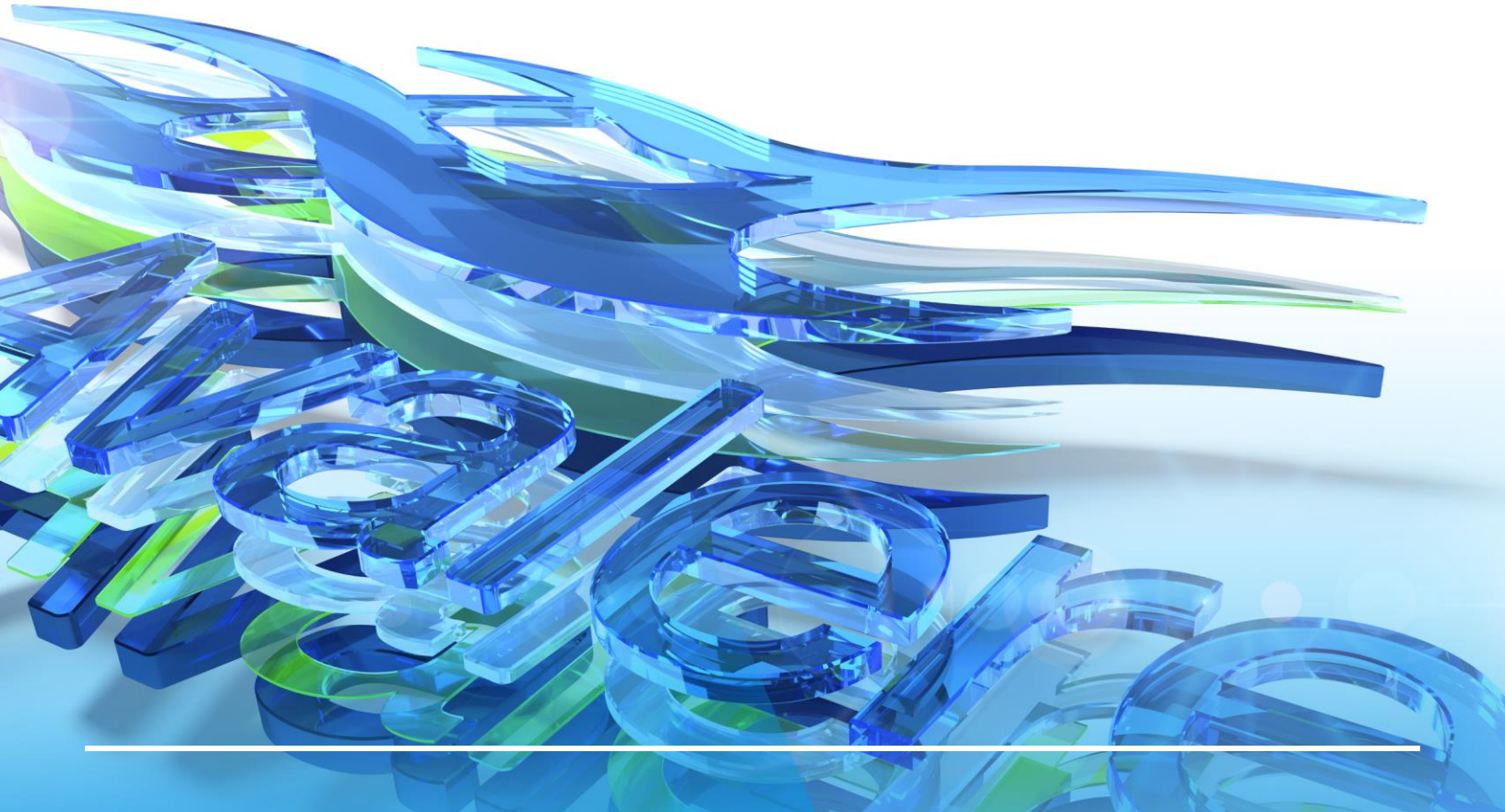
Generic Drugs in Medicare Part D.

Trends in Tier Structure and Placement.

5.22.18



Avalere Health
An Inovalon Company
1350 Connecticut Ave, NW
Washington, DC 20036

T | 202.207.1300
F | 202.467.4455

avalere.com

Table of Contents

Funding for this research was provided by the Association for Accessible Medicines. Avalere Health retained full editorial control.

