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DESERVING OF BETTER:

How American Seniors Are Paying For Misaligned Incentives Within Medicare Part D

REPORT SPONSORED BY -
AMERICAN PHARMACY COOPERATIVE, INC. (APCI)
& AMERICAN PHARMACISTS ASSOCIATION (APHA)

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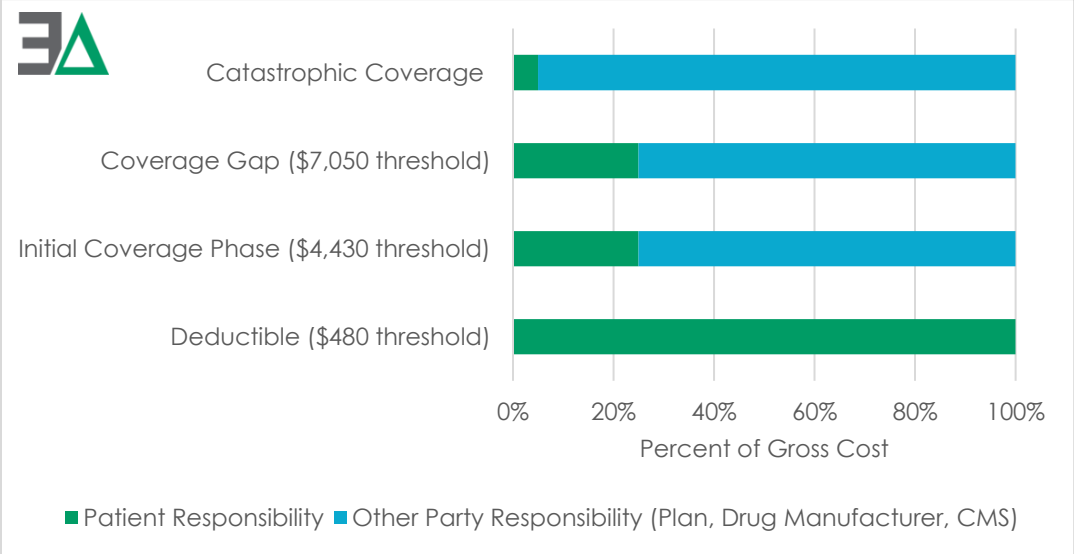
Executive Summary

Millions of America's elderly rely on the *Medicare Part D* program to afford prescription medications. Because adherence to prescription medications is a primary determinant of treatment success, Medicare Part D represents one of the most critical programs to the overall health of the elderly in this country. [1] However, despite the availability of a prescription drug benefit, many Medicare beneficiaries still struggle to afford prescription drugs. It is well documented that the United States pays more for prescription medications than any other country in the world. [2] As countless studies have demonstrated that as patient cost increases adherence to therapies decrease, it is perhaps unsurprising that America's health outcomes are not achieving the desired results. [3]

The Centers for Medicare and Medicaid Services (CMS), the federal body responsible for oversight of the Medicare Part D benefit, reports a growing disparity between *gross Part D drug costs*, calculated based on costs of drugs at the pharmacy counter, and *net Part D drug costs*, which account for all *Direct and Indirect Remuneration (DIR)*. DIR is a broad name given to additional discounts a *Part D plan sponsor* (or their contractor, i.e., *pharmacy benefit manager (PBM)*) negotiates within the drug supply chain above the *pharmacy counter price*, such as retroactive pharmacy price concessions, or manufacturer rebates. The growing divergence between gross and net spending in Medicare Part D has significant implications for the Part D program. This is because the majority of a Medicare enrollee's *cost share* is determined from gross, and not net, drug spending (**Figure 1**). [4]

Figure 1: Medicare Part D Standard Plan Parameters, Patient Cost Sharing Liability for 2022[1]



According to CMS' own analysis, the implications of this trend include: (1) higher Medicare Part D cost-sharing for members because cost-sharing is calculated based on the drug price at the pharmacy *point-of-sale (POS)*, without regard to *rebates* and other discounts received after the point-of-sale; (2) quicker progression of Part D enrollees through the Part D drug benefit phases due to higher beneficiary cost sharing; (3) higher costs to the federal government as more patients reach the

[1] Medicare enrollees in the low-income subsidy's (LIS) cost share amounts will differ from those presented. In 2020, approximately 20% of Medicare Part D members were enrolled in the LIS. [13]

catastrophic phase of Medicare coverage, where Medicare liability is generally about 80%; and (4) an increase cost to Medicare for covering cost-share requirements of the most needy seniors enrolled in Medicare's low income subsidy program. [5] Under current Part D rules, the largest share of all rebates and other discounts allocated to reduce the Medicare Part D plan liability. In other words, Part D sponsors, who control drug spending for Medicare, are in fact responsible for only a share of Part D drug spending, and as a result of the increasing preference for high price *Direct and Indirect remuneration (DIR)* arrangements, that proportion is shrinking each year.

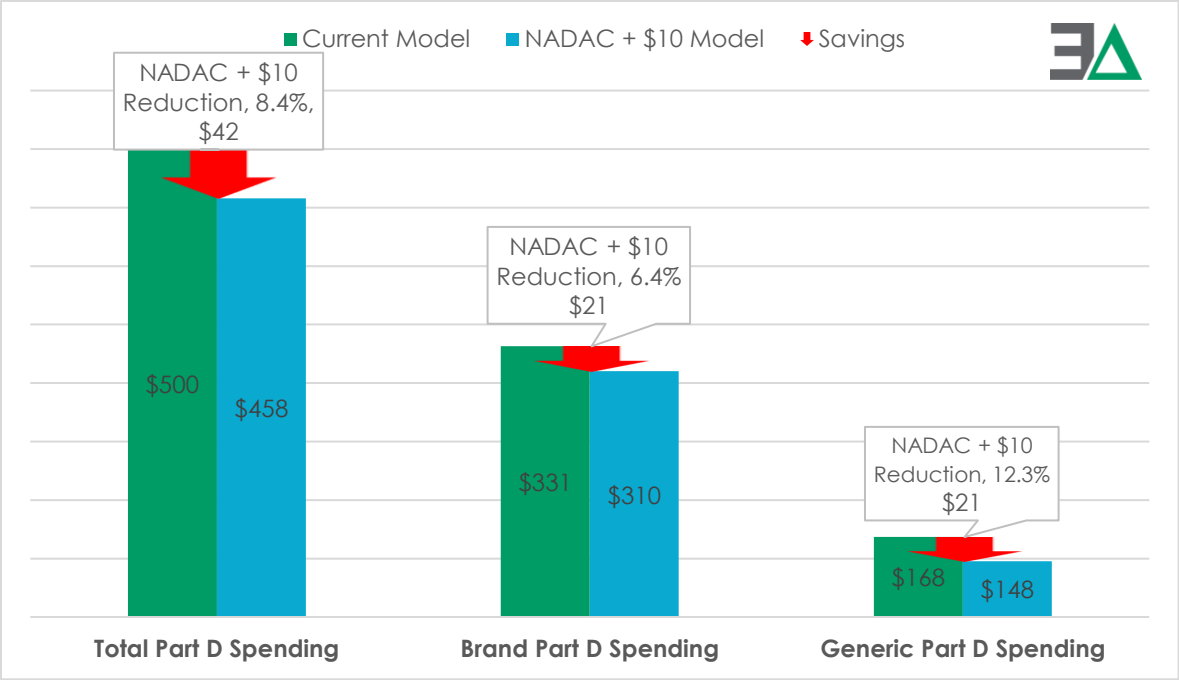
Medicare is not the first program to struggle with prescription drug costs. Medicaid, another federal program overseen by CMS, has adopted a relatively new model for paying for prescription drugs – one that aligns program costs to surveyed benchmarks meant to approximate the prices paid by pharmacies to purchase medications. The most common benchmark utilized by state Medicaid programs is *National Average Drug Acquisition Cost (NADAC)*, which is typically used as the basis for both the state's cost exposure and the pharmacy's reimbursement for the drug's ingredient cost. Because NADAC is meant to cover just the cost of the drug itself, it is then coupled with a *professional dispensing fee* that is meant to cover the cost of the service and overhead incurred by pharmacy providers.

Amidst growing complaints from providers and patients regarding the inflated and unpredictable prices for prescription drugs within the program, 3 Axis Advisors was asked by the American Pharmacy Cooperative, Inc. (APCI) and the American Pharmacists Association (APhA) to explore how application of the bedrock of Medicaid's drug pricing design into Medicare might alleviate ballooning costs within the program.

In this study, we found that Medicaid's NADAC-plus-professional-dispensing-fee model offered an overall point-of-sale spending decrease, and savings to Medicare beneficiaries as a result of their reduced cost-sharing obligations. Specifically, we found (**Figure 2** on the next page):

- Savings of 8.4% ($499.78 million to $457.86 million) on 8,553,375 Part D transactions dispensed in 2021 at over 1,000 community pharmacies;
- Reductions in average beneficiary cost at the pharmacy counter for brand prescriptions by $43.74 (487,507 transactions), and $2.56 (8,065,868 transactions) per generic prescription.

Figure 2: Part D (2021) Current Pricing to NADAC Model Differences (Millions ($))



Applying these results to the entire Medicare Part D program in 2021, the NADAC-based model offers **$18.17 billion in potential point-of-sale (POS) cost reductions** for the benefit of Medicare enrollees.

A detailed multiyear analysis of a large Part D plan demonstrated that the alternative NADAC-based model would have reduced the pharmacy counter brand prices by 8.0% and generic prices by 34.8% over the current PBM-managed model. Furthermore, patient cost sharing obligations under this new model, which do not receive the benefit of retrospective DIR, would see a savings of approximately $10 per claim for impacted claims (those with a cost share greater than the net pharmacy price) in this large Part D plan going forward.

America's elderly deserve a better Medicare Part D benefit. Efforts to reform Medicare Part D that fail to address inflated out-of-pocket costs for seniors will result in a current problem getting materially worse in the future. Similarly, efforts to reform Medicare that fail to address the incentives that encourage Part D plan sponsors to avoid appropriately managing costs at the pharmacy counter, and instead shift costs and risks onto the federal government, will only result in higher costs to the federal budget.

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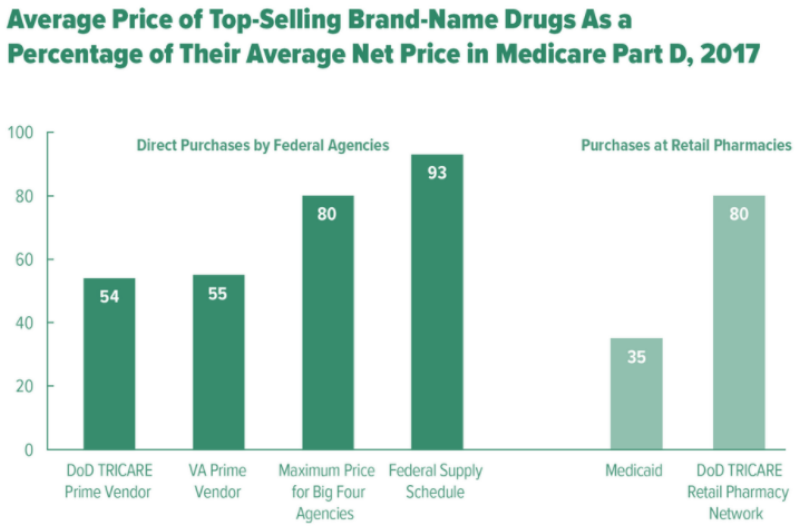
Introduction

It is well documented that the United States pays more for prescription medications than any other country in the world. [1] In countless studies, measured through a variety of methods, by organizations ranging from the U.S. Government Accountability Office (GAO), Congress, and non-profit research organizations, the U.S. stands apart from its peers in terms of drug prices. [6] [7] [8] On a more micro level, one of the most studied drugs, in terms of drug affordability, are the insulins. Our own prior work found that insulin prices in the U.S. are 14 times as much as that in other high-income nations. [9] Regardless of the reasons and caveats (of which there are many), there is little disputing the fact that when it comes to the price of prescription drugs, the U.S. bears a disproportionately high burden compared to our global peers.

However, what makes the U.S. system perhaps different than other nations is how consumer drug costs are determined. There is no central authority in the U.S. to determine a drug's cost, and the U.S. has a lot of different mechanisms it uses to quantify drug costs throughout the prescription drug supply chain. Consequently, a patient's cost exposure may be determined in any number of ways. Nevertheless, most patients in the U.S. have prescription drug insurance, and therefore don't shoulder 100% of a drug's costs. [10] Whether it be through Medicaid programs for the impoverished, Medicare for the elderly, commercial insurance, or drug discount cards, it is generally expected that our cost for drugs will be derived from a *negotiated price* discount on our behalf.

