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Understanding Provisions and Implications of the Inflation Reduction Act

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Understanding Provisions and Implications of the Inflation Reduction Act

The tangled web we weave…

Enactment of the Inflation Reduction Act ("IRA") was a long winding road. IRA opens the proverbial door to a new frontier of complex prescription drug provisions with far-reaching implications. For the first time in history, the federal government will negotiate prices for high-cost drugs covered under Medicare. Medicare price increases will be constrained by required inflation rebates when drug prices outpace inflation. Monthly cost sharing for insulin products will be capped at $35 for people with Medicare. Finally, Medicare Part D will be redesigned to eliminate the coverage gap ("donut hole"), cap beneficiary out-of-pocket costs at $2,000 per year, shift costs from the government to drug manufacturers & prescription drug plans and require pharma manufacturers to pay uncapped government rebates.
The purpose of this blog is to explain the major provisions of the Inflation Reduction Act and discuss the implications for patients, pharma manufacturers, prescription drug plans and the government.

Medicare Drug Price Negotiation

The government will select from a list of "negotiation-eligible drugs" (50 from Medicare Part B and 50 from Medicare Part D) to negotiate a new drug price. Note that the government is mandating rather than negotiating the price as there is a "maximum fair price" ceiling reflecting substantial discounts. The high-cost drugs are eligible for price negotiation nine years and thirteen years post FDA approval for small-molecule drugs and biologics, respectively. Drugs that have competing approved and marketed generics or biosimilars are excluded as are small biotech drugs (until 2028) and orphan drugs approved for one rare disease or condition.

The maximum number of drugs for Medicare beneficiaries, subject to negotiation, are as follows:

2026	10	Part D
2027	15	Part D
2028	15	Part D or B
2029	20	Part D or B
2030	20	Part D or B
2031	20	Part D or B
Subtotal	100	
Following years	20	Part D or B

There is potential to be 100 high-spend Medicare drugs in 2031 with a government negotiated price.

The negotiated ceiling "maximum fair price" is dependent on the number of years that have transpired since FDA approval. Maximum fair prices are as follows:

Number of Years Since Approval	Maximum Percent of Non-Federal Average Manufacturer Price
9-12*	75%*
12-16	65%
>16	40%

** Excludes biologics eligible for negotiation 13 years post approval.*

Implications of Medicare Drug Price Negotiation

Although there is a ceiling on the maximum price that can be charged, the government can demand a lower price (higher discount) based on their assessment of the pharma manufacturer's revenue for the drug, recovery of R&D costs, cost of sales, remaining years of exclusivity and evidence regarding alternative treatments as well as comparative effectiveness. Note that discounts from Medicare price negotiation are eligible for Medicaid Best Price which may result in lower Medicaid net sales. The maximum fair price is required to be given to 340B covered entities if the 340B ceiling price is higher.

Companies with drugs not subject to Medicare Price negotiation that have a similar indication to price-negotiated drugs may need to lower their prices to be competitive in the therapeutic category.

Medicare drug price negotiations will suppress innovation and may hamper pursuit of new indications for existing drugs. Fewer new drugs will be launched in disease states where there is a high percentage of sales derived from Medicare. The impact will be more pronounced for disease states with high-cost specialty drugs including oncology, multiple sclerosis and rheumatology.

Inflation Rebates

The Inflation Reduction Act requires drug manufacturers to pay a rebate if drug prices outpace inflation. Computation of the inflation rebate is similar to the CPI Penalty Rebate under Medicaid. The base year benchmark for measuring Medicare Part B and Part D cumulative price increases relative to inflation is 2021. Payments of inflation rebates will be effective beginning January 1, 2023 for Medicare Part B drugs and beginning October 1, 2022 for Medicare Part D drugs.

The Medicare Part B inflation rebate is based on the number of units sold in the rebate quarter multiplied by the amount the Medicare payment exceeds the inflation-adjusted benchmark (third quarter of 2021 for drugs approved after December 1, 2020) quarter.