Avalere

Introduction

The Medicare Part D benefit provides prescription drug coverage to millions of beneficiaries, covering 43.9 million Americans in 2018.[1] Beneficiaries can select from a standalone prescription drug plan (PDP) or Part D coverage bundled with their medical benefit through a Medicare Advantage plan with prescription drug coverage (MA-PD). Since the program's inception in 2006, plan benefit designs have evolved, and on average, include a growing number of formulary tiers with different levels of cost sharing.

In 2006, when the Medicare prescription drug benefit was first offered, 46% of PDPs and 60% of MA-PDs offered a benefit with 4 formulary tiers—comprised of a single generic tier, 2 brand tiers (preferred and non-preferred), and a single specialty drug tier.[2] By the 2018 benefit year, 95% of PDPs and 81% of MA-PDs had moved to a 5-tier benefit structure, with 2 generic tiers, 2 brand tiers, and a specialty tier; the remaining 5% of PDPs and 18% of MA plans had a 6-tier benefit structure.[3] Part D plans have considerable flexibility as to how they design formularies and tier structure, as long as they meet CMS' nondiscrimination requirements. In short, those requirements include that (1) tier labels (i.e., brand or generic) should correspond to the predominant type of drugs placed on that tier and (2) cost sharing for each tier cannot exceed maximum standards that correspond both to a coinsurance percentage and a copayment dollar amount.[1]

Over time, Part D plans have also placed an increasing number of generic drugs on brand tiers. In response to this trend, as well as plan sponsor feedback, CMS announced a major change to the formulary structure of the Part D program in 2016, allowing plan sponsors to create a "non-preferred drug" tier that explicitly includes both brand and generic drugs.[4] Plans were instructed that they could begin using the "non-preferred drug" tier in 2017, but could not use both a "non-preferred drug" tier and a "non-preferred brand" tier; by 2018, 98% of PDPs and 90% of MA-PDs were using the "non-preferred drug tier."[3] While this change was designed to create "flexibility and transparency in benefit design," CMS acknowledged that "the new non-preferred drug tier likely will contain a greater proportion of generic drug products than the current non-preferred brand tier composition." Specifically, CMS hypothesized that plan sponsors would include lower-cost generics on the "non-preferred" tier "in effort to…maintain actuarial equivalence" and keep premiums flat.

[1] CMS issued new guidance for 2019 that specifies that the non-preferred brand tier can have a maximum of 25% generic drugs

Analysis of Generic Drug Tier Placement in Medicare Part D

Methodology

We analyzed historical tier placement and cost sharing of generic drugs in the Medicare Part D program from 2011–2015 to see how plans covered generics in the years before the creation of the "non-preferred drug" tier.[2] In general, lower tiers are associated with lower cost sharing and lower rates of utilization management. The analysis encompassed all generic products that were included on formularies in both 2011 and 2015. To conduct this analysis, we cross-walked Medicare Part D public use files with the CMS Prescription Plan Formulary, Pharmacy Network, and Pricing Information Files and the CMS Medicare Part D Dashboard Files for 2011 and 2015. Because CMS is prohibited from disclosing data on rebates, the prices used here are exclusive of manufacturer rebates and other price concessions.

