

Brand-name Drug Pricing in the US: The Medicare Negotiation Era

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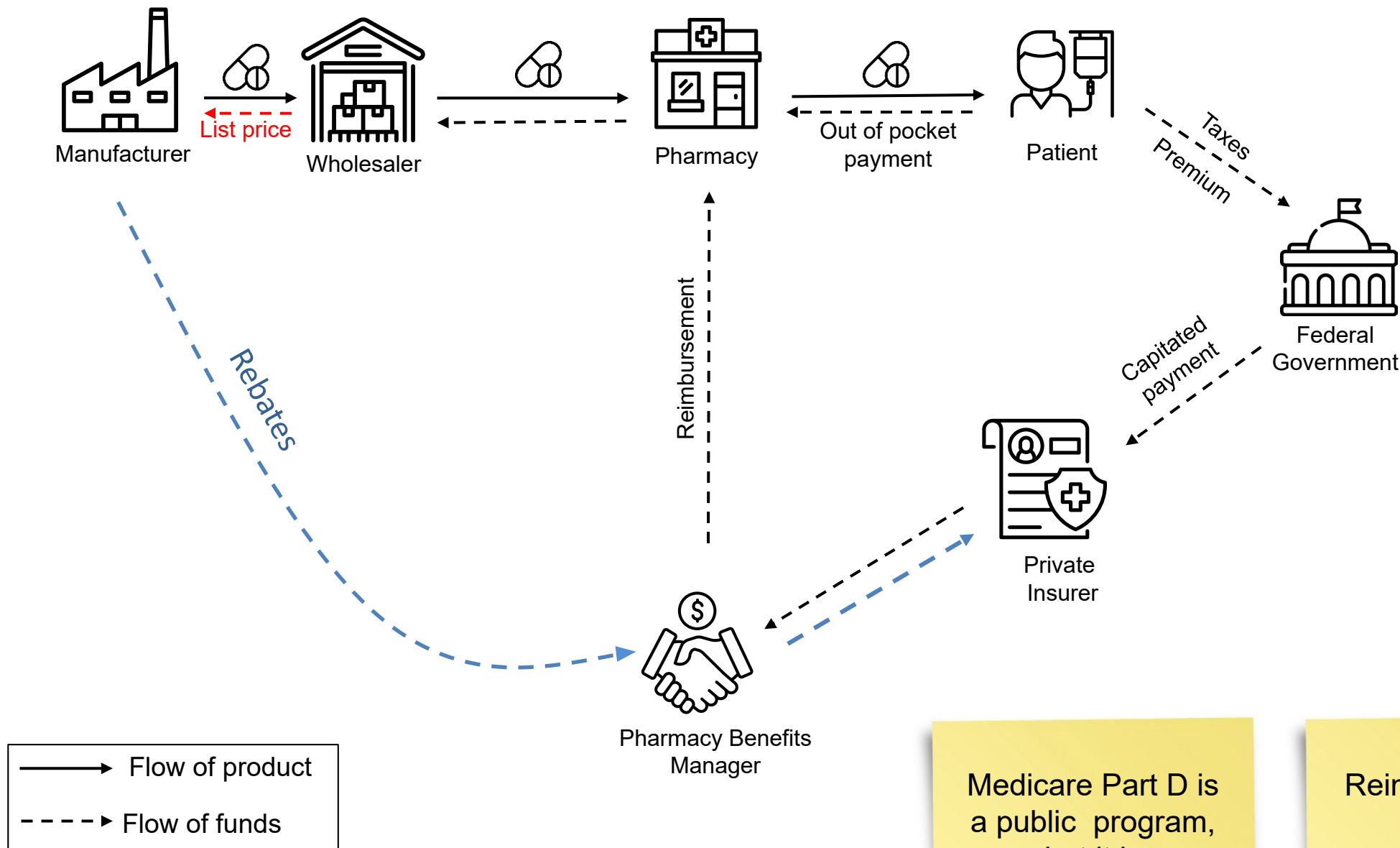


Outline

- How does Medicare pay for drugs dispensed by pharmacies?
- The Inflation Reduction Act of 2022
 - Medicare price negotiation
 - Inflation rebates
 - Out-of-pocket limit



How does Medicare pay for brand-named drugs dispensed by pharmacies?

