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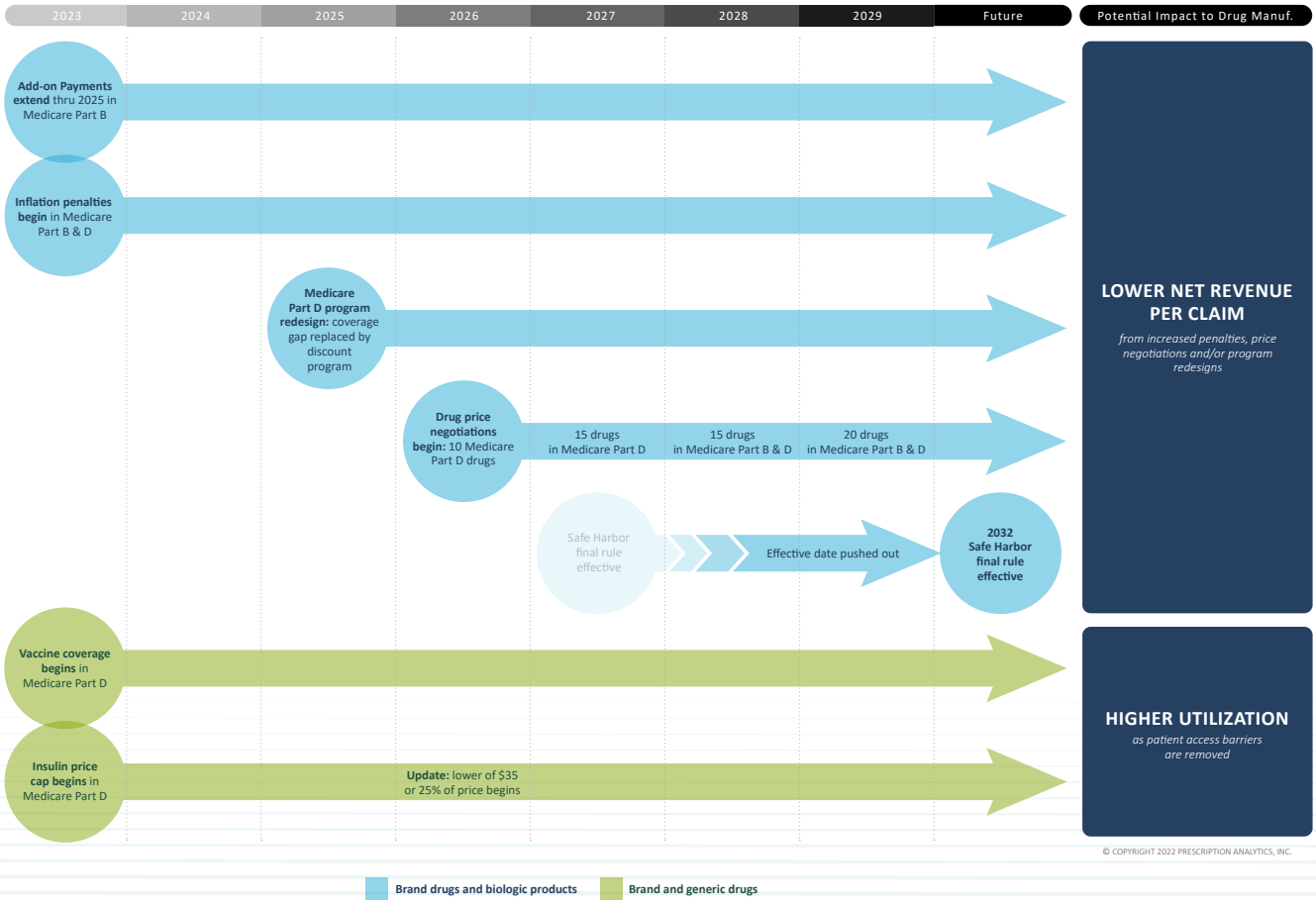
INFLATION REDUCTION ACT LIKELY TO HAVE A NEGATIVE FINANCIAL IMPACT ON MANY DRUG MANUFACTURERS

On August 16, 2022, the Inflation Reduction Act of 2022 was signed into law with provisions aimed at lowering drug, health care and energy costs for consumers in the United States. While all pharmaceutical manufacturers have the potential to be impacted by these rules, the legislative changes within the bill largely focus on brand drugs and biological products within government programs. A summary of the key legislative changes and estimated impacts to drug manufacturers is below:

INFLATION REDUCTION ACT TIMELINE FOR PRESCRIPTION DRUG PROGRAM CHANGES



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NOW – 2025 ADD-ON PAYMENT IN MEDICARE PART B

Overview: The BIOSIM Act originally increased the reimbursement on biosimilar drugs from ASP + 6% to ASP + 8%. The Inflation Reduction Act will temporarily extend the increased reimbursement percentage for certain biosimilars through the end of 2025. The hope is that this will further incentivize biosimilar development.

