

# ***The Patient Impact of Manufacturing Copay Assistance in an Era of Rising Out-of-Pocket Costs\****

Tomas J. Philipson

Troy Durie

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The University of Chicago

## **Abstract**

This paper measures the impact of manufacturer-provided copay assistance on total out-of-pocket costs, drug utilization, and implications for patient outcomes. Using data dating back to 2015, we find manufacturer-provided copay assistance mitigated the rise in copay costs attributed to changes in commercial insurance designs as total commercial out-of-pocket cost exposure for prescription drugs would have risen over this period without copay assistance but fell over time with such assistance. We find that during this period, total out-of-pocket copay costs would have increased by 3.4 percent without copay assistance, but when copay assistance is taken into account, patient out-of-pocket cost exposure fell by 6.3 percent. Disruptions due to COVID-19 led to a decline in out-of-pocket copay spending across the board in 2020 but increasing copay assistance continued to improve affordability. Overall, this has resulted in a reduction of out-of-pocket spending by about 24 percent annually since 2015 due to copay assistance. Utilization and health outcomes would have likely been harmed without copay assistance as total out-of-pocket obligations trended higher. Instead, we find that copay assistance closed important affordability gaps, increasing utilization by 4.8 to 16.7 percent which in turn raised health outcomes by 1.0 to 3.3 percent. This evidence suggests that the affordability and access copay assistance provides has substantial benefit to the patients receiving them in today's environment of rising overall out-of-pocket expenses. Despite these benefits, recent policy proposals are making it more difficult for patients to access the full benefit of copay assistance. Drug manufacturers' main role is discovering and developing drugs, but as the cost burden shifts onto patients, they temporarily expanded their role to help patient affordability until a better solution can be found. In this paper, we discuss how our findings can be used to inform future policy discussions and proposals.

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## Section 1: Introduction

To help patients afford the copays and coinsurance required by insurance plans, pharmaceutical companies offer what amounts to \$14 billion in 2020 alone in copay assistance (IQVIA 2021). This assistance is made available to patients to help them access medicines that are otherwise inaccessible due to high out-of-pocket (OOP) burdens. In this paper, we analyze the total effect of these copay programs on both the trend of overall copays paid by patients on commercial health plans as well as the implied impact on utilization and health outcomes.

Manufacturer copay assistance is only allowed for patients on commercial insurance, meaning Medicare and Medicaid beneficiaries are not allowed to share in the benefits of copay cards. The Office of the Inspector General in the Department of Health and Human Services (HHS) released a Special Advisory Bulletin in 2014 stating the use of copay cards for medications under a federal health care program implicates the Anti-Kickback Statute. Due to this, all the data presented in this paper refer to patients covered by commercial insurance.

We report evidence supporting three major findings. The first is that copay programs have lowered the OOP burden patients face as they have more than offset a well-documented trend in the rise of total copays over the last few years. The list price for a drug is the price pharmaceutical manufacturers set based on cost of development, manufacturing and distribution, clinical value, number of competitors, etc. This price then determines the cost burden on the different payers in the pharmaceutical distribution chain as payment agreements are made usually based on the list price between PBMs and pharmacies, pharmacies and wholesalers, and wholesalers and manufacturers (Sood et al 2017). Manufacturers also negotiate rebates with Pharmacy Benefit Managers (PBMs) that set the formulary, list of drugs covered under an insurance plan, creating a net price that manufacturers receive that removes the rebate from the list price. Rebates have grown in recent years suggesting increased market and negotiation power for PBMs (Kakani et al 2020). One example of their increased negotiation power is PBMs have increased drug exclusions from formularies in recent years (Fein 2021). Pharmaceutical manufacturers need to pay higher rebates to get a preferential spot on the formulary, so in response to higher rebates, pharmaceutical manufacturers increase the list price (Sood et al 2020).<sup>1</sup> Payments based on agreements throughout the distribution system are larger with higher list prices, so the incentive structure leads to higher list prices, and as prices and rebates are negotiated, it is difficult to then lower the list price later.

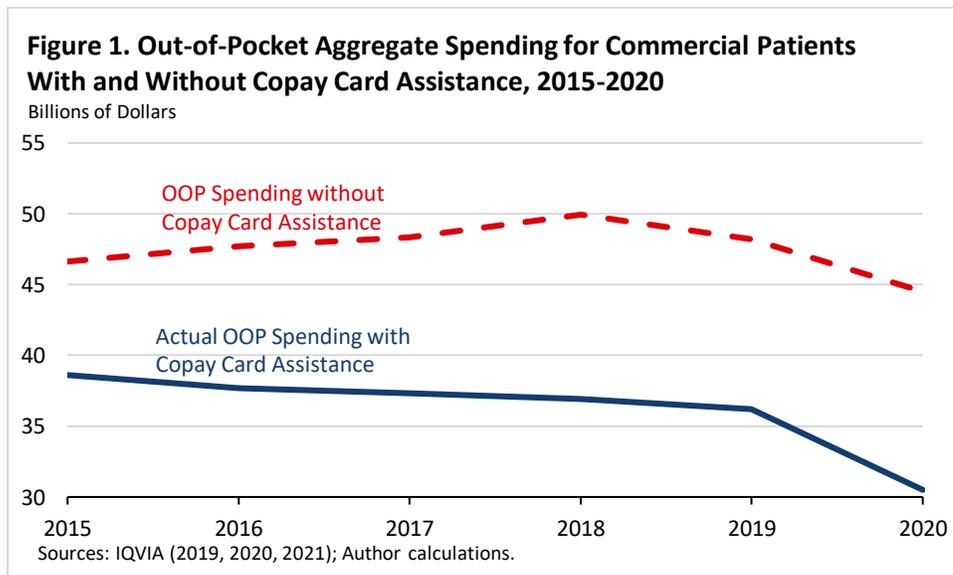
Manufacturer copay assistance is a tool to ensure drug affordability in response to higher list prices and shifts in benefit design that put more out-of-pocket burden on commercial patients. Uninsured patients and patients with a deductible or coinsurance pay their out-of-pocket costs based on list prices, so as list prices rise, patients will have higher initial cost exposures, if the rebates are not passed through to them. In 2018, 50 percent of patients faced a deductible or coinsurance, rather than a fixed copay, compared to 19 percent in 2010 with most of these patients enrolled in a High-Deductible Health Plan (Rae et al 2020; Kaiser Family Foundation

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<sup>1</sup> The authors find a \$1 increase in rebates leads to a \$1.17 increase in the list price creating a growing gap between list and net prices.

