

An update on Inflation Reduction Act IRA: What's Next?

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Disclosure to Learners

Iris Morant and Sara Ramos, faculty for this CE activity, have no relevant financial relationship(s) with ineligible companies to disclose.



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Objectives

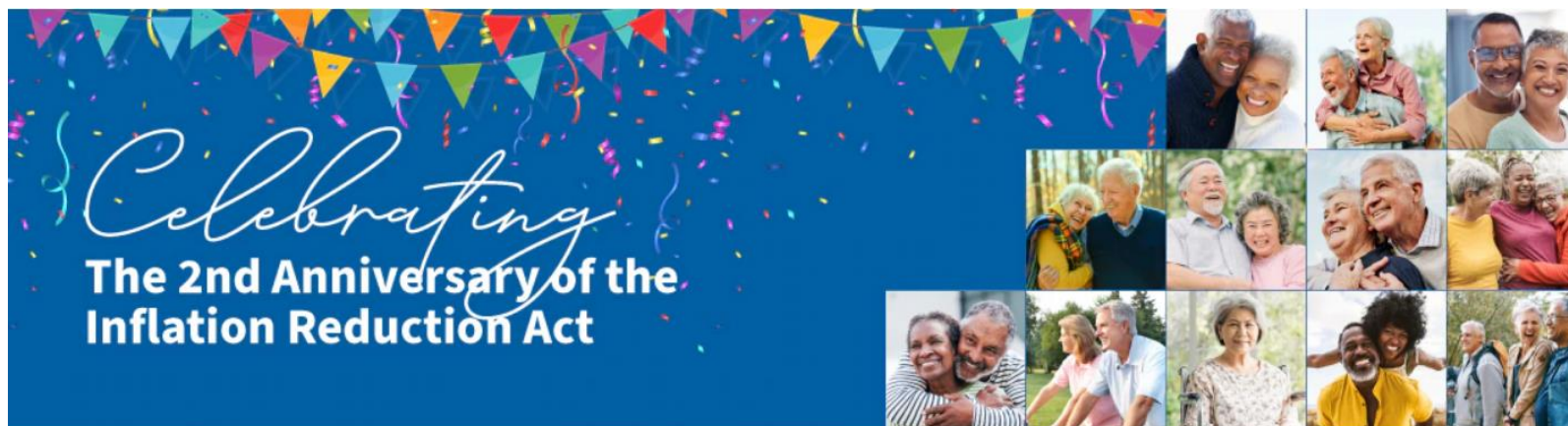
- 1 Summarize the current status of IRA implementation at this point in time.
- 2 Discuss how key stakeholders are responding to IRA.
- 3 Describe potential strategies stakeholders including community pharmacies may rely on in the future to adapt to the policies included in the IRA.

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Medicare And The Inflation Reduction Act (IRA)

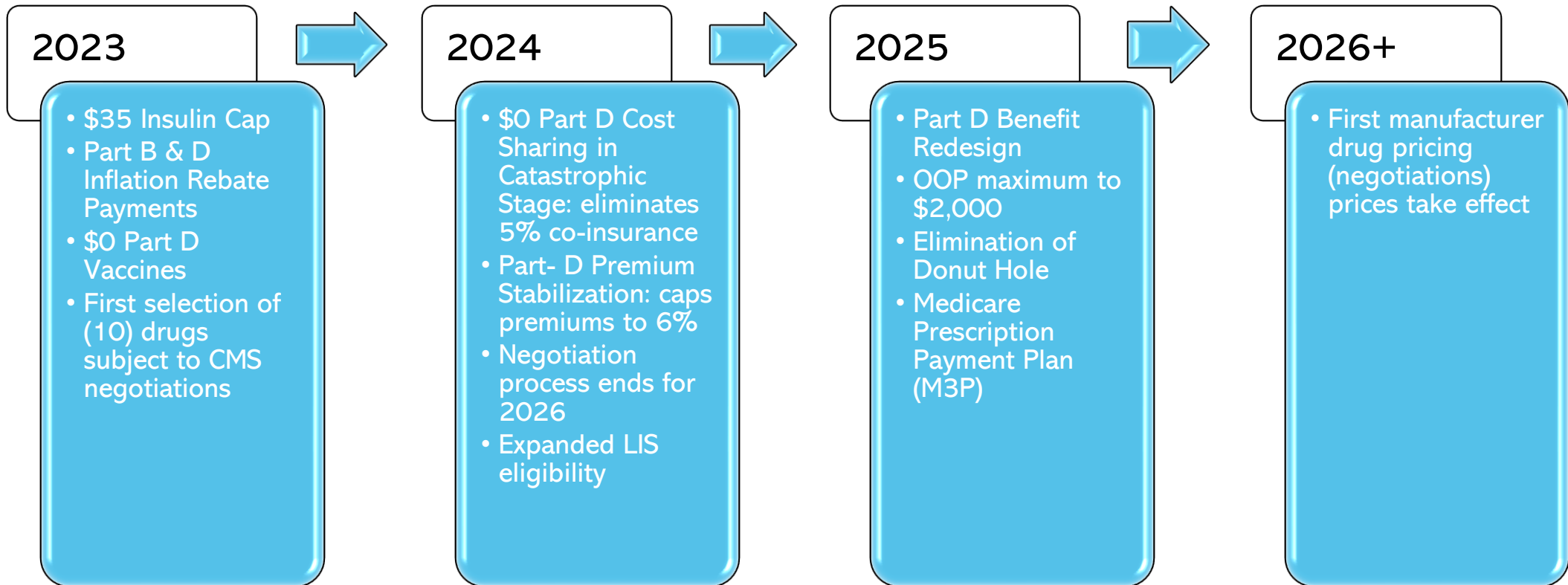
Inflation Reduction Act Overview

- This law was signed by President Biden on August 16, 2022
- According to the US. Department of Health and Human Services, the IRA is one of the most consequential health care laws since the Affordable Care Act.
 - Biggest improvement to Medicare since 2003
 - Delivered lower prescription drug costs
 - Make health insurance more affordable



