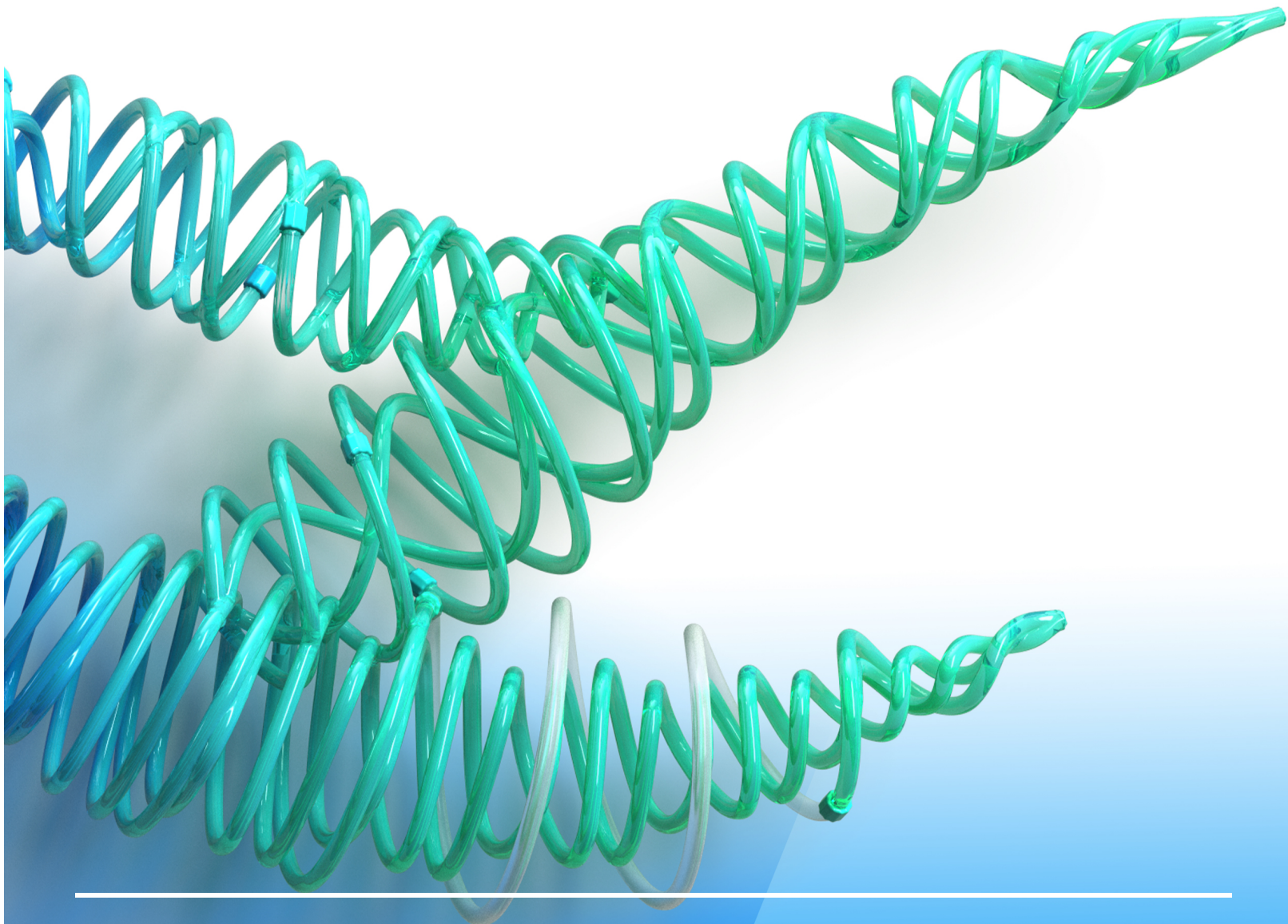

Charitable Assistance in Medicare Part D

Sponsored by the Patient Access Network (PAN) Foundation

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Charitable Assistance in Medicare Part D

Introduction

As policymakers discuss ways to curb program expenditures and improve patient affordability in Medicare Part D (Part D), the role of charitable assistance in helping beneficiaries with out-of-pocket (OOP) costs has garnered interest. In this study, Avalere analyzed charitable assistance by evaluating recent Part D costs and patient assistance trends for beneficiaries who do not receive the Low-Income Subsidy (i.e., non-LIS beneficiaries).

Part D offers federally subsidized prescription drug coverage for seniors and persons with disabilities. In addition to Part D premiums, beneficiaries are responsible for paying a share of their drug costs, or OOP costs. For non-LIS beneficiaries enrolled in a standard Part D plan, beneficiaries must first pay 100% of drug costs in the annual deductible. Beneficiaries then pay a 25% coinsurance for drugs through the initial coverage limit and coverage gap phase until they reach the true out-of-pocket threshold,¹ after which coinsurance drops to 5% for all drug spending during the remainder of the calendar year.

