Midnight Approaches

Reactions to Part D Reforms

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Caveats

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Introductions

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What are the latest developments in Part D changes?

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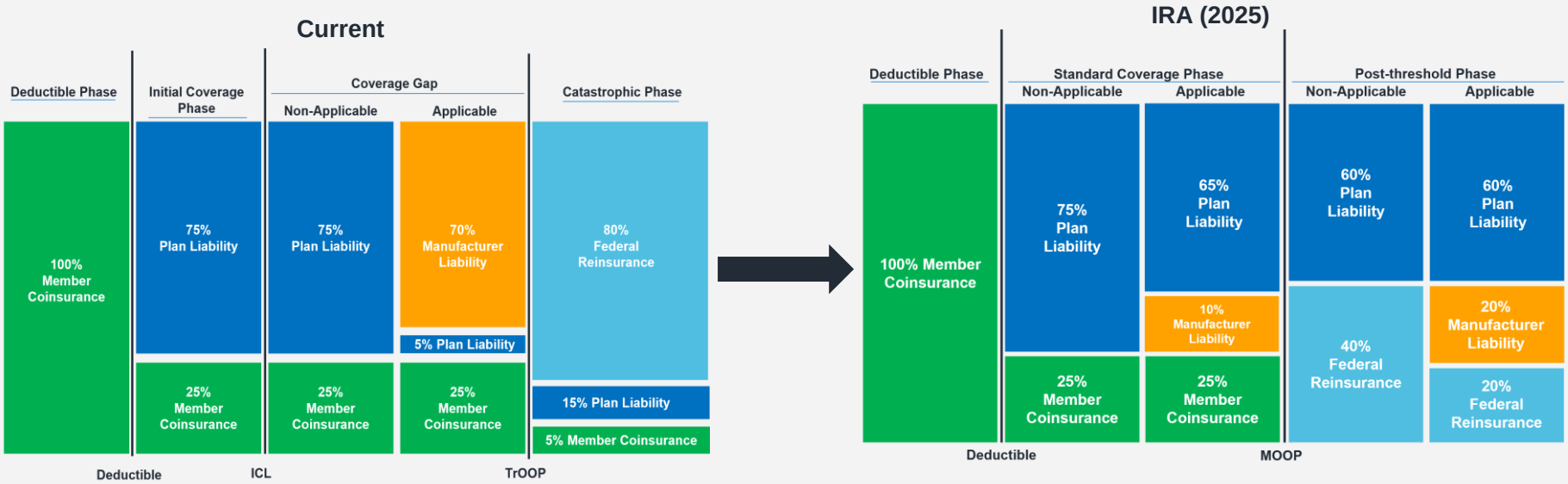
Benefit Redesign Refresher

Defined Standard Design – Non-Low Income Beneficiaries



Major changes:

- Member does not pay costs above catastrophic starting in 2024, full phase in by 2025
- Manufacturer liability applies to LI members under IRA. CMS pays manufacturer liability on behalf of the manufacturer for drugs selected for negotiation.
- Plan liability is significantly higher under IRA
- Option to smooth cost sharing over the course of the year

Applicable: applicable to the manufacturer discount program, as defined by the FDA. Typically brands.

Non-applicable: not applicable to the manufacturer discount program. Typically generics.

Medicare Payment Plan Program (M3P) Overview

Program overview

- Plans are required to offer beneficiaries to opt into the cost sharing smoothing program as of January 1, 2025
- Enrolled beneficiaries will pay $0 at the point of sale (POS)
- Plans are responsible for calculating and billing enrolled beneficiaries for cost sharing subject to a monthly cap as specified by the program calculation
- Plans must provide educational materials and notify beneficiaries who are “likely to benefit”

Key Notes

- Enrollees may not be billed more than their actual out-of-pocket costs in their first month of enrollment
- Plans must offer the program for all Part D covered drugs, and non-Part D covered drugs are not eligible
- The program will not impact a beneficiary’s progression through the Part D phases. In other words, accumulation towards the deductible and annual out-of-pocket threshold will be based on the cost sharing incurred, regardless of who pays at the counter.

Unanswered questions

- **Mechanics of beneficiary enrollment and marketing:** Will Part D beneficiaries understand this program? What will CMS’ educational materials look like? How will M3P be integrated into other tools like Medicare Plan Finder?
- **Operational challenges:** How will plan sponsors and pharmacies navigate the administrative burden of enrolling and collecting payments from enrollees?
- **Bad debt:** How much might bad debt be worth? Will plans be prepared to absorb the cost?

Calculation of Monthly Cost Share Cap for Part D Enrollees

First Month	$\frac{\text{Annual OOP Threshold}^{*} - \text{Incurred Costs of Beneficiary Prior to Program Enrollment}}{\text{\# of Months Remaining in Plan Year}^{**}}$
Subsequent Months	$\frac{\text{Sum of Remaining OOP Costs Not Yet Billed} + \text{Additional OOP Costs Incurred}}{\text{\# of Months Remaining in Plan Year}^{***}}$

**$2,000 for CY2025*
***Includes the month where beneficiary opted in*
****Includes the month for which the cap is calculated*

M3P Bad Debt: Questions to Guide Estimates

Plans must include an estimate of bad debt administrative expense in the BPT

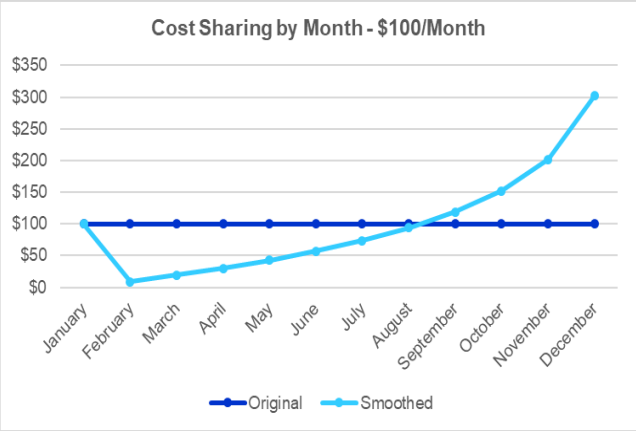
How many beneficiaries will participate in M3P?