Within the U.S., there are numerous factors which determine an individual's prescription drug cost, due to the array of programs which provide prescription drug insurance. Because of the variety of programs, drug costs are highly variable within the U.S. As can be seen in **Figure 3**, federal programs may pay very different costs for the same drug depending upon which program the drug is purchased within, with Medicare paying the highest amount for drugs relative to any other federal payer. *[11]*

Figure 3: CBO Comparison Report on Brand-Name Drug Prices Among Selected Federal Programs

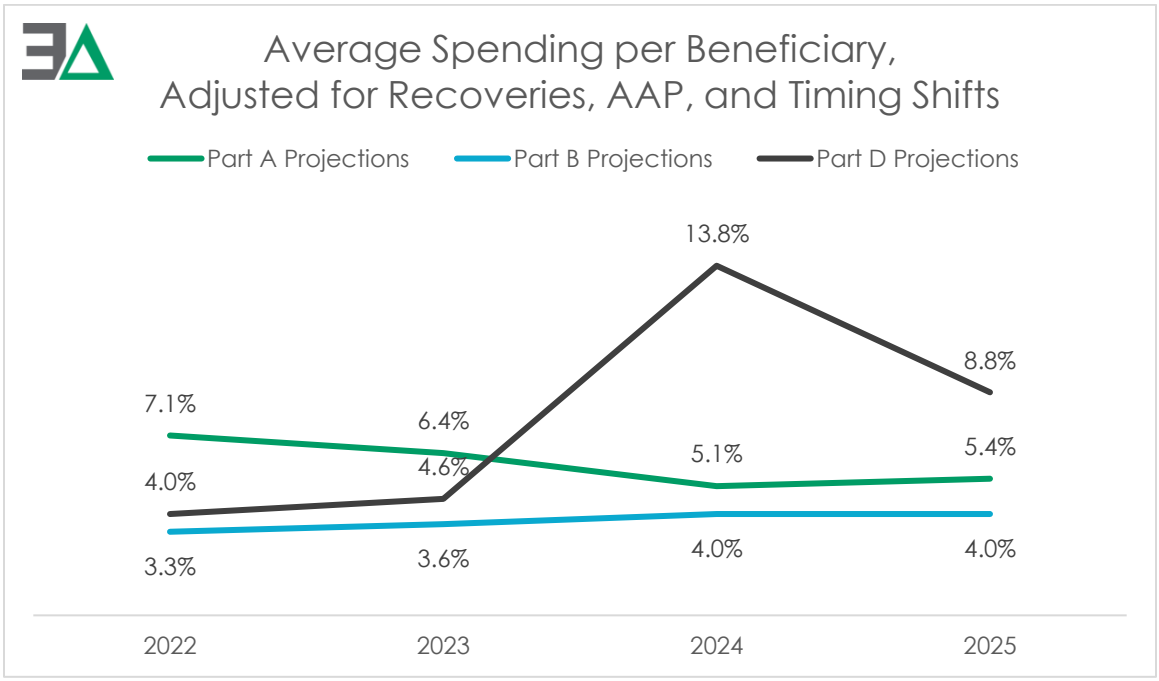


It should come as no surprise reviewing **Figure 3**, that patients pay different drug costs depending upon which program they are enrolled in. Even within the same source of benefits (i.e., Medicare,

commercial, etc.), the variety of benefit options and phases can result in patients paying very different costs, even within the same program.

The largest program that provides prescription benefits in the U.S., based upon drug expenditures, is Medicare. In 2020, more than 48.7 million Americans participated in the Part D program, accounting for more than $198 billion in annual expenditures by Medicare for drugs. [12] [13] It is currently estimated that the Medicare Part D drug benefit will be a key cost driver for Medicare in the coming years. [13] This is because the Congressional Budget Office (CBO) estimates that the annual increase for the Part D drug benefit will exceed that of Part A (hospital services) and Part B (physician services) in the coming years (**Figure 4**). [14] To that end, it can be easy to forget that the Medicare prescription drug benefit is relatively new and has only been around for 15 years, far less than Medicare's 56-year history.

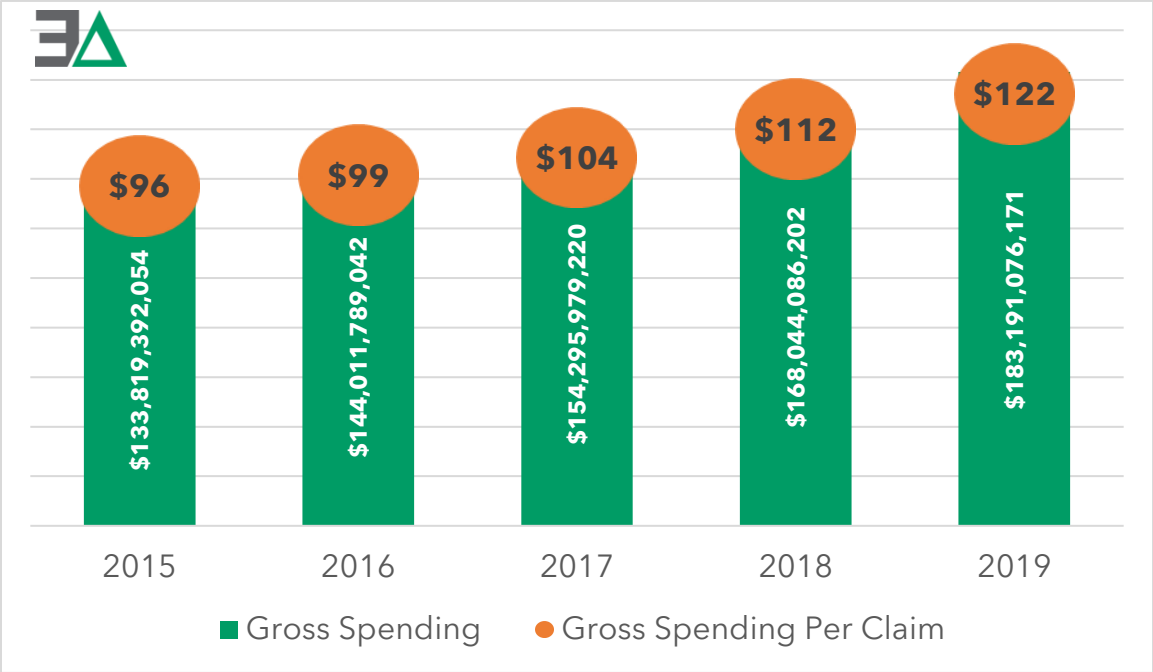
Figure 4: CBO Baseline Projections – Annual Growth Rate (%) in Medicare



Part D and Rising Retail Prices

One of the key factors influencing Medicare Part D spending projections is the growing disconnect between gross Part D drug costs, that is the calculated costs of drugs at the pharmacy counter, and net Part D drug costs, which account for all Direct and Indirect Remuneration (DIR). DIR is a broad name given to additional discounts a Part D plan sponsor (or their contractor, i.e., pharmacy benefit manager) negotiates within the drug supply chain above the pharmacy counter price, such as *retroactive pharmacy price concessions*, or manufacturer rebates. As can be seen in **Figure 5**, gross spending on prescription drugs with Medicare Part D has accelerated over the last several years (27% increase from 2015 to 2019). [15]

Figure 5: Medicare Part D Gross Spending Trends, 2015 to 2019



Part D and Rising Pharmacy Fees

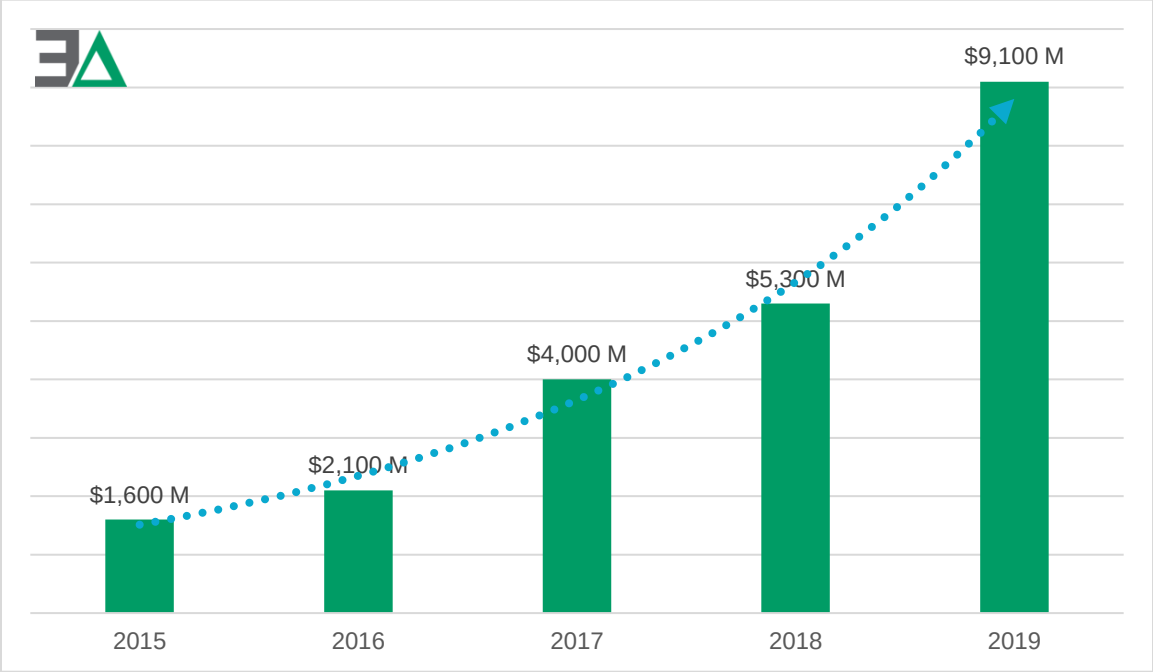
A contributing factor to higher gross spending in Medicare has been the increased collection of discounts, known as direct and indirect remuneration (DIR) in Medicare, from pharmacies and manufacturers. DIR was intended to capture all price concessions on a prescription to ensure that neither CMS nor the beneficiary overpaid for their medications. [16] DIR has been utilized in Part D since the program's inception, as it was recognized that not all price concessions such as manufacturer rebates, could be tracked at the point of sale.

Today, DIR includes 11 trackable price concession categories that are generated from pharmacies, manufacturers, or other sources that lower net spending. [17] Price concessions (DIR) that occur after the sale of the prescription help to lower overall net program costs but are not reflected in prescription prices at the pharmacy counter (gross price), the price in which beneficiaries are exposed to. CMS has acknowledged that higher gross spending may have a significant impact on beneficiary cost share and increase operational costs to the federal government due to higher *reinsurance* and low-income subsidy payments. [5]

Pharmacy DIR have increased substantially over the last decade. [18] Pharmacy DIR can be considered a reduction in the retail negotiated gross price (the price the beneficiary is exposed to) set by the PBM with the pharmacy as the DIR generally takes the form of a percentage of the drug price. Pharmacy DIR may be a mandatory price concession, performance based, or a combination of both. CMS definition requires that the negotiated price − the price that beneficiaries are exposed to − must include "all price concessions from network pharmacies except those contingent price concessions that cannot reasonably be determined at the point of sale." [19] The loose definition has provided pharmacy benefit managers (PBMs) and Part D plan sponsors the opportunity to utilize higher and higher performance-based pharmacy DIR metrics and forego efforts to lower the price at

the pharmacy counter. [5] The result has been a shift to higher *retail prices* managed by higher post point-of-sale (POS) pharmacy DIR. [5] So, while gross drug prices in Medicare are increasing (**Figure 5** previously), the net value of pharmacy DIR in Medicare Part D has grown as well (**Figure 6**), off-setting the gross spending trend to Medicare as a whole. [20]

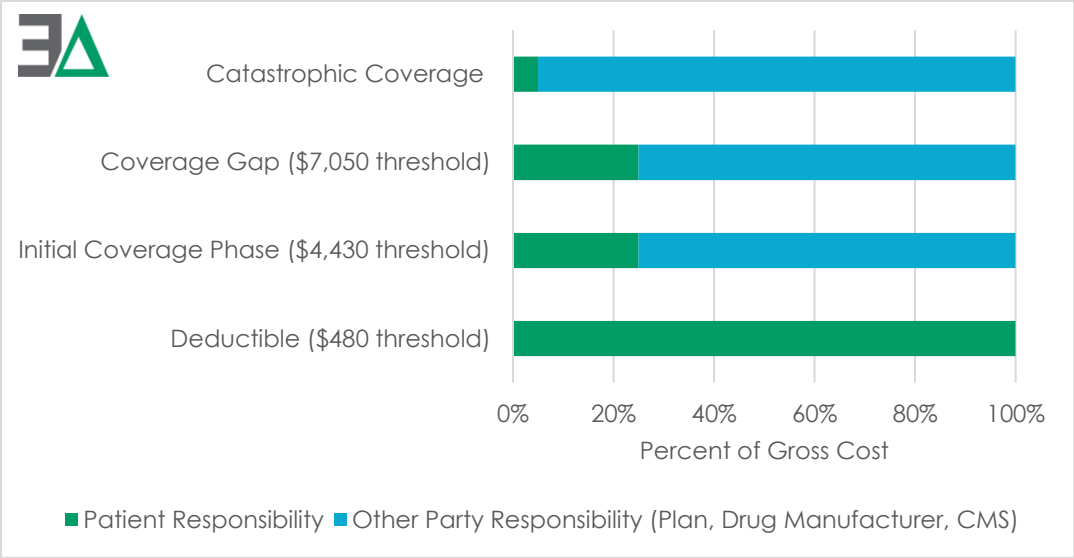
Figure 6: Pharmacy-related DIR value (Millions ($)), 2015 to 2019



