Assessing postsale rebates for prescription drugs in Medicare Part D

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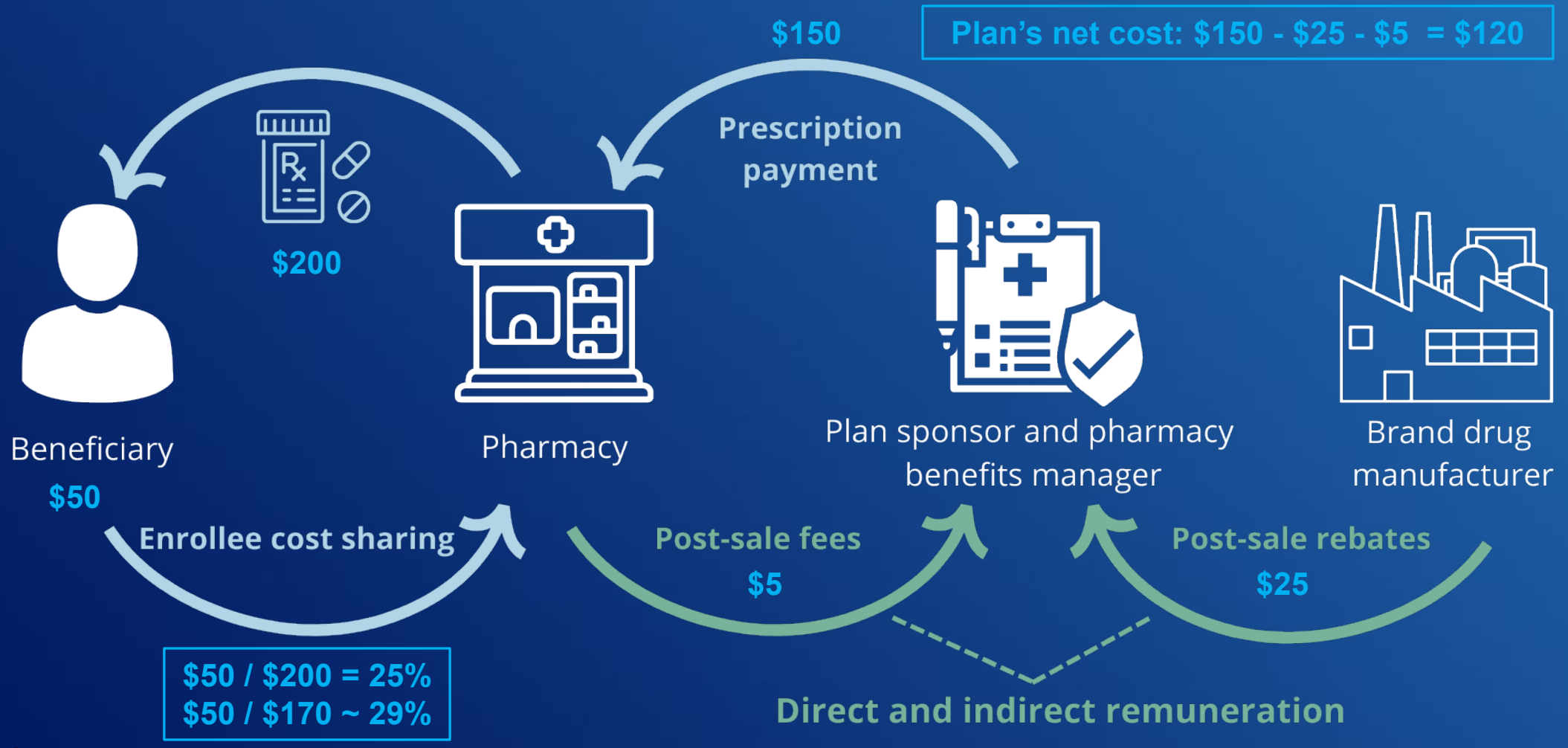
Considerations of a changing landscape

- Drug pricing provisions of the Inflation Reduction Act of 2022 may affect negotiated drug rebates
  - Part D benefit redesign
  - Mandatory inflation rebates
  - Price negotiation
- Our analysis of direct and indirect remuneration (postsale manufacturer rebates and pharmacy fees) provides a baseline for evaluating these and other changes

