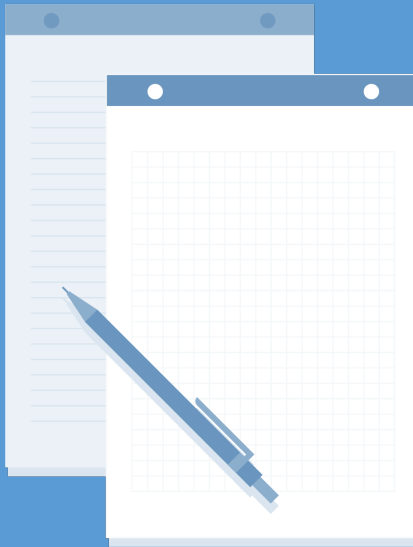


The Inflation Reduction Act's Overhaul of Medicare Part D

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Health Care Compliance Conference
Managed Care Compliance Conference
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Agenda



- Overview of IRA drug pricing changes
- Understand how the IRA changes Part D and how to approach implementation of the Part D reforms
- Address the impacts of the Part D reforms on Prescription Drug Plan sponsors and their members



Inflation Reduction Act

Disrupting prescription drug pricing

IRA Prescription Drug Provisions

- Price Negotiation
- Inflation Rebates
- Part D Redesign
- Insulin Cost Sharing Capped at \$35
- Vaccine Cost Sharing Eliminated
- Expanded LIS Eligibility
- Implementation of Drug Rebate Rule Delayed



Implementation Challenges for Plans

- Congress waived notice and comment rulemaking (Memos!)
- Part D redesign phased in beginning 2023
 - Major structural adjustment to benefit funding in 2025
 - CMS price negotiations take effect 2026
- Anticipate significant shift in costs to plans
- Destabilizing impact of CMS price negotiations and other changes
- Smoothing provisions put plans in cost-sharing collection role

Part B and D Inflationary Rebates - Overview

IRA §§ 11101 and 11102

- For certain drugs and biologicals, manufacturers must return to HHS any amounts from price increases that exceed inflation
 - Generally, single source drugs/biologicals
 - Exclusion for certain preventative vaccines
- Rebates calculated by HHS
 - Compare price data to benchmark period
 - Reduction or waiver for shortages and severe supply chain shortages
- Rebates paid by manufacturers to HHS are deposited in Medicare Trust Fund
- **Payments to MA or Part D sponsors will not be adjusted**

Impact of Inflationary Rebates

Potential reduction in rebates to MAOs, PDP Sponsors, and PBMs

Potential increase in member premiums

Potential impact on pharmacy pricing

Potential impact on commercial prices

Medicare Drug Price Negotiation Program

IRA §§ 11001

- Establishes Medicare Drug Price Negotiation Program
- Allows Medicare to negotiate “maximum fair prices” for certain high spend prescription Part B and Part D drugs
- Drug manufacturers will enter into agreements to negotiate with CMS
- CMS will publish maximum fair prices for negotiated drugs for each year
 - 2026: 10 Part D drugs
 - 2027: 15 Part D drugs
 - 2028: 15 Part B & D drugs
 - 2029: 20 Part B & D drugs
- Non-compliant manufacturers may be subject to civil monetary penalties / excise taxes

Medicare Drug Price Negotiation Program

- Drugs subject to negotiations
 - High spend drugs
 - No generic or biosimilar equivalents
 - Covered under Part B or Part D
 - At least 7 years (small molecule) or 11 years (biological) from FDA-approval
- Drugs excluded from negotiations
 - Small biotech exception
 - Orphan drugs
 - Plasma-derived products
- PDP sponsors facilitate access to MFP
 - Part D formulary access
 - Negotiated prices must not exceed applicable MFP (plus dispensing fees)

Negotiation Program: Guidance

- Jan 2023 – CMS outlines process for negotiation program implementation
- March 2023 – CMS publishes initial guidance
- June 2023 – CMS issues revised guidance regarding requirements and parameters for first round of negotiations
 - Includes details regarding Part D formulary inclusion for selected drugs
- January 2024 – CMS publishes FAQs for initial price applicability year