IRA Key Provisions

Timeline



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Changes of IRA

Benefit redesign

Benefit Changes: Insulin Cost-Sharing Cap

- ▶ No deductibles and capped out-of-pocket insulin costs in Part D & Part B
- ▶ **2023-2025:** Maximum of \$35 co-pay
- ▶ **2026:** Insulin cost-share will be the lesser of:
 - ▶ \$35 for a month's supply
 - ▶ 25% of the MFP, or
 - ▶ 25% of the *“negotiated price”*

Part D Benefit Redesign

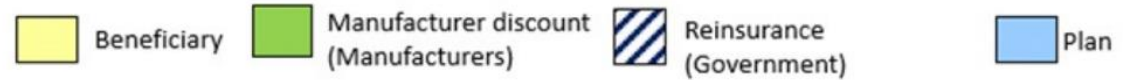
2024 Changes

- Elimination of cost sharing in catastrophic phase
- **Premium Stabilization:**
Premium amounts under Part-D plans may not increase more than 6% from preceding year

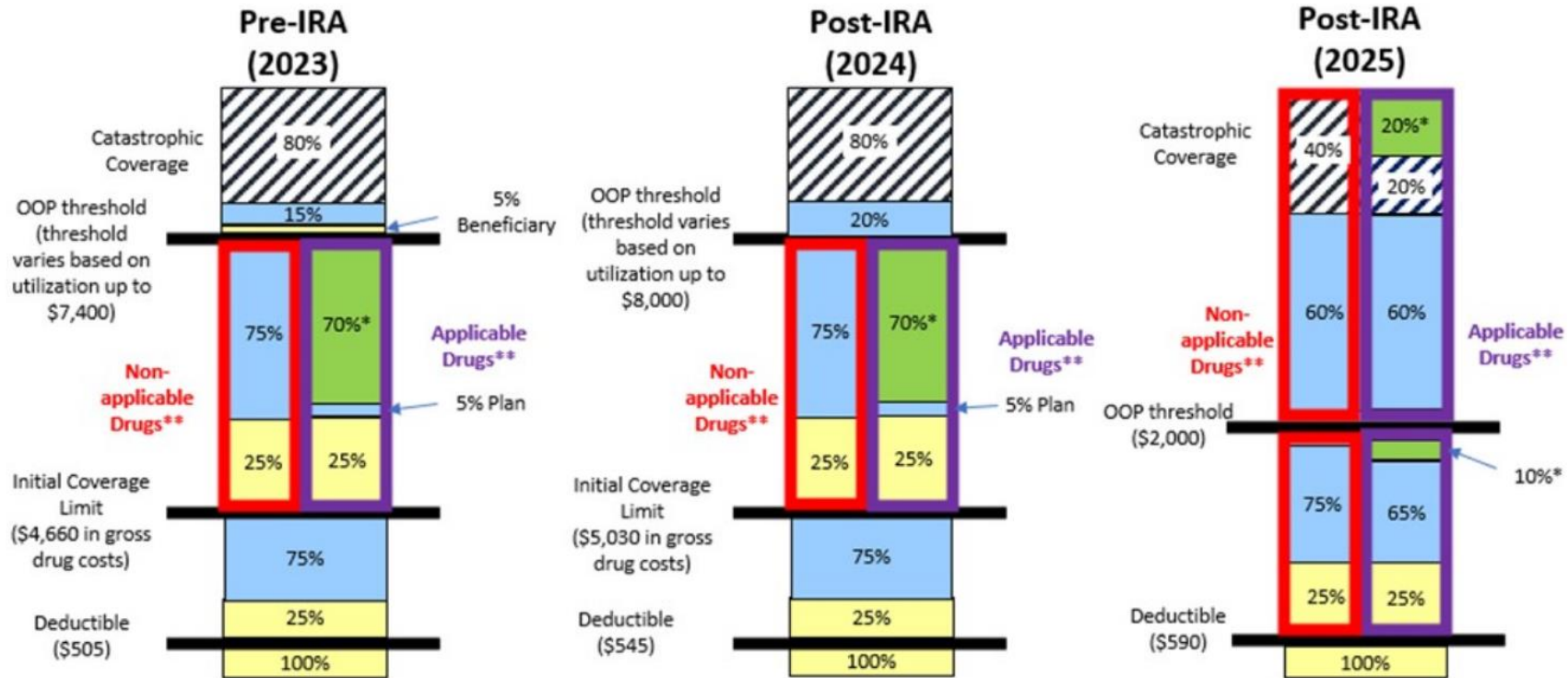
2025 Changes

- Elimination of the Donut Hole
- OOP Reduction
- Gov't Reinsurance Modification
- Sunset of the Coverage Gap Discount Program (CGDP) & establishment of the Manufacturer Discount Program (Discount Program).

