Analysis of Part D data on drug rebates and discounts

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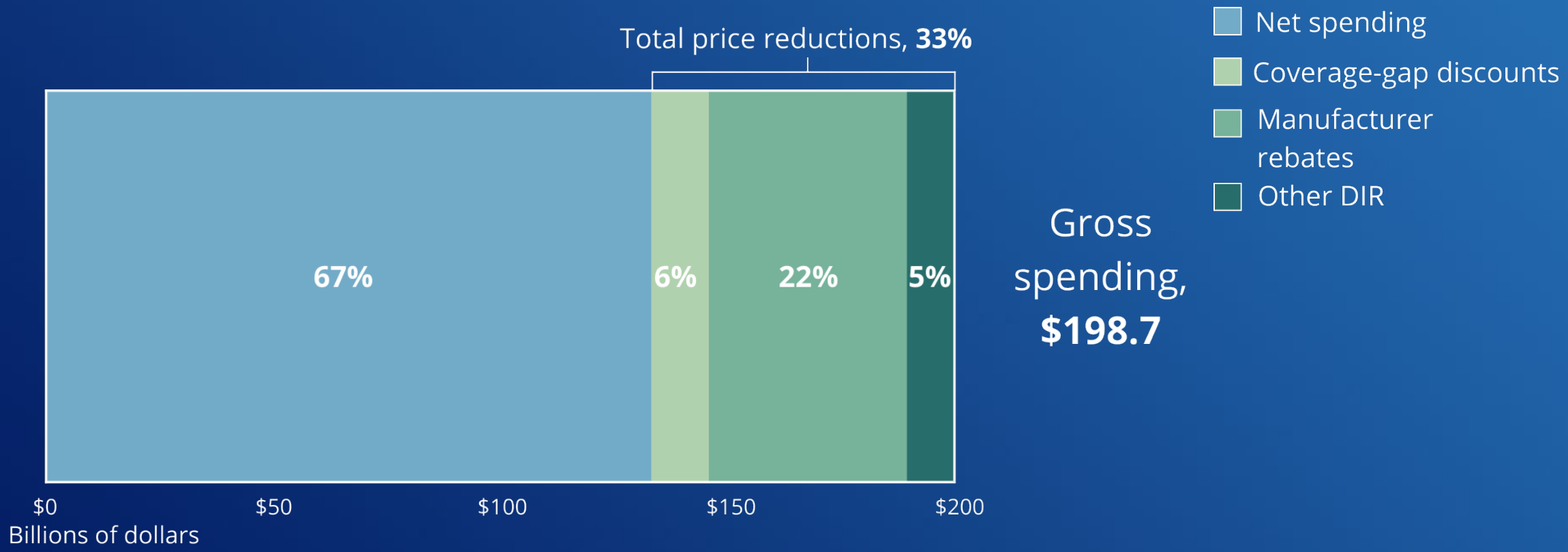
MEDPAC

In 2020, mandated and negotiated price concessions totaled 33 percent of gross Part D spending



Note: DIR (direct and indirect remuneration). Data are preliminary and subject to change. Gross spending refers to prescription spending at the point of sale. Coverage-gap discounts are mandated price concessions provided by manufacturers of prescriptions for brand-name drugs filled in the coverage-gap phase. Other DIR consists primarily of postsale payments from pharmacies to plan sponsors and their PBMs.

Source: MedPAC analysis of prescription drug event data and DIR data.

