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Preparation for New Excise Tax on Prescription Drugs Sold to Medicare and Medicaid Has Already Begun, Absent Substantive IRS Regulations, Because of Mandatory Price Negotiations

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Manufacturers and importers of specified drugs that are sold to Medicare and Medicaid are preparing to mitigate the punitive nature of a new excise tax.

A punitive excise tax, imposed by section 5000D of the Internal Revenue Code[1] on manufacturers and importers of specified drugs that are sold to Medicare and Medicaid, was enacted as part of the Prescription Drug Pricing Reform program ("Program") in Subtitle B of the Inflation Reduction Act.[2] Because the excise tax is only imposed if the requirements of the Program are not met, it incentivizes drug manufacturers to negotiate "maximum fair prices" for drugs identified by the Secretary of Health and Human Services that meet certain thresholds for government and individual spending. Thus, despite the January 1, 2026 effective date of the "maximum fair prices," manufacturers have begun modeling potential financial and portfolio effects of the Program, strategizing business implications for marketing, research and development, and identifying ways to mitigate the tax. Treasury and the IRS have issued preliminary guidance, including proposed regulations that are solely procedural in nature[3] and Notice 2023-52 (the "Notice") that introduced a presumption applicable to the tax calculation.[4]

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1 Unless otherwise indicated, section references are to the Internal Revenue Code of 1986, as amended (the "Code") or the applicable regulations promulgated pursuant to the Code (the "regulations").

2 To provide for reconciliation pursuant to title II of S. Con. Res. 14, Pub. L. No. 117-169, 136 Stat. 1818 (Aug. 16, 2022) (commonly called the "Inflation Reduction Act").

3 REG-115559-23, 88 Fed. Reg. 67690 (Oct. 2, 2023); Notice 2023-52, 2023-35 I.R.B. 650.

4 Notice 2023-52, 2023-35 I.R.B. 650.

Background

On August 16, 2022, the Inflation Reduction Act ("IRA") was signed into law.[5] Subtitle B of the IRA, entitled "Prescription Drug Pricing Reform," amended Title XI of the Social Security Act ("SSA")[6] and established a new program requiring the Secretary of the Department of Health and Human Services ("HHS") to negotiate the price of certain high-priced single source drugs that do not have generic or biosimilar competition ("designated drug").[7] The IRA generally requires HHS to periodically publish a list of drugs selected for negotiation, enter into negotiation agreements with the manufacturers of those drugs, and negotiate a maximum fair price ("MFP") for each drug.[8] The first year that MFPs will apply is 2026.[9]

HHS and the Center for Medicare and Medicaid Services ("CMS") selected the first ten drugs and published the list on August 28, 2023.[10] Upon selection, each drug's manufacturer was required to enter into an agreement to negotiate with CMS by October 1, 2023, for a negotiation period that will last until August 1, 2024.[11] All manufacturers have chosen to engage in negotiation.[12]

Several lawsuits have been filed by affected manufacturers and other stakeholders. These lawsuits generally question the classification of the Program as a "negotiation" and challenge its constitutionality under the First, Fifth, and Eight Amendments to the U.S. Constitution.[13]

Calculating the Section 5000D Excise Tax

To incentivize participation in the Program, the IRA added a corresponding excise tax, imposed on the manufacturer or importer's sale of any designated drug during a "noncompliance period."[14] There are four possible noncompliance periods each year, relating to the manufacturer's:

- Failure to timely enter into negotiation with CMS
- Failure to timely agree to MFP with CMS
- Failure to provide all information requested by CMS
- Sale of designated drug timed for the purpose of avoiding tax[15]

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5 136 Stat. 1818.

6 *Id.* at 1833.

7 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 or entered into the United States for consumption, use or warehousing. I.R.C. § 5000D(e)(1).

8 SSA § 1191, 42 USC 1320f(a).

9 SSA § 1191(b)(1), 42 USC 1320f(b)(1).

10 The selected drugs are: Eliquis, Jardiance, Xarelto, Januvia, Farxiga, Entresto, Enbrel, Imbruvica, Stelara, Fiasp and Novolog. HHS, Press Release, https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html.

11 SSA § 1191(a)(2), 42 USC 1320f(a)(2); SSA § 1193(a), 42 USC 1320f-2(a); SSA § 1191(d)(5)(C), 42 USC 1320f(d)(5)(C).

12 HHS, Press Release, https://www.hhs.gov/about/news/2023/10/03/biden-harris-administration-moves-medicare-drug-price-negotiations-lower-prescription-drug-costs-people-medicare.html.

13 *See* Merck v. Becerra, No. 1:23-cv-01615 (D.D.C. filed June 6, 2023); Nat'l Infusion Ctr. Ass'n v. Becerra, No. 1:23-cv-00707 (W.D. Tex. filed June 21, 2023); Bristol Myers Squibb Co. v. Becerra, No. 3:23-cv-03335 (D.N.J. filed June 16, 2023); Dayton Area Chamber of Commerce v. Becerra, No. 3:23-cv-00156 (S.D. Ohio filed June 9, 2023); Janssen Pharmaceuticals, Inc. v. Becerra, No. 3:23-cv-03818 (D.N.J. filed July 18, 2023).