Standard Benefit for CY 2024 & CY 2025



Non-Low Income



* Image accessed at: Available at: <https://www.cms.gov/newsroom/fact-sheets/draft-cy-2025-part-d-redesign-program-instructions-fact-sheet>

Standard Benefit for CY 2024 & CY 2025

	2024		2025	
Deductible Phase	Cost Sharing: 100%		Cost Sharing: 100%	
	Deductible: \$545		Deductible: \$590	
Initial Coverage Phase	Cost sharing: 25% Plan Pays: 75%		Applicable Drugs * Cost sharing: 25% Plan Pays: 65% Manufacturer Discount: 10%	Non-Applicable Drugs Cost sharing: 25% Plan Pays: 75%
	Initial Coverage Limit: \$5,030			
Coverage Gap	Applicable Drugs Cost sharing: 25% Plan Pays: 5% Manufacturer Discount: 70%	Non-Applicable Drugs Cost sharing: 25% Plan Pays: 75%		
	Out-of-Pocket Threshold: \$8,000		Out-of-Pocket Threshold: \$2,000	
Catastrophic Phase	Plan Pays: 20% Reinsurance: 80%		Applicable Drugs* Plan Pays: 60% Manufacturer Discount: 20% Reinsurance: 20%	Non-Applicable Drugs Plan Pays: 60% Reinsurance: 40%

* The Discount Program is phased in for certain drugs of qualifying drug manufacturers during the initial coverage phase from 2025 through 2028 and in the catastrophic phase from 2025 through 2030. For drugs subject to the phase-in, Part D sponsors will be responsible for the additional cost that would have otherwise been covered by the manufacturer discount



Changes of IRA

Pricing & negotiation:

Rebates & manufacturer drug
negotiation

Inflation Rebate Program

Part B & D Inflationary Rebates

- ▶ Under the IRA, manufacturers that raise the prices of certain drugs covered under Medicare Part B & D faster than the rate of inflation are required to pay Medicare a rebate.
 - ▶ **Part-D Inflationary Rebate:** 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
 - ▶ **Part B Inflationary Rebate:** 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.
- ▶ CMS determines inflation adjustment amount.
- ▶ Manufacturers will receive a report that identifies that amount of rebated owed, as well as several of the components used to calculate that amount.



CMS Drug Negotiation

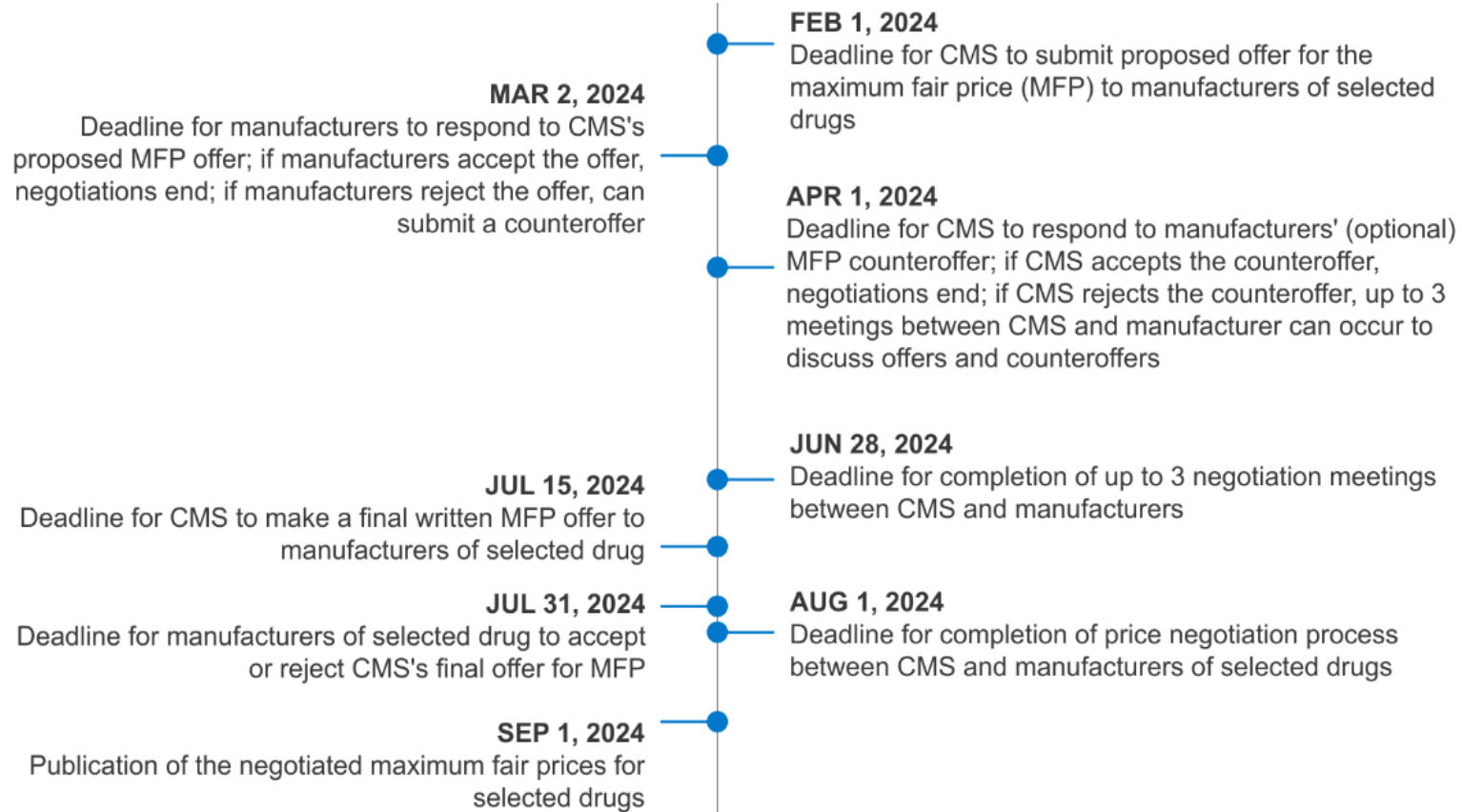
- The IRA allows HHS (thru the Department of Health Secretary) to negotiate the prices for select high-spend drugs and biologics covered in Medicare Parts B and Part D and do not have generic or biosimilar competition
- If a drug is selected, manufacturers are obligated to enter a negotiation with the Secretary and make selected drugs accessible at the negotiated price
- Negotiation Parameters:

