TIMELINE: OPERATIONALIZING THE IRA'S DRUG PRICING POLICIES

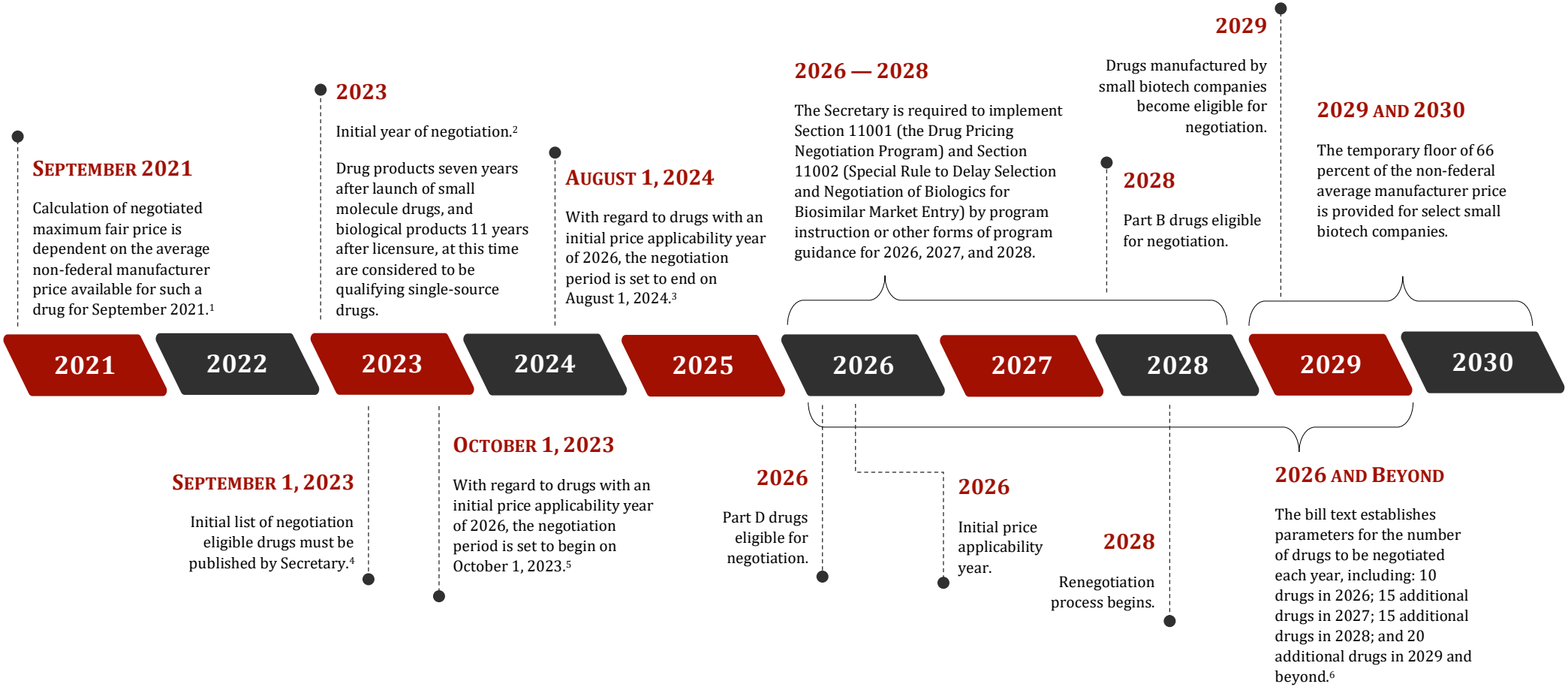
On August 7, the **Senate clinched final passage of their long-sought reconciliation bill**, the Inflation Reduction Act (IRA) (text), sending the measure to the House for a final vote later this week. The Senate Parliamentarian's "Byrd bath" rulings — along with the marathon "vote-a-rama" amendment process — resulted in a pair of key changes to the drug pricing policies originally included within the filibuster-proof measure: (1) the **removal** of a provision that would have **required drug companies to provide rebates if the cost of the products they sold to private insurers exceeded inflation**; and (2) **nixing a proposed price cap for insulin in the private marketplace**. Notably, the Senate-passed legislation includes provisions that would: (1) allow Medicare to negotiate drug prices; (2) redesign the Medicare Part D benefit to lower out-of-pocket costs for beneficiaries; (3) cap the monthly out-of-pocket cost of insulin to $35 for Medicare beneficiaries; and (4) extend the Affordable Care Act (ACA) subsidies for households with income exceeding 400 percent of the federal poverty level until 2025.