2020).<sup>2</sup> Across 7 therapeutic groups, one study found that commercial patients with deductibles and coinsurance spending account for on average 73.7 percent of total out-of-pocket costs for brand drugs in 2019 and pay on average 8 times more than patients with fixed copays (PhRMA 2021). Copay assistance programs have been effective in helping patient affordability, but they are in response to policies that shift the cost burden of drugs onto patients. For now, copay assistance has developed into a part of the system, but if the cost burden of patient affordability is eased through other means like a change in benefit design or pass-through rebates, patients will not need to be as reliant on copay cards.

Figure 1 below shows a growing gap between aggregate out-of-pocket (OOP) drug spending for commercial insurance patients without copay assistance compared to actual OOP drug spending with copay assistance. In other words, the OOP spending without copay assistance is the initial patient cost exposure before accounting for copay assistance. Without copay assistance, patients face the full burden of OOP spending, such that OOP spending would have increased 3.4 percent from 2015 to 2019, growing from \$46.6 billion to \$48.2 billion. However, due to the growing use of copay cards in response to growing OOP exposure, patients faced a lower OOP burden, so actual OOP spending paid by patients was lower and decreased 6.3 percent, from an estimated \$38.6 billion to \$36.2 billion. This implies that copay cards mitigate higher drug OOP cost exposures. Due to COVID-19 disruptions in 2020, from 2019 to 2020, OOP cost exposures fell 7.6 percent due to a decline in prescriptions dispensed, but actual out-of-pocket spending fell twice as fast, 15.7 percent, due to an increase in copay assistance. Overall, as patients face higher drug cost exposures, copay assistance has increased drug affordability, especially in times of economic hardship.



<sup>2</sup> The 2020 Kaiser Family Foundation’s Employer Health Benefits Survey finds almost one-third of employees are enrolled in a High-Deductible Health Plan. They define these as a plan with “a deductible of at least \$1,000 for single coverage and \$2,000 for family coverage offered with a [Health Reimbursement Arrangement]” or “high-deductible health plans that meet the federal legal requirements to permit an enrollee to establish and contribute to an [Health Savings Account]”.

Second, we argue affordability offered by copay assistance has resulted in increased utilization of needed drugs. As out-of-pocket cost exposures rise, patients will increasingly refuse to go to the pharmacy to pick up a prescription written by their doctor or take less than the prescribed amount to avoid paying for a refill of the prescription. Copay cards lower the out-of-pocket costs for patients leading them to increase their utilization by 4.8 to 16.7 percent. This is directly related to patients lowering their abandonment rate of prescriptions and increasing their likelihood of continuing full treatment.

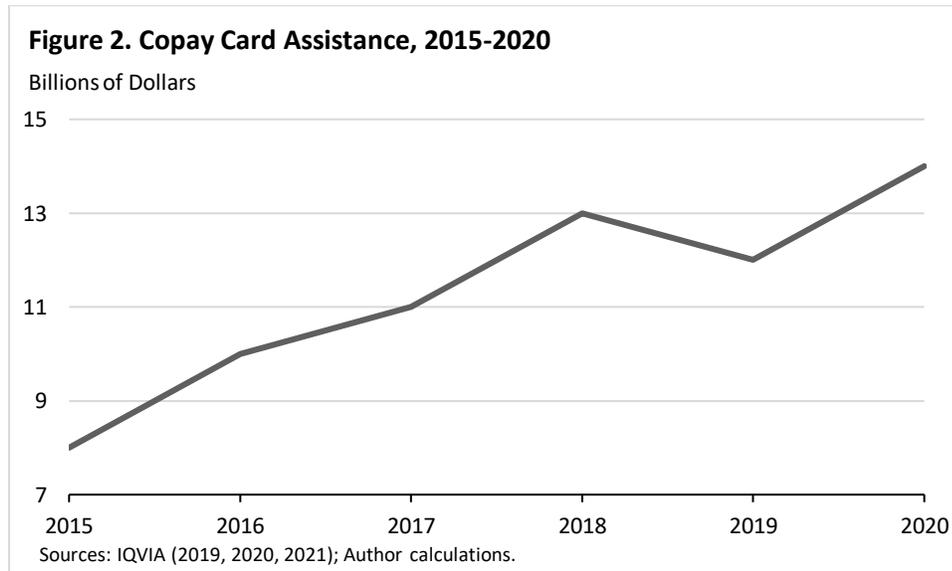
Third, we find that this increased utilization improved health outcomes. Failure to follow prescribed drug therapies in the present leads to worse clinical health outcomes in the future. Copay assistance leads to 1.0 to 3.3 percent better health outcomes as patients will not need future inpatient and outpatient services due to increased drug utilization. Another way to think about this is that the healthcare system saves \$8.1 to \$29.0 billion by avoiding worse health outcomes. Not only will future hospital or physician visits be unnecessary, but patients will be able to extend their lives through improved access to necessary drug treatment. Simultaneously, they will be less affected by their condition leading to an increase in the quality of their day-to-day life. Copay assistance lowers the cost burden on patients leading to increased drug utilization which provides better health to those in need.

This paper may be briefly outlined as follows: Section 2 discusses the impact of copay assistance on the overall trend of copays facing patients, Section 3 discusses the impact of the lower copays on utilization and health outcomes, Section 4 discusses the implications of the finding for accumulator programs, with concluding remarks in Section 5.