Two main types of DIR: Rebates and postsale pharmacy fees

How plan sponsors apply their share of DIR has inherent tradeoffs

- CMS retains a share of DIR to reflect price concessions on Medicare's reinsurance payments
- Plan sponsors typically use the rest to keep premium growth lower, which benefits all, including Medicare
- However, there are tradeoffs:
  - Disproportionately high cost sharing on rebated drugs paid by certain enrollees and Medicare's LIS
  - Higher Medicare reinsurance

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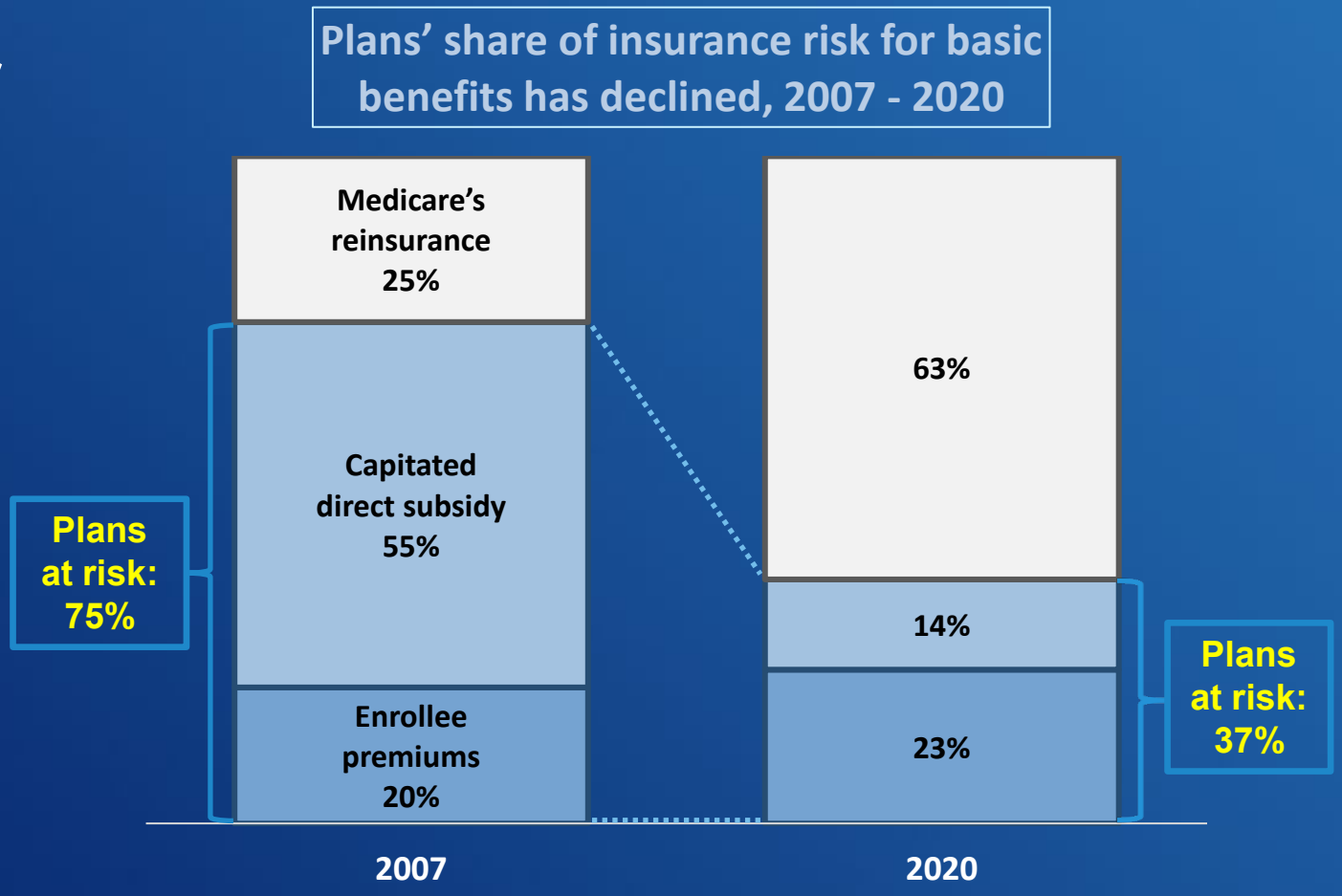
Note: DIR (direct and indirect remuneration), LIS (low-income subsidy).

