



Inflation Reduction Act of 2022 and its Impact on Medicare and Commercially Insured Patients

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Disclosures

The planners and speaker have indicated that there are no relevant financial relationships with any ineligible companies to disclose.

Learning Objectives

At the end of this session, learners should be able to:

- Summarize the provisions of the Inflation Reduction Act (IRA) that may impact healthcare costs
- Identify medications subject to price negotiation under the IRA
- Describe changes to Medicare prescription coverage under the IRA
- Discuss projected impacts of the IRA

Abbreviation Key

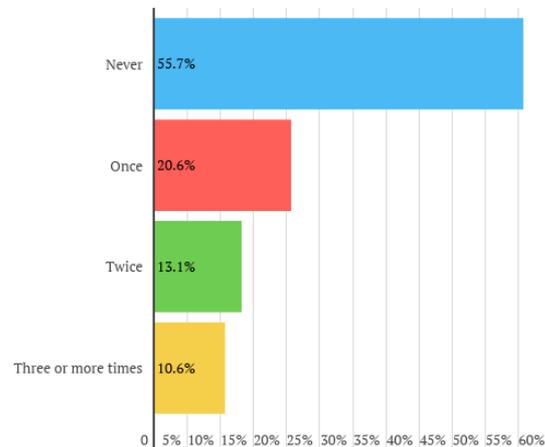
- ACA – Affordable Care Act
- ACIP – Advisory Committee on Immunization Practices
- CHIP – Children’s Health Insurance Program
- CMS – Centers for Medicare and Medicaid Services
- EPA – Environmental Protection Agency
- FPL – Federal Poverty Line
- HHS – Department of Health and Human Services
- IRA – Inflation Reduction Act
- IRS – Internal Revenue Service
- LIS – Low-Income Subsidy
- MDP – Manufacturer Discount Program
- MFP – Maximum fair price
- MOOP – Maximum Out-of-Pocket
- OOP – Out-of-Pocket
- R&D – Research and development

The Inflation Reduction Act

Background: Drug Affordability

- Prescription drug affordability is a major concern for Americans
- 2020 poll showed 44.3% of respondents did not purchase a medically necessary prescription drug due to cost
- Trending upward – similar polls conducted in years prior found about 33% of Americans made a similar choice
- Affordability challenges contribute to adherence challenges and ultimately poorer health outcomes

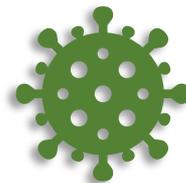
How often, in the past year, have you declined to purchase a necessary prescription because of cost?



Based on an online survey of over 1,000 U.S. adults conducted by [PawnGuru](#), an online marketplace that regularly surveys its community on a range of topics affecting low-income and under-banked Americans.

Background: COVID-19

- Americans experienced significant financial strain during the COVID-19 pandemic
 - Layoffs, inflation, economic uncertainty, loss of insurance coverage
 - Low-income adults disproportionately affected
- Initial mitigating strategy examples:
 - [Family First Coronavirus Response Act \(2020\)](#)
 - [Coronavirus Aid, Relief, and Economic Security Act \(CARES\) \(2020\)](#)
 - [American Rescue Plan \(2021\)](#)
- Some success found in attempts to alleviate healthcare affordability concerns
 - Medication affordability improved from 2019 to 2022
 - Delays in filling prescriptions were less common in 2022
 - Improvements in healthcare coverage among low-income adults
- Improvements highlight ongoing need to address healthcare affordability



Inflation Reduction Act of 2022

- Budget reconciliation package introduced to federal House of Representatives September 2021
 - Built from the framework of the previously introduced Build Back Better Act
 - Passed with partisan support from house democrats
- Signed into law by President Joe Biden on August 16th, 2022
- Key areas of focus:
 - Offset effects of inflation from COVID-19
 - Clean energy investment
 - Prescription drug and health insurance affordability



IRA Non-Healthcare Provisions



Clean Energy Investments

- Tax credits for renewable energy and electric vehicles
- Funding for programs that support renewable energy, conservation, and sustainability
- Funding for the Environmental Protection Agency (EPA) to address air pollution
- Funding for Bureau of Indian Affairs for programs to improve climate resilience for Native Americans and Native Hawaiians



Tax Reforms

- Alternative 15% minimum corporate tax rate for income statements that exceed \$1 billion
- 1% excise tax on corporate stock repurchases (buybacks)
- Allocates funding and resources to the Internal Revenue Service (IRS) to raise federal revenue

