The Inflation Reduction Act's Overhaul of Medicare Part D

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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**

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

- CMS Guidance
  - Jan 2023 – CMS outlines process for Negotiation Program implementation
  - Jan 2023 – CMS requests comment regarding burden estimates or any other aspect relating to small biotech exception
  - March 2023 – CMS publishes initial guidance regarding implementation of the Negotiation Program
  - 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

Negotiation Program: Upcoming Dates

- Sept 2023: CMS publishes list of 10 Part D drugs selected for 2026 negotiations
- Oct 2023: Manufacturers enter 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

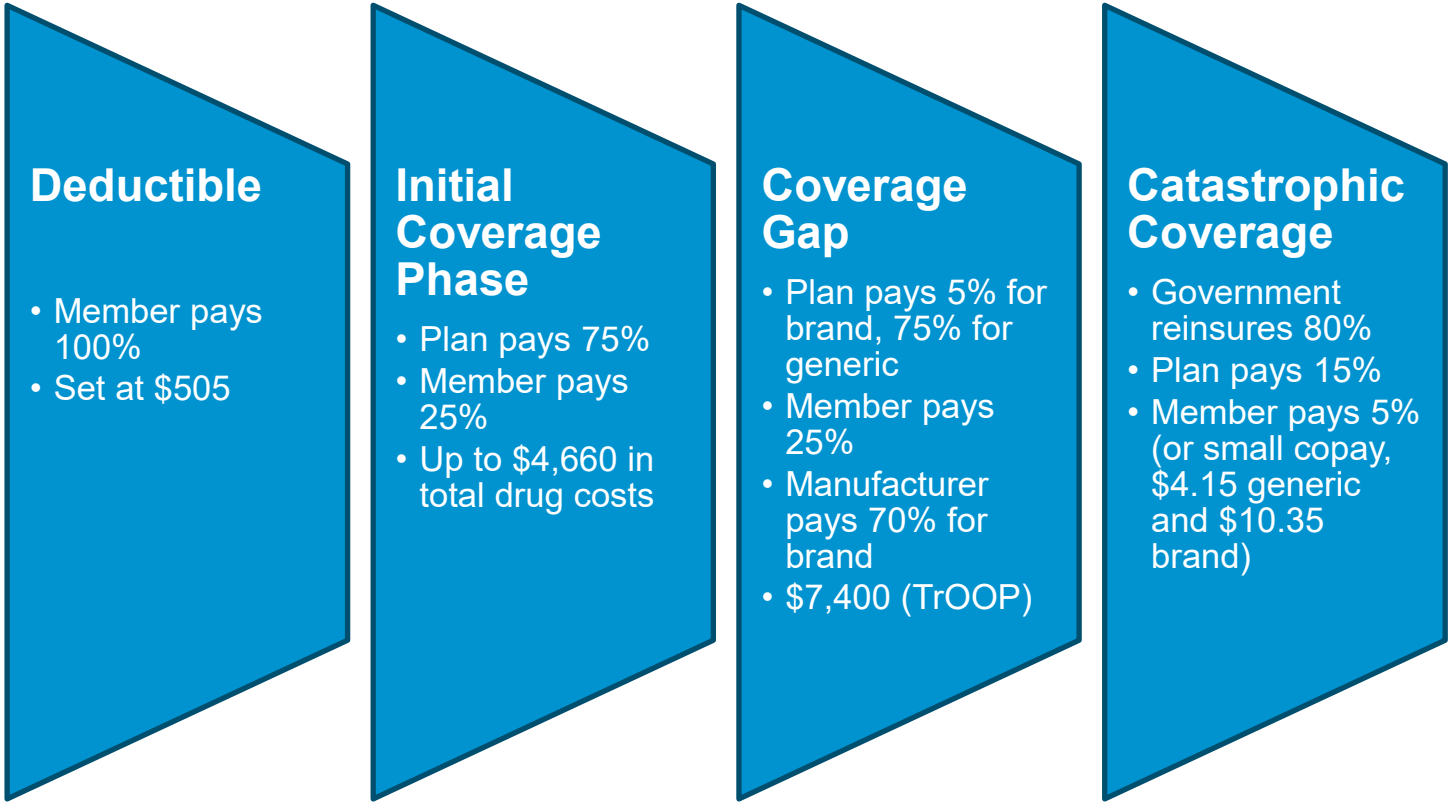
Negotiation Program: Industry Impact

- Novelty of government negotiating drug prices
- Lack of clarity in selection criteria and negotiation process
- Mounting legal challenges
- Potential changes in pharmaceutical research and development
- Unclear whether decreases in Medicare prices will impact commercial lines of business

