

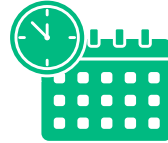
# Drug Pricing Reform: The Good, the Bad, and the Ugly

## The Good – Medicare Part D Benefit Redesign



Patient annual out-of-pocket spending capped at

**\$2,000**



Beneficiaries can pay their out-of-pocket balance on a rolling monthly basis



New payment structure eliminates coverage gap

**\$35**

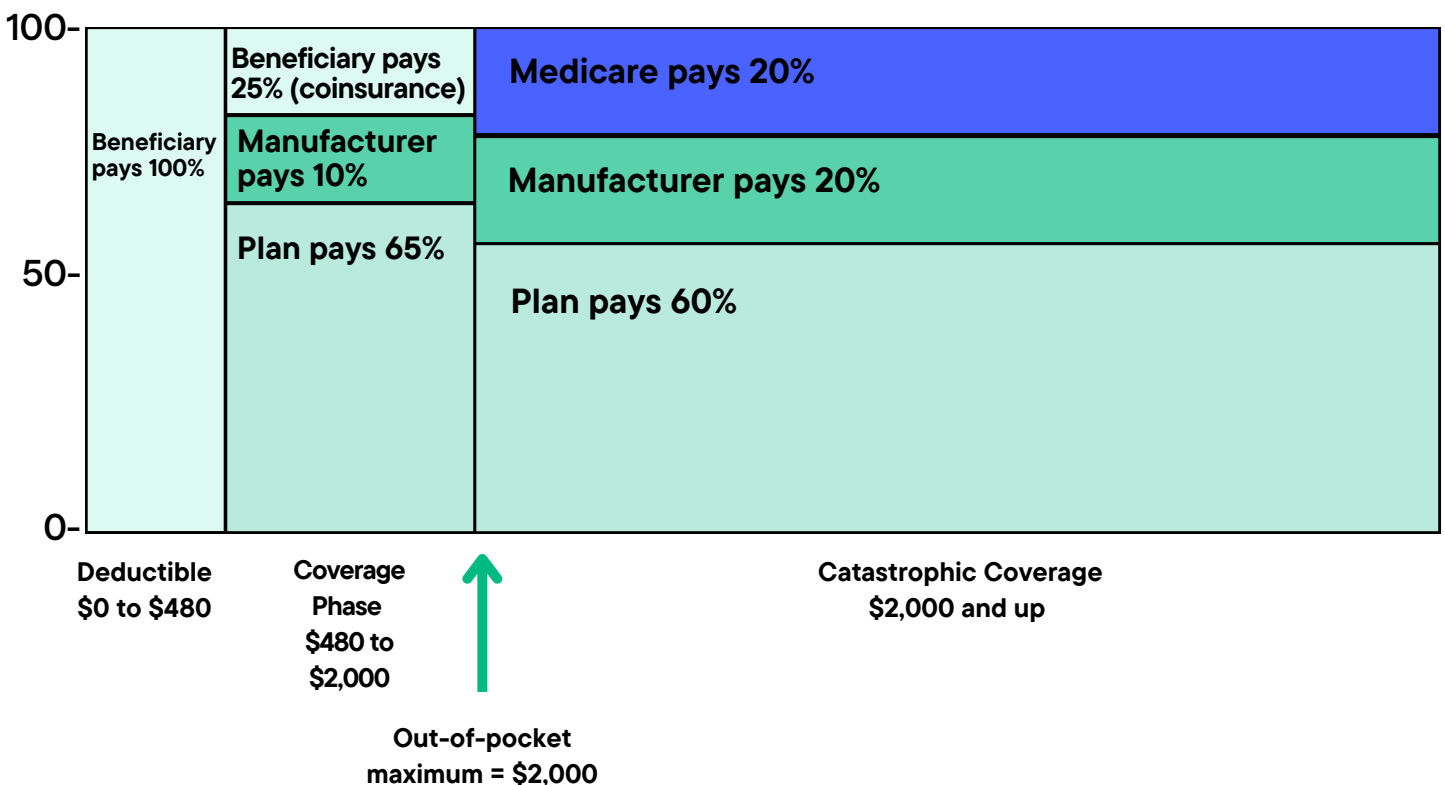
cost-sharing maximum for insulin products under Parts B & D



Takes effect in

**2025**

## Part D Benefit Redesigned



# The Bad – Medicare Price Setting




“We appreciate that the law does not include foreign price controls, but it still gives the federal government unilateral determination over the value of a medicine and, if a company does not agree with that valuation, it will be charged an excessive excise tax. **This is pure government price setting, not negotiation.**”

*Joe Panetta, President & CEO, Biocom California*

## Eligibility for Drugs

**Highest Medicare Parts B & D Expenditures**



On market for:  
**7 years**   
 for small molecules,  
**11 years**  
 for biologics

**No Approved Generic or Biosimilar**

## Timeline (Price Controls Take Effect)

**2026**  
 10 drugs  
 (Part D only)

**2027**  
 15 drugs  
 (Part D only)

**2028**  
 15 drugs  
 (Part D and Part B)

**2029 →**  
 20 drugs  
 (Part D and Part B)

## Price Determination

HHS will determine a Maximum Fair Price Ceiling (MFP) as a percentage of the Non-Federal Average Manufacturer Price (NFAMP) indexed for inflation each year:

**75%**

for “Short Monopoly Drugs and Vaccines” – **9-12 years** on market

**65%**

for “Extended-Monopoly Drugs” – **12-16 years** on market

**40%**

for “Long-Monopoly Drugs” – **16+ years** on market

**Small Biotech Price Floor** – for 2029 and 2030, “small biotech drugs” have a price floor of 66% Non-FAMP if they are selected for negotiation.

## Non-Compliance

**65% to 95% Tax**  
 on all sales of the drug for failing to negotiate

**Monetary Penalties 10x**  
 the difference between the price charged and MFP for failing to sell at or below MFP

**\$1 Million/Day**  
 for failing to provide information for negotiation

# The Bad – Medicare Price Setting

## Delayed Negotiation and Renegotiation

Negotiation on a biologic can be delayed if a biosimilar may enter the market within **2 years** of eligibility



Renegotiation if a **new indication** is added or the drug's monopoly status changes

## Exemptions

**Small biotech drugs:** (drug expenditure represents less than **1%** of total **Part D or B** expenditures and is equal to at least **80%** of the total expenditures for all covered Part D or B drugs for that company)



Single indication  
Orphan drugs

**> \$200m**

Low-cost drugs (Medicare  
expenditures less than \$200m/year)




Plasma-derived  
products


# The Ugly – Impact Studies



**\$300 billion**  
cost to manufacturers



**55%** reduction in  
innovators' revenue 

**104** out of **110** drugs or **95%** of  
the pipeline at **risk of**  
 **canceled** development 

 **100,000**  
California jobs lost



Between  
**\$455bn &**  
**\$5.1 trillion**  
in cost to manufacturers

