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The Inflation Reduction Act: What Medicare Drug Price Negotiation Means for Pharmacy

A presentation for HealthTrust Members
May 20, 2026

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Learning Objectives:

Pharmacists, Nurses & Healthcare Executives:

1. Recognize the key IRA (Inflation Reduction Act) drug pricing provisions, including negotiation eligibility and timelines.

2. Recall how IRA policies affect Medicare reimbursement and pharmacy operations.

3. Identify expected impacts of IRA implementation on pharmaceutical manufacturers, payors and health systems.

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Learning Objectives:

Pharmacy Technicians:

1. Recall how the IRA drug pricing provisions will impact a patient's access to prescription medications.

2. Recognize how IRA policies affect Medicare reimbursement and the impact this has on patient out-of-pocket expenses.

3. Identify expected impacts of IRA implementation to the patient population.

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Background

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Importance

Drug affordability remains a key policy focus

Medicare spending continues to rise

Structural changes to drug pricing and reimbursement introduced

Ongoing implementation of these changes creates uncertainty

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What Is the Inflation Reduction Act (IRA)?

- Enacted in 2022, the IRA is a broad piece of legislation intended to address concerns regarding inflation by achieving the following goals:

Energy

- Invest in climate and clean energy initiatives
- Support jobs within the energy sector
- Reduce cost of energy for Americans

Taxes

- Make tax code fairer by requiring companies making over $400k in annual profits to pay more Federal income tax

Healthcare

- Subsidize health insurance for Americans
- Allow Medicare to negotiate lower prices
- Penalize pharmaceutical suppliers for rapid price increases

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The IRA and Healthcare

- Extension of health insurance subsidies for middle- and low-income families
- First time Medicare granted authority to negotiate for lower drug prices
- Pharmaceutical suppliers punished if drug prices rise faster than inflation
- Operational impacts from Medicare Parts B and D redesigns

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Drug Price Negotiation

Key IRA provisions affecting pharmacy

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Medicare Drug Price Negotiation

- Medicare previously prohibited by law from directly negotiating with pharmaceutical suppliers
- The IRA allows Medicare to negotiate for lower drug prices for the most expensive drugs
- Negotiated prices apply directly to Medicare programs
  - However, these lowered prices have wider impact considerations within pharmacy

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Medicare Drug Price Negotiation Process

1. Medicare selects drugs

- Drugs ranked for eligibility according their total spend through Part B and Part D
- Pre-specified number of drugs allowed to be added to program each year

2. Medicare negotiates a Maximum Fair Price (MFP) for each drug

- Maximum Fair Price establishes ceiling price for Medicare patients and providers
- Negotiations must conclude ≥14 months prior to selected drugs' "go-live" date
- Medicare may occasionally renegotiate the Maximum Fair Price

3. Drugs remains on program until generics or biosimilars available

- Drugs with competition will be removed from program the following year

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Drug Selection Eligibility

Eligible Drug

- Patent Exclusivity
- High Spend
- Non-Orphan Status
- Non-Plasma Derived

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Drugs Targeted for Price Negotiation

- Drugs with the highest spend in Medicare Part B or Part D

- Branded drugs without available generics or biosimilars
  - Lack of competition may lead to runaway prices
  - 7 years of patent exclusivity for small molecule drugs
  - 11 years of patent exclusivity for biologics

- Significant burden for Medicare beneficiary out-of-pocket costs and healthcare provider acquisition costs

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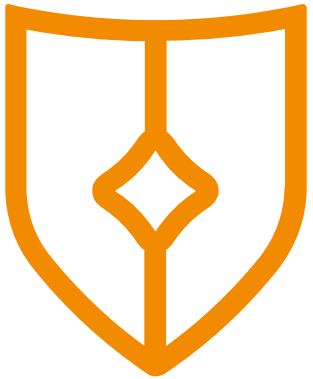
Biosimilar Safeguard

- Special rule in place to delay selection and negotiation for biologics if a biosimilar is expected to launch prior to a selected biologic's "go-live" date

- Intent is to encourage biosimilar investment and competition
  - Cutting the cost of the reference biologic via Medicare negotiations may discourage biosimilar manufacturers from launching their product



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Supplier Noncompliance: Monetary Penalties

