Breaking Bid: What just happened?

SEPTEMBER 18, 2024

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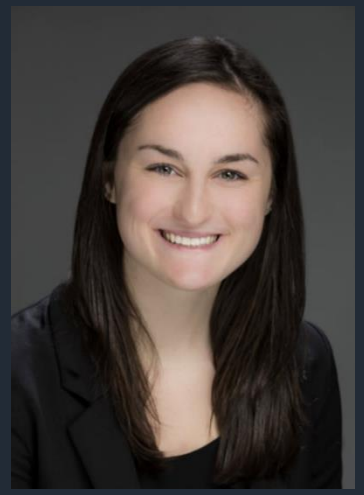
Presenters



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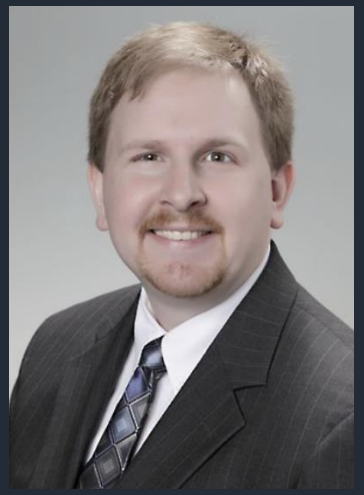

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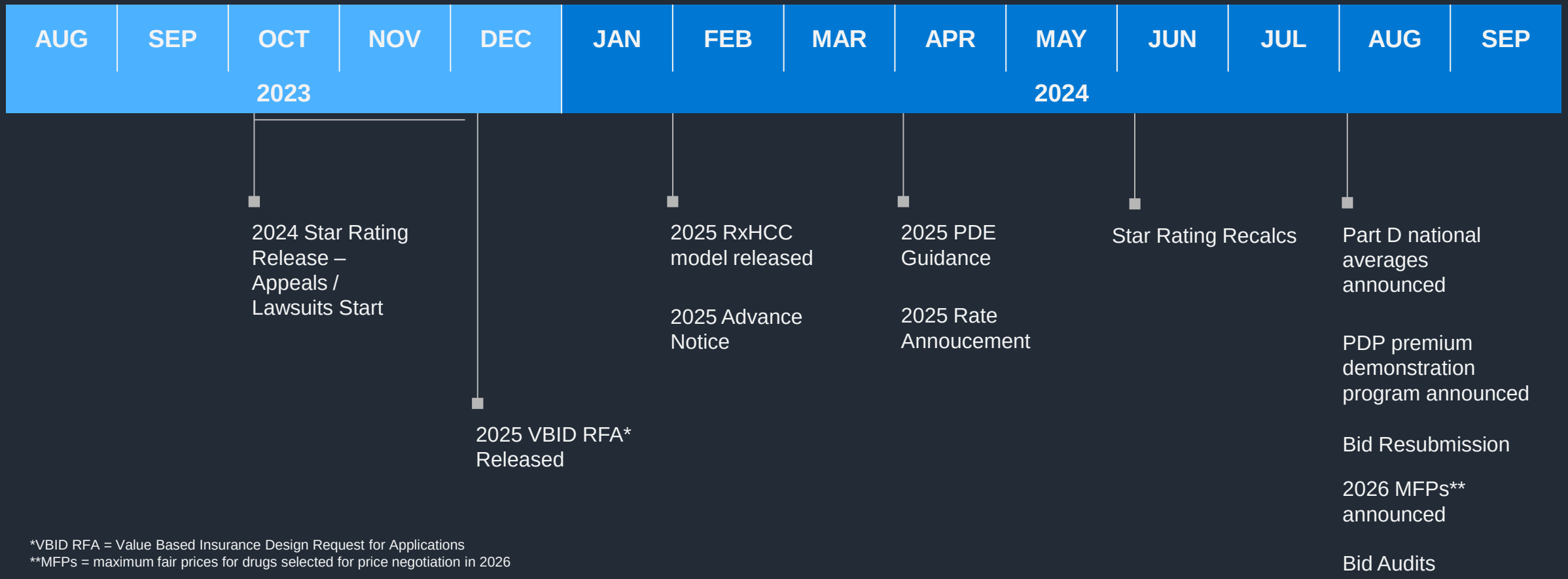
It's Been A Long Year …



*VBID RFA = Value Based Insurance Design Request for Applications
**MFPs = maximum fair prices for drugs selected for price negotiation in 2026

2025 Medicare Advantage and Part D

“I’d rather not go through that ever again …”

— Every Medicare Advantage actuary, probably

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CY2025 Part D Bids Hot Topics