Year	# of Drugs	Category
2026	10	D only
2027	+15	D only
2028	+15	B & D
2029+	+20	B & D

CMS Drug Negotiation

- ▶ **Ranking of 50 negotiation-eligible Part-D drugs based on total expenditures (total gross covered prescription drug cost)**
- ▶ **Eligible Drugs**
 - ▶ Brand name or biologics with no generic or biosimilar
 - ▶ At least 9 years for small molecule drugs or 13 years for biologics since their FDA approval date
 - ▶ Some exclusions for Orphan Drugs (one indication)
 - ▶ Selected based on highest Medicare gross cost, excluding rebates

Timeline of Key 2024 Activities in the Negotiation Process



Negotiation Process

CENTERS FOR MEDICARE & MEDICAID SERVICES

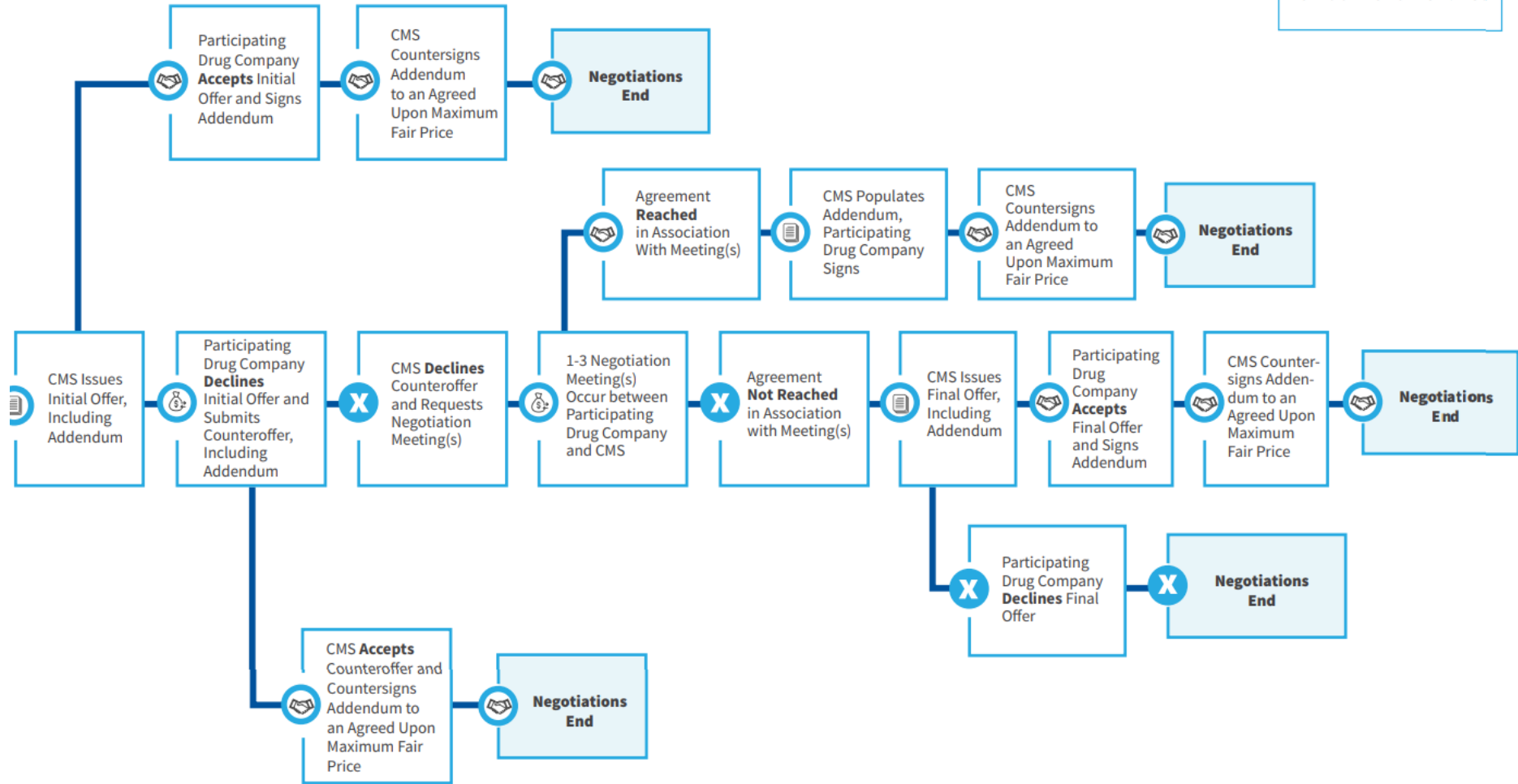


Image accessed at: <https://www.cms.gov/files/document/fact-sheet-negotiation-process-flow.pdf>