Negotiation Program: Significant and Upcoming Dates

- Sept 2023: CMS published list of 10 Part D drugs selected for 2026 negotiations
- Oct 2023: Manufacturers entered into negotiation agreements with CMS
- Feb 2024: Negotiations begin
- Aug 2024: Negotiations end
- Sept 2024: CMS publishes maximum fair prices
- Jan 2026: Prices for first 10 drugs go into effect

Negotiation Program Impacts

MA and Part D Plans

- MA cost-sharing for Part B drugs
- Part D negotiated prices
- Required formulary inclusion for negotiated drugs
- Reliance on Part D data

Healthcare Industry

- Mounting legal challenges
- Lack of clarity in selection criteria and negotiation process
- Potential changes in pharmaceutical research and development
- Potential impact on commercial prices

Part D Federal Funding and Premiums

- Part D plans receive 3 types of payments from CMS:
 1. Direct subsidy – government share of premium
 2. Low Income Subsidies (LIS) – premium and cost sharing
 3. Reinsurance – expected spending for government's share of costs for claims in catastrophic phase, reconciled and adjusted later
- Base Beneficiary Premium (BBP) for 2023 = \$32.74
 - National Average Monthly Bid Amount (NAMBA) was \$34.71
 - Government reinsurance amount was \$93.68 (estimated catastrophic phase costs)
 - BBP calculated taking into account NAMBA, reinsurance estimate, and percent beneficiary share of base premium (25.5%)
 - Plan premiums may be higher due to unsubsidized portion above BBP

Part D Redesign: Part D Standard Benefit for 2023

Deductible

- Member pays 100%
- Set at \$505

Initial Coverage Phase

- Plan pays 75%
- Member pays 25%
- Up to \$4,660 in total drug costs

Coverage Gap

- Plan pays 5% for brand, 75% for generic
- Member pays 25%
- Manufacturer pays 70% for brand
- \$7,400 (TrOOP)

Catastrophic Coverage

- Government reinsures 80%
- Plan pays 15%
- Member pays 5% (or small copay, \$4.15 generic and \$10.35 brand)