A key policy included in the Senate-passed IRA would allow Medicare to negotiate drug prices under Parts B and D. Under the bill, the **initial negotiated prices would be applicable starting in 2026** with negotiations for eligible drugs beginning in 2023. Notably, **Part D drugs are eligible for negotiation beginning in 2026; however, Part B drugs will not be eligible until 2028.** For the purposes of negotiation, **insulin is no longer treated as a separate class** as it was in the prior iteration of the provision. In addition to these policies, the legislation would also cap Medicare Part D **beneficiary catastrophic spending** before 2024, delay implementation of the **Trump-era rebate rule** until January 1, 2032, and implement **inflationary rebates** in Medicare for manufacturers who raise the price of drugs faster than inflation.

- **What's Next?** House lawmakers will return on Friday to consider the IRA. Passage of the bill — which is highly likely as the Democratic caucus appears to be unified at the moment — would send the roughly $740 billion measure to President Joe Biden's desk for signature. This will mark the end of a busy summer work period for both chambers, with the Senate breaking until Tuesday, September 6, and the House until Tuesday, September 13.

Drug Price Negotiation

Drug price negotiation provisions included in the recently released IRA would require the Secretary of the Department of Health and Human Services (HHS) to establish a Drug Price Negotiation Program, allowing Medicare to negotiate drug prices under Parts B and D for single-source drugs seven years after launch of small molecule drugs and 11 years after licensure of biologics. The legislative language would require that the Secretary of HHS create a ranked, combined list of the 50 highest-priced, single-source, brand-name drugs from Parts B and D, respectively, according to the total expenditures for such drugs under Parts B and D. The Secretary is required to select from such ranked drugs the negotiation-eligible drugs with the highest rankings.



Additional Dates of Note within Negotiation Provisions

[1] The Senate-passed language stipulates that a negotiated price cannot exceed a drug's 2021 non-federal average manufacturer price (AMP) in the following amounts: (1) 75 percent for drugs that are on the market between 9 and 12 years; (2) 65 percent for drugs that have been on the market for at least 12 years, but fewer than 16 years; and (3) 40 percent for drugs that have been on the market for at least 16 years.

[2] A drug's negotiation period begins on the sooner of either: (1) the date on which the manufacturer and the Secretary enter into an agreement with respect to such drug; or (2) February 28 following the selected drug publication date.

[3] The negotiation period is to end on November 1 of the year that begins two years prior to the initial price applicability year.