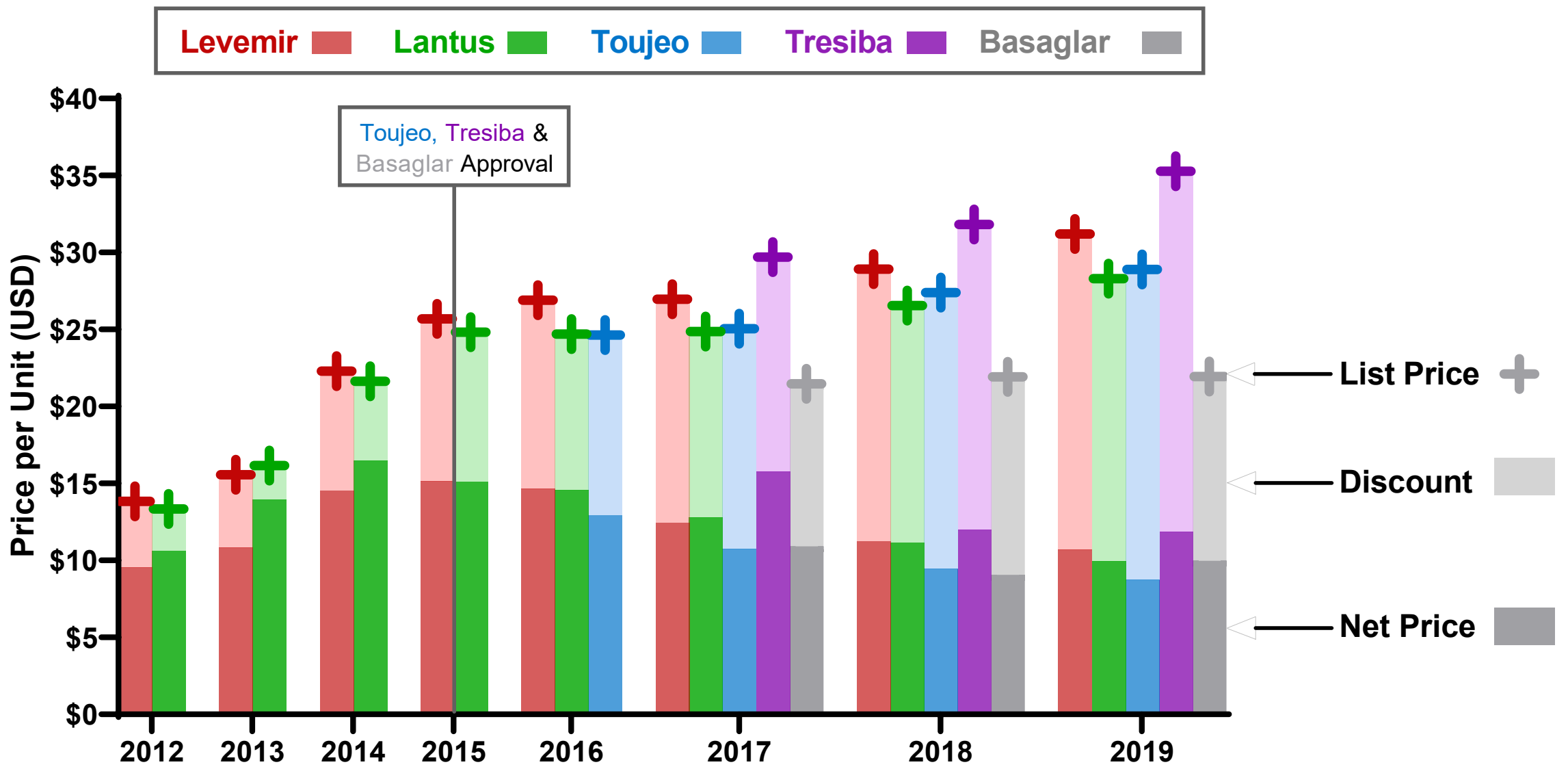


Medicare Part D is a public program, but it is administered by private plans

Reimbursement of provider-administered products follows a different model

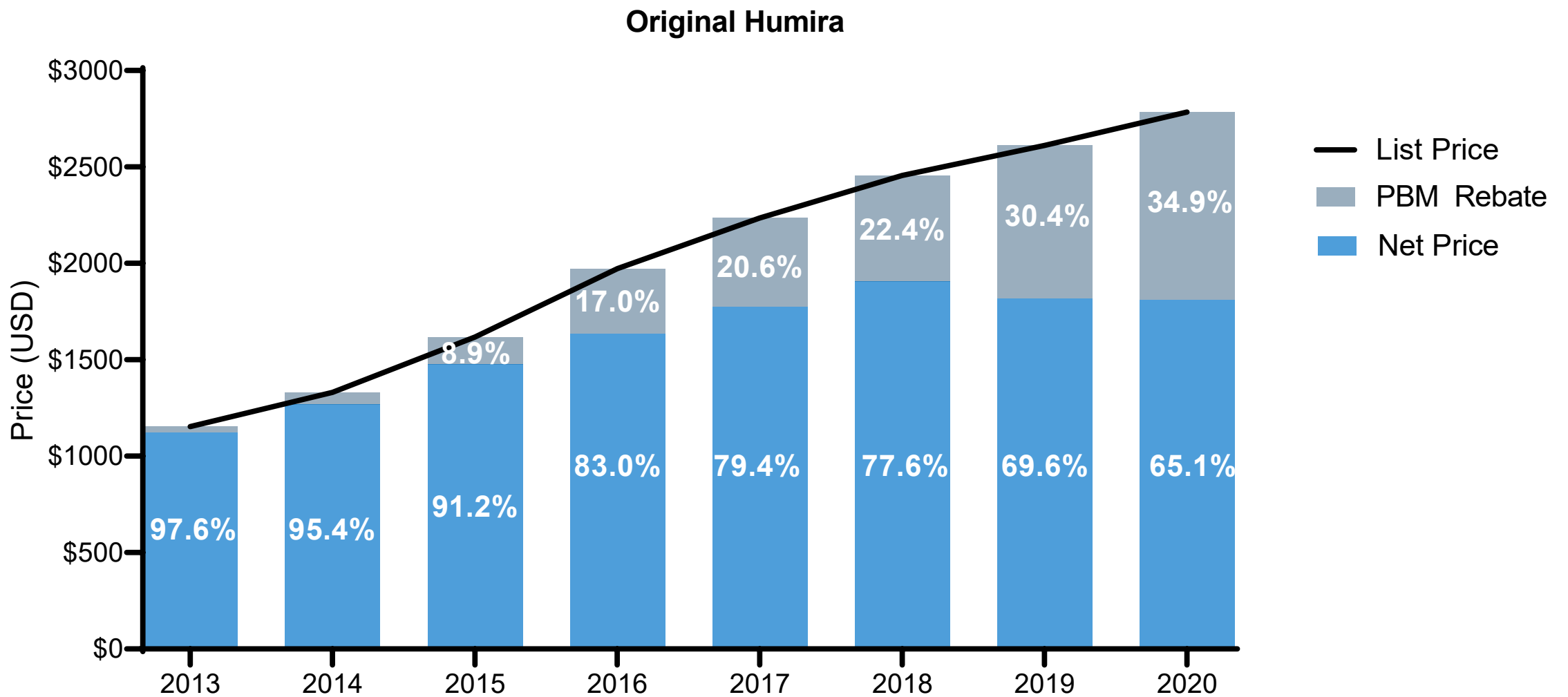


Rising disconnect between list prices and net prices due to increasing rebates





Rising disconnect between list prices and net prices due to increasing rebates





Drug pricing approach in Medicare before IRA

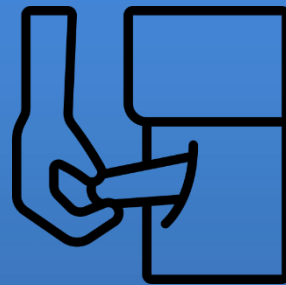
- Manufacturers freely set up list prices
- Part D plans negotiate discounts in exchange for formulary space
- Large variability in discounts across therapeutic classes based on:
 - Competition
 - Whether a drug belongs to a protected drug class