Part D Redesign: Major Provisions

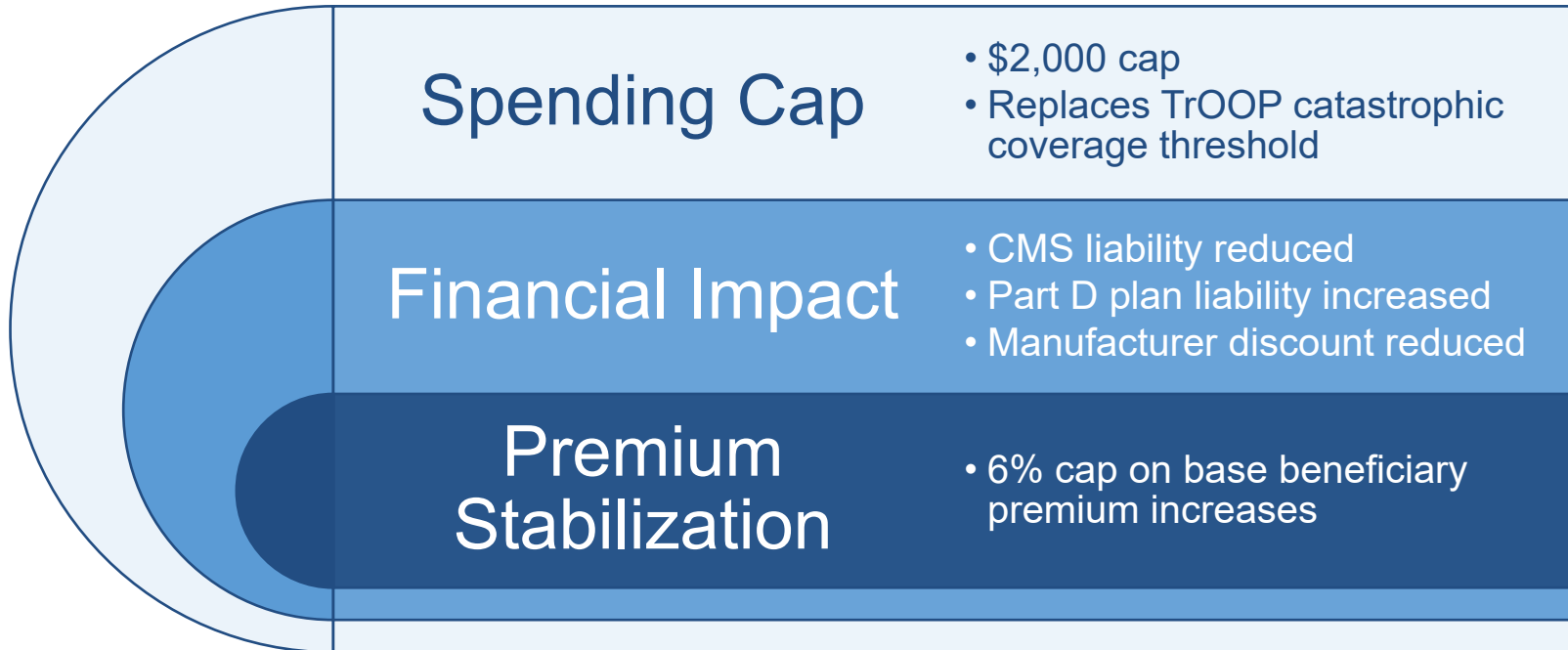
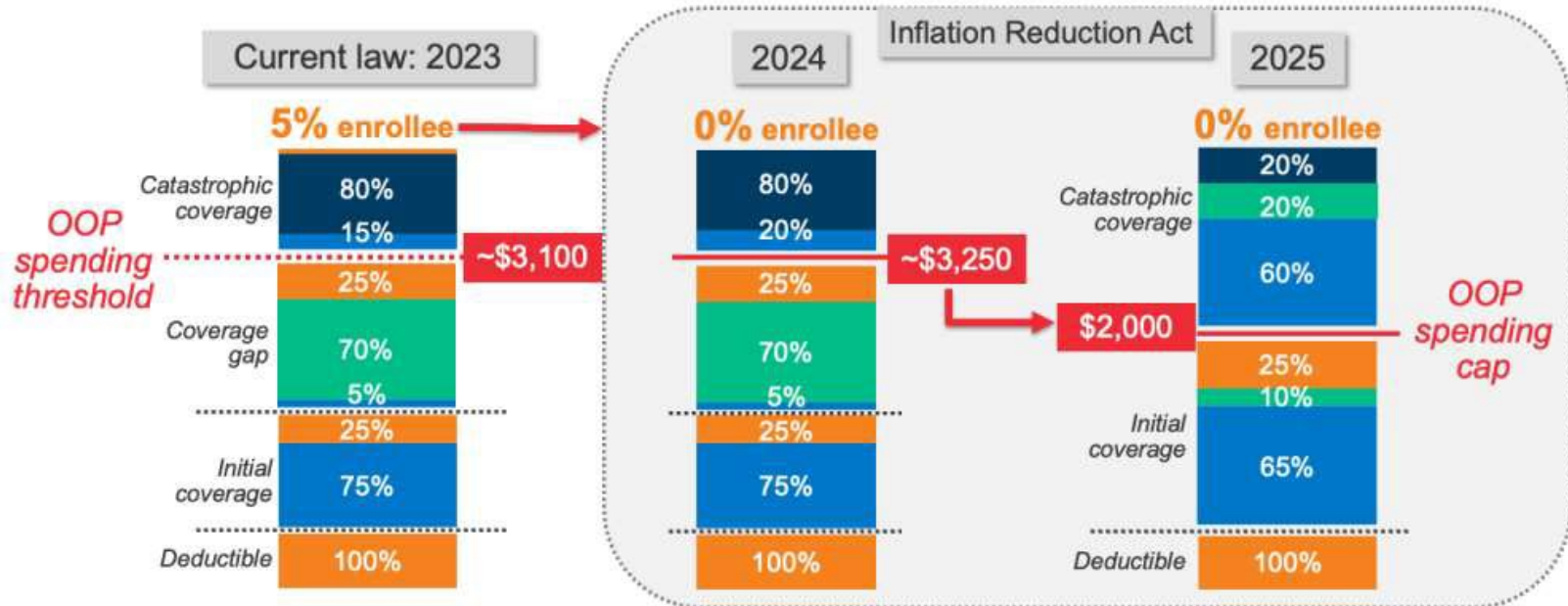