Drug Manufacturers Impacted: Biosimilar drug manufacturers with products covered by Medicare Part B.

Potential Future Impact: Temporary increase in biosimilar pull through as a result of pharmacies/hospitals receiving higher reimbursement; increased competition in biosimilar development.

2023 INFLATION PENALTIES IN MEDICARE PART B AND PART D

Overview: Historically, drug manufacturers have been subject to inflation limitation and penalties within the Medicaid Drug Rebate Program (MDRP), the Public Health Service (PHS), and VA/FSS. The new legislation within the Inflation Reduction Act introduces inflation penalties to Medicare Part B and Part D as well. Starting in 2023, brand drugs and biological products which have prices that rise faster than the rate of inflation will be subject to inflation penalties. For Part B drugs/utilization, inflation will be based upon ASP calculations reported. For Part D drugs, the inflation will be based upon AMP calculations reported by the manufacturer. Part B rebates will start accruing in Q1 2023 and Part D rebates will start accruing as of October 1, 2022 though the actual rebate invoices may be delayed in sending to manufacturers.

Drug Manufacturers Impacted: Brand drug and biological manufacturers.

Potential Future Impact: New inflation payments/rebates on Medicare Part B and D utilization that was not previously subject to penalties.

2023 VACCINE COVERAGE IN MEDICARE PART D

Overview: Cost sharing for Part D plan sponsors has been recommended, but optional until now. Starting in 2023, Medicare enrollees will be able to obtain vaccines, recommended by the Centers for Disease Control (CDC) and the Patient Advisory Committee (PAC) on Immunization Practices, for free as cost-sharing with enrollees has been eliminated.

Drug Manufacturers Impacted: Brand and generic drug manufacturers with vaccines recommended by the Advisory Committee on Immunization Practices.

Potential Future Impact: Increased utilization from the removal of access barriers for Medicare patients.

2023 INSULIN PRICE CAPS IN MEDICARE PART D

Overview: Starting in 2023, a 30-day supply of insulin (for Medicare covered drugs) will be capped at $35 for Part D patients, even if enrollees have not met deductibles. Starting in 2026, the cost could be even less as the patient costs will be the lower of $35 or 25% of the drug's negotiated price.

Drug Manufacturers Impacted: Insulin drug manufacturers.

Potential Future Impact: Increased utilization from the removal of access barriers for Medicare patients.

2026 DRUG PRICE NEGOTIATIONS IN MEDICARE PART B AND PART D

Overview: Select brand drugs and biological products (representing the highest Medicare sales) will be subject to negotiations in 2026. Applicable to both Part B and Part D, the number of drugs subject to negotiation will be scaled up from 10 Part D drugs in 2026 to 15 Part D drugs for 2027, 15 Part B and Part D drugs for 2028, and 20 Part B and Part D drugs for 2029 as well as each subsequent year. While an official list of drugs subject to negotiations has yet to be confirmed, the below list of Medicare drugs with the highest sales as of 2020 may highlight potential targets:

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	MEDICARE PART B - TOP 10 DRUGS BY SALES	
	Drug	2020 Sales ($B)
1	Keytruda	$3.50
2	Eylea	$3.01
3	Prolia	$1.63
4	Opdivo	$1.59
5	Rituxan	$1.30
6	Lucentis	$1.11
7	Orencia	$1.02
8	Neulasta	$0.90
9	Darzalex	$0.84
10	Avastin	$0.68
11	Remicade	$0.66
12	Tecentrig	$0.62
13	Ocrevus	$0.62
14	Soliris	$0.61
15	Cimzia	$0.51

MEDICARE PART D - TOP 10 DRUGS BY SALES	
Drug	2020 Sales ($B)
Eliquis	$19.87
Revlimid	$10.71
Xarelto	$9.40
Januvia	$7.73
Trulicity	$6.57
Imbruvica	$5.93
Lantus Solostar	$5.33
Jardiance	$4.75
Humira(Cf) Pen	$4.34
Ibrance	$4.22
Symbicort	$3.96
Xtandi	$3.94
Novolog Flexpen	$3.69
Biktarvy	$3.55
Myrbetriq	$3.50

Source: data.CMS.gov (2020 calendar year Medicare sales)

Negotiated prices are going to be driven by several factors including the drug's calculated NFAMPs, negotiated plan prices and or ASP/WAC, meaning that despite being labeled a negotiation, the values will be determined through existing computations (versus traditional negotiation between the two parties).

