecutive calendar quarters.* Except as provided in paragraph (a)(4)(iv)(E) of this section, a manufacturer, producer, or importer that uses the safe harbor described in paragraph (a)(4)(iv)(A) of this section must continue to use the safe harbor for a period of four consecutive calendar quarters, including the calendar quarter in which the safe harbor is first used.

(D) *Uniform application required.* A manufacturer, producer, or importer that uses the safe harbor described in paragraph (a)(4)(iv)(A) of this section for sales 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 paragraph (a)(4)(iii)(A) of this section 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).

(E) *Updates to safe harbor percentage.* Any update to the safe harbor percentage described in paragraph (a)(4)(iv)(A) of this section will use a calculation methodology similar to that described in paragraph (a)(4)(iv)(A) of this section, use the most recent analysis that the Internal Revenue Service (IRS) has received from CMS of data available to CMS, and relieve a manufacturer, producer, or importer from an existing obligation under paragraph (a)(4)(iv)(C) of this section to use the safe harbor described in this paragraph (a)(4)(iv) 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 this paragraph (a)(4)(iv) 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 paragraph (a)(4)(iv)(C) of this section.

(v) *Recalculation of liability not permitted.* Once a section 5000D tax liability is reported to the IRS for a particular calendar quarter, 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. The correction of a mathematical or clerical error, or the use of corrected data from the same historical period used to originally identify the applicable sales, does not alone constitute the recalculation of a section 5000D tax liability using a different method.

(b) *Calculation of tax*—(1) *In general.* (i) For any applicable sale of units of a designated drug during a day described in section 5000D(b), the amount of the section 5000D tax is the amount such that the applicable percentage is equal to the ratio of such tax divided by the sum of such tax and the price of such applicable sale expressed as a percentage. This ratio may be expressed as follows:

Equation 1 to Paragraph (b)(1)(i)

Applicable Percentage = Tax/(Tax + Price)

(ii) See paragraph (b)(2) of this section for rules relating to the effect of certain invoicing methods on the determination of price.

(2) *Charging tax as line item; effect on price*—(i) *Presumption if no separate charge for tax is made.* If no separate charge is made for the section 5000D tax on the invoice or similar document pertaining to an applicable sale, the amount charged for units of the designated drug is presumed to include both the proper amount of section 5000D tax and the price. In such cases, the price excludes the portion of the

amount charged allocable to the section 5000D tax so charged, and no section 5000D tax is due on the amount of section 5000D tax so charged.

(ii) *Separately charged tax not part of price.* If the section 5000D tax is separately charged on the invoice or similar document pertaining to an applicable sale, the section 5000D tax so charged is not included in the price. Thus, if a manufacturer, producer, or importer calculates the section 5000D tax and charges it as a separate item on the invoice or similar document pertaining to an applicable sale, the amount of section 5000D tax so charged is not included in the price for purposes of calculating the section 5000D tax under paragraph (b)(1) of this section, and no section 5000D tax is due on the amount of section 5000D tax so charged.

(3) *Example*—(i) *Facts.* Manufacturer X is the manufacturer, producer, or importer of 409,000 units of Designated Drug H (that is, it makes the first sale of those units). During a day described in section 5000D(b), and no more than 90 days since the first such day, Manufacturer X sells 100,000 units of Designated Drug H to Wholesaler A at $1.00 per unit, 300,000 units of Designated Drug H to Wholesaler B at $0.90 per unit, and 9,000 units of Designated Drug H to Wholesaler C at $1.12 per unit. Manufacturer X has reasonably determined that the applicable sale consists of 35 percent of the units of Designated Drug H in each such sale. Manufacturer X has not separately invoiced any section 5000D tax to Wholesalers A, B, or C.

(ii) *Analysis*—(A) *In general.* To calculate its section 5000D tax liability with respect to its sales of Designated Drug H to Wholesalers A, B, and C, Manufacturer X must aggregate its section 5000D tax liability for the applicable sales by applying the presumption described in paragraph (b)(2)(i) of this section.

(B) *Step 1.* Manufacturer X begins by determining the applicable sales within each of the sales described in paragraph (b)(3)(i) of this section. The applicable sale within the sale to Wholesaler A is 35,000 units (100,000 units × 0.35). The applicable sale within the sale to Wholesaler B is 105,000 units (300,000 units × 0.35). And the applicable sale within the sale to Wholesaler C is 3,150 units (9,000 units × 0.35).

