INFLATION REDUCTION ACT OF 2022
Executive Summary of PBM Provisions
August 9, 2022

The prescription drug provisions of the July 28 Inflation Reduction Act (IRA) of 2022 are nearly identical to the Build Back Better Act (BBBA) released on July 6, with one major exception; the July 6 bill included a complete repeal of the Rebate Rule, and the July 28 bill included a partial repeal – an additional five-year delay. Along with the prior version, the updated text included authorization for Medicare to negotiate prescription drug prices, penalties for increasing drug prices faster than inflation, and a part D redesign. The Part D insulin copay caps, which had been included in the Senate Finance Committee (SFC) version of the bill from 2021, were not included in the July 28 version of the IRA; however, separate insulin cost-sharing text was released July 30. On Saturday, August 6, the parliamentarian removed the provisions instituting inflationary caps and insulin copay caps in the commercial market. On Sunday, August 7, the Senate passed a revised version of the IRA. The below summary represents the updated, Senate passed bill language.

Rebate Rule

- Prohibits the Secretary from implementing the Rebate Rule until January 1, 2032.

Government Price Negotiation

- Includes qualifying single-source Part D and Part B drugs (chemical entity on the market at least seven years and biologics on the market at least 11 years with the highest spend in each program) – Part D only for 2026 and 2027.
- Initial negotiation period to determine "maximum fair price" is February 1 through November 1, 2024, with process beginning in September 2023.
- Negotiated prices effective as of 2026.
- The maximum fair price is included in Medicaid Best Price reporting, and by default, 340B ceiling price. It does not include international reference pricing.
- Requires HHS to identify 10 negotiation-eligible drugs year one (2026), 15 year two (2027), 15 year three (2028), and 20 year four (2029) and beyond.
- Small biotech and orphan drugs are excepted.
- Manufacturers who fail to comply will be subject to civil monetary penalties that increase over time and could face an excise tax for non-negotiation.

Inflationary Rebates

Part B Inflationary Rebates

- Applies to single-source drugs (chemical or biological).
- Excludes biosimilars with an Average Sales Price (ASP) below the reference product for the first five years the product is on the market, drugs costing less than $100 per year, drugs on the shortage list, and specified vaccines.
- Payment amount benchmark is for the quarter beginning January 1, 2023.
- CPI-U benchmark is January 2021.
- Effective July 1, 2023.
- Excludes Medicaid sales.
- Rebates calculated based on the amount by which the lesser of 106% of ASP or Wholesale Acquisition Cost (WAC) for chemical entities and biological reference products or ASP+6% for biosimilars exceeds the inflation-adjusted payment amount.
- Rebates are deposited into the Federal Supplementary Medical Insurance Trust Fund.

Part D Inflationary Rebates

- Applies to covered Part D drugs or biologicals.
- Excludes drugs costing less than $100 per year, drugs paid for by Medicaid or Part B, and those on the shortage list.
- Payment amount benchmark is for the period January 1 – September 30, 2021.
- CPI-U benchmark is October 2021.
- Effective October 1, 2022.
- Rebates calculated based on amount by which Part D paid for a drug (amounts reported by PDPs and MA-PDs) exceeds the inflation–adjusted payment amount of the drug.

Part D Redesign

- Effective plan year 2025.
- Establishes a $2,000 cap on out-of-pocket costs for Part D beneficiaries.
- Maintains the current coinsurance of 25% in the initial phase of the Part D benefit.
- Requires Part D plans to give beneficiaries the option of spreading out their cost sharing up to the out-of-pocket maximum over the course of the benefit year beginning in 2025.
- Caps the growth in Part D premiums at 6% per year from 2024 to 2029.
- Allows the Secretary to make a one-time adjustment to beneficiary Part D premium percentage in 2030.
- Lowers the reinsurance subsidy in the catastrophic phase from 80% to 20% for brand drugs and 40% for generics and increases plan liability to 60%.
- Sunsets the coverage gap and institutes a new manufacturer discount program as of January 1, 2025.
- Requires brand manufacturers to pay 10% in the initial phase and 20% in catastrophic.

Part D Insulin

- Effective plan year 2023.
- Applies the deductible exclusion language and a month-supply cap at $35 for plan years 2023-2025.
- Beginning in 2026, includes lower-of-logic based on $35, 25% of the negotiated rate, or 25% of the government-negotiated maximum fair price for insulin.
- Cap applies to all insulins on a plan's formulary.
- For 2023 and 2024 the cap applies regardless of whether an individual has reached the initial coverage limit or the out-of-pocket threshold.
- For 2025 and beyond, the cap applies prior to reaching the out-of-pocket threshold, which coordinates with the timing of the sunset of the initial coverage limit under the Part D redesign.
- Permits the Secretary to implement these provisions via guidance for 2023-2025 and allocates $1.5 million in 2022 for implementation.
- Provides a temporary retrospective subsidy under which the Secretary will reimburse Part D plans for the differences in cost sharing between what was expected based on the plan design offered during the bid cycle and what is required under the IRA.
- Requires Part D plans to refund beneficiaries cost-sharing amounts charged above the cap during a three-month window at the start of 2023 – presumably to allow PBMs and plans to adjust their systems.