



Advising the Congress on Medicare issues

Biosimilars in Medicare Part D

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Overview of this presentation

- Background on biologics and biosimilars
- Spending and use in Part D
- How Part D's coverage-gap discount may slow takeup of biosimilars
- Chairman's draft recommendation
- Next steps

What are biologics and biosimilars?

- *Biologics*: therapies derived from living cells or organisms and manufactured through biological processes
 - Treatments for diabetes, cancer, rheumatoid arthritis, multiple sclerosis
 - Injected or infused
 - Prices typically high
- *Biosimilars*: follow-on products that are highly similar to originator biologics
 - Like generic drugs, may introduce price competition
 - Unlike generic drugs
 - Not exact replicas of the originator products
 - But molecular structure of originators can also vary

How Medicare pays for biologics and biosimilars in Part D

- Costs of biologics are included in plans' bids
 - Medicare pays plans
 - Capitated amount (direct subsidy)
 - 80% reinsurance above out-of-pocket (OOP) threshold
 - Plan sponsors negotiate
 - Pharmacy payment rates, discounts, and fees
 - Rebates from manufacturers
- Enrollees who use high-priced biologics tend to reach the OOP threshold
 - Beneficiary pays 5% cost sharing
 - Medicare bearing most of catastrophic costs

Spending for and use of biologics under Part D, 2011-2015

	2011	2015	Cumulative growth	Average annual rate
Gross spending (billions)	\$6.8	\$18.7	\$11.9	29%
<i>As % of all Part D</i>	<i>8.0%</i>	<i>13.6%</i>		
Number of prescriptions (millions)	25.3	37.0	\$11.7	10%
<i>As % of all Part D</i>	<i>1.7%</i>	<i>1.7%</i>		

- Over 80% of Part D biologics spending and nearly 90% of spending growth attributable to three treatment categories:
 - Insulin
 - inflammatory diseases (e.g., rheumatoid arthritis)
 - Multiple sclerosis
- Double-digit percentage increases in prices per prescription

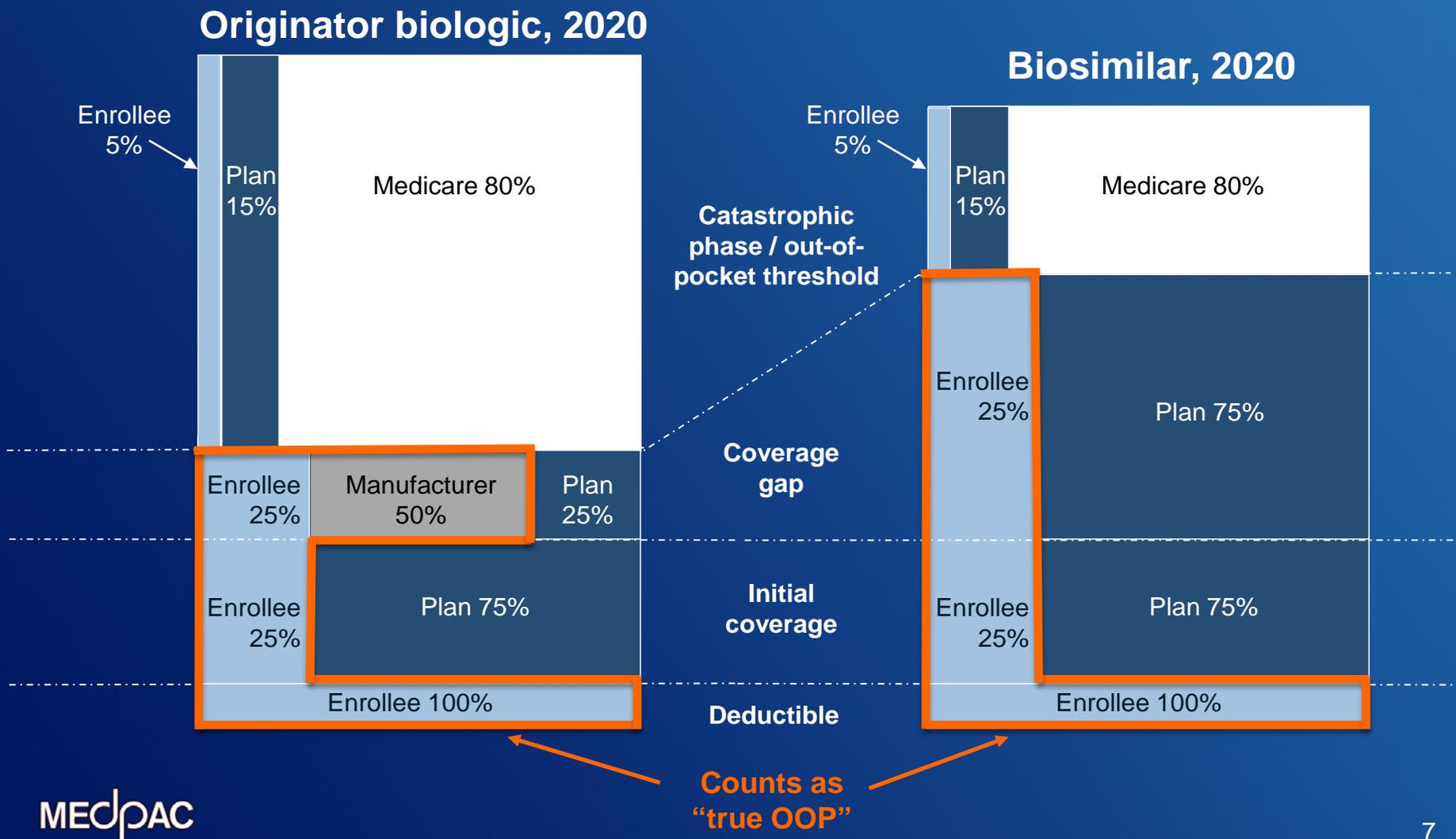
Note: Data are preliminary and subject to change. Gross spending means claims amounts prior to post-sale rebates and discounts.