14 P.L. 117-169 § 1103, 136 Stat. 1833, 1862 (adding Chapter 50A to the Code).

15 I.R.C. § 5000D(f)(2).

The excise tax is computed on the sale price of the drug, by first determining the applicable percentage. The applicable percentages increase for each additional calendar quarter of noncompliance as follows:[16]

Days in a Noncompliance Period	Applicable Percentage
First 90 days	65
Days 91 – 180	75
Days 181 – 270	85
Day 271 and later	95

The excise tax is equal to the amount that causes the ratio of the tax divided by the sum of the tax and the price for which the drug was sold to equal the applicable percentage.[17] Notice 2023-52 presumes that the tax is embedded into the price of the designated drug when the tax is not separately stated on the invoice or records pertaining to the sale.[18] The example provided in the Notice is as follows:

> *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.*[19]

By extension, if a manufacturer charged a purchaser $100 for a designated drug on day 271 or later, and did not make a separate charge relating to the section 5000D excise tax, $95 would be allocated to tax and $5 to price.

Unspecified in IRS guidance is the application of tax if it is shown as a separate line item on the invoice to the purchaser. The example in the Notice illustrates the presumption that tax is not separately stated. However, if tax is separately stated, the plain application of the statute seems to generate an extraordinarily punitive result. For example, if a manufacturer charged a purchaser $100 for a designated drug during the first 90 days in a noncompliance period and separately stated the tax, the manufacturer would compute the tax as follows:

> X [tax] / (X [tax] + 100 [price of drug]) = .65 [applicable percentage] or X = $185.7

Therefore, on an invoice that separately states the excise tax, during the first 90 days of noncompliance, each sale of the designated drug for $100 would be subject to tax in the amount of $185.70. For any sale of the same designated drug on day 271 or later, the tax would be a whopping $1,900 per $100 sale.

Thus, manufacturers are incentivized to limit time spent in noncompliance because the applicable percentage increases the longer the noncompliance period lasts. In addition, the presumption in the Notice appears to disincentivize separately stating the tax or passing on the economic burden of the tax to the customer. However, the tax generally does not apply to drugs that are not sold to Medicare or Medicaid,[20] or to any sale of a designated drug that is exported.[21]

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16 I.R.C. § 5000D(d).

17 I.R.C. § 5000D(a).

18 Notice 2023-52, § 3.02.

19 *Id.*

20 I.R.C. § 5000D(c)

21 I.R.C. § 5000D(g).

IRS Guidance and Proposed Regulations

To date, Treasury and the IRS have issued limited published guidance. First, Notice 2023-52 provides that the IRS will issue proposed regulations[22] that will:

- Provide that the section 5000D tax is imposed on sales of designated drugs dispensed, furnished, or administered to individuals under the terms of Medicare
- Provide a proposed method for taxpayers to compute the tax
- Include a rule providing that when the tax is separately charged on the invoice (or records pertaining to the sale of a designated drug) by the manufacturer, the separately stated tax is not part of the price of the drug; however, when no separate charge is made as to the tax on the invoice (or records pertaining to the sale of a designated drug), the IRS will presume that the amount charged includes the proper amount of tax and will allocate accordingly
- Provide that the Excise Tax Procedural Regulations in 26 CFR part 40 will generally apply with respect to return filing and other procedural aspects:
  - Form 720, *Quarterly Federal Excise Tax Return*, will be used to report the tax
  - A new form will be attached to Form 720 to compute liability
  - The deadline for filing Form 720 will be the last day of the first calendar month following the calendar quarter of the return[23]
  - The due date for the tax imposed is the Form 720 due date
  - The deposit rules will not apply, so taxpayers can expect that semimonthly deposits will not be required

Second, proposed regulations were issued October 2, 2023.[24] These proposed regulations solely address the return filing and other procedural aspects outlined in Notice 2023-52. The proposed regulations state that Treasury and the IRS will release a separate notice of proposed rulemaking to tackle the substantive issues associated with the section 5000D tax.[25]

Conclusion

HHS, CMS, Treasury, and the IRS appear poised and ready to enforce the Program and its associated excise tax. Thus, absent substantive regulations, preparation for the section 5000D has begun to mitigate the punitive nature of the tax. MFPs for the first ten drugs will be published no later than January 1, 2026. The next tranche of designated drugs will be published no later than February 1, 2025. The cycle of identifying designated drugs and negotiating MFPs will continue for future years. Affected manufacturers and importers continue to keep an eye out for substantive regulations.

Actions to prepare for the selection of a drug as a designated drug subject to negotiation with CMS include modeling potential financial and portfolio effects of the Program, strategizing business implications for marketing, research and development, and identifying ways to mitigate the tax.

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22 Notice 2023-52, § 3.

23 For example, for Forms 720 reporting section 5000D tax relating to the first quarter of a tax year (i.e., January, February, and March), the due date of the Form 720 would be April 30 of the same year. If any due date for filing Form 720 falls on a Saturday, Sunday, or legal holiday, the Form 720 is due on the next business day. *See* Treas. Reg. § 301.7503-1.

24 REG-115559-23, 88 Fed. Reg. 67690 (Oct. 2, 2023).

25 88 Fed. Reg. at 67691.

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