Biosimilars in Medicare Part D

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November 3, 2017

MEDPAC

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%
As % of all Part D	*8.0%*	*13.6%*		
Number of prescriptions (millions)	25.3	37.0	$11.7	10%
As % of all Part D	*1.7%*	*1.7%*		

- 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.

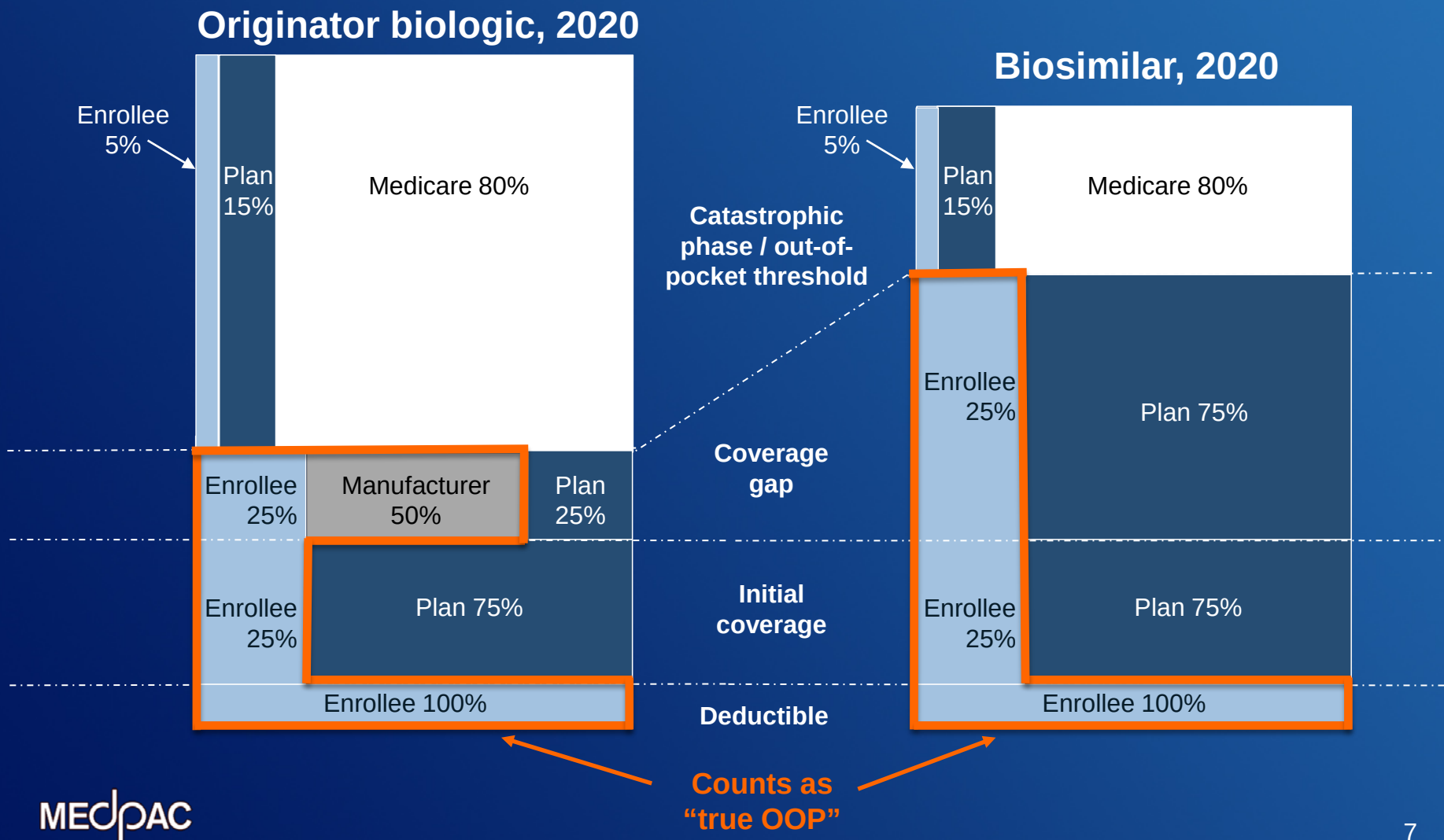
Will biosimilars be used by Part D enrollees?

