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There’s One for You, Nineteen for Me: IRS Issues Guidance on 1900% Pharmaceutical Excise Tax

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The Internal Revenue Service (IRS) has issued guidance on the pharmaceutical excise tax that may apply to certain drug manufacturers, producers, and importers that fail to negotiate a drug-pricing agreement with the US Secretary of Health and Human Services.

The Inflation Reduction Act of 2022 (**IRA**) enacted a new excise tax on sales by drug manufacturers, producers, and importers of designated drugs during the period that such manufacturer, producer, or importer fails to negotiate a drug-pricing agreement with the Secretary of the US Department of Health and Human Services (**HHS**) under which Medicare Part D plans would otherwise reimburse for the designated drug at a Maximum Fair Price (**MFP**) (*i.e.*, the noncompliance period).

Each year, HHS will publish the list of drugs (*i.e.*, designated drugs) that are subject to these rules*.* HHS’s first published list, available at Factsheet: Medicare Drug Price Negotiation Program (cms.gov), includes designated drugs targeted for MFP negotiation beginning in 2026. Although the excise tax is effective with respect to sales after August 16, 2022, it only practically applies during a noncompliance period, which will not occur before October 2, 2026. The excise tax has been criticized and challenged as unconstitutional in various lawsuits including by the National Infusion Center Association, Global Colon Cancer Association, and Pharmaceutical Research and Manufacturers of America in a lawsuit filed earlier this year, and we expect that this will continue to be a hot topic issue in the coming months and years.

The applicable statute describes the excise tax using a gross-up formula, where the tax is equal to the amount that will cause the applicable percentage to equal the amount set forth below, as of the time of sale for the drug:

$$Applicable\ Percentage = \frac{Tax}{Tax + Price\ of\ Drug}$$

This formula can be restated mathematically to solve for the amount of tax, as follows:

$$Tax = \frac{Price\ of\ Drug\ \times Applicable\ Percentage}{1 - Applicable\ Percentage}$$

For manufacturers, producers, or importers that have not entered into a drug-pricing agreement with the HHS Secretary, the applicable percentage will start at 65% and increase to up to 95% depending on the length of the noncompliance period, as set forth in the table below. The table below also illustrates how the tax would apply at various levels of applicable percentages.

NONCOMPLIANCE PERIOD	APPLICABLE PERCENTAGE	TAX IMPOSED (PER $100 PRICE OF DRUG)	TAX RATES AS A PERCENTAGE OF PRICE OF DRUG
Days 0 - 90	65%	$186	186%
Days 91 - 180	75%	$300	300%
Days 181 - 270	85%	$567	567%
Days 270 +	95%	$1900	1900%

On August 7, 2023, the US Department of the Treasury and the IRS issued Notice 2023-52, which provides certain guidance which taxpayers can rely on until further guidance (*e.g.*, proposed regulations) is issued. First, the Notice provides that the excise tax is imposed on taxpayer sales of designated drugs dispensed, furnished, or administered to individuals under the terms of Medicare.

Second, the Notice specifies that when the excise tax is separately charged on the invoice or records pertaining to the sale of such drug by the manufacturer, producer, or importer, the excise tax is *not* part of the price of the drug. This clarification avoids a double counting that might otherwise apply. Alternatively, if the excise tax is not separately charged on the invoice or records pertaining to the sale of a drug, it will be presumed that the amount charged for such drug includes the proper amount of excise tax and the price of the drug; therefore, the amount charged will be allocated between the amount of the excise tax and the price of the drug (*e.g.*, if a manufacturer charges a purchaser $100 for a designated drug during the first 90 days in a noncompliance period and does not make a separate charge for the excise tax, $65 is allocated to the excise tax and $35 is allocated to the price of the drug).

Third, the Notice describes certain procedural rules to help taxpayers meet their reporting and payment obligations with respect to the excise tax. Specifically, the IRS intends to issue a new form to compute and report the excise tax, which would be attached to Form 720, *Quarterly Excise Tax Return*. Such return (and payment of any such excise tax) is due on the last day of the first calendar month following the calendar quarter for which the return is made (*e.g.*, the return and payment with respect to the first quarter of a year would be April 30 of the same calendar year). Additionally, no semi-monthly deposits are required with respect to such excise tax.

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