Figure 2

Changes to Medicare Part D for Brand-Name Drug Costs

Share of **brand-name drug** costs paid by: ● Enrollees ● Part D Plans ● Drug manufacturers ● Medicare



NOTE: OOP is out-of-pocket. The out-of-pocket spending threshold will be \$7,400 in 2023 and is projected to be \$7,750 in 2024 and \$8,100 in 2025, including what beneficiaries pay directly out of pocket and the value of the manufacturer discount on brand-name drugs in the coverage gap phase. These amounts translate to out-of-pocket spending of approximately \$3,100, \$3,250, and \$3,400 (based on brand-name drug use only).



From Explaining the Prescription Drug Provisions in the Inflation Reduction Act, by Juliette Cubanski, Tricia Neuman Follow, and Meredith Freed Follow, January 24, 2023. Copyright 2023 by KFF.

Part D Redesign: Spending Cap and LIS Expansion

Spending Cap

- Changes for 2024:
 - Eliminates 5% beneficiary coinsurance in catastrophic phase
 - Effectively caps out-of-pocket costs at approximately \$3,250
- Changes beginning 2025:
 - Hard cap on out-of-pocket spending at \$2,000 per year
 - Subject to inflation increases based on drug prices

Low Income Subsidy (LIS) Expansion

- Effective 2024
- Full LIS eligibility increases for incomes from 135% to 150% of the federal poverty level
- Asset limits also increased

Part D Redesign: Medicare, Plan and Manufacturer Liability

Liability for Costs Above Cap

- Medicare: 80% → 20% (brand) / 40% (generic)
- Part D plans: 15% → 60% (brand and generic)
- Manufacturers: 20% price discount (brand)

Liability for Costs between Deductible and Cap

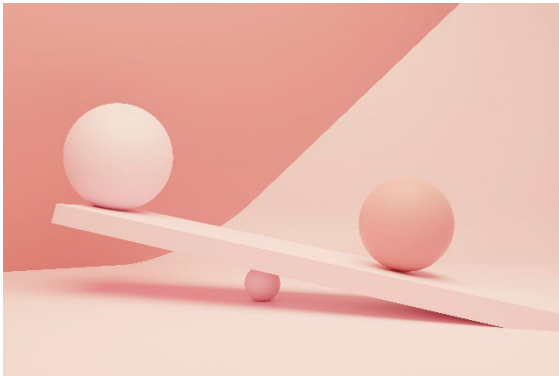
- Coverage gap eliminated
- Part D plans: 75% (initial) / 5% (gap) → 65%
 - Applies to LIS and non-LIS
- Manufacturer Discount: 70% (gap) → 10%

Polling Question

The premium stabilization provision applies to individual plan premiums.

- True
- False

Part D Redesign: Premium Stabilization



- 2024-2029: Increases in BBP capped at 6% from prior year
 - Lesser of BBP amount without IRA changes or 6% increase over prior year
 - Cap does not apply to unsubsidized member premium in excess of BBP
- 2030: HHS may reset base beneficiary premium percentage to not less than 20% to limit cost increase from 2029 to 6%

Part D Redesign: Projected Impacts

Beneficiary Impacts

- Savings for enrollees with high OOP costs
- 1.4M enrollees with OOP costs > \$2,000 in 2020
 - Average \$3,335/person
 - Includes 1.3M enrollees spending above catastrophic coverage threshold
 - \$2,700 in OOP costs (brand)
- With cap, savings of \$1,355 (40%)
- Top 10% (145,000 enrollees) would have saved \$3,567 (64%)
- Potential for higher Part D premiums
- May be mitigated by premium stabilization

