Policy in Flux: An Update from DC

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Your Presenter

JOEL WHITE

- Partner, Board Member: 2007-Current*
  - Helped enact 50+ federal and state laws
  - Procured $125 million in grant funding
  - Advanced, modified, or helped block dozens of regulations
- Congressional Staff: 1995-2007
  - Helped write 9 laws, including Medicare Part D, creation of HSAs, reforms to Medicare provider reimbursement and Value Based Care Programs

**Horizon Government Affairs was acquired by Monument Advocacy in 2025*

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Cencora has not influenced the content of this presentation, nor has it independently verified the presentation for accuracy

Policy Changes Driving Tough Environment

- **Price Compression**
- **Lower Reimbursement**
- **Reduced Access**
- **Consolidation Incentives**

PBM REFORM

- Part D and Commercial Market
- Transparency and financial reforms

ONE BIG BEAUTIFUL BILL

- Implementation of Medicare/caid, ACA reforms
- Coverage Changes/Disruption
- Reimbursement reductions

MAXIMUM FAIR PRICE

- Establishes ceiling prices for drugs
- ASP reduced to MFP for selected drugs
- Reduction in reimbursement, commercial spill over

340B ENVIRONMENT

- Upfront discounts -> back-end rebates
- HHS is going back to drawing board on pilot program

PROPOSED CMMI MODELS

- GLOBE: Part B rebate
- GUARD: Part D rebate
- GENEROUS: Medicaid rebate
- Rebates based on international prices

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PBM Reform

Commercial Market Requirements

Full Rebate Pass Through to ERISA Plans:

- Requires PBMs and affiliates remit 100 percent of rebates to health plans

Self Referrals:

- Requires PBMs to report any benefit design parameters that encourage or require self-steering practices

Commercial Market PBM Oversight:

- Forbids health plans and PBMs from contracting with entities who restrict transparency

Commercial Transparency:

- PBMs must report information to plan sponsors and HHS

Part D

Delinking and Rebate Pass Through:

- Restricts PBM compensation to bona fide service fees

Any Willing Pharmacy:

- Part D plan sponsors must contract with any willing pharmacy that meets their standard conditions

Transparency:

- PBMs must report information to plan sponsors and HHS

Trump 2.0 and Health Care

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OBBBA Implementation

CBO's estimate reflects a static projection of coverage loss for the year 2034 and does not account for potential transitions to private or employer-sponsored insurance.

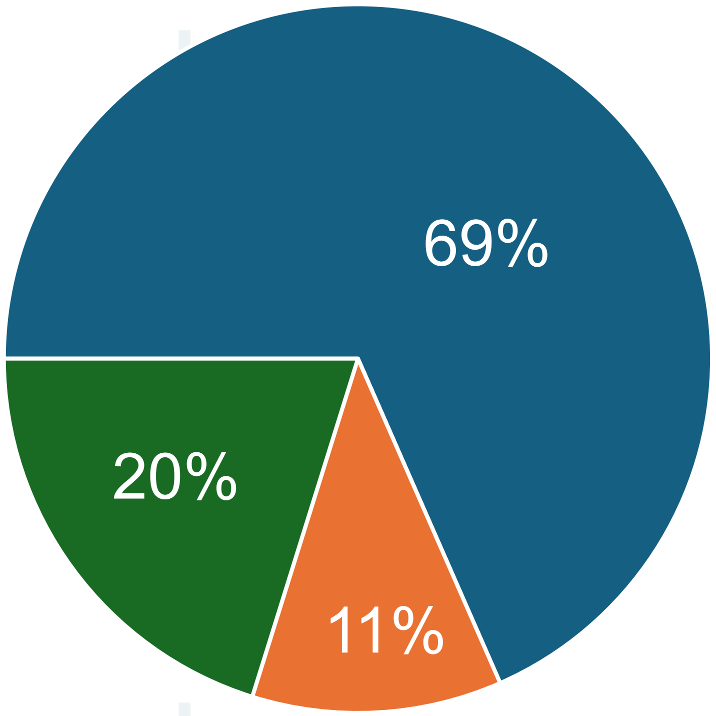
~10M No longer qualify for Medicaid or ACA Coverage