The data shows that pharmacy DIR is large enough to have a significant effect on a pharmacy's economics and the Medicare Part D program as a whole. Pharmacy DIR, that is DIR exclusive of manufacturer rebates, accounted for more than 18% of the total DIR paid to Part D plans in 2019. At the same time, pharmacy DIR is a growing percentage of pharmacy revenues, creating significant operational challenges to running a pharmacy. [20] Pharmacies pay out more to Part D plans in DIR than they earn in performance payments. For 2016 (the most recent year for which data are available), the GAO reported that Part D plan sponsors received $2.3 billion from pharmacies but paid only $211 million to pharmacies (see **Figure 6** above). [20]

Today, Medicare Part D has to reconcile the fact that gross costs for prescription drugs are escalating rapidly while the net price per prescription within the Part D program is declining. While it is tempting to focus only on the net price decline, one of the key consequences of this paradigm has been the rapid increase in people reaching catastrophic coverage, which significantly increases federal government expenses within Medicare Part D via reinsurance payments. [21] Additionally, the higher gross cost experience year-over-year can contribute to affordability problems for Medicare beneficiaries, whose cost share is often determined in relation to the drug's gross, and not net, cost (**Figure 7**). [4] [5]

Figure 7: Medicare Part D Standard Plan Parameters, Patient Cost Sharing Liability for 2022[2]



By transferring retail price concessions from point-of-sale (POS) reductions into pharmacy DIR (higher pharmacy retail prices in favor of collecting a post-sale discount), a plan can decrease its cost exposure in the initial coverage phase. [22] In so doing, the beneficiary cost share at times may exceed the net price of the prescription after the pharmacy pays the minimum DIR. This is often referred to as a "*clawback,*" as the price the patient pays is higher than the net price paid to the pharmacy. Said differently, if the retrospective DIR was not present, the patient would pay less for their drug at the pharmacy counter. Ultimately, the party that arguably benefits most from the current design of Medicare Part D is the private plan sponsor, as both the government and patient are faced with overinflated costs for prescription medications.

[2] Medicare enrollees in the low-income subsidy's (LIS) cost share amounts will differ from those presented. In 2020, approximately 20% of Medicare Part D members were enrolled in the LIS. [13]

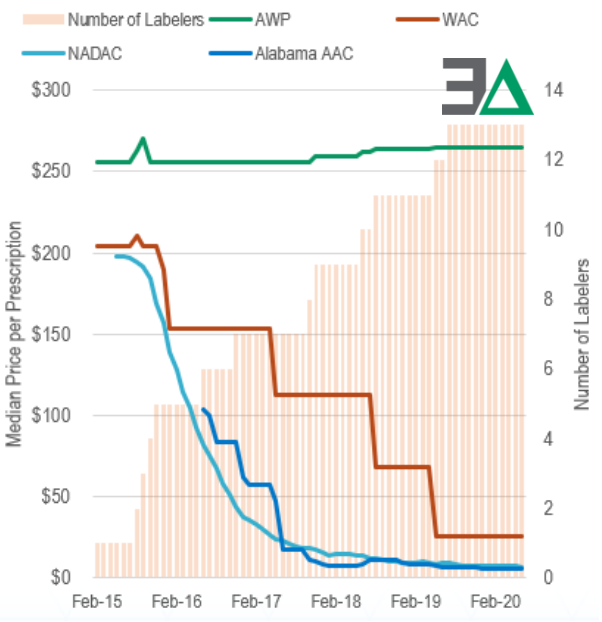
PBM Drug Reference Pricing Methods

Average Wholesale Price (AWP) Based Drug Reimbursement

Private Medicare Part D plans do not directly set pharmacy counter prices or DIR amounts. Rather, plan sponsors hire PBMs to form retail pharmacy networks such that their beneficiaries can get their medications filled. In forming retail pharmacy networks, PBMs and pharmacy groups agree to payment terms for prescription drugs which include a *price guarantee*. A price guarantee between a PBM and retail pharmacy is often based on a drug reference price known as *Average Wholesale Price (AWP)*. The AWP "was intended to represent the average price at which wholesalers sell drugs to physicians, pharmacies, or other customers." [23] However, AWP is a broken pricing benchmark in many regards, as it is routinely a multiple of a self-reported manufacturer list price and does not accurately track actual pharmacy acquisition costs. [23] Furthermore, there is a long-track record of documented issues with the reliability of AWP as a pricing benchmark. In July of 2011, the U.S. Department of Health & Human Services Office of Inspector General (OIG) released findings they conducted on AWP reimbursement within the state Medicaid system. The report was in response to the announcement of First Data Bank's agreement to cease publishing their AWP database due to legal allegations that they had improperly set AWPs on 95% of retail medications. [24] [25] The report concluded AWP reimbursement models are, "fundamentally flawed" and have led to excessive payment for prescription medications by state Medicaid systems. [24] The recommendation made by the OIG was for Medicaid to adopt an alternative method of payment rooted in pharmacy acquisition cost. [24]

Despite the significant disconnect that exists between AWP and actual acquisition cost (AAC) (see **Figure 8** for an example)[3], PBM contracted pricing guarantees to both plan sponsors and pharmacies remain rooted in AWP as the industry standard. To adhere to the guarantee on the pharmacy end, PBMs are responsible for accurately discounting the inflated AWP to capture supply chain discounts both at the retail price level (i.e. the pharmacy counter) and post prescription sale (i.e., via DIR or *effective rate* reconciliation). [26] Or put another way, whether the PBM reimburses the pharmacy in adherence to the guarantee at the point of sale, or if the PBM has to "*true up*" aggregate point-of-sale overpayments or underpayments at a later time, the terms that govern the PBM contract with the pharmacy necessitate that all payments will inevitably be reconciled to achieve the contract's guaranteed rate. [26]

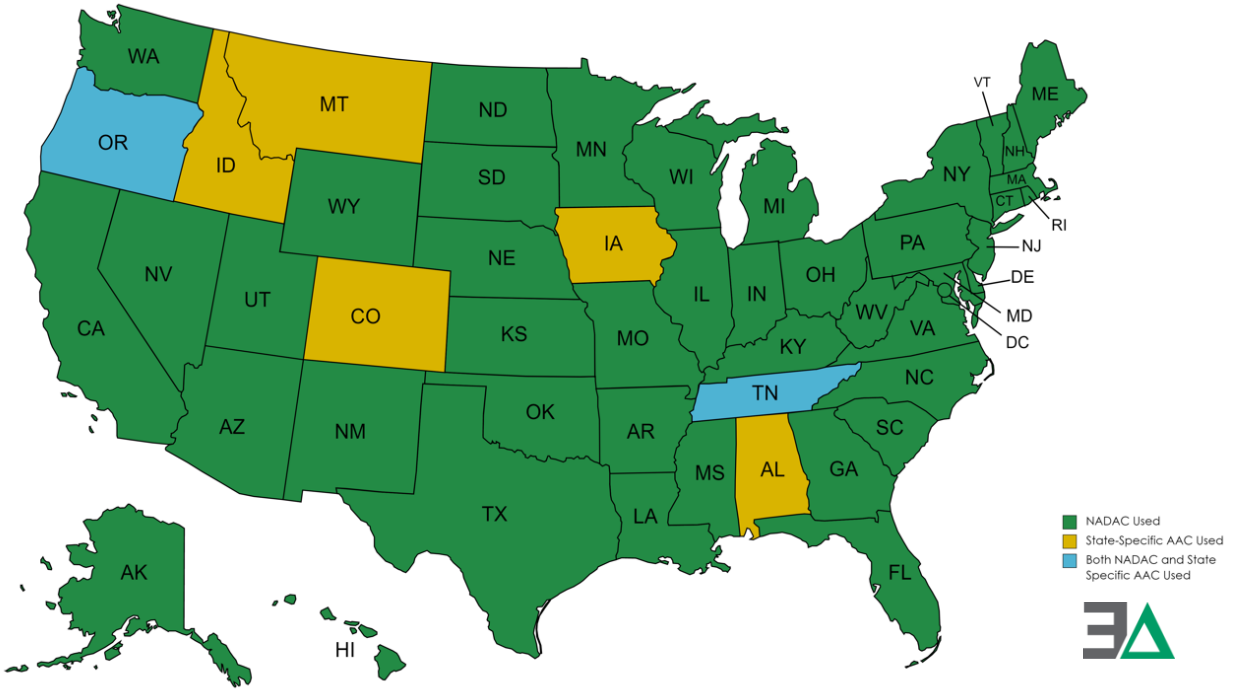
Figure 8: Generic Nexium Drug Pricing Benchmark Comparison



[3] 3 Axis Advisors analysis of internal data sets

Because of inconsistencies between AWP and pharmacy acquisition costs, there are many opportunities for members of the drug channel to engage in arbitrage – especially for those who control price setting, notably PBMs. Therefore, it should come as no surprise that CMS supported the earlier reviewed OIG findings on AWP dysfunction, and lacking an accurate national benchmark for drug pricing, established the National Average Drug Acquisition Cost (NADAC) database by surveying drug purchase invoices from retail pharmacies as an alternative reimbursement methodology to the prevailing AWP-based methodology. [24] Many *fee-for-service (FFS)* state Medicaid programs would eventually transition from AWP to NADAC-based reimbursement both as a means to determine the actual acquisition cost of a drug rather than relying upon AWP, but also because federal policy was changed via the Affordable Care Act (ACA) that required Medicaid programs to pay at actual acquisition costs. [24] [27] Today, nearly all Medicaid programs in the country rely upon NADAC in determining a portion of their drug costs (**Figure 9** on the next page) [28]

Figure 9: Current State Medicaid Program Use of NADAC for Drug Payment



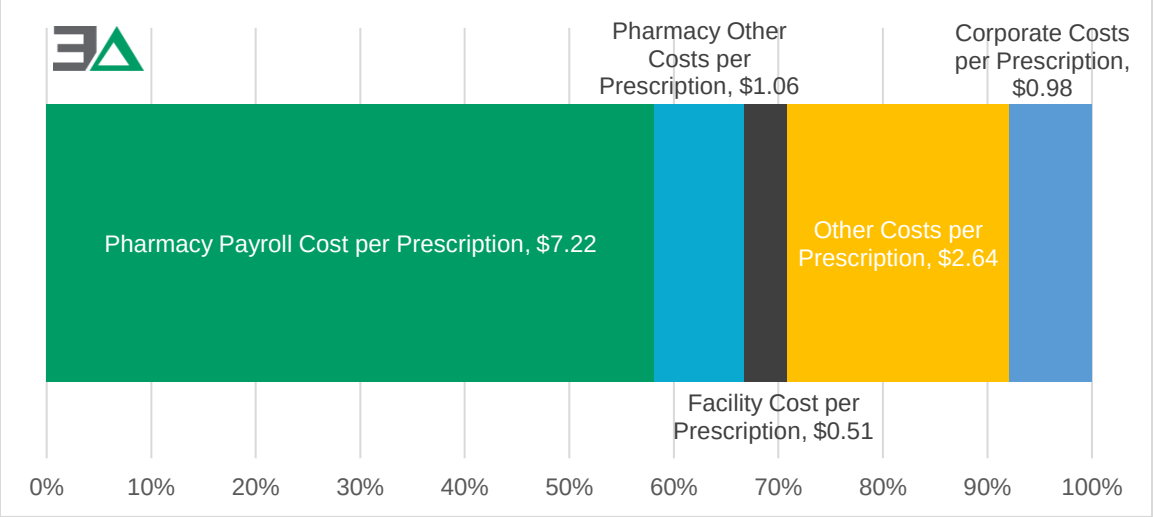
National Average Drug Acquisition Cost (NADAC) Based Reimbursement

In the NADAC-based payment model employed by Medicaid, the provider (pharmacy) is reimbursed at the average invoice cost for the drug plus a professional dispensing fee meant to cover the costs associated with the pharmacy's service. NADAC was developed by CMS, "to provide a national reference file to assist State Medicaid programs in the pricing of Covered Outpatient Drug claims to reflect the actual acquisition cost (AAC) of drugs." [29] As such, NADAC's goal is to be the most comprehensive public measurement of market-based retail pharmacy acquisition cost available. NADAC is compiled by Myers & Stauffer, an accounting firm that specializes with public health care and social service agencies, on behalf of CMS. It is generated from a voluntary monthly invoice cost survey of 2,500 randomly selected retail pharmacies (with 450 to 600 respondents). After Myers &

Stauffer completes its data processing and cleanup activities, it publishes the survey results at the *National Drug Code (NDC)* level on Medicaid.gov. [29] Any market invoice price erosion that occurs becomes reflected at the point of sale and shared with the beneficiary in groups that use a NADAC-based reimbursement strategy. As previously reviewed, this is not the case in AWP model because AWP-based prices often increase, rather than decrease, over time and/or as competition increases (see **Figure 8** previously).