## Section 2: Trends on out-of-pocket spending and copay assistance

Despite patients facing increased out-of-pocket exposure due to increasing list prices and shifts in benefit design over the last few years, manufacturer copay assistance has helped patients afford their medicines by lowering the final out-of-pocket price patients actually pay (figure 2). This decline can be seen in aggregate spending data as well as on a per claim basis.

Figure 1 illustrates how out-of-pocket costs generally increase when excluding copay card assistance. With the increase in high deductible and drug tiered benefit designs, the annual OOP initial cost exposure to patients is on average 2.8 times more expensive for specialty drugs (\$1,894) than traditional drugs (\$679) across 7 therapeutic groups (PhRMA 2021; Author calculations). Copay cards are even more important to offset high-cost exposures for patients taking specialty drugs as 50 percent of patients taking a specialty brand drug use copay cards versus 33 percent of patients on traditional brand drugs (IQVIA 2021). The savings from copay cards lead patients to have similar final OOP costs between specialty drugs and traditional drugs due to an average savings of \$1,548 for specialty drugs and only \$414 for traditional drugs. Copay cards help make needed drugs affordable when a patient's health plan fails to provide adequate coverage.



### 2.1 Trends in Aggregate and per Claim Spending

Copay cards are issued by pharmaceutical manufacturers to offset commercially insured beneficiaries' out-of-pocket costs for a brand-name drug. Patients face out-of-pocket cost exposures based on cost sharing determined by their insurance plan and the drug's price, but manufacturer copay assistance reduces the final cost a patient actually pays. Copay cards are distributed in many ways to patients, including directly from the manufacturer or through online websites. Manufacturers want to ensure patients are able to afford the medicines they need.

Studies have shown high out-of-pocket costs can hinder adherence – indeed, almost 3 in 10 patients cite high out-of-pocket costs as a main factor in taking less medication than the prescribed amount (Kirzinger et al 2019). Copay assistance lowers the actual out-of-pocket cost for patients which, as we show in section 3.1, increases drug adherence.

One way to look at the impact of copay assistance is to compare the initial cost exposure with the final out-of-pocket cost patients pay for drug treatment. Table 1 illustrates how the initial cost exposure at the beginning of the year, after deductibles reset to zero, has increased 27 percent from 2015 to 2018 for brand drugs with cost exposures above \$50 and 19.6 percent for all brand drugs. However, final costs paid by patients have actually declined 6.3 percent over this period for brand drugs with cost exposure above \$50 and remained steady across all branded drugs. One reason the final cost for brand drugs have stagnated despite increasing initial cost exposures is the increased use of copay assistance.

Table 1. Monthly Initial Cost Exposure and Final Cost of Brand Drugs for Commercial Patients at the Beginning of the Year Unconditional on Copay Card Assistance, 2015-2018

	Change in Initial Cost Exposure 2015-2018	Change in Final Cost 2015-2018	Copay Card Percent Savings in 2015	Copay Card Percent Savings in 2018
Brand Drugs with Cost Exposure Above \$50	27.0%	-6.3%	14.2%	36.7%
All Brand Drugs	19.6%	0.0%	17.6%	31.1%

Sources: IQVIA (2019); Author calculations.

Despite the increase in cost exposures, final commercial insurance out-of-pocket spending has declined primarily due to copay assistance offsetting these increases. Actual commercial OOP spending decreased by \$2.4 billion from an estimated \$38.6 billion to \$36.2 billion, a 6.3 percent drop, while copay card assistance increased from \$8 billion to \$12 billion from 2015 to 2019 (IQVIA 2019, 2020). As out-of-pocket cost exposure continues to increase, more patients are using copay card assistance. In 2020, 14 percent of commercially insured patients who used a branded drug used a copay card, up from 8 percent in 2015 (IQVIA 2021). From 2015 to the end of 2020, copay cards contributed average annual savings to patients of 23.9 percent in aggregate commercial out-of-pocket spending.<sup>3</sup> These aggregate savings numbers are in line with the savings of all brand drugs reported in a slightly shorter time period in table 1. Some of the decline in commercial insurance out-of-pocket spending can also be attributed to compositional effects of prescriptions and patients shifting from commercial insurance to Medicare and Medicaid (IQVIA 2021).

These aggregate savings numbers and the savings numbers in Table 1 represent aggregate savings unconditional on copay card use, so savings are even higher when looking exclusively at

<sup>3</sup> This calculation is the average percent change from 2015 to 2020 between a counterfactual aggregate out-of-pocket spending and actual aggregate out-of-pocket spending. The counterfactual for each year is calculated by summing the copay card savings and actual aggregate out-of-pocket spending. This is the basis for figure 1. Copay assistance led to a 31.5 percent reduction in commercial insurance out-of-pocket spending in 2020 alone, compared to 17.2 percent in 2015 (IQVIA 2021, Author calculations).

patients using copay card assistance. One estimate finds the median manufacturer copay card used saved 87.1 percent of out-of-pocket costs (Sen et al, 2021). Using estimates of copay card prevalence from IQVIA (2021) and Van Nuys et al (2018), a back of the envelope calculation using Sen et al (2021) results illustrate copay cards helped reduce 9.8 to 39.2 percent of total out-of-pocket costs giving validation to our annual 23.9 percent savings estimate and the estimates in table 1.<sup>4</sup>

We have established initial cost exposures have increased and have been offset by the increased use of copay cards leading to falling out-of-pocket spending. Final out-of-pocket spending can fall when either the quantity of prescriptions falls, the price of prescriptions falls, or a combination of the two. If copay cards are indeed a primary driver in the decline of actual OOP spending, then we would expect OOP spending on a per claim basis to fall faster than the quantities of prescriptions. The quantity of commercial retail prescriptions has slightly increased in most years. From 2017 to 2019, commercial retail prescriptions dispensed increased by just under 1 percent, yet actual out-of-pocket spending still fell (IQVIA 2020). Simultaneously, the average final OOP cost on a per claim basis of brand drugs are 24.6 percent lower in 2020 than they were in 2015 (IQVIA 2021; author calculations).<sup>5</sup> This suggests spending on a per claim basis is causing the decline in actual OOP spending, and manufacturer copay assistance is a main driver in this decline. Other contributing factors are an aging population with patients shifting from commercial insurance to Medicare that leads to a changing prescription mix. It is worth noting these patients lose access to copay assistance when they shift to Medicare. Overall, this finding is worth noting, and a place for further research that a more rigorous analysis can estimate the effect of different factors in the out-of-pocket final cost per claim decline.