Medicare Part B Quarterly Rebate

Year	Quarter	Rebate Period CPI-U (numerator)	Benchmark Period CPI-U (denominator)
2023	First	July 2022	January 2021
2023	Second	September 2022	January 2021
2023	Third	January 2023	January 2021
2023	Fourth	April 2023	January 2021
2024	First	July 2023	January 2021
2024	Second	September 2023	January 2021
2024	Third	January 2024	January 2021
2024	Fourth	April 2024	January 2021

The Medicare Part D inflation rebate is based on the number of units sold during the rebate "period" multiplied by the amount by which the weighted average manufacturer price for the rebate period exceeds the inflation-adjusted weighted average manufacturer price for the benchmark period (first through third quarter of 2021 for drugs approved prior to before October 1, 2021).

Medicare Part D Annual Rebate

Rebate Period	Rebate Period CPI-U (numerator)	Benchmark Period CPI-U (denominator)
October 2022 – September 2023	October 2022	January 2021
October 2023 – September 2024	October 2023	January 2021
October 2024 – September 2025	October 2024	January 2021

The impact of Medicare inflation rebates may be minimal due to the high level of prevailing inflation. Inflation as measured by the increase in CPI-U from January 2021 to July 2022 approximated 13%.

Implications of Inflation Rebates

Inflation rebates will have a profound impact on the launch prices established by pharmaceutical manufacturers for newly approved drugs. There is an incentive to launch at a higher price and then limit price increases to be commensurate with inflation to avoid payment of inflation rebates. Price increases in excess of inflation will not be realized for virtually all government programs and commercial contracts with price protection. Note that there could also be a double whammy on the same prescription comprised of Medicare inflation rebates and PBM-negotiated rebates (passed through to the prescription drug plan sponsor) for contracts with price protection.

Medicare Benefit Redesign

There will be a substantial redesign of Medicare Part D starting in 2024 when the 5% coinsurance paid by approximately 1.3 million patients in the catastrophic stage will be eliminated and shifted to the prescription drug plan sponsors. Currently, the amount paid by patients is uncapped. The patient out-of-pocket cap in 2024 for Medicare Part D drugs will approximate $3,250.

> *Example: A patient takes several high-costs Medicare Part D drugs in 2024 totaling $100,000. The patient out-of-pocket costs will be capped at $3,250 under IRA which is substantially lower than the annual out-of-pocket costs of $7,679 under the current law. The 58% reduction in patient out-of-pocket costs (assuming total retail drug costs of $100,000) will translate to higher prescriptions due to lower patient abandonment. More prescriptions written will be filled.*

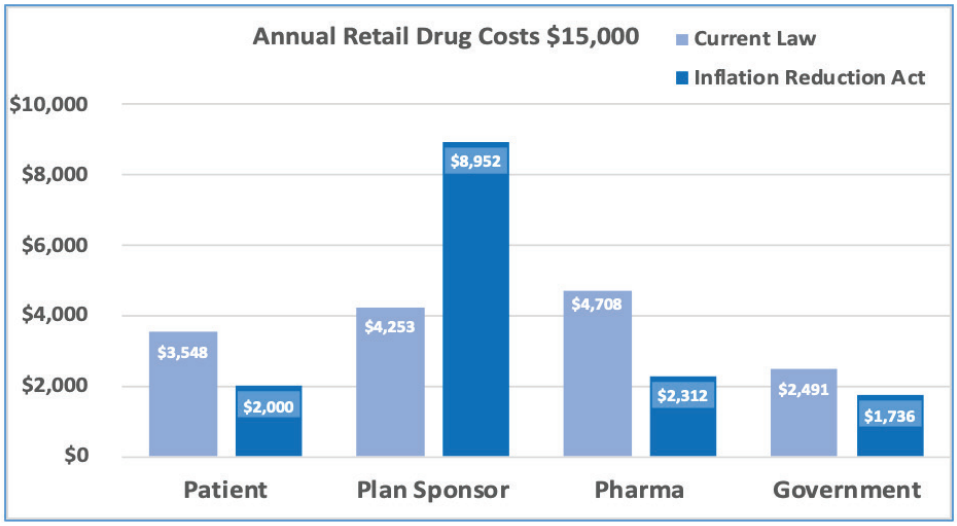
The Inflation Reduction Act restructures the Medicare benefit design and eliminates the donut hole starting in 2025. Patient annual out-of-pocket costs will be capped at $2,000 which can be spread over the course of the year. Beyond the $2,000 cap (patients reach catastrophic level), a patient's responsibility will decline from 5% to zero, Medicare's responsibility will decline from 80% to 20%, prescription drug plan sponsors responsibility will increase from 15% to 60% and drug manufacturers will be responsible for a new 20% share. Note that drug manufacturers will also be responsible for a government rebate of 10% during the initial coverage period before the patient reaches the $2,000 out-of-pocket spending cap. The volume of drug costs subject to rebates will be increased since Congress eliminated the exemption for drugs sold to Low Income Subsidy ("LIS") beneficiaries from the manufacturer discount program.