Source: MedPAC based on CMS prescription drug event data.

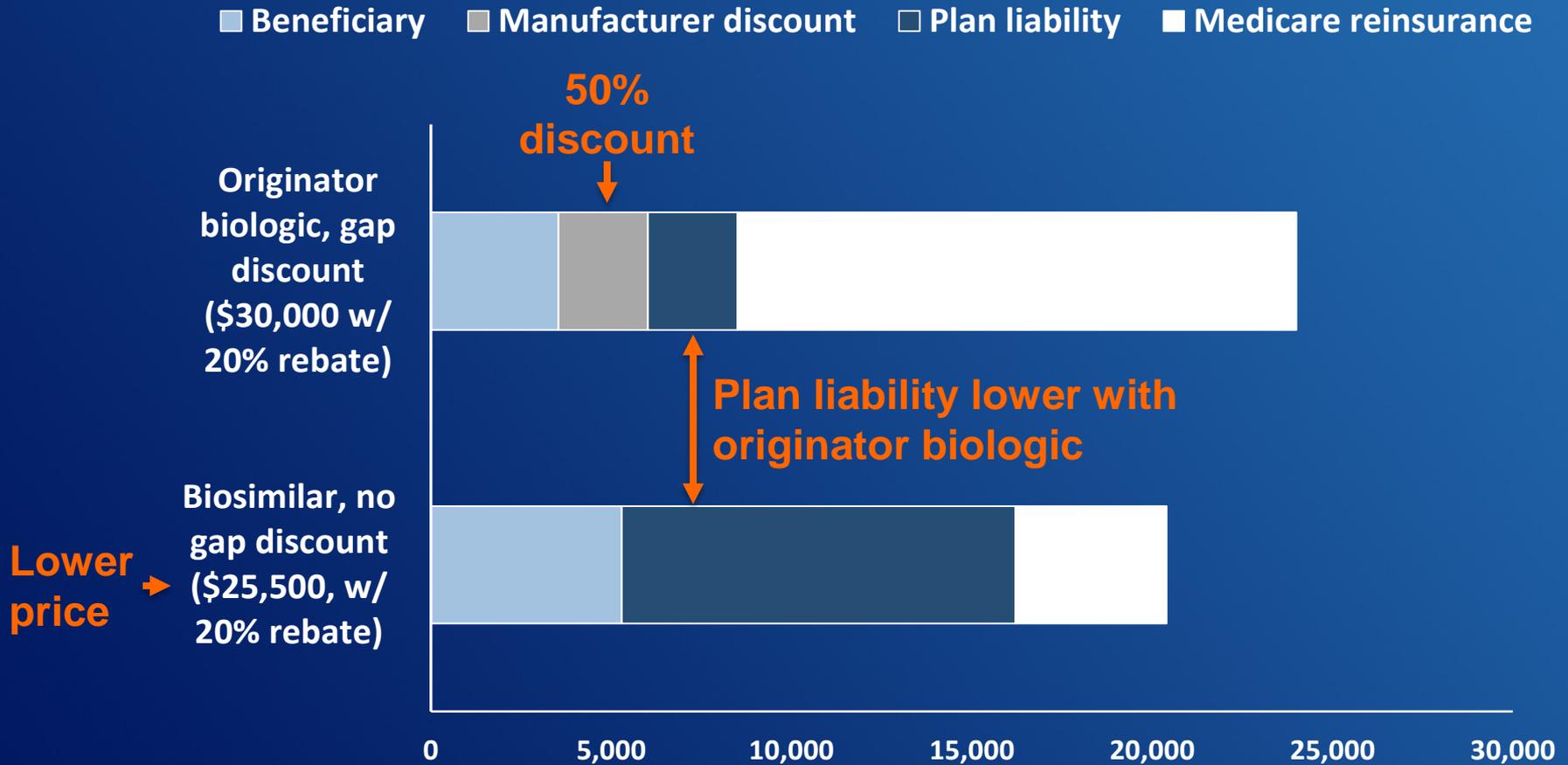
Will biosimilars be used by Part D enrollees?