Out-of-pocket spending in 2020 was unique due to the COVID-19 pandemic but illustrated the continued adoption of copay assistance. Aggregate out-of-pocket spending fell \$5.7 billion, or 15.7 percent in 2020 (IQVIA 2020; IQVIA 2021; author calculations). One reason is the quantity of drugs dispensed uncharacteristically declined as the COVID-19 pandemic disrupted new prescription medicines due to fewer doctor visits, screening, and diagnostics. Additionally, copay card assistance increased \$2 billion, 16.7 percent, to \$14 billion in 2020. Though this large decline is likely to be temporary, copay card assistance showed their increased worth to patients in times of economic hardship.

The extent to which copay assistance is contributing to lowering patient out-of-pocket cost burden is likely even higher, given the difficulties in tracking all forms of manufacturer copay assistance. One analysis puts patient savings due to copay assistance at \$12 billion in 2019. This estimate is based on evaluating claims data and determining the difference between the initial cost exposure and final patient out-of-pocket costs (IQVIA 2020). However, some forms of copay assistance are hard to track through claims data. Another estimate, based on pharmaceutical manufacturers' actual spending on copay card assistance, puts manufacturers copay assistance

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<sup>4</sup> This range is determined by multiplying the 87.1 percent savings from copay cards from Sen et al (2021) by the finding that 80 percent of drug spending is on branded drugs and 14 percent of patients using brand drugs use copay cards from IQVIA (2020 and 2021), and 45 percent of the top 200 drugs by expenditure had copay cards available from Van Nuys et al (2018).

<sup>5</sup> IQVIA (2021) shows the commercial insurance average final out-of-pocket cost per retail prescription in 2015 was \$27.00 and decreased to \$20.37. This indicates a 24.6 percent decline.

spend at \$15 billion in 2019 (Fein 2020a). Therefore, the copay card savings in table 1 as well as figures 1 and 2 are considered lower bound estimates of the full savings patients have received from all forms of copay cards.

Over the past half decade, copay card assistance has almost doubled while actual patient OOP spending per claim has fallen for branded drugs. The main mechanism driving this phenomenon is the increased use of copay card spending, especially for high-cost specialty drugs.

## 2.2 Copay Card Assistance in Specialty Drugs

Specialty drugs treat complex or chronic illnesses like cancer, rheumatoid arthritis, and hepatitis C. Many of them are often biologic medications, and some of the most expensive drugs on the market. They often require delivery via complex auto-injector or other devices or require special handling and distribution via specialty pharmacy channels. Biologics tend to have higher costs of manufacturing than small molecule drugs due to their complexity causing biologics to be 22 times more expensive to both develop and produce at scale than small molecule drugs (Makurvet, 2021). Despite their high costs, they bring needed health benefits. Chambers et al (2014) show how the costs of specialty drugs are higher than traditional drugs (\$12,238 versus \$784), but this higher cost comes with larger gains of Quality Adjusted Life Years (0.183 versus 0.002). Specialty drugs treat some of the most complex and rare diseases as well as the most debilitating and fatal. Patients taking specialty drugs need their drug treatment to improve or in some cases even save their lives, but sometimes benefit plan design puts too much of the cost burden on patients, making it difficult for them to reliably access these needed medications. Copay card assistance helps alleviate these access barriers. Starner et al (2014) estimate copay card assistance saves patients using specialty drugs 60.2 percent on their final OOP costs.

Copay assistance provides a steady decline in out-of-pocket costs across different kinds of therapy. Daubresse et al (2016) found new atorvastatin or rosuvastatin users between June 2006 and February 2013 who use copay assistance incur actual monthly out-of-pocket costs of \$9.70, while patients without copay assistance incur actual monthly out-of-pocket costs of \$15.10, a 35.8 percent difference.<sup>6</sup> This trend continued for new users after 4 years as actual monthly out-of-pocket costs remained 13.9 percent lower for copay card users (\$14.3 versus \$16.6). As another example, among 3,143 patients prescribed oral ALK inhibitors (ALKi's), patients using copay assistance (manufacturer's copay cards, other discount cards, or free-trial vouchers) decreased actual out-of-pocket cost on average by \$1,930 per claim covering over 98 percent of the cost (Seetasith et al, 2019).<sup>7</sup>

More patients are starting to need to utilize copay card assistance to afford these drugs as benefit plan designs shift the cost burden onto patients. One plan design change growing in prominence is accumulator adjustment and maximizer programs. These programs do not count copay assistance towards a patient's deductible or out-of-pocket maximum; thus, a patient essentially pays for their deductible and out-of-pocket maximum twice. The number of commercial patients taking traditional brand therapies using copay cards doubled from about 16

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<sup>6</sup> Atorvastatin and rosuvastatin reduce the risk of heart attack, stroke, and other heart complications.