Healthcare Provisions Summary

Drug Price
Negotiations

Medicare
Reforms

Affordable Care
Act (ACA) Subsidy
Extensions

Anti-Kickback
Safe Harbor
Extensions

Drug Price Negotiations

- IRA allows the Centers for Medicare and Medicaid Services (CMS) to negotiate maximum fair prices (MFP) for single-source drugs with high costs frequently utilized in the Medicare population
 - Starting with 10 drugs in 2026
 - Chosen drugs must be among the top-50 highest spend under Medicare
 - Allows delays in negotiations for drugs with pending biosimilars
 - Orphan drugs excluded from negotiation process
- Negotiation process:
 - CMS provides an initial offer, considering manufacturer needs (research & development costs, etc.)
 - Manufacturers provide counter-offer, final MFP is set after discussion
- Negotiations timeline:
 - **2026:** 10 drugs
 - **2027:** 15 drugs
 - **2028:** 15 drugs
 - **2029 and thereafter:** 20 drugs per year



2026 List

- Negotiated prices for these agents went into effect January 1, 2026
- Disease states represented:
 - Diabetes
 - Anticoagulation
 - Heart failure
 - Rheumatologic conditions
 - Leukemia

Drug	Discount of Negotiated Price from 2023 List Price
Eliquis [®] (apixaban)	56%
Enbrel [®] (etanercept)	67%
Entresto [®] (sacubitril/valsartan)	53%
Farxiga [®] (dapagliflozin)	68%
Fiasp [®] , Novolog [®] (insulin aspart)	76%
Imbruvica [®] (ibrutinib)	38%
Januvia [®] (sitagliptin)	79%
Jardiance [®] (empagliflozin)	66%
Stelara [®] (ustekinumab)	66%
Xarelto [®] (rivaroxaban)	62%

Drug	Number of Medicare Part D Enrollees Who Used the Drug (2023)	Total Part D Gross Covered Prescription Costs (2023)
Eliquis [®] (apixaban)	3,928,000	\$18,275,108,000
Enbrel [®] (etanercept)	48,000	\$2,951,778,000
Entresto [®] (sacubitril/valsartan)	664,000	\$3,430,753,000
Farxiga [®] (dapagliflozin)	994,000	\$4,342,594,000
Fiasp [®] , Novolog [®] (insulin aspart)	785,000	\$2,612,719,000
Imbruvica [®] (ibrutinib)	17,000	\$2,371,858,000
Januvia [®] (sitagliptin)	843,000	\$4,091,399,000
Jardiance [®] (empagliflozin)	1,883,000	\$8,840,947,000
Stelara [®] (ustekinumab)	23,000	\$2,988,560,000
Xarelto [®] (rivaroxaban)	1,324,000	\$6,309,766,000
Total 2023 Expenditure	\$56,215,482,000	

2023 Savings to Part D if 2026 Rates Were Effective

\$21,393,760,020

Centers for Medicare & Medicaid Services. Medicare Drug Price Negotiation Program: negotiated prices for initial price applicability year 2026. August 15, 2024. Accessed December 21, 2025. <https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026>

2027 List

- Broader range of disease states represented in 2027:
 - Diabetes
 - Asthma/COPD
 - Various cancers
 - Movement disorders
 - Psoriasis
 - Hepatic encephalopathy
 - Pulmonary fibrosis
 - Irritable bowel syndrome
 - Schizophrenia

Drug	Discount of Negotiated Price from 2024 List Price
Austedo® , Austedo® XR (deutetrabenazine)	38%
Breo Ellipta® (fluticasone/vilanterol)	83%
Calquence® (acalabrutinib)	40%
Ibrance® (palbociclib)	50%
Janumet® , Janumet® XR (sitagliptin/metformin)	85%
Linzess® (linaclotide)	75%
Ofev® (nintedanib)	50%
Ozempic® , Rybelsus® , Wegovy® (semaglutide)	71%
Otezla® (apremilast)	65%
Pomalyst® (pomalidomide)	60%
Tradjenta® (linagliptin)	84%
Trelegy Ellipta® (fluticasone/umeclidinium/vilanterol)	73%
Vraylar® (cariprazine)	44%
Xifaxan® (rifaximin)	63%
Xtandi® (enzalutamide)	48%

