MEDICARE AND THE INFLATION REDUCTION ACT REGULATIONS

Understanding Healthcare Provisions of the Inflation Reduction Act and the Impact on Healthcare Ecosystem

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DISCLOSURE STATEMENT

This is a voluntary service as members of the "Comisión de Aseguradoras y PBMs" of the Colegio de Farmacéuticos de Puerto Rico.

We have no potential conflict of interest to report.

LEARNING OBJECTIVES

- Describe the implications of the Inflation Reduction Act (IRA) that will impact the Medicare health system.
- Explain the IRA timeline of events and the major changes in healthcare over the next few years.
- Identify the key drug pricing provisions of the IRA.
- Explain how the different sectors of Managed Care should prepare to address the implications of IRA.
- Describe how IRA will impact manufacturers processes.

GLOSSARY

- Premium – is an individual's monthly payment to a Medicare plan for coverage
- Deductible – is the amount a patient must pay for health care expenses before the health insurance begins to pay.
- Copayment – is a set amount required to pay for a medical service.
- Coinsurance – is the portion of the cost of care that is required to pay after a health insurance pays. Is a percentage of the approved amount.
- Out-of-pocket-costs – are health care costs that patient must pay because Medicare or other health insurance does not cover them
- Maximum out-of-pocket (MOOP) - is an annual limit out-of-pocket costs for Medicare Advantage Plans.
    - Once the patient reach this amount, they will not owe cost-sharing for Part A or Part B covered services for the remainder of the year.
    - All Medicare Advantage Plans are required to set a maximum out-of-pocket
- True Out-of-Pocket (TrOOP) costs – are the payments that count toward a person's Medicare drug plan out-of-pocket threshold

KEY TERMS

- **Extended Monopoly Drugs:** A selected drug for which at least 12 years but fewer than 16 years have elapsed since the date of FDA approval or licensure, excluding vaccines and selected drugs with an initial price applicability year before 2030
- **Long Monopoly Drugs:** A selected drug for which at least 16 years have elapsed since the date of FDA approval or licensure, excluding vaccines
- **Maximum Fair Price:** The price negotiated by the Secretary is referred to as the "maximum fair price" (MFP) and takes effect at the start of a drug's initial price applicability year, to be updated on an annual basis for inflation.
- **Negotiation Eligible Drug:** This is a qualifying single source drug that is among the top 50 of such drugs under Medicare Part B or Part D with respect to the highest total expenditures.
- **Eligible Individuals:** those who are enrolled in a prescription drug plan under either Parts C or D

MEDICARE REVIEW

- Covers the **elderly population (65+ years old)** regardless of income or health status
  - Include individuals under **65 suffering from end-stage renal disease (ESRD)**
  - Disabled who received Social Security Disability Insurance (SSDI) payments
- When a person qualifies for Medicare, they have several options:
  - **First**, they can register for “traditional” Medicare – includes Part A and Part B, which provide hospital and medical services
  - **Second**, they can enroll in “traditional” Medicare with or without supplemental coverage (Medigap) and/or prescription drug plan (PDP) coverage
  - **Third**, they can enroll in a Medicare Advantage (MA) plan offered through private insurers

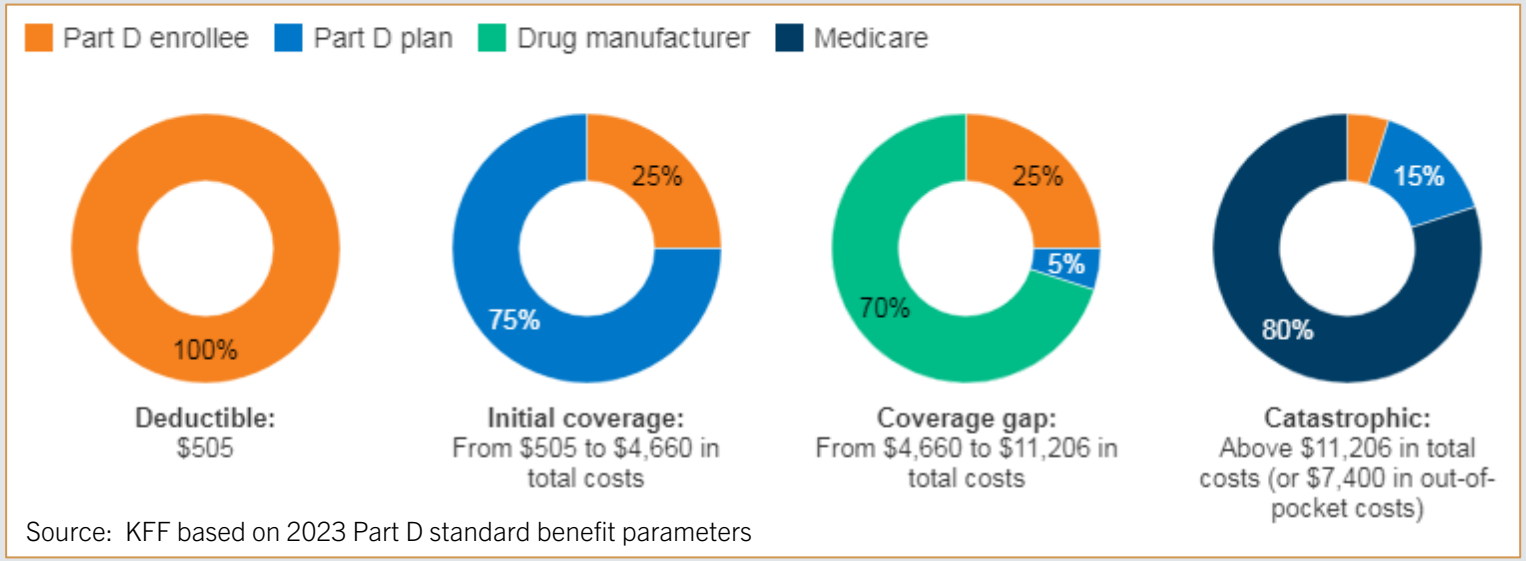
4 PARTS OF MEDICARE

- Part A – Medicare Hospital Insurance
  - Pays for inpatient hospital care
  - Hospice care services for persons with a life expectancy of 6 months or less
  - Home healthcare services following hospital discharge
- Part B – Supplementary Medical Insurance
  - Pays for physician care and annual wellness visits
  - Hospital Outpatient care
  - Medical Supplies and durable medical equipment
  - Emergency room and ambulance
  - Clinical Lab and diagnostic tests
  - Part B Drugs

4 PARTS OF MEDICARE

- Part C – Medicare Advantage
  - Covers benefits under Parts A, B, and D that are provided through a managed care plan like health maintenance organization (HMO), preferred provider organization (PPO), private fee for service plan (PFFS), or a special needs plan (SNP)
  - Medicare beneficiaries can voluntarily enroll in Part C during an annual enrollment period
- Part D – Prescription Drug Benefit
  - Provides coverage for prescription drugs
  - PDP is voluntary program for which beneficiaries pay a monthly premium

MEDICARE PART D IN 2023

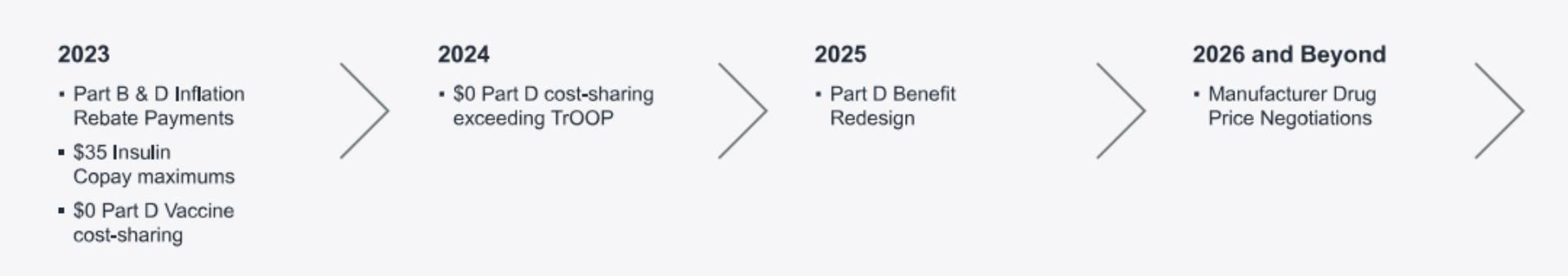


Source: KFF based on 2023 Part D standard benefit parameters

- Deductible phase – Part D enrollees pay 100% of their drug costs. Up to $505 in 2023
  - Not all Part D plans charge a deductible
- Initial Coverage Phase – Part D enrollees pay 25% of total drug costs and part D plans pay 75%
  - Up to $4,660 in 2023, will increase to $5,030 in 2021
- Coverage Gap Phase – Part D enrollees pay 25% of total drug cost for brand and generic drugs.
  - Part D plans pay the remaining 75% of generic drug costs and 5% of brand drug costs
  - Drug manufacturers provide a 70% price discount on brands
  - In 2024, the out-of-pocket threshold will be set at $8,000
- Catastrophic phase – Medicare pays 80% of total drug cost
  - Part D plans pay 15%
  - Part D enrollees pay 5%

