

TaxNewsFlash

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Proposed regulations: Amendments to branded prescription drug annual fee regulations

The U.S. Treasury Department and IRS today issued [proposed regulations](#) (REG-103430-24) that would amend the regulations relating to the annual fee imposed under section 9008 of the Patient Protection and Affordable Care Act (ACA), as amended, on covered entities engaged in the business of manufacturing or importing certain branded prescription drugs.

In particular, in response to the replacement of the Coverage Gap Discount Program with the new Manufacturer Discount Program under the Inflation Reduction Act of 2022 (IRA), the proposed regulations would amend the branded prescription drug annual fee regulations to update the discounts, rebates, and other price concessions used to determine branded prescription drug sales under Medicare Part D and to update the regulations for prior statutory changes.

Because the proposed regulations reflect statutory changes that took effect at the beginning of 2025, the proposed regulations are proposed to apply to fees calculated based on sales years beginning with calendar year 2025, which will also be sales years ending on or after the date the proposed regulations are filed in the Federal Register.

Comments on the proposed regulations and requests for a public hearing are due by the date that is 60 days after publication of the proposed regulations in the Federal Register, which is scheduled to be January 2, 2026.

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