- 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

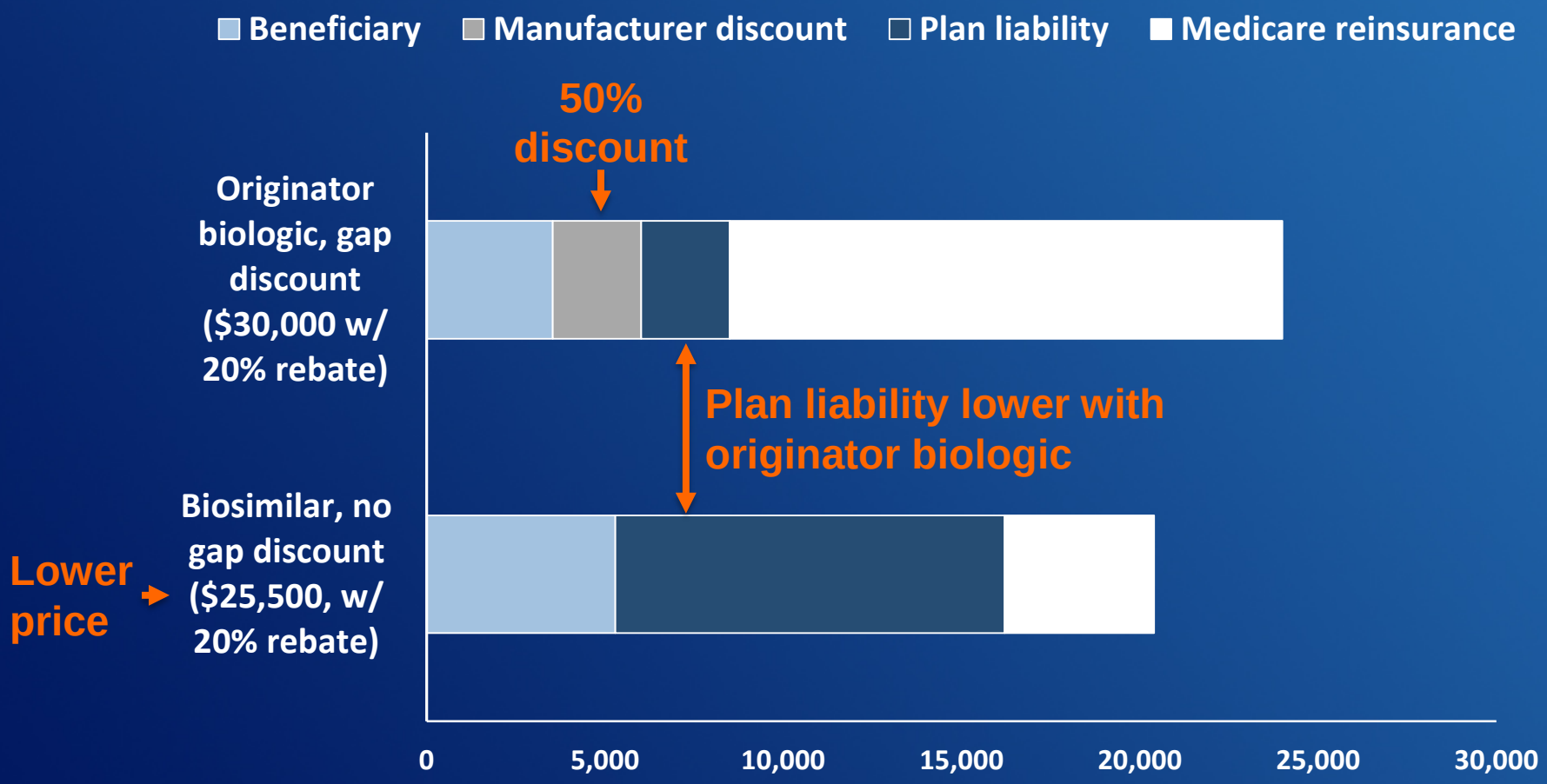
➔Plans may want to include originators on their formularies