Upon plan enrollment	During the year

How many participants will not pay their cost sharing?

Upon first script	Upon disenrollment	At other thresholds

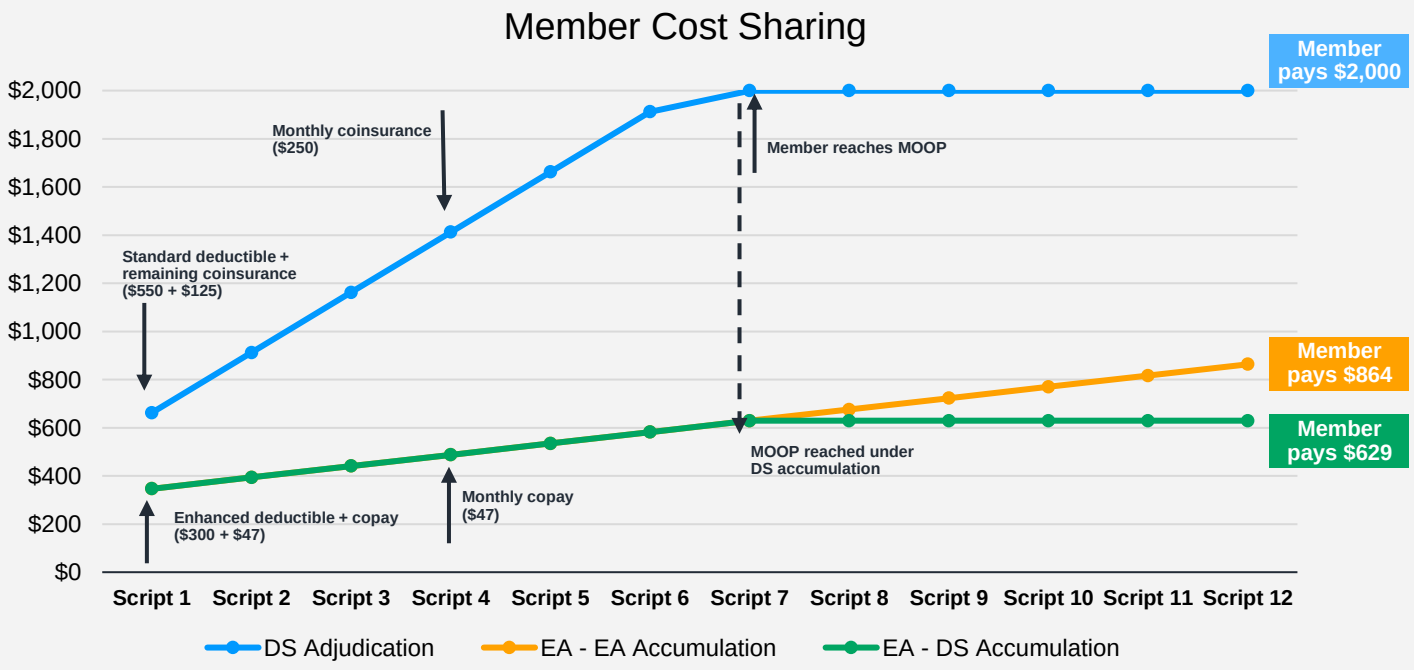
Example situation (participant with low cost sharing):



For a participant with monthly cost sharing of $100, M3P payments grow substantially throughout the year. Is there a threshold where they stop paying?

How will MOOP accumulation logic impact member cost sharing?

Enhanced adjudication example for member with a single tier 3 product



Assumptions:
Drug Cost: $1,000 / month
Drug Coverage: Tier 3
Tier 3 Copay: $47
Enhanced Deductible: $300
Standard Deductible: $550

- **Under DS adjudication,** member accumulates according to a $550 deductible, then 25% coinsurance ($250) until member pays $2,000 on script 7
- **Under EA adjudication based on EA benefits,** member accumulates enhanced deductible ($300), then $47 and does not reach MOOP
- **Under EA adjudication based on DS benefits,** member pays enhanced deductible ($300), then $47 until script 7 (when member reaches MOOP under DS adjudication)

Confirmed by Advance Notice

Adjudicated price will affect MOOP point under the accumulation rules.
Higher cost products will accumulate more quickly to the MOOP, regardless of actual member copay.

Implications of MOOP accumulation

Member impacts

- Most directly impacts cost sharing for members using non-specialty brand drugs
- Members with low spend or who reach MOOP right away won't see much impact

Value of benefits

- Plans are "giving up" more dollars by enhancing benefits, relative to pre-IRA benefits
- Considering this accumulation logic is critical to benefit strategy

Anti-selection impact

- Unclear what will be shown on Medicare Plan Finder
- "Reaching MOOP" may not mean the same thing for all plans

Risk adjustment

What is it and why is it important?

