November 30, 2023

Douglas W. O'Donnell, Deputy Commissioner for Services and Enforcement
Internal Revenue Service
CC:PA:LPD:PR (REG–115559–23), Room 5203
P.O. Box 7604, Ben Franklin Station
Washington, DC 20044

Re: IRS REG-115559-23

Dear Deputy Commissioner O'Donnell,

Arnold Ventures welcomes the opportunity to provide comments to the Internal Revenue Service (IRS) and the Treasury Department on the following notice of proposed rulemaking issued on October 2, 2023:

- *Excise Tax on Designated drugs; Procedural Requirements*.

Arnold Ventures is a philanthropy dedicated to investing in evidence-based policy solutions that maximize opportunity and minimize injustice. Our work within the health care sector is driven by the recognition that the system costs too much and fails to adequately care for the people it serves. Our work spans a range of issues including commercial-sector prices, provider payment incentives, prescription drug prices, clinical trials, Medicare sustainability, and complex care.

We thank you for this opportunity to provide comments on the procedures for implementing the excise tax under the drug price negotiation provisions of the Inflation Reduction Act.

Overview

Manufacturers of brand-name drugs that are selected for negotiation are penalized if they do not participate in the negotiation program. One such penalty is paying an excise tax on the sales of the selected drug to Medicare. Another is withdrawing the manufacturer's entire product line from Medicare and Medicaid coverage.[1] Of note, manufacturers choose which penalty to accept in the event they decide not to participate in the negotiation program.

During the negotiation process, if the manufacturer fails to take the following actions by a specific deadline, then they would enter a period of noncompliance. These actions include (i) entering into an agreement with the Secretary of HHS to negotiate the price of a selected drug, (ii) reaching an agreement with the Secretary on the negotiated price (known as the Maximum Fair Price), and (iii) providing certain information to the Secretary that supports the negotiation process.

If a manufacturer enters a period of noncompliance and they do not decide to withdraw their entire product line from Medicare and Medicaid coverage as mentioned above, they are subject to the excise tax. During periods of noncompliance, the excise tax starts at 65 percent of Medicare sales and reaches 95 percent after 270 days or more of noncompliance.

[1] A third alternative available to the manufacturer is to divest itself of the drug selected for negotiations. The entity which purchases the selected drug would be required to participate in the drug price negotiation program—or face the penalties discussed above.

This letter addresses the following aspects of the implementation of the excise tax: (1) Enhancing Data Quality and Timely Reporting of the Excise Tax, and (2) Excise Tax Enforcement Mechanisms.

1. **Enhancing Data Quality and Timely Reporting of the Excise Tax**

The Treasury and the IRS have indicated that the excise tax will be paid quarterly based on sales to Medicare of the drug that was selected for negotiation. [2] However, manufacturers do not have immediate access to data on the quantity of their drugs that are sold to Medicare beneficiaries. That is because when a manufacturer sells its drug to intermediaries (e.g. wholesalers, pharmacies) it does not know the share of those sales that will ultimately be paid for by Medicare. Manufacturers would need to work with actors in the supply chain such as pharmacy benefit managers, Part D plans, and wholesalers to accurately track drugs that are ultimately paid for by Medicare. However, the Center for Medicare and Medicaid Services (CMS) has access to more timely and accurate data on Medicare drug sales that could be useful to manufacturers that choose to pay the excise tax.

To facilitate accurate and timely estimates of the excise tax and help ease any reporting burden on manufacturers, Arnold Ventures recommends that:

(i) CMS provides affected manufacturers with data on quarterly Medicare sales to support manufacturers' efforts to estimate the amount of excise taxes owed.

(ii) The Treasury Department and the IRS propose methods that manufacturers can use to estimate the excise tax for a given quarter. This could include methods that rely on Medicare sales data from previous quarters to estimate the excise tax amount owed.

The process for manufacturers to meet the reporting requirements, estimate their excise taxes, and pay these amounts on a quarterly basis in a timely manner should not be burdensome or difficult. Further, a process is already in place for manufacturers to update their estimates of the excise tax amount as additional data become available.[3]

Excise Tax Enforcement Mechanisms

Arnold Ventures recommends that CMS publish a list of drugs where an excise tax is owed as well as the amounts paid by Medicare for those drugs in the last calendar year. This will facilitate enforcement of the tax by the IRS. If the excise tax is not properly estimated, reported, and paid, there are civil penalties that can be imposed by the IRS following an audit.

Conclusion

Arnold Ventures is prepared to assist with any additional information needed. Comments were prepared by Anna Anderson-Cook Ph.D. and Erin Jones, Health Care Manager at Arnold Ventures with assistance from Andrea Noda, MPP, Vice President of Health Care at Arnold Ventures and Mark E. Miller, Ph.D. Executive Vice President of Health Care at Arnold Ventures.

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[2] IRS and Treasury Notice 2023-52 *Section 5000D Excise Tax on Sales of Designated Drugs; Reporting and Payment of the Tax* The excise tax must be paid to the IRS within one month after the end of the calendar quarter.

[3] Manufacturers can file form 720X to adjust their excise tax payments for prior quarters.

Please contact Andrea Noda at anoda@arnoldventures.org or Mark E. Miller, Ph.D. at mmiller@arnoldventures.org with any questions.

Sincerely,

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Vice President of Health Care
Arnold Ventures

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