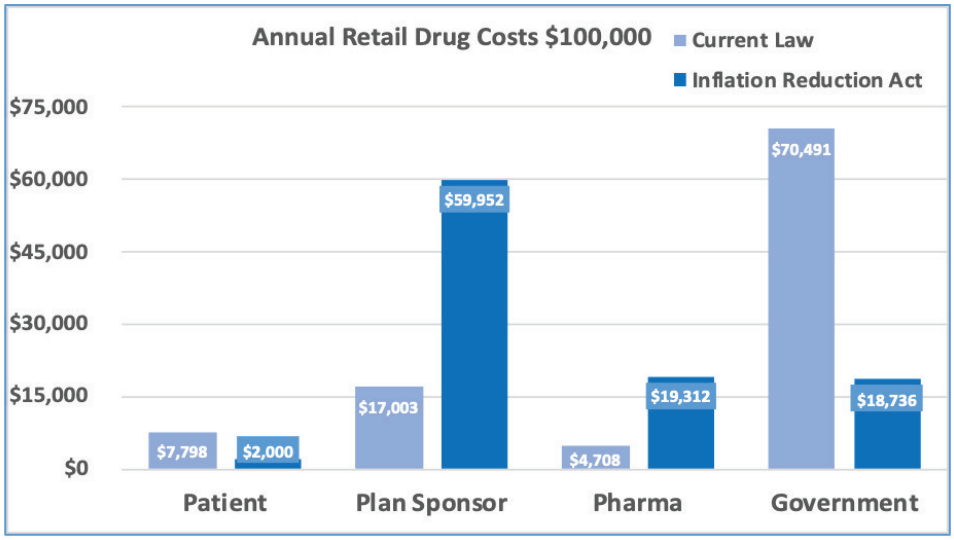
Following is a comparison showing the percentages paid for the coverage phases under the current law and Inflation Reduction Act:

Medicare Part D Coverage Stages – Who Pays What and When

Current Part D Benefit Design	BENEFICIARY	PLAN	DRUG MANUFACTURERS	GOVERNMENT
Coverage Phase (retail drug costs)				
Deductible (up to $560*)	100%	-	-	-
Initial Coverage ($560 - $5,160*)	25%	75%	-	-
Donut Hole – Brand ($5,160 - $11,886)	25%	5%	70%	
Catastrophic (> $11,886*)	5%	**15%**	-	80%
* 2025 estimate				
Inflation Reduction Act Benefit Design				
Coverage Phase (retail drug costs)				
Deductible (up to $560 2025 estimate)	100%	-	-	-
Initial Coverage ($560 - $6,320)	25%	65%	10%	-
Catastrophic (> $6,320 $2,000 OOP)	-	**60%**	20%	20%
				40% for generic drugs

The percentages and dollar amounts paid by patients (Medicare Beneficiaries), prescription drug plans, pharmaceutical manufacturers and the government varies considerably based on the current law and IRA for Medicare Part D. Following is a comparison (in 2025) between the current law and IRA for drugs with annual retail costs of $15,000 and $100,000.





