The Medicare prescription drug program (Part D): Status report

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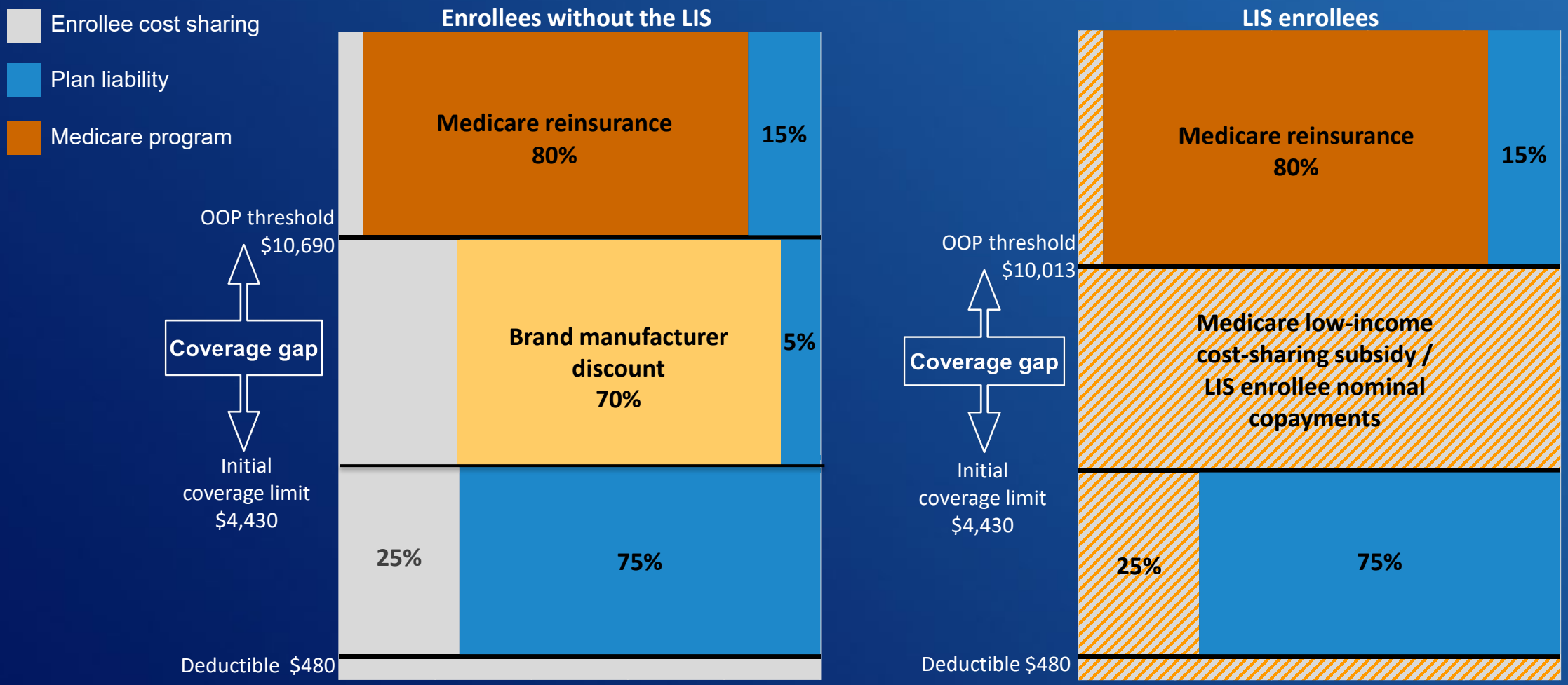
Part D's goals and approach

- Provide beneficiaries with access to prescription drug coverage
- Use a market-based approach:
  - Wide choice among competing stand-alone prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MA-PDs)
  - Program was intended to give plan sponsors tools and financial incentives to manage benefit spending
- Medicare subsidies, risk sharing, and late-enrollment penalty to encourage plan participation and broad enrollment
- Beneficiary protections and low-income subsidy (LIS)