Two main types of DIR: Postsale rebates and 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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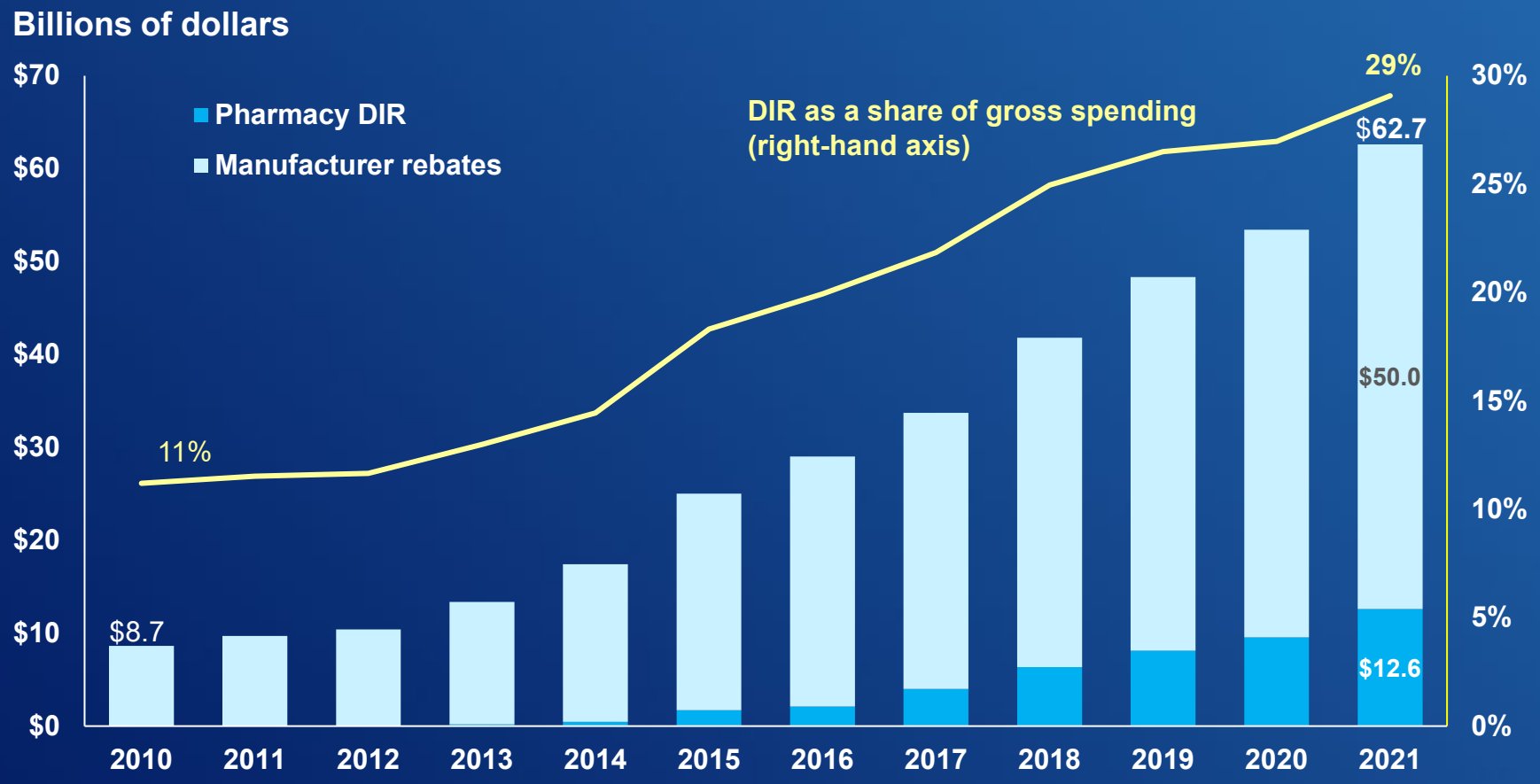
Note: DIR (direct and indirect remuneration), LIS (low-income subsidy).

DIR expanded rapidly in Part D, 2010-2021



Note: DIR (direct and indirect remuneration). Gross spending includes enrollee cost sharing and plan (and any other) payments to the pharmacy at the point of sale. Pharmacy DIR consists of net postsale payments from pharmacies to plan sponsors and their pharmacy benefit managers. Data are preliminary and subject to change. Totals may not sum due to rounding.