The amounts paid are dramatically reduced for the government and increased for the prescription drug plan sponsors. Rebates paid by pharma manufacturers under IRA may be higher or lower than the current law depending on the price of the specialty drug. Pharma rebates of $19,312 for a specialty drug with annual retail costs of $100,000 will be over four times higher under IRA than the current law.

Implications of Medicare Benefit Redesign

Patients

Patients will benefit from the annual maximum out-of-pocket ("OOP") cap of $2,000 per year (or 5% of median Medicare annual income) for Medicare Part D drugs. The cap will be most beneficial to Medicare beneficiaries taking high-cost drugs for conditions such as cancer or multiple sclerosis.

Under the current law, in 2025 the patient OOP annual costs would approximate $3,500 and $7,800 for a drug with annual costs of $15,000 and $100,000, respectively. The OOP costs as a percent of projected median income for Medicare beneficiaries is 9% and 20%, respectively. The maximum percentage of annual income will be reduced to 5% under IRA. Accordingly, volume for high-cost drugs will increase as fewer prescriptions will be abandoned due to cost considerations. Enhanced affordability will be coupled with existing favorable formulary access as Medicare requires coverage of at least two medications from 148 drug classes and most options in six drug classes (anti-seizure, antidepressants, antipsychotics, cancer, antiretrovirals & immunosuppressants).

Prescription Drug Part D Plans

A prescription drug plan's responsibility will quadruple from 15% to 60% of annual retail drug costs when the patient is in the catastrophic phase. The impact is exacerbated by the reduction in annual drug costs to reach catastrophic from approximately $11,900 under current law to $6,300 under IRA (2025 projections). Prescription drug plans will undoubtedly take measures to mitigate the severe financial impact by restricting access, demanding higher rebates from drug manufacturers and raising premiums. Note that IRA limits Medicare Part D premium growth to no more than 6% per year starting in 2024.

Pharmaceutical Manufacturers

Pharma manufacturers will benefit from higher Medicare Part D prescriptions as the $2,000 maximum out-of-pocket cap for Medicare beneficiaries in the Part D program will translate into lower abandonment. The impact on gross-to-net and net sales depends on the price for the drugs in the manufacturer's portfolio.

> *Example 1: A patient takes high-costs Medicare Part D drugs in 2025 totaling $15,000. The pharma manufacturers total government rebate would decline from approximately $4,700 under the current law to $2,300 under IRA. There will be an increase in net sales due to low rebates coupled with greater prescriptions from lower patient abandonment. Note that rebates would be approximately the same (~$4,700) under current law and IRA if annual drug costs are $27,000.*
>
> *Example 2: A patient takes high-costs Medicare Part D drugs in 2025 totaling $100,000. The pharma manufacturers total government rebate would increase from approximately $4,700 under the current law to $19,300 under IRA. Prescriptions would need to be at least 18% higher in order to achieve the same level of net sales under IRA.*

Government

The government will derive significant savings by reducing their responsibility from 80% to 20% of total drug costs for patients in the catastrophic level. Shifting the cost burden to prescription drug plans ("PDPs") and drug manufacturers has significant unfavorable implications including measures that may be undertaken by PDPs to limit utilization and higher manufacturer rebates for drugs with an annual cost above $27,000.

Summary

The Inflation Reduction Act is a game changer that embodies complex provisions transforming the Medicare Drug Program. Pharma manufacturers need to assess the profound financial, market access, clinical, commercial and strategic implications of the Inflation Reduction Act. Actions plans should be developed to mitigate risks associated with the key provisions to lower prescription drug costs for people with Medicare including Drug Price Negotiations, Medicare Inflation Rebates and Medicare Benefit Redesign. Hopefully, there will not be a significant curtailment of research and development as pharma manufactures need to be incentivized to continue to discover, develop and commercialize new drugs leading to cures and treatments for devastating diseases.

Go to the link below to learn more and ask Murray Kay your questions directly at one of our upcoming GTN Training Series sessions.

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