Plan sponsors' role and drug price negotiations

- Plan sponsors accept insurance risk and own or contract for services of a pharmacy benefit manager (PBM)
- Sponsors and PBMs negotiate with:
  - Pharmacies over payments for prescriptions filled, post-sale fees
  - Pharmaceutical manufacturers for rebates on brand-name drugs associated with formulary placement
- By law, Secretary may not interfere with negotiations among drug manufacturers, pharmacies, and plan sponsors, require a particular formulary, or institute a price structure

Plans' financial risk is limited in either of Part D's two distinct standard benefit structures



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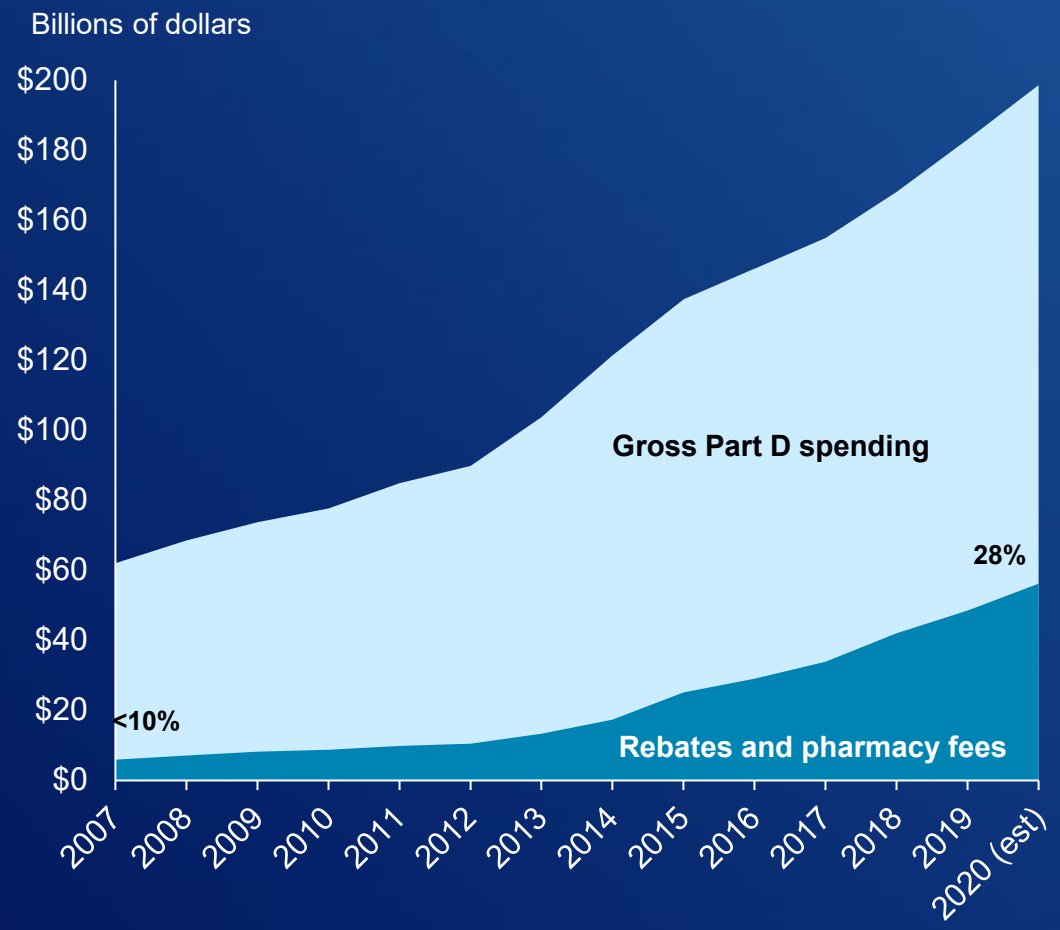
Note: LIS (low-income subsidy), OOP (out-of-pocket). The coverage gap for beneficiaries without the LIS is depicted as it would apply to brand-name drugs and biologics.