- **Medicaid** (7.8M)
  - *4.8 million able-bodied adults without dependents who fail to meet work requirements*
  - *1.6 million people enrolled in two state Medicaid programs*
  - *1.4 million undocumented*
- **ACA Eligibility** (1.3M)
- **ACA tax credit changes** (2.3M)

2025 → ***2034***

Regulations implementing changes will roll out in earnest between 2025 and 2028

Uninsured Increase by Major Category (OBBA)



Sources: Council for Affordable Health Coverage; CBO, Energy and Commerce Committee

IRA Policy Changes are Phased In

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2022	2023	2024	2025	2026
Medicare will pay more for certain biosimilars in Medicare's medical drug program (Part B)	Requires drug companies to pay rebates if Medicare drug prices rise faster than inflation	Eliminates beneficiary cost-sharing for Part D catastrophic coverage	Adds $2,000 out-of-pocket cap on beneficiary costs in Part D	Drug price controls begin in Medicare, first in Part D and ultimately in Part B (2028)
	Eliminates cost sharing for vaccines covered under Part D and caps insulin costs to $35/month	Expands income eligibility to 150% FPL for full Low-Income Subsidies	Shifts risks between plans and taxpayers Allows beneficiaries to "smooth" cost-sharing over the year	

MFP Impact on Provider Reimbursement

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Impact on Provider Reimbursement & Patient Access

Under the Medicare Drug Price Negotiation Program, provider reimbursement for a negotiated drug will shift from ASP +4.3% to MFP +4.3%.