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



Part D Redesign: Major Provisions

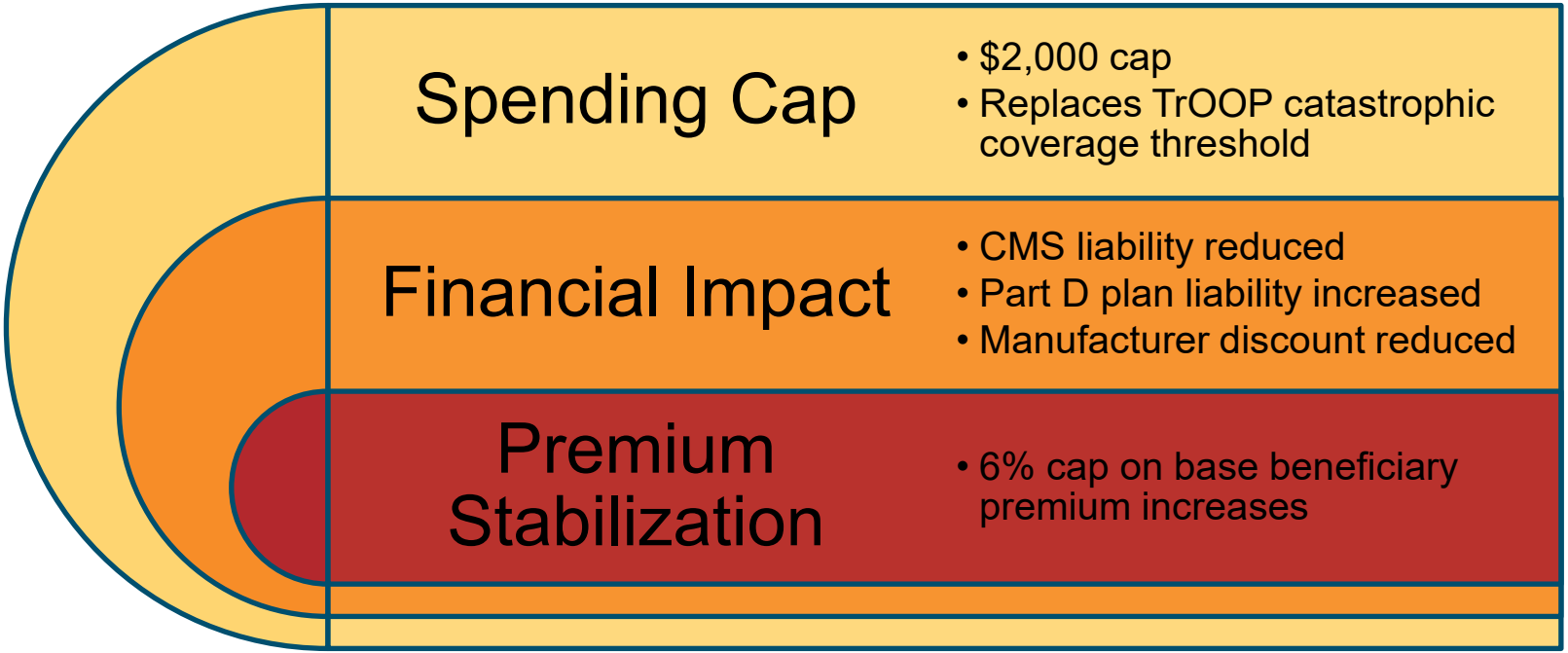
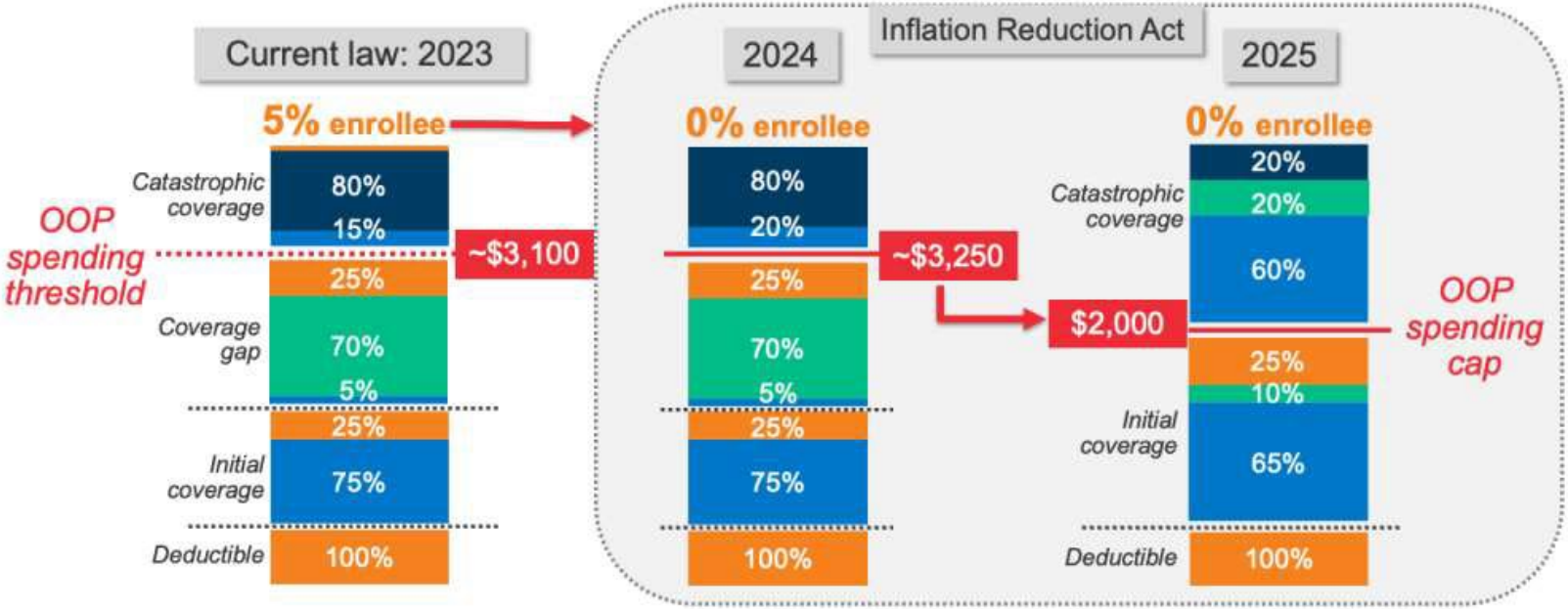