CMS Drug Negotiation

Drugs Selected for 2026

Drug Name	Participating Drug Company	Agreed to negotiated price for 30-day supply for CY 2026	List price for 30-day supply, CY 2023	Discount
Januvia	Merck Sharp Dohme	\$113	\$527	79%
Fiasp and Novolog	Novo Nordisk Inc	\$119	\$495	76%
Farxiga	AstraZeneca AB	\$178.50	\$556	68%
Enbrel	Immunex Corporation	\$2,355	\$7,106	67%
Jardiance	Boehringer Ingelheim	\$197	\$573	66%
Stelara	Janssen Biotech, Inc	\$4,695	\$13,836	66%
Xarelto	Janssen Pharms	\$197	\$517	62%
Eliquis	Bristol Myers Squibb	\$231	\$521	56%
Entresto	Novartis	\$295	\$628	53%
Imbruvica	Pharmacyclics LLC	\$9,319	\$14,934	38%

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Changes of IRA

Medicare prescription
payment plan (M3P)

M3P Overview

Beginning CY 2025, all Medicare prescription drug plans (except those who offer Part D drugs at \$0 Cost share) must offer enrollees the choice to spread out their Out-of-Pocket (OOP) prescription drug costs over the plan year through capped monthly installments, creating a \$0 copay at the Point-of-Sale.

Key Requirements

Pre-Enrollment
Outreach

Participant
Election/Termination

Invoicing &
Collection

Member Communications
& Notifications

Program Calculations:
Monthly Caps

Payment
Mechanisms

Ledgering &
Accounting

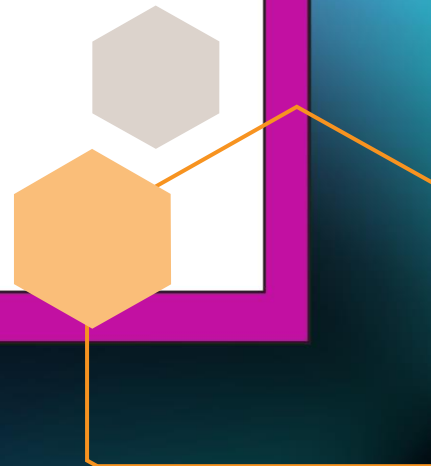
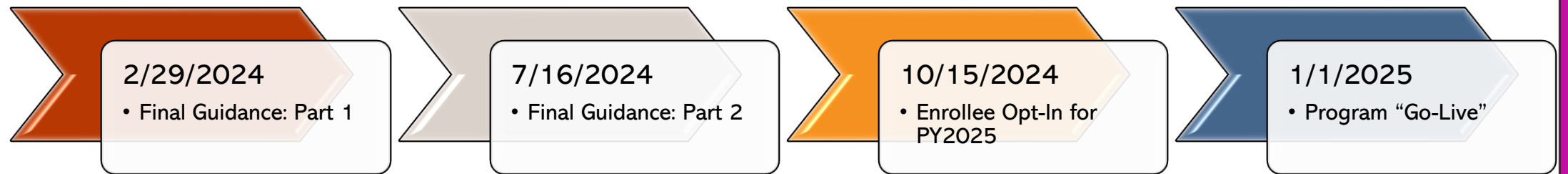
CMS
Reporting

Voluntary For Member

Ease Financial Burden

Distribute OOP in Monthly Payments

M3P Timeline



Key Responsibilities in M3P

Plan Sponsor

- Member Identification
- Member Education and Outreach
- Intake and Processing Enrollment Information (Opt-in, Preclusion, Terminations, Reinstatements)
- POS Messaging to Pharmacies
- Provider Education
- Manage monthly billing for OOP costs
- CMS Reporting

Pharmacies

- Inform enrollees that they may benefit from M3P a
- Provide a standard “likely to benefit” notice
- Submit the COB Transaction for the Claim that triggered M3P enrollment
- Submit the COB Transaction for other claims that have not been picket up, as per enrollee request
- Submit COB Transactions for prescriptions filled after M3P Enrollment is completed