ASP Today: $250

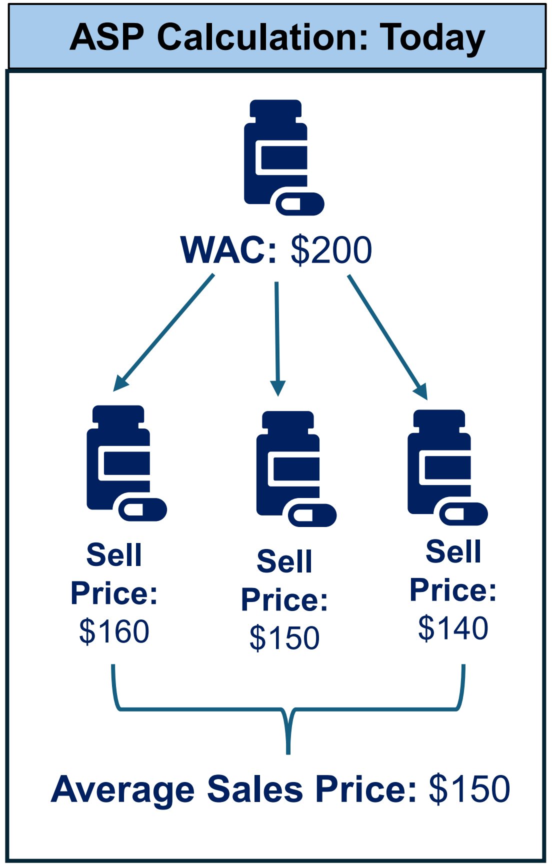
MFP: $125

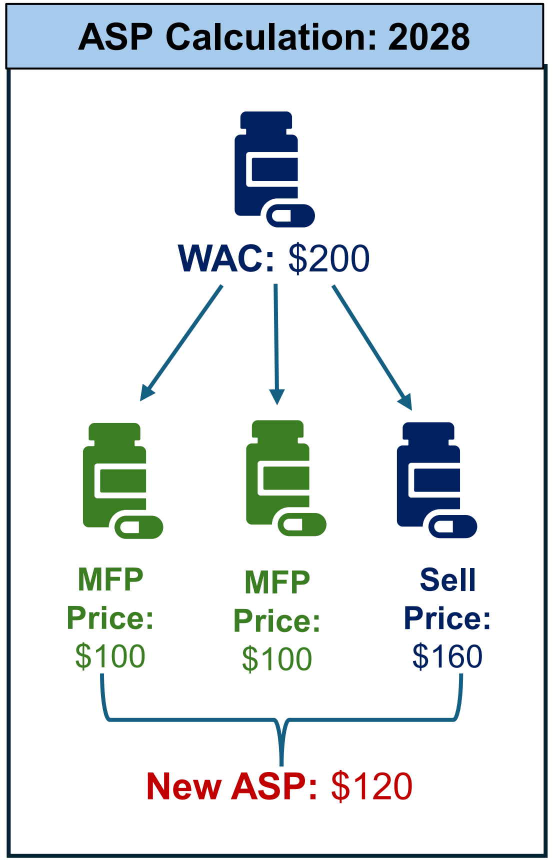
Lower Provider Add-On in Medicare:

4.3% of **$250** → 4.3% of **$125**

Patients May Face Disruptions to Treatment and Broader Access Issues

Impact on MFP on ASP Erosion & Commercial Market Spillover





Policies put downward pressure on a negotiated drug's ASP. The "ASP spiral" will have reduce provider reimbursement and the stability of practice economics

Selected Drug Discounts – 2027 and 2028

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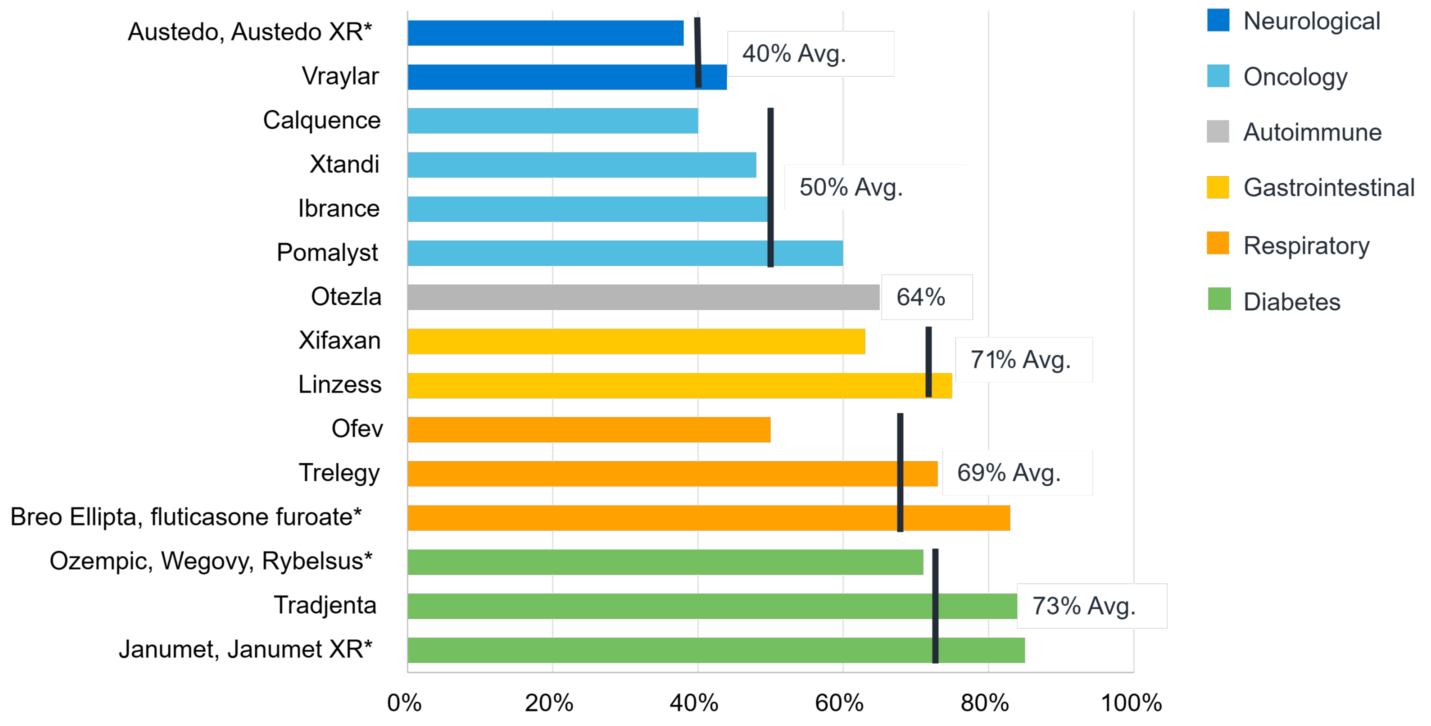
2027 Negotiated Discounts