<sup>7</sup> ALKi's are used to treat a rare subset of non-small cell lung cancer (NSCLC) that afflicts about 5 percent of the population with NSCLC illustrating the importance of copay assistance for these patients.

percent in 2015 to 33 percent in 2020 (IQVIA, 2021). Additionally, 50 percent of patients on branded specialty drugs used copay cards in 2020, up from about 40 percent in 2015 (IQVIA 2021). The growing cost exposure for patients requiring valuable specialty drugs for diseases like Multiple Sclerosis and Rheumatoid Arthritis drives the need for copay assistance to ensure access (Adler and Kapko 2020). Patients with HIV and Multiple Sclerosis use copay cards at high rates because brand drugs treating these diseases tend to be complex with “different mechanisms of action, different administration and different side effect profiles” making them non substitutable leading copay cards to be the best form of financial relief (Andrews 2018). These patients rely on copay assistance, yet the adoption of accumulator adjustment and maximizer programs limit the impact of this assistance.

Table 2 illustrates how copay assistance helps reduce patients’ actual out-of-pocket costs (PhRMA 2021). The 32.0 percent of Oncology patients using copay card assistance to help access their medications, save on average \$1,696, helping address 76.4 percent of their annual OOP cost exposure (PhRMA 2021). Similar savings are achieved in several other disease states as listed in Table 2. Despite an annual out-of-pocket cost exposure on average 2.8 times more expensive, patients only pay \$346.50 for specialty drugs compared to \$264.67 for traditional drugs when using copay cards. Copay assistance offset the high OOP exposure seen in specialty drugs to make these drugs cost in the same range as a traditional drug allowing patients to stay on their medications. These results were consistent across data sources.

Table 2. Share of Patients using Copay Assistance and Savings due to Copay Assistance by Therapy Class Conditional on Assistance, 2019

Therapy Class	Share of Patients with Copay Assistance (%)	Avg. Annual OOP Cost Exposure (\$)	Avg. Annual OOP Cost with Copay Assistance (\$)	Share of OOP Cost Saved (%)
HIV	55.4	1,814	165	90.9
MS	70.0	2,769	531	80.8
Anticoagulants	31.1	772	165	78.6
Oncology	32.0	2,221	525	76.4
Depression	44.9	729	241	66.9
Asthma/COPD	12.8	528	206	61.0
Diabetes	28.9	780	347	55.5
Traditional, 2020	33.0			
Specialty, 2020	50.0			

Sources: PhRMA (2021); IQVIA (2021); Author calculations.<sup>8</sup>

Note: We consider HIV, MS, Anticoagulants, and Oncology as specialty drugs, the rest as traditional drugs as shown in IQVIA (2021).

The use of copay assistance continues to grow in response to rising initial cost exposures. This has led final out-of-pocket costs to decrease since 2015, helping patients access and stay on their medications. A main reason for the increase in copay assistance is the lack of robust coverage offered for high cost of specialty drugs. These drugs have much larger cost exposures and treat critical conditions, so copay assistance is critical for these patients to access and benefit from their treatments.

<sup>8</sup> PhRMA (2021) utilized IQVIA’s U.S. Market Access Strategy and Consulting team in their report to estimate these numbers, so the two reports have similar underlying methodologies.

## Section 3: The Impact of Copay Assistance

Copay assistance reduces out-of-pocket costs for patients and thereby also increase patient utilization of pharmaceuticals prescribed to them. This in turn improves health outcomes. In this section we measure the magnitudes of these effects. Using data from 2015 to 2020, we find that copay assistance reduced average annual OOP spending by 23.9 percent while increasing utilization by 4.8 to 16.7 percent and increasing health outcomes by 1.0 to 3.3 percent. Accordingly, copay assistance not only saved patients \$12 billion in out-of-pocket costs in 2019, but they also avoided an additional \$8.1 to \$29.0 billion in other medical services linked to worse health outcomes.

Health outcomes can be measured by increases in life expectancy and Disability Adjusted Life Years (DALYs). Our drug utilization estimate's effect on life years reveals an average annual increase in life expectancy of 0.1 to 0.5 years. Looking at it another way, the increase in drug utilization identified here, also decreases DALYs by 3.5 to 12.2 percent.

### 3.1 The Impact on Utilization

Out-of-pocket initial cost exposures continue to increase over time. If final out-of-pocket costs increased at the same rate, drug adherence would decline as patients either abandon new prescriptions, take less than the prescribed amount, or end medicine treatment early. Copay assistance has emerged as an effective tool to mitigate the rising initial cost exposures, lowering out-of-pocket costs, and increasing drug adherence. Using the estimated 23.9 percent reduction in the average annual out-of-pocket costs due to copay assistance, we applied a range of demand elasticities, -0.2 to -0.7, from the literature to find these annual OOP cost reductions lead to aggregate drug utilization increases of 4.8 to 16.7 percent, defined as total drug spending. This means copay assistance incentivizes patients to increase their drug adherence through lower out-of-pocket cost burden on patients.

The basis of this range comes from a seminal literature review by Goldman et al (2007), cited favorably by the Congressional Budget Office in a 2012 report as evidence of the effect of price changes on the use of prescription drugs overall.<sup>9</sup> This literature review found an elasticity range of -0.2 to -0.6, which means that a 10 percent decrease in user costs for pharmaceuticals leads to a 2 to 6 percent increase in utilization.

More recent studies obtain similar results, ranging from -0.2 to -0.7 (Simonsen et al 2015; Chandra et al 2021; Lichtenberg and Sun 2007; Dafny et al 2017; Yeung et al 2018; Eaddy et al 2012).<sup>10</sup> The range of elasticities can be attributed to different methodologies and disease

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<sup>9</sup> This study relies on 130 observational studies as well as 2 studies that came from the often-cited RAND Health Insurance Experiment.