- Penalties levied against suppliers who:
  - Fail to negotiate a Maximum Fair Price during the negotiation period
  - Sell a selected drug above the negotiated Maximum Fair Price to eligible individuals or facilities
  - Knowingly provide false information when negotiating Maximum Fair Price (penalty of $100 Million per falsified item)

- Penalties range from 65-95% of all sales of a noncompliant drug, increasing the longer the drug is noncompliant

- Penalties continue until supplier is compliant

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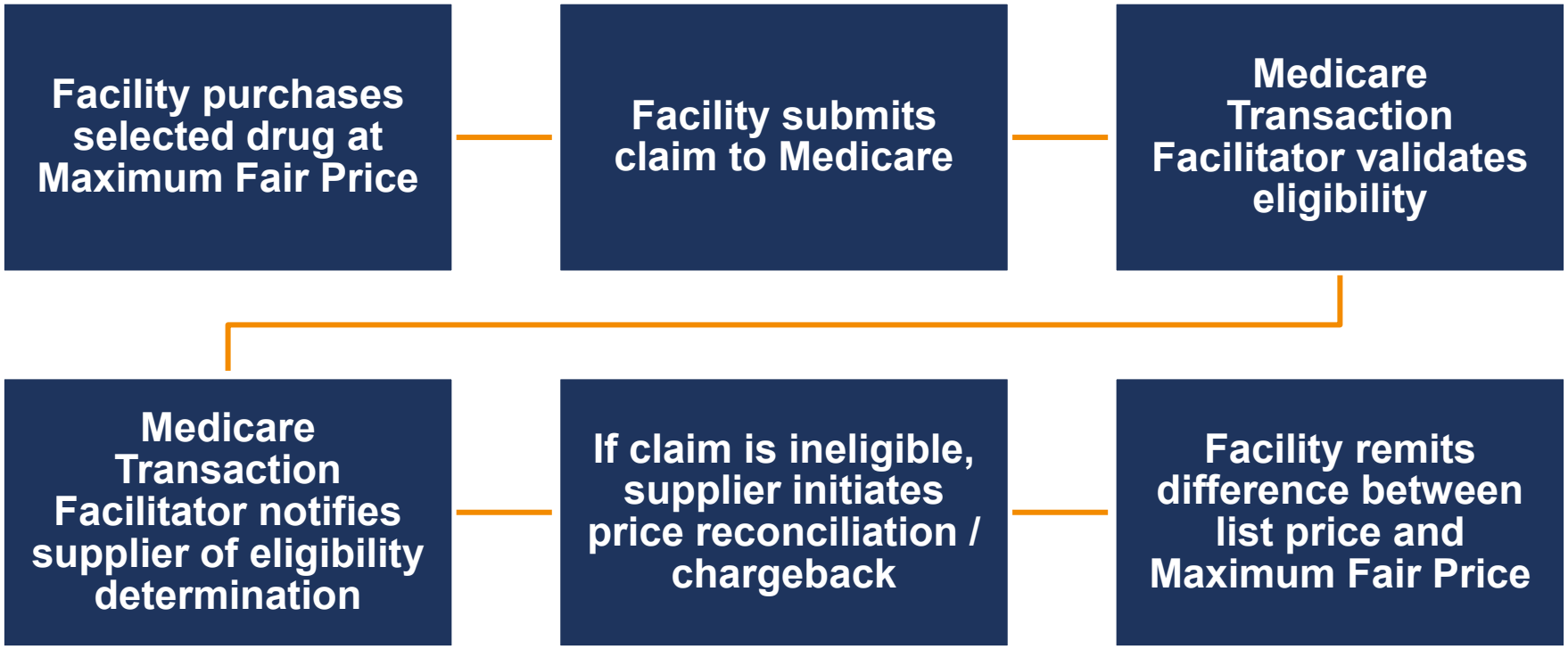
Maximum Fair Price Prospective Model

- Allows suppliers to provide Maximum Fair Price via upfront discount
  - Maximum Fair Price applied at time of purchase, subject to eligibility
  - Financial reconciliation required if drug is dispensed to an ineligible patient