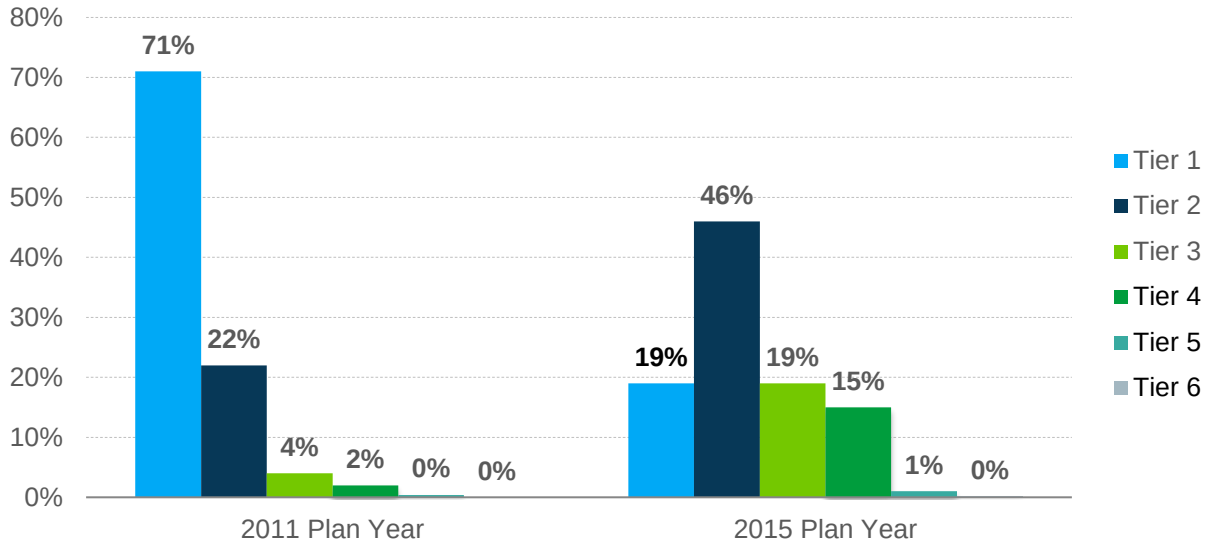
For the cost-sharing analysis, we relied solely on the cost sharing associated with each tier in the formulary benefit design and did not incorporate plan deductibles or OOP costs associated with the coverage gap; this methodology results in a conservative estimate and likely underestimates the true OOP costs that patients face. Additionally, because the publicly available data from CMS do not include product- or plan-specific claims, we weighted the plans and cost sharing according to the enrollment for each plan. Finally, because the Medicare Drug Dashboard reports claims aggregated to the chemical entity level, we assumed that claims for a chemical entity were distributed evenly across all dosages.

Results

In 2011, 71% of generic drugs were placed on the lowest tier (tier 1); by 2015, 19% of covered generics were placed on tier 1, with 46% placed on tier 2, and 35% placed on tier 3 or higher (Figure 1). This shift represents a 53 percentage point decrease in the number of generics being placed on the lowest tier between 2011 and 2015.

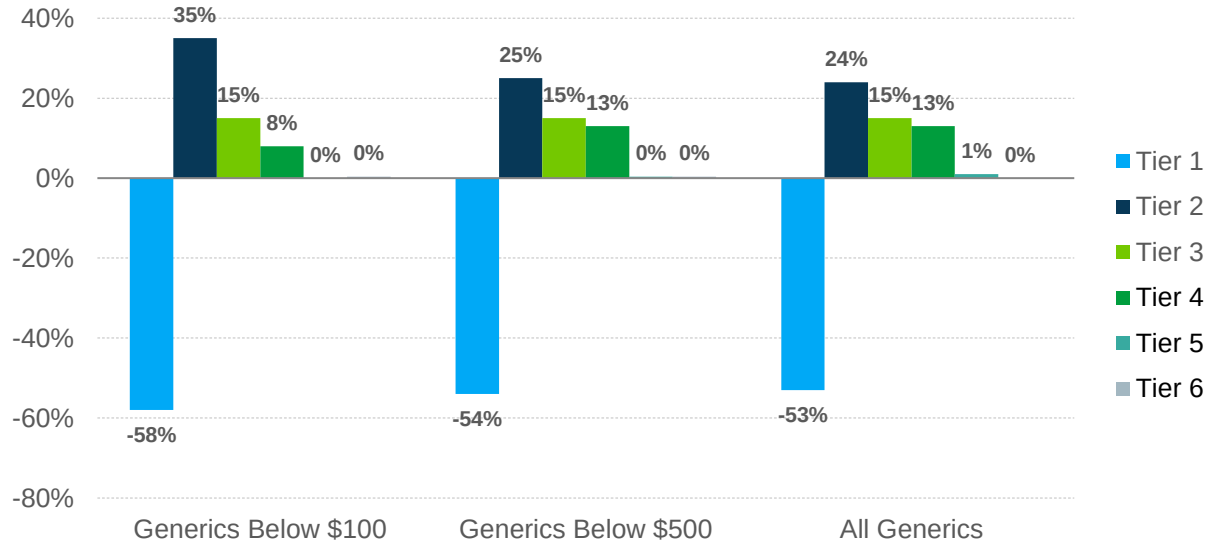
[2] The analysis ended in 2015 rather than 2016 when the new tiering policy was announced because Medicare Part D Dashboard data were only available up through 2015.