Enrollees

- Voluntary Program Enrollment
- Keeping Up to Date with Monthly Payments

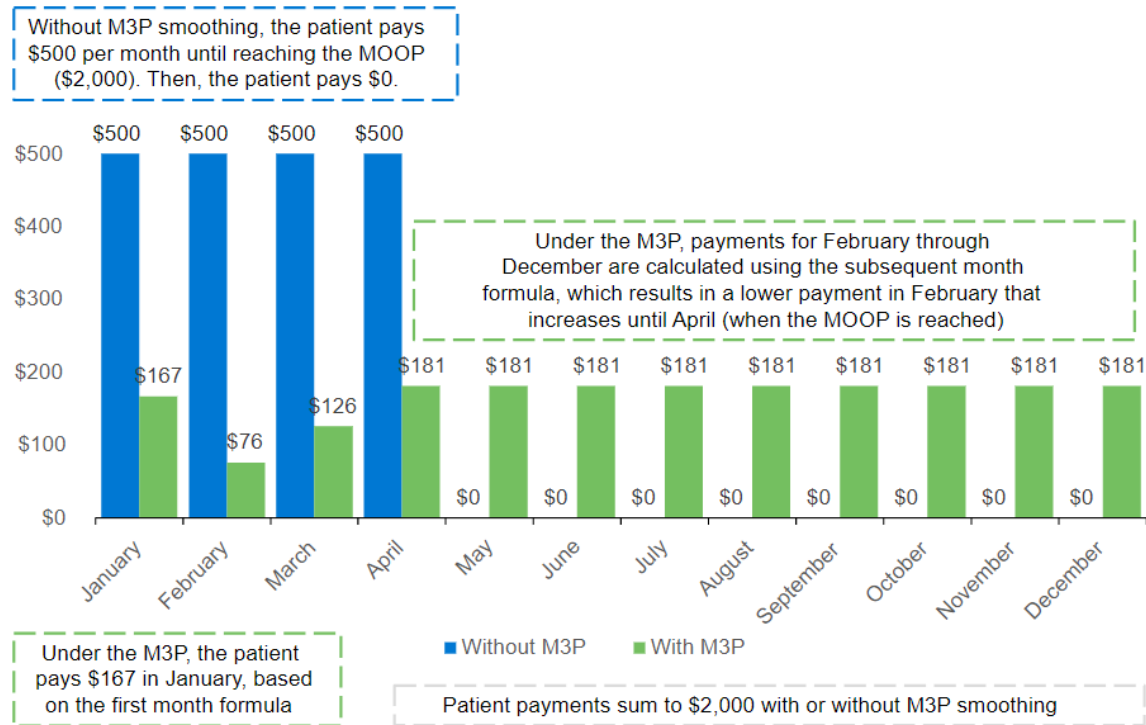
Part-D Sponsors Responsibilities

Election & Enrollment Process

- ▶ **Member Identification (“likely to benefit”)**
- ▶ **Member Education and Outreach**
- ▶ **Member Materials**
- ▶ **Intake and Processing Enrollment Information**
 - ▶ (Opt-in, Preclusion, Terminations, Reinstatements)
- ▶ **Member Mechanisms for Opt-In**
- ▶ **Member Services/Support**
- ▶ **M3P Disputes**

Likely to Benefit

Figure 1: Cost sharing calculation for monthly \$500 out-of-pocket cost



“Figure 1: Cost sharing calculation for monthly \$500 out-of-pocket cost” Graph. Milliman.com. Milliman, 10/2/2023. <https://www.milliman.com/en/insight/medicare-prescription-payment-plan-for-plan-sponsors>. Accessed 8/9/2024.

- The M3P is available to all Enrollees, but those with a Higher Cost sharing earlier in the year are most likely to benefit.
- \$600 Single Claim Cost Share Trigger
- Prequalification if likely to reach \$2,000 TrOOP in 2025 (*based on 2024 Claims*)

Part-D Sponsors Responsibilities

Pharmacy Claims

- ▶ Tracking of “True” Member Cost Share
- ▶ POS Messaging (\$0 copay)
- ▶ Pharmacy Reimbursement
- ▶ Pharmacy Education & Support
- ▶ Pharmacy Help-Desk Support
- ▶ Data Extracts (Claims, Eligibility)
- ▶ Claims Monitoring
- ▶ Claims Reprocessing
- ▶ Reporting & Data Submissions

Part-D Sponsors Responsibilities

Member Invoicing, Payments & Collections

- ▶ Monthly Bill Calculations
- ▶ Member Invoices
- ▶ Payment Methods & Acceptance
- ▶ Financial Reconciliation
- ▶ Payment Adjustments & Refunds
- ▶ Collections of unpaid balances
- ▶ Member Service/Support
- ▶ CMS Reporting
- ▶ Financial Risk Calculations (bad debt/unsettled balances)

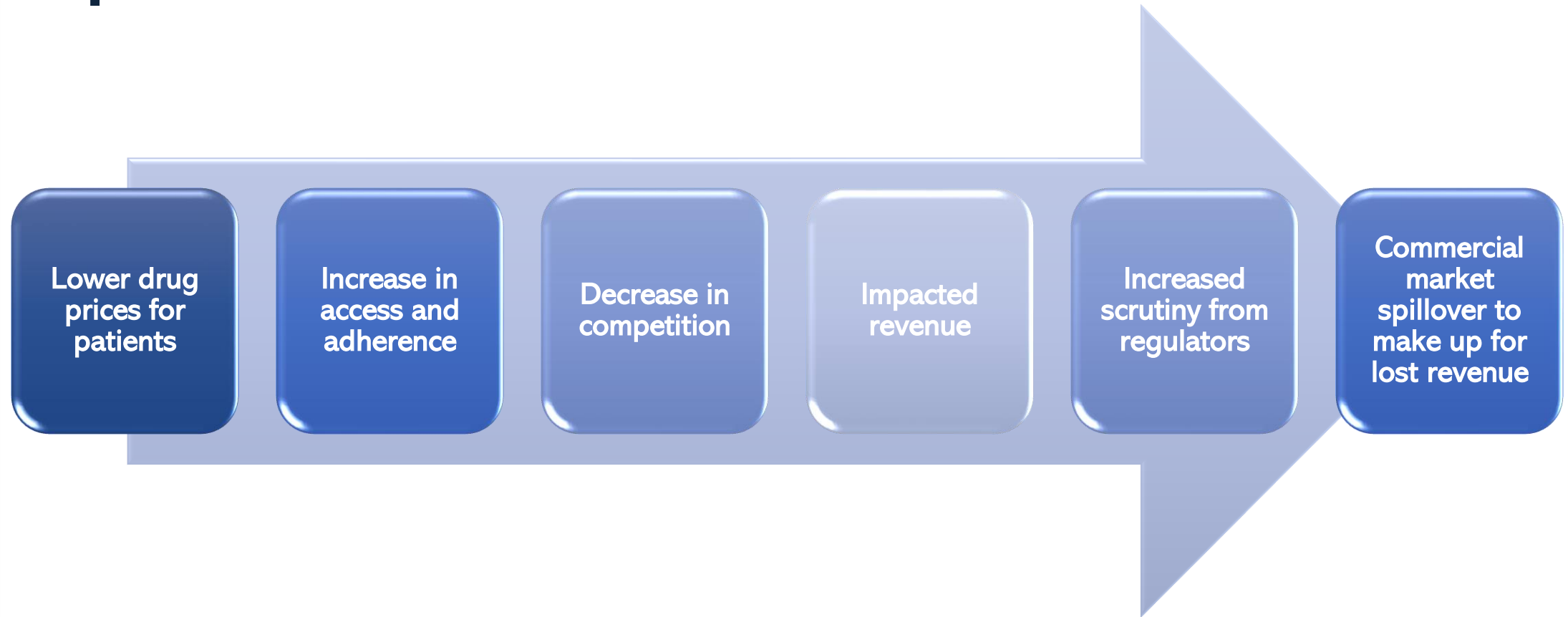
M3P Implications for Sponsors & Delegated Entities