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

Factors that have contributed to growth in DIR

- Part D's benefit structure and emphasis on premium competition
- Competition among brand products and Medicare formulary policies
- Plan sponsors with vertically integrated PBMs gained market share and negotiating leverage

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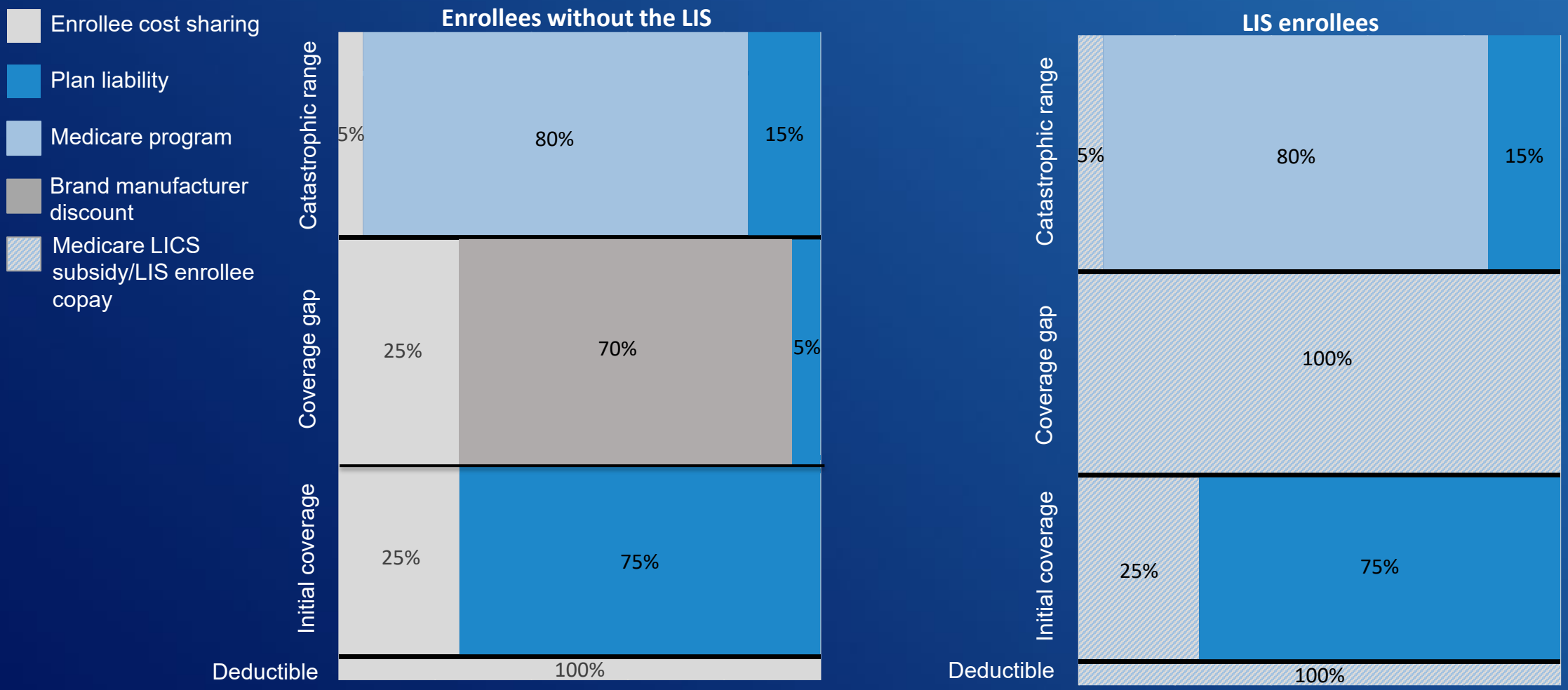
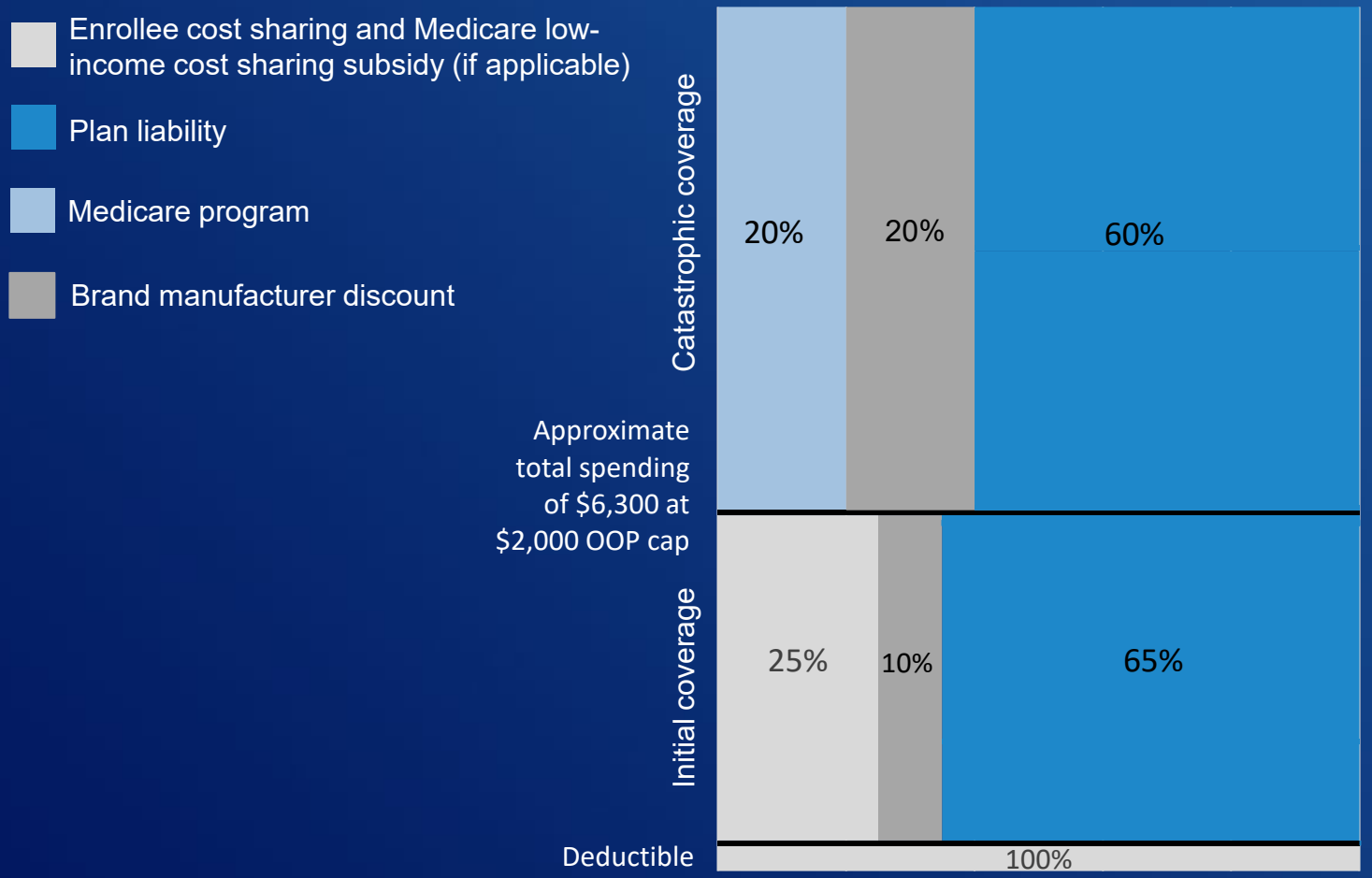
Note: DIR (direct and indirect remuneration), PBM (pharmacy benefit manager).