For many non-LIS beneficiaries, particularly those taking specialty drugs, OOP costs can be high,² and outside of the LIS program, most Part D beneficiaries have limited access to help paying for OOP costs. Manufacturer cost-sharing assistance (e.g., Patient Assistance Programs (PAPs) and manufacturer coupons) available for enrollees in other markets are not permitted in Part D due to the Office of Inspector General (OIG) guidance related to federal anti-kickback laws.³ And, while some beneficiaries may have the option to enroll in a more generous retiree plan through their former employers, this is not true for the vast majority of Medicare Part D beneficiaries, as they are usually limited to the standard or enhanced Part D plans available in their particular regions. Further, the Medicare Part D program lacks a limit on total annual OOP spending, as seen in commercial coverage. Finally, unlike the supplemental coverage available for Original Medicare Part A and Part B benefits, no such supplemental options exist for Part D coverage.

This leaves charitable assistance as one of few options for non-LIS beneficiaries to get relief from unaffordable OOP costs. Charitable organizations can provide patient assistance in Part D without triggering an anti-kickback violation if they meet requirements for approval from the federal government. However, some stakeholders have raised questions about whether lowering OOP costs for non-LIS beneficiaries, as a result of charitable assistance, contributes to higher drug spending.

1 True out-of-pocket, or TrOOP, refers to the total amount spent in a year on Part D drugs prior to entering the Catastrophic Coverage phase of a Part D plan, which includes beneficiary cost sharing in addition to TrOOP-eligible payments made by qualified entities on behalf of a beneficiary, such as manufacturer coverage gap discounts (e.g., 70% of brand name drugs in the coverage gap discount). The 2020 TrOOP threshold is set at \$6,350. Available [here](#).

2 Kaiser Family Foundation, "No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs Without a Hard Cap on Spending," November 2017, Available [here](#).

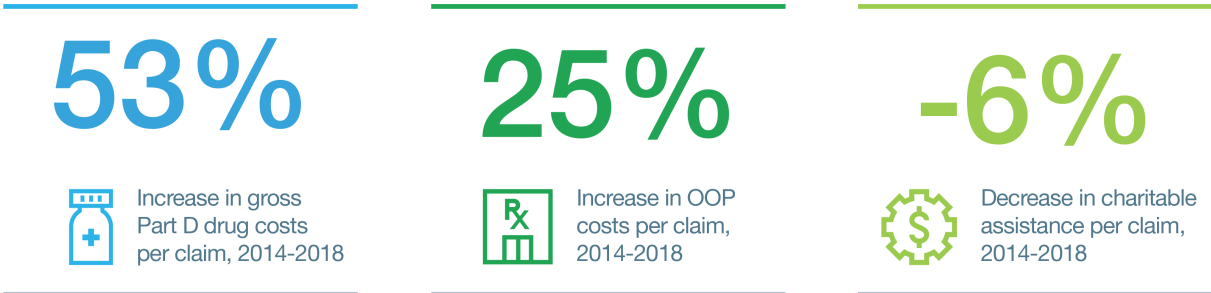
3 Office of Inspector General (OIG) interpretation of federal anti-kickback laws, Available [here](#).

Analysis and Results

To understand the impact charitable assistance may have on Part D spending, Avalere examined Part D prescription drug claims for non-LIS beneficiaries for 2014 and 2018. Avalere identified 100 branded drugs that were among the top drugs by total spending in both 2014 and 2018 and had the highest total charitable assistance in both 2014 and 2018. For each drug, Avalere determined the respective number of prescriptions (with and without charitable assistance), gross Part D drug costs, OOP costs per prescription, and charitable assistance amounts per prescription in both years. Avalere then examined utilization and cost trends over the 5-year study period. Avalere did not evaluate nor make assumptions around rebate levels; therefore, the analysis focuses on gross Part D drug costs and spending trends rather than net Part D drug costs or spending. Namely, Avalere determined gross Part D drug costs by calculating the Part D pharmacy reimbursement amounts on a per prescription basis.

This analysis finds that charitable assistance offsets only a very small share—less than 3%—of total non-LIS beneficiary OOP costs for the set of drugs in both years. In addition, this analysis finds that, for these drugs, the amount of charitable assistance used by beneficiaries has declined over time, despite growth in both OOP costs per claim and gross Part D drug costs per claim.