<sup>10</sup> Simonsen et al (2015) use a regression kink design on Danish drug purchase records to find an elasticity range of -0.2 to -0.7 for patient price responsiveness. Chandra et al (2021) find an as-if-random drug out-of-pocket price increase in Medicare Part D of 33.6 percent leading to a 22.6 percent drop in utilization, meaning a drug utilization elasticity of -0.7. Lichtenberg and Sun (2007) find Medicare Part D lowered the user cost of pharmaceuticals for the elderly by 18.4 percent, increasing their use of prescription drugs by 12.8 and total spending by 12.5 percent in 2006 for an elasticity of -0.7. Dafny et al (2017) finds a demand elasticity of copay card assistance of at least -0.6

severities across therapeutic groups. Patients with severe diseases rely heavily on specialty drugs leading them to face a substantial amount of risk of high out-of-pocket spending creating inelastic demand of specialty drugs, while traditional disease groups tend to have higher demand elasticities (Goldman et al 2006; Goldman et al 2004).<sup>11</sup> Yeung et al (2018) documents other recent literature that illustrate varying elasticities across therapeutic groups. Overall, demand elasticities of -0.2 to -0.7 provide a reasonable range to measure the effect of copay assistance on drug utilization.

The importance of copay assistance on drug adherence is evident by looking at studies focused on patients with Rheumatoid Arthritis (RA). Many of the drugs that treat RA – a debilitating disease that can lead to permanent disability – are considered specialty drugs.<sup>12</sup> This disease requires constant treatment and sometimes multiple medications just to achieve symptom relief and slow the progression of the disease (Heidari and Crawford 2018). Treatments for RA are often categorized as specialty drugs, which on many commercial plans, can mean higher out-of-pocket cost exposure. This means patients may be tempted to take less than the prescribed amount to save costs if symptoms are not bothering them that day or their RA is in the beginning stages. From 2004 to 2013, the average expenditure of \$2,300 for RA drugs stayed constant over this time period but the out-of-pocket cost rose 256 percent from \$36 to \$128 (Atzinger and Guo 2017).<sup>13</sup> Using the established relationship between OOP cost exposure and abandonment rates for RA drugs established in Hopson et al (2016), this OOP cost increase likely corresponds to initial abandonment rate to rise from about 5.0 percent to about 12.5 percent over this time period.<sup>14</sup> Taking the 150 percent increase in abandonment and the OOP cost increase of 256 percent gives an utilization elasticity of 0.59, near the upper end of the elasticity range established above. This is a disease group that faces increasing costs of treatment, and copay card assistance provides financial relief to combat these costs to help patient's health and quality of life now and in the future through constant treatment.

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for brand utilization, this estimate is made on branded drugs with copay cards available that receive generic entry during their study period. Yeung et al (2018) estimates an elasticity of demand of -0.16 based on a natural experiment investigating the change in cost sharing on the number of prescriptions filled due to a policy shift to a value-based formulary from Premera Blue Cross in the Pacific Northwest. Eaddy et al (2012) also conducted a comprehensive literature review from January 1974 to May 2008 finding a \$10 increase in patient cost sharing led to a 3.8 percent drop in adherence overall.

<sup>11</sup> Goldman et al (2006) estimates low demand elasticities of specialty drugs like cancer, kidney disease, and multiple sclerosis in the range of -0.01 to -0.21. Goldman et al (2004) finds traditional drug elasticities ranged from antidiabetics (-0.25) to nonsteroidal anti-inflammatory drugs (-0.45) with antihistamines, antihyperlipidemics, anti-asthmatics, anti-hypertensives, and antidepressants somewhere between when looking at increases in copayments and drug days supplied (Goldman et al, 2004).

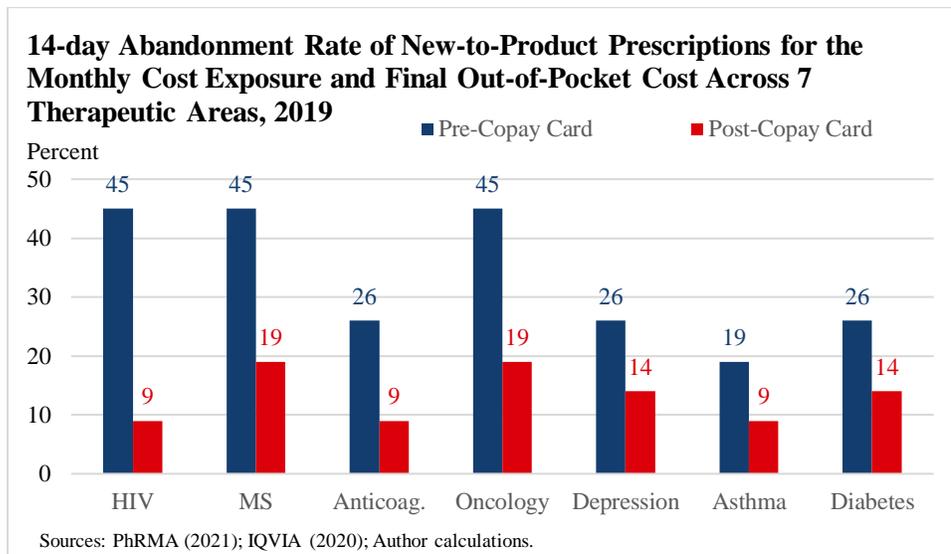
<sup>12</sup> Reference section 2.2 for definition and discussion of specialty drugs.

<sup>13</sup> Over this time period, 9 biologic drugs and 1 non-biologic drug were approved (Atzinger and Guo 2017).