Part D's benefit structure and emphasis on premium competition created incentives to maximize rebates



Note: LIS (low-income subsidy), LICS (low-income cost-sharing). The coverage gap for beneficiaries without the LIS is depicted as it would apply to brand-name drugs and biologics.

Redesigned Part D benefit structure for all enrollees, effective in 2025



- Hard OOP cap
- Higher plan liability
- Lower Medicare reinsurance
- No coverage gap
- New manufacturer discount

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Note: OOP (out-of-pocket), LIS (low-income subsidy). The standard benefit is depicted as it would apply to brand-name drugs and biologics. For generics, plan sponsors must pay 75% of covered benefits between the deductible and OOP cap. Medicare will pay 40 percent reinsurance above the OOP cap. *For LIS beneficiaries and for certain small manufacturers, the new manufacturer discount program will be phased in over time, reaching final levels by 2031.

Drug classes with brand-brand rivalry and limited generic or biosimilar entry had higher rebates

Therapeutic class ranked by gross Part D spending in 2021		2021			2015
		Gross spending in billions	Negotiated rebates as a share of gross spending	Rank by net spending	Negotiated rebates as a share of gross spending
1	**Diabetic therapies**	**$39.7**	**≥50%**	**2**	30% to 39%
2	Antineoplastics*	28.8	<10%	1	<10%
3	**Anticoagulants**	**18.6**	**40% to 49%**	**3**	10% to 19%
4	**Asthma/COPD therapy agents**	**15.5**	**40% to 49%**	**4**	20% to 29%
5	Disease-modifying anti-rheumatoid drugs	10.4	20% to 29%	5	10% to 19%
6	Antipsychotics*	7.5	10% to 19%	7	<10%
7	Antiretrovirals*	7.3	<10%	6	<10%
	Total all drug classes	215.8	23%		17%

Note: COPD (chronic obstructive pulmonary disease). *Protected class. Data are preliminary and subject to change.
Source: MedPAC analysis of Part D prescription drug event and direct and indirect remuneration data from CMS.