Part D has incentives to maximize rebates

- Private plans compete for enrollees, largely based on premiums
- Plan sponsors' share of financial risk for benefit spending is small or absent in certain benefit phases



Note: DIR (direct and indirect remuneration).

Source: MedPAC analysis based on Table IV.B10 of 2021 annual report of the Boards of Trustees of the Medicare trust funds.

Other factors that have contributed to growth in DIR

- Case studies of three drug classes with large and growing rebates showed strong brand-brand rivalry but little or no generic or biosimilar entry
- Consolidation of plan sponsors and vertical integration with pharmacy benefit managers has increased bargaining leverage for manufacturer rebates and pharmacy fees

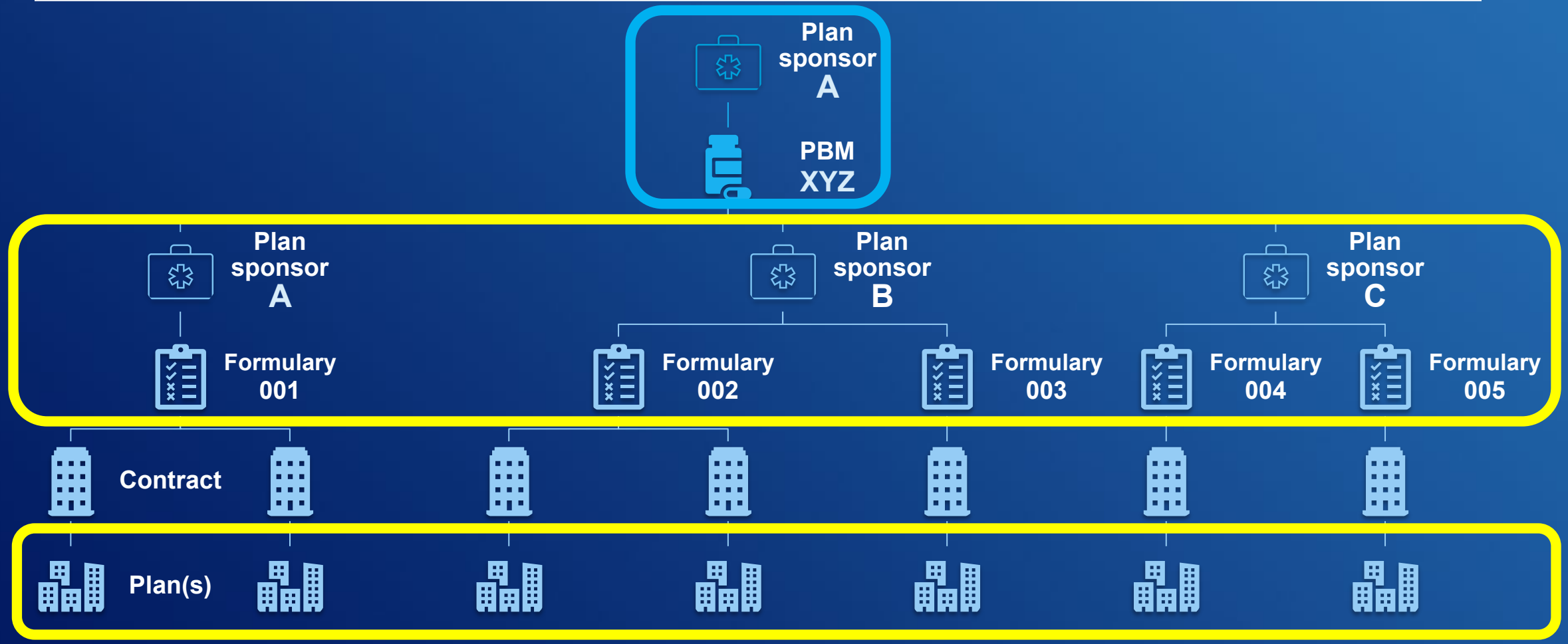
Note: DIR (direct and indirect remuneration).

