# FAQ: Inflation Reduction Act

## House Vote Timeline, President Biden to Sign ASAP

- **Today the House will vote on the Inflation Reduction Act (IRA) around 4 pm ET.** The schedule is as follows,
    - 10:00 am: The House will come into session and vote on the rule that sets the parameters for debate for the reconciliation bill.
    - 12:00 pm: There will be three (3) hours of debate equally divided between the Budget, Ways and Means and Energy and Commerce committees. Since it's a Senate amendment to a House bill, there are no amendments to consider.
    - 3:00 pm: The House will move to a final vote on the reconciliation bill by 4 p.m.

- **Given the complexity of drug reforms, we wanted to publish a FAQ.** What started as a $4T Jobs & Families plan (remember free community college?) slimmed to a $2T Build Back Better before losing steam before Christmas. When Manchin resuscitated the bill in June, we paid attention. We saw the writing on the wall as Manchin-Schumer hammered much of the detail during recess, without interest groups or staff to interfere.

- **See below for incoming Qs we have received.**

**Q. When do Part B drugs start being negotiated? What is the timeline?**

A. **2028**. Part D will be negotiated first with 10 Part D drugs subject to negotiations in 2026. In 2027, 15 Part D drugs will be negotiated. In 2028, Part B drugs will start to be negotiated. 2028 will have 15 Part B and Part D drugs subject to negotiations.

**Q. When will we see a list of the drugs that they will negotiate in 2026? How will they pick the selected drugs?**

A. **We can expect to see a list of selected Part D drugs by September 1, 2023.** The Medicare data used for selection will be from June 1, 2022, to May 31, 2023. These drugs will be selected by ranking total expenditures of Part D drugs during the most recent 12-month period and picking from the top 50 qualifying single source drugs with the highest total expenditures. The selected drugs must be at least 7 years since FDA approval, and 11 years for selected biologics.

**Q. Can the Drug Reforms impact the rebates that pharma pays into the system/PBMs?**

A. **Yes, in both ways**—We also understand that states are unhappy because it will significantly reduce the amount they receive in rebates under Medicaid.

**Q. If the government tried to negotiate a price (off of the list price) and pharma paid a rebate under Medicare Advantage, then could this impact those rebates?**

A. We do **not** see this happening since there is guaranteed coverage.


Contact Ipsita Smolinski - 202.250.3741 - Ipsita@capitol-street.com

**Q. Pharma will try to recoup some lost revenues and any loss in rebates could drive up premiums for which the govt is on the hook?**

A. **Yes**. Very much so.

**Q. The inflation cap applies to Medicare but on list price ? What's your take -- will it mean differentiated list prices between commercial and Medicare you think?**

A. **CBO certainly believes it would** – given that it believes this change will reduce the potential savings by $40 B. We are assuming their analysis is based on the fact that companies will make up for losses under Medicare by increasing the price of their products in the commercial market (which hospitals and physicians already do).

**Q. What happens in protected classes if a company opts out of Medicare**? Would Merck with Keytruda or Bristol with Opdivo decide not to participate in Medicare?

A. Unlikely, in our view. There is still revenue to be gained. It's the company that has a small Medicare target population that may refuse to participate at launch.

**Q. What is the specific timeline for negotiations for 2026? When will we see the maximum fair price for 2026?**

A. **We can expect the see the maximum fair price by September 1, 2024**. The timeline for 2026 is below.

- Selected drug publication date: September 1, 2023
- Data period used for selection: June 1, 2022, to May 31, 2023
- Negotiation period: October 1, 2023- August 1, 2024
- Written initial offer deadline: February 1, 2024
- Negotiated Price publication deadline: September 1, 2024
- Negotiated Price explanation deadline: March 1, 2025

**Q. What information will manufacturers have to provide?** i.e., Who can see the information that will be provided?

A. **Biopharma must submit to the Secretary information on the non-Federal average manufacturer price and any information that the Secretary requires to carry out the negotiation (or renegotiation process).** Info submitted by a manufacturer that is proprietary information will be used only by the Secretary or disclosed to and used by the Comptroller General. When determining the maximum fair price, the Secretary will look at (1) R&D and the extent to which the manufacturer has recouped the R&D costs. (2) Current unit costs of production and distribution of the drug. (3) Prior Federal financial support for novel therapeutic discovery and development with respect to the drug. (4) Data on pending and approved patent applications and exclusivities. (5) Market and sales data (6) Info on therapeutic alternatives including the extent to which such drug represents a therapeutic advance, the cost of therapeutic alternatives, comparative effectiveness, and FDA approved prescribing info.

**Q. What are the <u>minimum</u> discounts that the Secretary will have to negotiate?**

A. **25**%, **35% or 60%.** The maximum 'fair price' would be based on the minimum discounts required, a plan-specific enrollment weighted price for Part D drugs or an average price for Part B

drugs. The Secretary must negotiate minimum discounts based on how long the drug has been on the market. Minimum discounts would be:

- 25% of the nonfederal average manufacturer price for a short-monopoly drug (< 12 years since launch)
- 35% of the nonfederal average manufacturer price for post-exclusivity drug (> 12 years and < 16 years since launch)
- 60% of the nonfederal average manufacturer price for a long-monopoly drug (> 16 years since launch)

**Q. What drugs will be subject to renegotiations?**

A. **Starting in 2028, some drugs may be selected for renegotiations rather than a yearly inflation update**. A selected drug must be chosen for renegotiations if the drug changes to being an extended-monopoly drug or a long-monopoly drug. The Secretary may also be permitted to renegotiate if there is a new indication added to the drug or if there is a material change in any of the factors considered for negotiations.

**Q. How long will be drugs subject to negotiations? What about when a generic or biosimilars launch?**

A. **A drug will no longer be subject to the maximum fair price the year that begins at least 9 months after a generic or biosimilar comes to market.** The Secretary may also delay selection for a biological product by one or two years if there is a high likelihood that a biosimilar biological product will be licensed and marketed before the price applicability year. For a delay to be approved, the product must be an extended-monopoly drug, and must be requested by the biosimilar manufacturer. Generic and biosimilar manufacturers will have to pay a rebate if they don't make good progress or do not launch the biosimilar at the end of the 1 year or 2-year delay period.

## Background