➔Beneficiaries may have higher cost sharing with biosimilars

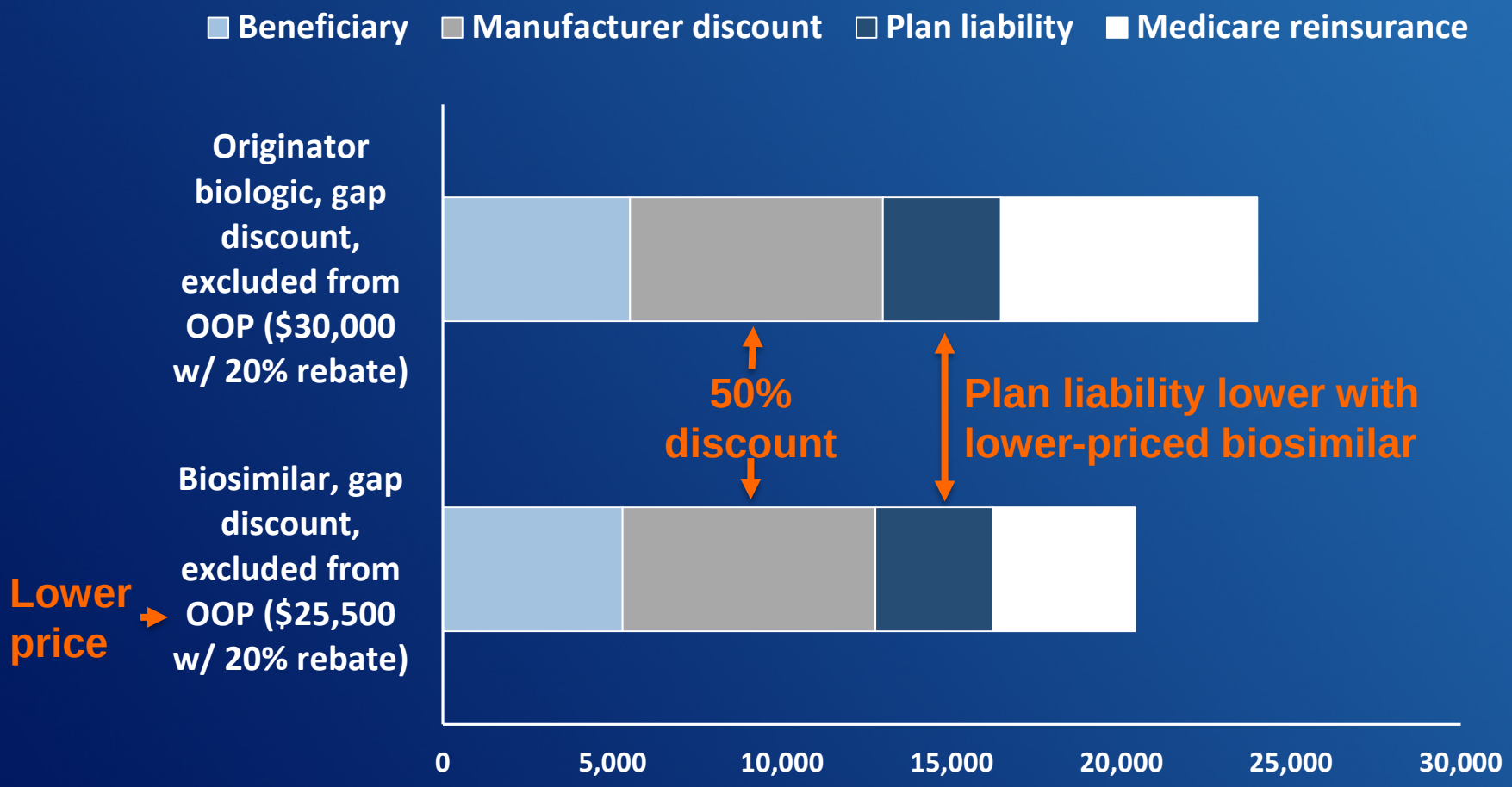
Coverage-gap discount currently favors originator biologics



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



Policy option improves price signals



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Applying coverage-gap discount to biosimilars would align incentives

	Current law		Under policy option		
	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*	
Originator biologics	✓	*yes*	✓	*no*	*≈75%*
Biosimilars	*N/A*	*N/A*	✓	*no*	

Note: OOP (out of pocket), N/A (not applicable). The estimated share of gross spending is based on 2015 Part D prescription drug event data. Data are preliminary and subject to change.

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*