

Advising the Congress on Medicare issues

The Medicare prescription drug program (Part D): Status Report Tara Hayes and Shinobu Suzuki January 11, 2024

Presentation roadmap

- $\begin{pmatrix} 1 \end{pmatrix}$ Background and basic information
- (2) Enrollment trends and plan offerings
- (3) Program costs
- $\left(oldsymbol{4}
 ight)$ Upcoming changes to the Part D program
- (5) Beneficiary access and program quality
- 6 Discussion

In Part D, private plans compete to deliver outpatient pharmacy benefits to enrollees

- Plan sponsors accept insurance risk and own or contract for services of a pharmacy benefit manager (PBM)
 - Stand-alone PDPs available for FFS beneficiaries
 - MA-PDs for Medicare Advantage beneficiaries
- Sponsors and PBMs negotiate with:
 - Pharmacies for prescription payments
 - Pharmaceutical manufacturers for rebates on brand-name drugs
- Enrollees pay premiums based on plan bids reflecting their expected costs
- Medicare facilitates plan and enrollee participation
 - Premium subsidies, a low-income subsidy, a late-enrollment penalty, and other protections encourage beneficiary enrollment
 - Risk sharing (reinsurance, risk adjustment, and risk corridors) encourages plan participation

Note: PBM (pharmacy benefit manager), PDP (prescription drug plan), FFS (fee for service) MA-PD (Medicare Advantage-Prescription Drug [plan]).

Part D Basics



Plans available, 2024

709 PDPs; 3,500+ MA-PDs; 1,300+ SNPs



Enrollees, 2023

51.5 million (78%)



Program spending, 2022

\$101.9 billion



Premiums, 2022

\$15.4 billion



Enrollee OOP spending, 2022

\$18.5 billion

Note:

PDP (prescription drug plan), MA-PDs (Medicare Advantage-Prescription Drug [plan]), SNP (special needs plan), OOP (out of pocket).

Snapshot of the Part D program



Enrollment 2023

- Growing share of Medicare beneficiaries
- Continued shift towards MA-PDs
- Steady share of LIS enrollees
- Average premium stable around \$30 per month



Plan availability 2024

- Slight drop in number of conventional MA-PDs
- More SNPs
- Fewer PDPs and benchmark plans
- All regions have at least 2 premium-free PDPs



Program costs 2022

- Up 7.5% from 2021
- Cost-based payments accounted for most program spending
- More beneficiaries reached the catastrophic phase than in 2021



Access and quality 2021/2022

- Overall, high program satisfaction
- A majority describe their plan as a good value and convenient to use
- Access issues due to high-cost drugs likely to be lessened by OOP cap

Note:

MA-PD (Medicare Advantage-Prescription Drug [plan]), LIS (low-income subsidy), SNP (special needs plan), PDP (prescription drug plan), OOP (out of pocket).

Enrollment continued to shift towards MA-PDs, particularly among LIS beneficiaries

		2019	2023	Average Annual Change (2019- 2023)
Total enrollment in Part D plans (millions)		45.4	51.5	3%
	As a share of total Medicare enrollment	74%	78%	
Part D plan enrollment, by plan type (millions)				
	PDP	25.5	22.5	-3%
	MA-PD	20.0	29.1	10%
LIS enrollment (millions)				
	PDP	7.3	5.2	-8%
	MA-PD	5.4	8.6	12%

- Share of beneficiaries enrolling in Part D continues to grow
 - 78% of all Medicare beneficiaries
 - Up from 77% in 2022
- Enrollment continues to shift toward MA-PDs for both LIS and non-LIS
 - 56% of all enrollees in MA-PDs
 - 62% of LIS enrollees in MA-PDs
 - LIS are primarily moving into D-SNPs

Note:

PDP (stand-alone prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]), SNP (special needs plan), LIS (low-income subsidy). Enrollees in

employer group waiver plans included in these figures.

Source:

MedPAC tabulations of CMS enrollment data.

Outside of SNPs, most enrollees chose enhanced coverage in 2023

	PDP	SNP	
		MA-PD	3141
Total (millions)	18.5	18.9	5.6
Type of coverage			
Basic	42%	<1%	70%
Enhanced	58	99	30
Type of deductible			
Zero	14%	76%	6%
Reduced	11	22	4
Defined standard	75	2	90

- PDP and MA-PD enrollees much more likely to be in enhanced plans
 - Enhanced plans often offer reduced deductibles and additional coverage in the coverage gap; may have lower premiums
- SNP enrollees are primarily in basic plans
 - 90% of SNP enrollees are LIS
 - LIS enrollees' limited cost sharing makes a reduced deductible and other financial incentives less attractive
 - The LIS only covers basic (not supplemental) premium costs

Note: SNP (special needs plan), PDP (stand-alone prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]), LIS (low-income subsidy). Enrollees in employer

group waiver plans excluded from these figures.