- The Part D Risk Adjustment (RxHCC) model predicts plan liability for prescription drugs under the Part D program
- The model uses medical diagnosis codes from the prior year and demographic information from the current year to predict prescription drug plan liability on a member-level basis.
- The risk score is used to adjust the monthly Part D direct subsidy

Example

At 0.85:	**0.85**	**$140**
At 1.15:	**1.15**	**$200**

Risk adjustment

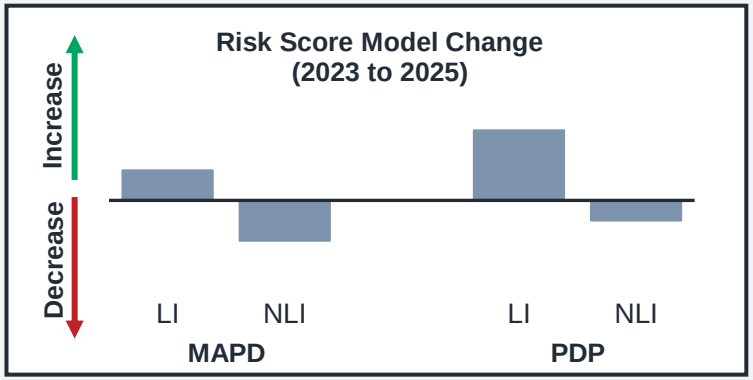
Changes for 2025

Changes

- **Separate normalization factors for MAPDs and PDPs**
  - PDP risk scores increase by 11%
  - MAPD risk scores decrease by 1%
- **Model recalibrations using more recent data years**
  - Data updated from 2018/2019 to 2021/2022
  - Better reflects market events (new launches, price changes, patent losses, etc)
- **Model recalibrations reflecting the new PY2025 Part D defined standard benefit structure**
  - Incorporates increased plan liability under defined standard IRA benefit

Implications

- Increases to risk scores for low income members and decreases for non-low income members
- Larger increases on PDP due to normalization factor



OOPC Changes

Requirements

- **15% differential between basic and enhanced PDPs**
  - Was previously subject to an outlier threshold
- **Formulary and benefits for enhanced plans may be no worse than defined standard (measured separately)**
  - New requirement

Implications

- Defined meaningful difference threshold makes it easier for MAOs to make adjustments ahead of bid submission
- Generally, OOPC requirements are more difficult to meet now
- Plans with skinny formularies, particularly low cost enhanced plans, may be need to add coverage to meet defined standard equivalence

How might plans react to these changes?

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Changes from the IRA will increase costs for Part D payers, introducing new uncertainties for Medicare Part D plans

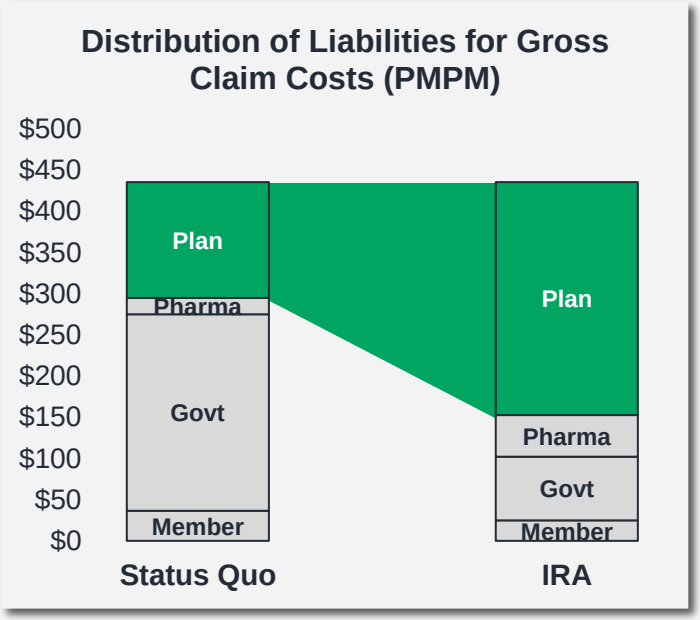
Patient cost sharing will be reduced:

- Copays reduced on insulins and vaccines
- Coverage gap eliminated
- OOP maximum set at $2,000, with no patient cost sharing in the catastrophic phase

Lower patient cost sharing will likely lead to increased drug utilization.

Health plan costs will be correspondingly higher. Most notably, health plan responsibility in the catastrophic phase increases from 15% to 60%.

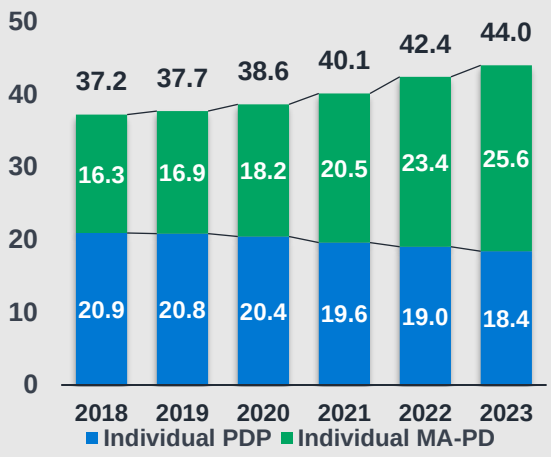
Estimated Nationwide Changes



*Based on 2020 individual market claims

**Pharma includes CGDP / MDP (excludes rebates)

The PDP market is already tightening



Source: CMS Enrollment Files, https://www.milliman.com/en/insight/low-income-disruption-0-dollar-premium-introduction-2024-individual-medicare-pdp-market

Enrollment continues to shift from PDP to MAPD

- Low income members are shifting towards DSNPs
- Many carriers actively try to move membership from PDP to MAPD where it is easier to manage total costs and revenue dollars are higher

Meaningful plan consolidation in 2024

- Elixir (Rite Aid) exited the individual PDP market
- Clear Spring PDP consolidated its two plans in 2024 and is also under intermediate sanctions – they cannot enroll new beneficiaries and will be terminated at the end of 2024

There are fewer basic PDPs below the regional benchmark than ever before

- This impacts low income members in particular, who can be auto-assigned to these plans
- Aetna, Humana, and Cigna all significantly reduced their offerings of basic plans below benchmark
- 1 region (Nevada) has no basic PDPs below benchmark

More plans are using coinsurance in 2024

- More than half of PDPs will have a coinsurance benefit on the preferred brand tier in 2024, compared to only about one third in 2023
- Nearly all PDPs already had coinsurance on the non-preferred brand tier

Cost Pressures for Part D Plans

Some plans are starting to show cost pressure through premium increases

- 2024 PDP premiums increased by 21% (~$5) on average
- United, Aetna, and Humana all had significant increases
- One notable exception is WellCare, who is offering a $0 PDP
- This is the first time a $0 PDP has been offered
- This may be a strategy to capture enrollment

Source: CMS Enrollment Files, CMS Basic Formulary Files

Plans are looking to narrow formularies to better manage costs

- The average portion of Part D spend excluded from formulary increased from 2023 to 2024
- Notable products with the greatest decrease in coverage (excluding products with generic launches) include Creon, Ingrezza, and Gammaplex
- Notable products with the greatest increase in coverage include Stelara, Otezla, and Mounjaro

There’s darkness.

