CAPITOL STREET

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48 Meds Targeted for Inflationary Rebate Penalties

HHS Revises Guidance on CPI Rebates & Biden Touts March-In at NIH Today

Relevant Companies

Our Take & Next Up

Today, CMS released 48 new drugs that will be penalized for inflationary rebates. The list was accompanied by revised guidance for the IRA inflationary rebate program for Part B (here) and Part D (here). The newest list of drugs (48) of the 64 total in the past 4 quarters will be rebated in Part B and subject to lower copay percentages in Q1 2024. Notable additions are CAR-T (Kymriah, NVS) along with other immunology agents and generics. Separately, President Biden traveled to the National Institutes of Health in Bethesda MD today to tout new March-In rules, as the controversial guidance was released last week. Our take is here. HHS also released here characteristics of the Top ten for negotiation in 2026 (50 page reports). Overall, the administration is taking advantage of the quiet holiday season to highlight drug pricing "wins" as Presidential election season is already under way with Iowa caucuses on Jan 15, and Trump leading Biden in national polling.

Key Points

Now what? Manufacturers are invoiced for penalties in 2025. In total, prices of 64 drugs had increased faster than inflation over the last four quarters. Now (1) CMS will release a preliminary report to each manufacturer, followed by (2) a period of 30 days for Part B manufacturer to review and 10 days for a Part D manufacturer to review and reply with any calculation errors. (3) CMS has until September 30, 2025, to send drug manufacturers invoices for Part B rebates and has until December 31, 2025, to send invoices for manufacturers that owe Part D rebates. (4) Manufacturers have until 30 days of receiving a rebate invoice to pay or they may be subject to a civil monetary penalty (CMP) of at least 125% of the rebate amount.

The announcement takes advantage of CMS's current IRA work as pre-election messaging on a winning political issue: high prescription drug prices. The release of revised inflationary rebate guidance coincides with the recent release of the administration's guidance on:

- March-in rights (our analysis here) and Pres. Biden's scheduled remarks today on prescription drug prices at the National Institutes of Health (NIH).
- ASPE Report on the Top Ten (here) Drugs for negotiation (2026). We note that most Americans do not know what the IRA drug provisions entail. CMS is expected to provide its offer by Feb 1, 2024, to manufacturers. We will see the MFP by Sept 1, 2024.

CMS released the latest list of drugs subject to inflationary rebates and adjusted co-pay percentages in Q1 2024 (here). 48 drugs were rebate eligible with inflation-adjusted co-pay percentage ranging from 15% to

19.9% (normally 20%). The list of rebated drugs has more than doubled from when CMS released the first quarter's list of Part B rebatable drugs (20) in April 2023. See below.

Drugs newly added include certain generics, a CAR-T therapy and immunology drugs.

- **Oncology**: Newly listed drugs include Kymriah (*NVS*), a CAR-T treatment for lymphoma,
- **Immunology**: GamaSTAN (*Grifols*) a human immune globulin used after exposure to Hepatitis A, rubella, and measles, Envarsus (*Veloxis Pharma*) an immunosuppressive drug to prevent organ rejection and treatment of atopic dermatitis, Varizig (*Kamada*) a therapy for the prevention of varicella, and
- **Cardiovascular**: Thrombate (*Grifols*) a treatment for thromboembolism.
- **Generics** added include Bortezomib (*Dr. Reddy's & Fresenius Kabi* generics) a generic for Velcade (chemotherapy for multiple myeloma), Fosaprepitant (*Teva*) generic for Emend (antinausea medication for chemotherapy), Fulvestrant (*Fresenius Kabi)* a generic for Faslodex (a hormone treatment for breast cancer), Argatroban (*Eurgia*) a blood thinner used to treat heparin-induced thrombocytopenia (HIT), Gemcitabine (*Accord*) a generic for Gemzar (chemotherapy for breast, ovarian, and pancreatic cancer), Cefepime (*B. Braun & Baxter* generics) an antibiotic agent, and Meropenem (*B. Braun*) an antibiotic agent.

Drugs can come off & go back on to the list for rebate penalties: Humira (ABBV), Cresemba (Astellas), and Aggrastat (Medicure). Humira (ABBV) had been on the list until this quarter and may still have a sizable rebate amount owed to the government. Cresemba (Astellas) is an antifungal treatment for invasive aspergillosis and invasive mucormycosis which was newly listed in September and not seen today. As a reminder, the list will shift quarter to quarter for Part B as price and inflationary rates fluctuate and drugs not seen in a quarter may be including in the following period.

Drugs that have consistently been subject to Part B CPI penalty include:

- **Oncology drugs, including chemotherapy drugs, a bone marrow stimulant, and an anti-nausea medication used in chemo regimens**. - Padcev (*Astellas*), Leukine (*Partner Therapeutics*), Akynzeo (*Helsinn Therapeutics*).
- **Immunology, including a treatment for anemia.** - Atgam (*PFE*).
- **Other categories include antibacterial/antifungal agents**: Bicillin C-R (*PFE*), Bicillin L-A (*PFE*), Minocin (*NVS*), **anticoagulants**: Fragmin (*PFE*), **hormone & enzyme therapies**: Signifor LAR (*Recordati Rare Diseases*), and Xiaflex (*Endo Pharmaceuticals*).

NEW INFLATIONARY REBATE GUIDANCE

Part B guidance changes (here) released today include clarifications to the exclusion criteria, revisions to the calculation process, and additional details on the rebate reporting process. The revised guidance clarifies that generic drugs (approved under ANDA), multiple source drugs, and radiopharmaceuticals are excluded from being Part B rebatable drugs. CMS also clarified that the Part B rebate amount will not be adjusted for sequestration. Drugs in shortage will have their rebate amount reduced by determining the number of days such drug is described as "currently in shortage" on an FDA shortage list in a calendar quarter, divide by the number of days in the calendar quarter, and then multiply that amount by a percentage that is decreased over time. CMS will also provide a time-limited standard reduction of 75% for a Part B rebatable drug that is a biosimilar biological product when there is a supply disruption. CMS also states biosimilar biological products that are not packaged into the payment amount for an item or services are separately payable, will be included in the Part B inflation rebate calculation.

Part D guidance changes (here) released today include inflationary changes to low-cost drug exclusion criteria, and revisions to rebate amount calculations. The guidance clarifies that sole source generic drugs may be subject to inflationary rebates. Starting Q4 2023, the $100 per individual per year threshold amount will

be increased by the percentage increase in the CPI-U from October 2023 to October 2024, consistent with the law. CMS also clarifies that to identify the billing unit for each National Drug Code (NDC) for each Part D rebatable drug, they will cross-reference the information from Part D PDE record to a database (such as FDA's Comprehensive NDC Structured Product Labeling (SPL) Data Element File (NSDE) or Medi-Span) that includes the unit type matching on the NDC of the Part D rebatable drug.

CMS has not yet decided on how to accurately identify 340B units in Part D. In Part B guidance, CMS requires all 340B covered entities to include the "JG" or "TB" modifier, for drugs acquired through the 340B Program starting on January 1, 2024, to ensure they will be removed from the rebate calculation. CMS has not yet released how they will identify 340 B in Part D and plan to finalize a policy for excluding 340B units by plan year 2026 as allowed by the law.

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