aam
Association for Accessible Medicines

AAM WHITE PAPER

# Sidelined:

## How Seniors Miss Out On Savings Available Through Generic Substitution

JANUARY 2020

AAM WHITE PAPER

# Sidelined:

## How Seniors Miss Out On Savings Available Through Generic Substitution

JANUARY 2020

# Executive Summary

Generic medicines are an integral component of America's pharmaceutical care system, driving substantial savings to patients and public programs. Even as spending on prescription drugs continues to rise in public programs, the use of generic medicines has blunted increasing brand drug prices, generating savings of $293 billion in 2018 alone.[1] In fact, the average price of generic drugs covered under Medicare Part D in 2017 was only 26% of their average price in 2006. Conversely, brand drug prices have increased by 224% over the same time period.[2] In the last 10 years, generic medicines have saved nearly $2 trillion for America's patients, health system payers and taxpayers.[3]

However, a new analysis conducted by consulting firm Avalere Health reveals substantial gaps in generic substitution for seniors participating in Medicare. Today, some Medicare Part D plans are less likely to substitute generics for expensive brands, and Medicare plans' overall rates of generic substitution are less than that of the commercial market.[4,5,6]

**The analysis found that:**

- Almost half of Part D plans have substitution rates of 75% or less;
- Almost a quarter of beneficiaries are in Part D plans with generic substitution rates of 80% or less;
- Over half of first generics – 64% – have substitution rates of 80% or less;
- Expensive brand drugs with generic alternatives do not face robust generic substitution; and
- Generic substitution rates decrease as the cost of the brand drug increases.

These findings highlight the need to ensure that Medicare policies are aligned to ensure seniors' access to generic products. The findings show significant opportunities in Medicare to increase the utilization of generics, saving money for patients and taxpayers.

1 Association for Accessible Medicines (AAM). (May 2019). 2019 Generic Drug and Biosimilars Access and Savings in the U.S. https://accessiblemeds.org/resources/blog/2019-generic-drug-and-biosimilars-access-savings-us-report.
2 MedPAC. (June 2019). "Health Care Spending and the Medicare Program." http://www.medpac.gov/docs/default-source/data-book/jun19_databook_entirereport_sec.pdf?sfvrsn=0.
3 AAM. (May 2019). 2019 Generic Drug and Biosimilars Access and Savings in the U.S. https://accessiblemeds.org/resources/blog/2019-generic-drug-and-biosimilars-access-savings-us-report.
4 Avalere. (January 2020). Avalere Analysis Finds Variation in Generic Substitution Rates Among Part D Plans.
5 U.S. Office of Personnel Management (March 2019). FEHB Program Carrier Letter. www.opm.gov/healthcare-insurance/healthcare/carriers/2019/2019-01.pdf.
6 Utilization Review Accreditation Commission. (December 2018). URAC Pharmacy Benefit Management Performance Measurement, Aggregate Summary Performance Report. https://www.urac.org/sites/default/files/2019-05/URAC_PBM_Aggregate%20Summary%20Report_2018_FINAL_WebVersion_20190123.pdf.

# Background

Policymakers have long recognized the need for robust generic competition to help control prescription drug costs. The Medicare Part D prescription drug program – which covers 43 million American seniors – relies on the assumption that health plans would drive generic adoption.[7] While this assumption has historically been true, misguided Medicare policies have created loopholes that lead some health plans to prefer higher-cost brand products over lower-cost generics, blocking beneficiary access to generics and generating additional costs to the Medicare program.

In fact, a 2018 analysis by the Department of Health and Human Services (HHS) found that the program spent approximately $9 billion on brand drugs with generic competitors in 2016. If those generics had been fully substituted for the brands, Medicare would have saved an additional $3 billion in 2016 alone.[8]

Moreover, the Centers for Medicare and Medicaid Services (CMS) 2020 Annual Notice and Call Letter drew attention to instances when Part D sponsors are not achieving optimal generic substitution and access.

### GENERIC DRUG QUALITY AND PATIENT SAFETY

Food and Drug Administration (FDA)-approved generic drugs are proven as safe and effective as their brand-name counterparts, and patients can be confident in the quality, safety and effectiveness of their generic medicines. As such, therapeutically equivalent generic drugs are automatically substitutable for their brand counterparts at the pharmacy counter, and today 90 percent of prescriptions in the U.S. are filled with generics. Independent research consistently demonstrates the safety and efficacy profile of generic medicines.