Peril and risk.

You’re up at midnight.

Uncertainty at every corner – risk scores, benefit redesign…

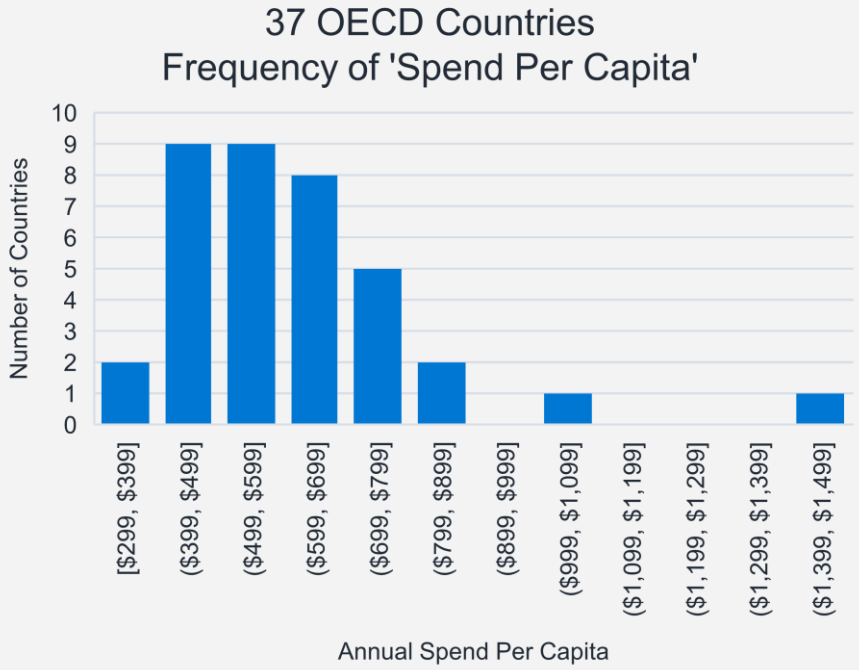
Part D changes are… Revolutionary…

Actuaries are true American heroes. (Pharmacists too)

… this is the midnight ride of Paul Revere; ‘the midnight bids of twenty-five’

Which country's annual per capita spend exceeds $1,400?

See the histogram below.



Source: OECD Health Statistics, 2021

Most of the Organisation for Economic Co-operation and Development (OECD) countries are developed, high-income countries.

There are many well-tested strategies that can also help with the IRA

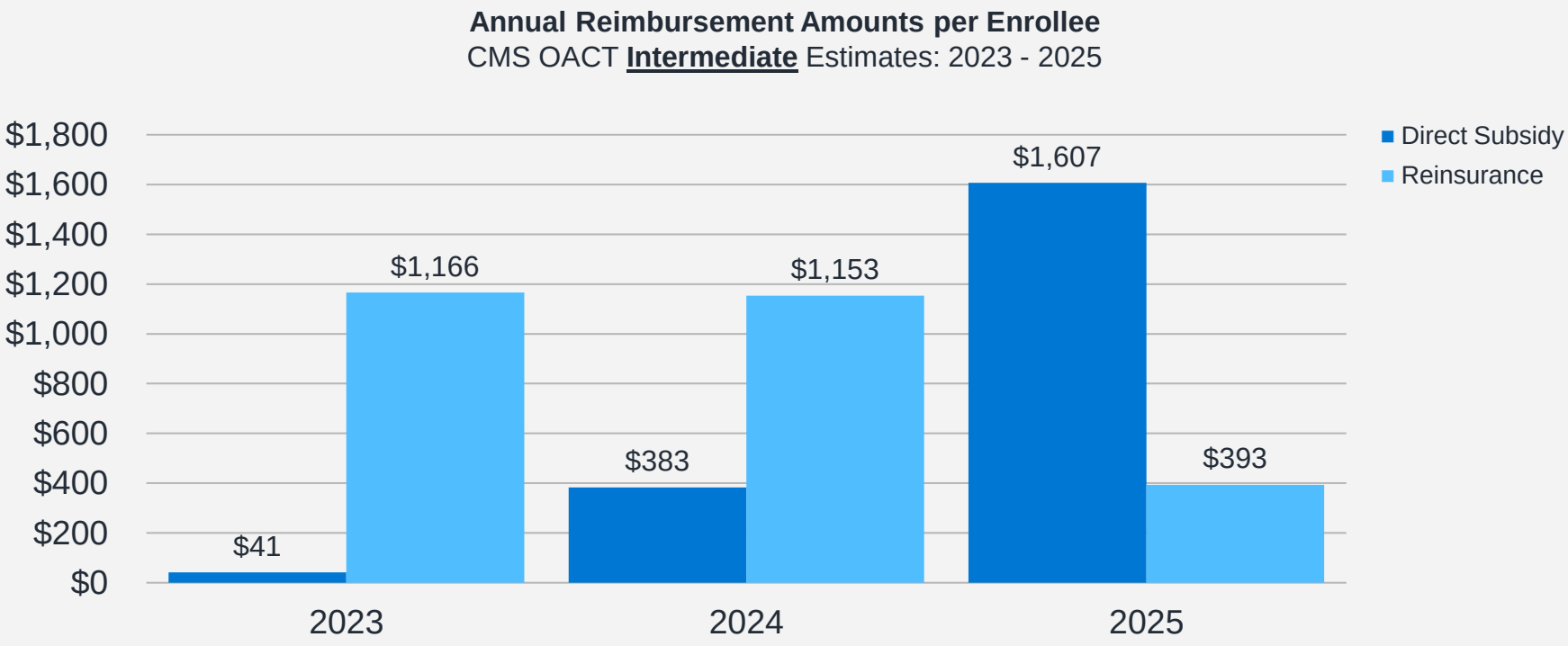
The goal of Part D benefit design is to create an attractive benefit that is financially sound, ensuring there are sufficient rebate dollars to develop attractive Part C benefits (MA-PDs) or maintain low premiums (PDPs).

