President Biden has now signed into law the $700 billion Inflation Reduction Act of 2022, a package comprised of health care, climate change, and taxation policy reforms. It is a scaled-back version of the Build Back Better Act that passed the House last year, and is the culmination of months of negotiation by top Democrat lawmakers, particularly Senate Majority Leader Chuck Schumer (D-NY) and Sen. Joe Manchin (D-WV). The final text, a Senate-amended version of H.R. 5376, was passed through the reconciliation process and on a party-line vote in both chambers. The Parliamentarian ruled that the language requiring drug companies to pay Medicare for inflationary rebates in the private market was not compliant with the Senate rules on reconciliation. Prior to the Parliamentarian’s ruling, the Congressional Budget Office (CBO) projected that the drug pricing provisions of the bill may save up to $287 billion over the next 10 years, a number that would presumably be reduced by the private market carve-out.

Among many other things, the Inflation Reduction Act has significant implications for the pharmaceutical industry due to Medicare drug price negotiation, some inflationary rebates, and Medicare Part D redesign. Below are the relevant details:

**Price Negotiation and Maximum Fair Prices**

Subtitle B, Part I, of Title I (Committee on Finance) reforms prescription drug pricing through the creation of a program that allows the federal government to negotiate prices for a limited number of high-cost single-source drugs (lacking generic and/or biosimilar substitutions). The Secretary of Health and Human Services will have the ability to choose a list of 50 pharmacy drugs (Medicare Part D) and 50 drugs administered at a physician’s office (Medicare Part B) that will be priced in accordance with this methodology.

The timeline will work as follows:

- By September 1, 2023, the Center for Medicare and Medicaid Services (CMS) must publish
the highest ranked Medicare Part D drugs selected for negotiation. These single source drugs must have been on the market for at least seven years at the time of the selection. While the effective date of the first round of ten Part D drug is not until CY2026, those drugs will be selected in CY2023. For this first year, a total of 10 drugs can be selected, and can only be from the Part D program.

- The number of drugs selected in CY2025 will increase to 15 for the effective release of CY2027 (totaling 25), and can still only be from the Part D program. Beginning this year, the Maximum Fair Pricing will be published on November 30 of the selection year.

- Medicare Part B drugs become eligible for selection on February 1, 2026, and these single source drugs must have been on the market for nine years or more at the time of selection. A total of 15 drugs from Part D or Part B (combined) will be selected in CY2026 for the effective date of CY2028 (totaling 40).

- The Secretary will choose a total of 20 drugs in the Part D or Part B programs each of the subsequent years for the next three years - CY2027, CY2028, CY2029 – for the effective dates of CY2029, CY2030, and CY2031. In total, by 2031, 100 drugs will be subject to negotiation.

The Department of Health and Human Services (HHS) will rank negotiation-eligible drugs according to total expenditure for them under Medicare Parts B and D during the most recent period of 12 months prior to the selected drug publication date (two years prior to the price applicability date). Drugs with the highest total expenditures will be selected to become negotiation-eligible. HHS will request information from the manufacturers of selected drugs and will provide a written initial offer, with justification included, based on several criteria. The manufacturer has a chance to counteroffer.

Negotiated prices will be capped by the length of time a drug has been on the market as of the drug applicability date. This maximum fair price (Maximum Fair Price) is capped at 75 percent of the Average Manufacturer Price for those on the market for nine to 11 years (25 percent discount offered by the drug maker); or 65 percent for 12 to 15 years (35 percent discount offered by the drug maker); or 40 percent for 16 years or longer (60 percent discount offered by the drug maker).

There are several guidelines for the negotiation process, including:

- Medicare Part D drugs selected for negotiation are required to have been on the market for at least seven years as of the date of selection.

- Medicare Part B drugs selected for negotiation are required to have been on the market for at least nine years as of the date of selection.

- Medicare Part B drugs are ineligible until February 1, 2026.

- Drugs have to have been on the market for at least nine years for small-molecule drugs and at least 13 years for biologics.

- Drugs owned by companies where a single drug accounts for at least 80 percent of revenue but less than one percent of overall Medicare expenditure on prescription medicines are exempt from negotiation.
• Drugs approved for a single condition (rare disease) and products derived from plasma are excluded from negotiation.

• Manufacturers are eligible for two one-year exemptions if they have a reasonable expectation that they will face competition by generic and/or biosimilar competition by the price applicability date (as opposed to the selection date).
  
  ◦ However, if a generic or a biosimilar does not end up coming to market, the biologic manufacturer must pay a fee to HHS.

• Should a drug maker choose not to participate in the negotiation process, the federal government will tax the company at 65 percent of the previous year’s sales of the drugs, with a concurrent increase of 10 percent per quarter up to 95 percent for being out of compliance for 270+ days.

Inflation Rebates

Subtitle B, Part II, of Title I (Committee on Finance) provides guidance to discourage pharmaceutical companies from raising drug prices faster than inflation, with the penalty fine being the difference between the actual price and the inflated price. It is important to note that such inflation rebate liabilities apply only to Medicare Part B drugs without competition and Part D drugs that cost more than $100 per year, and not to private market sales (though these types of rebates already exist within Medicaid). Section 11101, Medicare Part B Rebate by Manufacturers, and Section 11102, Medicare Part D Rebate by Manufacturers, require drug manufacturers to issue a rebate to the federal government based on the Average Sales Price beginning in the first quarter of 2023 relative to the third quarter of 2021 (Part B) or the Annual Manufacturer Price beginning in FY2023 relative to FY2021 (Part D). Whereas the rebate amount for Medicare Part B is to be paid quarterly, that for Part D is to be paid annually. Anyone who chooses not to pay the penalty fee will get fined a further fee that costs 125 percent of the original penalty.

Part D Redesign

Subtitle B, Part III, of Title I (Committee on Finance), Part D Improvements and Maximum Out-of-Pocket Cap for Medicare Beneficiaries, makes changes to the way Medicare covers expensive drugs, including:

• Elimination of five percent cost-sharing in the catastrophic phase of the Part D benefit, effective in 2024;

• Capping patients’ out-of-pocket costs at $2,000, effective in 2025;

• Capping out-of-pocket insulin spending at $35 per month;

• Cost smoothing throughout the year;

• Limiting premium growth to no more than six percent each year between 2024 and 2029;

• Making private insurance plans and manufacturers pay more, with Medicare spending significantly less overall.
Miscellaneous

Among other provisions, the Inflation Reduction Act also:

- Extends enhanced Affordable Care Act subsidies passed as part of the American Rescue Plan for an additional three years through 2025.

- Allows Medicare patients to receive vaccines that are covered by pharmacy benefits free of cost beginning in January 2023.

- Further delays the implementation of a drug rebate rule published under then-President Donald Trump until January 2032. The rule can be found [here](https://www.natlawreview.com/article/inflation-reduction-act-2022-medicare-drug-pricing-provisions-will-change-health).