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# Pharmaceutical Pricing in 2026

## Dramatic Changes or More of the Same?

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SpencerFane®

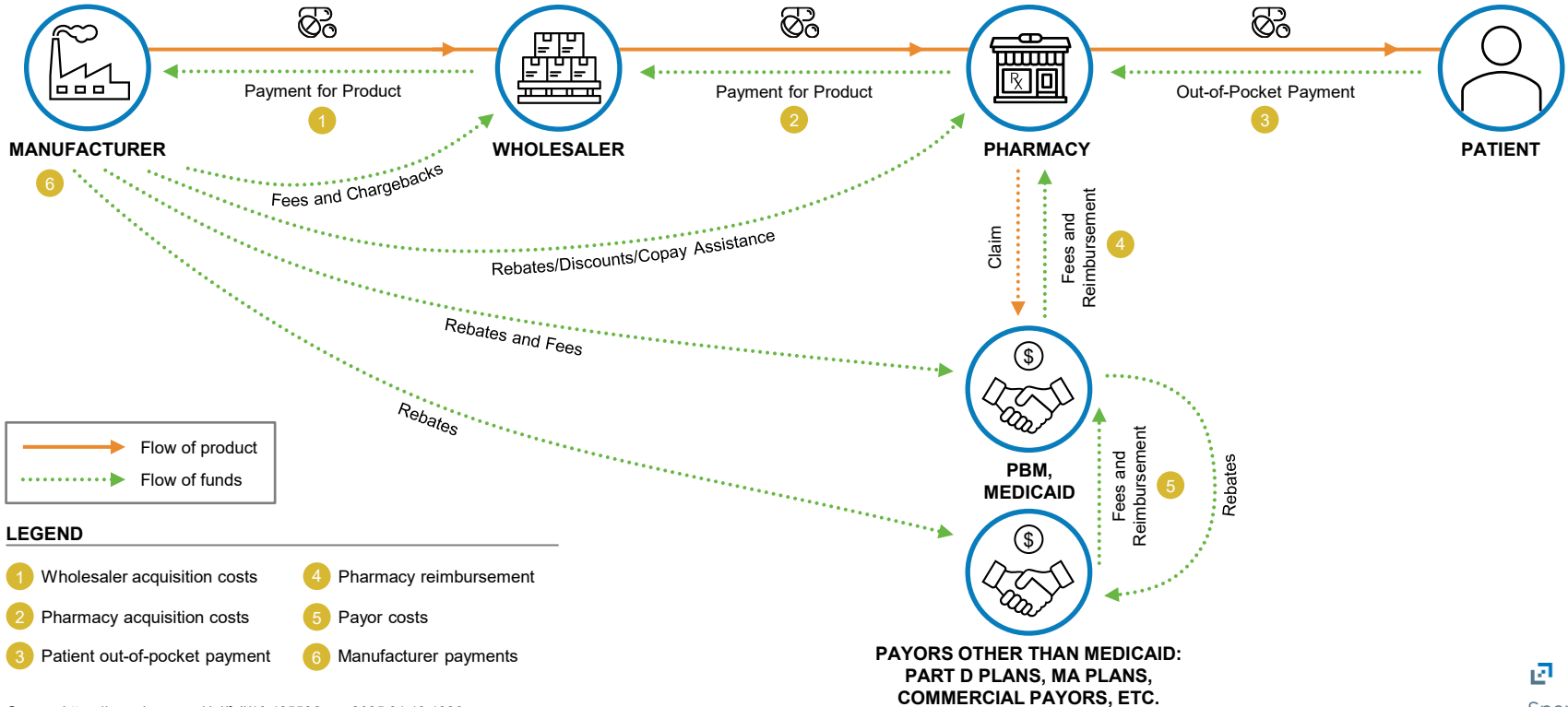
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# Agenda

- Background – What is “Pricing”?
- Medicaid Best Price
- 340B Discounted Price
- Inflation Reduction Act
  - Drug Price Negotiation Program
  - Inflation Rebates
- “Most-Favored-Nation” Price
- Direct-to-Consumer Price
- PBM Reforms Impacting Pricing
- State Reforms Impacting Pricing

# Background – What is “Pricing”?



# Medicaid Best Price

- What is it?
  - A federal statute that requires manufacturers to provide rebates to Medicaid programs to ensure they get the “best price” available in the market for the manufacturer’s products
- What governs It?
  - Omnibus Budget Reconciliation Act of 1990 42 USC 1396r-8, as amended
  - 42 CFR 447.500-522
- Direct impact?
  - Medicaid
- Mechanism?
  - #6 Statutory and supplemental rebates from manufacturers (along with CMS rebate)