The FDA oversees a rigorous approval process for all prescription drugs, including stringent manufacturing regulations and continuous inspections of domestic and foreign manufacturing facilities. These align to ensure that "medicines at all levels of the supply chain, from active pharmaceutical ingredients (API) to the finished product sold to consumers at the pharmacy counter are safe, effective and high quality." Regardless of where they are made, all pharmaceuticals, generic and brand, must be manufactured in accordance with rigorous regulatory standards that require high levels of scientific diligence and accompanying documentation.

The Generic Drug User Fee Amendments (GDUFA) of 2012 and its reauthorization in 2017 included a $4 billion commitment from the generic drug industry to increase FDA's review capacity and the frequency of inspections globally. As a result, the FDA is equipped with the financial resources to hire and train more than 1,500 additional employees who will continue to strengthen its oversight of generic drugs.

Patient safety is the number one priority for AAM and its member companies. Because of the daily commitment to quality from AAM's member companies and strong FDA oversight, the U.S. has one of the safest drug supply chains in the world and America's patients can take their generics with confidence.

7 Kaiser Family Foundation. (October 2018). An Overview of the Medicare Part D Prescription Drug Benefit. https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/.

8 U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation. (July 2018). Savings Available Under Full Generic Substitution of Multiple Source Brand Drugs in Medicare Part D. https://aspe.hhs.gov/system/files/pdf/259326/DP-Multisource-Brands-in-Part-D.pdf.

Specifically, CMS noted "there are limited instances when Part D sponsors are not including generic alternatives when available. Instead, sponsors are covering only the brand drugs, which decreases generic substitution and increases beneficiary costs. Further, we have noted that some sponsors, despite having the generic at a more preferred formulary status than the brand, are not achieving optimal generic substitution."[9] While CMS declined to make policy changes for 2020, it noted that it may consider future changes to encourage generic coverage and substitution.

While lower generic substitution and utilization is a well-known challenge for low-income subsidy beneficiaries, this new analysis demonstrates that generic drug substitution shortcomings are pervasive in the Medicare drug program.[10]

9 Centers for Medicare & Medicaid Services. (April 2019). Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.

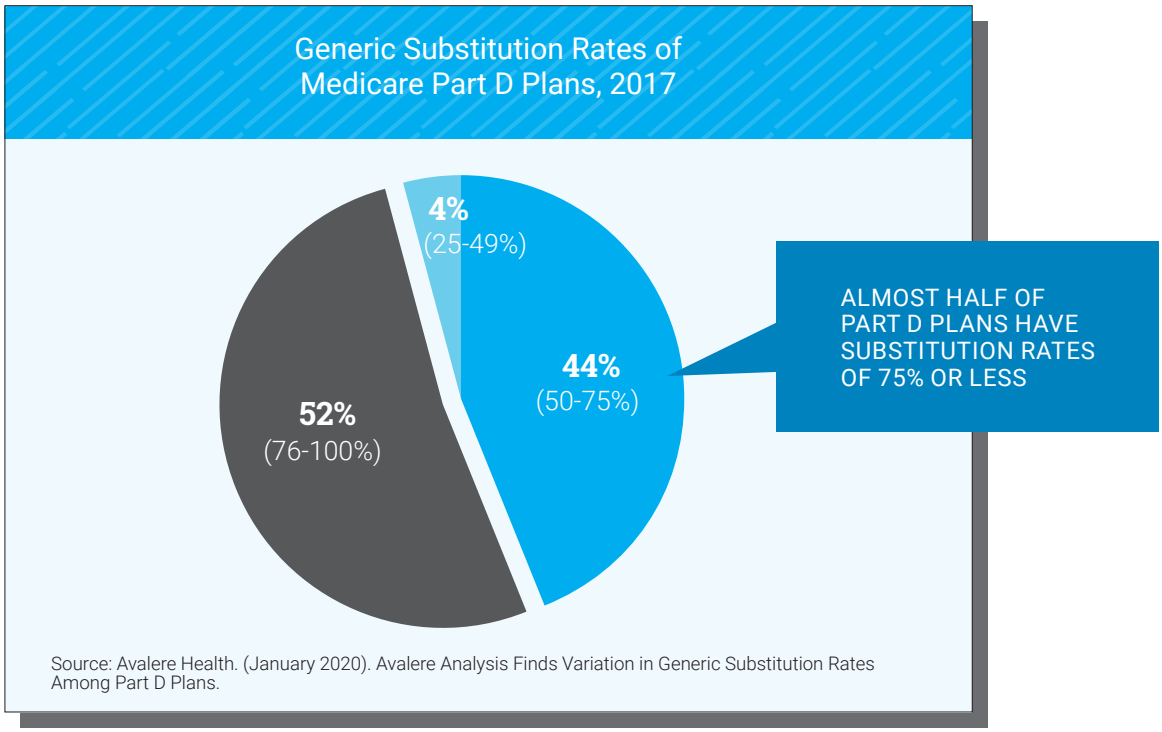
10 MedPAC. (March 2017). Status report on the Medicare prescription drug program (Part D). Chapter 14. http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch14.pdf.

