

House Passes Inflation Reduction Act

IRA Completes Legislative Run, Earliest Provisions Start Oct 2022

- **Moments ago the House voted to pass the Inflation Reduction Act (text & summaries here).** The text was unchanged from the Senate version with the House rules committee scrapping the previous BBB text with the new Senate Inflation Reduction Act. Despite GOP attempts to include new amendments, the House Dem. Leadership shot down any attempts at changing the bill text.
- **No CBO score yet.** We note that CBO has not released their new cost/savings estimates based on Senate passed text yet they did release [this](#). Summary of the provisions and what's next below. It is unusual for a vote to take place without official
- **NEXT STEPS:** The bill will still need to be signed by President Biden to be passed into law. After that it will be up to HHS to enact the provisions as written. We can expect to see rulemaking from HHS on Part D restructuring and inflationary rebates as early as 2H 2022. We wait to see which drugs will be subject to negotiations. We note that generics and biosimilars are expected to enter the market in 2023+ as the patent cliff approach. We estimate that this bill will refocus manufacturers' R&D to medicines taken in a more commercial population and/or orphan indications, while shortening the lifecycle of drugs overall with shorter periods of exclusivity, but a greater impact is expected in fields like oncology (oral) and primary care where step therapy is the norm. We also expect higher launch prices as well as potentially different price points in Medicare vs. Commercial.

WHAT'S INCLUDED

- **Inflationary Rebates for Part D start in October 2022, Part B go into effect in January 2023.** Manufacturers that raise prices above inflation (CPI-U) will have to "rebate" the difference back to the government for Part B & D drugs. The civil monetary penalty is equal to units sold to Medicare using the Part B & D billing and payment code multiplied either by the amount by which the Part B payment rate exceeds the inflation-adjusted Part B payment rate or by the amount the volume-weighted average annualized AMP exceeds the inflation-adjusted volume-weighted average annualized AMP.
- **Medicare negotiations start in 2026 (saves \$101 B over ten), but the list of selected drugs will be released by September 2023.** *See our FAQ for more details on negotiations.*
 - HHS will be directed to negotiate a specific number of drugs every year, rather than "up to" the required number of drugs.
 - Negotiated prices will go into effect in 2026. First year of negotiation is 2023.
 - 10 qualifying drugs must be negotiated in 2026, 15 additional drugs in 2027-28 and 20 each year in 2029 and beyond
 - Small biotech protections will go into effect in 2026 and end after 2028. For 2029 and 2030, there would be a maximum fair price protection of a maximum 34% discount for small biotech drugs.
 - For drugs subject to Medicare negotiation, there will be minimum discount of 25% in years 9-11, 35% for years 12-15, and 60% for year 16+ based on a 'maximum fair price' while there is no cap on the negotiated discount.
 - Manufacturers not participating in negotiation will be subject an exercise tax beginning at 65% and increasing 10% quarterly up to 95%.
 - There is a negotiation exception for vaccines (unless 'short monopoly' 9-12 years) and orphan drugs

- **Part D restructuring (costs \$25 B over ten) starts in 2024** with beneficiaries owing \$0 out-of-pocket in the catastrophic phase. By 2025, beneficiary total out-of-pocket spending for Part D drugs will be capped at \$2,000 per year. Drugmakers have largely embraced these changes as good for patient access.
 - Small manufacturer phase in and Part D premium stabilization will take place starting and ending a year later, to conform with new implementation dates.
 - Expands Part D LIS. The income threshold for eligibility for the Part D low-income subsidy has been expanded from 135% to 150% of the federal poverty level.
 - Stabilizes premiums. Premium growth will be capped at 6% per year through 2029.
 - Beneficiary premium percentage adjustment. To provide beneficiary premium protection in the long run, the Secretary will be authorized make a one-time adjustment to the beneficiary Part D premium percentage in 2030.
 - Part D vaccine out-of-pocket protection. \$0 cost-sharing for vaccines will go into effect in January 2023.
 - Instead of 70% in the donut hole, manufacturer discounts are 10% in initial phase and 20% in the catastrophic phase
- **Insulin co-pay cap for Medicare start in 2023.** While the larger commercial insulin reform failed Byrd review and Senate vote, the bill will cap insulin at \$35 per month for Medicare beneficiaries.
- **PBM Rebate Rule almost-repeal in ten-year window (to 2032) and generates \$122 B over ten (paper savings).** The Rebate Rule was unlikely to happen anyway; it is currently delayed to 2027 (via Gun reform legislation passed in June: from 2026, saving \$20 B for an incremental year). See *our June 22 memo for details.*
- **Insurance Subsidies: Three years of ACA subsidies (2023-25) helps CNC, MOH, UNH, ANTM, others, which we thought may happen so as to get past the Presidential election.** The text allows for three years of ACA subsidy extension, which we had expected, versus only two, costs \$33 B over 10 with a revenue loss of \$31 B over 10. The CBO score allowed for more generous subsidies (\$288 deficit reduction from drug reform) and positively there is no means testing of the extension.
- **Managed care plans bear more responsibility in the Part D benefit.** The Part D benefit plan design lowers reinsurance and shifts more risk onto MCOs, but they should be able to offset with premium increases (within limitations of new cap) and formulary management as incentives flip to favor more generics over high rebate brand drugs to get into the catastrophic phase.