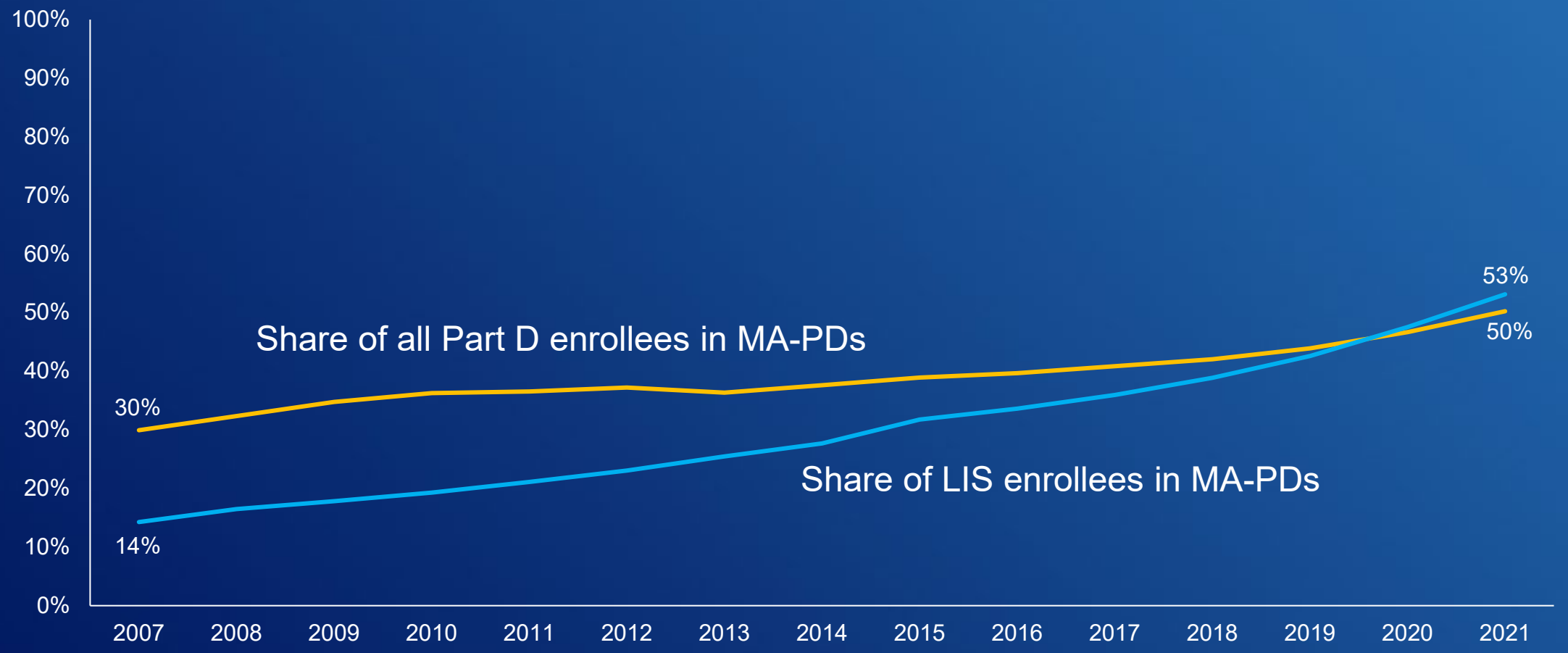
Manufacturer rebates and post-sale pharmacy fees have mixed effects for Part D enrollees



- Used to offset plan liability / lower premiums
- Enrollee deductibles and coinsurance are based on the higher pharmacy prices
- Only modest effects on restraining brand price growth in Part D

Note: Data are preliminary and subject to change.
Source: MedPAC based on Table IV.B.8 of the Medicare Board of Trustees' report for 2021 and Part D prescription drug event data.

Notable trends: Growing share of Part D enrollees in MA-PDs, including LIS enrollees



Note: MA-PD (Medicare Advantage-Prescription Drug [plan]), LIS (low-income subsidy). Data are preliminary and subject to change.
Source: MedPAC based on CMS Part D enrollment data.