Figure 2

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).

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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

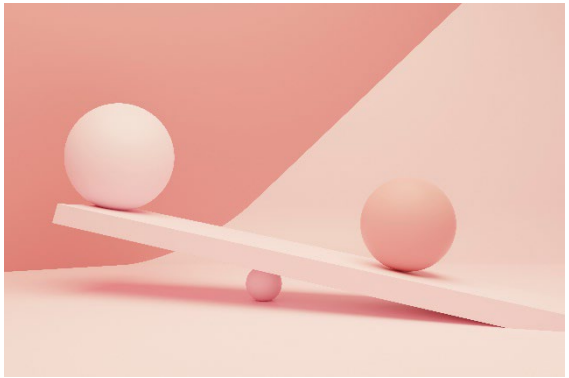
Liability for Costs Above Cap

- 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%

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

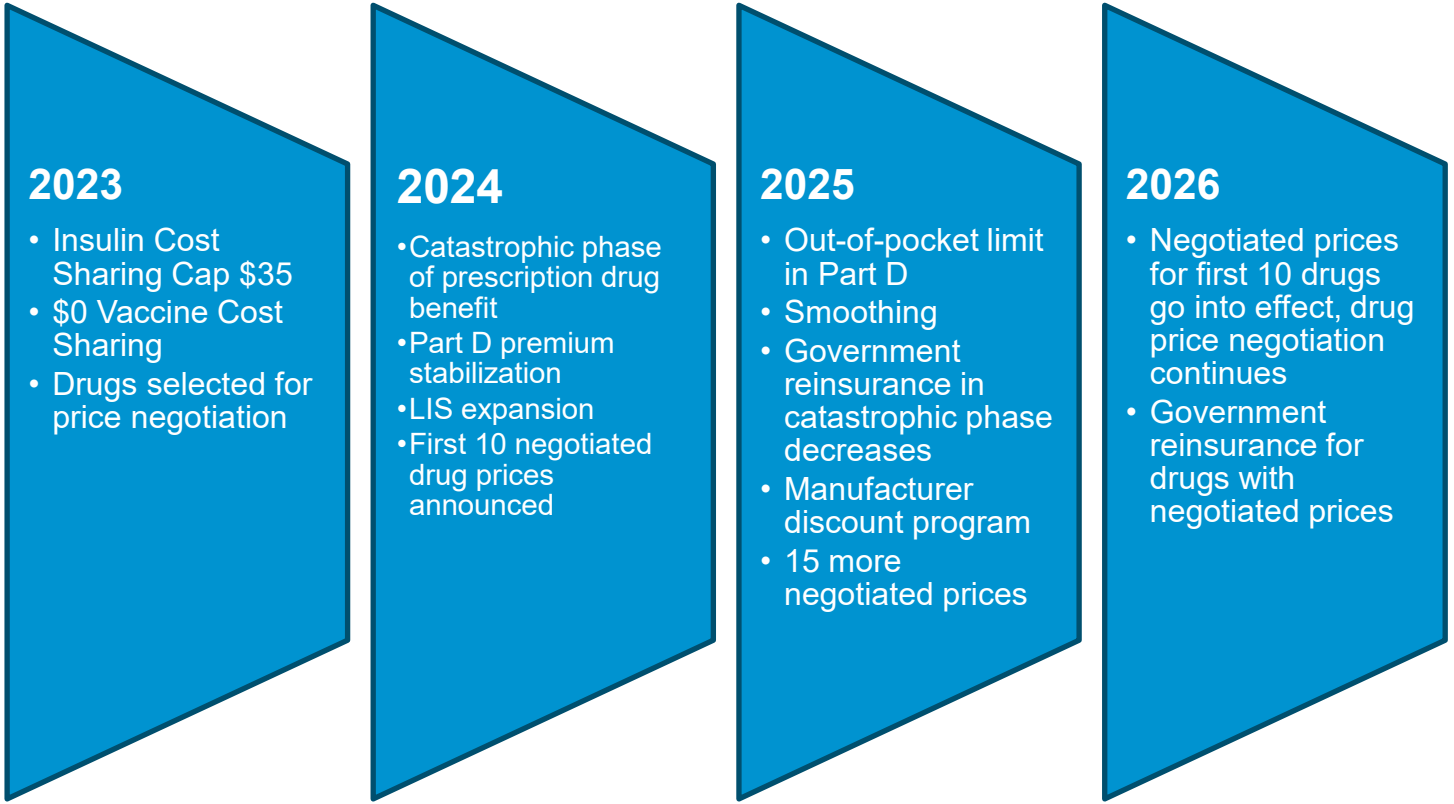
- Increased liability above spending cap
- Increased liability below cap (elimination of coverage gap)
- Increased liability for LIS beneficiaries
- Increase in portion of payments that are risk-adjusted
  - Accuracy
  - Aligned incentives
- Incentive to manage costs
  - Utilization management
  - Increased 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
- *What if member changes plans mid-year?*
- Not clear how collections of past-due amounts will work, except,
  - Plans are not precluded from billing enrollees
  - Unsettled balances are treated as plan losses *vis a vis* CMS

CMS Implementation Timeline



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

Thank You

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