Inflation Reduction Act



Drug
negotiation



Out-of-pocket
cap



Inflation
discounts



Drug negotiation under the Inflation Reduction Act

- Medicare will negotiate prices of highest gross-spending drugs
 - 10 pharmacy-dispensed drugs in 2026 (selected in 2023)
 - 15 pharmacy-dispensed drugs in 2027
 - 15 pharmacy-dispensed or provider-administered drugs in 2028
 - 20 pharmacy-dispensed or provider-administered drugs per year after 2029
- **Medicare** (and not the plans) will negotiate
 - Negotiated price “maximum fair price” will apply to all Medicare plans

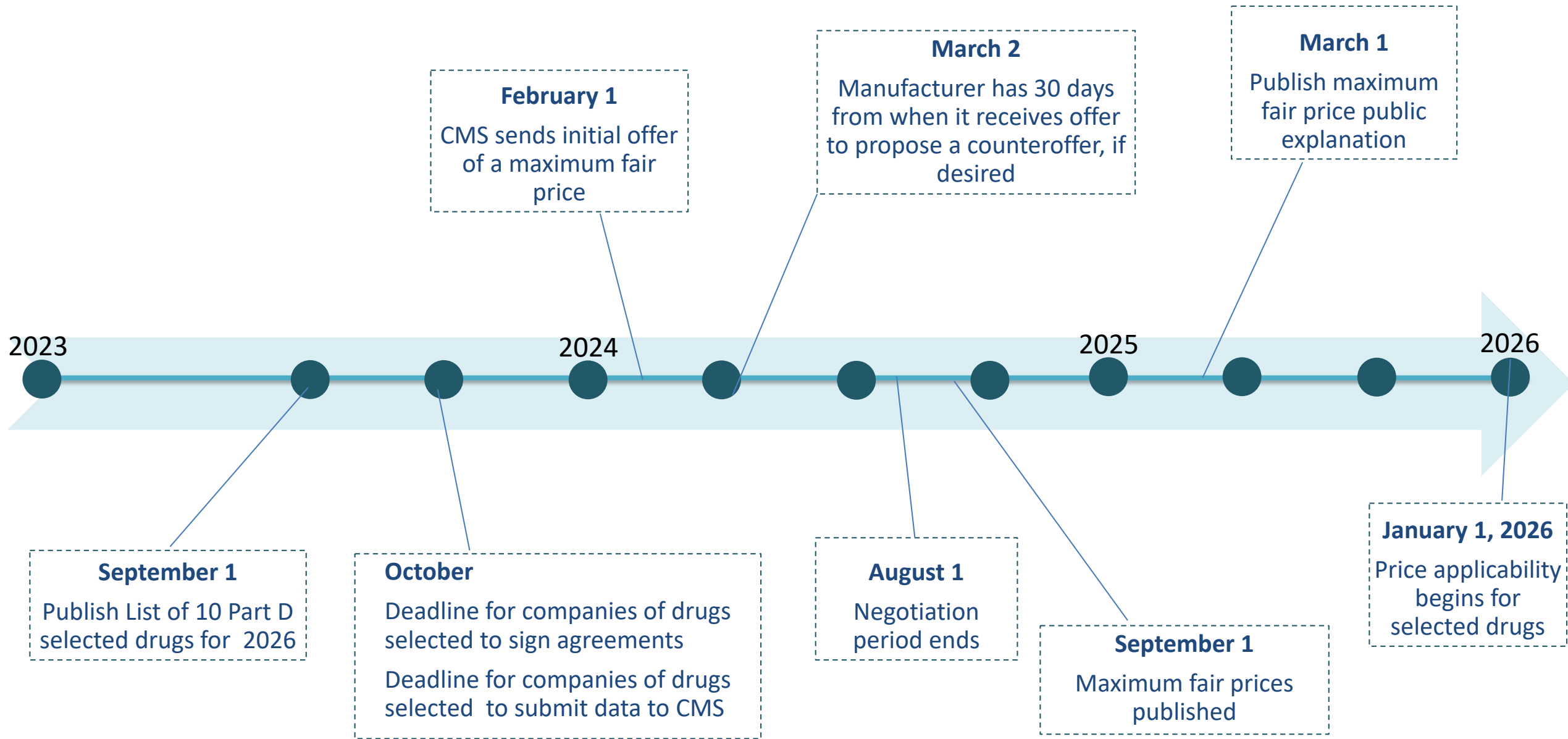


Drug negotiation under the Inflation Reduction Act

- Selection based on
 - Gross Medicare spending
 - Time on the market
 - Small Molecule Drugs - 9 years from FDA approval
 - Biologics - 13 years from FDA approval
- Drugs are ineligible for negotiation if
 - They have a generic / biosimilar marketed
 - They only have orphan indications
 - They account for 80% of company's revenue