Mandatory coverage of protected classes limited price competition and rebates

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Mandatory coverage of protected classes limited rebate growth over time

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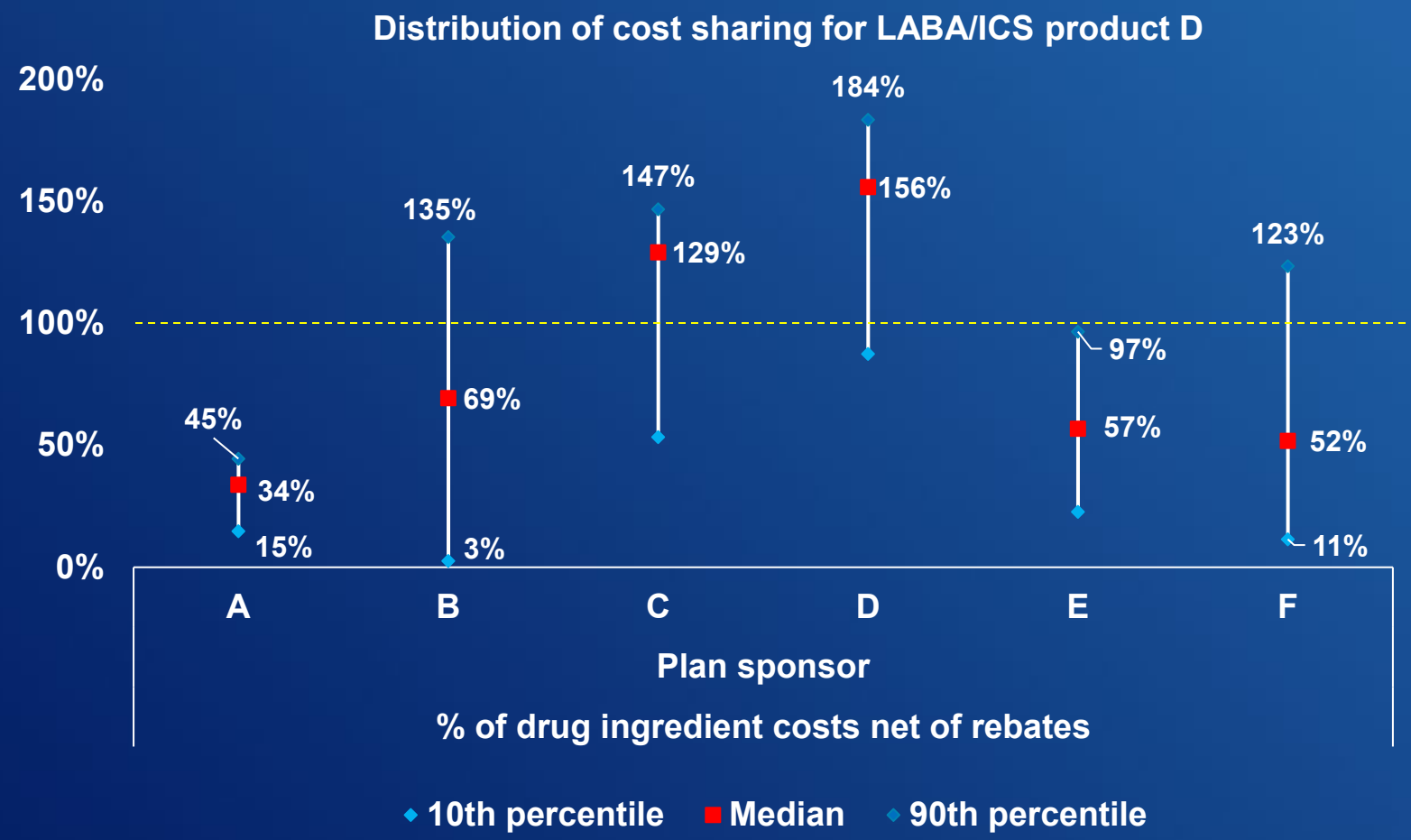
For drugs with high rebates, cost sharing sometimes exceeded plans' net drug ingredient costs, 2021



Note: LABA (long-acting beta agonist), ICS (inhaled corticosteroid). Each vertical line depicts the range of each sponsors' plans' aggregate cost sharing as a share of aggregate ingredient cost net of rebates.