(C) *Step 2.* Next, Manufacturer X determines the amount charged for the applicable sales. The amount charged for the applicable sale to Wholesaler A is $35,000.00 (35,000 units × $1.00 per unit). The amount charged for the applicable sale to Wholesaler B is $94,500.00 (105,000 units × $0.90 per unit). And the amount charged for the applicable sale to Wholesaler C is $3,528.00 (3,150 units × $1.12 per unit).

(D) *Step 3.* Manufacturer X then determines the correct tax and price with respect to each amount charged for the applicable sales under the presumption provided in paragraph (b)(3)(i) of this section. Of the $35,000.00 Manufacturer X charged for the applicable sale to Wholesaler A (35,000 of 100,000 units), Manufacturer X allocates $22,750.00 to the section 5000D tax and $12,250.00 to the price ($22,750.00/($22,750.00 + $12,250.00) = 0.65). Of the $94,500.00 Manufacturer X charged for the applicable sale to Wholesaler B (105,000 of 300,000 units), Manufacturer X allocates $61,425.00 to the section 5000D tax and $33,075.00 to the price ($61,425.00/($61,425.00 + $33,075.00) = 0.65). And of the $3,528.00 Manufacturer X charged for the applicable sale to Wholesaler C (3,150 of 9,000 units), Manufacturer X allocates $2,293.20 to the section 5000D tax and $1,234.80 to the price ($2,293.20/($2,293.20 + $1,234.80) = 0.65).

(E) *Step 4.* Manufacturer X's section 5000D tax liability for the applicable sales is $86,468.20 ($22,750.00 + $61,425.00 + $2,293.20 = $86,468.20). This amount, when divided by the sum of the tax and the price of the applicable sales, equals 65 percent ($86,468.20/($86,468.20 + $46,559.80) = 0.65).

(c) *Anti-abuse rule.* If a manufacturer, producer, or importer engages in any transaction (or series of transactions) with a principal purpose of avoiding the section 5000D tax or substantially reducing the purported price at which a sale is made, including transactions made other than at arm's length, such transaction (or series of transactions) may be adjusted, recharacterized, or otherwise recast by the Secretary for purposes of determining the correct section 5000D tax liability. Whether a transaction (or series of transactions) has a principal purpose of avoiding the section 5000D tax or substantially reducing the purported price of an applicable sale is determined based on all of the facts and circumstances, including, but not limited to, a comparison of the purported business purpose for, and the section 5000D tax consequences of, the transaction (or series of transactions).

(d) *Severability.* The provisions of this section are separate and severable from one another and any other section of this part. If any provision of this section is stayed or determined to be invalid, it is the intention of the Department of the Treasury and Internal Revenue Service that the remaining provisions and sections of this part shall continue in effect.

(e) *Applicability date.* This section applies to sales of designated drugs on or after [date of publication of final regulations in the **Federal Register**].

Douglas W. O'Donnell,

Deputy Commissioner.

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DEPARTMENT OF JUSTICE

28 CFR Part 5

[Docket No. NSD 102; AG Order No. 6121–2024]

RIN 1124–AA00

Amending and Clarifying Foreign Agents Registration Act Regulations

AGENCY: Office of the Attorney General, Department of Justice.

ACTION: Proposed rule; request for comments.

SUMMARY: The Department of Justice (''DOJ,'' ''the Department'') is proposing amendments and other clarifications to the scope of certain exemptions, to update and add various definitions, and to make other modernizing changes to the Attorney General's Foreign Agents Registration Act (''FARA'') implementing regulations.

DATES: Electronic comments must be submitted and paper comments must be postmarked or otherwise indicate a shipping date on or before March 3, 2025. Paper comments postmarked on or before that date will be considered timely. The electronic Federal Docket Management System at *https://www.regulations.gov* will accept electronic comments until 11:59 p.m. Eastern Time on that date.

ADDRESSES: If you wish to provide comments regarding this rulemaking, you must submit comments, identified by the agency name and reference RIN 1124–AA00 or Docket No. NSD 102, by one of the two methods below:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail/Commercial Courier:* Jennifer Kennedy Gellie, Chief, Counterintelligence and Export Control Section, National Security Division, U.S. Department of Justice, FARA Unit, 175 N Street NE, Constitution Square, Building 3—Room 1.100, Washington, DC 20002.

Instructions: All submissions received must include the agency name and docket number or Regulatory