# Generic Substitution Varies Dramatically Among Medicare Part D Plans

## GENERIC SUBSTITUTION AMONG MEDICARE PART D PLANS

An analysis conducted by Avalere of non-low income subsidy (LIS) beneficiaries in Medicare Part D found substantial differences between the generic substitution rates of Medicare Part D plans.[11] For 2017, a slim majority of Part D plans had generic substitution rates above 75%. Another 44% of plans had generic substitution rates between 50% and 75%, while 4% of Part D plans had substitution rates below 50%. In other words, nearly half of plans have generic substitution rates of 75% or less.

**Figure 1**



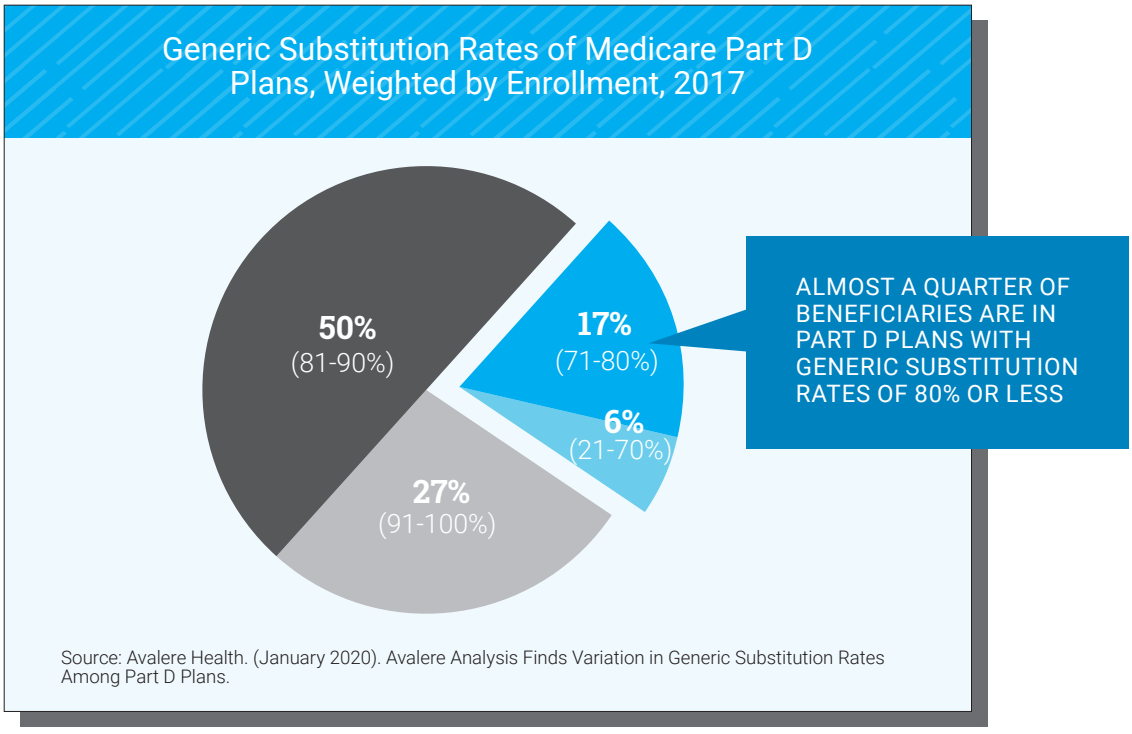

11 Avalere. (January 2020). Avalere Analysis Finds Variation in Generic Substitution Rates Among Part D Plans. https://avalere.com/insights/avalere-analysis-finds-variation-in-generic-substitution-rates-among-part-d-plans

## GENERIC SUBSTITUTION BY PLAN/ENROLLEES

Notably, Medicare Part D enrollees are not distributed evenly among plans, with the most popular plans enrolling the vast majority of beneficiaries. However, even when accounting for enrollment, generic substitution rates among plans still trail commercial payers.