Part D Benefit Redesign & 2025 RxHCC Model

- Many plans considered **major changes to Part D benefits** (e.g., higher deductibles, brand drug coinsurance)
- The **high WAC / high rebate model may be upended** by changes to Part D plan economics and the risk adjustment model, although rebates are still more valuable to plans than list price discounts
- PBMs / plan sponsors re-evaluated the economics in key therapeutic areas ahead of 2025, and we expect **more year-over-year negative formulary changes** than usual
- There was some uncertainty around adjudication dynamics for enhanced alternative plans prior to clarifying guidance from CMS

Drug Trend

- Utilization of GLP-1s continued to dominate drug trend narratives, amplified with Wegovy's CVD indication
- Rezdiffra for MASH launched after much anticipation

Medicare Prescription Payment Plan (M3P)

- How many beneficiaries will sign up?
- How many beneficiaries will default on their payments and leave plans with bad debt?
- How much will operating this program cost?

Utilization Increases?

- Affordability improvements by way of the $2,000 MOOP and the M3P spurred much discussion of just how much drug benefit utilization may increase in 2025

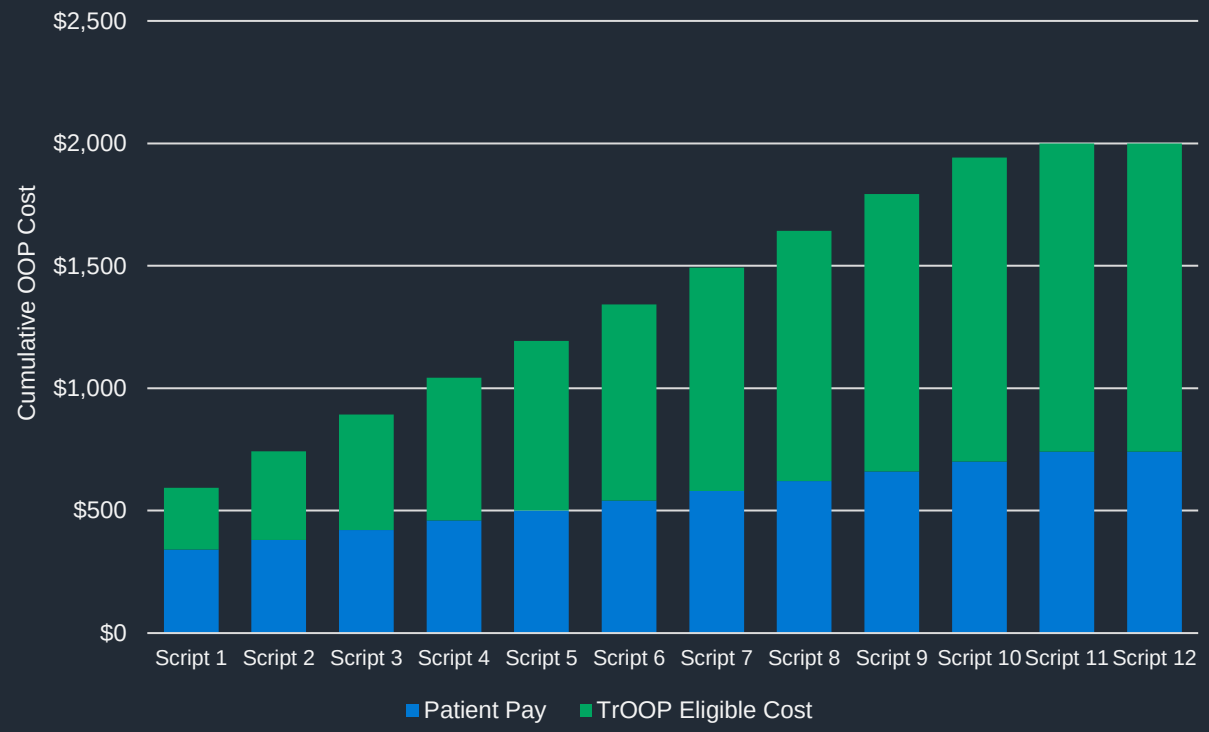
Path to Profitability

- Some carriers publicly stated they expect membership declines as they cut benefits and / or exit certain service areas

Source: https://www.milliman.com/en/insight/navigating-new-waters-inflation-reduction-act-medicare-part-d

Some Beneficiaries Will Spend Significantly Less Than $2,000 to Satisfy The MOOP in 2025.