Part D Plan Impacts

- Increased liability above spending cap
- Increased liability below cap (elimination of coverage gap)
- Increased liability for LIS beneficiaries
- Increase in portion of payments that are risk-adjusted
 - Accuracy
 - Aligned incentives
- Incentive to manage costs
 - Utilization management
 - Increased generic drug utilization
- Opportunity to engage in implementation

“Smoothing” of Part D Cost Sharing

More complicated than it sounds

- Starting 2025, Part D sponsors must offer option to pay cost sharing in monthly amounts
- Use “maximum monthly cap” as defined in IRA
- Separate formulas for
 - the first month for which an enrollee has elected to participate in the smoothing program and
 - the remaining months of the plan year
- Plan involved cost sharing collection and distribution
- Notice to beneficiaries, who can opt in
- If enrollees don’t pay monthly bill, can terminate smoothing election
 - Required notices
 - 15-day grace period before termination
 - 2-month grace period for reinstatement
- Members who change plans mid-year may make monthly payments to two plans
- Unclear how collections of past-due amounts will work, except,
 - Plans are not precluded from billing enrollees
 - Late fees and interest payments are prohibited
 - Unsettled balances are treated as plan losses *vis a vis* CMS



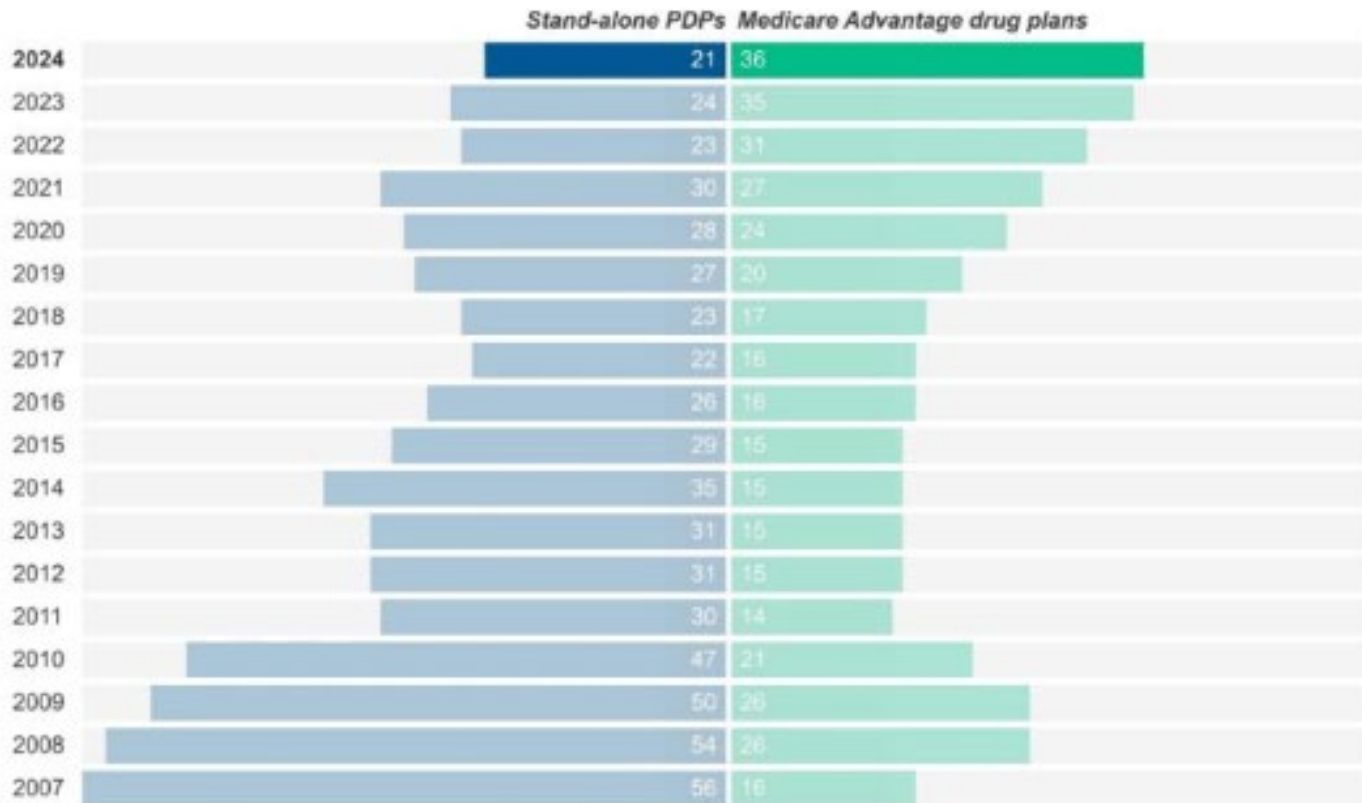
Industry Perspective, Trends and Impacts