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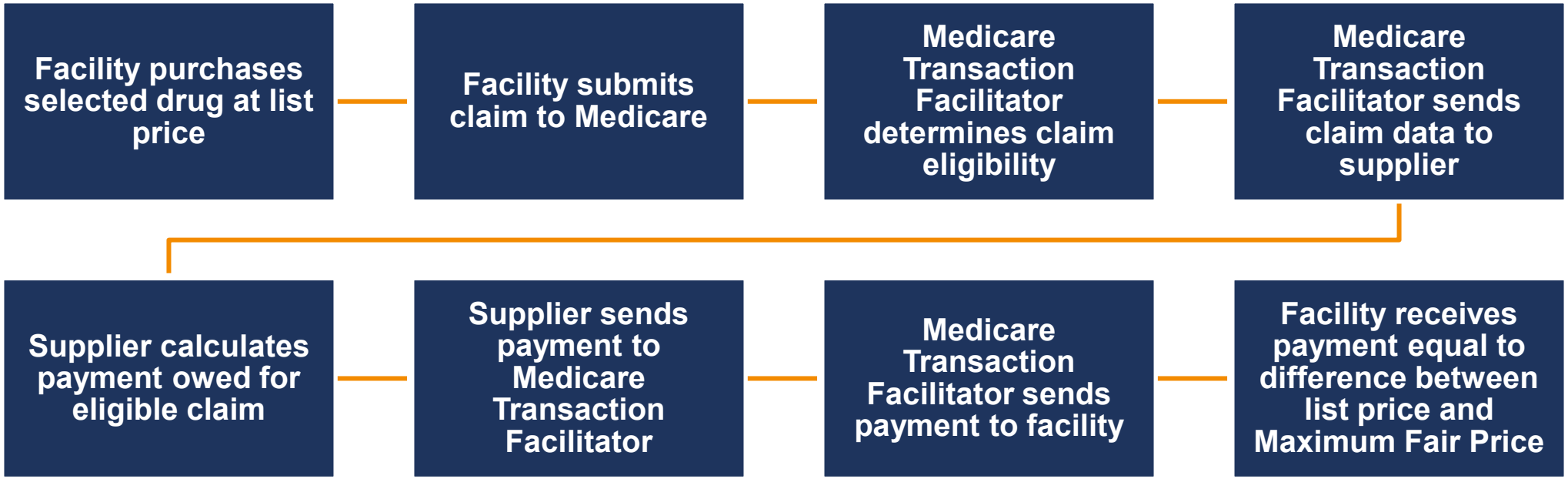
Maximum Fair Price Retrospective Model

- Allows suppliers to control access to Maximum Fair Price via retrospective refund
  - Refund = [List price] – [Maximum Fair Price]
  - Refund must be sent within 14 days of supplier receiving claim data



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2026 Selected Drug List

$56 Billion in Medicare Spend, 2023

Brand Name (Generic Name)	Common Indication(s)	Route(s) of Administration	Medicare Spend
Eliquis (apixaban)	Atrial Fibrillation, Venous Thromboembolism	Oral Tablet	$18.3 Billion
Jardiance (empagliflozin)	Diabetes Mellitus	Oral Tablet	$8.8 Billion
Xarelto (rivaroxaban)	Atrial Fibrillation, Venous Thromboembolism	Oral Tablet	$6.3 Billion
Farxiga (dapagliflozin)	Diabetes Mellitus	Oral Tablet	$4.3 Billion
Januvia (sitagliptin)	Diabetes Mellitus	Oral Tablet	$4.1 Billion
Entresto (sacubitril/valsartan)	Heart Failure	Oral Tablet	$3.4 Billion
Stelara (ustekinumab)	Plaque Psoriasis, Crohn's Disease	SQ	$3.0 Billion
Enbrel (etanercept)	Rheumatoid Arthritis, Plaque Psoriasis	SQ	$3.0 Billion
Fiasp/Novolog (insulin aspart)	Diabetes Mellitus	SQ	$2.6 Billion
Imbruvica (ibrutinib)	Lymphocytic Leukemia, Graft-vs-Host Disease	Oral Capsule	$2.4 Billion

SQ = subcutaneous

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2026 Selected Drugs: International Comparison