Illustrative Out-of-pocket Accumulation to MOOP – NLI Beneficiary with Copay Benefit



Assumptions:
Cost / script = $600
Deductible = $300
Copay = $40

→ Beneficiary accumulates $2,000 TrOOP

→ Beneficiary pays $740 to hit MOOP

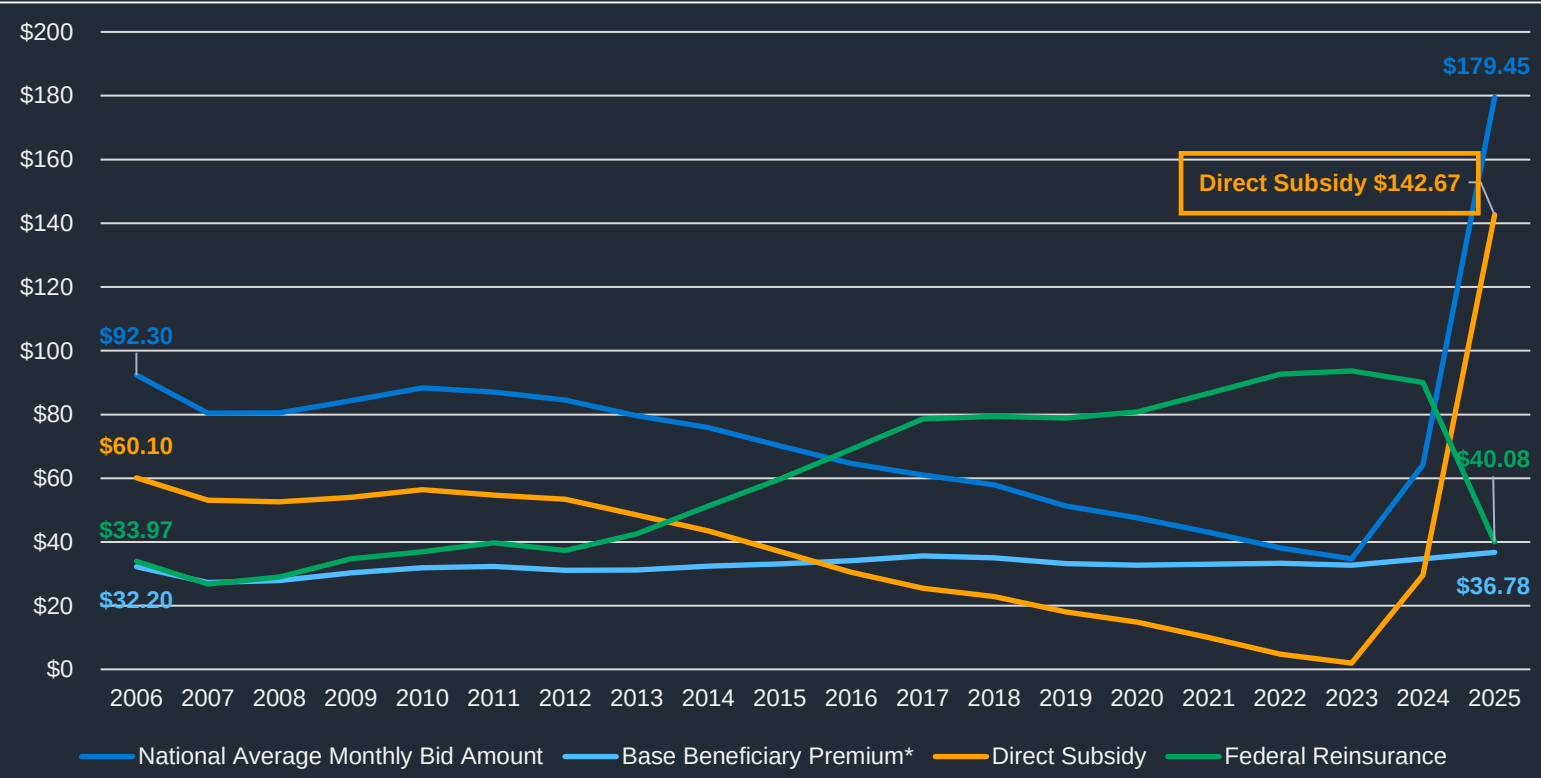
When the IRA was initially signed into law, we knew there was language around TrOOP accumulation according to the basic benefit – but few understood the magnitude of the differences in actual patient pay vs. the $2,000 MOOP until CMS provided additional detail in the 2025 Advance Notice, and subsequently in the 2025 PDE Guidance.

In this example, a NLI beneficiary pays $740 in OOP costs for the year and still satisfies their $2,000 MOOP.

https://www.milliman.com/en/insight/out-of-whose-pocket-inflation-reduction-act

The Numbers We Were All Waiting For…

Part D National Averages 2006-2025



From fall 2023 up to the bid deadline, many in the industry had differing opinions on the magnitude of the 2025 direct subsidy...keeping it a key topic of conversation throughout the bid season. The **$142.67 direct subsidy** announcement value brought shock to some, and relief to others, depending on their expectations at bid submission.

The 2025 direct subsidy announcement was promptly overshadowed for some by the concurrent announcement of the voluntary PDP premium stabilization demonstration.