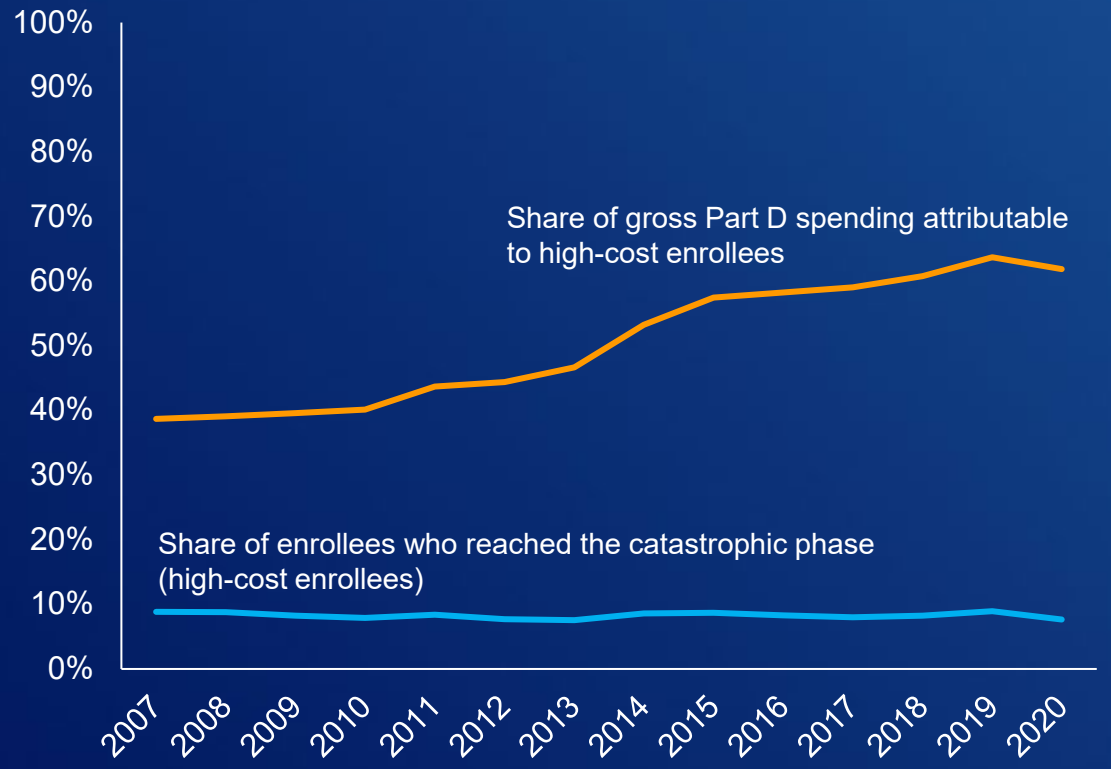
Notable trends: Small decline in 2021 average premium, more 2022 MA-PD plan offerings

- In 2021, average monthly premium decreased by 3% to $26
  - Stable at around $30 per month since 2010, but wide variation
  - Average PDP premium much higher than average MA-PD premium because Part C payment rebates used to pay for Part D benefits
- Plan offerings for 2022:
  - Continued growth in MA-PDs (7%) and SNPs (19%)
  - Sharp decline in PDPs (-23%) and LIS benchmark PDPs (-24%)
    - Due mostly to sponsor mergers
    - Still at least 4 LIS benchmark PDPs in each region of the country