Drug Manufacturers Impacted: Branded/biological manufacturers with high Medicare utilization.

Potential Future Impact: Affected manufacturers may have to lower certain drug prices to Medicare.

2025 MEDICARE PART D PROGRAM REDESIGN

Overview: Currently, covered drug manufacturers are responsible for 70% of the cost of drugs only during the coverage gap period. In 2025, the coverage gap program/manufacturer discount program will be eliminated and replaced by a new discount program that requires covered drug manufacturers to pay 10% of patient costs for all branded drugs/biologicals prescribed to Part D patients in the coverage period and 20% of patient costs during the catastrophic period.

Drug Manufacturers Impacted: Branded/biological drug manufacturers enrolled in the Medicare Coverage Gap Discount Program.

Potential Future Impact: Additional rebates will be owed because all utilization will be subject to rebates, however the actual dollar amount per claim will decrease as a result of the change in reimbursement percentage. The overall financial impact of this will vary depending on the products being reimbursed but does have the potential to increase Medicare Part D rebates for drug manufacturers.

2032 FEDERAL ANTI-KICKBACK STATUTE SAFE HARBOR

Overview: Currently, there are certain anti-kickback safe harbor protections for rebates paid directly or negotiated between drug manufacturers and PBMs/plan sponsors, to Medicare Part D/Medicare Advantage Plans. The implementation of this Final Rule would eliminate those protections. The Inflation Reduction Act clarifies that changes adopted in the Safe Harbor Final Rule cannot go into effect until January 1, 2032. Previously outlined for 2027, this change reflects the fourth time that the Final Rule's implementation has been pushed back.

Drug Manufacturers Impacted: Primarily brand/biological drug manufacturers engaged in contracts/rebate agreements, directly or with PBMs, for Medicare coverage.

Potential Future Impact: A redesign of the contracts and fees paid by manufacturers to PBMs/Health Plans for Medicare utilization.

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PRELIMINARY ACTION YOU CAN TAKE NOW

In Summary — The Inflation Reduction Act is bringing several large-scale changes to pharmaceutical government pricing that will likely increase costs and utilization for manufacturers in the future, particularly those with brand drugs and biologic products. Medicare Part B will extend add-on payments, introduce new base rebates and inflation penalties, and engage in price negotiations with select high sales volume drugs. Medicare Part D will require rebates on all utilization (not just for the Donut Hole/Coverage Gap), introduce inflation penalties and price negotiations, and implement changes to vaccine and insulin coverage. Furthermore, the rules governing contracts and fees paid by drug manufacturers to Medicare PBMs/Health Plans will be subject to change.

Preliminary Actions — As seen with prior legislative changes, timelines may be subject to change – especially given the multi-year runway for implementation. While no immediate actions or changes are required of pharmaceutical manufacturers, we recommend the following in preparation for the upcoming changes:

- If you're launching a new brand drug or have existing products on the market, take care in understanding the initial values for these programs as it will serve as a baseline for potential Inflation Penalties in Medicaid, 340B, VA/FSS, Medicare Part B, and Medicare Part D in the future.
- Gain a robust understanding of your current Medicare utilization and any liabilities so that you can start to model how Medicare negotiations and/or the redesign of these programs could impact your financials in the future.
- As the complexity of Government Pricing continues to increase, ensure you have a knowledgeable partner guiding strategic pricing decisions and performing financial modeling as these legislative changes approach to support the long-term success of your organization.

Stay Tuned — Look for additional information and updates from Prescription Analytics in the future related to the Inflation Reduction Act and other legislative changes impacting pharmaceutical manufacturers. Our goal is to help you achieve your growth, profitability and compliance objectives wherever possible.

Prescription Analytics supports pharmaceutical manufacturers in strategically managing Government Pricing, Rebate Processing, Commercial Contract Management, Licensing, Commercial Operations Support and Chargeback Processing. For additional information on how we can support your business, contact us at info@prescriptionanalytics.com or (262) 297-3007.