

Part III - Administrative, Procedural, and Miscellaneous

Section 5000D Excise Tax on Sales of Designated Drugs; Reporting and Payment of the Tax

Notice 2023-52

SECTION 1. PURPOSE

This notice announces that the Department of the Treasury (Treasury Department) and the Internal Revenue Service (IRS) intend to propose regulations (forthcoming proposed regulations) addressing § 5000D of the Internal Revenue Code (Code), including how taxpayers would report and pay the excise tax imposed by § 5000D (§ 5000D tax).¹

SECTION 2. BACKGROUND

.01 Sections 1191 through 1198 of the Social Security Act (SSA), added by §§ 11001 and 11002 of Public Law 117-169, 136 Stat. 1818 (August 16, 2022), commonly referred to as the Inflation Reduction Act of 2022 (IRA), require the Secretary of Health and Human Services to establish a Medicare prescription drug price negotiation program (Program) to negotiate maximum fair prices (MFPs) for certain high expenditure, single-source drugs covered under Medicare. Under the Program, the

¹ Unless otherwise specified, all “section” or “§” references are to sections of the Code or the Excise Tax Procedural Regulations (26 CFR part 40).

Secretary of Health and Human Services must, among other things: (1) publish a list of selected drugs in accordance with § 1192 of the SSA; (2) enter into agreements with willing manufacturers of selected drugs in accordance with § 1193 of the SSA; and (3) negotiate MFPs for such selected drugs in accordance with § 1194 of the SSA. Under § 1193(a)(3) of the SSA, manufacturers of selected drugs that choose to enter into agreements with the Secretary of Health and Human Services and that agree to an MFP commit to provide access to selected drugs at the negotiated prices to MFP-eligible individuals (as defined in § 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 such individuals.

.02 Section 5000D, added to the Code by § 11003 of the IRA, imposes the § 5000D tax on the sale by the manufacturer, producer, or importer (manufacturer or taxpayer) of any designated drug² during a day that falls within a period described in § 5000D(b) (statutory period). The amount of § 5000D tax imposed on such a manufacturer equals the amount that causes the ratio of (1) the § 5000D tax, divided by (2) the sum of the § 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.” Section 5000D(a).

.03 Section 5000D(d) defines the term “applicable percentage” as follows: (1) in the case of sales of a designated drug during the first 90 days in a statutory period with respect to such drug, 65 percent; (2) in the case of sales of such drug during the 91st day through the 180th day in a statutory period with respect to such drug, 75 percent;

² The term “designated drug” means any negotiation-eligible drug (as defined in § 1192(d) of the SSA) included on the list published under § 1192(a) of the SSA that is manufactured or produced in the United States or entered into the United States for consumption, use, or warehousing. See § 5000D(e)(1).

(3) in the case of sales of such drug during the 181st day through the 270th day in a statutory period with respect to such drug, 85 percent; and (4) in the case of sales of such drug during any subsequent day in a statutory period, 95 percent.

SECTION 3. GUIDANCE TO BE ISSUED

.01 Scope of taxable sales. The Treasury Department and the IRS intend that, under the forthcoming proposed regulations, the § 5000D tax would be imposed on taxpayer sales of designated drugs dispensed, furnished, or administered to individuals under the terms of Medicare. The Treasury Department and the IRS intend that the forthcoming proposed regulations will also propose a method for taxpayers to calculate their § 5000D liability.

.02 Separately charged tax not part of price; presumption where no separate charge for tax is made. The Treasury Department and the IRS intend that the forthcoming proposed regulations will propose a rule providing that when the § 5000D tax is separately charged on the invoice or records pertaining to the sale of a designated drug by the manufacturer, the tax is not part of the price of the designated drug. Thus, if a manufacturer computes the § 5000D tax and charges it as a separate item on the invoice or records pertaining to the sale in addition to the stated sale price, the amount of § 5000D tax so charged does not become part of the price and no § 5000D tax is due on the amount of § 5000D tax so charged. When no separate charge is made as to the § 5000D tax on the invoice or records pertaining to the sale of a designated drug, it will be presumed that the amount charged for the designated drug includes the proper amount of § 5000D tax and the price of the designated drug; therefore, the amount charged will be allocated between the amount of the § 5000D tax and the price. For

example, if a manufacturer charges a purchaser \$100 for a designated drug during the first 90 days in a statutory period and does not make a separate charge for the § 5000D tax, \$65 is allocated to the § 5000D tax and \$35 is allocated to the price of the designated drug. This example only illustrates the presumption in section 3.02 of this notice; it does not illustrate other concepts described in this notice.

.03 Procedural rules. The Treasury Department and the IRS intend that the forthcoming proposed regulations will propose applying the Excise Tax Procedural Regulations in 26 CFR part 40 (Excise Tax Procedural Regulations) generally to chapter 50A of the Code (and thus to § 5000D), with some limited exceptions. In particular, the Treasury Department and the IRS intend to propose that the Excise Tax Procedural Regulations will apply to chapter 50A of the Code as follows:

(1) Returns: § 40.6011(a)-1(a)(1). The Treasury Department and the IRS intend to propose that taxpayers would be required to report any § 5000D tax liability on IRS Form 720, *Quarterly Federal Excise Tax Return*, according to the instructions applicable to the form. The IRS also intends to issue a new form that taxpayers would be required to attach to Form 720 to compute any § 5000D tax liability and report the § 5000D tax.

(2) Time for filing returns: § 40.6071(a)-1(a). The Treasury Department and the IRS intend to propose that the deadline for filing quarterly returns on Form 720 to report any § 5000D tax liability would be the last day of the first calendar month following the quarter of a calendar year (calendar quarter) for which the return is made. Therefore, taxpayers would be required to file a Form 720 reporting any § 5000D tax liability arising in a calendar quarter as follows:

Calendar Quarter Covered by Form 720	Due Date for Form 720 Would Be³
1st calendar quarter (Jan., Feb., Mar.)	April 30 of same calendar year
2nd calendar quarter (Apr., May, June)	July 31 of same calendar year
3rd calendar quarter (July, Aug., Sept.)	October 31 of same calendar year
4th calendar quarter (Oct., Nov., Dec.)	January 31 of following calendar year

(3) No semimonthly deposits. The Treasury Department and the IRS intend that the forthcoming proposed regulations would not apply § 40.6302(c)-1(a)(1) or any of the other semimonthly deposit rules in the Excise Tax Procedural Regulations to chapter 50A of the Code. Therefore, taxpayers liable for the § 5000D tax would not be required to make semimonthly deposits of § 5000D tax.

(4) Payment of tax: § 40.6151(a)-1. The Treasury Department and the IRS intend to propose that the deadline for payment of the § 5000D tax would be the same as the filing deadline for Form 720. Taxpayers liable for the § 5000D tax would, therefore, be required to pay the § 5000D tax when they file the Form 720 for the calendar quarter during which the § 5000D liability arose. See § 40.6071(a)-1(a).

SECTION 4. RELIANCE

Until the Treasury Department and the IRS issue further guidance, taxpayers may rely on section 3 of this notice.

SECTION 5. DRAFTING INFORMATION

This notice was authored by the Office of the Associate Chief Counsel (Passthroughs & Special Industries). For further information regarding this notice, contact Passthroughs & Special Industries at (202) 317-6855 (not a toll-free call).

³ If any due date for filing Form 720 falls on a Saturday, Sunday, or legal holiday, the Form 720 would be due on the next business day. See § 301.7503-1 of the Procedure and Administration Regulations (26 CFR part 301).