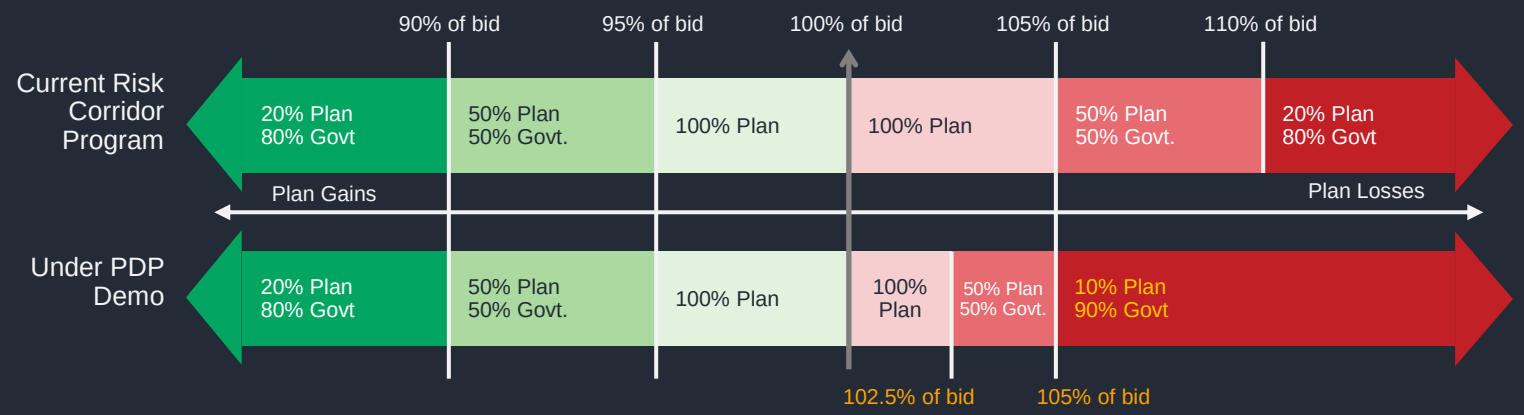
*Base Beneficiary Premium is capped at 6% annual growth in 2024 and 2025.

CMS Took Action to Curb Premium Growth in The PDP Market by Creating a Voluntary Demonstration Program.

Illustrative Example: Impact of PDP Demo on Revenue**

	Beneficiary Premium PMPM	Direct Subsidy PMPM	Total Revenue PMPM
2024	$100	$30	$130
2025 pre-demo	$150	$143	$293
2025 post-demo	$135	$158	$293

Risk Corridor Changes



If participating in the demonstration program, PDPs will first apply a $15 reduction in base beneficiary premium, and then further will be limited to a **$35 PMPM premium increase** relative to 2024 in exchange for offsetting direct subsidy revenue*.

Further, plans will receive additional downside risk corridor protection. CMS has indicated it does not intend to release the pre-demonstration premiums.

CMS stated the demonstration program will span for three years (with exact parameters subject to change) and estimates the program will cost ~$5B if all plan sponsors participate in 2025.***

*Of note, direct subsidy payments are subject to sequestration, so revenue components will not completely offset.
**Assume basic PDP, such that total premium = basic premium. On 1.0 risk score basis.
***https://news.bloomberglaw.com/health-law-and-business/medicare-draws-ire-for-plan-to-hold-down-drug-premium-increases

Source: https://www.milliman.com/en/insight/navigating-new-waters-inflation-reduction-act-medicare-part-d

2026 Will be The First Year with Maximum Fair Prices (MFPs) in Effect.

Drug Name	Participating Drug Company	Commonly Treated Conditions	Agreed to Negotiated Price for 30-day Supply for CY 2026	List Price for 30-day Supply, CY 2023	Discount of Negotiated Price from 2023 List Price
Januvia	Merck Sharp Dohme	Diabetes	$113.00	$527.00	79%
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Novo Nordisk Inc	Diabetes	$119.00	$495.00	76%
Farxiga	AstraZeneca AB	Diabetes; Heart failure; Chronic kidney disease	$178.50	$556.00	68%
Enbrel	Immunex Corporation	Rheumatoid arthritis; Psoriasis; Psoriatic arthritis	$2,355.00	$7,106.00	67%
Jardiance	Boehringer Ingelheim	Diabetes; Heart failure; Chronic kidney disease	$197.00	$573.00	66%
Stelara	Janssen Biotech, Inc.	Psoriasis; Psoriatic arthritis; Crohn's disease; Ulcerative colitis	$4,695.00	$13,836.00	66%
Xarelto	Janssen Pharms	Prevention and treatment of blood clots; Reduction of risk for patients with coronary or peripheral artery disease	$197.00	$517.00	62%
Eliquis	Bristol Myers Squibb	Prevention and treatment of blood clots	$231.00	$521.00	56%
Entresto	Novartis Pharms Corp	Heart failure	$295.00	$628.00	53%
Imbruvica	Pharmacyclics LLC	Blood cancers	$9,319.00	$14,934.00	38%

How are point-of-sale (POS) / plan costs changing for MFP drugs?