Source: MedPAC tabulations of CMS landscape and enrollment data.

Growth in plan offerings strongest among MA-PDs, particularly SNPs, in 2024

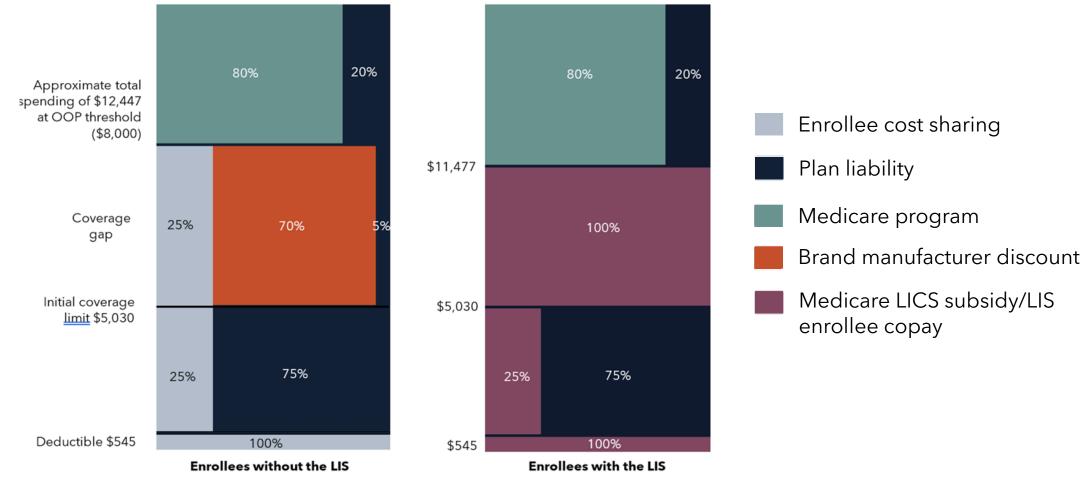
- Number of MA-PDs has grown 9.6% per year, on average, from 2016 to 2024
 - 17% of all MA-PDs are now D-SNPs, growing 12% per year
- Number of stand-alone PDPs has declined 2.7% per year, on average, from 2016 to 2024
 - Each region has 21 PDPs, on average, and a minimum of 15 plans in 2024
 - Declining number of benchmark PDPs, though each region continues to have at least 2, and the average is 4
 - More LIS enrollees than last year were reassigned to avoid paying a premium
 - If PDP enrollees remained in the same national plans as 2023, most saw a premium increase of more than \$8 per month, on average

Note: MA-PD (Medicare Advantage-Prescription Drug [plan]), SNP (special needs plan), D-SNP (dual-eligible special needs plan), PDP (stand-alone prescription drug

plan), LIS (low-income subsidy).

Source: MedPAC analysis of CMS landscape data.

Part D, 2024: Final year with two distinct benefit structures, without and with the LIS



Note:

LIS (low-income subsidy), LICS (low-income cost-sharing), OOP (out-of-pocket). The coverage gap for enrollees without the LIS is depicted as it would apply to brand-name drugs, which are eligible for a 70 percent manufacturers' discount in the coverage gap. There is no manufacturer discount for generic prescriptions, and thus cost sharing in the coverage gap is 25 percent and plans are responsible for 75 percent.

Source:

Cost-based payments account for a growing share of program spending

	2018	2022	Average annual change			
In billions of dollars						
Total Part D spending	\$83.3	\$101.9	5.2%			
Capitated direct subsidy	13.5	4.8	-22.8			
Cost-based payments						
Reinsurance	40.6	56.8	8.8			
Low-income subsidy (LIS)	28.5	39.7	8.6			
Retiree drug subsidy*	0.7	0.6	-3.8			
Enrollee premiums for basic benefits	14.2	15.4	2.0			

Note:

Figures for capitated payments account for risk-sharing payments that plans make or receive under Part D's risk corridors. *Subsidy for employers providing coverage that is comparable

with or more generous than the basic Part D benefit.