The weighted average generic substitution rate in Medicare Part D in 2017 was 85%.[12] By comparison, the Federal Office of Personnel Management (OPM) expressed concern in its 2020 call letter about an overall generic substitution rate of 92% in the Federal Employees Health Benefit Program, while noting the average generic substitution rate in commercial plans is 98%.[13,14] However, nearly one quarter of Medicare beneficiaries are enrolled in plans with generic substitution rates below 80%, and the majority of beneficiaries are in plans with less than 90% substitution.

**Figure 2**



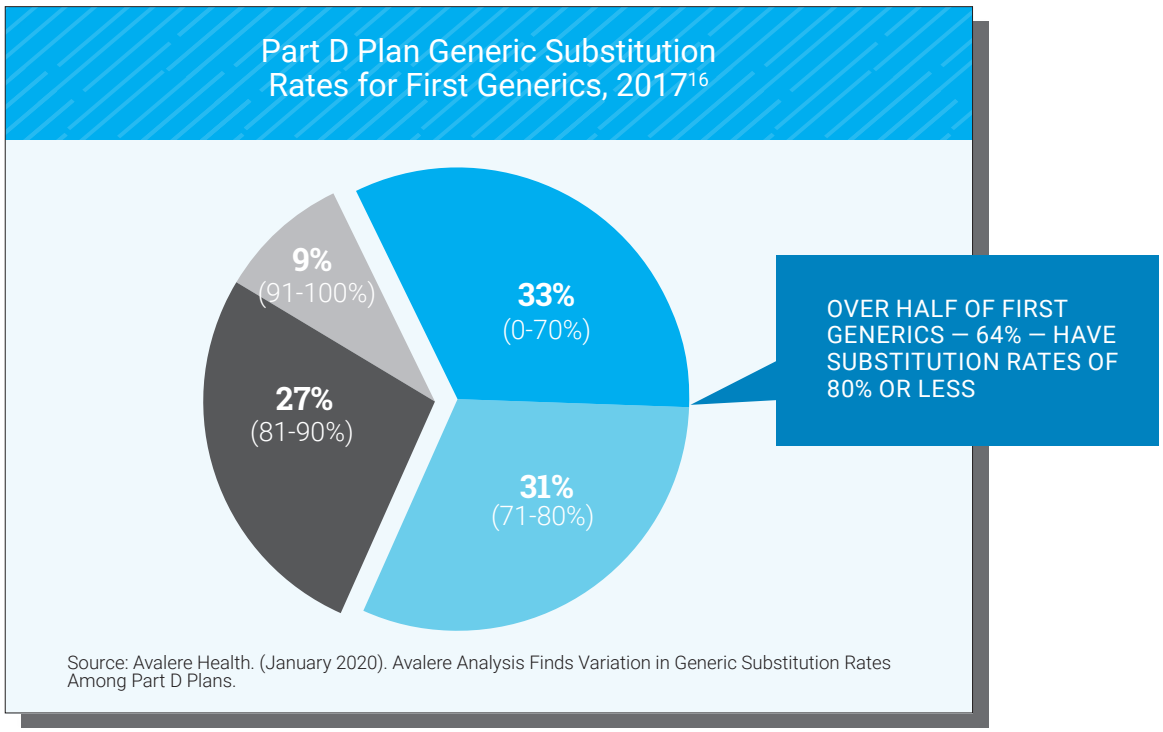

These findings demonstrate the wide variation among Medicare Part D plans in formulary coverage and tier placement of low-cost generics, as well as an important opportunity to deliver additional savings for patients and taxpayers.