Because NADAC-based reimbursement removes much, but not all, of the ingredient cost margin for dispensing drugs, NADAC-based reimbursement also includes a professional dispensing fee for pharmacies to support operations. The professional dispensing fee is calculated to be approximately $10 based on the *cost of dispensing (COD)* surveys conducted within state Medicaid programs. [28] These costs of dispensing surveys are intended to identify and quantify the costs incurred by pharmacies across the United States in dispensing prescription drugs. If NADAC accurately tracks a drug's cost, the professional dispensing fee needs to track these other costs in order to sustain business operations. Such costs include payroll costs for the professional staff to dispense medications, facility costs to have a physical location for the pharmacy, and other overhead costs such as supplies. **Figure 10** demonstrates that the majority of the pharmacy's cost to dispense is consumed by pharmacy staff. [30]

Figure 10: Average Overall Cost of Dispensing



Medicare's definition of negotiated price has provided warped incentives to PBMs who use the nature of the inflated AWP benchmarks to move invoice price concession away from the POS and out of reach of beneficiaries. It is possible that the NADAC-based model of reimbursement, most often employed by state Medicaid programs (but increasingly within the commercial space), may represent a possible solution to lower retail prices and provide drug cost savings to American seniors. [31]

In this study, we will analyze historic pharmacy counter prices for claims dispensed within the Medicare drug benefit in comparison to the NADAC-based pricing model used within Medicaid. We will determine if the NADAC specific per-unit cost of a particular drug, plus a fixed dispensing fee, generates a more favorable retail price. Specifically, one which would lower out-of-pocket costs to the beneficiary and decrease reinsurance payments, while preserving patient accessibility.

Summary of Methods

For this analysis, pharmacy transaction data was obtained from 1,070 retail independent and small-chain pharmacies across multiple states with dates of service between January 1, 2019, and June 30, 2021. Claims were filtered for Part D transactions based on Part D Bank Identification Number (BIN), Processor Control Number (PCN), and Group combinations from the CMS database.[4] [32] Transactions were limited to *oral solid* dosage forms, as our experience with other data sets demonstrates that non-oral solid dosage forms can create errors in pricing due to variances in unit reporting amounts.

After identifying Medicare claims, transactions were classified as brand or generic. The pharmacy transactional data does not include the PBM's designation of brand and generic. As a result, claims were considered brand if the NDC's Medi-Span data field brand name code (BNC) field was marked trademark ("T"), AND the marketing category was not abbreviated new drug application (ANDA) OR new drug application authorized generic (NDA Authorized Generic). All other transactions were considered generic.

The pharmacies provided us with the appropriate reference price of average wholesale price (AWP) and national average drug acquisition cost (NADAC) on the claim. This enables us to compare the point-of-sale claim reimbursement from the PBM to these pricing benchmarks (i.e., AWP claim value or NADAC-plus-$10-professional-dispensing-fee claim value[5]) to conduct our analyses. Two primary data sets were utilized in this analysis: an aggregate set that included all Part D pharmacy transactions between January 1, 2021, and June 30, 2021, and a single plan analysis using all pharmacy transactions for a single payer between January 1, 2019, and June 30, 2021. The single payer analysis was based upon identifying the plan with the largest claim representation from the pharmacies within the data set. This plan had claims present in over 97% of all pharmacies included in our analysis. Because of the variability in pricing structures between Part D plan sponsors, particularly in setting gross price as well as DIR amounts, the single plan analysis was performed to enable representative trending over a 30-month period while controlling for potential confounding variables, such as Medicare plans entering or exiting participation in the Part D program. The aggregated 2021 data set included 8.6 million Medicare claims, while the individual 30-month plan analysis included 5.2 million claims (more information available within the **Detailed Methodology**).

[4] The BIN and PCN numbers identify the payer of the claim while the Group may identify individual plans.

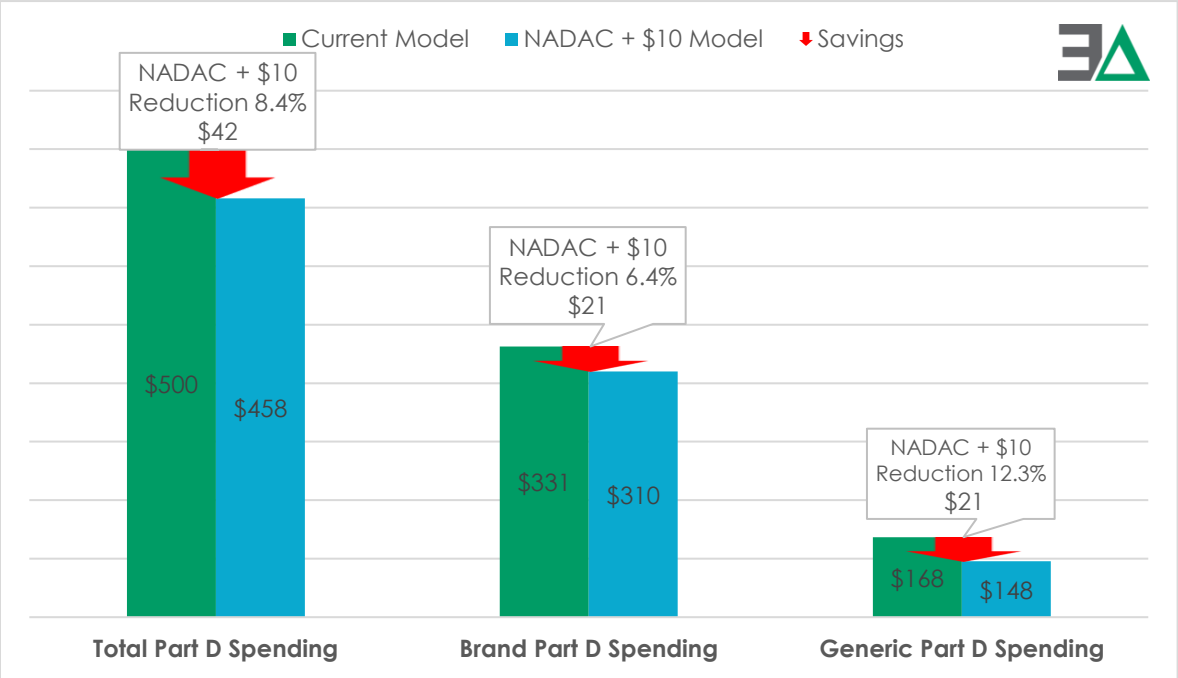
[5] In order to make appropriate comparisons between existing claim cost and the NADAC price, a $10 professional dispensing fee was included to each transaction. A $10 professional dispensing fee was selected, as it was in line with the average Medicaid dispensing fee in programs utilizing NADAC payment rates across the country. [28]

Results

Estimated NADAC-based Savings in Medicare Part D

In comparing existing 2021 reimbursements at the pharmacy counter to the NADAC-plus-professional-dispensing-fee pricing model, the latter reduced the gross price for Medicare Part D claims by $41.92 million (equivalent to 8.4% savings) over the first two quarters of 2021 (**Figure 11**). Savings are achieved across both brands and generics. Brand drug point-of-sale (POS) costs reduced by $21.32 million (on 487,507 claims) while generics decreased by $20.59 million (on 8,065,868 claims). The mean brand point-of-sale (POS) prescription price decreased 6.4% ($43.74 per claim) while the generic decreased by 12.3% ($2.56 per claim) (**Figure 11**)[6].

Figure 11: Part D (2021) Current Pricing to NADAC Model Differences (Millions($))



The decrease in the pharmacy counter price benefits enrollees in the Medicare program. Because Medicare beneficiary cost share is influenced by the gross price, these NADAC-based savings will be directly shared with many Medicare beneficiaries. Recall from earlier (**Figure 7**), an American senior's cost share is determined as a portion of the gross drug price at the pharmacy counter. [4] Any savings at the pharmacy counter has a direct impact on the beneficiary, regardless of the coverage phase.

To demonstrate the significance of these savings, we modeled the impact to the overall Part D program based upon the experience of the pharmacies within our study. Gross Part D spending for 2021 was estimated from historic spending publicly available through Medicare (see **Detailed Methodology** section). [15] Applying the retail pharmacy experience in **Figure 11** to the estimated

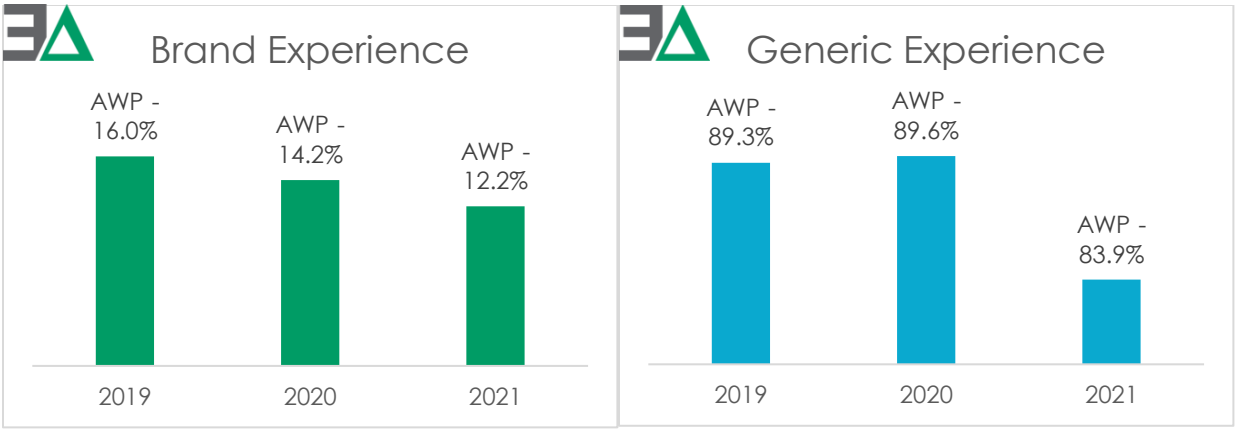
[6] Values are rounded to nearest whole dollar.

spending of Medicare Part D in 2021, **the NADAC-based pricing offers $18.17 billion in potential savings to Medicare patients in 2021**.

Thirty Month Single Plan Trend Analysis

The 30-month sub analysis (2019-2021) identifies increases to pharmacy counter prices as quantified by a decrease in the mean pharmacy counter AWP discount (**Figure 12**). Recall that PBM pricing methods rely upon an AWP discount for drugs rather than acquisition cost reimbursement methodology (see **PBM Drug Reference Pricing Methods**). While AWP is not representative of any drug price point within the U.S. drug supply chain, it can be appropriate to contextualize AWP as a manufacturer's suggested retail price (MSRP) (i.e., a "sticker" or list price). In negotiating a pharmacy network, PBMs are securing a discount against this sticker price. As a result***, the lower the discount secured at the pharmacy counter, the higher the cost of the medication is to obtain for American seniors***.

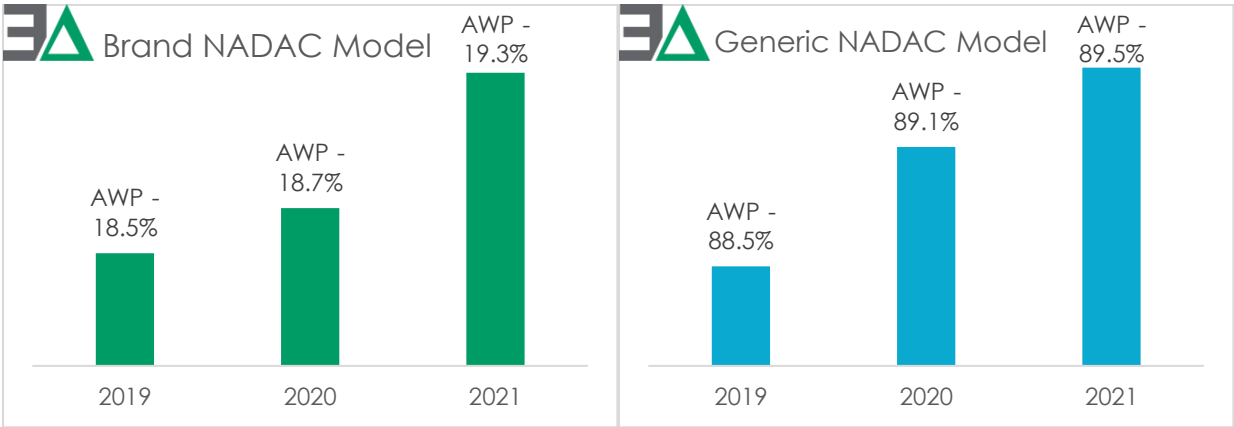
Figure 12: Pharmacy Counter Brand & Generic AWP Discounts (Actual Experience)



In reviewing the top Medicare plan for the pharmacies in our study, the average brand AWP discount decreased 3.8% (i.e., the AWP discount in 2019 to 2021 worsened from AWP - 16% to AWP - 12.2%) (**Figure 12**). While potentially counter intuitive, a lower percentage of discount to an AWP value represents increased gross costs to the Medicare program and shared with patient via their cost share and Medicare via higher occurrences of reinsurance payments. Similar to brands, generic AWP discounts decreased at the pharmacy counter from AWP - 89.3% in 2019 to AWP - 83.9% in 2021.