The public MFP, plus a dispensing fee, will be the new point-of-sale price in Medicare for this subset of drugs. The list price (i.e., wholesale acquisition cost) is unchanged via CMS drug price negotiation.

Drugs with MFPs in effect will no longer be consider applicable for the Manufacturer Discount Program (MDP). The federal government will instead pay these costs via increased reinsurance and the new selected drug subsidy, ultimately holding the plan harmless.

For Novolog, most of the 76% cost reduction shown here is already accounted for via Novo Nordisk decreasing the price in early 2024. As of January 2024, the package price for Novolog Pen decreased from $537 to $134.

Two anticoagulants, Xarelto and Eliquis, have similar list prices yet will have a 17% MFP differential in 2026.

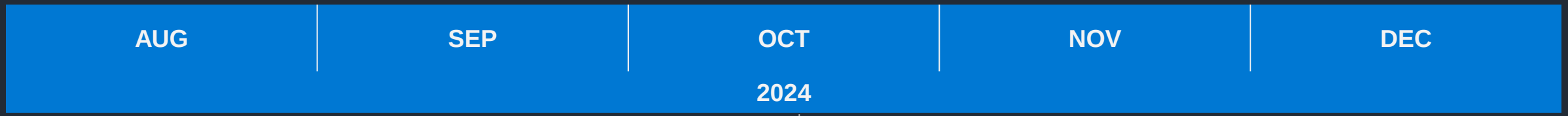
Imbruvica may be a unique case where the MFP discount may translate more directly to plan savings than other drugs, because oncology drugs (like other protected class drugs) typically have low / no rebates in Part D.

Other Key Considerations

- Given the expectation that MFP discounts may largely replace rebates for negotiated drugs (subject to manufacturer actions), negotiated prices may translate to higher net plan liability than without negotiation in place – depending on how the MFP compares to the former net price.
- Some organizations with less favorable rebates may benefit from the MFPs, but other organizations where the former net price (via rebates) was roughly equal to or lower than the MFP may see higher net plan liability as a result.

Source: https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf; https://www.milliman.com/en/insight/medicare-price-negotiation-anchored-drug-prices

What's Next for Part D?



Sept - Oct

- 2025 premiums released
- 2025 formulary, benefit, network information releases

10/15/2024

- Open enrollment begins
- Beneficiaries can begin electing to participate in the M3P

Meanwhile, back in Part C …

“Those are some mighty nice payment rates you got there. It’d be a shame if something happened to them.”

— MedPAC, kind of, but definitely over and over and over again

Changes Afoot in Part C

Being less impactful than a pile driver doesn't mean you can't bring the pain

Part C Payment Rates are up! We swear!

But only because we assume you'll code that much better-er

All the LIS in the club get D-SNP-y

CMS continues to crack down on D-SNP lookalikes

Supplemental benefits and SSBCI

Where **offering** a free lunch comes with strings attached

VBID

You could probably do a whole webinar on this topic alone …

Your 2025 Map to the Stars

“Aim for the moon. Even if you miss, you’ll land among the stars. And if you miss those, no worries you can keep appealing in hopes CMS will relent. When someone else lawyers up, you can hope the federal courts will declare it was all done wrong, and CMS will recalibrate everything after all the bids are filed.

But don't worry, CMS may relent, make the winners whole and hold the losers harmless—after everything’s already in place. It’s all part of the plan ... sort of.”

— Every exhausted Quality Director right now

Initial 2024 Star Rating Release: Hold Onto Your Cut! *(points)*

Tukey Outliers Unleashed

Guardrails and Tukey Outliers

- **Tukey Outliers Removed:** CMS incorporated the removal of Tukey outliers for the first time. This approach was applied to remove statistical anomalies that could skew the results and distort performance evaluations across MA contracts
- **Objective:** The goal was to create more stable cut points and ensure extreme outlier contracts didn't artificially inflate or deflate Star Ratings, improving predictability

Application Controversy

- **5% Guardrails:** CMS applied a 5% limit on how much cut points could change from the previous year, but controversially applied these guardrails to hypothetical 2023 cut points rather than actual data
- **CMS Justification:** CMS argued that using hypothetical data would prevent extreme year-to-year fluctuations, though this decision was not codified in regulatory rules, raising concerns about legality

Rating Implications and Reactions

- **Impact:** The average Star Rating across the Medicare Advantage industry dropped significantly, with the national average falling from 4.18 in 2023 to 4.05 in 2024
- **Revenue Impact:** This reduction in Star Ratings is expected to result in $1.0 billion in CMS savings (reduced MA plan revenues) by 2025
- **Lawsuits:** SCAN and Elevance filed lawsuits, claiming that CMS's reliance on hypothetical data violated regulatory rules that require guardrails to be applied to actual prior-year data

Sources: https://www.milliman.com/en/insight/future-of-medicare-star-ratings-reimagined-cms-bonus-system
https://www.milliman.com/-/media/milliman/pdfs/2023-articles/11-27-23_the-next-stage-of-star-ratings-evolution.ashx
https://www.milliman.com/en/insight/recalculating-medicare-advantage-scan-elevance-ruling-implications

The Regs of Cut Points Are Simple and Finite

Exercise Gives You Endorphins, and Recalculations Give You Bonuses!