Drug	Number of Medicare Part D Enrollees Who Used the Drug (2024)	Total Part D Gross Covered Prescription Costs (2024)
Austedo® , Austedo® XR (deutetrabenazine)	27,000	\$1,675,176,000
Breo Ellipta® (fluticasone/vilanterol)	626,000	\$1,428,106,000
Calquence® (acalabrutinib)	15,000	\$1,703,116,000
Ibrance® (palbociclib)	16,000	\$2,036,178,000
Janumet® , Janumet® XR (sitagliptin/metformin)	239,000	\$1,067,594,000
Linzess® (linaclotide)	632,000	\$1,982,587,000
Ofev® (nintedanib)	24,000	\$2,087,330,000
Ozempic® , Rybelsus® , Wegovy® (semaglutide)	2,282,000	\$15,161,908,000
Otezla® (apremilast)	31,000	\$1,045,443,000
Pomalyst® (pomalidomide)	14,000	\$2,150,644,000
Tradjenta® (linagliptin)	274,000	\$1,128,335,000
Trelegy Ellipta® (fluticasone/umeclidinium/vilanterol)	1,269,000	\$5,296,660,000
Vraylar® (cariprazine)	118,000	\$1,136,814,000
Xifaxan® (rifaximin)	105,000	\$1,158,988,000
Xtandi® (enzalutamide)	35,000	\$3,401,099,000
Total 2024 Expenditure	\$42,459,978,000	

2024 Savings to Part D if 2027 Rates Were Effective

\$15,088,557,240

Inflation Rebate Program



- Drug manufacturers must issue rebates to CMS for brand-name drugs (covered under Medicare parts B and D) without generic equivalents if:
 - Drug costs > \$100 per year per individual
 - Price of the drug is increased at a rate higher than the rate of inflation
- Purpose is to disincentivize manufacturers from increasing drug prices at unmanageable rates
- Manufacturers may request rebate reductions under certain circumstances:
 - Severe supply chain disruption
 - Drug is experiencing shortage (or if shortage is likely)

Assessment Question #1

Which of the following is not a drug that will have its price negotiated by CMS effective January 1, 2026?

- A. Imbruvica[®] (ibrutinib)
- B. Jardiance[®] (empagliflozin)
- C. Eliquis[®] (apixaban)
- D. Humira[®] (adalimumab)
- E. Enbrel[®] (etanercept)

Medicare Reforms Summary

Insulin and
Vaccine
Cost-Sharing

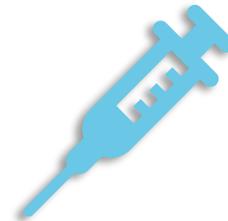
Cost-Sharing
Structure
Changes

Manufacturer
Discount
Program

Extra Help
Program
Extensions

Insulin Cost-Sharing

- As of January 1, 2023: Medicare prescription drug plan enrollees pay no more than **\$35 per month** out-of-pocket (OOP) for insulin
- Medicare part D deductibles do not apply to covered insulin products
- July 2023: these rules also applies to traditional Medicare enrollees receiving insulin via pump covered under a part B benefit
- As of January 1, 2026, maximum monthly insulin OOP cost limited to:
 - \$35
 - 25% of government's negotiated price
 - 25% of plan's negotiated price } *whichever is less*
- *Clarification: President Trump's rescinding of President Biden's Executive Order 14087 (Lowering Prescription Drug Costs for Americans) did not remove this price cap*



Vaccine Cost-Sharing



IRA eliminates cost-sharing for
ACIP-recommended adult vaccines for:

Medicare Part D
Enrollees

Medicaid
Enrollees

CHIP Enrollees

Medicare Part D Cost Sharing

- Before the IRA:



Significant challenges with this structure:

- Flat percentages in donut hole and catastrophic coverage periods: expensive drugs are difficult to afford
- High OOP thresholds for reaching catastrophic coverage
- Financial hardship contributes to adherence challenges and poor outcomes



- After the IRA:

5% cost-share in catastrophic phase eliminated starting in 2024

- Enrollee pays \$0.00 in Medicare D costs once catastrophic is reached

\$2,000 annual out-of-pocket cap starting in 2025

- Annual adjustments thereafter (\$2,100 in 2026)

Coverage gap eliminated altogether

- Shift to a 3-phase benefit structure: **Deductible → Initial Coverage → Catastrophic**

Annual increases to base premiums limited from 2024-2030

- Limit 6%, *or* amount that would apply under prior methodology
- *Whichever is less*

Manufacturer Discount Program (MDP)