# Medicaid Best Price

- Indirect impacts?
  - Generally excludes specific government programs from the “best price” calculation (e.g., IHS, DVA, 340B), but not IRA negotiated price
  - Generally excludes cash prices directly to patients and bona fide services fees
  - Impacts pricing offered in other markets for concerns about reducing the manufacturer’s “best price” that would then apply across Medicaid
- Changes in 2026?
  - Best price reductions from implementation of IRA negotiated prices
  - Financial impact on state Medicaid budgets in lost rebates from having fewer Medicaid participants

# 340B Discounted Price

- What is it?
  - A federal statute that requires manufacturers to provide their drugs to certain non-profit, safety-net health care providers (340B Covered Entities) at a discounted price, so they can then charge payors a higher price and use the margin to fund programs
- What governs it?
  - Section 340B of the Public Health Services Act of 1992, codified at 42 USC 256b, as amended
  - 42 CFR Part 10
- Direct impact?
  - 340B Covered Entities
- Mechanism?
  - #2, #6 Discounted pricing through wholesalers with chargebacks from manufacturers

# 340B Discounted Price

- Indirect impacts?
  - Medicaid – duplicate discount prohibition
  - Contract pharmacies – MFP rebate nonduplication, dispensing fees
  - PBMs, rebate aggregators, and commercial payors – rebate exclusions
  - 340B administrators and other consultants
- Changes in 2026?
  - Exclusions in contract pharmacy arrangements of MFP products
  - Proposed conversion from purchase discounts to rebates
  - Data transparency – state laws and manufacturer policies
  - Restoration of contract pharmacy access under certain state laws
  - Litigation

# Inflation Reduction Act (IRA)

- What is it?
  - Federal law enacted in 2022 that includes multiple provisions intended to reduce Medicare Part B and Medicare Part D (including MA-PD) spending on prescription drugs
  - Two provisions of the IRA work in tandem to decrease the amount Medicare (and Medicare beneficiaries) spend on drugs:
    - Drug Price Negotiation Program
    - Inflation Rebates
- What governs it?
  - Drug Price Negotiation Program – Pub. L. 117-169 § 1191-1198 (administered by CMS)
  - Inflation rebates – Pub. L. 117-169 § 1101-1102; 42 C.F.R. Parts 427 & 428 (CMS)

# IRA Drug Price Negotiation Program

- Direct impacts?
  - CMS negotiates a “Maximum Fair Price” (MFP) for Medicare for selected Medicare Part B and D high-cost, brand-name drugs without current generic or biosimilar competitors
  - Medicare plans are required to cover MFP drugs
  - Medicare Part D (and MA-PD) beneficiaries only pay a cost share based on the MFP for the selected drugs at the point-of-sale
  - Manufacturers and dispensing entities required to participate in the Medicare Transaction Facilitator (MTF), a CMS-administered software, in order to exchange MFP claims data
- Mechanism?
  - #6 Rebates from manufacturers paid to pharmacies

# IRA Drug Price Negotiation Program

**Table 1: Negotiation Program Timeline for Drug Prices to Take Effect in 2026 Through 2029**

	<b>Number of drugs<sup>a</sup></b>	<b>Negotiation period</b>	<b>Maximum fair prices announced</b>	<b>Maximum fair price goes into effect</b>
Price year 2026	10 Part D drugs	October 21, 2023 – August 1, 2024	No later than September 1, 2024	January 1, 2026
Price year 2027	15 additional Part D drugs	February 28, 2025 – November 1, 2025	No later than November 30, 2025	January 1, 2027
Price year 2028	15 additional Part D or Part B drugs	February 28, 2026 – November 1, 2026	No later than November 30, 2026	January 1, 2028
Price year 2029	20 additional Part D or Part B drugs	February 28, 2027 – November 1, 2027	No later than November 30, 2027	January 1, 2029

Source: GAO analysis of Inflation Reduction Act of 2022. | GAO-25-106996

- 2026 – Includes diabetes, auto-immune, and blood disorder medications
- 2027 – Includes diabetes, weight-loss, auto-immune, respiratory, mental health, and cancer medications
- 2028 – Includes diabetes, HIV, auto-immune, respiratory, migraine, mental health, and cancer medications

