



**Medicare Drug Inflation Rebates and
Drug Negotiation Programs
All Tribes Briefing**

May 17, 2023



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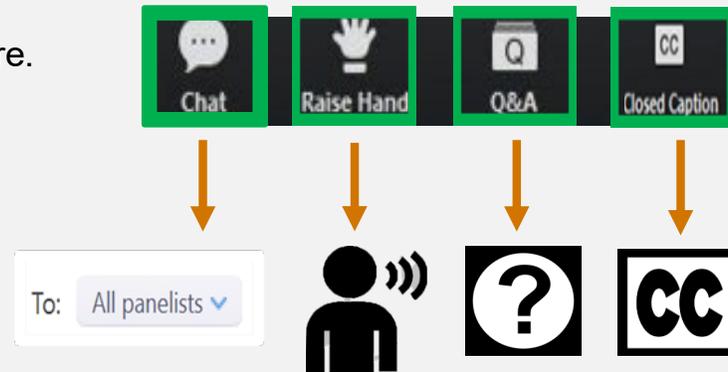
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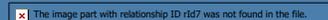
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Program Overview

- Under the Inflation Reduction Act (IRA) of 2022, Medicare has authority to negotiate with manufacturers for prices for certain Part B and Part D drug starting in 2026. In addition, through a separate program, Medicare can collect rebates from manufacturers if the prices of certain Part B and Part D drugs increase faster than the rate of inflation.
 - CMS issued [guidance](#) on the Part B and Part D Inflation Rebates on February 9, 2023, and solicited comment on key topics. CMS will issue revised guidance later in 2023.
 - CMS issued [guidance](#) on the Medicare Drug Price Negotiation Program on March 15, 2023, and solicited comment on key topics. CMS will issue revised guidance in Summer 2023.
- There are multiple places in the two programs that intersect with the 340B Drug Pricing Program.

IRA Timeline: Key Milestones

- **2022**
 - **October 1 - Part D Manufacturer Inflation Rebates began**
- **2023**
 - **January 1 – Part B Manufacturer Inflation Rebates began**
 - **April 1 - Part B Beneficiary Cost Sharing Reduction for Part B drugs whose payment limits increase faster than Inflation**
 - **September 1 – First set of 10 Part D Drugs Selected for Negotiation for 2026 year**
- **2025**
 - **CMS proposing to start billing manufacturers for Part B and Part D inflation rebates**
- **2026**
 - **January 1 – Maximum Fair Price (MFP) for first top 10 Part D drugs goes into effect**
- **2027**
 - **January 1- MFP for next top 15 Part D drugs goes into effect**
- **2028**
 - **January 1 – MFP for next top 15 Part B and Part D drugs goes into effect**

Inflation Rebates: Background

- Manufacturers of certain Part B and Part D drugs whose prices rise faster than the rate of inflation must pay back the difference to the Federal Supplementary Medical Insurance Trust Fund.
- Requires CMS to monitor drug prices during the applicable period, compare them to the benchmark price (adjusted for inflation), make adjustments in certain cases (e.g. shortages), and invoice manufacturers for the remaining difference.
- In each case, we are to identify and exclude 340B units from rebate billings (starting January 1, 2023 for Part B and January 1, 2026 for Part D). This is to avoid manufacturers paying a Medicare inflation rebate and a 340B discount on the same drug.

Overview: Medicare Part B Drug Inflation Rebates

- Rebates are calculated quarterly beginning January 1, 2023 and billed within 6 months of the end of each applicable period, based on the drug's utilization, and the manufacturer has 30 days to pay the rebates.
- For the first two years (January 2023-December 2024), CMS has until September 2025 to bill the manufacturer for rebates.
- **Units purchased under the 340B program are to be excluded from the rebate billings. CMS issued guidance at the end of 2022 on how this policy would be implemented for 340B hospitals and other providers**
- Beginning April 1, 2023, if the Medicare payment amount for a calendar quarter exceeds the inflation-adjusted payment amount, beneficiary coinsurance is equal to 20% of the inflation-adjusted payment amount.



Excluding 340B Units from Part B Drug Inflation Billings

- Requirement for all Medicare providers/suppliers (hospital and non hospital based) to use the 340B modifiers published in a separate program instruction; CMS will use enforcement discretion during 2023, but use of modifier will be a requirement in 2024.
 - <https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf>
- For 2023 only, CMS intends to remove units in all institutional claim lines that were billed with the “JG” or “TB” modifiers and also to exclude units for hospitals that were not required to report the modifiers during 2022 and claims submitted by practitioners/suppliers that are associated with 340B covered entities.
 - JG modifier: hospitals, clinics (e.g. Ryan White, Hemophilia Treatment Centers)
 - TB modifier: rural, children’s hospitals, PPS-exempt cancer hospitals

Overview: Medicare Part D Drug Inflation Rebates

- CMS bills manufacturers no later than 9 months after the end of each annual applicable period (October-September), based on the drug's utilization, and the manufacturer has 30 days to pay the rebates.
 - For the first two applicable periods (October 2022-September 2024), CMS has until December 2025 to bill the manufacturer for rebates.
 - 340B units are excluded from the Part D inflation rebate calculation beginning in 2026; CMS will need to determine a mechanism to accomplish this exclusion prior to 2026, and solicited comment in the initial guidance on whether a 340B modifier being included in the Prescription Drug Event (PDE) record of the claim would be the preferred mechanism.

Drug Negotiation: Background

- Requires CMS to establish a **Drug Price Negotiation Program** for negotiating (and re-negotiating) with drug manufacturers to establish "maximum fair prices" (MFPs) for Medicare Part B and Part D drugs selected for negotiation ("selected drugs.")
- Negotiated MFPs will apply for 10 Part D drugs beginning in the "initial price applicability year 2026." For 2027, 15 additional Part D drugs; 15 Part B and Part D drugs in 2028.
- CMS must develop and use a consistent methodology and process for negotiations to achieve the lowest MFPs for selected drugs.
- MFP is passed through to the beneficiary at the pharmacy, and is the basis of the beneficiary's Part D cost sharing amount.
- Statute has a non duplication provision which indicates that a manufacturer only has to provide the MFP or the ceiling price to Medicare-eligible individuals, which ever is lower.

Summary

- CMS must exclude 340B obtained units from Part B rebate billings (starting 1/1/23) and Part D rebate billings (starting 1/1/26)
 - We have issued guidance on use of a 340B modifier for Part B, and have received comments on the approach to exclude Part B 340B units and mechanisms to exclude Part D 340B units; further guidance is forthcoming by end 2023.
- CMS initial drug negotiation guidance indicates that a manufacturer should only pass through to an Medicare-eligible individual the lower of the MFP for a Part D drug or the 340B ceiling price, but there should be no “duplication”.

Questions