- Replaces the Medicare D coverage gap (*fills in the donut hole!*) starting 2025
- Manufacturer pays 10% of allowed part D drug costs after deductible is met
 - Continues until maximum out-of-pocket (MOOP) is met
- Once beneficiary reaches catastrophic coverage, manufacturer pays 20%
- **Previously, manufacturers paid:** (*under the Coverage Gap Discount Program, which ended with the MDP*)
 - 0% during initial coverage period
 - 70% during the coverage gap (*this phase is now eliminated*)
 - 0% during catastrophic coverage
- **Takeaway:** *manufacturer contribution to Medicare D drug costs no longer ends once catastrophic coverage is reached. However, percentage contribution is smaller*



Assessment Question #2

Which of the following phases of Medicare part D coverage was eliminated by the Inflation Reduction Act?

- A. Deductible phase
- B. Initial coverage phase
- C. Coverage gap phase
- D. Catastrophic phase
- E. Enrollment phase

Extra Help Program Extensions

Medicare Prescription Drug Benefit Extra Help Program (Low-Income Subsidy [LIS])

LIS designed to offset out-of-pocket drug costs for low-income households

Beneficiaries qualify automatically if:

- Dual-enrolled in Medicaid
- Receiving state aid for Medicare part B premiums
- Receiving Supplemental Security Income benefits from Social Security
- *All others need to apply for LIS*

2026 Benefits

\$0.00 Medicare part D premiums and deductible

Pay **\$5.10** for generic drugs and **\$12.65** for brand names

Once \$2100.00 OOP costs met, pay **nothing further**

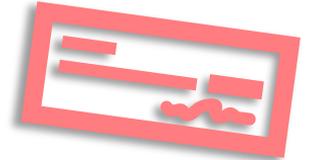
Previous LIS Structure

Full LIS benefit for those with income up to **135%** of federal poverty line (FPL)

Partial subsidy for those with income up to **150%** of FPL

After the IRA

Starting 1/1/2024, **full LIS benefit** available to those with income up to **150%** of FPL



Federal Poverty Guidelines 2026

Persons in Family/Household	Poverty Level
1	\$15,960
2	\$21,640
3	\$27,320
4	\$33,000
5	\$38,680
6	\$44,360
7	\$50,040
8	\$55,720

HHS 2026 Poverty Guidelines for 48 contiguous states and District of Columbia

Example: under the IRA, a household of 2 Medicare part D beneficiaries with combined income up to **\$32,460** are eligible for full LIS benefit

$$(\$21,640 \times 150\%) = \$32,460$$

Under previous LIS structure, the same household would qualify for full benefit at incomes up to \$29,214 and a *partial* benefit up to \$32,640

Miscellaneous Healthcare Provisions

Affordable Care
Act (ACA) Subsidy
Extensions

Anti-Kickback
Safe Harbor
Extensions

ACA Subsidy Extensions



- Premium tax credit established by the [Affordable Care Act \(2010\)](#)
 - Lowered payments by eligible households towards qualified health plans offered on ACA public exchanges
 - Available to those with incomes between 100%-400% of FPL
 - Available since 2014
- Enhanced credits established by the [American Rescue Plan \(2021\)](#)
 - Removed the 400% FPL eligibility upper limit
 - Increased subsidy amounts available to eligible households
 - Enhanced credits originally available from 2021-2022
- Enhanced credits Further extended for 3 more years by the IRA
 - Extended the American Rescue Plan enhanced credits from 2023-2025
 - Enhanced credits sunset January 1, 2026

Anti-Kickback Safe Harbor Protections

(Inflation Reduction Act Sec. 11301) The act further delays until 2032 implementation of a Department of Health and Human Services rule relating to the treatment of certain Medicare prescription drug benefit rebates from drug manufacturers for purposes of federal anti-kickback laws.

- Federal anti-kickback statutes prevent solicitation of business reimbursable under federal healthcare programs (e.g. Medicare, Medicaid)
- Safe harbor protections describe scenarios in which federal anti-kickback statutes will not be enforced *(Even though, in theory, these would be violations)*
- November 30th, 2020: Department of Health and Human Services (HHS) final rule eliminated safe-harbors for certain rebate behaviors
 - Value-based arrangements were previously protected
 - IRA **delays** implementation of this HHS rule until January 1, 2032



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<https://oig.hhs.gov/compliance/safe-harbor-regulations/>

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Assessment Question #3

As of 2026, a Medicare beneficiary whose household income is 140% of the federal poverty line now qualifies for which of the following?