When we re-price claims within this plan sponsor based upon the NADAC + $10 professional dispensing fee model, we observe a significant decrease over time for both brands and generics. While this observation is in keeping with our earlier estimates (see **Estimated NADAC-based Savings in Medicare**), in **Figure 13** (on the next page), we demonstrate the impact based upon the equivalent AWP pricing discount the NADAC-based model would produce.

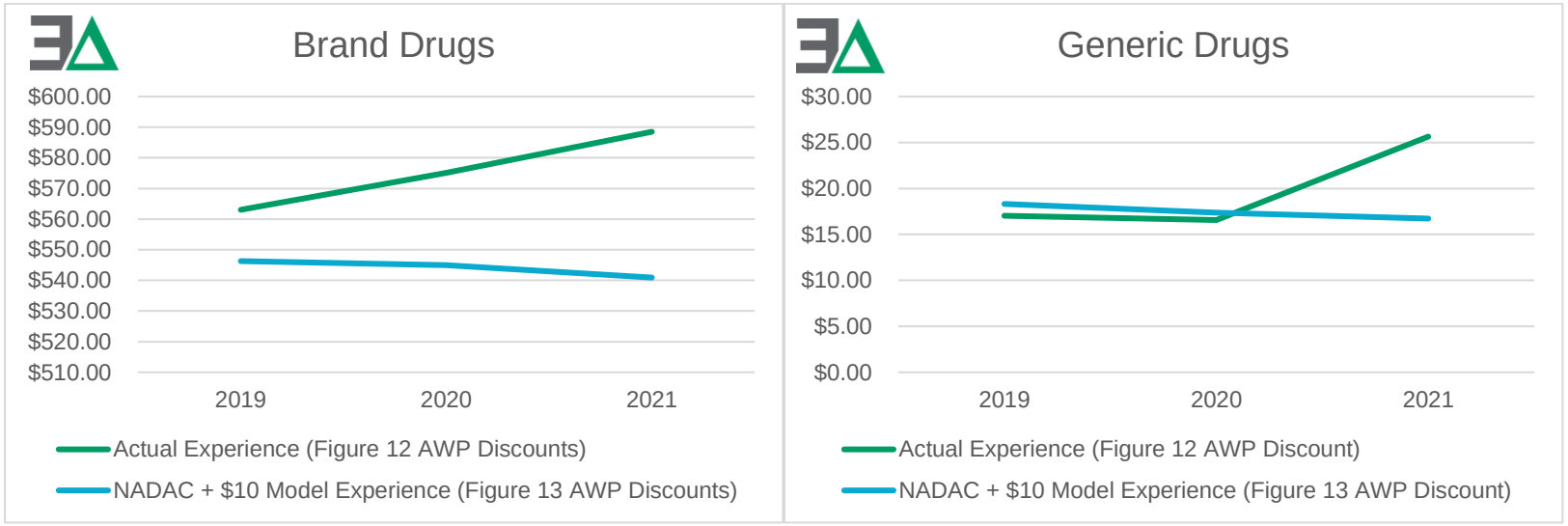
Figure 13: Pharmacy Counter Brand & Generic AWP Discounts (NADAC + $10 Model)



Repricing of claims using the NADAC-plus method shows the NADAC model supplies consistent pricing decreases for both brand (18.5% to 19.3%) and generics (88.5% to 89.5%) (**Figure 13**). In 2021, the NADAC-based model improved the beneficiary AWP POS discount significantly for both brand and generic transactions when compared to the current PBM-managed AWP discount model. The beneficiary cost exposure would decrease by 7.1% (12.2% in **Figure 12** vs 19.3% in **Figure 13**) for brand AWP discounts and 5.6% (89.5% vs 83.9%, respectively) for generics.

To help quantify the effects AWP-based discounts at the pharmacy counter have, a normalization of the data was performed. First, we calculated the average per claim brand and generic prices in Medicare for this large plan in 2019. These were calculated to be $670.29 and $159.28 respectively. The mean AWP prices were then used to calculate the retail price in each year (2019-2021) based on the historic discounts observed in both actual experience (**Figure 12**) and the NADAC-based model (**Figure 13**). Based upon the change in AWP discount recognized at the pharmacy counter, and regardless of any increase in price elsewhere within the drug supply chain (i.e., manufacturer list price increases), the current AWP-based pricing model employed by the Part D plan resulted in a 4.5% increase in brand price ($563.04 to $588.51) and a 50% increase in generic price ($17.04 to $25.64) (**Figure 14** on the next page). In contrast, the NADAC + $10 model resulted in savings of 1% and 8.7% respectively (**Figure 14** on the next page).

Figure 14: Projected Brand & Generic Pharmacy Counter Price based upon Normalized 2019 AWP Price and AWP Discounts from 2019 to 2021



Brand	**Avg AWP Price in 2019 = $670.29**	
	Actual Experience (**Figure 12** AWP Discounts)	NADAC + $10 Model Experience (**Figure 13** AWP Discounts)
2019	$563.04 (AWP – 16%)	$546.29 (AWP – 18.5%)
2020	$575.11 (AWP – 14.2%)	$544.95 (AWP – 18.7%)
2021	$588.51 (AWP – 12.2%)	$540.92 (AWP – 19.3%)
Generic	**Avg AWP Price in 2019 = $159.28**	
	Actual Experience (**Figure 12** AWP Discounts)	NADAC + $10 Model Experience (**Figure 13** AWP Discounts)
2019	$17.04 (AWP – 89.3%)	$18.32 (AWP – 88.5%)
2020	$16.57 (AWP – 89.6%)	$17.36 (AWP – 89.1%)
2021	$25.64 (AWP – 83.9%)	$16.72 (AWP – 89.5%)

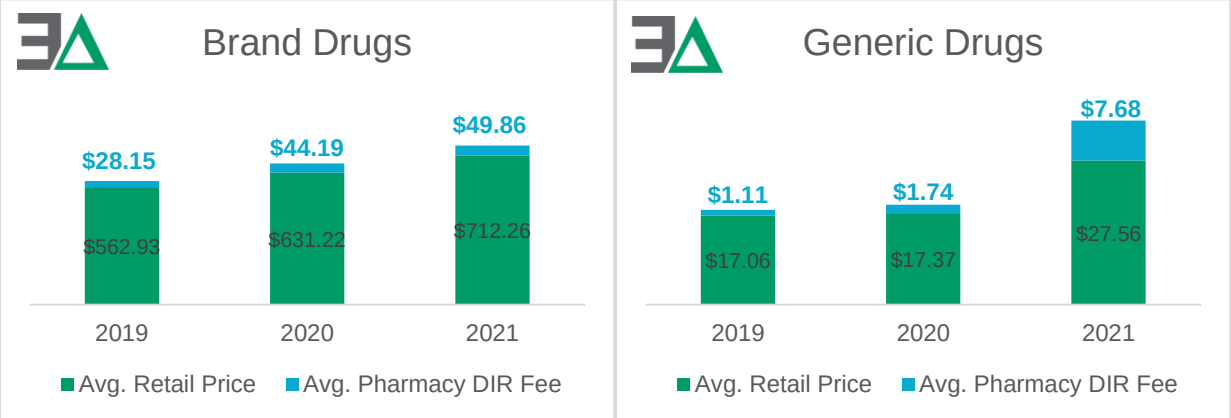
This analysis demonstrates that absent any effect of drug manufacturer price increases, American seniors have spent more for medications in Part D at the pharmacy counter year-over-year due to reductions in negotiated price discounts. This is because the analysis is conducted based upon normalized drug pricing in 2019. Regardless of drug manufacturer actions, which we know increased during the time frame, the change in negotiated price discount of the Part D plan shifted increases in costs to the member over the 30-month period of our analysis. Said differently, **American seniors faced drug pricing affordability challenges independent from, and beyond, drug manufacturer price changes.**

Assessing the Impact of Pharmacy DIR

Based on these findings, we wanted to determine if higher prices at the pharmacy counter were being offset with greater DIR discount arrangements between the pharmacy and plan sponsor. We were particularly interested in performing this assessment, as it was previously identified that growing DIR has kept net Medicare expenditures in check. [5] [33] However, this arrangement comes at a cost, as it has been acknowledged that while DIR may keep net drug pricing in check for the plan sponsor and Medicare as a whole, the retrospective nature of the DIR potentially shifts excess costs onto our seniors. [5]

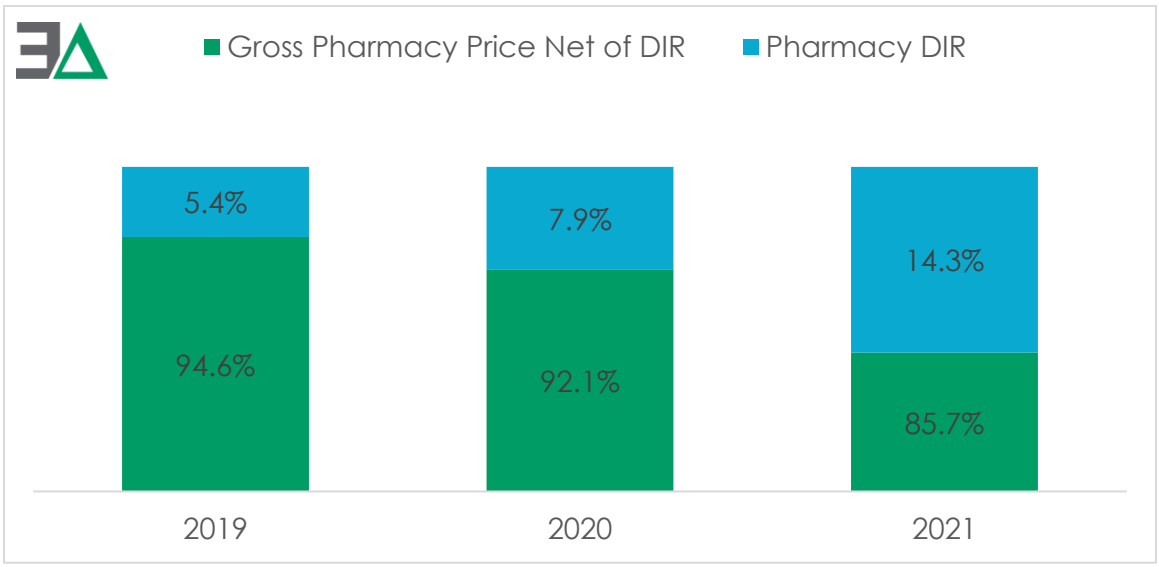
We began this analysis by first estimating each claim's DIR is based upon the claim's brand or generic status. The DIR was estimated at the lowest possible rate based upon channel checks and the assumption that the pharmacy would earn 100% of any performance bonuses. Based upon these assumptions, the average DIR increased yearly for both the brand and generic drugs (**Figure 15**). The minimum pharmacy DIR on brand prescriptions increased 77.2% from $28.15 per transaction in 2019 to $49.86 in 2021, while the average generic minimum pharmacy DIR increased 591.9% from $1.11 in 2019 to $7.68 in 2021.