2024 Highlights Part D for Standalone PDP

- There continues to be a steady decline in standalone PDP options with 2024 being lowest since Part D started.
- The number of MA-PD options continues to grow with more than double available for the same time period.
- Medicare beneficiaries who receive Part D Low-Income Subsidies (LIS) will have access to fewer so-called “benchmark” PDPs in 2024 than in any year since Part D started.
- While the premium stabilization provision capped annual Part D BBM at 6% growth, this cap does not apply to individual plan premiums that enrollees pay. Estimated average enrollment-weighted PDP premium expected to be \$48 up from \$40 in 2023.
- Most PDP enrollees will face higher cost sharing for brands than generics, including coinsurance for non-preferred drugs of 50% (max allowed for this tier)

Medicare Plan Options

The Average Medicare Beneficiary Has a Choice of Close to 60 Medicare Plans Offering Drug Coverage in 2024, Including 21 Stand-Alone Drug Plans and 36 Medicare Advantage Drug Plans



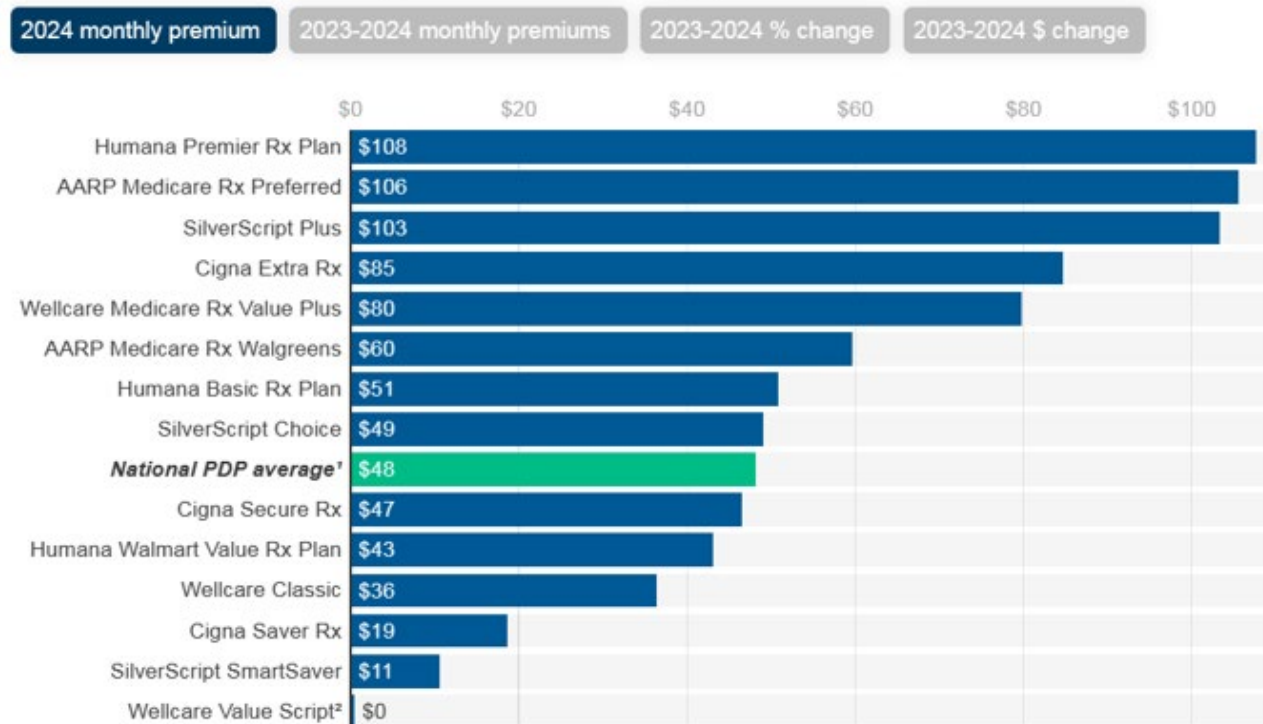
NOTE: PDP is prescription drug plan. Plan counts are beneficiary weighted. Number of PDPs is reported at the region level; number of MA-PD plans is reported at the county level and excludes Special Needs Plans, Medicare-Medicaid plans, and plans without drug coverage.
SOURCE: KFF analysis of Centers for Medicare & Medicaid Services 2007-2024 Part D plan files.