12 Avalere. January 2020. Avalere Analysis Finds Variation in Generic Substitution Rates Among Part D Plans.
13 U.S. Office of Personnel Management (March 2019). FEHB Program Carrier Letter. www.opm.gov/healthcare-insurance/healthcare/carriers/2019/2019-01.pdf.
14 Utilization Review Accreditation Commission. (December 2018). URAC Pharmacy Benefit Management Performance Measurement, Aggregate Summary Performance Report. https://www.urac.org/sites/default/files/2019-05/URAC_PBM_Aggregate%20Summary%20Report_2018_FINAL_WebVersion_20190123.pdf.

## GENERIC SUBSTITUTION FOR FIRST GENERICS

These shortfalls and variations in generic substitution among Medicare Part D plans are even more pronounced among first generics. A previous analysis found that it takes three years before first generics are included on as many as half of Part D formularies, limiting patients' access to lower-cost medications.[15] This practice of not covering first generics leads to low substitution rates for beneficiaries in Medicare Part D. In fact, the generic substitution rate for first generics that launched in 2016 was approximately 75% in 2017, the first full plan year after launch.

**Figure 3**



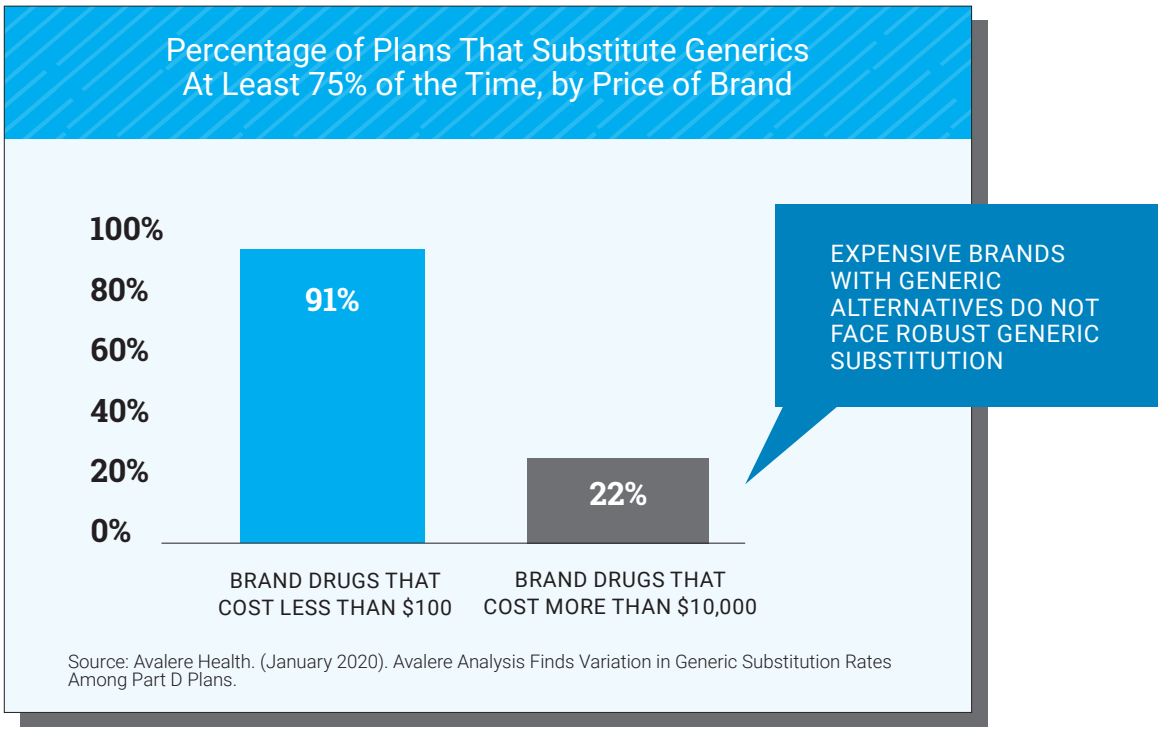

15 AAM. (September 2019). Access Denied: Why New Generics are Not Reaching America's Seniors. https://accessiblemeds.org/sites/default/files/2019-09/AAM-White-Paper-Access-Denied-First-Generics-web_0.pdf.