For this cohort of 100 branded drugs, the analysis found the following trends between 2014 and 2018:

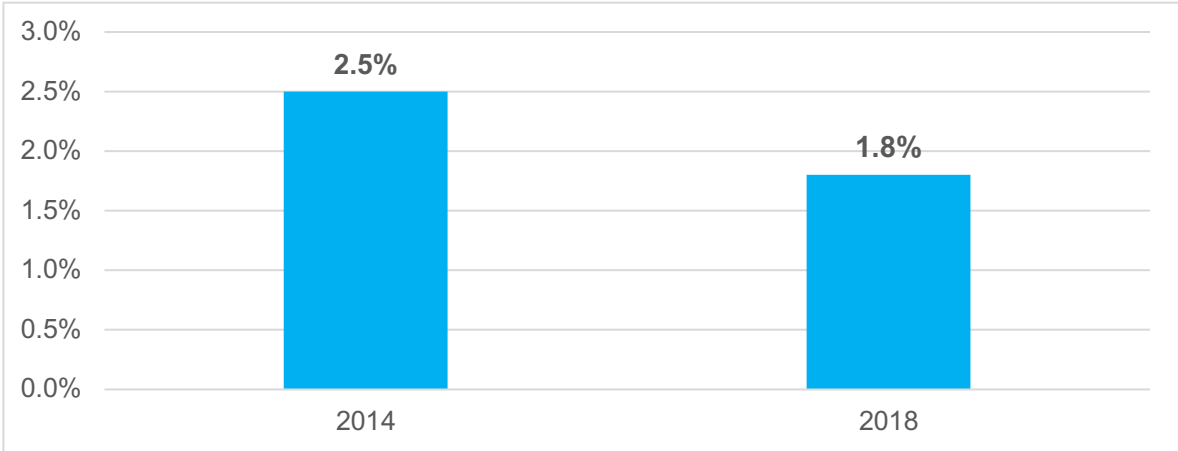


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For this cohort of branded drugs, the analysis showed that average charitable assistance amounts declined slightly from \$2.25 per prescription in 2014 to \$2.12 in 2018. During the same period, the average prescription costs for these drugs changed from \$428.59 to \$654.55 per prescription (a 53% increase) while the OOP costs paid by patients changed from \$72.27 to \$90.50 per prescription (a 25% increase).

Additionally, Avalere examined the share of prescriptions filled for the cohort of branded drugs in the analysis that received charitable assistance (Figure 1). In 2014, 2.5% of the prescriptions filled for this cohort were provided with charitable assistance. In 2018, however, a smaller share of prescriptions—1.8%—received charitable assistance.

Figure 1: Share of Claims Subject to Charitable Assistance (2014-2018), 100 Branded Drug Cohort



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Discussion

For the cohort of drugs analyzed, gross Part D drug costs and OOP costs trended up between 2014 and 2018. This analysis confirms prior analyses demonstrating that gross Part D drug costs have been going up over time. Notably, OOP costs per claim increased despite decreases in the coverage gap coinsurance amounts between 2014 and 2018. At the same time, and for the same set of drugs, patient assistance trended down and became a smaller share of OOP costs per claim and gross Part D drug costs per claim over this 5-year period.

Though this study did not evaluate a causal role between the elements of the analysis, it does demonstrate that patient assistance compared to OOP spending and gross Part D drug costs has not increased at the same rate for the drugs included in this analysis. These findings indicate that charitable financial assistance for this cohort of drugs is associated with only a small share of OOP costs and an even smaller share of gross Part D drug costs. For the drugs included in this analysis over the 5-year period, none of the findings suggest that the amount of charitable financial assistance provided has a meaningful influence on gross Part D drug costs.

Methodology

Avalere used Medicare Part D Drug Event (PDE) data from 2014 and 2018, accessed under a research-focused data use agreement with CMS. The PDE data contains comprehensive information on Part D drug costs, including claim-level information on "Other TrOOP" such as charitable assistance and payments from State Pharmaceutical Assistance Programs (SPAPs). For each year of the analysis, Avalere identified a sample of non-LIS beneficiaries no larger than 20% of Part D beneficiaries in any given year. To do this, Avalere excluded from this sample beneficiaries enrolled in the Low-Income Subsidy (LIS) for any month in the year, who resided outside the 50 states and DC, or where total drug costs for the claim are equal to zero. Avalere then weighted the results of the analysis to reflect the full non-LIS population.



To compare the level of charitable assistance in 2014 and 2018, Avalere identified brand drugs that were on the market in both years. Avalere then assessed product-level drug costs, patient out-of-pocket costs, and "Other TrOOP." To adjust the data on "Other TrOOP" to reflect only assistance provided by charitable foundations and not State Pharmaceutical Assistance Programs (SPAPs), Avalere surveyed SPAPs and excluded "Other TrOOP" that is likely provided by an SPAP based on key beneficiary characteristics (e.g., use of antiretroviral drugs, residence in key states). Avalere then identified a cohort of 100 drugs with highest total Part D drug spend and charitable assistance to use in this analysis. This analysis does not include utilization or costs for products that were not on the market in either 2014 or 2018 or were outside this 100-drug cohort. Finally, this analysis does not account for product-level rebates; therefore, the results focus on gross, not net, Part D costs.

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