INFLATION REDUCTION ACT BACKGROUND

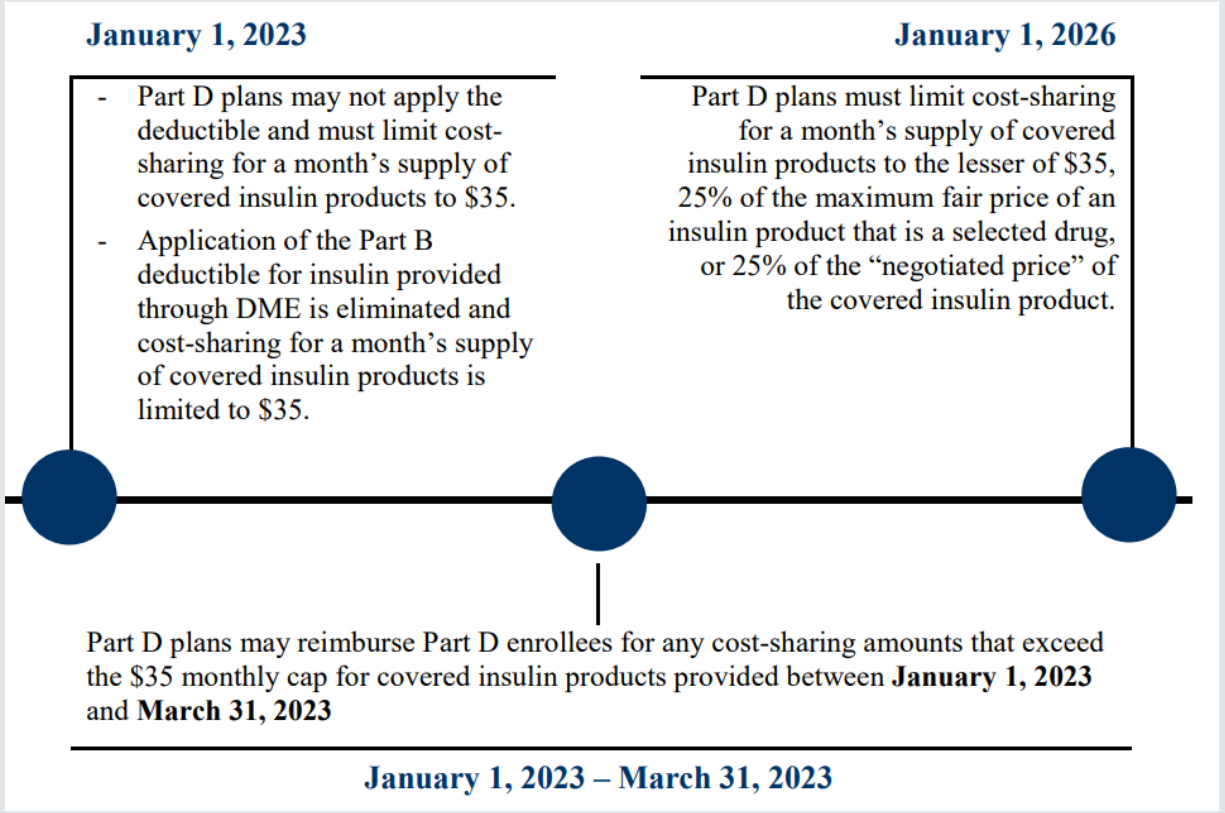
- On August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 (IRA)
- The provisions included within the Act will have changes in the following Medicare areas:
  - Government authority to negotiated drug costs
  - Medicare Part D benefit changes
  - Premium limitations
- Much of the implementation work will be started by the Biden Administration in 2023 and 2024
- Key provisions including price negotiations become effective in 2026 and may be impacted by the 2024 Presidential election.



Source: Inflation Reduction Act. What health plans and Part D sponsors need to know to be prepared

INSULIN COST-SHARING CAP

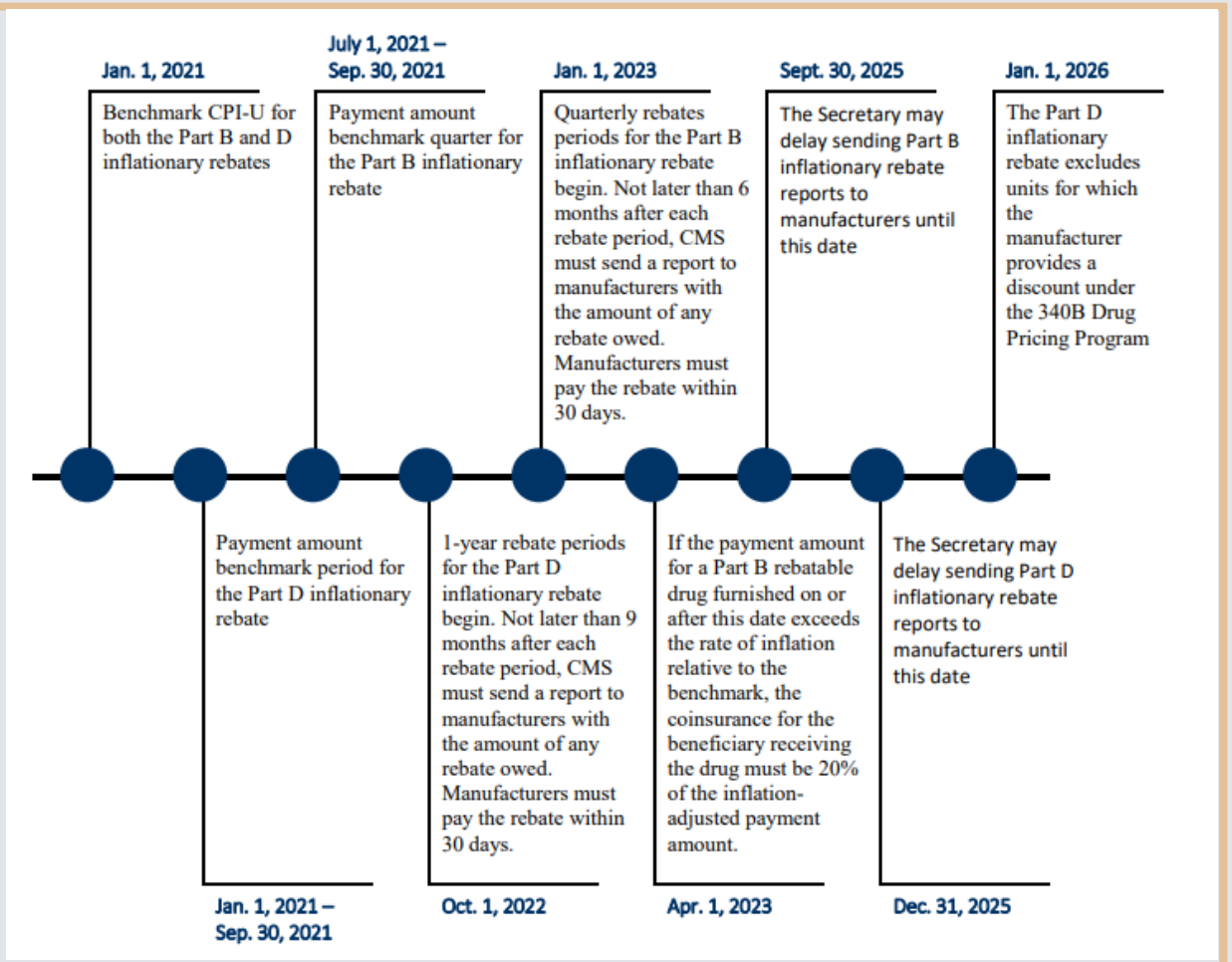
- IRA eliminates the deductible and caps out-of-pocket insulin costs in Part D and Part B
- Limits cost-sharing during 2023-2025 to $35 for a month's supply
- Beginning January 1, 2026, cost sharing for covered insulin will be the lesser of $35 for a month's supply, 25% of the MFP, or 25% of the *"negotiated price"*



Source: Summary of Inflation Reduction Act of 2022: Key Drug Pricing Provisions and Implementation Timeline

MEDICARE DRUG INFLATIONARY REBATES

- IRA imposes an inflationary rebates penalty on a broader class of drugs and biologicals covered under Medicare Parts B and D.
- Beginning in 2023, manufacturer with price increases that exceed the rate of inflation will be required to pay a rebate to CMS
    - Based on certain specified benchmark price amounts and inflationary rates determined by the Department of Labor