Brand Name (Generic Name)	Common Indication(s)	Route(s) of Administration	2023 CMS Negotiated Price*	2024 Peer Nation Average Price*
Eliquis (apixaban)	Atrial Fibrillation, Venous Thromboembolism	Oral Tablet	$249	$76
Jardiance (empagliflozin)	Diabetes Mellitus	Oral Tablet	$204	$52
Xarelto (rivaroxaban)	Atrial Fibrillation, Venous Thromboembolism	Oral Tablet	$206	$82
Farxiga (dapagliflozin)	Diabetes Mellitus	Oral Tablet	$182	$54
Januvia (sitagliptin)	Diabetes Mellitus	Oral Tablet	$117	$39
Entresto (sacubitril/valsartan)	Heart Failure	Oral Tablet	$314	$139
Stelara (ustekinumab)	Plaque Psoriasis, Crohn's Disease	SQ	$4,490	$2,822
Enbrel (etanercept)	Plaque Psoriasis, Psoriatic Arthritis	SQ	$2,335	$734
Fiasp, Novolog (insulin aspart)	Diabetes Mellitus	SQ	$134	$50
Imbruvica (ibrutinib)	Lymphocytic Leukemia, Graft-vs-Host Disease	Oral Capsule	$10,619	$5,670

*Prices listed are per 30-day supply. SQ = subcutaneous

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https://www.healthsystemtracker.org/brief/how-medicare-negotiated-drug-prices-compare-to-other-countries

2026 Selected Drugs: Real-World Effects

Brand Name (Generic Name)	2023 CMS Estimated Price Reduction	2026 List Price Reduction	Notes
Eliquis (apixaban)	56%	43%	Loss of patent exclusivity expected 2028
Jardiance (empagliflozin)	66%	44%	Loss of patent exclusivity expected 2032
Xarelto (rivaroxaban)	62%	N/A	Set for removal in 2027 with generic launches
Farxiga (dapagliflozin)	68%	37%	Patent expired; generics recently launched
Januvia (sitagliptin)	79%	42%	Loss of patent exclusivity expected 2026
Entresto (sacubitril/valsartan)	53%	N/A	Set for removal in 2027 with generic launches
Stelara (ustekinumab)	66%	N/A	Set for removal in 2027 with biosimilar launches
Enbrel (etanercept)	67%	N/A	Unclear why list price has not decreased
Fiasp, Novolog (insulin aspart)	76%	75%	No competitors expected within next 5 years
Imbruvica (ibrutinib)	38%	41%	No competitors expected within next 5 years

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2028 Selected Drug List

$27 Billion in Medicare Spend, 2025

Brand Name (Generic Name)	Route(s) of Administration	Medicare Part	Medicare Spend, 2025
Trulicity (dulaglutide)	SQ	D	$4.898 Billion
Biktarvy (bictegravir/emtricitabine/tenofovir)	Oral Tablet	D	$3.904 Billion
Orencia (abatacept)	IV, SQ	IV=B; SQ=D	$2.450 Billion
Cosentyx (secukinumab)	IV, SQ	IV=B; SQ=D	$2.327 Billion
Erleada (apalutamide)	Oral Tablet	D	$1.948 Billion
Kisqali (ribociblib)	Oral Tablet	D	$1.579 Billion
Entyvio (vedolizumab)	IV, SQ	IV=B; SQ=D	$1.483 Billion
Verzenio (abemaciclib)	Oral Tablet	D	$1.429 Billion
Botox (onabotulinumtoxinA)	IM	B	$1.143 Billion
Lenvima (lenvatinib)	Oral Capsule	D	$1.088 Billion
Xolair (omalizumab)	SQ	B; D	$1.077 Billion
Rexulti (brexpiprazole)	Oral Tablet	D	$1.075 Billion
Xeljanz & Xeljanz XR (tofacitinib)	Oral Tablet	D	$1.013 Billion
Anoro Ellipta (umeclidinium/vilanterol)	INH	D	$813 Million
Cimzia (certolizumab pegol)	SQ	B; D	$787 Million

IM = intramuscular, INH = Inhaled, IV = intravenous, SQ = subcutaneous

Pharmacists and Healthcare Executives

Knowledge Check #1

Which drug is **most likely eligible** for Medicare price negotiation under the IRA?

A. A branded drug with multiple generic competitors

B. A high-spend brand drug without generic or biosimilar competition

C. A newly approved orphan drug

D. A low-cost over-the-counter medication

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Pharmacists and Healthcare Executives

Knowledge Check #1: Correct Response

Which drug is **most likely eligible** for Medicare price negotiation under the IRA?