 - They are plasma-derived



Drug negotiation under the Inflation Reduction Act





First 10 drugs selected for 2026

Rank	Brand	Company	Therapeutic Area	Gross Spending
1	Eliquis	BMS	Cardiovascular	\$16.5B
2	Jardiance	BI	Cardiovascular, Diabetes	\$7B
3	Xarelto ¹	J&J	Cardiovascular	\$6B
4	Januvia	Merck & Co.	Diabetes	\$4.1B
5	Farxiga	AstraZeneca	Diabetes, Cardiovascular	\$3.3B
6	Entresto	Novartis	Cardiovascular	\$2.8B
7	Enbrel	Amgen	Immunomodulators	\$2.8B
8	Imbruvica	Abbvie	Oncology	\$2.6B
9	Stelara ¹	J&J	Immunomodulators	\$2.6B
10	Novolog, Fiasp	Novo Nordisk	Diabetes	\$2.6B



Drug negotiation under the Inflation Reduction Act

- The statute sets a cap for the negotiated price, which is the lower of:
 - Average net price paid by Part D plans in 2022 (after discounts)
 - Minimum discount based on time since approval, until 2030:
 - » 25% for 9-16 years
 - » 60% for 16+years



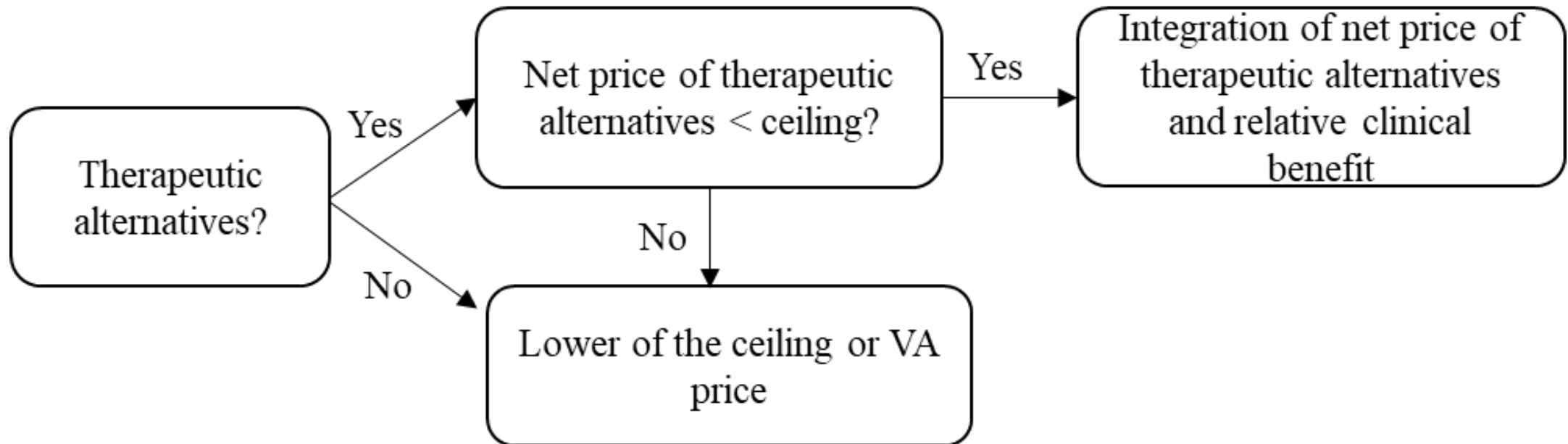
Drug negotiation under the Inflation Reduction Act