Consider the following which may help address some IRA uncertainties

1. **Rigorously estimate direct subsidy**
2. **Address generic dispensing rate**
3. **Lean into health equity**
4. **Consider biosimilar strategy and reducing unit costs for specialty drugs**
5. **Reconsider discounts and rebates**
6. **Address low value drugs**

1. Rigorously estimate the direct subsidy.

Annual Funding Amounts per Enrollee
CMS OACT **Intermediate** Estimates: 2023 - 2025



Source: 2023 Medicare Trustees Report (March 31, 2023).

These estimates are from CMS and should not be interpreted as Milliman estimates.

1. Rigorously estimate the direct subsidy or face consequences.

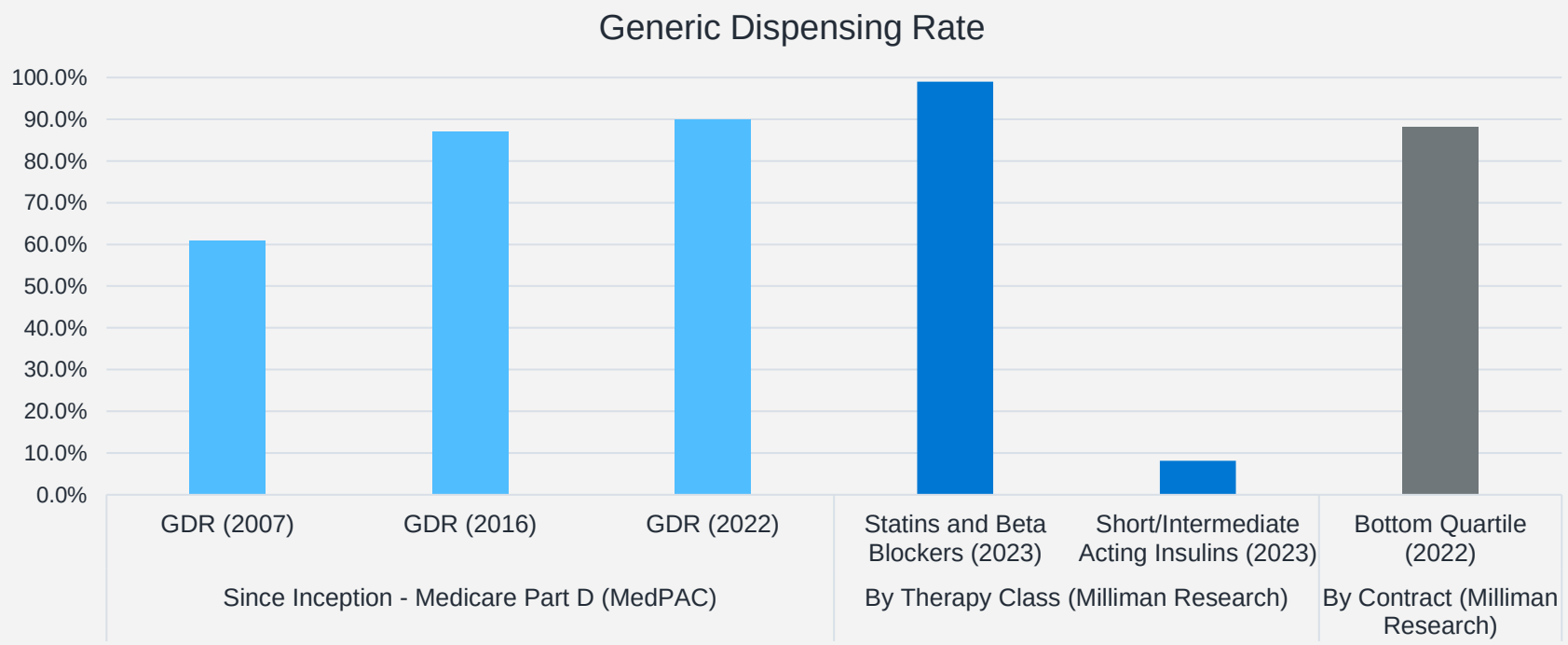
Based upon the initial submission and subsequent actual funding determined in August, plans may lose out on competitiveness and/or the ability to support profit margins.

Scenario A			Scenario B			Scenario C		
Estimated In June	Actual in August	Surplus / (Deficit)	Estimated In June	Actual in August	Surplus / (Deficit)	Estimated In June	Actual in August	Surplus / (Deficit)
$29.58	$29.58	$0.00	$39.58	$29.58	($10.00)	$19.58	$29.58	$10.00

In Scenario A, the health plan cannot change their premium rate or benefits during the August rebate reallocation. The health plan will end up with the same premium rates and benefits that they filed in June.	In Scenario B, the health plan must increase their premium rate or reduce Part C supplemental benefits during the August rebate reallocation. The health plan will end up with some combination of a premium rate that is higher than they filed in June, and/or Part C supplemental benefits that are lower than they filed in June.	In Scenario C, the health plan must reduce their premium rate or increase Part C supplemental benefits during the August rebate reallocation. The health plan will end up with some combination of a premium rate that is lower than they filed in June, and/or Part C supplemental benefits that are higher than they filed in June.