Figure 1: Percent Distribution of Generic Drugs on Part D Formulary Tiers, 2011 to 2015



Additionally, this movement from tier 1 to higher tiers was observed across all generics, regardless of cost (Figure 2). In fact, there was a greater percentage point change (58 percentage points) in generics under $100 that shifted from the lowest tier to a higher tier between 2011 and 2015 compared to the overall average (53 percentage point change).

Figure 2: Change in Percentage Point Distribution of Generic Drugs on Part D Formulary Tiers, By Generic Price, 2011 to 2015

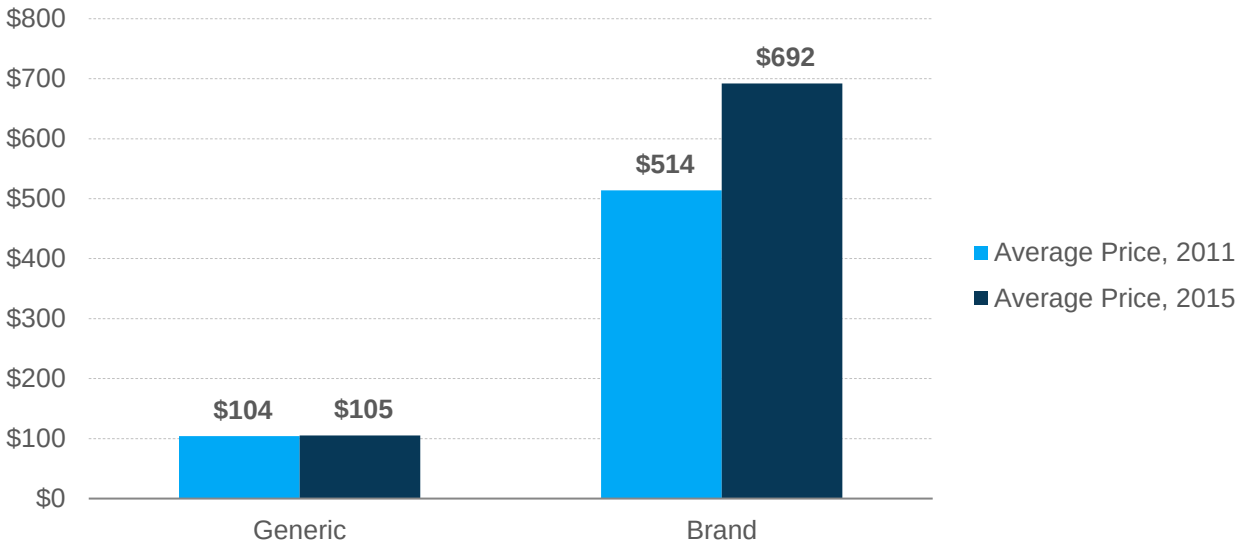


Because our analysis examined drugs that were covered in both 2011 and 2015, we were also able to examine the impact on patient OOP costs that resulted from the shifting of generics from lower to higher tiers for these medicines. We found that total patient OOP costs for the same basket of generic products increased by $6.2 billion between 2011 and 2015, or 93%. In other words, over the 5 years included in our study period, patient OOP spending nearly doubled for the same medications. At the same time, the volume of generics purchased by Part D beneficiaries increased by only 22%.

The higher cost sharing and movement of generics to higher tiers did not correspond with an increase in the underlying price of generic drugs. A recent MedPAC analysis of drug prices found that between 2006 and 2015, the average point-of-sale price of all drugs covered by the Part D program increased by an average of 66%, while the average price of all generic drugs covered by Part D decreased by 74% over the same time period.[5] These findings parallel another study conducted by GAO examining price trends of generics over time; between 2010 and 2015, GAO found that generic prices dropped by 59% for all drugs and declined by 14% for a constant market basket of generics over the same time period.[6]

To see if these overall trends observed by MedPAC and GAO were reflected in the basket of drugs used in our analysis, we analyzed the average volume-weighted price of brands and generics that were included on plan formularies in both 2011 and 2015. We found that average generic drug prices remained almost flat (1% increase) over the study period; in comparison, the average list price of brand drugs increased by 35% over the same period (see Figure 3). Thus, it seems likely that the sharply increased cost sharing borne by Medicare Part D beneficiaries is driven by the higher cost sharing associated with higher tier placement rather than underlying increases in generic drug prices.