A. A branded drug with multiple generic competitors

B. A high-spend brand drug without generic or biosimilar competition

C. A newly approved orphan drug

D. A low-cost over-the-counter medication

Rationale: IRA negotiation targets high Medicare-spend, single-source branded drugs without generic or biosimilar competition

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Pharmacy Technicians

Knowledge Check #2

What is a primary intended effect of IRA drug pricing provisions on Medicare beneficiaries?

A. Increased drug shortages

B. Reduced access to medications

C. Lower prices of certain high-spend drugs

D. Elimination of prescription drug cost-sharing

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Pharmacy Technicians

Knowledge Check #2: Correct Response

What is a primary intended effect of IRA drug pricing provisions on Medicare beneficiaries?

A. Increased drug shortages

B. Reduced access to medications

C. Lower prices of certain high-spend drugs

D. Elimination of prescription drug cost-sharing

Rationale: Negotiation aims to reduce costs for Medicare patients

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Inflation-Based Price Control

Key IRA Provisions Affecting Pharmacy

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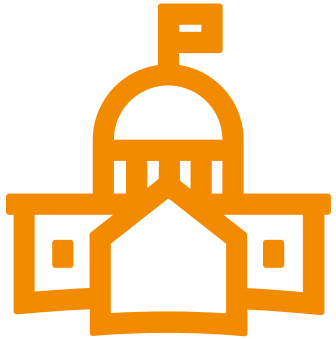
Federal Price Control Precedent

- Medicaid requires suppliers to pay additional rebates for increasing drug prices above national inflation rate
  - Additional rebates proportional to price increase above inflation

- Health Resources and Services Administration (HRSA) requires suppliers to reduce their 340B ceiling price proportional to price increases above national inflation rate
  - May result in “penny-pricing”, where the 340B ceiling price is temporarily reduced to $0.01



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Medicare Inflation-Based Taxes

- Applied to most drugs covered by Medicare Part B or Part D
  - Part A not directly affected, but may benefit from controlled prices
- Suppliers must pay taxes in the form of rebates if prices rise faster than inflation
  - Rebates different for drugs covered under Part B and Part D
- Inflation-based tax used to reduce monthly premiums, out-of-pocket costs, and coinsurance for Medicare beneficiaries
- Failure to pay results in penalties ≥ 125% of the rebate owed

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Inflation-Based Rebates for Part B

$14 Million owed in 2023

$121 Million owed in 2024

- Applies to provider-administered, “buy-and-bill” drugs
- Rebates proportional to Average Sales Price (ASP) increase above inflation and number of units billed to Medicare
- Exceptions for drugs billed via 340B, drugs on shortage, or not separately payable

Billing Code	Brand Name (Generic Name)	2024 Rebate Owed
J0897	Xgeva (denosumab)	$79.9 Million
J9177	Padcev (enfortumab vedotin-ejfv)	$15.5 Million
J0775	Xiaflex (collagenase clostridium histolyticum)	$4.7 Million

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Inflation-Based Rebates for Part D

$501 Million owed in 2023

$780 Million owed in 2024

- Applies to self-administered drugs
- Rebates proportional to Annual Manufacturer Price (AMP) increase above inflation and number of units billed to Medicare
- Exceptions for drugs billed via 340B, drugs on shortage, and very low-spend generics

NDC-9	Brand Name (Generic Name)	2023 Rebate Owed
00169-4132	Ozempic (semaglutide)	$191.9 Million
00078-0639	Cosentyx (sekunimab)	$56.8 Million
55513-0137	Otezla (apremilast)	$34.0 Million

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Interaction with Drug Price Negotiation Program

- When a drug enters a negotiation or renegotiation period, inflation-based rebates are paused until negotiations conclude
- Once negotiation or renegotiation period ends, inflation-based rebates are reset
- Prevents double-penalties stemming from negotiation-reduced prices and inflation-based rebates

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Pharmacists and Healthcare Executives

Knowledge Check #3

A health system is managing a drug selected for IRA negotiation. How does the Maximum Fair Price (MFP) most directly impact them?