MedPAC analysis based on Table IV.B10 of the 2023 annual report of Trustees of the Medicare Source:

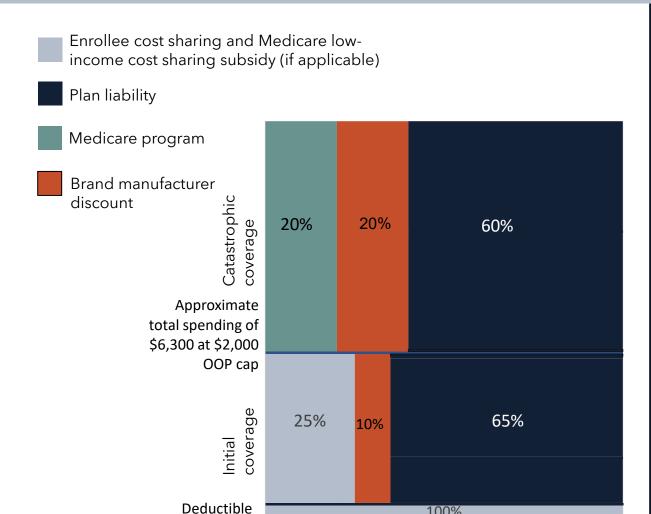
trust funds.

- Between 2018 and 2022, program spending grew by 5.2% per year
- Payments for reinsurance and LIS are both largely driven by prices at the pharmacy
 - Nearly 90% of LIS costs are for costsharing subsidies; LIS enrollees account for the majority of individuals who incur very high spending
 - In 2022, over 482,000 enrollees filled a single prescription sufficiently expensive to meet the OOP threshold, up from just 33,000 in 2010

Note:

LIS (low-income subsidy), OOP (out of pocket).

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



- Cap on beneficiary OOP spending
- Higher plan liability
- Lower Medicare reinsurance
- No coverage gap
- New manufacturer discount*

Note: OOP (out-of-pocket). 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% reinsurance above the OOP cap. *For beneficiaries receiving the low-income subsidy and for certain small manufacturers, the new manufacturer discount program will be phased in over time, reaching final levels by 2031.

Implementation timeline of Part D-related provisions in the Budget Reconciliation Act of 2022

2023

2024

2025

2026

- Mandatory manufacturer rebate to Medicare if drug prices rise faster than inflation
- \$35 monthly cap on insulin cost sharing
- No cost sharing for recommended adult vaccines
- No cost sharing once Part D enrollees reach OOP threshold (\$8,000)
- Growth in national average premium limited to 6%
- Expanded eligibility for full LIS benefits

- New benefit design for Part D takes effect, including \$2,000 OOP cap
- Negotiated prices take effect for first 10 drugs

Drug price negotiation

Note: OOP (out-of-pocket), LIS (low-income subsidy).

Going forward, legislative and regulatory changes will increase plans' share of insurance risk

- In 2024, plan bids show a decrease in cost-based payments:
 - Average direct subsidy rose to \$30 PMPM (from \$2 PMPM in 2023)
 - Average reinsurance decreased to \$90 PMPM (from \$94 PMPM in 2023)
 - 6% cap on annual premium growth contributed to higher Medicare subsidy
- Part D related provisions in the BRA increase plan liability
 - More generous coverage of insulins and vaccines (2023)
 - Elimination of cost sharing in the catastrophic phase of the benefit (2024)
 - 6% cap for annual premium growth increased Medicare's overall subsidy rate (2024)
 - Benefit redesign (2025)
- Regulatory change requiring all possible pharmacy price concessions to be applied at the point of sale (i.e., lower POS prices) (2024)
- Lower cost sharing and lower POS prices will tend to increase plan liability and slow beneficiaries' progression towards the catastrophic phase

Note: PMPM (per member per month), BRA (Budget Reconciliation Act of 2022), POS (point-of-sale).

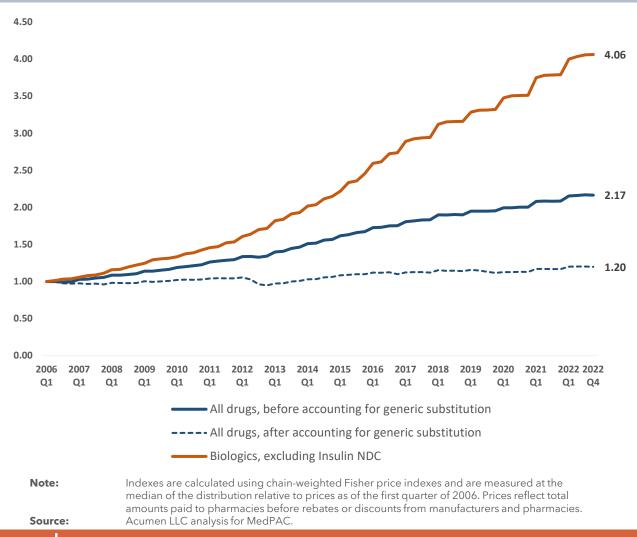
Recent regulatory change to "negotiated price"

- Postsale pharmacy price concessions have grown from less than \$500 million in 2014 to over \$17 billion in 2022*
 - Enrollee cost sharing grew more disconnected from the price net of all pharmacy price concessions
 - Larger-than-expected price concessions primarily contribute to plan profits
- May 2022 final rule redefined the "negotiated price" to be the lowest possible reimbursement. CMS expects the change will:
 - Reduce enrollee OOP costs (higher premiums and lower cost sharing)
 - Increase plan liability
 - Increase Medicare's program spending
 - Provide more predictable revenues for pharmacies

Note:

OOP (out of pocket). *Postsale pharmacy payments can flow from a plan sponsor (or its pharmacy benefit manager) to a pharmacy or vice versa. However, pharmacies, on the whole, have paid increasing amounts to plan sponsors.