- ▶ Increased oversight over new program functions
 - ▶ FDR v. Internal (depending on delegation)
- ▶ New CMS Reporting Requirements
 - ▶ Data on M3P Participation
 - ▶ Bad Debt/Unsettled Balances
- ▶ Compliance with M3P Regulatory Timeframes/Notices

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Implications of IRA on the Healthcare Sector

Implications of IRA



Lawsuits & Constitutional Challenges

National Infusion Center Association et al. v. Becerra et al.

Bristol Myers Squibb Co. v. Becerra et al.

STATUS
Appeal Filed

Dayton Area Chamber of Commerce et al. v. Becerra et al.

Merck et al. v. Becerra et al.

STATUS COURT GOAL
Waiting on a District of Block

STATUS
Waiting for decision

Janssen Pharmaceuticals, Inc. v. Becerra et al.

Astellas Pharma US, Inc. v. U.S. Department of Health

STATUS
Decision issued
Appeal filed

AstraZeneca Pharmaceuticals LP et al. v. Becerra et al.

STATUS	COURT	GOAL
Appeal Filed	Delaware, Wilmington	Block the government from applying the IRA to the plaintiff +2 additional goal(s)

Boehringer Ingelheim Pharmaceuticals, Inc. v. U.S. Department of Health and Human Services et al.

STATUS	COURT	GOAL
Decision issued: Appeal Filed	Connecticut	Block government from enforcing results of negotiation +1 additional goal(s)

Novo Nordisk et al. v. Becerra et al.

Novartis Pharmaceuticals Corporation v. Becerra et al.

STATUS
Decision

AstraZeneca Pharmaceuticals LP et al. v. Becerra et al.

National Infusion Center Association et al. v. Becerra et al.

STATUS
Briefing ongoing

Janssen Pharmaceuticals, Inc. v. Becerra et al.

STATUS	COURT	GOAL
Briefing is ongoing	Third Circuit	Block government from enforcing results of negotiation +1 additional goal(s)

Bristol Myers Squibb Co. v. Becerra et al.

STATUS	COURT	GOAL
Briefing is ongoing	Third Circuit	Block government from enforcing results of negotiation +1 additional goal(s)

Lawsuits & Constitutional Challenges

First Amendment

Coercion to agree to maximum price & sign agreements = **violation against free speech**

Fifth Amendment: Takings Clause

Program considered and **unconstitutional taking of property** by forcing pharma to provide access to drugs at substantially reduced prices without fair compensation

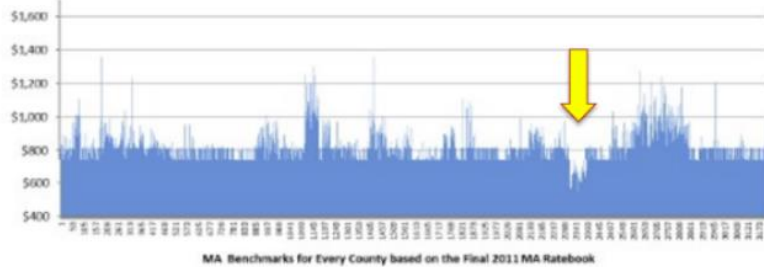
Eighth Amendment

Excise tax imposes **“excessive fines”** on pharmaceutical manufacturers that amount to **punitive action**

Medicare Advantage in Puerto Rico

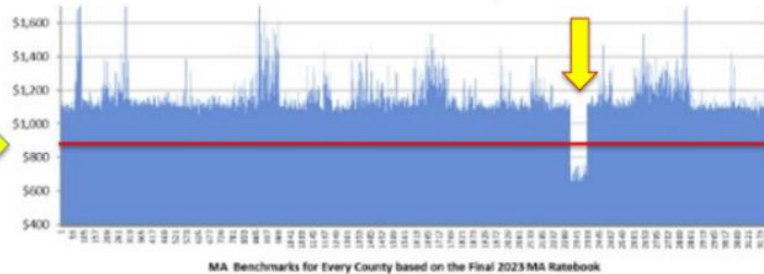
MA Funding Disparity in PR – 2024 v. 2011