- A. Partial low-income subsidy
- B. Full low-income subsidy
- C. Standard Affordable Care Act premium tax credit
- D. Enhanced Affordable Care Act premium tax credit
- E. No subsidies or tax credits



IRA Impacts

- **Improved part D affordability for high-OOP drugs & insulin**
 - Per one study, OOP drug costs in the coverage gap were 3x that of initial coverage costs for 3 heart failure medications
 - Costs were lowest in the catastrophic phase
 - IRA removed the coverage gap, eliminating the phase with the highest OOP costs
- **Improved access to critical vaccinations**
 - In 2021, Medicare enrollees paid ~\$234 million OOP in vaccine costs (3.4 million patients)
 - OOP costs will be reduced to zero for eligible vaccines
 - Per one study, rate of shingles vaccination before/after IRA:
 - **Increased** for Medicare part D beneficiaries
 - **Decreased** for commercially insured patients
- *Note that majority of the direct impact is felt by Medicare D beneficiaries, but commercial patients will feel some downstream effects (such as negotiated prices)*

Trish E, Van Nuys K, Wu J, Desai NR. The Inflation Reduction Act and patient costs for drugs to treat heart failure. JAMA Netw Open. 2024;7(10):e2441915.

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Tang E, Arnold BF, Acharya NR. Shingles vaccination in Medicare Part D and commercial enrollees after the Inflation Reduction Act. Vaccine. 2025;62:127545. doi:10.1016/j.vaccine.2025.127545



IRA Impacts

- **Anticipated doubling of Medicare D drug costs paid by manufacturers**
 - Despite smaller *percentages* paid under the IRA, payment continues after OOP max
 - Wide variability based on type of drugs a manufacturer may produce
 - More part D costs paid by manufacturers = less costs paid by patients
- **Potential shift in pharmacy benefit formulary design**
 - High list-price, high-rebate drugs have been preferred by pharmacy benefit managers
 - Fewer rebates expected to be offered due to MFP negotiations
 - PBMs may include a larger proportion of low-rebate, low-list price drugs on formulary

Criticisms & Adverse Impacts



Lack of transparency in calculation of maximum fair price

- Negotiation process can be better described as a price setting methodology
- Manufacturers *are* allowed to make a counter-offer on the initial MFP, but there is a set upper limit for each drug based financial data

Reduction in research and development of new treatments

- Estimated to decrease manufacturer revenue by ~31% through 2039
- Estimated 135 fewer new drug approvals during this time
- Lower incentives to expand indications for existing treatments

Criticisms & Adverse Impacts



Reduced competition in the generic and biosimilar markets

- Lower brand prices push down generic prices relative to startup costs
- This disincentivizes new generic launches
- May result in delayed or reduced availability of cheaper alternatives to brand name drugs, preventing reductions in OOP prices paid by patients for brands

Inflation rebates make it more difficult for manufacturers to plan for an uncertain future

- Prices cannot dynamically respond to market forces as easily
- Initial prices may be set higher since manufacturers know they cannot raise prices later
- Less incentive to spend money on ventures that increase market share (new indications, new efficacy research, etc.) if prices are firm

Assessment Question #4

Which of the following is not a potential adverse consequence of the Inflation Reduction Act?

- A. Reduced research and development for new treatments
- B. Less expansion of labeled indications for existing drugs
- C. Fewer generic products entering the marketplace
- D. Estimated reduction in new drug approvals
- E. Increased premiums for Medicare part D beneficiaries

Impact for Advocate Health



- **Medical Utilization Management**
 - Affordable access to negotiated medications may reduce medical spend for the consequences of poor adherence
 - Increasing representation of negotiated oral oncolytics may improve affordability relative to IV infusion alternatives (20% deductible) allowing for more diverse treatment options
- **Population Health - Medicare STARS metrics**
 - Price negotiations affect several drugs tracked for STARS adherence scoring:
 - *Farxiga[®], Januvia[®], Jardiance[®], Janumet[®], semaglutide products, Tradjenta[®]*
 - Price reductions may improve adherence in cases where affordability is a concern
 - Better affordability of Medicare coverage could also result in improvements for medication adherence, readmission rates, and overall health outcomes

Summary



- Prescription drug affordability is a major concern, particularly following COVID-19
- Inflation Reduction Act includes many provisions aimed at addressing these concerns
- Provisions expected to help alleviate drug-related expenditures for Medicare part D beneficiaries (and commercially insured patients, indirectly)
- The IRA is subject to criticism, primarily regarding potential consequences for drug manufacturers and market competition

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Questions?

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