A. It replaces all commercial payor pricing

B. It establishes a payment ceiling that may compress margins

C. It sets pharmacy dispensing fees

D. It applies only to Medicaid claims

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Pharmacists and Healthcare Executives

Knowledge Check #3: Correct Response

A health system is managing a drug selected for IRA negotiation. How does the Maximum Fair Price (MFP) most directly impact them?

A. It replaces all commercial payor pricing

B. It establishes a payment ceiling that may compress margins

C. It sets pharmacy dispensing fees

D. It applies only to Medicaid claims

Rationale: The Maximum Fair Price functions as a ceiling price for Medicare, which can affect reimbursement relative to acquisition cost and impact margins

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Pharmacy Technicians

Knowledge Check #4

How do inflation-based rebates affect Medicare beneficiaries?

A. Increase patient coinsurance when prices rise faster than inflation
B. Reduce patient coinsurance when prices rise slower than inflation
C. Reduce patient coinsurance when prices rise faster than inflation
D. Eliminate all patient cost-sharing

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Pharmacy Technicians

Knowledge Check #4: Correct Response

How do inflation-based rebates affect Medicare beneficiaries?

A. Increase patient coinsurance when prices rise faster than inflation

B. Reduce patient coinsurance when prices rise slower than inflation

C. Reduce patient coinsurance when prices rise faster than inflation

D. Eliminate all patient cost-sharing

Rationale: Under Medicare Part B, coinsurance for patients is based on the inflation-adjusted Average Sales Price

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Additional Medicare Redesign

Key IRA Provisions Affecting Pharmacy

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Medicare Part B Under the IRA

- Part B reimbursement for most drugs: 106% of Average Sales Price (ASP)
  - Newly-launched biosimilars: Temporarily increased to 108% of Average Sales Price
  - Selected drugs: 106% of Maximum Fair Price (MFP)

- Coinsurance inflation protection for Medicare beneficiaries

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Medicare Part D Under the IRA

- Annual out-of-pocket cap for Medicare beneficiaries
  - $2,000 for 2025, increasing annually with inflation
  - Replaces the coverage gap (“donut hole”)
  - Part D plans may elect to spread out-of-pocket costs smoothly throughout the year, instead of high up-front costs

- Elimination of beneficiary cost-sharing for certain vaccines
  - Applies to vaccines covered by Part D and recommended by the Advisory Committee on Immunization Practices (ACIP)

- Catastrophic coverage liability shifted away from Medicare and toward plans and suppliers

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Pharmacists and Healthcare Executives

Knowledge Check #5

Which response is most likely from pharmaceutical suppliers as a result of IRA implementation?

A. Increase prices faster than inflation

B. Eliminate all contracting strategies

C. Moderate price increases and adjust launch pricing

D. Discontinue high-cost drug development

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Pharmacists and Healthcare Executives

Knowledge Check #5: Correct Response

Which response is most likely from pharmaceutical suppliers as a result of IRA implementation?

A. Increase prices faster than inflation

B. Eliminate all contracting strategies

C. Moderate price increases and adjust launch pricing

D. Discontinue high-cost drug development

Rationale: Suppliers are expected to moderate pricing strategies and reconsider launch pricing due to negotiation and rebate pressures

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Pharmacy Technicians

Knowledge Check #6

Which statement best reflects a current limitation of the IRA's impact?

A. It applies immediately to all drugs
B. It eliminates all patient cost-sharing
C. Its full impact is gradual and still evolving
D. It replaces all commercial drug pricing

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Pharmacy Technicians

Knowledge Check #6: Correct Response

Which statement best reflects a current limitation of the IRA's impact?

A. It applies immediately to all drugs

B. It eliminates all patient cost-sharing

C. Its full impact is gradual and still evolving

D. It replaces all commercial drug pricing

Rationale: IRA implementation is phased and evolving, and long-term system-wide effects remain uncertain

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Responses From Major Pharmacy Organizations

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PhRMA Position Statement

- Pharmaceutical Research and Manufacturers of America (PhRMA) is a professional organization of biopharmaceutical researchers and manufacturers.

- PhRMA objects to the IRA, stating it:
  1. Stifles pharmaceutical innovation and post-approval research
  2. Incentivizes insurance plans to move drugs to higher-cost tiers
  3. Ultimately punishes patients

https://phrma.org/policy-issues/government-price-setting/inflation-reduction-act

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AMCP Position Statement

- The Academy of Managed Care Pharmacy (AMCP) is a professional organization of health plans, pharmacy benefit managers, and other managed care organizations.