Figure 15: Estimated Impact of DIR on Pharmacy Net Price based upon Actual Experience (2019 to 2021)



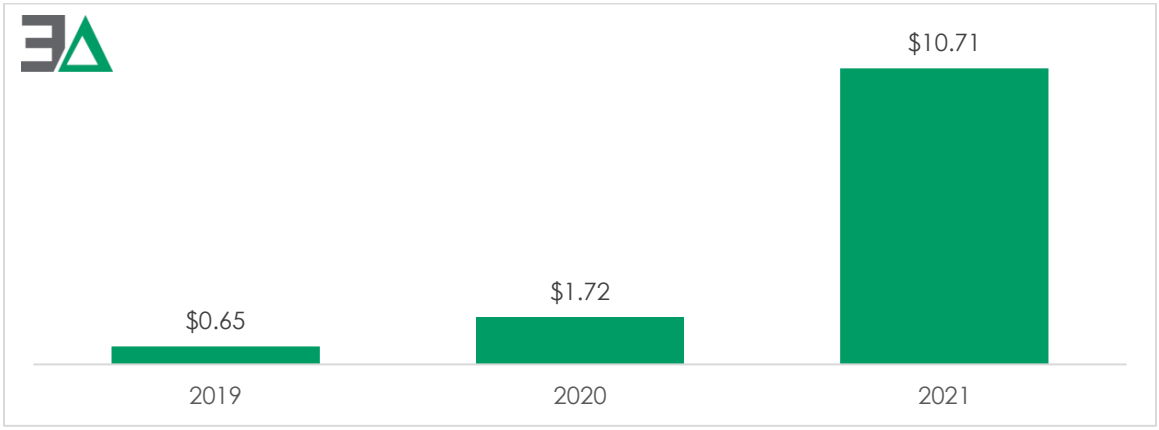
Combining the brand and generic experience together, the pharmacy-based DIR grew an estimated 264% over the 30-month period from 5.4% of the gross price value (i.e., pharmacy counter price) in 2019 to 14.3% in 2021 (**Figure 16** on the next page).

Figure 16: Estimated Minimum Pharmacy DIR Experience (2019 to 2021)



Now that the impact to pharmacy has been appropriately contextualized, we can assess the impact of minimum DIR to a Medicare Part D enrollee. To do this, all claims were identified in which the beneficiary's copay amount in 2021 was higher than the projected net price after pharmacy DIR was calculated.[7] In essence, we identified any claim where the patient had a larger out-of-pocket cost than what the pharmacies' total net compensation would be after the minimum DIR was collected. Given the pharmacy is experiencing lower net reimbursement than the patient pay amount, this indicates that a portion of the patient's copay or coinsurance is being returned to the Medicare Part D plan sponsor in the form of a DIR through the pharmacy. Many consider this arrangement a form of a "clawback." Over the 30-month period for this plan, the average value of the "clawback" experienced by Medicare enrollees increased by 1,648% from $0.65 in 2019 to $10.71 per "clawback" in 2021 (**Figure 17**).

Figure 17: Estimated Beneficiary "Clawback" (Claims where Patient Cost Share Exceeded Pharmacy Net Price)

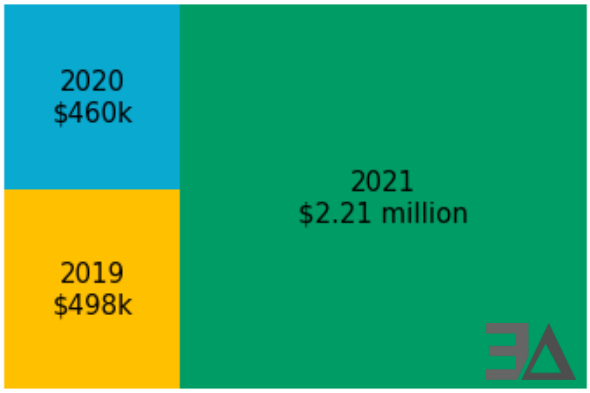


[7] We excluded $0 patient pay amounts from this analysis as, by definition, no amount was 'clawed back' from the patient.

Note that this is not the total DIR, but the average value of the patient "clawback," or the amount of the patient pay amount that flowed back to the PBM in the form of DIR.

When comparing the total value of "clawbacks" across the group of pharmacies in our study, there has been a 481% increase in the value of the discounts from 2020 to 2021 ($460 thousand vs $2.2 million) (**Figure 18**). Beneficiaries are financially harmed by DIR, as the discounts are being utilized to offset the lower negotiated pharmacy counter discounts (resulting in higher pharmacy counter prices) outlined above. By itself, the figure is remarkable, however, it is even more striking, considering the 2021 data set consists of just six months of pharmacy data while the 2020 and 2019 data sets had an entire 12 months' worth of transactions.

Figure 18: Estimated Total Value of Yearly "Clawbacks"



Discussion

Over the last decade, average pharmacy counter prices have climbed in the Part D program, despite a reduction in overall net spending per prescription. [34] Despite the overall reduction in net spending, many consumers, including Part D beneficiaries, continue to identify challenges affording prescription medications. We understand that these sentiments are unlikely to change in the foreseeable future given that:

(1) Medicare beneficiary cost sharing is tied to gross drug prices at the pharmacy counter; and
(2) There is a growing trend which shifts drug pricing concessions away from the point of sale and towards retrospective pharmacy discounts.

Part D plan sponsors, and their PBM partners, are reducing net drug spending liability by shifting plan cost exposure onto the beneficiary and the federal government. This is because plan benefit design decisions can shift members into catastrophic coverage faster through higher pharmacy counter prices. This ultimately reduces the financial liability to the plan from the Medicare beneficiary thanks to Medicare-provided reinsurance payments as well as growing DIR whose primary purpose are to off-set the plan sponsor's financial liabilities. This is a warped incentive design that Part D has set for plan sponsors. However, beneficiaries ultimately pay for this perverse incentive. Beneficiaries bear 100% of the inflated cost when they are in the deductible phase, and decreasing percentages as they proceed through their benefit phases (see **Figure 7**).

In this study, a NADAC-plus-professional-dispensing-fee model was found to offer an overall point-of-sale spending decrease of 8.4% ($499.78 million to $457.86 million) on roughly 8.6 million Part D transactions dispensed across a variety of pharmacies in 2021. This reduction in pharmacy gross price was also associated with decreases in beneficiary cost exposure by $43.74 per brand prescription and $2.56 per generic prescription. A 30-month analysis of the Part D plan with the largest pharmacy representation in our data set (97% of pharmacies) confirmed this large plan increasingly favored retrospective DIR payments rather than retail price management. The PBM decreased – rather than maintained or increased – the mean AWP point-of-sale discount to beneficiaries by 3.8% for brands and 5.4% for generics during the 30-month period. This AWP point-of-sale trend ultimately increases prices paid by beneficiaries due to coinsurance requirements within Medicare Part D. Similarly, the reduction in retail price management was associated with higher estimated pharmacy DIR. The mean pharmacy DIR per prescription within the plan increased by 77.2% on branded prescriptions ($28.15 to $49.86) and 591.9% for generics ($1.11 to $7.68). By effectively calculating the minimum DIR inclusive of all potential earned bonuses, we reasonably determined a figure that represents a price concession that could have – and should have – been offered at the point of sale (POS) to the beneficiary in keeping with CMS' definition of negotiated price. [19]

To quantify the potential financial impact to beneficiaries of the existing misaligned incentives within Part D plan design, we calculated the average "clawback" impacting beneficiaries. We found the average "clawback" increased by 1,648% per affected claim from $0.65 in 2019 to $10.71 in 2021. In other words, the PBM's price management used to be much tighter at the pharmacy counter. The average value of a "clawback" used to be significantly smaller (i.e., $0.65) a few years ago than it has become (i.e., $10.71).

To better contextualize the mechanics of a "clawback" from the perspective of an American senior, assume their cost share for a drug is $20. To make it easier, assume this also happens to be the total negotiated fee schedule at the pharmacy counter. In this case, the PBM would not pay towards the claim, as the patient cost share ($20) would satisfy the negotiated retail price. However, in this example, let's also assume that the PBM assessed a DIR to the pharmacy that resulted in a total pharmacy payment of $11. In this case, the PBM would "bill" the pharmacy for the $9 overpayment ($20 collected from the patient minus $11 net kept by the pharmacy). In other words, the PBM would receive $9 of the beneficiary's $20 payment to the pharmacy. In addition, the entire $20 would be applied to current benefit stage accumulator, accelerating movement through the particular benefit stage despite the net pharmacy payment being lower than $20.

The "clawbacks" represent a transfer of revenue directly from the beneficiary to the PBM, which simply flows through the pharmacy. This supports the findings that AWP-linked discounts are becoming less favorable for the patient at the pharmacy counter (due to poor PBM incentives for retail price management), but those same claims are being reconciled after the sale of the prescription through increased PBM DIR imposed on the pharmacy. The incentive for this action appears plain, given the reinsurance option available to plan sponsors within the catastrophic coverage phase of Medicare plan design, and given that DIR is apportioned between Medicare and the Part D plan (meaning as DIR grows, plans make keep more money via their apportionment). [35] A NADAC-based pricing model would protect beneficiaries by generating a significantly higher point-of-sale AWP discount as demonstrated in our analysis.

Ultimately, if federal policy solutions to the challenges of drug affordability to American seniors are limited only to addressing manufacturer list prices, they may fail to prove meaningful. This is because such policies would not address the current misaligned incentives of the Medicare Part D plan sponsors. As demonstrated in this study, Part D plan sponsors, independent of drug manufacturer price changes, can influence patient costs and shift liability to beneficiaries, and Medicare, through changes to drug prices at the pharmacy counter (see **Figure 14**). The end result being Medicare's own acknowledgement that patients are moved through the coverage phases faster, with costs ultimately shifting back to Medicare via increased reinsurance payments. [5]

Significant increases in gross Part D drug prices at the pharmacy counter, specifically around highly accessible low-cost generics, jeopardizes drug compliance rates and positive health outcomes within the program. A NADAC-based model removes many of the conflicts of interest within the drug supply chain, as demonstrated in the other drug program managed by CMS (i.e., Medicaid), as well as offers potential savings to Medicare patients as shown in this study.

Detailed Methodology

Data Sources

All analytics performed in this study were based on the combination of the following raw data sources:

1. Transaction data collected from participating pharmacies
2. CMS' National Average Drug Acquisition Cost (NADAC) database [36]
3. CMS' Medicaid covered outpatient prescription drug reimbursement information by state
4. CMS' Part D Information for pharmaceutical manufacturers
5. Medi-Span PriceRx by Wolters Kluwer Clinical Drug Information Inc. (WKCDI)

Transactional database

Transactional data was received from 1,070 independent and small chain pharmacies with dates of service between January 1, 2019, and June 31, 2021. Note, we only received a year indicator on the claims and therefore could not independently confirm the accuracy of the date of service window supplied to us. These claims were uploaded into an SQL Server. Two separate analyses were conducted, one that included all claims between January 1, 2021, and June 30, 2021, and a single plan analysis which reviewed yearly data between January 1, 2019 and June 30, 2021. The raw data for each analysis was extracted from the SQL database, and the analysis portion was conducted using the Python programming language and the Pandas and NumPy libraries.

The following fields (**Table 1**) were utilized from the source data to conduct the analysis:

Table 1: Transactional Data Fields from Participating Pharmacies

Field	Description
NDC	The National Drug Code (NDC) is an 11-digit code maintained by the FDA that includes the labeler code, product code, and package code
PRODUCT_NAME	Medi-Span Product Name based on NDC
QTYDISP	Total quantity billed for particular transaction
NADAC	The National Average Drug Acquisition Cost per transaction based on quantity
TOTALREVENUE	The Total Retail Price including Beneficiary Cost Share, Dispensing Fee, and Third-Party Payer Amount Paid
PATIENTPAYAMT	Beneficiary Out-of-Pocket Amount for transaction
BRAND_GENERIC	"B" if Brand and "G" if Generic based on determination in the Methods section
DAYS	Days' supply of transaction
AWP	Average Wholesale Price for transaction
CLAIMIDREVERSAL	ID of Claim Reversal if claim was reversed, else "Null"
YEAR	Year of Claim
MARKETING_CATEGORY	Medi-Span NDC marketing Category

Field	Description
BRAND_NAME_CODE	Medi-Span brand name code field: "T" for trademark "G" for generic "B" for brand
PROCESSORCTRNBR	Processor Control Number (PCN)
BINNBR	Payer Bank Identification Number (BIN)
GROUPID	Payer Group Identification Number

National Average Drug Acquisition Cost (NADAC)

NADAC was developed by CMS, "to provide a national reference file to assist State Medicaid programs in the pricing of Covered Outpatient Drug claims to reflect the actual acquisition cost (AAC) of drugs." [28] As such, NADAC's goal is to be the most comprehensive public measurement of market-based retail pharmacy acquisition cost available. NADAC is compiled by Myers & Stauffer on behalf of CMS. It is generated from a voluntary monthly invoice cost survey of 2,500 randomly selected retail pharmacies (with 450 to 600 respondents). After Myers & Stauffer completes its data processing and cleanup activities, it publishes the survey results at the National Drug Code (NDC) level on Medicaid.gov. As of January 2022, the NADAC database included prices for 46,707 different NDCs. [36] As state Medicaid FFS programs have shifted to an AAC basis to comply with the Covered Outpatient Drug Rule (CMS-2345-FC), many states have used NADAC as the primary proxy for acquisition cost. As a result, we believe NADAC is the best publicly available pricing benchmark to approximate average pharmacy invoice costs. We relied on the NADAC database extensively throughout this report as the best estimate for a drug's AAC.

NADAC information (**Table 2**) is provided in the following data format [36].

