

Advising the Congress on Medicare issues

Generic drug pricing under Part D

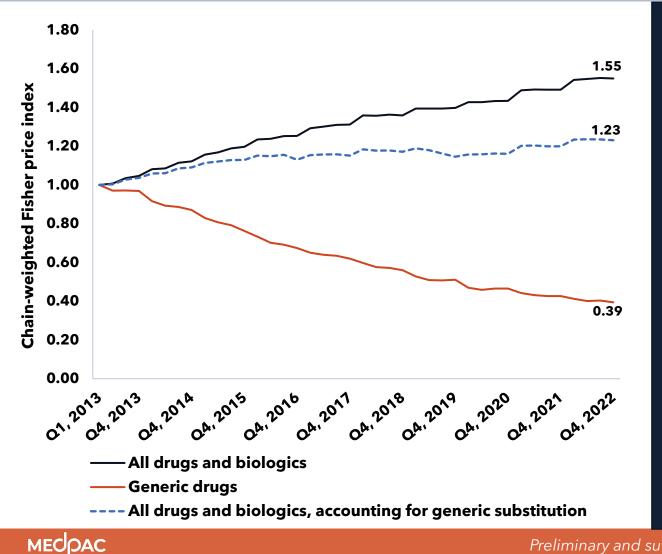
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Presentation roadmap



Background

Decrease in generic prices has slowed in recent years, 2013-2022



- Generic drugs account for **90%** of prescriptions but less than 20% of gross spending in Part D
- Generic drugs have played an important role in moderating the growth in Part D spending
- Slower decrease in generic prices has likely contributed to uptick in overall Part D prices
- Note: Source:

Q1 (first guarter), Q4 (fourth guarter). Price indexes reflect total amounts paid to pharmacies and do not reflect retrospective rebates or discounts from manufacturers and pharmacies. Acumen LLC analysis of Part D prescription drug event data from CMS for MedPAC.

Different definitions of Part D prices for generic drugs

- Pharmacies are reimbursed by the patient and their plan sponsor
- Components of pharmacy reimbursement*
 - A. Payments for ingredient cost
 - **B.** Dispensing fee
 - **C.** Pharmacy fee (postsale net payments from pharmacies to plans)^{^1}
- Gross (point-of-sale) price: **A** or **A** + **B**
- Net price: **A** + **B** +/- **C**
- Both A and B are available on the prescription drug event data,
 C is reported to CMS but not publicly available

Note:

*Pharmacy reimbursements may also include sales tax. In 2021, sales tax averaged about \$0.02 per claim for generic prescriptions. ^As of January 1, 2024, the pharmacy reimbursement at the point of sale (POS) must reflect the lowest possible payment a pharmacy may receive for a given drug, including pharmacy fees. Because our analysis is based on 2021 data, when pharmacy fees were paid after the POS, we refer to these fees as "postsale pharmacy fees."



External studies examining prices for generic drugs

Studies find that generic POS prices in Part D are often higher than cash prices and can vary widely

- Evidence of relatively high and varying prices in Part D compared to discount retailers (such as Costco or MCCPDP) and cash prices
- Numerous factors associated with wide price variation
 - E.g., where drug is purchased (type of pharmacy), when it is purchased, dosage form and strength, and plan sponsor/PBM
- However, these studies examined POS prices, which do not include postsale pharmacy fees
 - Postsale pharmacy fees for generic drugs increased more than 30% per year on average, from \$0.5 billion in 2015 to \$3.5 billion in 2022
 - Gross Part D spending for generic drugs, in contrast, grew by less than 3% per year on average during the same period

Note: POS (point-of-sale), MCCPDP (Mark Cuban Cost Plus Drug Program), PBM (pharmacy benefit manager).

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



How might high or wide variation in generic prices affect Medicare and Part D enrollees?

- Potential cost and access concerns:
 - Are plans and beneficiaries overpaying for generic drugs?
 - Is cost sharing affected by variation in POS price?
- In Part D, POS prices may not directly affect enrollee and Medicare costs:
 - Most generic prescriptions used by Part D enrollees are on formulary tiers with no cost sharing or copay*
 - Most of the benefit costs for generic drugs occur when the beneficiary is below the catastrophic threshold and costs are covered by capitated payments
- Note:

POS (point-of-sale).

*Analysis was limited to plans that use formulary tiers, which accounted for just under 80% of the generic prescriptions dispensed in 2021. Plans that do not have formulary tiers use defined standard benefit with a deductible and a 25% coinsurance until an individual reached the annual out-of-pocket threshold. The vast majority of these plans are special needs plans that serve beneficiaries who receive Part D's low-income subsidy (LIS), which covers most of the cost-sharing liability on behalf of LIS beneficiaries.