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PART B INFLATIONARY REBATES

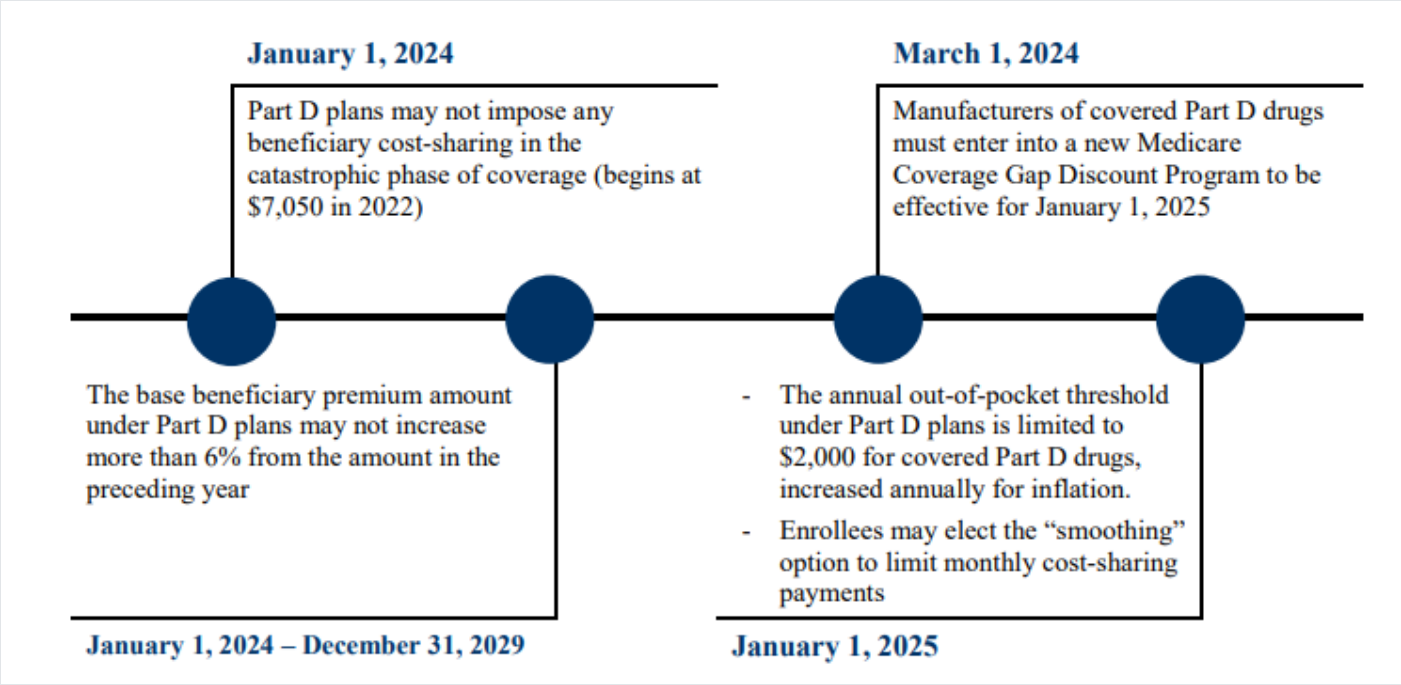
- Applies to single source drugs and biologicals (including biosimilars)
- January 1, 2021, is the benchmark for CPI-U
  - Payment amount benchmark quarter is July 1 to September 30, 2021
- Part B inflationary rebate is calculated based on the product of the total number of billing units for the drug's billing and payment code paid for under Part B and the amount by which the ASP exceeds the inflation-adjusted payment amount.
- The inflation adjusted payment amount will be determine by CMS
  - CMS will identify the payment amount for the billing and payment code for the Part B rebatable drug in the applicable period and increase the payment amount by the percentage by which the rebate period's CPI-U exceeds the January 2021 CPI-U
- Manufacturers will receive a quarterly report from HHS that identifies the amount of rebate owed, as well as several components used to calculate that amount
  - Payment to CMS is required within 30 days of receipt of the report
- Patient coinsurance receiving the Part B rebatable drug must be 20% of the inflation adjusted payment amount

PART D INFLATIONARY REBATES

- Applies to covered Part D Drugs
- It started in October 1, 2022
- January 1, 2021 is the benchmark for CPI-U
  - Payment amount benchmark quarter is January 1 to September 30, 2021
- Inflationary rebate is calculated by taking the product of the total number of units paid under Part D, and the amount by which the "annual manufacturer price" for a rebatable drug exceeds the inflation-adjusted payment amount of the drug
- The inflation adjusted payment amount will be determine by CMS
  - CMS will identify the benchmark period manufacturer price and increase the payment amount by the percentage by which the applicable period's CPI-U exceeds the January 2021 CPI-U
- Manufacturers will receive a report that identifies that amount of rebated owed, as well as several of the components used to calculate that amount.
  - Part D report is annually sent not later than 9 months after the end of the applicable period

MEDICARE PART D BENEFIT REDESIGN

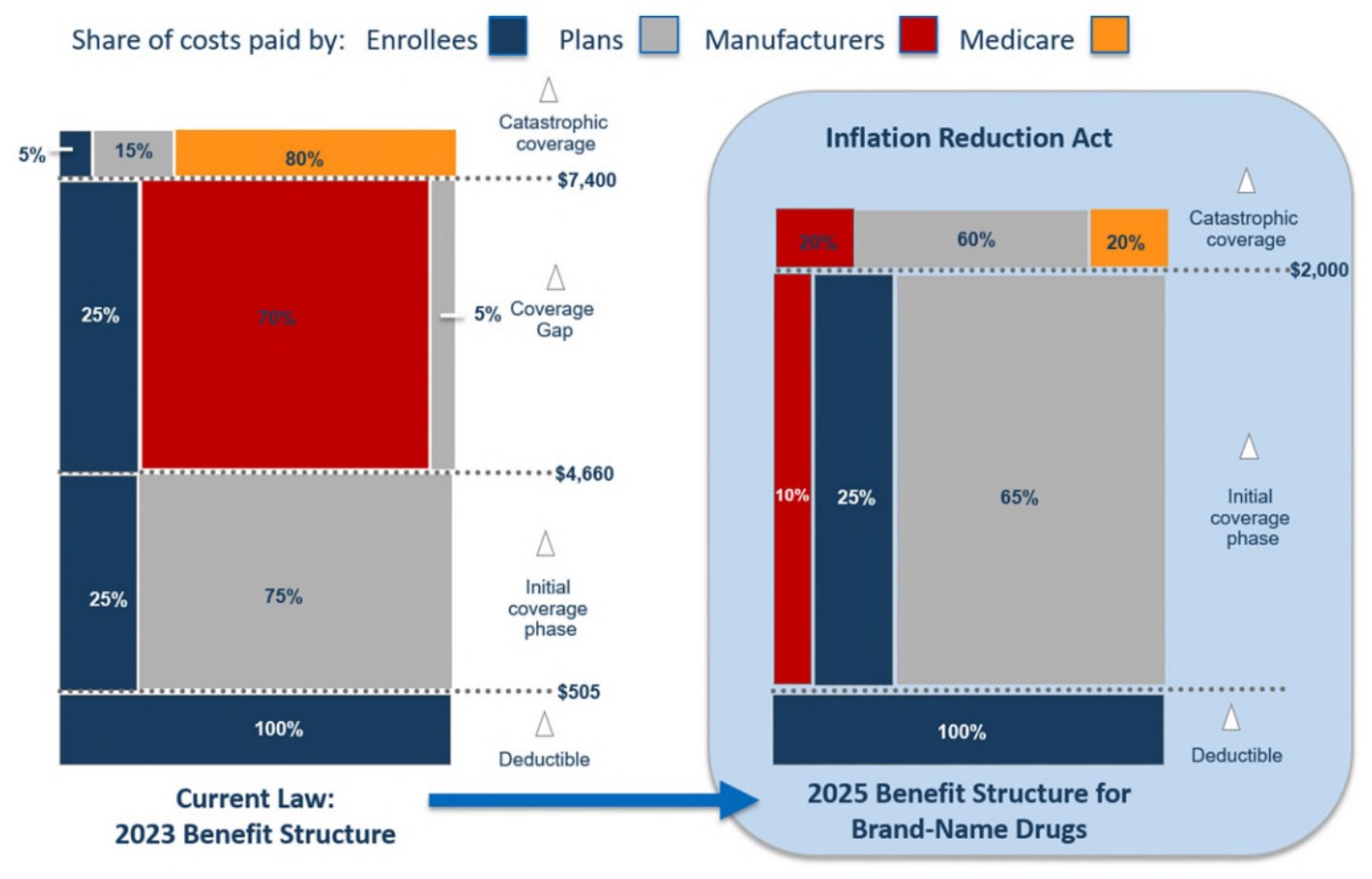
- IRA makes changes to the Part D benefit to reduce patient out-of-pocket costs and to change manufacturer and plan responsibility
- Beginning in 2024, enrollee cost sharing in the catastrophic phase is eliminated



Source: Summary of Inflation Reduction Act of 2022: Key Drug Pricing Provisions and Implementation Timeline