Table 2: NADAC Data Fields

Field Name	Description
NDC Description	Identifies the name, strength, and dosage form of the drug product.
NDC	The National Drug Code (NDC) is an 11-digit code maintained by the FDA that includes the labeler code, product code, and package code.
NADAC_per_Unit	The National Average Drug Acquisition Cost per unit.
Effective_Date	The effective date of the NADAC per Unit cost.
Pricing_Unit	Indicates the pricing unit for the associated NDC for pharmacy claims processing (ML, GM, or EA).
Pharmacy_Type_ Indicator	The source of pharmacy survey data used to calculate the NADAC. C/I indicates data was collected from surveys of Chain/Independent pharmacies. Other pharmacy type indicators are not used at this time.
OTC	Indicates whether the NDC is for an over-the-counter (OTC) product (Y or N).
Explanation_Code	Codes that pertain to how the NADAC was calculated. • Code 1: The NADAC was calculated using information from the most recently completed pharmacy survey. • Code 2: The average acquisition cost of the most recent survey was within ± 2% of the current NADAC; therefore, the NADAC was carried forward from the previous file. • Code 3: The NADAC, based on survey data, has been adjusted to reflect changes in published pricing, or as a result of an inquiry to the help desk. • Code 4: The NADAC was carried forward from the

Field Name	Description
	previous file. • Code 5: The NADAC was calculated based on package size. • Code 6: The CMS Covered Outpatient File drug category type of S/I/N (Single Source/Innovator/Non-Innovator) has not been applied. Most S/I drugs with the same strength, dosage form, and route of administration were grouped together for the purpose of the NADAC calculation, and N drugs were also grouped. In some cases, however, in calculating a NADAC, the CMS S/I/N designation was not applied when the state Medicaid brand or generic payment practices for these drugs generally differed from the CMS Covered Outpatient File designation. For example, authorized generic drugs are listed in the CMS Covered Outpatient File as I drugs for the purpose of rebates as they were approved under a New Drug Application (NDA). However, they are grouped as N for the NADAC calculation since they are generally designated as generic by most state Medicaid programs for the purposes of reimbursement. Another example of this occurrence is when proprietary named drugs, approved under an Abbreviated New Drug Application (ANDA), are in the CMS Covered Outpatient Drug file as N for the purpose of rebates. However, they are grouped as S/I for the NADAC calculation since they are generally reimbursed as brand drugs by state Medicaid programs. • Codes 7 through 10: Reserved for future use.
Classification_for_Rate_ Setting	Indicates whether the NDC was considered brand (B) or generic (G) for the NADAC rate calculation process. If the NDC was considered B and approved under an Abbreviated New Drug Application (ANDA), the indicator is shown as B-ANDA.
Corresponding_Generic_Drug_NADAC_per_Unit	The NADAC for the corresponding generic drug.
Corresponding_Generic_Drug_Effective_Date	The effective date of when the Corresponding Generic Drug NADAC Per Unit is assigned to a multiple source brand drug NDC. This date may not correspond to the NADAC effective date for the generic drug due to the method by which the corresponding generic drug NADAC effective date is assigned. The corresponding generic drug NADAC effective date is the latter of the following dates: a) date of the NADAC reference file upon which the corresponding generic drug NADAC first appears; b) the current corresponding generic drug NADAC effective date plus one day (one day is added to the previous date so that there are no overlapping rate segments); or c) the NADAC Effective Date for the generic drug group. This data assignment process is necessary to eliminate the potential for applying corresponding generic drug NADACs to past claims.
As of Date	Survey date for which data is accurate.

CMS' Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State

CMS provides state prescription drug resources that offer an overview of the federal Medicaid prescription drug policies that directly influence state reimbursement of prescription drugs. Included within these materials is a detailed look into each state's drug coverage and reimbursement methodologies. [28] The information was last updated in September 2021 as of the date of publication of this report. We used the state reimbursement methodology to reasonably determine the average professional dispensing fee within Medicaid.

The following table (**Table 3**) summarizes the information we relied upon to arrive at our $10 dispensing fee:

Table 3: Medicaid State Reimbursement Policies Data

Field	Description
State	Identifies which state the reimbursement methodology applies to
Ingredient Cost	Identifies the basis of drug ingredient cost reimbursement. All methodologies include a "lower of" logic, whereby the actual payment amount will be determined at the point-of-sale based upon a variety of drug reference pricing benchmarks
Dispensing Fee	Identifies the professional dispensing fee to be paid alongside the ingredient cost reimbursement to arrive at the total reimbursement available for the drug. Note that some states have a tiered dispensing fee structure (i.e., multiple values). For these states, their dispensing fee was calculated as a simple average of the listed retail dispensing fees.
State Maximum Allowable Cost (MAC)	A true / false field that identifies whether the state permits MAC based pricing of drug

CMS' Part D Information for Pharmaceutical Manufacturers

CMS provides important information related to Part D program for pharmaceutical manufacturers. Included within this information is a list of BIN and PCN values unique to Medicare prescription drug claims processing according to the requirements of the Medicare Pharmacy manual. [32] This list of BIN and PCN values was relied upon to identify Medicare claims within the transactional data.

Medi-Span PriceRx by Wolters Kluwer Clinical Drug Information, Inc. (WKCDI)

Medi-Span PriceRx is an online pricing and drug information portal developed by Wolters Kluwer Clinical Drug Information, Inc. (WKCDI). PriceRx offers one of the most extensive histories of drug manufacturer pricing, with NDC-level drug pricing dating back to the 1980s. PriceRx was the source of the raw data that we used for AWPs for our analyses. It was used to classify brand vs. generic status. Medi-Span information is not in the public domain and requires a subscription service to access the data and field descriptions.

Data Transformations

The following describes the transformations made to the data sources used in the report in order to arrive at our conclusions.

Pharmacy Count Top 10 Plans for single plan analysis:

The top plan represented within the dataset was determined by identifying the unique number of pharmacies which processed each group.

```
SELECT TOP (10)
        GroupID, PLAN
        COUNT(Distinct pharmacy_number) PHARMACY_CT
 FROM [db].[dbo].[db]
 GROUP BY GroupID
 ORDER BY COUNT(Distinct pharmacy_number) desc
```

The results of this plan identification are summarized below (**Table 4**):

Table 4: Top 10 Plan Identification Results

PLAN	PHARMACY COUNT
1	1045
2	1037
3	1030
4	1029
5	1024
6	1007
7	960
8	955
9	934
10	874

NDC Transformation

In order to identify brand vs. generic, we utilized Medi-Span clinical drug reference to identify the Brand Name Code (BNC) as well as the FDA application type. We used these two fields to define a brand claim as any NDC whose BNG code = "T" and FDA application type was not = "'ANDA' or 'NDA AUTHORIZED GENERIC'". We defined generic as all other claims which did not satisfy the brand claim requirement.

Database Creation

The aggregated 2021 databased resulted in 10,219,917 transactions in which 8,553,375 transactions were used, while the 30-month analysis had 7,282,105 transactions where 5,146,976 were used. Transactions were excluded if they were not solid oral dosage forms, were not joined with both an AWP and NADAC price benchmark, or had a reversal ID indicating the transactions were reversed.

Aggregated Analysis

The following Python script, using the Pandas library, details the aggregation of data undertaken. Note that the code itself contains the details regarding how aggregation was performed.

```
#Create standardized drug name table from Medispan database

product_name = pd.read_sql_query(""" SELECT Product_Name,

      NDC_UPC_HRI_Unformatted

  FROM [MediSpan].[dbo].[db] """, conn_coportate,index_col='Product_Name')

product_name.columns = ['NDC']

product_name.reset_index(inplace = True)


#Change datatype to datetime for effective and end dates
```

```
awp_table.History_Effective_Date = pd.to_datetime(awp_table.History_Effective_Date)

awp_table.History_End_Date = pd.to_datetime(awp_table.History_End_Date)

#change price to float

awp_table.History_Unit_Price = awp_table.History_Unit_Price.astype('float')


#Extract claims data from SQL database

db = pd.read_sql_query(“”” Select *

FROM [db].[dbo].[claims]

WHERE ['DATEOFSERVICE'] >= '2021-01-01' and ['DATEOFSERVICE'] <= '2021-06-30"""", conn_coportate)


#Filter for claims that have positive revenue (non-reversals) and oral solids

db_clean = db.loc[(db.TOTALREVENUE != 0)&(db.Oral_Solid == 'Y')&(db.ClaimIDReversal.isna() == True)].copy()

#Standarize NDC to 11-digit fomat

db_clean.NDC = db_clean.NDC.astype('str').str.zfill(11)


#Remove unused columns

db_clean.drop(columns =

['ClaimIDReversal','PATIENTPAYAMT','Oral_Solid'],inplace = True)


#Create brand generic column - set column default to 'G'

db_clean['brand_generic'] = 'G'


#Create filter for Brand and change all applicable 'G' to 'B' based on method criteria

db_clean.loc[~(db_clean.Marketing_Category.isin(['ANDA','NDA AUTHORIZED GENERIC']))

& (db_clean.Brand_Name_Code_BNC == 'T'),'brand_generic'] = 'B'


#Memory optimization

db_clean.brand_generic = db_clean.brand_generic.astype('category')
```

```
#Drop unneeded columns in identifying claims as brand or generic
db_clean.drop(columns =['Brand_Name_Code_BNC','Marketing_Category'],inplace = True )

#Multiply AWP per unit by total claim unit to get claim AWP
db_clean['AWP'] = (db_clean.History_Unit_Price * db_clean.QTYDISP).round(2)

#Drop 'AWP_Unit_Price' column
db_clean.drop(columns='AWP_Unit_Price',inplace=True)

#Memory optimization
db_clean.BINNbr = db_clean.BINNbr.astype('str')

#Replace any empty group id with 'blank'
db_clean.GroupID.fillna('blank', inplace = True)

#Create column bin_pcn_grp and concat columns for filtering row
db_clean['bin_pcn_grp'] = db_clean.BINNbr+'_'+db_clean.ProcessorCtrlNbr+'_'+db_clean.GroupID

#Drop unneeded columns
db_clean.drop(columns = ['BINNbr','ProcessorCtrlNbr','GroupID'], inplace = True)

#Create columns with NADAC plus $10 dispensing fee calculation
db_clean['nadac_plus_10'] = (db_clean.NADAC + 10).round(2)
```

Single plan analysis

The following Python script, using the Pandas library, details the aggregation of data undertaken. Note that the code itself contains the details regarding how aggregation was performed.

```
#Extract data from SQL database for single plan analysis, add brand/generic SQL field with case, filter for oral solids dosage forms, remove any reversed and duplicated claims

df = pd.read_sql_query(f"""

  SELECT

      [DATEOFSERVICE]

      ,[NDC]

      ,[QTYDISP]

      ,[Product_Name]

      ,[PATIENTPAYAMT]

      ,[NADAC]

      ,[TOTALREVENUE]

      ,Case

      when [Brand_Name_Code_BNC] = 'T'

      and [Marketing_Category] not in ('ANDA','NDA Authorized Generic') then 'B'

      else 'G' END brand_generic

  FROM [db].[dbo].[selected_plan]

  where Oral_Solid = 'Y' and [ClaimIDReversal] is Null and DuplicateInd is Null and [BINNbr]* = 'plan bin' and [ProcessorCtrlNbr]* = 'plan pcn' and [GroupID]* = 'plan group """, conn_local)
```

***Actual search fields masked to protect proprietary data**

```
#Add AWP column that multiplies awp per unit by total units for claim

df2['AWP'] = df2.QTYDISP * df2.History_Unit_Price


#Aggregate data by year for sums and total count

group = df2.groupby(['Year','brand_generic']).aggregate(NADAC = ('NADAC','sum'),AWP = ('AWP','sum'),TOTALREVENUE = ('TOTALREVENUE','sum'),rx_ct = ('NADAC','count'))


# Create effective rate column for AWP and NADAC
```

```
group['AWP_ER'] = (1-(group.TOTALREVENUE/group.AWP)).round(3)
group['NADAC_ER'] = (1-(group.NADAC_10/group.AWP)).round(3)

#Create mean rx price column for NADAC and historic
group['mean_price'] = (group.TOTALREVENUE/group.rx_ct).round(2)
group['mean_nadac_price'] = (group.NADAC_10/group.rx_ct).round(2)
```

Part D Total Spending Analysis

The following Python script, using the Pandas library, details the aggregation of data undertaken. Note that the code itself contains the details regarding how aggregation was performed.

```
#read CMS csv outpatient spending file and load spending columns

pd.read_csv('Medicare_Part_D_Spending_by_Drug_2020.csv',usecols=['Mftr_Name','Tot_Spndng_2016','Tot_Spndng_2017','Tot_Spndng_2018','Tot_Spndng_2019','Tot_Spndng_2020'])

#filter for 'Overall' spending rows

part_d_spending = part_d_spending.loc[part_d_spending.Mftr_Name == 'Overall'].copy()

#drop 'Mftr_Name' column

part_d_spending.drop(columns=['Mftr_Name'],inplace=True)

#create totals row

part_d_spending.loc['total'] = part_d_spending.sum()

#change total row to billions

part_d_spending = (part_d_spending.loc['total']/1000000000).round(2).to_frame()

#determine % change YoY

part_d_spending['change'] = part_d_spending.total.pct_change()
```

Estimating Part D Expenditures in 2021

After having performed analysis based upon the experience of 1,070 pharmacies, we were interested in determining the overall impact to Medicare based upon the results observed within the 1,070 pharmacies of our study. However, Medicare spending data is not currently available for 2021. As a result, we needed to estimate Medicare Part D gross expenditures in 2021 in order to perform our analysis. To do this, we simply used the trend in spending over the last five years to estimate trending into 2021.