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 - Average net price paid by Part D plans in 2022 (after discounts)
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 - Current market-based approach to price negotiation:
 - Will continue to apply on the earlier years after market entry
 - Will set the reference for price negotiation once a drug is eligible for negotiation



Drug negotiation under the Inflation Reduction Act

- Simplified overview of process to determine initial price offer



- Qualitative integration of clinical benefit and pricing data
 - No implicit threshold of willingness to pay
 - No QALY-based data
- Other factors will be used to adjust price offer: unmet need, population-specific data, R&D costs, production and distribution costs, % of R&D subsidized by federal funds



Sources of uncertainty

- What is considered a therapeutic alternative?
- How is the price – clinical benefit trade-off quantified?



Inflation Reduction Act



Drug
negotiation



Out-of-pocket
cap



Inflation
discounts



Out-of-pocket maximum

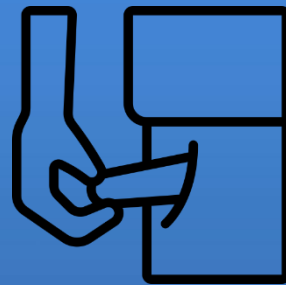
- Out-of-pocket expenses towards pharmacy-dispensed drugs capped at \$2,000 / year
 - Will benefit 15% of beneficiaries (3.1-3.5 million)
 - Average savings of \$1,529/beneficiary
- No limit for provider administered drugs



Inflation Reduction Act



Drug
negotiation



Out-of-pocket
cap



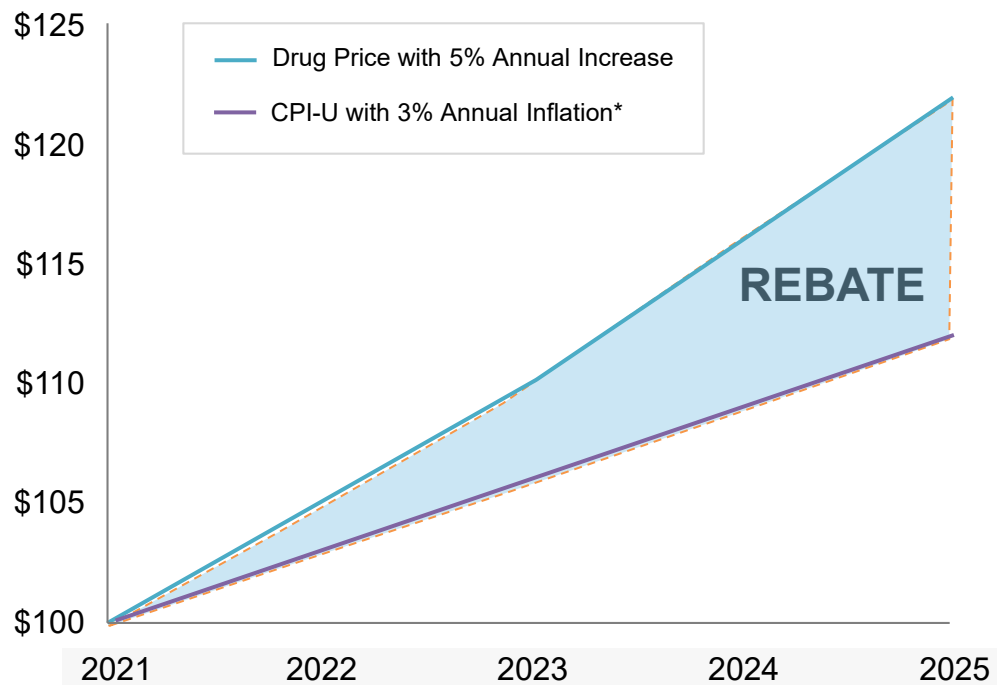
Inflation
discounts



Inflation discounts

- Drugs with prices that increase faster than inflation will be subject to rebates for the amount that exceeds inflation
- Price protection against post-launch increases
- Concerns regarding incentives for higher launch prices