Illustrative. The complete rules on rebate reallocation are very complicated. They are published in Appendix E of the CY2024 MA BPT Instructions.

2. Generic dispensing rates vary widely – temporally and by therapy



Source: MedPAC and Milliman Research

2. Reevaluate and improve generic dispensing

Three misconceptions on generic dispensing rate:

1. Generic dispensing rate is already at "saturation" and has plateaued.

See previous slide on bottom quartile.

Also, *"..beneficiaries in Kaiser Permanente, a tightly managed staff model health maintenance organization, were 49% more likely to fill a generic than beneficiaries in other plans."*

"Variation in Generic Dispensing Rates in Medicare Part D", Christine Buttorff, PhD

Takeaway: Research is available to help.

2. Favoring highly rebated brand drugs will always continue be a sound financial strategy.

With the enactment of the IRA, rebates will still be very important for plan financials. That said, increasingly, discounts and ingredient costs will gain importance on net plan liability (Milliman).

Also, there are clinical implications for drugs with cost sharing (JAMA, Kesselheim, 2016)

Takeaway: Your actuaries and pharmacists can model this.

3. It is not possible to influence generic dispensing rate via copays because a plan already has $0 for some tiers.

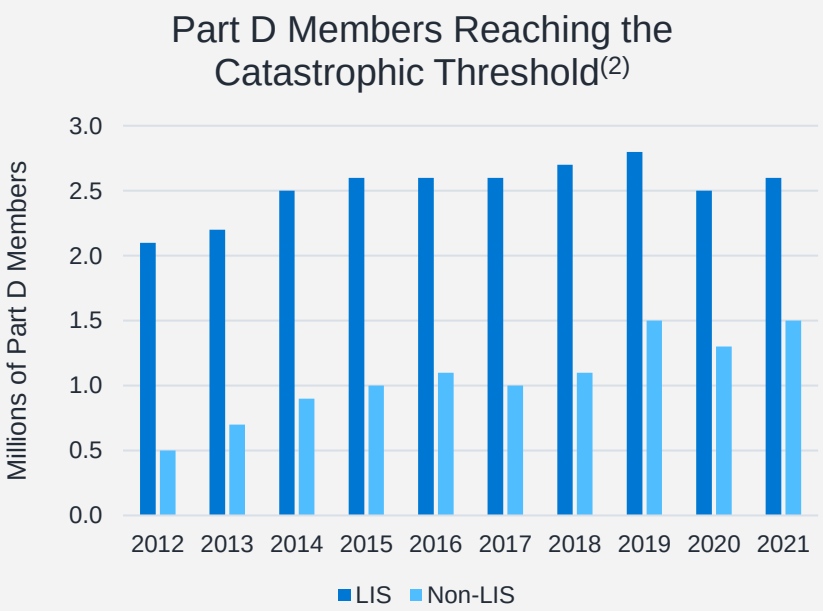
Influencing member behavior can also take the form of increasing cost sharing on other tiers.

Also, consider that there may be generics on tiers with copays.

Takeaway: Over the next few years, continue to reevaluate benefits and formulary tiering.

3. Lean into Health Equity

Nearly 3 million seniors are eligible for extra help and have not enrolled(1)



Source: (1) CMS, 2/15/2024, "CMS Issues Additional Guidance on Program to Allow People with Medicare to Pay Out-of-Pocket Prescription Drug Costs in Monthly Payments" ; (2) MedPAC, Table 14-9, The Medicare prescription drug program (Part D): Status report, March 2019

LIS enrollment, for those who qualify, is likely to be more advantageous to the member than participation in the Medicare Prescription Payment Plan

The plan sponsor may benefit from this – through risk adjustment and medication adherence

‘— One, if biosimilar, and two, if let’s see’

"One, if by land, and two, if by sea;
And I on the opposite shore will be,"

4. Focus on biosimilar strategy and specialty medications


Forbes

FORBES > INNOVATION > HEALTHCARE

Inflation Reduction Act May Curb Patent Practices That Forestall Market Entry Of Biosimilars

Joshua Cohen Senior Contributor

I write about prescription drug value, market access, healthcare systems, and ethics of distribution of...

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The Inflation Reduction Act's harms go beyond drug pricing — they're threatening your Medicare

BY JOE GROGAN, OPINION CONTRIBUTOR - 12/23/23 11:00 AM ET

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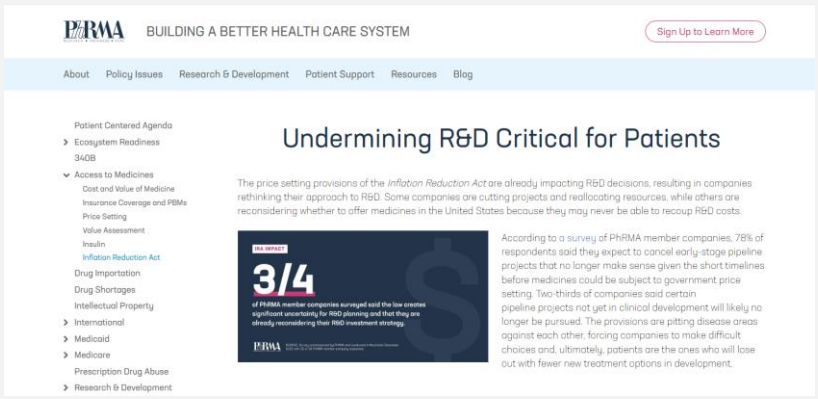
ISSUES NEWSROOM ABOUT PCMA PCMA EVENTS

PCMA Statement on CMS' Proposal to Promote the Use of Biosimilars in Medicare Part D

November 7, 2023

Press Releases

(Washington, D.C.) — The Pharmaceutical Care Management Association (PCMA) supports the Centers for Medicare and Medicaid Services' (CMS) proposal to promote the use of biosimilars in Medicare Part D. Pharmacy benefit companies, or PBMs, have long supported the development of a healthy biosimilar market to increase competition and reduce costs for biologic medications, as well as to provide added choice and flexibility for health plan sponsors.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Undermining R&D Critical for Patients

The price setting provisions of the *Inflation Reduction Act* are already impacting R&D decisions, resulting in companies rethinking their approach to R&D. Some companies are cutting projects and reallocating resources, while others are reconsidering whether to offer medicines in the United States because they may never be able to recoup R&D costs.