- AMCP supports the IRA, stating that it:
  1. Improves patient access to biosimilar products
  2. Lowers drug costs
  3. Enhances treatment outcomes for the future

https://www.amcp.org/press-releases/amcp-statement-passage-inflation-reduction-act

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ASHP Position Statement

- The American Society of Health-System Pharmacists (ASHP) is a professional organization of pharmacy professionals in multiple health-system based care settings.

- While ASHP supports the IRA, they have expressed concern for Medicare's support of the retrospective refund model. In a 2025 letter addressed to CMS, ASHP stated this model:
  1. Is inconsistent with the IRA both by intent and as-written
  2. Is inconsistent with CMS' commitment to "regulatory simplification, administrative efficiency, and pharmaceutical price transparency"
  3. Is inconsistent with a sustainable healthcare delivery system

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https://news.ashp.org/-/media/assets/advocacy-issues/docs/2025/Pharmacy-Memo-to-CMS-IRA-Implementation-Legality-10-30-25-A.pdf

ASHP Position Statement

- ASHP further emphasized that:
  - Manufacturers are solely responsible for effectuating the Maximum Fair Price under the IRA
  - Retrospective rebates unlawfully shift financial risk to pharmacies, making them “cash lenders to manufacturers”
  - Rebate models undermine price transparency and predictability

- ASHP pointed to the 340B program as clear federal precedent:
  - CMS has an established model for prospective, upfront discounts
  - Upfront discounts ensure “uniformity, predictability, and efficiency”

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https://news.ashp.org/-/media/assets/advocacy-issues/docs/2025/Pharmacy-Memo-to-CMS-IRA-Implementation-Legality-10-30-25-A.pdf

Operational Implications

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Operational Considerations for Pharmacy

- Reduced costs and reimbursement for selected drugs
  - May require more frequent formulary updates
- More complex processes required to navigate prospective and retrospective Maximum Fair Price models
  - Complexity increases as selected drug list grows
- Long-term effects on 340B covered entities remain unclear

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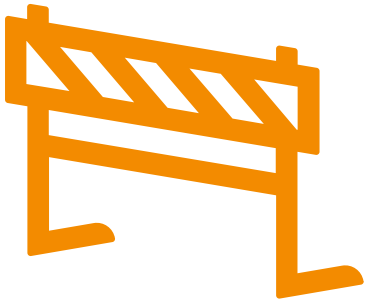
Operational Impacts on 340B Covered Entities

- Increased financial burden
  - Covered entities may need to purchase drugs at prices higher than the Maximum Fair Price or 340B ceiling price and wait for retrospective refunds, effectively floating prices to manufacturers
  - Disproportionally impacts safety-net facilities with thin margins



- 340B vs Maximum Fair Price claim identification challenges
  - Many covered entities rely on virtual inventory models, making it impractical to identify 340B claims at the point of sale
  - Suppliers lack visibility into 340B eligibility data, increasing risk of erroneous eligibility determination
  - Current reports show up to 20% of eligible Maximum Fair Price refunds are missing

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https://340breport.com/three-operational-challenges-as-medicares-maximum-fair-price-scales-sponcon-plenful

Assessing Early Outcomes

- The IRA's negotiated prices for 2026 are currently active
- Mixed pricing signals to date
  - Some suppliers providing up-front discount
  - Others relying on retrospective refund model
  - Unclear if one model will predominate
- Operational challenges ongoing
- Too early to determine success

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Future Considerations

- Rapid expansion of selected drug list
  - 15 drugs added annually for 2027-2028
  - 20 drugs added annually for 2029+

- Continued policy refinement
  - Prospective discount model vs retrospective refund model

- Legislative pressures from pharmaceutical suppliers, managed care organizations, and health systems make predicting the future difficult

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What Pharmacy Needs to Do Now

- Work with pharmacy leadership to support decision-making and rollout new operational initiatives

- Stay up to date on CMS plans
  - Changes to Maximum Fair Price discount models
  - Announcement of 2028 negotiated Maximum Fair Prices

- Monitor quarterly Part B reimbursement changes
  - Reimbursement lags behind price reductions

- Educate providers and patients

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Thank you!

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