MedPAC analysis of generic price variation in Part D

Analysis of the Part D data

- To better understand generic price variation in Part D
- Generic drugs* selected from 2021 Part D data based on highest total number of annual fills and/or gross spending
 - 108 unique chemical molecules
 - About 570 PEPs with different dosage forms and strengths
 - About 5,900 unique NDCs
- Selected drugs accounted for about 60% of total gross spending on generic drugs in 2021

Source : Acumen LLC analysis of 2021 Part D prescription drug event data for MedPAC.



Note: PEP (pharmaceutically equivalent product), NDC (national drug code).

^{*}A generic drug may include products with different dosage forms and strengths (PEP). An NDC uniquely identifies the drug, its labeler, dosage form, strength, and package size.

Part D data analysis: Generic price variability depends on how drug and price are defined

- Lower variation when a drug is defined more narrowly (NDC vs. PEP)
- Higher variation when price includes dispensing fees (POS price) and postsale pharmacy fees (net price)
 - CMS data for pharmacy fees are aggregated across claims for each NDC, which may be masking even greater variation
- Effects of including dispensing fees and pharmacy fees were greater for lower-priced drugs
 - Dispensing fees are typically a fixed dollar amount (e.g., \$1), so they account for a larger share of lower prices

Note: NDC (national drug code), PEP (pharmaceutically equivalent product), POS (point-of-sale). We measured price variation using a relative standard deviation, where the standard deviation of each drug's price distribution is expressed relative to the median value of that distribution.
 Source: Acumen LLC analysis of 2021 Part D prescription drug event and direct and indirect remuneration data for MedPAC.



Part D data analysis: Complex interactions among factors affecting price variability

- Lower-priced products tended to have higher variability
 - Small fluctuations in price can translate into large percentage changes
 - However, relationship between price and variability was not linear
- Price variability exhibited different patterns across therapies
- Further analysis of 15 drugs revealed different patterns of price variation across and within products
- We also found instances in which prices varied more for a subgroup than for the drug product as a whole:
 - Higher variation for individual NDCs vs. variation measured at the PEP level
 - Higher variation for chain pharmacies vs. variation across all pharmacies

Note: NDC (national drug code), PEP (pharmaceutically equivalent product). We measured price variation using a relative standard deviation, where the standard deviation of each drug's price distribution is expressed relative to the median value of that distribution.
 *Prices were calculated as ingredient costs per unit on each claim. Results for analysis by therapy were similar when other definitions of price (including dispensing fees and/or postsale pharmacy fees) were used.

Source: Acumen LLC analysis of 2021 Part D prescription drug event and direct and indirect remuneration data for MedPAC.



What did we learn from the analysis of the Part D data?

- For generic drugs for which Part D plans negotiated postsale pharmacy fees, POS prices do not accurately reflect the final prices paid by Part D plans
- Price variation did not exhibit consistent patterns across therapies, products, or at the individual NDC level
- Variations across pharmacy types or individual plans may explain some, but not all, of the price variation for a given product
- To understand why there may be nonsystematic variation in prices of generic drugs in Part D, we turned to the experts and conducted interviews with pharmaceutical supply chain participants

Note: POS (point-of-sale), NDC (national drug code).

Source: Acumen LLC analysis of 2021 Part D prescription drug event and direct and indirect remuneration data for MedPAC.



Stakeholder interviews

Scope of the stakeholder interviews

- We conducted 14 interviews* with individuals and organizations representing pharmacies, PBMs, plan sponsors, wholesalers, and other pharmaceutical supply chain intermediaries and experts
- A semi-structured discussion on topics related to:
 - How prices of generic drugs are determined and the nature of interactions among supply chain participants
 - How Part D plans set their reimbursement rates ("price") for generic drugs
 - Other factors that affect generic price variation in Part D

Note: PBM (pharmacy benefit manager).

*Commission staff contracted with B&J Health Policy LLC to conduct external stakeholder interviews. Interviews were conducted between August 2023 and March 2024.