# IRA Drug Price Negotiation Program

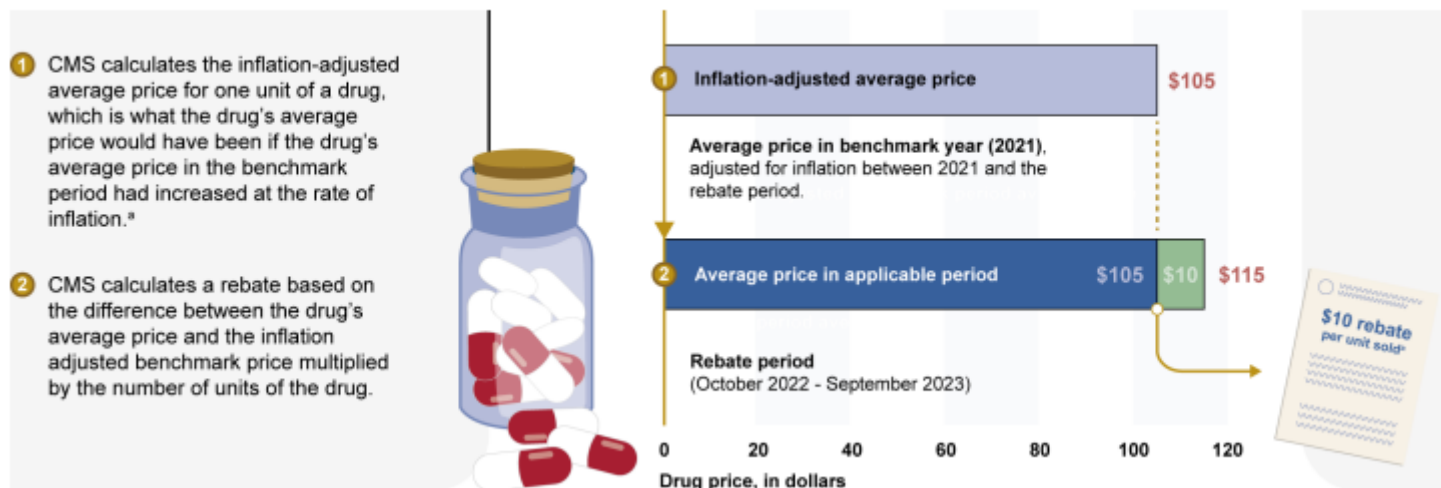
- Indirect impacts?
  - Traditional cash flow to wholesalers and dispensing entities is disrupted
  - Reduced 340B margin
  - Downward pressure on drug prices of MFP drugs (or non-MFP drugs in same therapeutic category as MFP drugs) to commercial payors
- Changes in 2026?
  - 1/1/26 first 10 MFP effective for pricing and coverage requirements
  - Negotiation of 2028 MFP (first inclusion of Part B)

# IRA Inflation Rebates

- Direct impacts?
  - Manufacturers pay rebates to Medicare if they raise prices for certain drugs covered by Part B and nearly all drugs covered by Part D faster than the rate of inflation
    - Drugs with a MFP excluded from rebate calculation, but still subject to inflation rebates
    - First invoices sent to manufacturers in 2025
  - Reduces Medicare drug spending because price increases are capped
    - For 2023 and 2024, CMS calculates that manufacturers owe about \$1.32 billion in total inflation rebates
- Mechanism?
  - #6 Statutory rebates from manufacturers (paid to Medicare)

# IRA Inflation Rebates

**Figure 2: Illustration of a Part D Inflation Rebate Calculation**



Source: GAO analysis of Inflation Reduction Act of 2022 and Centers for Medicare & Medicaid Services documentation; GAO (illustration). | GAO-25-108996

# IRA Inflation Rebates

- Indirect impacts?
  - May keep price increases down for commercial payors as well as Medicare
  - Potential incentive to launch new products at higher initial prices
  - For Part B, Medicare beneficiary coinsurance for certain covered drugs reduced to reflect average inflation-adjusted price
- Changes in 2026?
  - First payments due from manufacturers
  - Implementation of claims-based methodology for exclusion of drugs for which a manufacturer provided a 340B discount from Part D inflation rebate calculation

# “Most-Favored-Nation” Price

- What is it?
  - Objective for manufacturers to “provide” drugs in the U.S. at prices that are aligned with the lowest prices paid for the same drugs in other similarly-situated countries
- What governs it?
  - Expectation of compliance expressed in 5/12/25 Trump Executive Order and 7/31/25 Trump Letters to 17 manufacturers
  - Voluntary, confidential agreements with manufacturers
- Direct impact?
  - Objective is to impact Medicare, Medicaid, commercial payors, and direct-to-consumer pricing
- Mechanism?
  - To be determined



THE WHITE HOUSE  
WASHINGTON  
July 31, 2025

Mr. David Ricks  
Eli Lilly and Company

Dear Mr. Ricks,

On May 12, 2025, I signed an Executive Order—*Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients*—to stop global freeloading and guarantee that Americans pay the same prices enjoyed by other developed nations. Right now, brand name drug prices in the United States are up to three times higher on average than elsewhere for the identical medicines. This unacceptable burden on hardworking American families ends with my Administration.