- How Part D plans treat biosimilars on their formularies will affect takeup
- Plans generally encourage use of lower-priced products to keep premiums low
- **BUT** coverage-gap discount provides financial advantage to originator biologics over biosimilars
 - ➔ Plans may want to include originators on their formularies
 - ➔ Beneficiaries may have higher cost sharing with biosimilars

Coverage-gap discount currently favors originator biologics

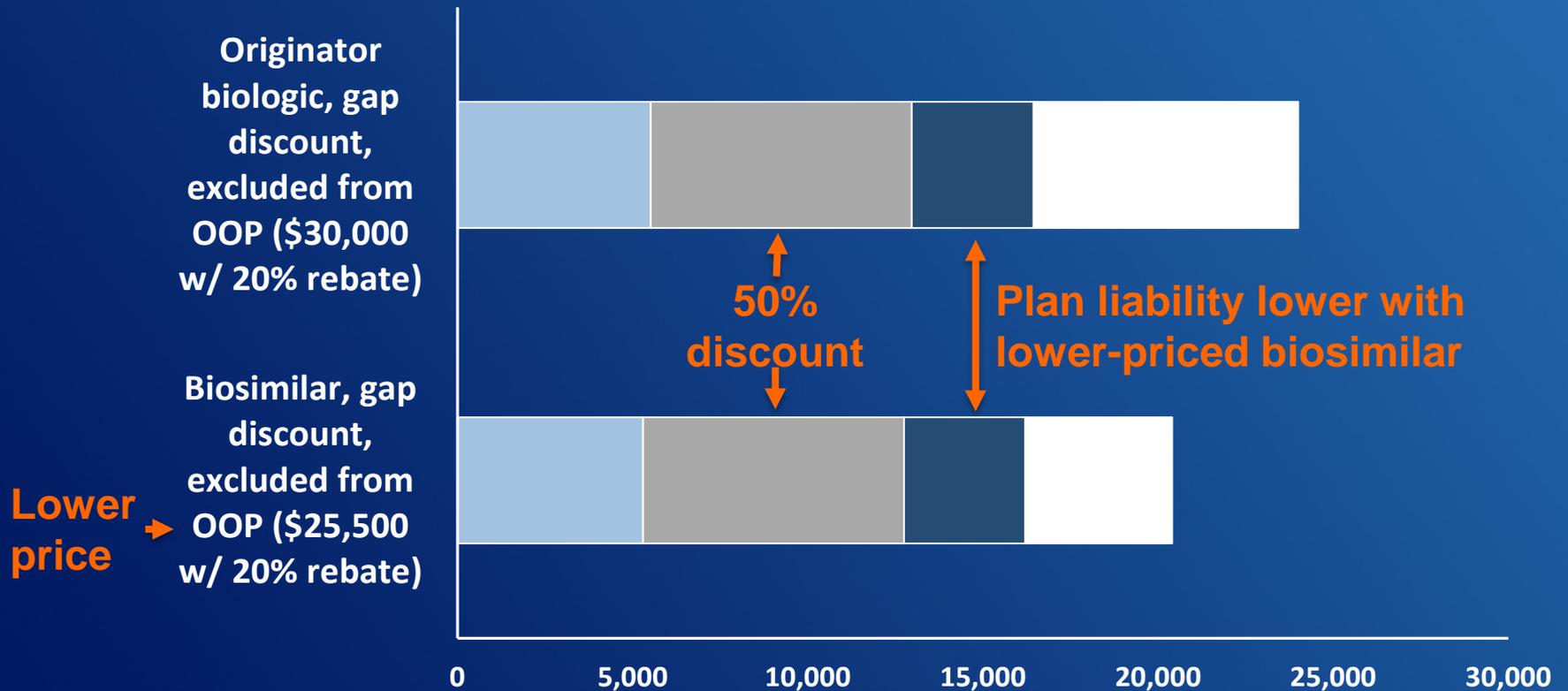


Example of how current law coverage-gap discount distorts price signals



Policy option improves price signals

■ Beneficiary ■ Manufacturer discount □ Plan liability ■ Medicare reinsurance



Applying coverage-gap discount to biosimilars would align incentives

	<u>Current law</u>		<u>Under policy option</u>		
	Coverage-gap discount applies	Discount treated as enrollees' OOP	Coverage-gap discount applies	Discount treated as enrollees' OOP	Total spending
Brand-name drugs	✓	yes	✓	no	} ≈75%
Originator biologics	✓	yes	✓	no	
Biosimilars	N/A	N/A	✓	no	

The Commission's June 2016 Part D recommendations

- Change Part D to:
 - Transition Medicare's reinsurance from 80% to 20% of catastrophic spending and keep Medicare's overall subsidy at 74.5% through higher capitated payments
 - Exclude manufacturers' discounts in the coverage gap from enrollees' "true OOP" spending
 - Eliminate cost sharing above the OOP threshold
- Make moderate changes to LIS cost sharing to encourage use of generics and biosimilars
- Greater flexibility to use formulary tools

Next steps

- Revisions based on commissioner comments
- Vote in January 2018
- Include in March 2018 *Report to the Congress*