Theme 1: Pharmacies often face different acquisition costs for the same generic drug

- Interviewees generally agreed that most variation in pharmacies' acquisition costs resulted from different prices charged by wholesalers, not generic manufacturers
- Pharmacies' acquisition costs reflect purchasing decisions of wholesalers (e.g., the wholesaler's manufacturer of choice)
- Some interviewees noted that differences in bargaining leverage likely contribute to variation in pharmacies' acquisition costs
 - E.g., large chain pharmacies' greater bargaining leverage (via their consortia) allows them to obtain lower acquisition costs than independent pharmacies



Theme 2: Wholesalers' prices for generic drugs may be tied to prices of brand-name drugs

- Interviewees described "tying arrangements" between wholesalers and pharmacies, which "tie" discounts for branded drugs to the volume and price of generic drugs purchased
- Some interviewees noted that independent pharmacies often agree to these tying arrangements to avoid losing money on branded drugs, even if they must pay more for generics
- Some independent pharmacies have formed cooperative-style wholesale businesses that provide transparent pricing and some control over purchasing decisions



Theme 3: Part D payments do not reflect pharmacy acquisition costs or manufacturers' prices

- Payments for generic drugs are typically based on PBMs' MAC prices
 - Unless U & C price or discounted AWP is lower
 - Updated periodically, sometimes as often as every week
 - Vary widely across PBMs and by pharmacy
 - Many voiced concerns about the lack of transparency in setting MAC prices
- Many discussed PBMs' use of a target generic effective rate (GER) as a factor contributing to price variation
 - Adjust MAC prices and/or postsale pharmacy fees to meet the GER target across generic drugs
- In recent years, some pharmacies have negotiated reimbursements based on AWP-based prices rather than MAC prices

Note: PBM (pharmacy benefit manager), MAC (maximum allowable cost), U & C (usual & customary), AWP (average wholesale price). Source: B&J Health Policy LLC stakeholder interviews for MedPAC.



Theme 4: POS payments may not provide an accurate picture of prices paid by Part D plans

- Some interviewees considered Part D overpayments for generic drugs a possibility, although not after postsale fees and dispensing fees were accounted for
- Several interviewees noted that GER makes it difficult for pharmacies to know the profit margin on individual drugs because GER is determined across generic drugs
- Some interviewees emphasized that any meaningful Part D price comparisons would need to go beyond POS payments
 - Factor in any differences in dispensing fees
 - Account for postsale pharmacy fees

Note: POS (point-of-sale), GER (generic effective rate).



Theme 5: PSAOs typically do not negotiate reimbursement contract terms with PBMs

- We consistently heard from interviewees that PSAOs have little effect on determining pharmacy reimbursements
 - Some commented that pharmacy reimbursement rates are generally not up for negotiation
 - One interviewee noted that even when there were negotiations around price schedules, there "ha[ve] not been stellar results"
- Interviewees conveyed that PSAOs primarily serve as facilitators for pharmacies, existing largely to relieve independent pharmacies of contractual and administrative burdens

Note: PSAO (pharmacy services administrative organization), PBM (pharmacy benefit manager).



Theme 6: Pharmacy fees may continue to create financial uncertainties for independent pharmacies

- Interviewees generally agreed that postsale pharmacy fees make it difficult to know the true reimbursement amount for a specific drug
 - Differences in postsale fees across pharmacies contributed to price variation
 - Interviewees were dissatisfied with the lack of transparency in how postsale fees determined
- A few commented on the policy change to reflect pharmacy fees at the POS beginning in 2024:
 - One interviewee said that pharmacy fees will be indistinguishable from ingredient costs, preventing pharmacies from appealing MAC prices
 - Another interviewee thought the policy may allow pharmacists to decide not to fill a prescription if they expected to incur a loss

Note: POS (point of sale), MAC (maximum allowable cost).



Theme 7: Part D plan payments, in general, do not contribute to generic drug shortage

- Several interviewees noted that large purchasers are contributing to "race to the bottom" pricing until prices reach a level that is too low for some generic manufacturers to operate profitably
- Some added that requiring higher reimbursements for generic drugs would "only contribute to pharmacy margins"
- One interviewee, however, suggested that higher payments for generic drugs may flow through to the generic manufacturers and help address shortages caused by financial rather than other supply chain-related issues



Summary and discussion

Key takeaways

- In most cases, generic POS prices only indirectly affect beneficiaries and Medicare
 - Premiums/program costs are based on net prices accounting for all pharmacy fees
 - Cost sharing for most generic prescriptions are subject to copays*
- Part D plan payments for generic prescriptions:
 - Reflect MAC prices set by PBMs and vary widely by plan and pharmacy
 - Change periodically through adjustments to MAC prices or pharmacy fees to achieve specific target "prices" across all (or most) generic prescriptions

Note: POS (point-of-sale), MAC (maximum allowable cost), PBM (pharmacy benefit manager).
 *Analysis was limited to plans that use formulary tiers. The vast majority of plans excluded from the analysis were special needs plans that serve beneficiaries who receive Part D's low-income subsidy, which covers most of the cost-sharing liability on behalf of LIS beneficiaries.
 Source : MedPAC analysis of Part D prescription drug event and formulary data from CMS.



Discussion

- Continue to monitor prices and access in Part D
- Questions or comments about this work?





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