Analysis of the 2020 DIR data for 30 brand-name drugs

- From 10 categories of drugs with a varying degree of brand-brand competition
  - One category each from antineoplastics, anticoagulants, and anti-rheumatoid drugs
  - Three categories of asthma/COPD therapies
  - Four categories of diabetic therapies
- Average rebates ranged from <10% for antineoplastics to ≥50% for diabetic therapies
- Analysis based on average rebate amount per standardized prescription

Note: DIR (direct and indirect remuneration), COPD (chronic obstructive pulmonary disease).

Differences in organizational structure may contribute to variation in DIR



Note: DIR (direct and indirect remuneration), PBM (pharmacy benefit manager).

Source: MedPAC depiction of a hypothetical structural relationships among entities involved in providing the Part D benefit.

Analysis of the 2020 DIR data: Rebates received for the same product can vary widely

- Among the six largest plan sponsors, the median rebate ranged as much as 2.5 times
- Rebates for a given product can vary widely even among plans operated by the same sponsor
  - Large sponsors tend to use multiple formularies
  - Use of different formularies could explain why rebates vary among plans operated by the same sponsor

Note: DIR (direct and indirect remuneration), TNF (tumor necrosis factor).

Analysis of the 2020 DIR data: Plans using the same formulary may face widely divergent costs

- Plans using the same formulary tended to receive similar rebates, BUT
  - We found instances where large differences remained
  - The extent of the variation differed across plan sponsors, individual formularies, and by product

➔Net-of-rebate cost of a given product may vary widely even among plans using the same formulary

➔Implications for cost sharing paid by beneficiaries and Medicare's low-income cost-sharing subsidy

Note: DIR (direct and indirect remuneration).

Analysis of the 2020 DIR data: For drugs with high rebates, cost sharing can exceed plans' net costs

- For the six largest plan sponsors, cost sharing for some products exceeded 50% of plans' net-of-rebate costs
- In some cases, cost sharing exceeded plans' total net costs:
  - Plans did not incur any benefit costs for these prescriptions
  - Beneficiaries and Medicare's LIS *paid more than the total cost of the drug*
  - In many instances, the highest cost sharing involved LIS enrollees, where Medicare paid most of the cost sharing

Note: DIR (direct and indirect remuneration), COPD (chronic obstructive pulmonary disease).