As shown in **Table 5**, the mean percent increase between 2016 and 2020 was determined to be 8.9%.

Table 5: Estimated Medicare Expenditures in 2021

Year	Gross Spending (Billions)	Percent Change (%)
2016	141.22	-
2017	151.96	7.6
2018	167.07	9.9
2019	183.03	9.6
2020	198.65	8.5
2021 (estimate)	*216.35*	*8.9*

Limitations

Limitations to this study include limited data that may not accurately represent aggregate Part D claims. Our data comprised of 1,070 pharmacies, approximately 1.7% of the estimated 62,145 retail pharmacies as of 2019. [37] As a result, our analysis is also limited to the geographical regions in which those pharmacies were located. Similarly, the mix of plans and composition of beneficiary type (i.e., age, disease states, drug utilization mix) may not represent the aggregate Part D program. Furthermore, the study is limited to pharmacies in the retail setting, and not other pharmacy practice settings such as large retail chains, mail order, and *specialty*. Nevertheless, we feel our sampling of greater than 1,000 pharmacies is sufficiently large to overcome these limitations.

The calculations in this report are based on point-of-sale data. Lacking representation from all channels, the retail prices and patient cost share amounts may vary from network to network beyond what we have in our transactional data. As the majority of claims are dispensed within the retail pharmacy channel, we feel this limitation is appropriately addressed within our analysis. Furthermore, these transactions likely underestimate the degree of extended days' supply use within Medicare, as they cannot account for PBM-based mail order fulfillment of medications.[8] We believe extended day fills are greater in the overall Part D program in part due to PBM offered mail order solutions, where the facility sends medications directly to the beneficiary typically in three-month supply quantities. PBMs often incentivize beneficiaries financially by providing lower cost share structures to use mail order facilities, and in 2018, it was estimated that 18% of Part D beneficiaries used such mail services, potentially increasing the program's overall extended day dispensing. [38] In such a case, the expected reductions with the NADAC + $10 dispensing fee model on pharmacy prices would increase based upon a reduction in the number of $10 dispensing fee events, reducing claim costs even further than our retail pharmacy findings would suggest.

Along these same lines, the analysis may underestimate brand drug costs savings, and therefore be a more conservative estimate of potential savings with the NADAC model. Upon further analysis of the data, the brand fill rate in the data set for these pharmacies was identified at 5.7%. 46brooklyn's Medicare Part D Drug Pricing Dashboard estimates the Part D program's brand fill rate to be 10.4% in 2019. [38] The 46brooklyn number is approximately equal to the CBO's stated Medicare Part D brand fill rate identified in 2018 of 10%. [34] Regardless, an underrepresentation of brand fill percentage in the analyzed data represents another potential limitation of our analysis. This is because it would result in an underestimation of cost savings through the NADAC-plus model, as the mean dollar reduction per fill at the pharmacy counter is much greater in brands than generics ($43.74 brands vs $2.56 generics as identified above).

Another limitation is that not every drug has a NADAC published price and therefore not every NDC could be included in our analysis. Similarly there can be differences between transactional units and drug reference pricing unit measures. Because NADAC is available for greater than 95% of retail claims and because we limited our analysis to oral solid dosage forms, we feel that these limitations are appropriately addressed.

[8] Within the data set relied upon for this analysis, 26% of claims were for fills for 36 days or greater. We were unable to identify any independent sources to confirm whether Medicare has higher extended day supply fills on average than this sample suggests.

The single plan review across the 30-month period is not represent behaviors of all Part D plans. The 30-month analysis consisted of two full years of data (2019 and 2020) and six months in 2021. Data from 2021 has less potential data points when compared to the full year data sets. Data from 2021 may represent a higher percentage of claims in which beneficiaries are in deductible phases. Nevertheless, there is a reasonable degree of certainty to assume that if these limitations were addressed, the model presented here would still be applicable, particularly given the significant difference in pricing behavior observed (i.e., greater than 5% differences in most categories). We also feel that the size of the plan within these pharmacies is sufficiently large that we can appropriately rely upon aggregate estimates of DIR activity. That said, we did not use the single plan analysis to project out total Medicare experience given that it is unlikely to represent all of the diverse Part D plan offerings.

Our determination of brand vs generic prescription was based on data fields extracted from the Medi-Span database. There is not a standard definition of what classifies a NDC as brand or generic, and therefore it is possible and highly likely that some transactions that are classified as brand may be consider generic by the payer and vice versa. However, as previously identified, our ability to approximate brand and generic appears to closely mirror that of the federal government given the similarities in brand percentages identified between the 46brooklyn and CBO analysis of Part D data. We therefore feel this limitation is appropriately addressed.

Finally, the $18.17 billion reduction calculation if the NADAC-model experience of the 1,070 pharmacies in our study was applied to all Medicare expenditures relies on the ability to accurately project 2021 gross spending from historical mean increases. We believe our estimate of 2021 Medicare Part D gross expenditures is performed appropriately given the current availability of data and follows best practices associated with forward looking projections. However, the degree to which actual experience differs from our projections may materially impact our analysis.

About 3 Axis Advisors LLC

3 Axis Advisors LLC is an elite, highly specialized consultancy that partners with private and government sector organizations to solve complex, systemic problems and propel industry reform through data-driven advocacy. With a primary focus on identifying and analyzing US drug supply chain inefficiencies and cost drivers, 3 Axis Advisors LLC offers unparalleled expertise in project design, data aggregation and analysis, government affairs, and media relations. 3 Axis Advisors LLC arms clients with independent data analysis needed to spur change and innovation within their respective industries. The cofounders of 3 Axis Advisors LLC were instrumental in exposing the drug pricing distortions and supply chain inefficiencies embedded in Ohio's Medicaid managed care program. They are also the cofounders of 46brooklyn Research, a nonprofit organization dedicated to improving the transparency and accessibility of drug pricing data for the American public. To learn more about 3 Axis Advisors LLC, visit www.3axisadvisors.com.

Acknowledgements

American Pharmacy Cooperative, Inc. (APCI)

APCI is a member-owned cooperative of 1,700 member pharmacies in 30 states. Established in 1984 and headquartered in Bessemer, Ala., APCI is proud to work on behalf of its members to reduce costs, enhance their operations and efficiencies through innovative programs, and empower them to provide world class pharmacy care, all while leading the fight for prescription drug pricing transparency and reform.

American Pharmacists Association (APhA)

Founded in 1852, the American Pharmacists Association (APhA) is the only professional organization in the United States advancing the entire pharmacy profession. APhA members practice in community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

APhA's expert staff and strong volunteer leadership, including many experienced pharmacists, allow APhA to deliver vital leadership to help pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians find success and satisfaction in their work and advocate for changes that benefit them, their patients, and their communities. For more information, please visit www.pharmacist.com.

Glossary

Average Wholesale Price (AWP)

A prescription drug pricing benchmark that estimates the average price paid by a retailer to buy a prescription drug product from a pharmacy wholesaler. Note AWP is not a true representation of the actual market price to acquire prescription drug products.

Clawback

A PBM clawback occurs when the PBM requires a copay or cost share charge for the patient that is higher than the price the PBM negotiated with the pharmacy to dispense the drug. The pharmacy ends up collecting the required copay; however, the PBM keeps the difference between the excess patient payment and the payment to the pharmacy for itself.

Cost of dispensing (COD)

The calculated amount of pharmacy costs incurred to ensure that possession of an appropriately covered outpatient drug is transferred to a Medicaid beneficiary. As per 42 CFR § 447.502, pharmacy costs included in this calculated amount include, but are not limited to, reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy.

Cost Share

The price the beneficiary directly pays for prescription at the pharmacy counter.

Direct and Indirect Remuneration (DIR)

A term used in Medicare Part D to identify price concessions that impact gross prescription drug costs not captured at the point of sale. They include but are not necessarily limited to discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, upfront payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies, or similar entity.

Effective Rate Contracts

A contract where the full cost (reimbursement plus copay) of all drugs over a certain time frame must equal a certain percentage discount to a reference price, such as AWP. Usually, the effective rate varies by the type of drug (i.e., brand vs. generic).

Fee-for-service (FFS)

Medical and/or pharmacy claims where the state pays providers directly for the delivered healthcare service.

Gross Cost (aka gross Part D drug cost, Pharmacy Counter Price, Point-Of-Sale (POS) price)

The entire acquisition cost of a product or service. In prescription drugs, this is often the transactional price paid for the drug at the point-of-sale.

Medicare Part D

The Medicare Prescription Drug Benefit that offers Medicare beneficiaries the option to purchase a prescription drug policy.

National Average Drug Acquisition Cost (NADAC)

A national prescription drug pricing benchmark that is reflective of the invoice prices paid by retail community pharmacies to acquire prescription and over-the-counter covered outpatient drugs.

National Drug Codes (NDCs)

A unique, three-part segmented number published by the Food and Drug Administration (FDA) used to identify for drugs within the US drug supply chain.

Negotiated Price

The retail price a PBM secures for a prescription below the pharmacy's asking price. The price does not include additional post sale price concession that may occur from pharmacies or manufacturers such as DIR or rebates.

Net Cost (aka Net Price)

The realized cost of a good or service after the gross cost is reduced by any benefits gained from acquiring the good or service. In prescription drugs, this is the cost of the drug after accounting for any rebates or other price concessions associated with the purchase of the drug.

Oral Solid

An oral solid is a drug product with a route of administration of oral and a dosage form with a description including either capsule or tablet.

Part D Plan Sponsors

Non-governmental entities under contract with CMS to offer prescription drug benefits through PDPs, MA-PDs, PACE plans, or cost plans offering qualified prescription drug coverage.

Pharmacy Benefit Manager (PBM)

A third-party administrator of prescription drug programs for health plans whose responsibilities generally include developing and maintaining the formulary, contracting with pharmacies, negotiating discounts and rebates with drug manufacturers, and processing and paying prescription drug claims.

Price Concessions

Any discount that reduces net price of goods including negotiated rates, pharmacy DIR, and manufacturer rebates.

Price Guarantees (aka Guarantees)

Also referred to as effective rate. A contract where the full cost (reimbursement plus copay) of all drugs over a certain time frame must equal a certain percentage discount to a reference price, such as AWP. Usually, the effective rate varies by the type of drug (i.e., brand vs. generic).

Professional Dispensing Fee (PDF)

Pharmacy fee associated with ensuring that the possession of the appropriate outpatient drug is transferred to a Medicaid beneficiary. This fee is included to cover, but are not limited to ensuring the following:

- Costs associated with checking the computer about an individual's coverage;
- Performing Drug Utilization Review and Preferred Drug List Review activities;
- Measurement or mixing of the drug;
- Filling the container;
- Beneficiary counseling;
- Physically providing the completed prescription to the Medicaid beneficiary;
- Delivery, special packaging and overhead associated with maintaining the facility;
- Equipment necessary to operate the pharmacy.

Rebates

A contractual relationship between a health plan and a drug manufacturer or other intermediary that generate financial value in a form of price concession.

Reinsurance payments

Occurring in catastrophic coverage, Medicare limits plan liability and beneficiary cost share by paying 80% of gross cost prescription claims. Beneficiaries will be responsible for 5%, while PBMs/plans are responsible for the remaining 15%.

Retail Price

The price at which the prescription is sold not inclusive of any post point-of-sale price concessions and effectively the cost the beneficiary is exposed to. Also referenced as gross price.

Retroactive Price Concessions

Additional discounts that occur after the sale of a prescription and used to determine net final price for a prescription. Retroactive price concessions often come from manufacturer rebates and DIR from pharmacies.

Specialty Drugs / Medication

There is no industry recognized definition for specialty medication, but PBMs generally identify drugs for inclusion on specialty medication lists they maintain based upon the drug's cost, administration, and handling requirements.

Specialty Pharmacy

There is no industry recognized definition for specialty medication, but PBMs generally identify drugs for inclusion on specialty medication lists and may limit those drug's dispensing from a narrow network of pharmacies identified as "Specialty Pharmacies".

True Up

A process to resolve any differences between a contractual reimbursement rate in a given agreement and the actual experienced reimbursement provided.

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