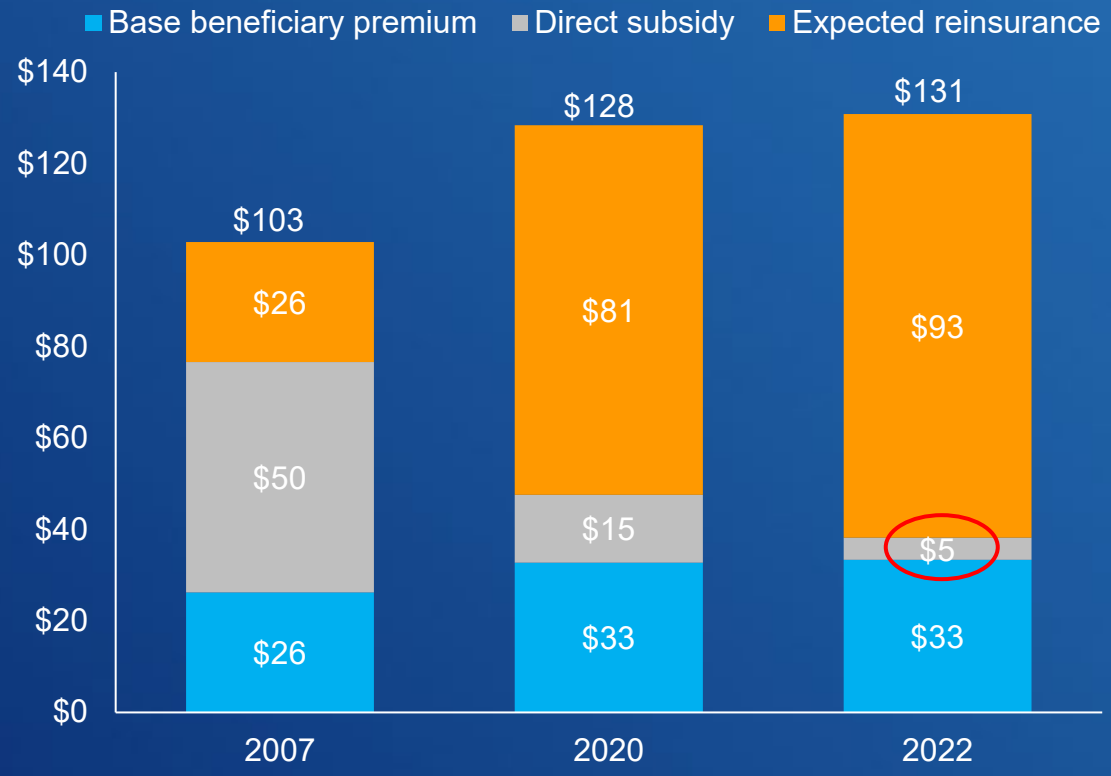
Note: MA-PD (Medicare Advantage-Prescription Drug [plan]), PDP (prescription drug plan), SNP (special needs plan). Data are preliminary and subject to change.

Notable trends: Small share of enrollees who reach catastrophic phase drives overall spending and plan bids