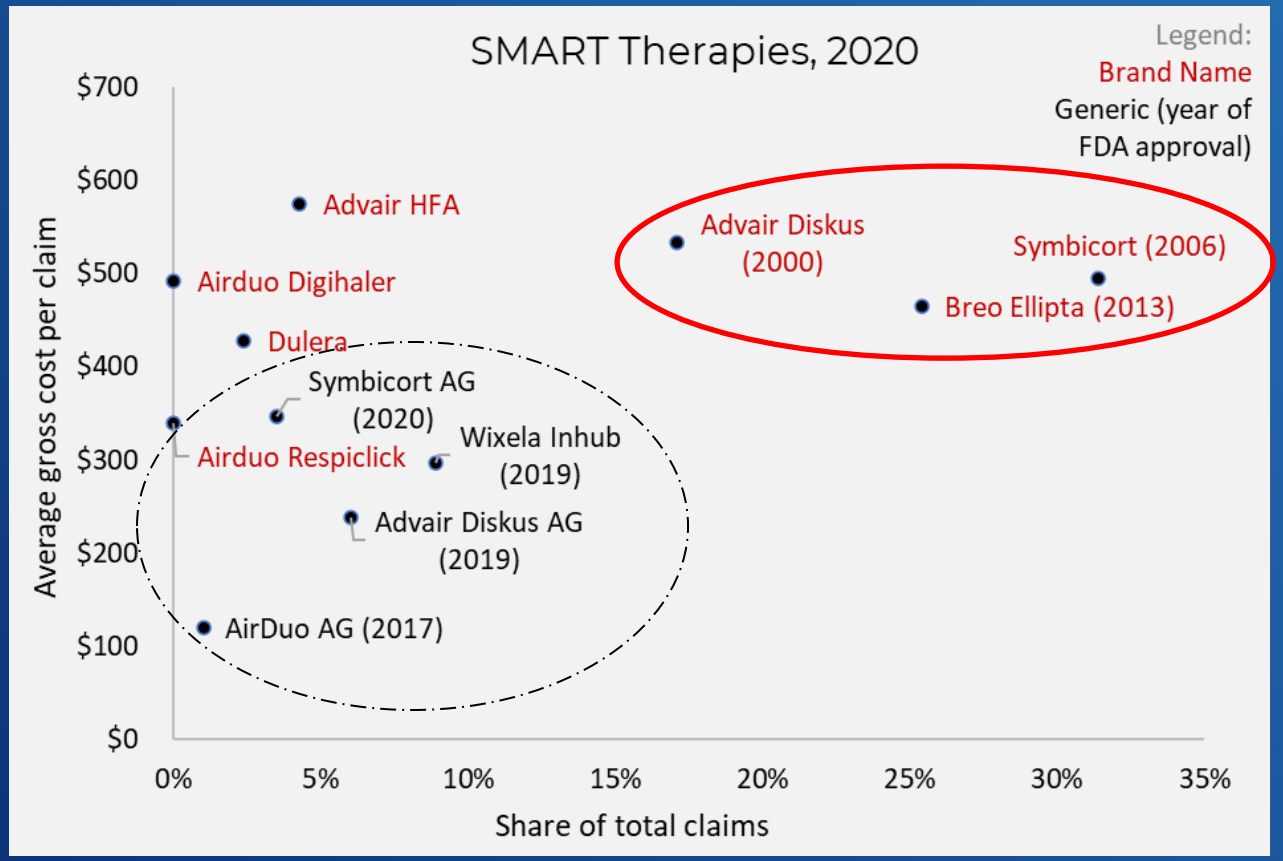
Case study: Asthma and COPD medications

- Rebates as a share of gross spending are estimated to have grown substantially:
  - ~30% in 2016
  - 40% to 49% in 2020
- Significant brand-brand competition
  - In a majority of the subclasses, brand-name products accounted for 75% or more of Part D claims in 2020
- Unique characteristics create regulatory hurdles that may inhibit generic entry
  - Drug-device combination products
  - Large numbers of patents

Note: COPD (chronic obstructive pulmonary disease).

Brand-name asthma/COPD products have higher prices, but still maintained market share over generics in 2020