16 For 2016 first generics and weighted by plan enrollment.

## GENERIC SUBSTITUTION BY PRICE

Similarly, generic substitution rates in Medicare vary significantly as brand drug prices increase. In fact, as a brand drug with generic competition increases in price, it is less likely to be substituted with its corresponding generic. This means that the most expensive brand-name products are the least likely to be substituted by a lower-priced generic. For example, brand drugs that cost less than $100 are substituted by generics at least 75% of the time by the vast majority of plans. However, brand drugs that cost more than $10,000 are rarely substituted by generics, with fewer than a quarter of plans achieving generic substitution rates for these products above 75%.[17]

**Figure 4**




This trend is alarming. High-cost specialty medicines are rapidly approaching half of medicine spending, increasing from 26.2% in 2009 to 49.5% in 2018.[18] As specialty medicines drive spending, generic competition is vital to curbing this trend. Yet generic versions are less likely to be substituted for higher-priced brand products – increasing patient out-of-pocket costs for patients and undermining potential savings.

17 Avalere. (January 2020). Avalere Analysis Finds Variation in Generic Substitution Rates Among Part D Plans.

18 IQVIA Institute for Human Data Science. (May 2019). Medicine Use and Spending in the U.S. A Review of 2018 and Outlook to 2023. www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us---a-review-of-2018-outlook-to-2023.pdf?_=1571247409218.

Figure 5 further illustrates how generic substitution rates decrease as the cost of the brand increases.

**Figure 5**

Generic Substitution Rates Above Price Thresholds, 2017

| Price of the Brand | Average Generic Substitution Rate in Medicare Part D |
|---|---|
| Brand Cost < $450 | 81% |
| Brand Cost $450+ | 71% |
| Brand Cost $500+ | 70% |
| Brand Cost $550+ | 70% |
| Brand Cost $600+ | 69% |
| Brand Cost $670+ | 69% |

GENERIC SUBSTITUTION RATES DECREASE AS THE COST OF THE BRAND DRUG INCREASES

Source: Avalere Health. (January 2020). Avalere Analysis Finds Variation in Generic Substitution Rates Among Part D Plans.

Using high-quality, FDA-approved generic medicines in place of higher-cost, specialty brand products is a key mechanism to control drug spending. Missed generic substitution means higher health care spending and beneficiary costs.

# Subpar Generic Substitution Is Caused by Poor Generic Access

AAM previously detailed the extent to which Part D plans delay formulary coverage of new generic competitors.[19] The delayed formulary coverage of new generics, as well as the shortcomings in generic substitution detailed above, can largely be attributed to two unique design features of the Medicare Part D program. Specifically, the combination of the Coverage Gap Discount Program (CGDP) and the treatment of brand drug rebates in the catastrophic phase of Part D create powerful incentives for payers to prefer higher-cost brand drugs – even when those come with a higher net cost. This dynamic has been noted by MedPAC and other independent observers.[20]

Created to help alleviate patient out-of-pocket costs in the coverage gap, the CGDP requires brand drug manufacturers to provide 70% discounts on such drugs dispensed in the coverage gap. But this creates an incentive for a plan to lower its financial liabilities, and increase Medicare's financial liabilities, through preferred treatment of higher-priced brand drugs.

Under the program, Part D plans pay substantially more for generics in the coverage gap than for similarly priced branded products. Part D plans are liable for only 5% of a brand drug's cost in the coverage gap, compared to 63% — increasing to 75% in 2020 — of the generic drug's cost. This means, for instance, that in 2019 a plan might pay approximately $6,000 for generics and only $200 for brands in the coverage gap even when the generics are priced less than the brands.[21] This creates an incentive for Part D plans to advantage higher-cost brands and has been found by researchers to lead to patients paying more out-of-pocket for generic medications than for brand-name drugs in the coverage gap.[22]

Not only do Part D plans benefit by paying less for brand drugs in the coverage gap, but they also benefit from preferring higher-cost brands, as this speeds the rate at which beneficiaries move into catastrophic coverage, where plans have less financial responsibility.

19 AAM. (September 2019). Access Denied: Why New Generics are Not Reaching America's Seniors. https://accessiblemeds.org/sites/default/files/2019-09/AAM-White-Paper-Access-Denied-First-Generics-web_0.pdf.

20 MedPAC. (June 2019). "Health Care Spending and the Medicare Program." http://www.medpac.gov/docs/default-source/data-book/jun19_databook_entirereport_sec.pdf?sfvrsn=0.