More than 60% of gross spending attributable to 8-9% of enrollees



Cost-based reinsurance dominant source of plan payments



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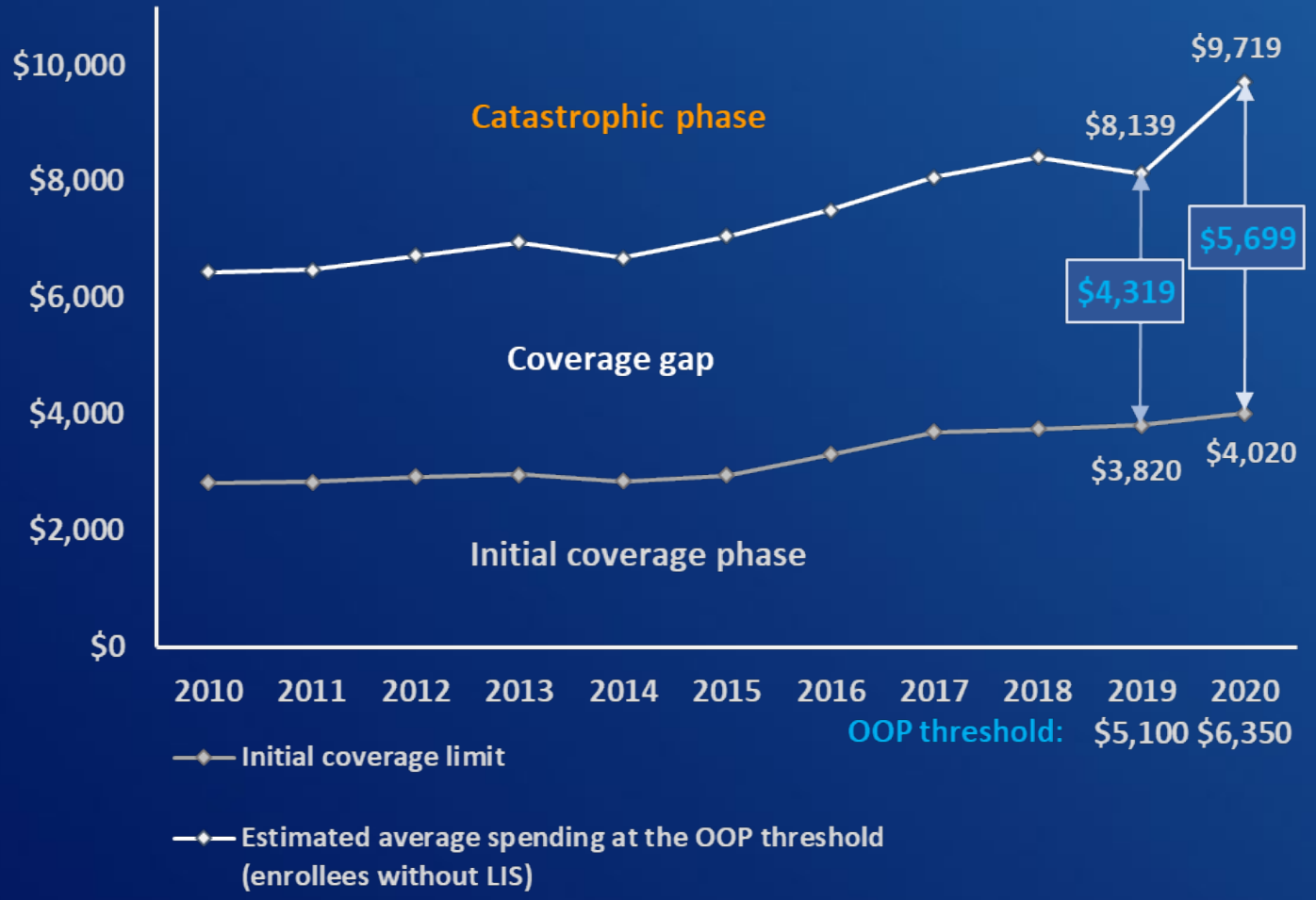
Note: Data are preliminary and subject to change.

Source: MedPAC based Part D prescription drug event data and CMS Part D national average bid amount announcements.

In 2020, statutory increase in the OOP threshold increased spending in the coverage gap



- OOP threshold for 2020 increased by $1,250 (to $6,350 from $5,100 in 2019)
- Higher OOP threshold:
  - Delays the point at which an individual reaches the catastrophic phase
  - Increases spending in the coverage gap where non-LIS enrollees pay 25% coinsurance

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Note: OOP (out-of-pocket), LIS (low-income subsidy). Data are preliminary and subject to change.

Overall, higher OOP threshold does not appear to have affected prescription drug use

- Preliminary data for 2020 shows that:
  - Growth in per capita prescription drug use was in line with recent trends
  - Many continued to fill brand-name drugs in the coverage gap (total coverage-gap discounts increased by 25%)
- Number of high-cost, non-LIS enrollees (1.3 million) was higher than in all years prior to 2019
- 443,000 beneficiaries filled at least one prescription for which a single claim is sufficient to reach the catastrophic phase

Note: LIS (low-income subsidy). Data are preliminary and subject to change.

Steep rise in the OOP threshold in 2020 slowed the growth in reinsurance while increasing LIS costs

Program spending category	Spending in billions			Average annual growth	
	2007	2019	2020	2007-2019	2019-2020
Direct subsidy*	$17.6	$11.8	$10.2	-3.3%	-13.6%
Reinsurance	8.0	46.1	47.8	15.7%	3.7%
Low-income subsidy	16.7	29.7	33.1	4.9%	11.4%
Retiree drug subsidy	3.9	0.6	0.6	-14.4%	0%
Medicare total	$46.2	$88.4	$91.7	5.5%	4.0%

- **Higher OOP threshold increases spending in the coverage gap, which is primarily paid by:**
  - **Medicare** (low-income cost-sharing subsidy)
  - **Manufacturers** (coverage gap discount)
  - **Enrollees** (cost sharing)

Note: *Net of Part D risk-corridor payments. Data are preliminary and subject to change.
Source: MedPAC based on Table IV.B.10 of the Medicare Board of Trustees' report for 2021.