Source: Milliman

**Products with the same active moiety, or the same active ingredient used to treat a condition, are grouped together by CMS for the purposes of price negotiation. Averages are weighted on 2024 Part D gross costs.*

IPAY 2028 Selections

Neurology/Specialty (Migraine, Spasticity, Bladder):
Botox / Botox Cosmetic (OnabotulinumtoxinA)
Oncology (Breast and Prostate Cancer):
*Erleada (Apalutamide)
*Kisqali (Ribociclib)
*Lenvima (Lenvatinib)
*Verzenio (Abemaciclib)
Autoimmune/Inflammatory Diseases
Cimzia (Certolizumab pegol)
Cosentyx (Secukinumab)
Entyvio (Vedolizumab)
Orencia (Abatacept)
*Xeljanz / Xeljanz XR (Tofacitinib)
Xolair (Omalizumab) (Also used for asthma/hives)
Respiratory/Other:
*Anoro Ellipta (Umeclidinium/Vilanterol)
Diabetes and Cardiovascular Disease:
*Trulicity (Dulaglutide)
Human Immunodeficiency Virus (HIV):
*Biktarvy (Bictegravir/Emtricitabine/Tenofovir alafenamide)
Mental Health/CNS:
*Rexulti (Brexpiprazole)

**Products in Part D*

GLOBE/GUARD

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<table>
<tr><th>Category</th><th>Global Benchmark for Efficient Drug Pricing (GLOBE) Model</th><th>Guarding US Medicare Against Rising Drug Costs (GUARD)</th></tr>
<tr><td>Manufacturer Participation</td><td colspan="2">• Assess a rebate for certain drugs if prices exceed those paid in certain countries
• Rebates are paid to government, minimizing impact on providers, plans, and excluded from 340B</td></tr>
<tr><td>Included Drugs</td><td>• Part B drugs with annual Part B spending >$100M
• Regardless of time on market, without generic/biosimilar competition
• In specific therapeutic areas: oncology, rheumatology, immunology, ophthalmology, and endocrinology</td><td>• Part D drugs with gross Part D spending >$69M
• Regardless of time on market, without generic/biosimilar competition
• In 17 specific therapeutic areas, inclusive of the six protected classes</td></tr>
<tr><td>Geographic Area</td><td colspan="2">Random selection of 25 percent of ZIP code related areas</td></tr>
<tr><td>Reference Countries</td><td colspan="2">19 OECD countries based on GDP criteria</td></tr>
<tr><td>Benchmark</td><td colspan="2">Two different benchmarks, depending on manufacturer disclosure of net prices:
• Method I: CMS uses the lowest price among the reference countries
• Method II: If manufacturers submit net pricing data, volume-weighted average among the countries</td></tr>
<tr><td>Impact on patients</td><td>• GLOBE coinsurance lowered proportionately to the model benchmark</td><td>• GUARD increases premiums by $3 billion, cost sharing by $0.6 billion</td></tr>
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GLOBE/GUARD

