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
- $35 cost-sharing maximum for insulin products under Parts B & D
- New payment structure eliminates coverage gap
- Beneficiaries can pay their out-of-pocket balance on a rolling monthly basis
- Takes effect in 2025

Part D Benefit Redesigned

<table>
<thead>
<tr>
<th>Deductible</th>
<th>Coverage Phase</th>
<th>Catastrophic Coverage</th>
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<tbody>
<tr>
<td>$0 to $480</td>
<td>$480 to $2,000</td>
<td>$2,000 and up</td>
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- Out-of-pocket maximum = $2,000

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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 expends 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

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