High cost sharing could be a barrier to access for non-LIS beneficiaries

- >80% satisfied with their plans and cost sharing*
- However, for non-LIS beneficiaries, *coinsurance* on high-priced drugs and biologics may make them unaffordable
- CMMI is testing a model to cap cost sharing for insulins at $35
  - May improve access to insulins, but does not address structural issues contributing to high prices
  - As prices continue to rise, many more will face affordability issues
- Need to balance access with effective tools for plans to manage drug use and spending

Note: LIS (low-income subsidy), CMMI (Center for Medicare & Medicaid Innovation). *Medicare Today senior satisfaction survey 2021.

In 2020, prices remained stable but low generic prices may be less effective at restraining future price growth

	Price index as of December*		Average annual change		
	2019	2020	2006-2018	2018-2019	2019-2020
All drugs and biologics	1.91	1.96	5.3%	2.6%	2.6%
Single-source brand-name drugs	3.55	3.74	10.6%	5.7%	5.2%
Generic drugs	0.15	0.14	-13.7%	-11.0%	-9.3%
After accounting for generic substitution	1.11	1.13	1.1%	-2.1%	1.3%

- Generics' share of prescriptions have plateaued at about 90% since 2017
- Prices of brand-name drugs are much higher, averaging 38x that of generics in 2020, up from 6x in 2007
- Generic or biosimilar alternatives may not be available due to longer market exclusivity periods and/or extensive patent protection

Note: LIS (low-income subsidy). Prices reflect point-of-sale prices before accounting for postsale rebates and discounts. *Relative to prices as of January 2006. Data are preliminary and subject to change.

Source: Acumen, LLC, analysis for MedPAC.

Part D faces multiple challenges in creating effective biosimilar competition

- Rebates may distort plans' formulary incentives to prefer reference biologics with higher prices
  - Use of follow-on insulins lag Medicaid
  - E.g., in 2019, Basaglar* market share was 17% vs. 52% for Medicaid
- Extensive patent protection has delayed entry of biosimilars
  - E.g., Seven FDA-approved Humira biosimilars will not launch until at least 2023**
- Manufacturer tactics may reduce market for biosimilars
  - E.g., a *new* formulation of Humira was launched in July 2018. It rapidly gained market share, and by 2020, accounted for 61% of all Humira products sold under Part D

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Note: *Basaglar was approved in 2014 as a follow-on biologic to Sanofi's Lantus and has been available in the U.S. since December 2016. **Humira was first approved in December 2002 and launched in 2003 for the treatment of rheumatoid arthritis. Rather than challenge patents in courts, Humira biosimilar manufacturers agreed to launch no earlier than 2023. Data are preliminary and subject to change.

Plans' focus on post-sale rebates and pharmacy fees contributes to misaligned incentives

- Plans benefit from high-priced drugs with rebates because:
  - **COSTS** are mostly borne by Medicare (reinsurance and low-income cost-sharing subsidy), brand manufacturers (coverage gap discount), and enrollees, *while*
  - **REBATES** disproportionately accrue to plans
- Plans' share of benefit liability (at risk) continued to decline
  - Less than 37% in 2020, down from 75% in 2007
  - In 2020, two-thirds of all post-sale rebates and pharmacies fees were used to offset plan liability

Note: DIR (direct and indirect remuneration). Data are preliminary and subject to change.

Commission's 2020 recommendations to improve Part D

- Address distortions in plan incentives created by rebates and discounts that increase Medicare's costs
  - Eliminate coverage-gap discount
  - Increase plan liability in the coverage gap and the catastrophic phase of the benefit
- Address high prices and high cost sharing
  - Manufacturer discount in the catastrophic phase
  - Complete insurance protection in the catastrophic phase
- Reduce plans' reliance on cost-based reinsurance to improve incentives to manage benefits

Discussion

- Questions or feedback on draft chapter for the March 2022 report to the Congress

- Upcoming work (Spring 2022):
  - PDP market segmentation
  - Initial results from the analysis of Part D's direct and indirect remuneration and other pricing data