Lawsuit Overview

- **SCAN Health Plan Lawsuit:**
  - Filed in December 2023, the lawsuit challenged the 3.5 Star Rating it received after CMS applied the hypothetical 2023 cut points
  - SCAN argued that CMS violated its own regulations, costing SCAN approximately $250 million in Quality Bonus Payments
- **Elevance Health Lawsuit:**
  - Elevance also focused on the hypothetical cut point application
  - Elevance additionally raised concerns about errors in CMS' call center data calculations

Key Arguments

- **Preamble vs. Regulation:**
  - CMS' defense rested on statements made in preamble comments from the 2021 Final Rule (which were not codified into formal regulations)
  - The preamble comments conflicted with existing regulations
  - The court found that regulations override preamble statements in conflicts
- **Call Center Data Issues:**
  - Elevance contended that many missed calls never actually connected to their call centers due to technical or network issues that were beyond the plan's control

Court Rulings

- Both SCAN and Elevance won their cases shortly after the initial bid submission.
- The court ordered CMS to recalculate the Star Ratings for SCAN and Elevance, applying the proper cut point rules.
- No specific ruling was made on the call center data, which was settled outside of court.
- The court had no jurisdiction to mandate a recalculation for all plans but welcomed other health plans to take legal action if needed.

Source: https://www.milliman.com/en/insight/recalculating-medicare-advantage-scan-elevance-ruling-implications

Total Recall

Bid Season 2.0

Star Rating Recalc

- Following the successful lawsuits by SCAN and Elevance in June 2024, CMS decided to recalculate the 2024 Star Ratings for all Medicare Advantage plans
- CMS implemented a hold harmless provision to ensure that health plans only received increases in Star Ratings
- Affected health plans could resubmit their bids with the new Star Ratings by June 28, 2024.
- This recalculation marked the first time a widespread rating recalibration caused such a disruption to the normal Medicare Advantage bid process

Health Plan Impact

- Both cut points and individual call center data appeals significantly affected Star Ratings across multiple plans
- 63 contracts saw a 0.5 Star increase, boosting their overall performance
- These increases impacted approximately 1.8 million members, providing improved benefits and ratings
- Additionally, 44 contracts received revenue increases, affecting around 1.4 million members, further enhancing plan competitiveness