IRA IMPACT

3/4

of PhRMA member companies surveyed said the law creates significant uncertainty for R&D planning and that they are already reconsidering their R&D investment strategy.

According to a survey of PhRMA member companies, 78% of respondents said they expect to cancel early-stage pipeline projects that no longer make sense given the short timelines before medicines could be subject to government price setting. Two-thirds of companies said certain pipeline projects not yet in clinical development will likely no longer be pursued. The provisions are pitting disease areas against each other, forcing companies to make difficult choices and, ultimately, patients are the ones who will lose out with fewer new treatment options in development.

5. Reconsider the value of rebates and discounts.

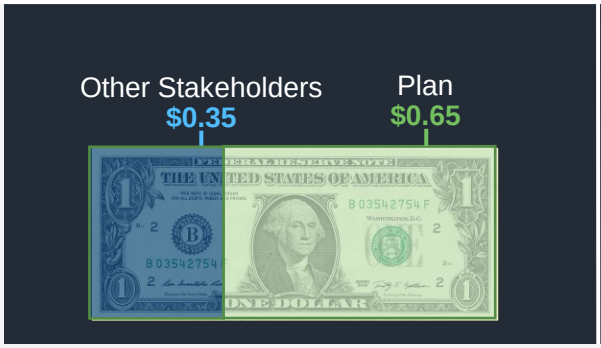
Benchmarking discounts in a consistent and actionable manner is a valuable exercise.

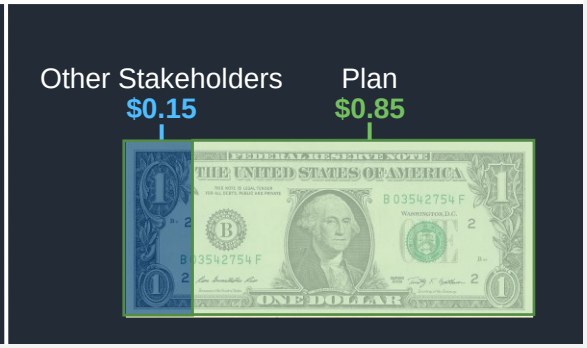
Brand and Specialty Discounts

For every **$1** increase in brand and specialty discounts, plans keep roughly **$0.30** pre-IRA, and **$0.65** post-IRA.

Manufacturer Rebates

For every **$1** increase in rebates, plans keep roughly **$0.65** pre-IRA, and **$0.85** post-IRA.





Point estimates reflect best estimates of future changes. Actual plan share of rebates and discounts will vary by plan and member type (e.g., NLI vs. LI).

‘For, borne this night -- when BPTs are cast,
Far into ‘27 the implications last…’

"For, borne on the night-wind of the Past,
Through all our history, to the last,…"

6. Identify low value drugs

The generally accepted industry definitions of low value drugs can be broken into four segments. These definitions allow experts to identify wasteful drug claims in pharmacy claim experience data.

1

High-Cost Drugs with Alternatives

- Brand drugs with generic alternatives
- Generic drugs with inflated prices

2

Combination Drugs

- Multiple low-cost drugs combined into one high-cost drug

3

“Me Too” Drugs

- Novel drugs that provide little or no clinical advantage

4

Proprietary Supplements

- Combinations of cheap vitamins and supplements

Inflation Reduction Act – Other Perspectives on Impacts to Plans

Federal Price Negotiations

- Financial strategy
  - Trade-off between MFP and traditional rebates; net cost neutral
  - Potential for manufacturer to no longer contract via traditional rebates
- Formulary strategy
  - Requirement to cover MFP negotiated drugs
  - Identify whether MFP drug offers lower plan liability within a therapeutic class
- Increased administrative costs
  - Additional resources for formulary development, rebate contracting, and benefit designs
  - Compliance with CMS requirements
  - Changes in how beneficiaries select plans due to mitigated cost share

Inflation Rebate Program

- Impact of price reductions on other lines of business
  - Formulary, rebate contracting and risk, and administrative impact
- Higher launch prices for new-to-market drugs can increase overall plan costs
  - Results in higher premiums
  - Need for management of high-cost utilizers

Plan Benefit Design

- Increased plan liability with potential to offset through increases CMS direct subsidy
  - Elimination of Coverage Gap Phase shifts liability to plan sponsor
  - Replacement of Catastrophic Phase with “Post-Threshold” Phase increases plan liability from 15% to 60%
  - Beneficiary payment plan charge-offs
  - $2,000 maximum-out-of-pocket patient cost-sharing limit
  - Insulin capped at $35/month at plan sponsor expense
  - $0 copay for vaccines at plan sponsor expense

How might manufacturers and pharmacies react to these changes?