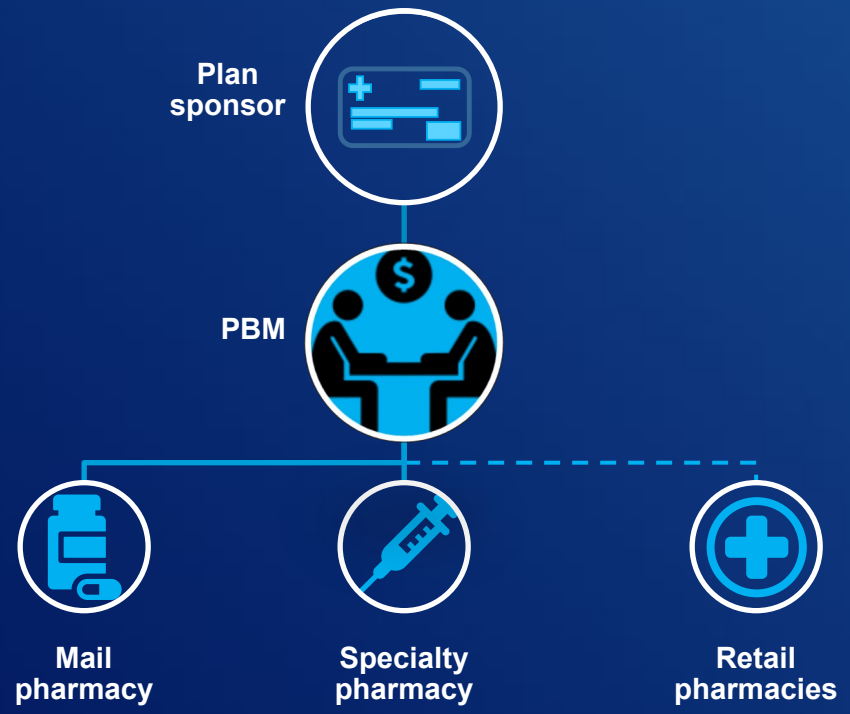
Source: MedPAC analysis of Part D prescription drug event and direct and indirect remuneration data from CMS.

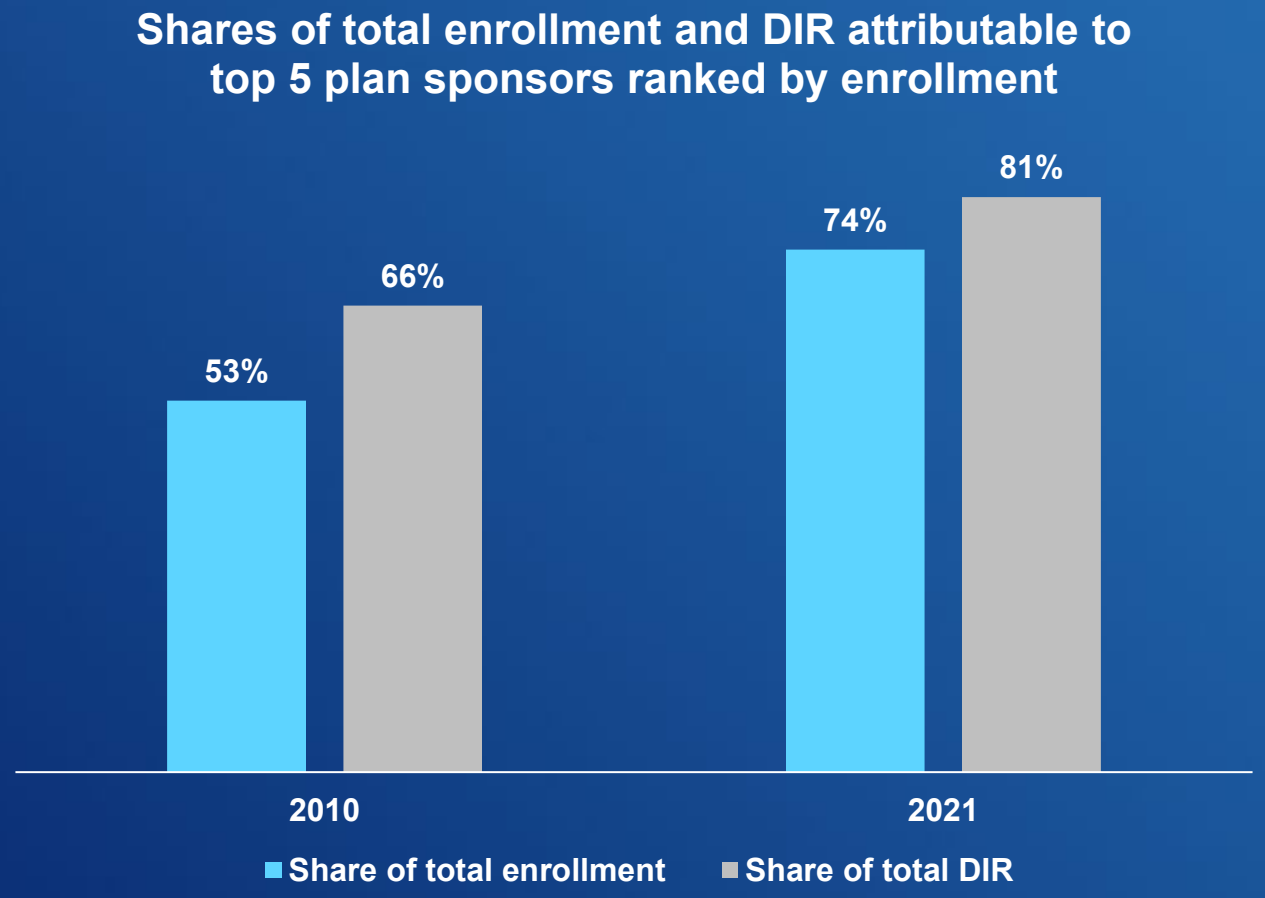
Medicare's LIS paid for most instances in which cost sharing exceeded net drug costs