MEDICARE PART D BENEFIT REDESIGN

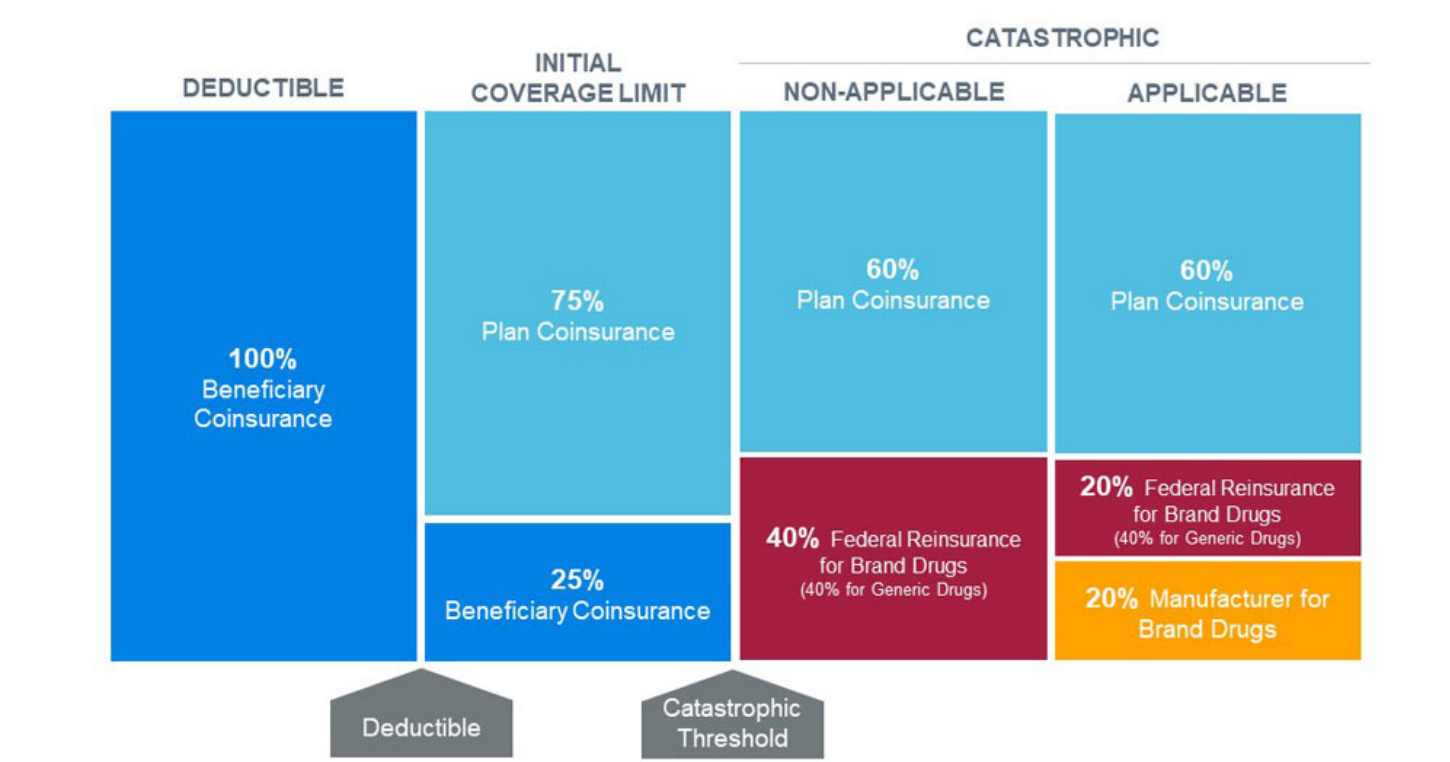
- Beginning in 2025, Part D prescription coverage will consist of a 3-phase benefit
- Patient out-of-pocket costs capped at $2,000
- Expansion of the required discounted price under a new Manufacturer Discount Program
  - Replace the existing Coverage Gap Discount Program



Source: Summary of Inflation Reduction Act of 2022: Key Drug Pricing Provisions and Implementation Timeline

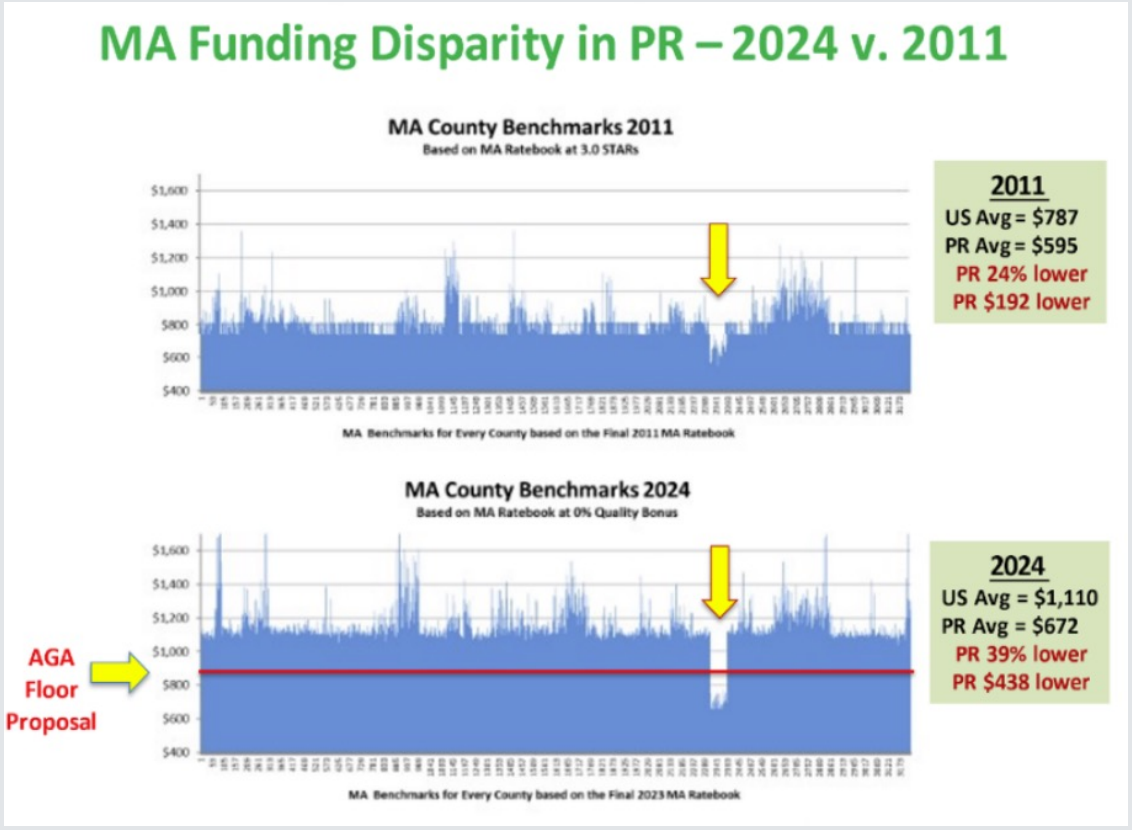
MEDICARE PART D BENEFIT REDESIGN

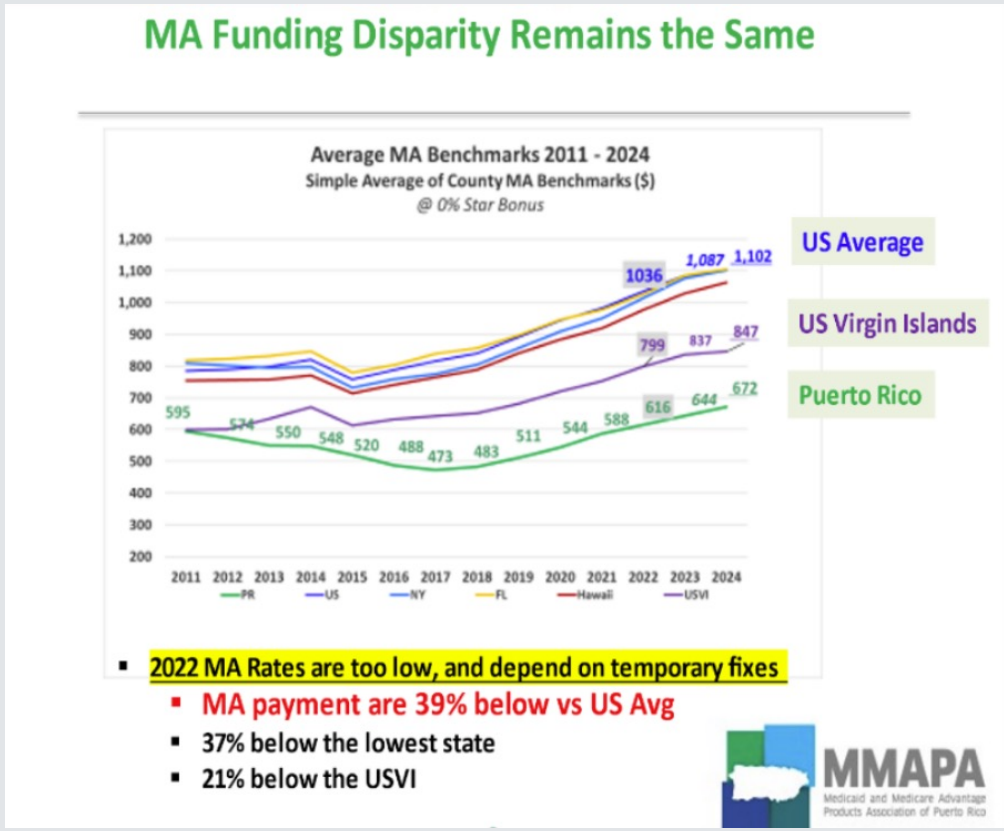
- Government reinsurance in the catastrophic phase of Part D will decrease from 80% to 20% for most brand, biologicals and biosimilars and will decrease from 80% to 40% for generics



Source: A new Part D benefit design? Prescription Drug Pricing Reduction Act proposes major changes to Part D