Figure 3: Volume Weighted Average Price Brands and Generics, 2011 to 2015



Discussion

While the Medicare Part D program has brought affordable drug coverage to millions of Americans, research has shown that beneficiaries generally select plans based on premiums rather than total expected OOP costs—which would also include deductibles and cost sharing.[7,8] Thus, because plans must compete for enrollment, they have a strong incentive to keep premiums low and potentially shift costs to these other spending categories. Indeed, examination of Part D premiums demonstrates that plans have largely been successful in keeping Part D premiums flat, with the average enrollment-weighted premium growing by only 1% annually between 2007 and 2017.[5] At the same time, federal spending on retail medicines in the Medicare program grew at an average rate of 8% annually over the same time period.[9] Several factors have allowed plans to keep premium costs flat in the face of rising drug costs but may have also had the consequence of driving up patient OOP costs for generic drugs.

Pressure to Keep Premiums Low May Drive up Other Costs

While plans face pressure to keep premiums low, they have flexibility in determining formulary placement, cost sharing, and use of utilization management tools. However, plans must meet coverage and actuarial requirements when designing their benefit structure; plan sponsors must offer benefit designs that are actuarially equivalent to the standard benefit defined by CMS.[10] Although recent data indicate that brand price increases have moderated in the past year, multiple analyses of drug price trends have found that brand prices have increased, while generic prices have either decreased or remained largely flat over the past decade.[5,6,11] This trend is reflected in our analysis of a market basket of drugs covered by plans in both 2011 and 2015, which found significant divergence in the average price trend between brands and generics, demonstrating that rising prices of generics are not a driver of increased costs.

As plans face pressure to cover new, innovative, and sometimes costly branded medications, they have responded with increased utilization management and creative tier placement strategies to moderate the average cost of covered drugs on each tier. If a plan is faced with higher priced branded drugs, one way they can reduce the overall average price of all drugs on a particular formulary tier is to increase the number of lower cost generics on that same tier. Moving less expensive generics onto a tier with a mix of higher-cost branded medicines will reduce the overall average price and cost sharing—and thus increase the actuarial value—associated with that tier. The result of this tiering strategy is that some patients may ultimately pay more out-of-pocket for generic drugs when those drugs are placed on higher tiers. Thus, while the strategy of shifting lower-cost generics onto higher tiers may help plans meet actuarial equivalence requirements and keep premiums and plan liabilities low, as demonstrated by our analysis it can also result in increased patient OOP cost sharing for low-cost generics.

Multiple External Factors May Also Result in Cost Shifting to Beneficiaries

In addition to plan responses to drug price trends, there are several larger contextual factors that may also result in the increased patient OOP cost sharing for low-cost generics that we observed. A recent CMS analysis of plan costs found that between 2011 and 2015, annual plan liability decreased from $798 per beneficiary to $666 per beneficiary.[12] This reduction in plan liability in the face of rising drug costs may be partially due to increased use of rebates, discounts, and growth in the Medicare reinsurance subsidy. While plan liability decreased by 16.5% between 2011 and 2015, our findings show a 93% increase in patient OOP cost for generic drugs over the same time period. Thus, while several tools and programs help limit overall drug costs to plan sponsors and benefit patients by keeping premiums low, they do not necessarily result in lower out-of-pocket costs for patients. This shift to higher cost sharing for generic drugs may threaten plans' previous success in keeping costs down by increasing generic substitution.

Potential Policy Solutions

Part D was designed to bring affordable drug coverage to beneficiaries, filling a critical gap in the original design of the Medicare program, and generics play a crucial role by offering high-value, low-cost therapies to beneficiaries. Ultimately, Part D plan sponsors are required to work within the limitations established by CMS for various tiering structures. If policymakers seek to improve Part D beneficiary access to generic drugs, they may consider several possible solutions. For example, if CMS wishes to reduce cost-sharing for generics in the program, it could consider revisiting the rules governing costs for products on each tier. Requirements around average costs and which products are eligible for each tier could be altered to shift generics towards lower tiers with lower cost-sharing.