- In 2021, 8% of gross Part D spending was for drugs in which aggregate cost sharing was greater than aggregate drug ingredient cost net of rebates
- About 75% of prescriptions for those drugs were filled by LIS enrollees (45% of all brand prescriptions were filled by LIS enrollees)
- Medicare's low-income cost-sharing subsidy paid for most of their cost sharing
- For beneficiaries without the LIS, high cost sharing may affect their decision to fill a prescription

Note: LIS (low-income subsidy).

Part D plan sponsors consolidated, became vertically integrated, gained market share and negotiating leverage





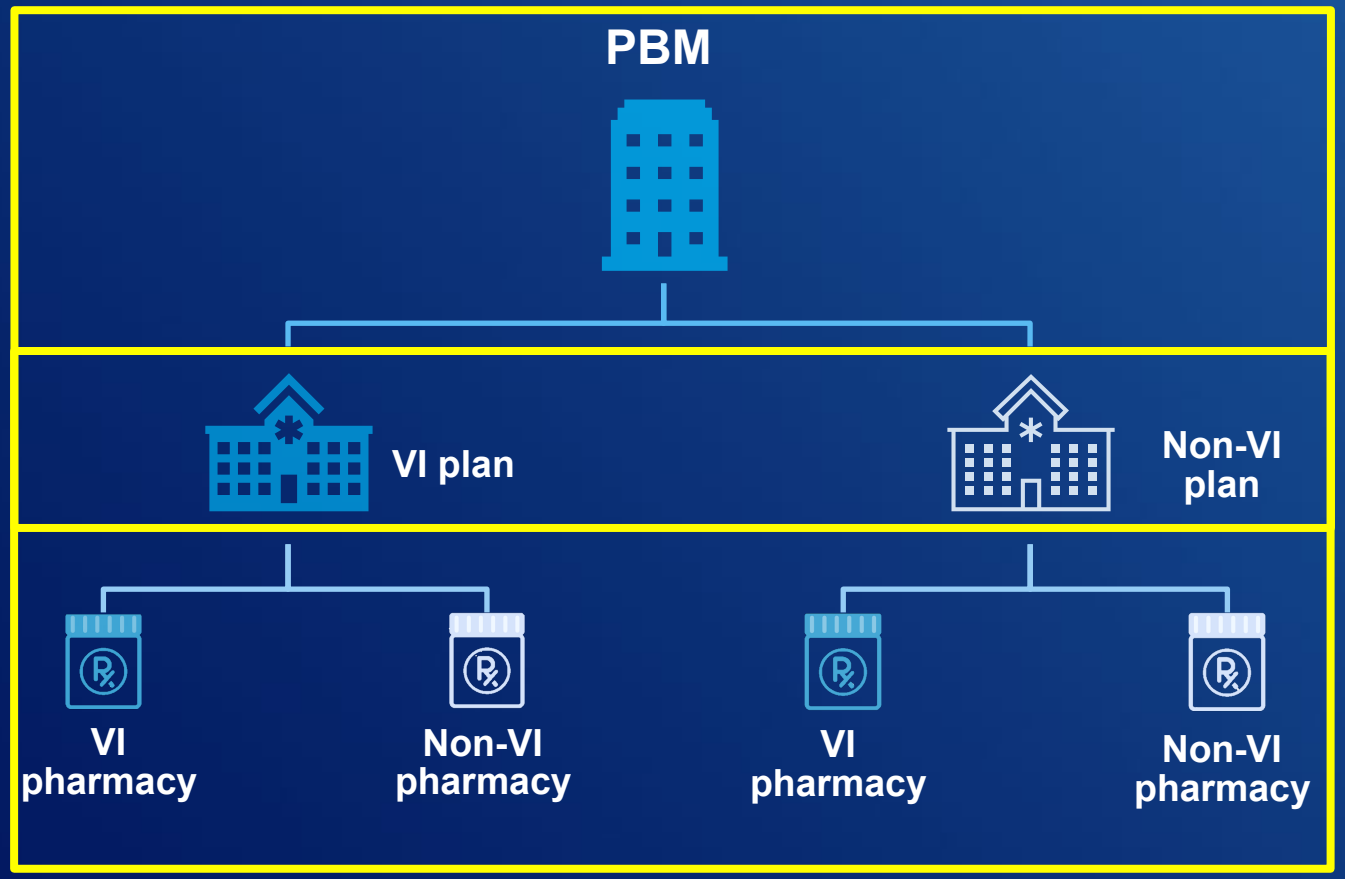
Note: PBM (pharmacy benefit manager), DIR (direct and indirect remuneration). Top 5 plan sponsors by enrollment has changed over time. Data are preliminary and subject to change.