MEDICARE ADVANTAGE IN PUERTO RICO

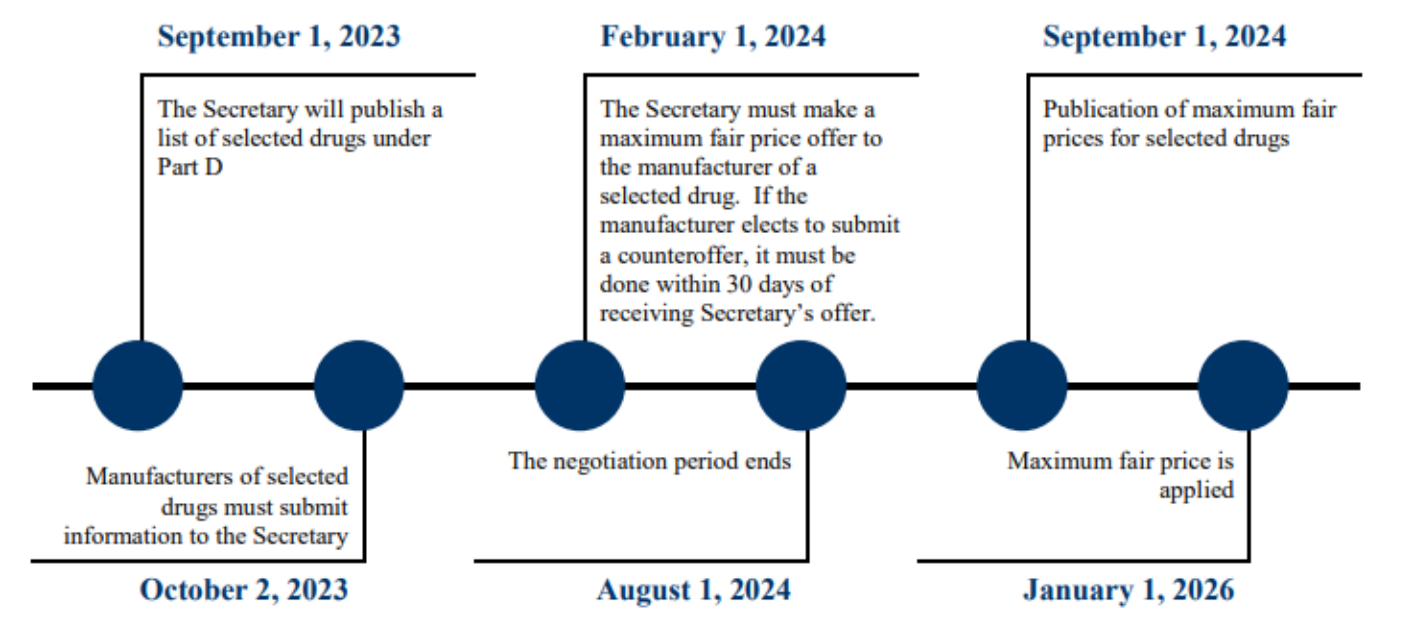




Full implementation of the proposed changes to the current MA risk score model could lead to a 9.1% reduction in MA payments in Puerto Rico, marking a disproportionate decrease in funding compared to the national average reduction of 3.4%.

GOVERNMENT PRICE NEGOTIATION AUTHORITY

- Secretary is required to negotiate the prices for select high-spend drugs and biologics covered in Medicare Parts B and Part D and do not have generic or biosimilar competition
- If a drug is selected, manufacturers are obligated to enter into a negotiation with the Secretary and make selected drugs accessible at the negotiated price



Source: Summary of Inflation Reduction Act of 2022: Key Drug Pricing Provisions and Implementation Timeline

MEDICARE DRUG PRICE NEGOTIATION PROGRAM

- Scope of negotiation will be phased:

2026
- 10 drugs from the Part D
- Total Drugs 10

2027
- 15 drugs from the Part D
- Total Drugs 25

2028
- 15 drugs from the Parts B and D
- Total Drugs 40

2029
- 20 drugs from the Part B and D
- Total Drugs 60

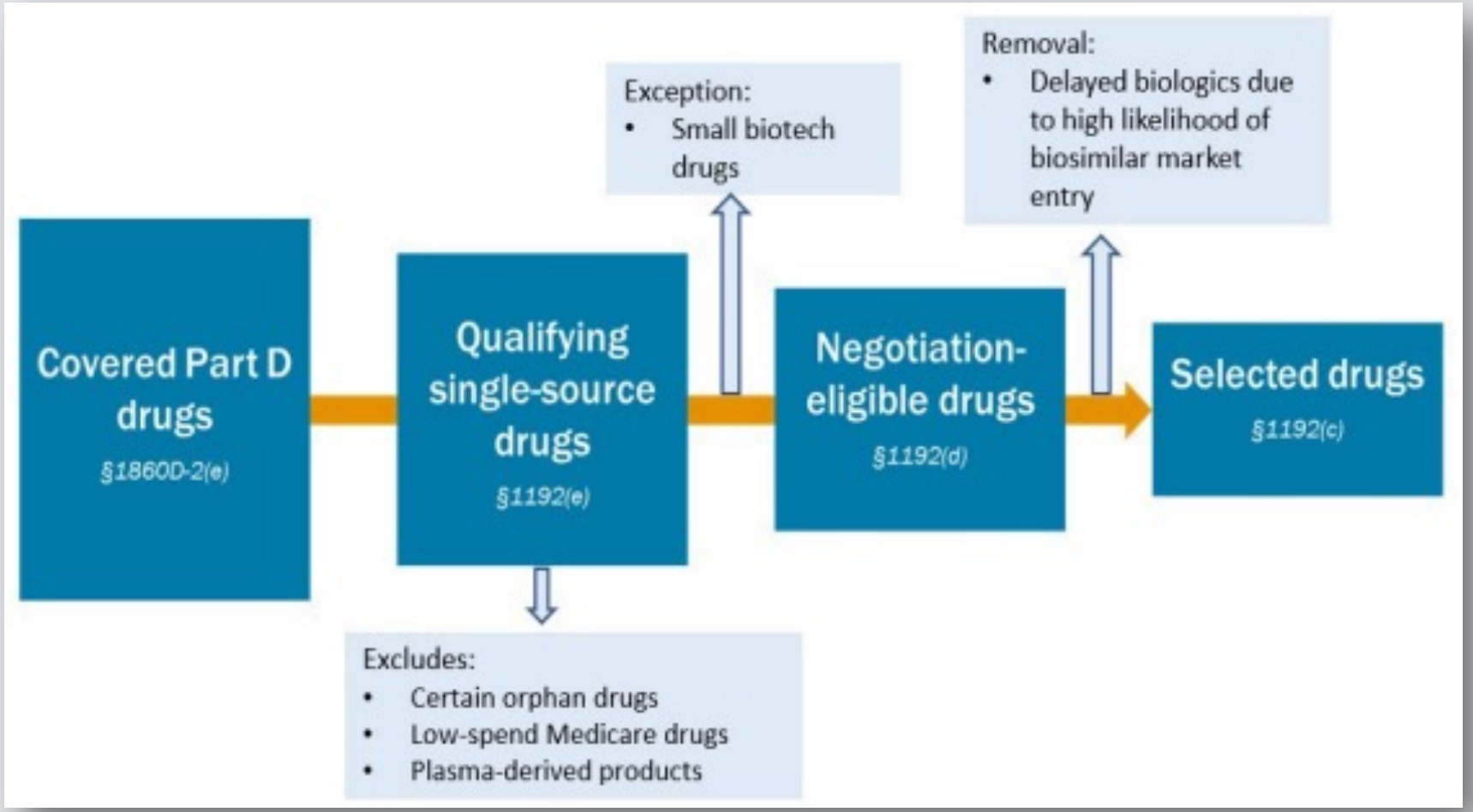
- It is expected that by 2031, up to approximately 100 drugs could be subject to price negotiations

MEDICARE DRUG PRICE NEGOTIATION PROGRAM

- CMS will rank the top 50 negotiation-eligible Part D drugs with the highest Total Expenditures under Medicare Part D (total gross covered prescriptions drug cost). Then CMS will select for negotiation the 10 highest ranked drugs in the list.
  - Eligible drugs:
    - Single-source brand drug or biological products without therapeutically-equivalent generic or biosimilar alternatives
    - At least 7 years (small-molecule drugs) or 11 years (for biologics) past their FDA approval or licensure date without competition.
  - Excluded drugs:
    - Small biotech drugs
    - Drugs of a manufacturer acquired by a certain manufacturer after 2021
    - Orphan drugs for only one rare disease or condition for which there is only one indication
    - Drugs or biologicals with Part B and D spend less than $200 million per year (increased annually by inflation)
    - Plasma-derived products

***CMS will use PDE data from the previous 12-month period (June 1, 2022-May 31, 2023) to calculate the Total Expenditures for each qualified single source drug.*

MEDICARE DRUG PRICE NEGOTIATION PROGRAM



NEGOTIATION METHODOLOGY

- Establish a consistent methodology and process for drug negotiation.
- Legislation provides the Secretary with broad discretionary authority for conducting the negotiations
- Secretary is required to assess a variety of factors submitted by the manufacturer:
  - Research and development costs
  - Unit cost of production
  - Federal financial support for drug discovery
  - Patent and revenue
  - Sales volume
- Secretary may consider whether the drug represents a therapeutic advance and the effects of the product on specific populations

MEDICARE DRUG PRICE NEGOTIATION PROGRAM

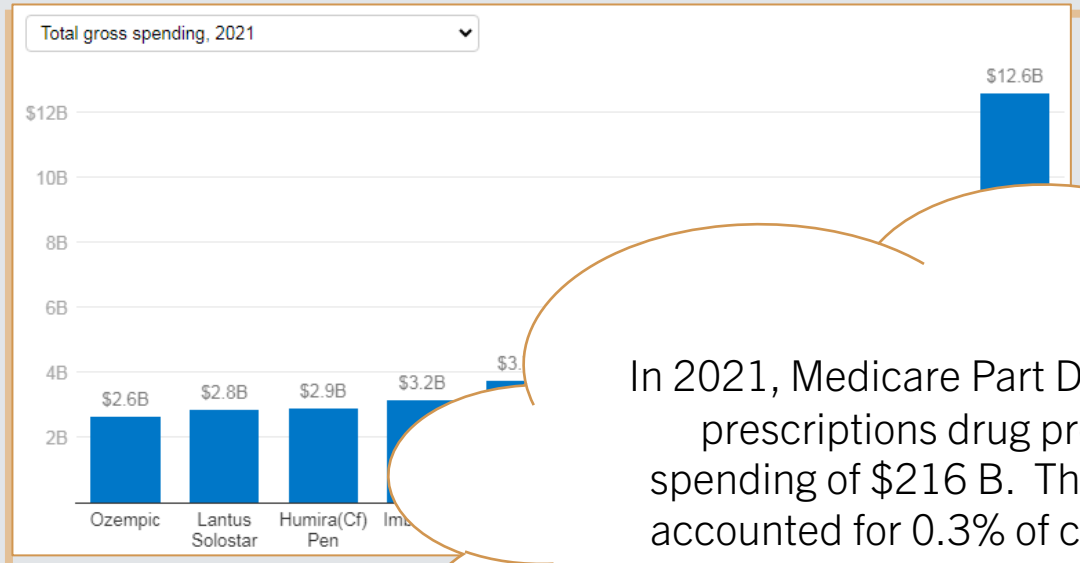
Manufacturers are required to submit the following information to CMS for the IRA drug negotiation process:

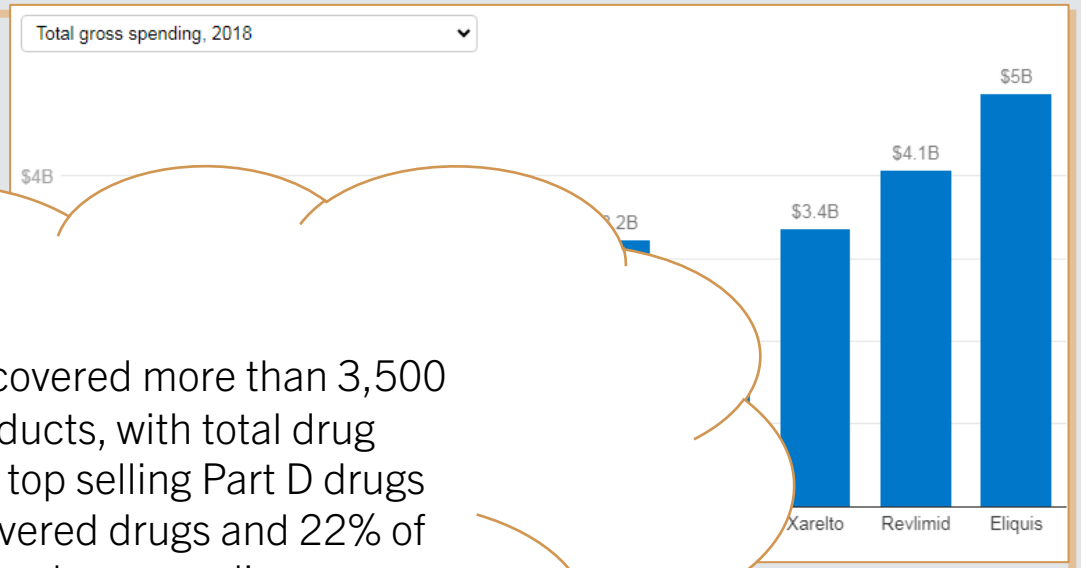
- List price: The drug's list price.
- Historical price increases: The drug's historical price increases.
- Clinical value: The drug's clinical value, including its effectiveness and safety.
- Monopoly power: The drug's monopoly power, meaning the extent to which it is the only available treatment for a particular condition.
- Cost of research and development: The drug's cost of research and development.
- Manufacturing costs: The drug's manufacturing costs.
- Profit margins: The drug's profit margins.
- Any other information that CMS determines is relevant

***Manufacturers may also submit other information that they believe is relevant to the negotiation process.*

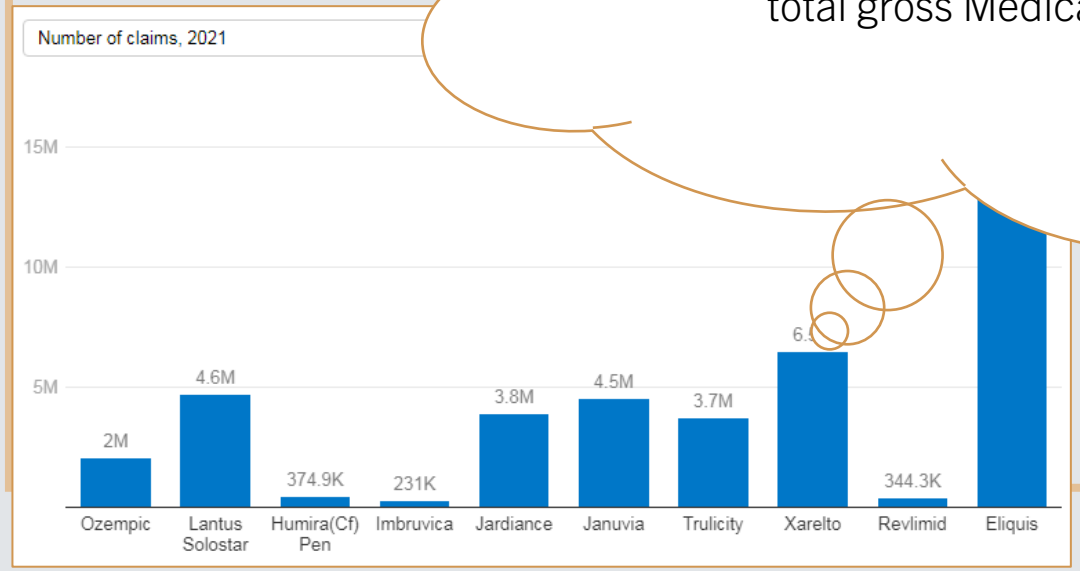
CMS will review all of the information submitted by manufacturers and will undergo a negotiation process with the drug manufacturer to reach the **Maximum Fair Price (MFP)** for the drug. The MFP must ultimately be no more than the price ceiling that CMS will also calculate.

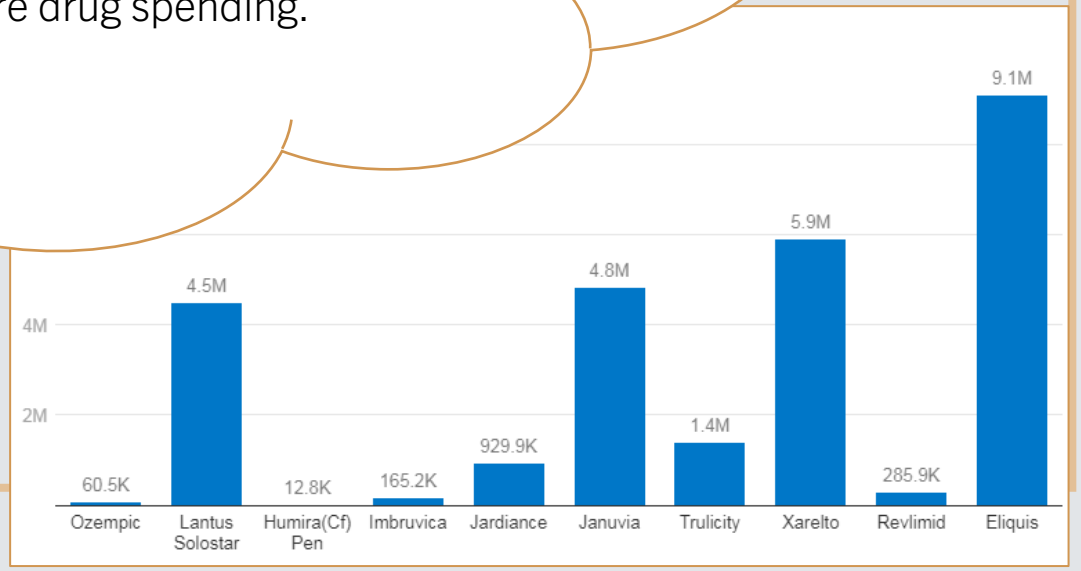
MEDICARE DRUG PRICE NEGOTIATION PROGRAM





In 2021, Medicare Part D covered more than 3,500 prescriptions drug products, with total drug spending of $216 B. The top selling Part D drugs accounted for 0.3% of covered drugs and 22% of total gross Medicare drug spending.