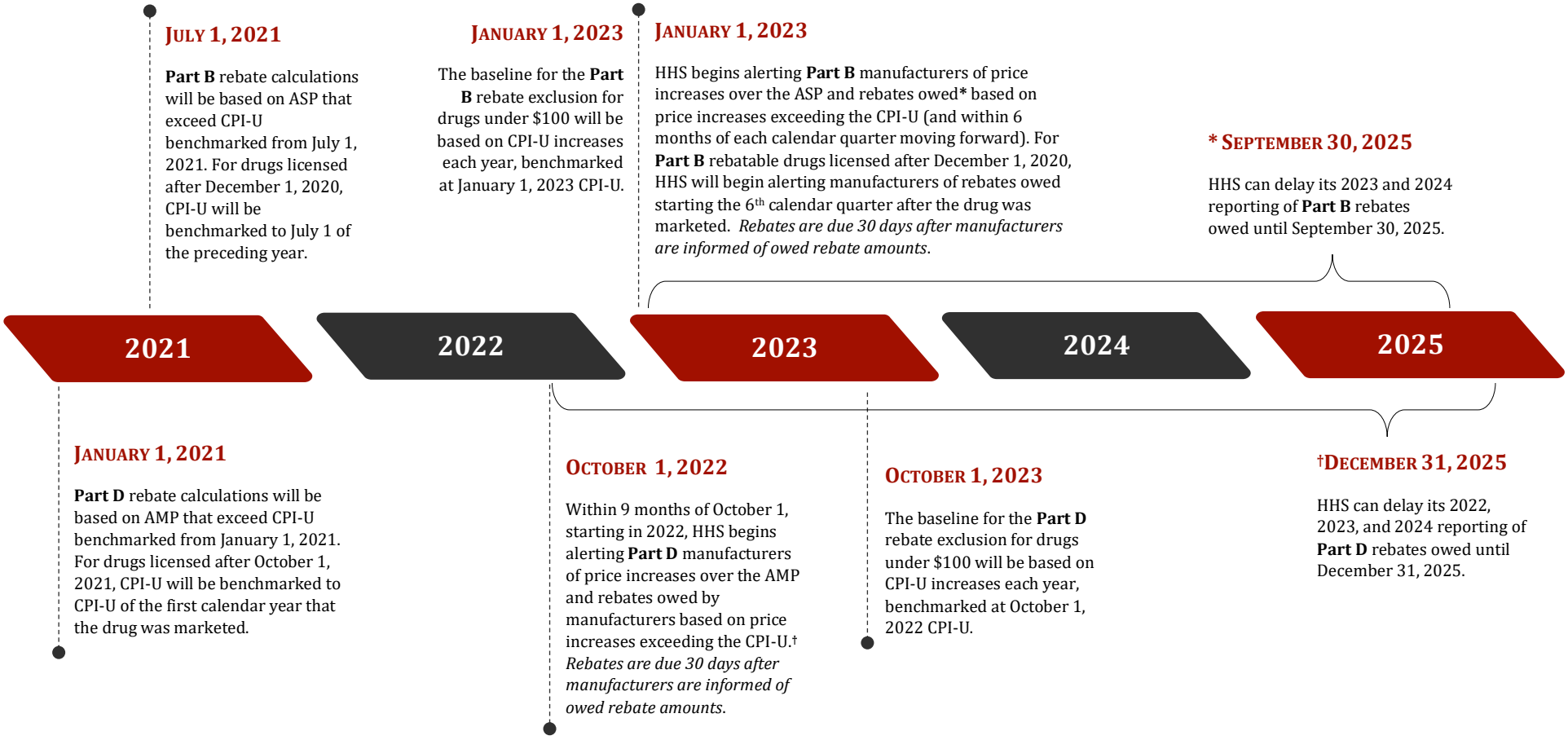
[4] The bill excludes from negotiation low spend Medicare drugs — those that contribute less than $200 million in Medicare spending beginning in 2021 and adjusted for increases in the consumer price index (CPI) as of September for each subsequent year. Notably, this bill defines "low spend Medicare drugs" as drugs that, for 2026, contribute less than $200 million of Medicare spending between June 1, 2022, and May 31, 2023. For the price applicability year beginning in 2027, a drug qualifies as a low spend Medicare drug if spending for the drug is less than $200 million of Medicare spending between June 1, 2022, and May 31, 2023, adjusted for the annual percentage of CPI-U between June 1, 2023, and September 30, 2024.

[5] The bill, if enacted, would allow the Secretary to delay the negotiation of a biologic drug for up to two years provided a biosimilar demonstrates "high likelihood" of entering the market before the negotiated price would take effect. The delay is limited to two years with no extensions.

[6] The bill establishes an excise tax to be levied against manufacturers during periods when the manufacturer is non-compliant with the requirements of the negotiation program. Specifically, the tax would begin at 65 percent of the sales for the first 90 days of non-compliance and would increase at regular intervals until reaching 95 percent for any period of non-compliance beyond 270 days.

Inflationary Rebates

Similar to the House-passed BBB and original Senate BBB text from December 2021 as well as the updated Senate Finance Committee language, the IRA would implement inflationary rebates. Specifically, manufacturers would be required to pay rebates if Part B and D drug prices rise faster than inflation based on CPI-U. Failure to pay the mandatory rebate would result in a 125 percent civil monetary penalty (CMP) of the rebatable amount for that quarter. Additionally, the proposal would appropriate a total of $160 million for FY 2022 through 2031 to CMS to implement the Parts B and D inflationary programs. Notably, the Senate Parliamentarian's rulings called for the removal of a provision that would have required drug companies to provide rebates if the cost of the products they sold to private insurers exceeded inflation.



Part D Redesign

Similar to the House-passed BBB and original Senate BBB text from December 2021, and the updated Senate Finance Committee language, the IRA would implement a redesign of Medicare Part D which would include changes to out-of-pocket (OOP) costs, reinsurance amounts, and the current coverage gap discount program. This updated bill would delay Part D redesign until 2025, but beginning in 2024, beneficiaries would pay zero coinsurance in the catastrophic phase.