Illustration of Price Increase Penalty



$\% \Delta$ CPI-U = 13% (1.00 to 1.13)
 $\% \Delta$ P = 22% (\$100 to \$122)
 \Rightarrow rebate = \$122 - \$113 = \$9

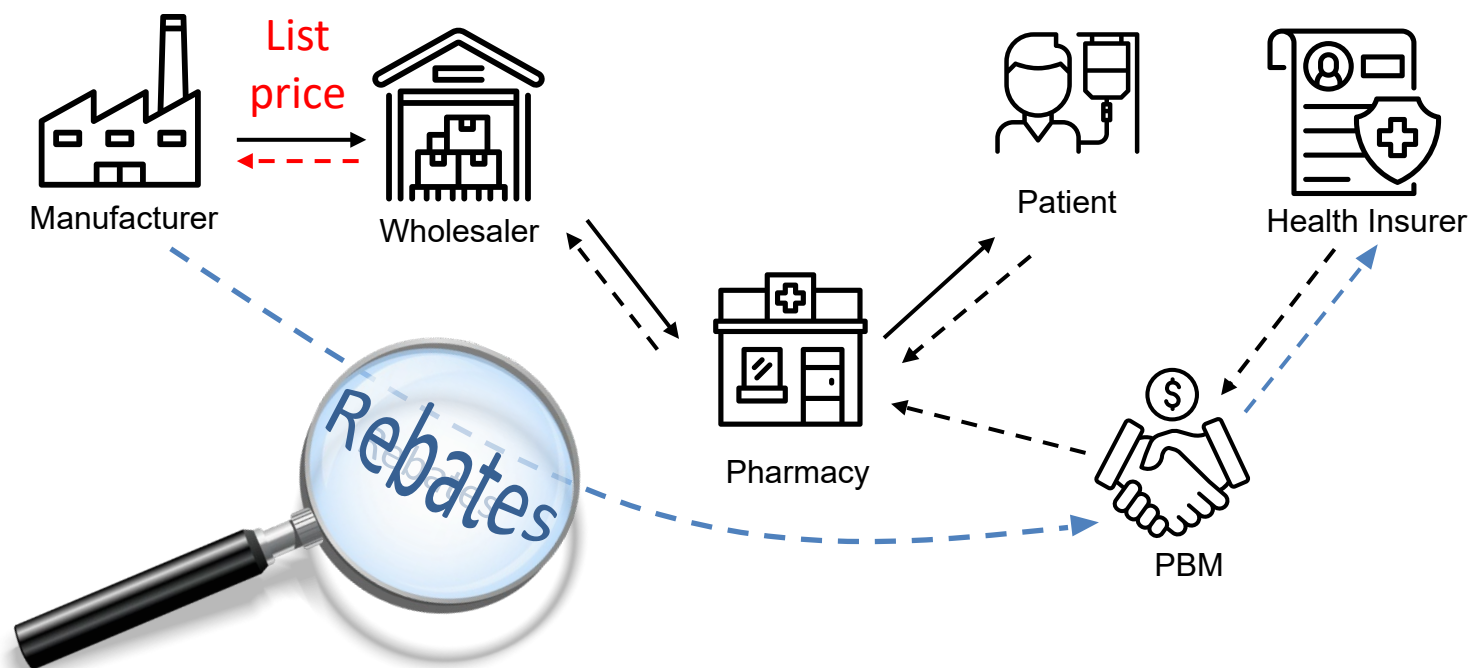


Inflation index is consumer price index January 2021



Takeaway Points

- The Inflation Reduction Act of 2022 is the most significant pharmaceutical policy reform in the US since Medicare Part D was enacted
- Medicare price negotiation may be the most known provision, but not the only one
 - Inflation discounts provide protection from post-launch increases and apply to all drugs
 - Out-of-pocket maximum will limit patient liability for pharmacy-dispensed drugs
- Private insurer negotiation for rebates will remain the main approach
 - Before drugs become eligible for negotiation
 - For drugs ineligible for negotiation





Thank you!

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