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1. Excludes providers, plans, 340B

2.
   - Patients get little: no requirement to change formulary or coverage of GUARD drugs.
   - Part D costs increase for enrollees (by $3.6 billion)
   - Most Part B patients have supplemental coverage and do not pay coinsurance

3. MA plan costs increase and may limit supplemental benefits and increase OOP costs/premiums

4. Unclear what CMMI is testing by imposing rebates on drug manufacturers

5. Does not explicitly exclude manufacturers who voluntarily agreed to price discounts
   Does explicitly exclude providers, plans, 340B

GENEROUS

Category	GENErating cost Reductions fOr U.S. Medicaid (GENEROUS) Model
Manufacturers will provide supplemental rebates to participating states for drugs included in the model to align Medicaid net prices with what certain other countries pay	
Participation	Voluntary participation for both manufacturers and states; Manufacturers must already be participating in the Medicaid Drug Rebate Program
Included Drugs	All single source drugs or innovator multiple source drugs of a participating manufacturer States can decide drugs they will accept MFN pricing Covered outpatient drugs that are included in the CMMI Cell and Gene Therapy model are excluded
Reference Countries	Canada, Denmark, France, Germany, Italy, Japan, Switzerland, and the United Kingdom
Benchmark	The second-lowest net price across reference countries, adjusted for GDP
Rebate Calculations	The supplemental rebate equals a drug's WAC minus the Guaranteed Net Unit Pirce (derived from the MFN benchmark) and the standard Unit Rebate Amount

Major Election Year Deadlines

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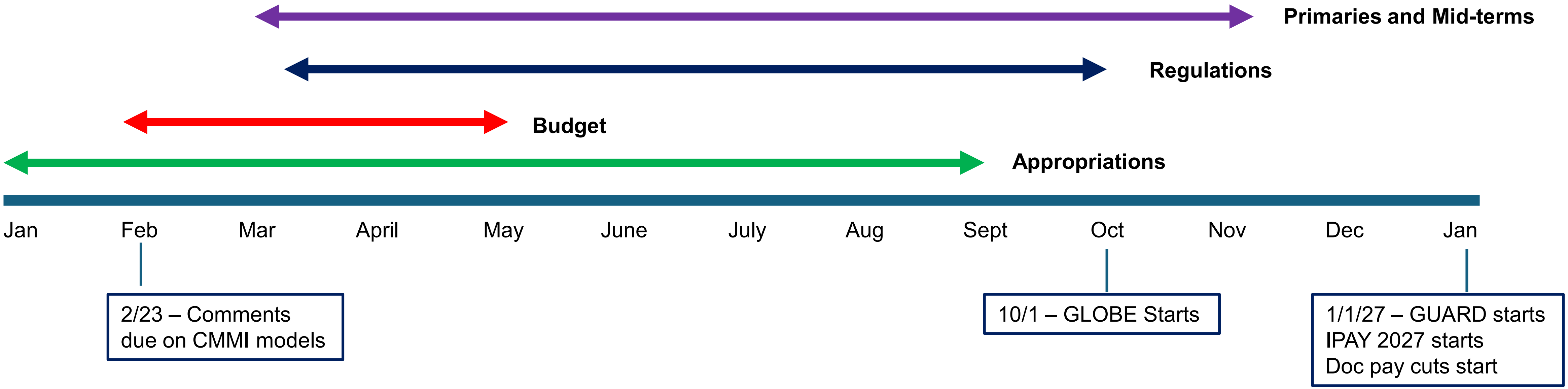
1 **Budget Pressures**

2 **Affordability Issues**

3 **Heavy Regulatory Year**



- **Budget – additional health care changes possible**
  - Leadership will decide whether to use budget reconciliation or not – Housing, Energy, Health Care
- **Hearings and Legislation focused on Affordability**
- **Appropriations**
- **Mid-Terms and Lame Duck Driving Congressional Calendar**

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