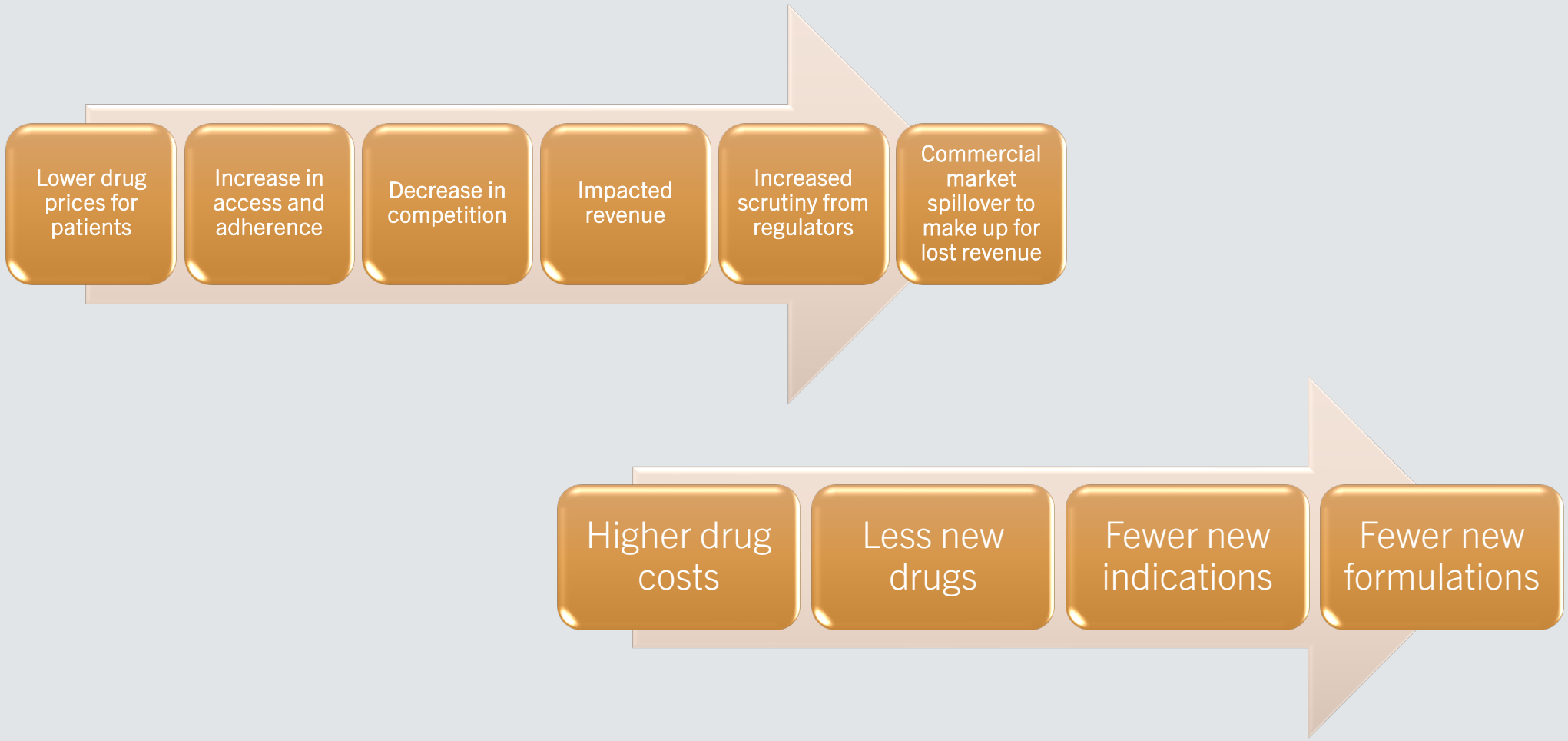




SOURCE: KFF analysis of Centers for Medicare & Medicaid Services 2021 Medicare Part D Spending by Drug. PNG

IMPLICATIONS OF THE INFLATION REDUCTION ACT ON MANAGED CARE

IMPLICATIONS OF THE IRA ON MANAGED CARE



KEY IMPACT TO MANUFACTURERS

- Excise Tax to Compel Negotiation
  - Price negotiation is enforced by CMS through an excise tax that applies when manufacturer delays entering into a negotiation agreement or fails to agree upon an MFP
  - Applies if the manufacturer fails to provide an MFP once it is determined.
  - It is applied to sales of the selected drug and progressively increases bases on how long the manufacturer is in non-compliance
    - Begins at 65% and escalates to as high as 95% of the price at which the drug is sold.
  - This tax may be suspended if the manufacturer terminates agreements to participate in Medicare and Medicaid.

KEY IMPACT TO MANUFACTURER PROCESSES

- Increased scrutiny from regulators leading to increased cost of compliance.

  - The IRA gives the government more authority to regulate drug manufacturers. This could result in fines or other penalties for manufacturers that violate the law.

  - The IRA includes a number of new compliance requirements for manufacturers, including submission of significant amount of data relating to research and development, patents, sales and marketing in the format specified by CMS and ensuring access to the selected drug at or below the MFP to MFP-eligible individuals. These requirements are expected to increase the cost of compliance for manufacturers.

KEY IMPACT TO MANUFACTURERS

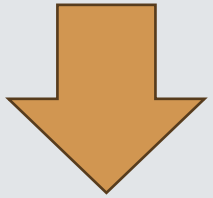
- Fines and Penalties

- Failure to comply with administrative requirements, including the submission of information, to carry out the Negotiation Program **($1 million** for each day of a violation); and
- Knowingly providing false information required to inform negotiation proceedings **($100 million** for each item of such false information)
- Failure to provide access to the selected drug at or below the MFP to MFP-eligible individuals

- To satisfy the statutory requirements for providing access to the MFP, CMS would require manufacturers to:
  - At least 30 days before the start of the initial price applicability year, submit its process in writing to CMS for making the MFP available. CMS will publish on IRA website.
  - Retain for at least 10 years from the date of sale any records relating to sales of the selected drug to entities that dispense the selected drug to MFP-eligible individuals.
  - Ensure that pharmacies, mail order services, and other dispensers as well as intermediate entities, such as wholesalers, as applicable, are reimbursed timely for the full amount of the difference between their acquisition cost for the selected drug and the MFP within 14 days. Manufacturers or their contracted entities shall not charge any transaction fee for this process.

ADVERSE EFFECTS OF THE IRA

- The IRA may reduce the discovery of new treatments.
  - Reduced revenue to pharmaceutical manufacturers from the combined effects of drug price negotiation, inflation rebates, and required manufacturer discounts
  - Less R&D investment lead to fewer drug discoveries over time

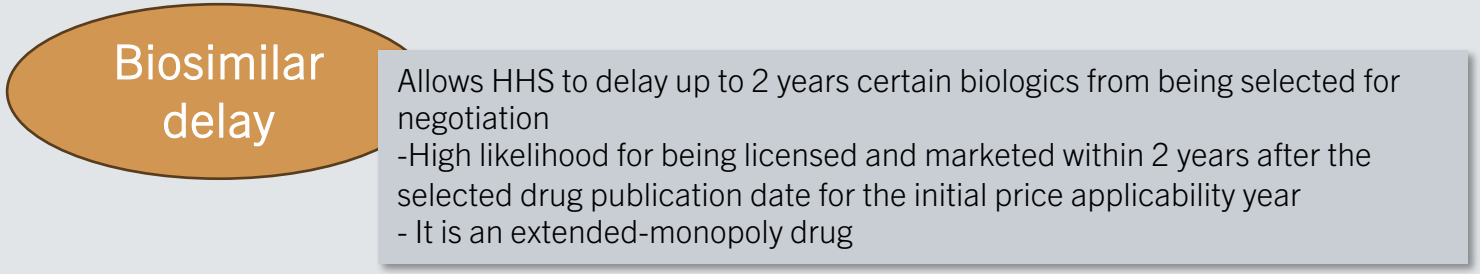


Estimated 31% decrease in US pharmaceutical revenues through 2039 and 135 fewer new drug approvals during that period

- The IRA may reduce discovery of new uses for existing drugs.
  - Less investment in studies that quantify efficacy, safety and value of applications of existing products to new disease areas
  - Reduced net present value of investments in new indications due to shorter timespan over which firms can earn returns on those investments

ADVERSE EFFECTS OF THE IRA

- The IRA could reduce generic competition.
  - Decrease in brand prices due to negotiations could reduce the prices that any generic firm can charge, disincentivizing generics from pursuing exclusivity benefit and thus from entering the market.



- Inflation rebates may harm plans' abilities to negotiate prices for drugs with promising but uncertain benefits.
  - Payers may be faced with increased launch prices since price changes will be based on inflation rates and less on real-world effectiveness and safety information.

WHAT CAN MANUFACTURERS DO?

- **Reassess revenue projections**. Revise long-range revenue forecasts based on a detailed evaluation of the range of potential impacts.
- **Improve efficiency and long-term planning**. Streamlining production processes, reducing waste, and optimizing supply chains to reduce costs.
- **Portfolio reprioritization decisions.** Consider greater investment in precision medicines, with more-defined patient populations, and single-disease orphan medicines, which are excluded from pricing negotiation eligibility.
- **Increasing transparency** in pricing and business practices in order to build trust with patients and payers.
- **Work with payers** such as insurance companies and government agencies to develop more affordable pricing models for prescription drugs.
- **Partner with other companies**, such as generic drug manufacturers or distributors, to share resources and expertise and to reduce costs.
- **Advocate for changes** to the IRA that would be more favorable to their industry. This could involve lobbying lawmakers or educating the public about the impact of the law.
- **Be prepared for change** and adapt their business models and operations accordingly. This includes staying up-to-date on the latest developments and being open to new ideas.

IRA CONSTITUTIONAL CHALLENGES

- Multiple lawsuits have now been brought that encompass a range of constitutional challenges to the Medicare Drug Price Negotiation Program:

Notice & Comment

- The IRA does not require CMS to go through the notice-and-comment procedure and instead implement requirements through instruction or guidance.

First Amendment

- Complainants allege that the excise tax effectively coerces pharmaceutical manufacturers into agreeing to a maximum price that they must endorse, against their will, as "fair" pursuant to the negotiations. The Complainants allege that this coerced speech endorsement amounts to a violation of their **First Amendment right to free speech**, and question why Congress chose this indirect approach instead of simply giving HHS the authority to set drug prices for Medicare beneficiaries.

IRA CONSTITUTIONAL CHALLENGES

Fifth Amendment

- The US Constitution's Fifth Amendment requires the federal government to follow a fair process before taking away an individual's life, liberty, or property. Procedural due process typically entails fair notice and an opportunity for a hearing before an impartial decision maker.
- Complainants allege that the Drug Price Negotiation Program violates Due Process Clause by depriving pharmaceutical manufacturers of their property without "just compensation" or procedural protections. This provision in the context of considering a drug's patents and market exclusivities in determining the initial offer for the drug's maximum fair price (MFP).

Eighth Amendment

- Complainants allege that the excise tax imposes **"excessive fines"** on pharmaceutical manufacturers that amount to **punitive action** in violation of the Eighth Amendment.

Article I Allegation

- Complainants allege that the Drug Price Negotiation Program grants HHS **unchecked power to set pharmaceutical prices in violation of the Separation of Powers Clause included in Article I of the Constitution.** They argue that without discernable legal standards and procedural safeguards, such as formalized opportunities for public input and judicial review, HHS is not held accountable as is required by the Constitution.