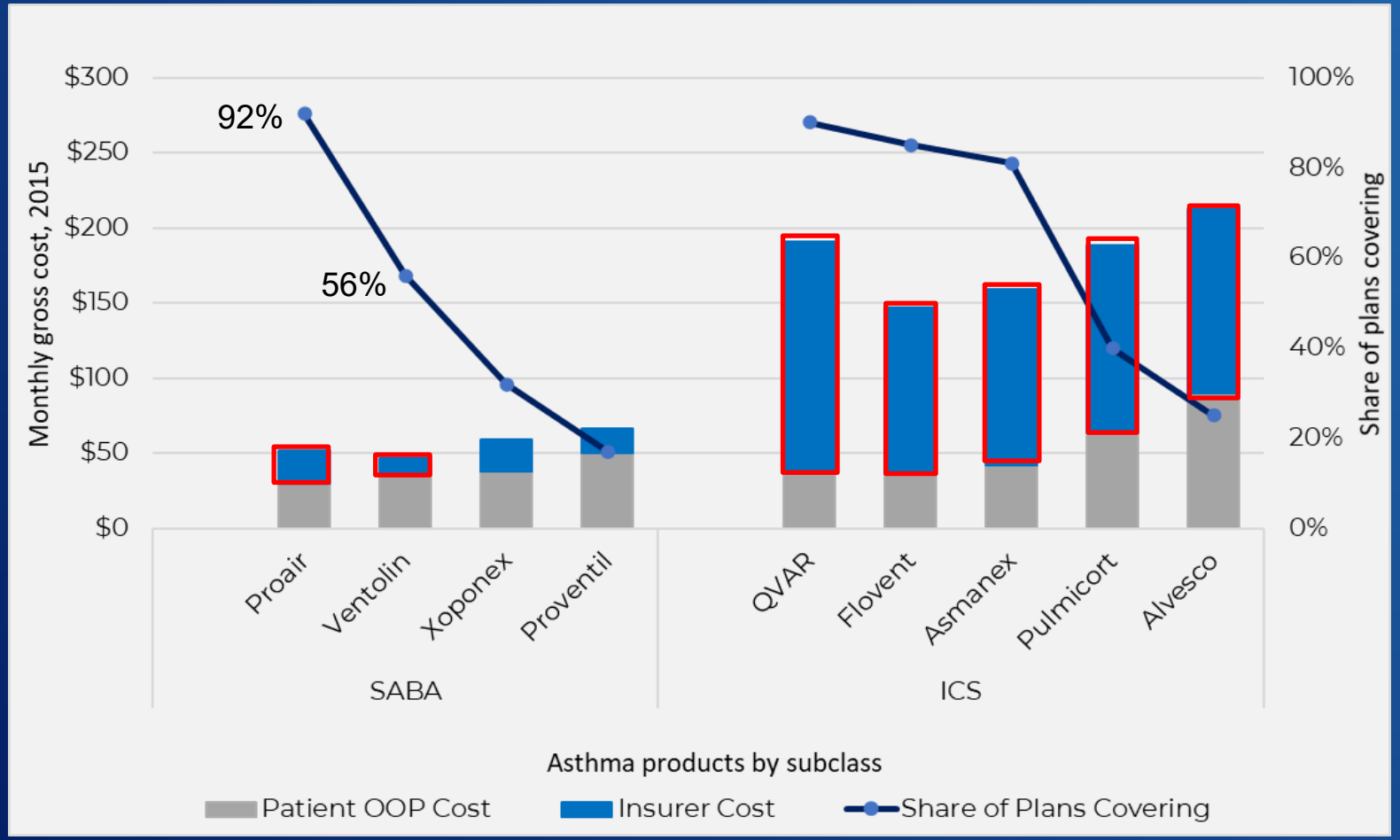
- Long-standing competition among brand-name products
- Generics (and authorized generics) have only recently come to market
- Gross prices for brand-name products have grown ~8% annually since 2012
- Indicates competition is happening via rebates rather than list prices



Notes: AG (authorized generic), SMART (single maintenance and reliever therapies). Branded products shown in red, generics in back. Authorized generics are products manufactured by or on behalf of the same manufacturer as the branded product, but without the branded product's name and labeling.