Most proposals my Administration has received to “resolve” this critical issue promised more of the same: shifting blame and requesting policy changes that would result in billions of dollars in handouts to industry. Moving forward, the only thing I will accept from drug manufacturers is a commitment that provides American families immediate relief from the vastly inflated drug prices and an end to the free ride of American innovation by European and other developed nations. Accordingly, I am calling on Eli Lilly and Company and every manufacturer doing business in our great country to take the following actions within the next 60 days:

- **Extend Most-Favored-Nation (MFN) pricing to Medicaid:** Provide your full portfolio of existing drugs at MFN rates for every single Medicaid patient.
- **Guarantee MFN pricing for newly-launched drugs:** Contract with the United States to guarantee Medicare, Medicaid, and commercial payers receive MFN prices on all new drugs—both upon launch and moving forward.
- **Return increased revenues abroad to American patients and taxpayers:** Domestic MFN pricing will require you, and all manufacturers, to negotiate harder with foreign freeloading nations. U.S. trade policy will endeavor to support this. However, increased revenues abroad must be repatriated to lower drug prices for American patients and taxpayers through an explicit agreement with the United States.
- **Provide for Direct Purchasing at MFN Pricing:** Participate in Direct-to-Consumer (DTC) and/or Direct-to-Business (DTB) distribution models for high-volume, high-rebate prescription drugs so all Americans get the same low MFN prices that manufacturers already offer to third-party payers.

My team, including Secretary Kennedy and Administrator Oz, stand ready to implement these terms. I expect you to further engage with them immediately, in good faith, to deliver relief for American families.

Make no mistake: a collaborative effort towards achieving global pricing parity would be the most effective path for companies, the government, and American patients. But if you refuse to step up, we will deploy every tool in our arsenal to protect American families from continued abusive drug pricing practices.

Americans are demanding lower drug prices, and they need them today. Other nations have been freeloading on U.S. innovation for far too long; it is time they pay their fair share. I look forward to your binding commitments to each of these goals by September 29, 2025, and my team stands ready to assist with implementation questions. Thank you for your immediate attention to this vital national priority.

Sincerely,

# “Most-Favored-Nation” Price

- Indirect impacts?
  - To be determined
- Changes in 2026?
  - Proposed Medicare Part B GLOBE Model (Oct. 2026)
  - Proposed Medicare Part D GUARD Model (Jan. 2027)
  - Proposed Medicaid GENEROUS Model (Jan. 2026; voluntary)

# Direct-to-Consumer Price

- What is it?
  - Manufacturer or government maintained (TrumpRx) platforms facilitating cash payment and dispense of selected drugs at “most favored nation” prices
- What governs it?
  - Expectation of compliance expressed in 5/12/25 Trump Executive Order and 7/31/25 Trump Letters to 17 manufacturers
  - Voluntary, confidential agreements with manufacturers
- Direct impact?
  - Patient access to cash pricing through various means
- Mechanism?
  - #6 Generally as rebates, discounts, or chargebacks from manufacturers to pharmacies or wholesalers

# Direct-to-Consumer Price

## TrumpRx



## AstraZeneca Direct

- 1 ASPN Pharmacies will text you to confirm they have received your prescription
- 2 ASPN Pharmacies will check if you qualify for AstraZeneca Support programs and provide your lowest cost options to consider
- 3 You choose how to receive your medication
- 4 Your medication arrives with clear instructions for use and information on how to get support if needed

# Direct-to-Consumer Price

- Indirect impacts?
  - Traditional cash flow to dispensing entities may be disrupted
  - Could decrease commercial payor spending on drugs due to increase in cash pay
  - Integration of telehealth with direct-to-consumer platforms
- Changes in 2026?
  - Launch of TrumpRx in February 2026
  - HHS issued a Request for Information on 1/29/26 soliciting feedback on the need for an Anti-Kickback Statute safe harbor related to direct-to-consumer programs

# PBM Reforms Impacting Pricing

- What is it?
  - Statutory reform provisions for PBMs included in Consolidated Appropriations Act, 2026, passed 2/3/2026 that require 100% pass through of rebates from PBMs to plans (along with other requirements not directly related to pricing)
- What governs it?
  - PL 119-75 Section 6224 (Medicare Part D and Medicare Advantage); Section 6702 (ERISA)
- Direct impact?
  - Medicare Part D Plans (for plan years after 1/1/28)
  - Medicare Advantage Part D Plans (for plan years after 1/1/28)
  - ERISA Plans (for plan years after 8/3/28)
- Mechanism?
  - #5 Pass-through rebates to payors from PBMs