LAWSUITS OVER IRA DRUG PRICING NEGOTIATION

- On June 6,2023, **Merck** filed a lawsuit in federal district court in Washington, D.C., arguing that the drug negotiation process is unconstitutional. The lawsuit states that the statutory design and operation of the IRA constitutes an uncompensated taking, which violates the Fifth Amendment. Merck lawsuit claims that the IRA "appropriate[s] [Merck's'] personal property" by forcing the sale of its drugs at discounted rates to Medicare beneficiaries. It also argues that the IRA compels Merck to endorse speech it does not agree with, in violation of the First Amendment.

- On June 9, 2023, four **Chambers of Commerce** filed a lawsuit jointly against the HHS claim that the IRA violates multiple provisions of the U.S. Constitution and that the Drug Price Negotiation Program constitutes a unilateral drug price control mandate. Complainants alleged violation of First, Fifth and Eighth Amendments.

- **Bristol Myers Squibb (BMS)** also challenged the IRA. Their lawsuit argues that the statutory design and operation of the IRA constitute an uncompensated "taking" in violation of the Takings Clause of the Fifth Amendment, which states that "private property [shall not] be taken for public use, without just compensation."

- Most recently, in August 21, 2023, PhRMA filed a lawsuit along with the **Global Colon Cancer Association** and **the National Infusion Center Association,** claiming that the IRA's excise tax, imposed on any drugmaker that doesn't comply with Medicare's price-setting negotiations, violates the Eighth Amendment's Excessive Fines Clause. They also raised arguments over the Fifth Amendment's Due Process Clause, claiming that the IRA breaches the clause by denying public input on how the law will be implemented.

*Companies are putting up a unified resistance to the new law, with Merck calling the negotiation setup "extortion" in one court filing. Aside from **Merck** and **BMS**, **Johnson & Johnson, Janssen, Astellas** and **Boehringer** have filed lawsuits challenging the law.*

LAWSUITS OVER IRA DRUG PRICING NEGOTIATION

HOW CAN MANAGED CARE ORGANIZATIONS PREPARE FOR THE IRA

Managed Care Organizations will need to be agile and adaptable in order to meet the challenges.

- Health plans:
  - Pay close attention to the requirements of this regulation and the financial impact these provisions will have on daily operations.
  - Implement required operational changes for 2023 for Part D coverage of vaccines and insulin and future changes that have an operational impact
  - Develop internal and external communications and education strategies.
  - Adjustments to drug formularies and benefit designs.
    - Pharmacy and Medicare product leaders should develop a roadmap in consultation with their PBMs and actuarial partners to ensure that premiums and benefits remain competitive.
  - Plans may also explore new initiatives to increase generics or biosimilars over brand drugs with larger post-purchase rebates to lower costs.
  - Develop strategies for managing the increased costs of prescription drugs and utilization, including emphasis in care coordination, as plan liability above the out-of-pocket threshold increases.
  - Leverage data analytics to monitor chronic conditions and strengthen medication therapy management, disease management and patient outreach programs to ensure medication adherence.
- Pharmacy benefit managers (PBMs):
  - Pay close attention to the requirements of this regulation and the financial impact these provisions will have on daily operations. Be prepared to handle potential increased volume of prescriptions expected as a result of the IRA's cost-sharing provisions.
  - Ensure operational requirements are implemented accordingly and strengthen compliance oversight.
  - Work with health plans to adjust formularies and develop new strategies for managing drug utilization.
  - Invest in data analytics to better understand the cost of prescription drugs and identify opportunities for savings. This could involve using data to identify high-cost drugs, track drug utilization, or predict future demand.

HOW CAN MANAGED CARE ORGANIZATIONS PREPARE FOR THE IRA

- Pharmacies:
  - Stay up to speed with the law's provision in order to be aware of implications and educate patients.
  - Develop strategies for maintaining financial stability and addressing lower reimbursement.
  - Enhance negotiation efforts for deeper discounts with drug manufacturers.
  - Increase automation to reduce costs, track inventory, and manage customer data.
  - Use inventory management systems that ensure compliance with program rules. For example: prevent MFP inventory from being used for non-Medicare patients.
  - Improve supply chain management to meet increased demand.
  - Using data to identify trends in prescription drug usage.

- Providers:
  - Stay up to speed with the law's provision in order to be aware of implications and educate patients.
  - Ensure operational requirements are implemented accordingly and in compliance with applicable requirements
  - Develop strategies for maintaining financial stability. For example, consolidated physician practices.
  - Consider adjusting their treatment plans to accommodate an increased demand and decreased reimbursement due to capped copays and "maximum fair price".

HOW CAN MANAGED CARE ORGANIZATIONS PREPARE FOR THE IRA

Some additional specific strategies that managed care organizations can implement to address the implications of the IRA

- Stay up to speed on regulatory updates and continuously assess impact in revenue and operations.
- Use data analytics to identify opportunities for cost savings.
- Focus on preventive care.
- Industry partnerships to improve care coordination.
- Educate patients about their health care options.

REFERENCES

- *Glossary* (2021) *Medicare Interactive*. Available at: https://www.medicareinteractive.org/resources/glossary (Accessed: 06 August 2023).
- Juliette Cubanski and Tricia Neuman. Published: Jul 12, 2023 (2023) *A small number of drugs account for a large share of Medicare Part D Spending*, *KFF*. Available at: https://www.kff.org/medicare/issue-brief/a-small-number-of-drugs-account-for-a-large-share-of-medicare-part-d-spending/ (Accessed: 13 August 2023).
- Juliette Cubanski and Tricia Neuman. Published: Apr 20, 2023 (2023) *Changes to medicare part D in 2024 and 2025 under the Inflation Reduction Act and how enrollees will benefit*, *KFF*. Available at: https://www.kff.org/medicare/issue-brief/changes-to-medicare-part-d-in-2024-and-2025-under-the-inflation-reduction-act-and-how-enrollees-will-benefit/ (Accessed: 13 August 2023).
- Barker, T. *et al.* (2022) *Summary of Inflation Reduction Act of 2022: Key Drug Pricing Provisions and Implementation Timeline*, pp. 1–17.
- *Ma rate announcement still imposes disproportionate risk model reductions to Puerto Rico, but changes are diluted over 3 years* (2023) *MMAPA*. Available at: https://mmapapr.org/ma-rate-announcement-still-implements-disproportionate-risk-model-reductions-to-puerto-rico-but-changes-are-diluted-over-three-years/ (Accessed: 24 August 2023).
- *Press release HHS announces key dates for the first year of the Inflation Reduction Act's Medicare Drug Price Negotiation Program* (no date) *CMS*. Available at: https://www.cms.gov/newsroom/press-releases/hhs-announces-key-dates-first-year-inflation-reduction-acts-medicare-drug-price-negotiation-program (Accessed: 13 August 2023).
- (May 12, 2023) *Center for medicare date: To: From - centers for Medicare & Medicaid ...* Available at: https://www.cms.gov/files/document/part-d-manufacturer-discount-program-draft-guidance-may-2023.pdf (Accessed: 13 August 2023).
- *Fact sheet CMS releases 2024 projected Medicare part D premium and bid information* (no date) *CMS*. Available at: https://www.cms.gov/newsroom/fact-sheets/cms-releases-2024-projected-medicare-part-d-premium-and-bid-information (Accessed: 13 August 2023).
- *Fact sheet the inflation reduction act lowers health care costs for millions of Americans* (no date) *CMS*. Available at: https://www.cms.gov/newsroom/fact-sheets/inflation-reduction-act-lowers-health-care-costs-millions-americans#:~:text=Government%20reinsurance%20in%20the%20catastrophic,for%20generics%20beginning%20in%202025. (Accessed: 13 August 2023).
- Goldman, D. et.al. *Mitigating the Inflation Reduction Act's Adverse Impacts on the Prescription Drug Market.* Published April 13, 2023. Available at: https://healthpolicy.usc.edu/research/mitigating-the-inflation-reduction-acts-potential-adverse-impacts-on-the-prescription-drug-market/ (Accessed: August 11, 2023)
- Cubanski, Juliette. Published: Aug 8, 2023. *FAQs about the Inflation Reduction Act's Medicare Drug Price Negotiation Program, KFF.* Available at: https://www.kff.org/medicare/issue-brief/faqs-about-the-inflation-reduction-acts-medicare-drug-price-negotiation-program/ (Accessed: August 15, 2023)
- Kramer, Katie and Modi, Rianna. Published July 5,2023. *CMS Issues Final Guidance on the Inflation Reduction Act (IRA) Drug Price Negotiation Program.* Available at: https://www.jdsupra.com/legalnews/cms-issues-final-guidance-on-the-7523303/ (Accessed August *15, 2023)*
- Audrey Crowell & Lotan Helfman. Published June 21, 2023. *The Drug Price Negotiation Program Faces Pushback from Private and Public Industry Participants, SheppardMullin.* Available at: https://www.sheppardhealthlaw.com/2023/06/articles/drug-and-pharmaceutical-law/the-drug-price-negotiation-program-faces-pushback-from-private-and-public-industry-participants/ (Accessed August 18, 2023
- Haitham Aly, Matthew Smith, and Louisa Bonds. Published December 12, 2022. *Inflation Reduction Act: What Health Plans and Part D Sponsors need to know to be prepared – Whitepaper.* Available at: https://www.milliman.com/en/insight/inflation-reduction-act-health-plans-and-part-d-sponsors-need-to-know (Accessed August 18, 2023)