Prices of biologics will increasingly drive the growth in overall Part D prices



- Between 2006 and 2022, overall Part D list prices:
 - More than doubled (index value = 2.17)
 - After accounting for generic substitution, grew by just 20% (index value = 1.20)
- List prices of biologics grew by more than 300% (index value = 4.06)
 - Biologics are a growing share of Part D spending*
 - Successful launch and adoption of biosimilars will be key to lowering prices of biologics

Note:

Source:

*Gross Part D spending on biologics other than insulins have grown from just 3% in 2006 to 15% by 2022. In comparison, gross Part D spending for insulins have grown from about 2% in 2006 to 6% by 2022.

Acumen LLC analysis for MedPAC.

Availability of Humira in multiple versions may complicate biosimilar uptake

- Humira (adalimumab) is a biological product used to treat a wide range of autoimmune conditions (e.g., rheumatoid arthritis)
 - Annual therapy costs at list price can exceed \$80,000
 - Available in different doses and strengths, as well as in several injection devices
 - In 2023, nearly all Part D plans covered most/all Humira products
 - Over 80% of Part D sales are for the newer, high-concentration, formulation
- Nine Humira biosimilar products were launched in 2023*
 - Three products are available in high-concentration formulation
 - Two products have the interchangeable designation
 - Some products launched with list prices 5% below Humira's list price, while others have steeper list price discounts ranging from 55% to over 80%

Note: *Based on publicly available information as of November 2023.

Formulary coverage of Humira and its biosimilars, 2024

- Most plans continue to cover most/all Humira products
- Nearly 60% of all Part D enrollees are in plans that include at least one Humira biosimilar product on formulary*
 - About half of these enrollees are in plans that cover just one biosimilar product
 - About two-thirds are in MA-PDs (including SNPs)
 - Most plans place any covered biosimilar products on the same cost-sharing tier as Humira
- An interchangeable biosimilar product was most likely to be included on plan formularies, followed by a high-concentration formulation biosimilar product (both products priced at a 5% discount off Humira's list price)
- Having a low list price did not appear to give the biosimilar product an advantage in formulary placement over other biosimilar products with higher list prices

Note:

MA-PDs (Medicare Advantage-Prescription Drug [plan], SNP (special needs plan). *The analysis was conducted in the fall of 2023 using the formulary files released in November. Consequently, the results do not reflect any formulary changes made after November 2023 files were released. Enrollment for 2024 is estimated using 2023 enrollment, assuming beneficiaries remained in the same plan for 2024.

Source:

MedPAC analysis of Part D formulary and enrollment files.

Recent medication therapy management demonstration yielded no significant impacts

- 5-year demonstration provided regulatory flexibilities and financial incentives
- 40% of more than 1 million eligible enrollees received MTM services
- Final evaluation found:
 - No improvements in health outcomes as measured by medication adherence, use
 of potentially unsafe medication, and downstream medical expenditures
 - No statistically significant effects on Medicare Part A and Part B spending

Note:

MTM (medication therapy management).

Source:

Acumen LLC. 2023. Evaluation of the Part D Enhanced Medication Therapy Management (MTM) Model: Fifth evaluation report. Report prepared by Acumen for the Center for Medicare & Medicaid Innovation. Burlingame, CA: Acumen.

Enrollee satisfaction with Part D remains high

- A majority describe their Part D plan as a good value and convenient to use
- Most agree that they have good access to medicines
- However, coinsurance on high-priced drugs and biologics may be unaffordable for some beneficiaries
 - In our focus groups, physicians and beneficiaries were acutely aware of drug costs
 - Nearly a quarter of enrollees reported an affordability issue
 - No significant differences in rates of affordability challenges between PDP and MA-PD enrollees or by LIS status (MCBS)
- Benefit redesign should lessen access issues related to high OOP costs

Note: PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]), LIS (low-income subsidy), MCBS (Medicare Current Beneficiary Survey, OOP

(out-of-pocket).

Source: Medicare Today senior satisfaction survey 2023; Medicare Current Beneficiary Survey, 2021; MedPAC focus groups 2023.

Discussion

- Questions?
- Feedback on draft chapter for the March 2024 report to the Congress



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