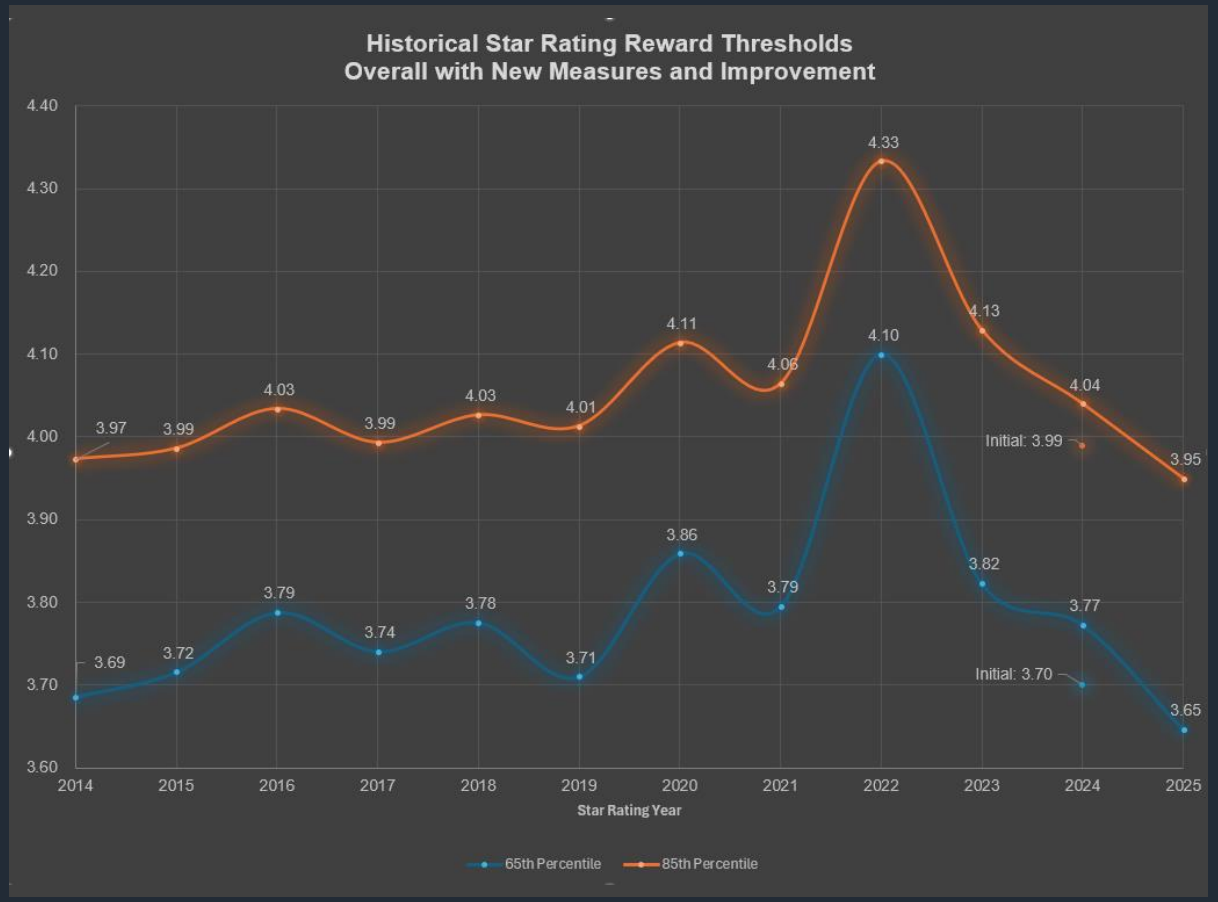
Star Rating Surprises

- CMS quietly updated the 2024 Star Ratings through July 25, with some health plans winning Call Center appeals
- Some health plans declined their Star Rating increases
- BCBS of Kansas City exited the Medicare Advantage market before the initial bid submission, but they would have received a Star Rating and revenue increase had they remained in the market during the recalculation

Source: https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data

2025 Second Plan Preview

Star Ratings – How Low Can They Go?



Plan Preview Release (September 5, 2024)

- The second plan preview for 2025 Star Ratings revealed updated cut points and reward thresholds in the 2025 Draft Tech Notes
- These thresholds, released in September 2024, included detailed information on the 65th and 85th percentile reward factors
- The cut point methodology in 2025 is consistent with CMS regulations, so we don't expect significant pushback or lawsuits, like the SCAN/Elevance cases.

