



# TaxNewsFlash

United States

No. 2024-496  
December 31, 2024

## Proposed regulations and Rev. Proc. 2025-9: Excise tax under section 5000D on designated drugs

The U.S. Treasury Department and IRS today released [proposed regulations](#) (REG-115560-23) relating to the excise tax imposed under section 5000D (introduced by the “Inflation Reduction Act of 2022” (IRA)) on sales of “designated drugs” during a “statutory period” with respect to such drugs, by manufacturers, producers, and importers on and after August 16, 2022.

The term “designated drug” means any negotiation-eligible drug (as defined in section 1192(d) of the Social Security Act (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.

The proposed regulations adopt rules consistent with the substantive rules described in Notice 2023–52, which the Treasury Department and IRS issued in August 2023 to provide interim guidance on the excise tax imposed under section 5000D.

The Treasury Department and IRS also issued final regulations (T.D. 10003) in July 2024 providing guidance on how taxpayers must report liability for the excise tax imposed under section 5000D, which are effective as of August 5, 2024. Read [TaxNewsFlash](#)

The proposed regulations are proposed to apply to tax years beginning on or after the date of the proposed regulations are finalized, but taxpayers may continue to rely on sections 3.01 and 3.02 of Notice 2023-52 until that date.

Comments on the proposed regulations and requests for a public hearing are due by the date that is 60 days after the proposed regulations are published in the Federal Register, which is scheduled to be January 2, 2025.

### Rev. Proc. 2025-9

The Treasury Department and the IRS today also released [Rev. Proc. 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.

Rev. Proc. 2025-9 is effective for returns filed on or after December 31, 2024.

[kpmg.com/socialmedia](https://kpmg.com/socialmedia)



The information contained in TaxNewsFlash is not intended to be "written advice concerning one or more Federal tax matters" subject to the requirements of section 10.37(a)(2) of Treasury Department Circular 230, as the content of this document is issued for general informational purposes only, is intended to enhance the reader's knowledge on the matters addressed therein, and is not intended to address the circumstances of any particular individual or entity. Although we endeavor to provide accurate and timely information, there can be no guarantee that such information is accurate as of the date it is received or that it will continue to be accurate in the future. No one should act on such information without appropriate professional advice after a thorough examination of the particular situation.

The KPMG name and logo are trademarks used under license by the independent member firms of the KPMG global organization.

KPMG International Limited is a private English company limited by guarantee and does not provide services to clients. No member firm has any authority to obligate or bind KPMG International or any other member firm vis-à-vis third parties, nor does KPMG International have any such authority to obligate or bind any member firm.

Direct comments, including requests for subscriptions, to [Washington National Tax](#). For more information, contact KPMG's Federal Tax Legislative and Regulatory Services Group at +1 202.533 3712, 1801 K Street NW, Washington, DC 20006-1301.

To unsubscribe from TaxNewsFlash, reply to [Washington National Tax](#).

[Privacy](#) | [Legal](#)