Source: MedPAC analysis of Part D prescription drug event and direct and indirect remuneration data from CMS. Icon by Adioma.

Rebates received by large Part D plan sponsors varied widely

- Examined several drug classes across years
- Wide variation across sponsors reflecting different combinations of plan types and formularies
- Between 2015 and 2021, magnitude of average rebates grew and variation declined in 2 out of 3 classes examined
- Variation was greater across sponsors than within, but was still considerable for some sponsors

Part D prescriptions dispensed at VI pharmacies grew from just over a quarter to about a third, 2015 -2021



- All four major PBMs operate mail and specialty pharmacies
- Three of the four PBMs serve both VI and other (non-VI) Part D plans
- Four types of plan-pharmacy transactions
- Conflicting incentives from vertical integration could raise or lower costs

Note: PBM (pharmacy benefit manager), VI (vertically integrated), DIR (direct and indirect remuneration). *Humana Pharmacy Solutions has only two plan-pharmacy types, "VI plans and VI pharmacies" and "VI plans and other (nonVI) pharmacies", because it only serves its own (Humana) health plans.

Vertical integration may have resulted in higher costs to Part D and their plan enrollees

- Gross payments to pharmacies and net-of-rebate costs were more likely to be:
  - Highest for VI pharmacies filling prescriptions for VI plans
  - Lowest for non-VI pharmacies
- Could indicate that a VI organization may financially benefit from higher payments to their (VI) pharmacies
- No visibility into prices between upstream and downstream entities

Note: VI (vertically integrated). From the analysis of four PBMs (CVS Caremark, Express Scripts, Humana Pharmacy Solutions, and Optum Rx) and six categories of drugs (disease-modifying anti-rheumatoid drugs, multiple sclerosis agents, two categories of antineoplastics, antiretrovirals, and pulmonary antihypertensive therapies).

Key takeaways

- Therapeutic competition and regulatory policies can affect drug pricing and rebates:
  - Larger rebates offered in classes with strong brand-brand rivalry but no generics or biosimilars
  - Mandating coverage of certain drug classes weakened price competition and hindered plans' ability to negotiate rebates
- Tradeoffs associated with using rebates to reduce enrollee premiums: cost sharing for some beneficiaries may exceed a drug's cost net of rebates
  - IRA's OOP cap will help address this issue

Note: IRA (Inflation Reduction Act of 2022), OOP (out-of-pocket).

Key takeaways (cont.)

- Vertical integration may pose a particular challenge for Part D
  - Conflicting interests among the vertically integrated entities may increase costs for Part D and its enrollees
  - CMS may have less insight into prices between upstream and downstream companies

Next steps and discussion

- This material will be included in the June 2023 report
- Serves as a baseline for evaluating changes in pricing and rebates as the provisions of the Inflation Reduction Act are implemented
- Questions?