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Inflation Reduction Act – Key Provisions Impacting Pharmacy Industry

Federal Price Negotiations

- Direct negotiations with pharmaceutical manufacturers for the highest cost Part B and Part D drugs
  - Negotiations will set “maximum fair price” (MFP)
  - Specific criteria for inclusion of drugs that can be negotiated
  - Specific criteria to be considered by HHS when negotiating the MFP
  - Specific criteria of upper limit for negotiated price
  - Initially will negotiate pricing for 10 of the highest cost Part D drugs beginning in 2026 with annual additions
  - Expanding to Part B drugs for 2028

Inflation Rebate Program

- Requires pharmaceutical manufacturers to pay a rebate if prices for Part B or D single-source drugs, or Part D generic drugs, increase faster than rate of inflation (CPI-U)
  - Price changes measured by average sales price (ASP) for Part B drugs
  - Price changes measured by average manufacturer (AMP) price for part D drugs
  - Rule for Part D drugs went into effect October 1, 2022
  - Rule for Part B drugs went into effect January 1, 2023

Plan Benefit Design

- Medicare Prescription Payment Plan
  - Part D sponsors must provide enrollees the option to pay out-of-pocket drug costs in the form of monthly payments during the year versus all at once at the pharmacy for 2025
- Expand eligibility for Low-Income Subsidy benefits
- Eliminate 5% coinsurance during catastrophic coverage phase
  - Part D beneficiary out-of-pocket spending cap of $3,250 for 2024 and $2,000 for 2025
- Eliminate cost share for vaccines
- Cap insulin out-pocket-costs at $35/month per covered insulin product

Ongoing litigation from key stakeholders will determine which provisions become law

Inflation Reduction Act – Manufacturer Impact

Drugs Identified by CMS for Medicare Part D Price Negotiation for 2026

Drug Name	Manufacturer	Drug Class	Part D Gross Cost (June 2022 - May 2023)
Eliquis	Bristol-Myers Squibb	Anticoagulant	$16,482,621,000
Jardiance	Boehringer Ingelheim	Diabetes	$7,057,707,000
Xarelto	Johnson & Johnson	Anticoagulant	$6,031,393,000
Januvia	Merck	Diabetes	$4,087,081,000
Farxiga	AstraZeneca	Diabetes	$3,268,329,000
Entresto	Novartis	Heart Failure	$2,884,877,000
Enbrel	Amgen	Auto-immune	$2,791,105,000
Imbruvica	Johnson & Johnson	Oncology	$2,663,560,000
Stelara	Johnson & Johnson	Auto-immune	$2,638,929,000
Fiasp & Novolog	Novo Nordisk	Diabetes	$2,576,586,000
		TOTAL	**$50,482,188,000**

Centers for medicare and medicaid services. (2023, august). Medicare drug price negotiation program: selected drugs for initial price applicability year 2026. https://www.Cms.Gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf

Inflation Reduction Act – Manufacturer Impact

Federal Price Negotiations

- Reassess market access strategies
  - Drugs with negotiated MFP are required to be covered on all Part D formularies
  - Alignment on Medicare, Medicaid, and Commercial strategy
- Reduced investment in research and development
  - Reduced and shortened revenue stream
  - Pipeline investment and long-term resource allocation
- Reduced generic drug competition
  - Lower margins during 180-day exclusivity
- Increase administrative costs due to CMS data requests when negotiating MFP
  - Need for comparative and real-world data

Inflation Rebate Program

- Lower drug price of existing single-source drug
  - Already occurring, e.g. insulins
  - Net cost neutral or additional cost to system
- Increase launch prices for new-to-market drugs
- Focus on Part D “protected class” drugs

Plan Benefit Design

- Increased utilization of drugs and reduced patient sensitivity to high cost drugs
  - Beneficiary payment plan
  - Significantly lower maximum out-of-pocket expense due to spending cap
  - Increased number of LIS beneficiaries
  - Insulin capped at $35/month at plan sponsor expense
  - $0 copay for vaccines

Inflation Reduction Act – Retail Pharmacy Impact

Federal Price Negotiations

- Price negotiations will impact drug acquisition costs and reimbursement rates
  - Updating PBM reimbursement contracts, e.g. CVS Pharmacy moving to cost plus reimbursement arrangement for brands
  - Smarter purchasing and increased reliance on alternative revenue streams, e.g. front-end sales, cash-based pharmacy, home health, long-term care
  - New strategies such as Cordavis, a subsidiary of CVS that will commercialize and co-produce biosimilars

Inflation Rebate Program

- Inventory management due to higher cost drugs
  - Increased cost of generic drugs
  - Increased cost of new-to-market brand drugs
  - Potential better reimbursement for brand drugs with renegotiated PBM contracts
- Direct and indirect remuneration (DIR) fees will be applied at point-of-sale to lower drug costs for members in 2024

Plan Benefit Design

- Presents opportunity to grow customer base and increase dispensing
  - Lower patient out-of-pocket costs and the Medicare prescription payment plan will lower financial barriers for patients
  - Ability to offer all vaccines at $0
  - Front-line educator on drugs, but also on benefit design and drug coverage
  - Increased foot traffic for front-end sales
- Complexity of benefit could lead to longer counseling times and increased administrative burden on pharmacy staff
- Potential to incentivize pharmacists for drug and therapy optimization
- Increased 30-day utilization

Questions

The Midnight Bid of Twenty-Five [Without the help of ChatGPT]

Adapted from “The Midnight Ride of Paul Revere” by Henry Wadsworth Longfellow

Listen, my friends, and you shall hear
Of the midnight ride of many here,
On the third of June, in twenty-four; Hardly a soul is now ready
Who can answer every question for next year.

We’ll say to a colleague, “oh trends we’ll watch
Biosimilars and negotiations forthright,
Risk scores and subsidies we also regard
Until the last, we can’t hold our bids all night,
— One, if biosimilar, and two, if let’s see;
And so many factors to account for they’ll be,
Ready to bid and spread the risk
As we process CMS data on the hard disk
Time is now short, oh be brisk”

The Midnight Bid of Twenty-Five [Without the help of ChatGPT]

Adapted from “The Midnight Ride of Paul Revere” by Henry Wadsworth Longfellow

So through the night we bid for twenty-five;
And through the season went this sense of alarm
To every possible risk and potential harm,—
A measure of concern, within reach of arm,
A voice in the darkness, a knock at the door,
And a bid we’ll remember forevermore!

For, borne this night -- when BPTs are cast,
Far into ‘27 the implications last,
In the hour of darkness and peril and need,
The desk review comments will soon arrive
The hurrying questions answered with speed,
And by August we’ll certify the bids of twenty-five.