Average Part D Monthly Premiums

Average Monthly Premiums for the 14 National Part D Stand-alone Drug Plans in 2024 Are Projected to Range from a High of \$108 Down to Less Than \$1

The National PDP Average Monthly Premium is Increasing by \$8, or 21%



NOTE: PDP is prescription drug plan. Estimates are weighted by June 2023 enrollment; assume current PDP enrollees remain in their same plan; and make no assumptions about plan choices by new enrollees for 2024. ¹National average includes premiums for basic and enhanced PDPs. ²2024 average monthly premium for Wellcare Value Script is \$0.43 cents.

SOURCE: KFF analysis of Centers for Medicare & Medicaid Services 2023-2024 Part D plan files. • PNG



IRA Impacts and Considerations

Premium

- Base beneficiary premium (BBP) capped at 6% growth
- Low –income subsidy amounts
- RxHCC model calibration

Benefit Design

- Expansion of low income subsidy benefit to include 135-150% federal poverty level
- Insulin no deductible along with cost sharing may not exceed \$35 for months supply
- Vaccines exempt from any coinsurance or other cost sharing
- Eliminated 5% beneficiary cost sharing in catastrophic phase

Formulary Design

- Utilization management criteria
- Tiers and drug placement
- Reduced manufacturer costs/rebates

Polling Question

How many enrollees do you expect will chose the option to pay out-of-pocket Part D drug costs through monthly payments rather than upfront payments at the pharmacy point of sale?

- Less than 15%
- About 30%
- 50%
- More than 80%

Planning for 2025 Part D Benefit Design Changes

2025 Part D Benefit Design Changes

- \$2,000 member out of pocket maximum
- Elimination of the Part D Coverage Gap benefit phase
- Sunsetting of the current Coverage Gap Discount Program (CGDP)
- Debut of a brand-new pharmaceutical Manufacturer Discount Program (MDP).
- Offering Part D enrollees the option to pay out-of-pocket Part D drug costs through monthly payments over the course of the plan year, as opposed to upfront payments at the pharmacy point of sale.

Operational Impacts

- While it's expected that the beneficiary will pay less, what is less clear is who will pay more? Developing 2025 bids will be more challenging than 2006 initial bid.
- System changes to support tracking of drug cost and monthly billing option.
- STAR Measures Impact

A lot of variables changing at once



Action Items

- Get legal counsel involved in strategic analysis and change management planning
- Review Part D PBM agreements to determine what changes are needed to reflect updates
- Evaluate your Pharmacy Benefit Manager's preparations for the Part D changes, especially those coming in 2025
 - Claims Administration
 - Rebate negotiations
- Confirm actuaries are contemplating how to incorporate funding changes into future bids and are ready to escalate serious concerns early

Contacts and Questions

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