<sup>14</sup> The increase in abandonment rate takes the price levels found in Atzinger and Guo (2017) and applies them to abandonment rates at different price levels for Rheumatoid Arthritis calculated by Hopson et al (2016). For example, they find abandonment rates could be as high as 32.7 percent for patients who face out-of-pocket costs above \$550

Other studies have begun to illustrate the connection between copay assistance and an increase in drug adherence. Due to patients being able to access their prescriptions at lower out-of-pocket costs through copay assistance, they continue therapy longer, thus increasing the value of the treatment (Daubresse et al 2016).<sup>15</sup> Accordingly, patients are quicker to start their treatment, have a lower risk of abandoning their first approved prescription, and a lower risk to discontinue treatment (Seetasith et al 2019).<sup>16</sup>

Additional evidence illustrates the relationship between lower out-of-pocket costs achieved through copay assistance and adherence to prescriptions. IQVIA (2020) calculates the 14-day abandonment rates for new-to-product prescriptions by monthly out-of-pocket cost across all drugs and payers. Table 2 shows the average annual cost exposure and final out-of-pocket costs for 7 therapeutic groups calculated by PhRMA (2021). After converting these values into monthly terms, we merged these datapoints together to show the change in abandonment rate for the average drug in these therapeutic groups. For these 7 therapeutic groups, copay cards cut the 14-day abandonment rate by half or more for 6 of the 7 therapy groups (figure 3). The pre-Copay card bar (blue) in the graph below shows the abandonment rate related to the average out-of-pocket cost exposure of the average drug in that therapeutic group. The post-Copay card bar (red) shows the abandonment rate related to the average monthly final out-of-pocket cost for that group when factoring in the price discount from the copay card. Specialty drug classes tend to have higher abandonment rates due to higher initial cost exposures, but copay cards provide cost savings which lowers the abandonment rate to be on par with traditional drugs.



<sup>15</sup> Daubresse et al (2016) finds among statin users, patients using copay cards were 20.2 percent (31.3 percent versus 39.2 percent) less likely to stop treatment after 1 year and 17.2 percent less likely after 4 years (50.6 percent versus 61.1 percent) compared to non-copay card users.

<sup>16</sup> Seetasith et al (2019) found patients using copay assistance went to the pharmacy to pick up their ALKi prescriptions sooner than patients without copay assistance, 2.6 days versus 25.7 days. They further find after patients' first approved prescription, patients using copay assistance had 88.2 percent lower risk of abandoning this prescription and 24.3 percent lower risk of discontinuing treatment.

Copay assistance is an effective way to lower final out-of-pocket costs which helps patients using copay cards increase their drug utilization. Drug utilization is directly tied to positive health outcomes. Drug non-adherence accounts for about 10 percent of hospitalizations and causes about 125,000 deaths annually (Viswanathan et al, 2012). The Massachusetts Health Policy Commission released a 2020 report emphasizing the financial challenges patients would face if the state reverted back to banning copay cards as it would lower drug utilization and hurt clinical outcomes (Commonwealth of Massachusetts, 2020). In a time of rising cost exposures, patients have begun to rely on copay assistance to take their medication and improve their health.

### **3.2 The Impact on Health Outcomes**

We identified three different metrics that demonstrate how the increase in drug utilization precipitated by manufacturer copay assistance, led to improved health outcomes. First, the increase in drug utilization improved patient health, decreasing other health spending by lowering their need for future inpatient and outpatient procedures or emergency room visits. Second, the increase in drug utilization contributed to patients experiencing an average annual increase in life expectancy. Third, increased drug utilization led to a decrease in disability adjusted life years. The World Health Organization defines Disability Adjusted Life Years (DALYs) as a way to measure the burden of a disease that is not fully captured just by mortality as “one DALY represents the loss of the equivalent of one year of full health.” Increased drug utilization not only extended patient’s lives, but it also increased their quality of life by lowering the burden of the disease on their day-to-day life. This section calculates these measurements using the estimated drug utilization increases and elasticity estimates from the literature.

#### **3.2.1 Increased Drug Utilization Impact on Other Health Spending**

With the 4.8 to 16.7 percent increase in drug utilization, we applied an elasticity of -0.2 to find health outcomes improved by 1.0 to 3.3 percent in terms of other health spending.

For many years, CBO determined there was “insufficient evidence” for the effect of drug utilization on other medical spending, so they did not incorporate any offsetting effects of drug spending when estimating legislative budgetary changes (CBO, 2012). However, in 2012, they changed their methodology to include an elasticity effect between drug utilization and other medical spending, defined as medical and surgical services other than self-administered prescription drugs. They synthesized 8 studies across three broad categories to find an elasticity of -0.2. Applying the 1.0 to 3.3 percent in avoided other health spending to the 2019 National Health Expenditures data released by the Center for Medicare and Medicaid Services (CMS) reveals increased drug utilization avoided an additional \$8.1 to 29.0 billion linked to worse outcomes.<sup>17 18</sup> Another way to think of this range is the increased drug utilization avoided the

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<sup>17</sup> The 2019 National Health Expenditures data shows hospital care and professional services expenditures for private insurance totaled \$839.1 billion. The \$8.1 to \$29.0 billion savings come from applying the 1.0 to 3.3 percent number to the \$839.1 billion.

<sup>18</sup> An alternative estimate shows a 10 percent increase in drug utilization leads to a 6.4 percent (elasticity of -0.64) decrease in hospital care expenditure through lower hospital admissions, hospital days, and inpatient surgical

dollar amount equivalent of about 583,000 to 2.1 million hospitalizations, using the average cost for hospitalizations from Jha et al (2012) of \$13,904 (adjusted to 2019 dollars using healthcare CPI).<sup>19</sup> These savings come on top of the \$12 billion patients directly saved from using copay cards.

Other literature illustrates the link between drug utilization and other medical spending. One estimate that CBO (2012) used in their report finds a \$1 increase in drug copayment leads patients to reduce drug utilization with 35 percent of the decrease in overall drug spending offset by increases in medical spending (Gaynor et al 2006). Other studies also show how higher drug adherence leads to less medical spending as patients are at lower risk of needing hospitalization (Roebuck et al 2011; Ho et al 2006; Jha et al 2012).<sup>20</sup> Jha et al (2012) even projects an increase in drug adherence would save \$4.7 billion annually by avoiding 699,000 annual emergency department visits and 341,000 annual hospitalizations. Increasing drug utilization is crucial to better future health outcomes.

### **3.2.2 Increased Drug Utilization Impact on Life Expectancy**

Another way to estimate health outcomes is in terms of life expectancy. Based on the increase in drug utilization calculated above, our analysis shows that increased use of copay assistance leads to an average annual increase in life expectancy of 0.1 to 0.5 years.