# PBM Reforms Impacting Pricing

- Indirect impacts?
  - Could result in restructuring of arrangements throughout the industry
- Changes in 2026?
  - Since PBM contracting is typically for three-year terms, contracts entered in 2026 should include flexibilities

# State Reforms Impacting Pricing

- Many states are taking action that can impact drug pricing
  - 340B contract pharmacy protections
  - 340B nondiscrimination provisions
  - Transparency reporting requirements
  - Licensure requirements for entities engaged in PBM activities
  - Prohibition on ownership of pharmacies by payors
- Can be applicable to areas that are typically regulated at the state level
  - State-regulated plans (state-sponsored and fully-insured)
  - Hospitals
  - Pharmacies
  - Pharmaceutical distribution activities

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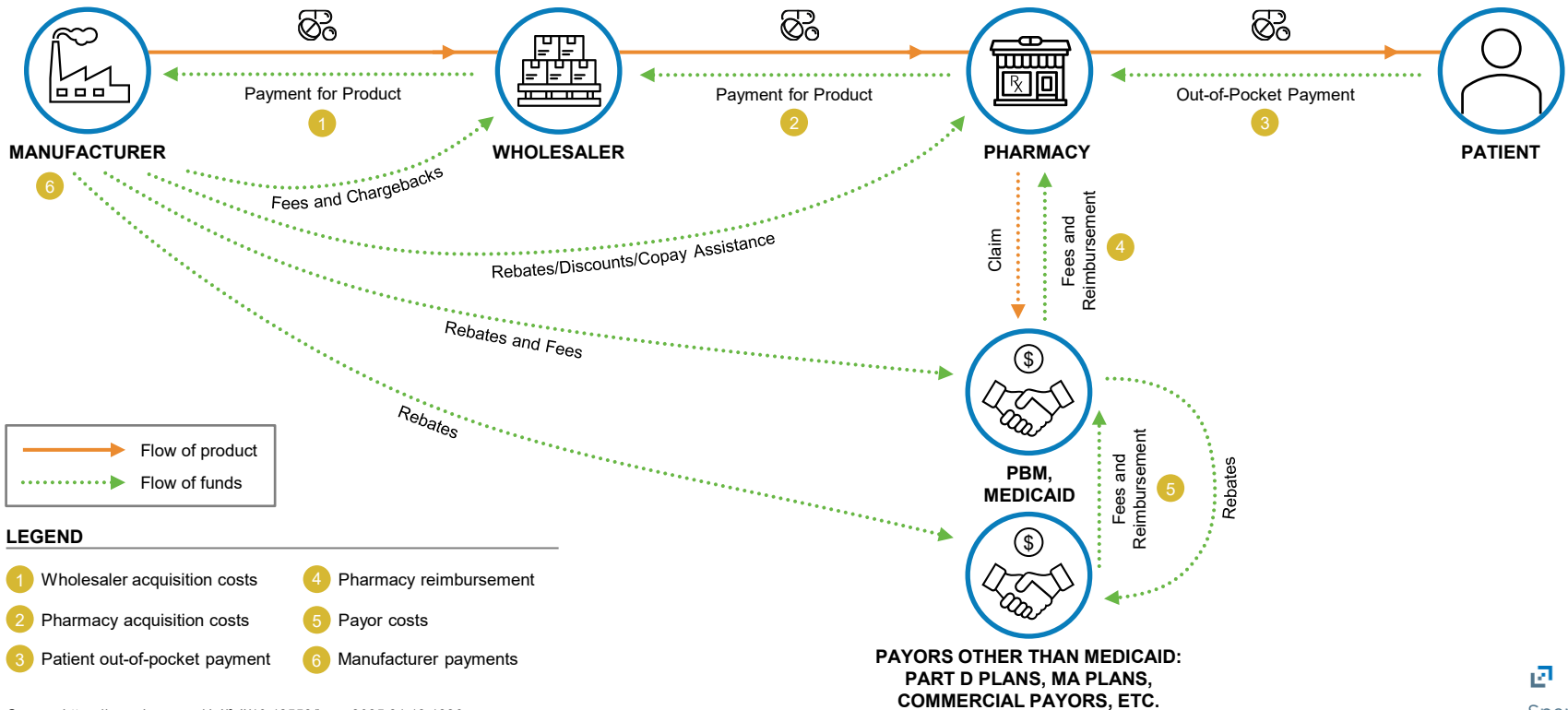
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# Thank You!



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