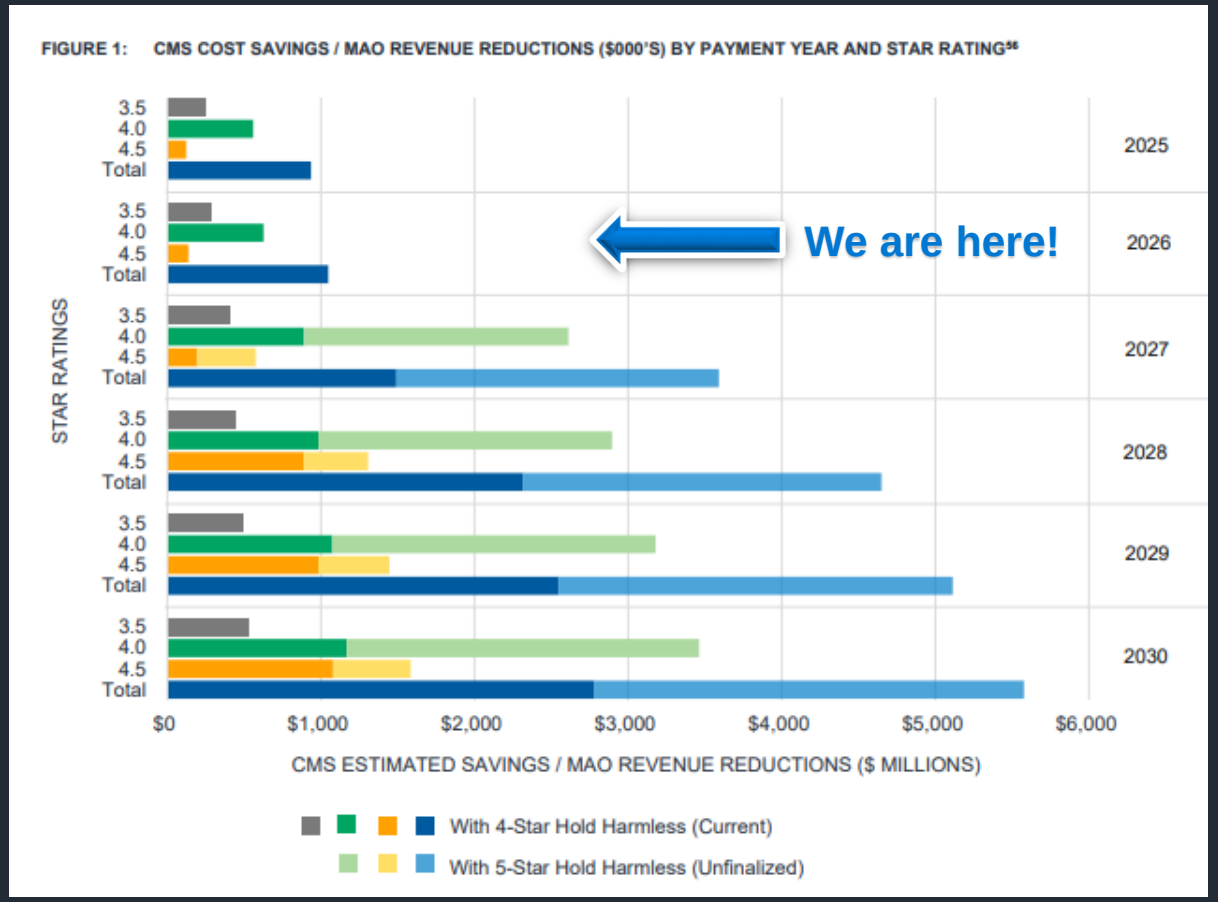
Key Observations

- This analysis shows that the 2025 reward thresholds are the lowest they've ever been across both percentiles
- The removal of Tukey Outliers did not necessarily bring the expected stability to cut points, indicating that guardrails may still be needed for volatility.
- Higher cut points and lower reward thresholds suggest increased dispersion in contract results, pointing to more scattered performance instead of better general performance.

Source: 2014 to 2024 Technical Notes: https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data
Final 2024 Reward Factors released by CMS upon request
Draft 2025 Star Rating tech notes released to health plans with Second Plan Preview

Future Methodology Changes

Get Ready - It Has Only Just Begun



- **Tukey Outlier Removal:** CMS implemented the Tukey Outlier removals for the 2024 Star Ratings (2025 Payment Year). The full impact was dampened due to recalculations but will be fully realized in the coming years
- **Measure Reweighting:** Starting with the 2026 Star Ratings (2027 Payment Year), CMS will reweight measures, shifting the focus more toward clinical outcomes and less on patient experience measures
- **Health Equity Index (HEI) Rewards:** Beginning with the 2027 Star Ratings (2028 Payment Year), the current reward system will be replaced by the HEI system, boosting Star Ratings for contracts that provide high-quality care to members with social risk factors (SRFs)
- **Hold Harmless Provision:** CMS may introduce (unfinalized) an expanded “hold harmless” provision that penalizes plans unless they are continually improving up to the 5.0 Star Rating threshold

Source: https://www.milliman.com/en/insight/future-of-medicare-star-ratings-reimagined-cms-bonus-system

Meanwhile, back in the courtroom …

“I’ve got the power!”

— Federal Judges

Attacking Federal Rules in the Courts: A Primer

Three Key Avenues of Attack

Challenging a Federal Regulation

Can the law do that?

Can the agency do that?

Can it be done that way?

Attacking Federal Rules in the Courts: A Primer

And what do we have behind Door #1?

Can the law do that?	Can the agency do that?	Can it be done that way?
Does it conflict with other statute?	Rule clearly violates the law	Was statute ambiguous?
Did Congress delegate to the right people?	Agency doesn’t have authority	Were timelines met?
Did Congress delegate too much?	Is this a major question?	Were all comments considered?
		Did the agency do what it said it would?

SCOTUS: Relentlessly Reshaping Administrative Law Since 2023

So a Loper Bright, Corner Post, and Jarkezy walked into a federal courtroom …

Loper Bright Enterprises v. Raimondo

- **Chevron Deference:** a 1984 precedent requiring courts to respect federal agency interpretations of ambiguous statutory provisions
- **Loper Bright:** U.S. fishermen required to pay for federal inspectors riding along
- **Raimondo:** Secretary of Commerce
- **The Ruling:** Chevron deference begone!
- **Implications:** The sky will fall. Either that or nothing changes. The reality? Somewhere in between.

… and its little friends, too!

- **Corner Post v. Fed BOG:** The default statute of limitations used in most administrative law cases starts when an organization is first subjected to an agency regulation.
- **Jarkezy v. SEC:** Administrative penalties violate the 7th amendment right to a jury trial
- **(Bonus item!)**
  Ohio v. EPA stay: SCOTUS, as currently constructed, is increasingly willing to lean into arguments that reduced federal regulatory authority, even when resulting actions are neither required nor customary

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Q&A

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Thank you

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