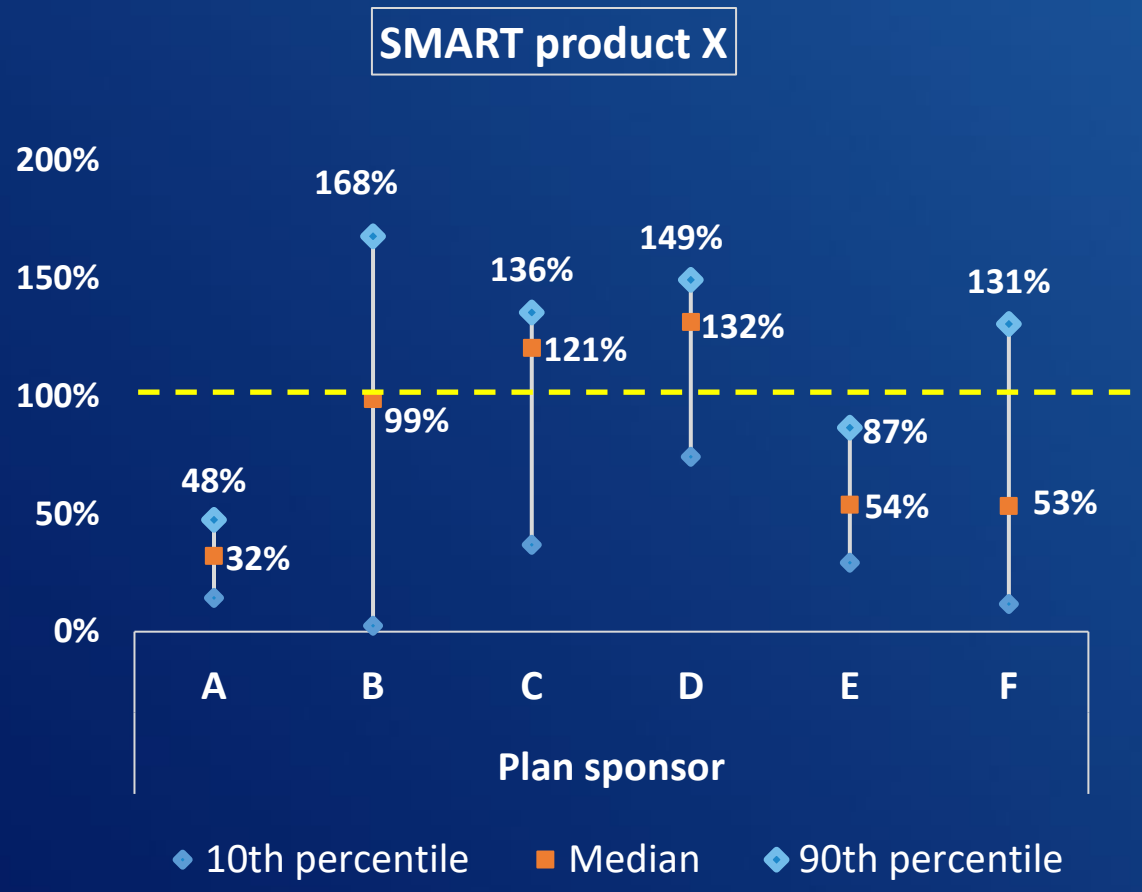
Source: MedPAC based on CMS Drug Spending Dashboard.

Formulary coverage decisions also suggest competition is not based on point-of-sale price (2015)



Notes: SABA (short-acting beta agonist), ICS (inhaled corticosteroid),, OOP (out-of-pocket).
Source: MedPAC based on Tseng, C., J. Yazdany, R. Dudley, et al. 2017. Medicare Part D plans' coverage and cost-sharing for acute rescue and preventive inhalers for chronic obstructive pulmonary disease. JAMA Internal Medicine. https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2603488

Cost sharing for asthma/COPD products varies widely across sponsors' plans (2020)



- Median cost sharing often exceeded 50% of plans' net costs and sometimes exceeded 100%
- When cost sharing exceeds plans' net cost, plans bear no cost for the product and may earn a profit on that drug
- Observed similar patterns among other products

Note: COPD (chronic obstructive pulmonary disease), SMART (single maintenance and reliever therapy). Data are preliminary and subject to change.
Source: MedPAC analysis of Part D prescription drug event and direct and indirect remuneration data from CMS.

Summary of initial findings

- Wide variation in rebates, sometimes even among plans using the same formulary
- For highly rebated drugs, cost sharing can exceed plans' net costs
  - Beneficiaries and Medicare may pay more than drugs' costs to the plans
- Factors contributing to large rebates may vary widely across drug classes and products and likely evolve over time

Considerations of a changing landscape

- Drug pricing provisions of Inflation Reduction Act may affect rebates
  - Part D benefit redesign
  - Inflation rebates
  - Price negotiation
- Our DIR analysis provides a baseline for evaluating these and other changes

Next steps and discussion

- Analyze other years of data to better understand the relationship between rebates and changes in competitive dynamics
- Examine rebates for drugs affected by specific policies, such as protected classes or specialty-tier drugs
- Focus on understanding the potential implications for beneficiaries and Medicare program spending