While any potential policy proposals may rectify the higher OOP costs associated with some generics by reversing the movement of these drugs onto higher tiers, these types of policy changes may negatively affect patients in other ways. Research has shown that beneficiaries place high value on low monthly premiums, and the flexibility that plans enjoy in designing their benefit structures has allowed plan sponsors to keep premiums low over time; restricting tier structure may result in increased premiums. Additionally, patients may face higher cost sharing for branded products if plans have less flexibility in how they place products across tiers. A thorough analysis of the total costs and benefits to beneficiaries of restricting tier placement of drugs in the Part D program would help clarify how to best optimize the benefit structure. CMS has already proposed a range of policies that would affect the availability of generics in Medicare Part D. It could consider building on its efforts to include a consideration of how to ensure that Medicare patients see the full value of their generic drugs.

Conclusion

The increasing use of generic drugs in the Medicare Part D program has saved billions of dollars.[13,14] However, some patients who take generic drugs have seen their cost sharing for the same generic drugs nearly double over a 5-year period despite the price of those drugs remaining flat over time. This is largely due to market trends around management of high-cost branded products and other factors that may be exogenous to the cost of generic products themselves. While the generic dispensing rate in Part D is relatively high, continuing to realize the cost savings from high generic utilization may require CMS to examine some of the policy options outlined in this paper to encourage beneficiaries to continue to utilize low-cost generics.

References

1. Avalere Health. *Analysis of 2018 Part D Enrollment*. (2018).
2. Hoadley, J., Cubanski, J. & Neuman, T. *Medicare Part D in 2016 and Trends over Time*. (2016).
3. Avalere Health. *2018 Medicare Part D Formularies: An Initial Analysis*. (2017).
4. Centers for Medicare & Medicaid Services. *Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*. (2016).
5. MedPAC. *March 2018 Report to the Congress: Medicare Payment Policy*. Chapter 14: The Medicare prescription drug program (Part D): Status report
6. Government Accountability Office. *Generic Drugs Under Medicare*. (2016).
7. Abaluck, J. & Gruber, J. Choice Inconsistencies Among the Elderly: Evidence from Plan Choice in the Medicare Part D Program. *Am. Econ. Rev.* **101,** 1180–1210 (2011).
8. Heiss, F., Leive, A., McFadden, D. & Winter, J. Plan selection in Medicare Part D: Evidence from administrative data. *J. Health Econ.* **32,** 1325–1344 (2013).
9. Centers for Medicare & Medicaid Services. National Health Expenditure Data, Projected. (2018). Available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html. (Accessed: 16th April 2018)
10. Centers for Medicare & Medicaid Services. *Medicare Prescription Drug Benefit Manual, Chapter 6 – Part D Drugs and Formulary Requirements*. (2016).
11. IQVIA Institute. *Medicine Use and Spending in the U.S. A Review of 2017 and Outlook to 2022*. (2018).
12. Centers for Medicare & Medicaid Services. Medicare Part D – Direct and Indirect Remuneration (DIR). (2017). Available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html. (Accessed: 17th April 2018)
13. Duru, O. K. *et al.* Potential Savings Associated with Drug Substitution in Medicare Part D: The Translating Research into Action for Diabetes (TRIAD) Study. *J. Gen. Intern. Med.* **29,** 230–236 (2014).
14. Association for Accessible Medicines. Generic Drug Access & Savings in the U.S. (2017). Available at: https://www.accessiblemeds.org/sites/default/files/2017-06/2017-AAM-Access-Savings-Report-2017-web2.pdf. (Accessed: 18th April 2018)

About Us

Avalere is a vibrant community of innovative thinkers dedicated to solving the challenges of the healthcare system. We deliver a comprehensive perspective, compelling substance, and creative solutions to help you make better business decisions. As an Inovalon company, we prize insights and strategies driven by robust data to achieve meaningful results. For more information, please contact info@avalere.com. You can also visit us at **avalere**.com.

Contact Us

Avalere Health
An Inovalon Company
1350 Connecticut Ave, NW
Washington, DC 20036
202.207.1300 | Fax 202.467.4455
avalere.com