MA County Benchmarks 2011
Based on MA Ratebook at 3.0 STARS



2011
US Avg = \$787
PR Avg = \$595
PR 24% lower
PR \$192 lower

MA County Benchmarks 2024
Based on MA Ratebook at 0% Quality Bonus

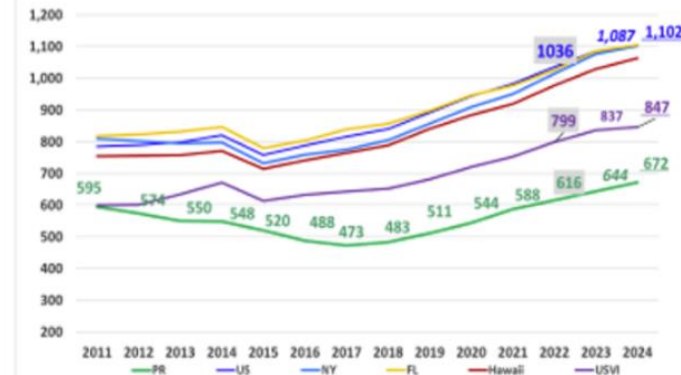


2024
US Avg = \$1,110
PR Avg = \$672
PR 39% lower
PR \$438 lower

AGA Floor Proposal →

MA Funding Disparity Remains the Same

Average MA Benchmarks 2011 - 2024
Simple Average of County MA Benchmarks (\$) @ 0% Star Bonus



US Average
US Virgin Islands
Puerto Rico

- 2022 MA Rates are too low, and depend on temporary fixes
 - MA payment are 39% below vs US Avg
 - 37% below the lowest state
 - 21% below the USVI



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%.

Possible Adverse Effects of IRA

- Reduction in:
 - Discovery of new treatments
 - Discovery of new uses for existing drugs
 - Generic competition
- Inflation rebates may harm plans' abilities to negotiate prices for drugs with promising but uncertain benefits

Strategies to Address IRA Implications

Plan Sponsors & Pharmacy Benefit Managers

- ▶ Regulatory Monitoring and Impact Analysis
- ▶ External & Internal Educational & Communication Strategies
- ▶ Management of Increased Claims Volume
- ▶ Compliance Oversight
 - Formulary Strategies
- ▶ Data Analytics

Strategies to Address IRA Implications

Pharmacies

- Regulatory monitoring and impact analysis
- Strategies for addressing lower reimbursement
- Automation efforts to reduce costs, track inventory, and manage customer data.
- Use inventory management systems that ensure compliance with program rules (i.e. prevent MFP inventory from being used for non-Medicare patients)
- Improve supply chain management to meet increased demand
- Data analytics & utilization trends

CMS National Pharmacy IRA Educational Campaign

- *CMS is spearheading a National Pharmacy Educational Outreach Campaign on the Medicare Prescription Payment Plan, a provision of the Inflation Reduction Act (IRA). The presentation is intended to educate pharmacy professionals about the new payment option offered to Part D enrollees under the Medicare Prescription Payment Plan and how it fits into the pharmacy process effective January 1, 2025. Pharmacy professionals from all practice settings that serve Part D enrollees in any capacity are highly encouraged to attend. CMS will hold ten recurring webinars that will begin Friday, September 6, 2024, and end on Monday, September 30, 2024. Please use this link to register soon before seats reach capacity:*

[https://cms.zoomgov.com/webinar/register/WN_xCyx8ChnTjmKlCfApF4LQw#/registration.](https://cms.zoomgov.com/webinar/register/WN_xCyx8ChnTjmKlCfApF4LQw#/registration)



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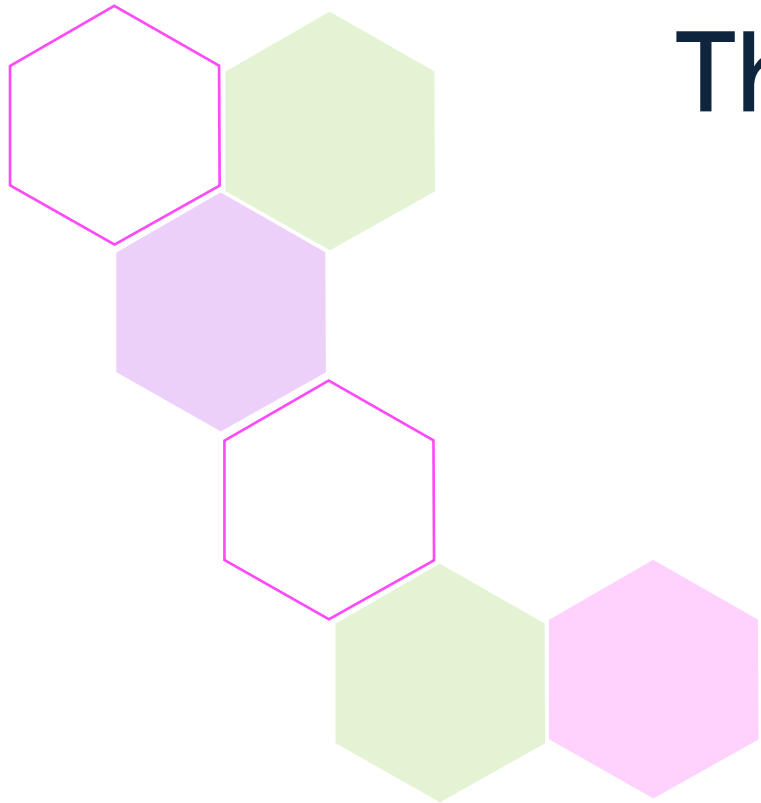
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Tiene hasta el 5 de octubre para completar la evaluación y prueba para poder obtener su certificado.



Thank you



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