21 Assumes that a beneficiary is utilizing, in each scenario, either all generics or all branded products. The beneficiary is using a sufficient quantity and price of these products to move the beneficiary entirely through the coverage gap. The analysis assumes that the beneficiary has no additional coverage in the coverage gap and that previous beneficiary true-out-of-pocket (TrOOP) spending was 25% of his or her total spend after exceeding the deductible. The remaining quantity of spending required to exit the coverage gap is calculated for the beneficiary in each scenario and used to calculate total Part D plan and manufacturer discount.

22 Dusetzina, Stacie B, et al. (July 2019). Sending the Wrong Price Signal: Why Do Some Brand-Name Drugs Cost Medicare Beneficiaries Less Than Generics? Health Affairs (Project Hope), U.S. National Library of Medicine. www.ncbi.nlm.nih.gov/pubmed/31260351.

**Figure 6**

**"Rebate Trap" Illustrated in Medicare Part D**
**Brand Versus Generic**

| Spending for a beneficiary who takes one prescription drug | Brand with list price of $12,000, 25% rebate | Generic with a price of $3000, no rebate |
|---|---|---|
| **Gross drug spending** | | |
| Beneficiary cost sharing | $3,089 | $1,050 |
| Coverage-gap discount | $2,069 | $0 |
| Covered benefits | $6,842 | $1,950 |
| **Subtotal** | **$12,000** | **$3,000** |
| **Allocation of rebates and fees assuming 80% reinsurance** | | |
| Medicare reinsurance (at 80%) | $800 | $0 |
| Plan liability | $2,200 | $0 |
| **Subtotal** | **$3,000** | **$0** |
| **Net effect** | | |
| Beneficiary cost-sharing | $3,089 | $1,050 |
| Medicare reinsurance after rebates | $2,529 | $0 |
| **Plan liability after rebates and reinsurance** | **$1,313** | **$1,950** |

Source: MedPAC. (March 2017) Report to Congress: Medicare Payment Policy.

Finally, once a beneficiary is in the catastrophic phase of the benefit, the manner in which brand drug rebates are shared between plans and the Medicare program further incentivizes coverage of high-cost, high-rebate brands even when the net cost is greater to Medicare. This occurs because the rebate calculation is based on the share of each plan's gross spending that was above the catastrophic threshold, and despite the fact that plans generate rebates based on drug spending below the out-of-pocket threshold as well. As a result of this uneven calculation, plans retain more rebate dollars while cost savings are not passed on to the beneficiaries.

# Policy Solutions to Ensure Access to Generic Drugs

Lower than optimal rates of generic substitution as well as inappropriate tiering decisions lead to seniors receiving little to no coverage for their generic drugs in Medicare Part D. This situation requires policy solutions to ensure that patients have sufficient access to their needed generic drugs.

Policymakers can take three specific steps to lower out-of-pocket costs for patients and taxpayers through greater generic substitution:

- Ensuring Medicare Part D plans cover new generic drugs at launch, particularly first generics;
- Providing for the placement of all generic products on tiers designated as generic and separate from high-priced brand drugs; and,
- Creating a separate specialty tier to allow for differentiation among specialty brands versus generics and biosimilars.

These solutions would prevent a health plan from preferring a higher-priced brand drug over a generic and restore the appropriate incentives for plans to encourage patients to switch to lower-cost generics. Instead, competition would be based on list price, benefitting patients and taxpayers through lower out-of-pocket costs as well as lower overall spending.

Importantly, creating a separate specialty tier for generics and biosimilars reflects a vital and needed update to the Medicare program for a class of lower-priced medicines that did not exist when Part D was created. The dedicated specialty tier would allow Part D plans to create financial incentives through lower cost-sharing for specialty generics and increase utilization of these products in the Medicare Part D program, thus improving the substitution rates for specialty generics.

These policies would support greater patient access to lower-priced generics, ensuring competition in the pharmaceutical marketplace to drive down costs and provide substantial savings for America's patients.

# Summary

This analysis of generic substitution adds further support to the growing body of evidence that there should be additional incentives in Medicare Part D for plans to cover and prioritize patient access to generic medicines. The Medicare Part D drug program represents a crucial safety net for seniors but is also a bellwether for health plan and drug formulary design trends over time. Without rapid action to improve generic substitution rates – particularly among the most expensive brand drugs, policymakers risk continued increases in drug costs for patients and taxpayers alike.


aam
Association for Accessible Medicines

accessiblemeds.org