Drug innovation has been illustrated to have a significant positive impact on people's health outcomes, quality of life, and worker productivity (see Lichtenberg's extensive work on drug innovation). One example of this is in HIV drugs from 1993 to 2001. Expenditures for HIV drugs per person living with AIDS increased 429 percent, \$1,700 to about \$9,000, over this time period (Lichtenberg, 2006). This was mainly driven by the 368 percent increase in the quantity of prescriptions per number of people living with AIDS, up from 2.2 to 10.29. The increased drug expenditures led to life expectancy of someone with HIV/AIDS to increase by 13.4 years. Using this elasticity of 0.031 (13.4/429), the increase in drug utilization from copay assistance increases life expectancy by 0.1 to 0.5 years annually. This elasticity is for specialty drugs developed to treat HIV/AIDS patients, so this entire range can be thought of as an upper bound when factoring in traditional drugs as well.

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procedures (Lichtenberg, 1996). Applying this elasticity to the increase in drug utilization estimate due to copay cards would indicate a 3.1 to 10.7 percent increase better health outcomes, leading to \$13.8 to \$52.5 billion savings for just inpatient hospital care from the 2019 National Health Expenditures data. This equates to avoiding 1.0 to 3.8 million hospitalizations using the average cost for hospitalizations from Jha et al (2012).

<sup>19</sup> Hospitalizations are for inpatient care only. The -0.2 elasticity calculated by CBO (2012) is for drug utilization's effect on other hospital spending: inpatient and outpatient. This means increased drug utilization from copay cards avoided future inpatient and outpatient care. Therefore, the savings from increased drug utilization is the dollar amount equivalent of hospitalizations, not hospitalizations directly.

<sup>20</sup> Roebuck et al (2011) provides further evidence of patients with chronic vascular disease reaping the benefit of drug adherence leading to less total annual health care spending. Ho et al (2006) found diabetes mellitus patients in a managed care organization with less than 80 percent drug adherence have increased risk for an all-cause hospitalization with an odds ratio of 1.58. Jha et al (2012) uses a national sample of diabetes patients from 2005 to 2008 to show that the 27.8 percent of patients who improved their drug adherence had a decreased likelihood of hospitalizations or emergency department visits with an odds ratio of 0.87.

Another example is Hostenkamp and Lichtenberg (2015) use of Danish diabetes data to show differing life expectancies across patients based on their level of drug adherence. They find patients taking the appropriate number of pharmaceuticals prescribed to them (90 to 110 percent of their prescription) have a life expectancy 2.5 years longer than patients consuming 70 percent or less of their prescription and 1.5 years longer than people with adherence levels between 70 to 90 percent. We convert these findings to life expectancy estimates, (see formula below), based on increased drug utilization by assuming the increase in drug utilization will occur uniformly across all adherent groups based on their size (<70 percent: 14.2 percent of patients and 70-90 percent adherent: 15.3 percent of patients).<sup>21</sup> Our calculations demonstrate that increased drug utilization as a result of copay card assistance led to a life expectancy increase of 0.1 to 0.5 years annually.

There is uncertainty around whether this is an upper bound or lower bound estimate. If we assume the share of the percent increase in utilization is equal to the share of total patients in that adherence group, then this is a lower bound estimate.<sup>22</sup> On the other hand, assuming copay assistance benefits the lowest adherent groups more, this estimate could be more of an upper bound. Specifically, since we assume an average percent increase in adherence for people in the lowest adherent group percent increase then this is an upper bound as patients in this group are more likely to have a higher variance in how much they actually need than other groups.

$$\begin{aligned}
 & \textit{Life Expectancy Change} \\
 & \textit{70-90\% adherent} \\
 = & \sum_{i=<70\% \textit{ adherent}} \textit{L.E. Increase}_i \frac{\textit{4.8 to 16.7\% utilization * \% patients not compliant}_i}{\textit{Utilization \% Change needed to be compliant}_i}
 \end{aligned}$$

Other literature illustrates the link between drug utilization and life expectancy. Simpson et al (2006) performed a meta-analysis of 21 studies for the effect of drug therapy adherence on mortality finding good adherence, compared to poor adherence or just a placebo, leads to a decreased likelihood of death with an odds ratio of 0.56. This means moving from low adherence to good adherence will decrease the risk of dying. Chandra et al (2021) estimates a 33.6 percent price increase in Medicare leads to a 32.7 percent increase in monthly mortality through a reduction in drug utilization. Ho et al (2006) also finds diabetes mellitus patients in a managed care organization with less than 80 percent drug adherence have increased risk of death with an odds ratio of 1.81

### 3.2.3 Increased Drug Utilization Impact on Disability Adjusted Life Years

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<sup>21</sup> This is normalized by how much increase in utilization patients need in each group to become compliant (we assume 28.6 percent for <70 percent and 12.5 percent for 70-90 percent adherent). This can be thought of how much progress the group made to becoming compliant. Then take this number for each group and multiply by the life expectancy increase if they became fully compliant and sum the two groups. This assumes a linear increase in benefits to full compliance.

<sup>22</sup> People are the worst off when they are in the less adherent groups. If we were to assume the utilization benefits go solely to the lowest adherent groups instead of spreading the utilization increase across groups, then we would see a much larger benefit.

Finally, we find that the increase in drug utilization associated with copay assistance, decreases disability adjusted life years by 3.5 to 12.2 percent. A decrease in disability adjusted life years means life expectancy increased or the amount of time that a patient is hampered by the disease decreased. Essentially, the burden of diseases fell as patients' health improved.

Lichtenberg (2018) estimates DALYs reduced by cancer drug innovation. Specifically, this study found that cancer drug expenditure increased 11.5 percent globally from 2014 to 2015, mainly due to drug launches in the late 2000s. The increase in drug expenditures from drug launches corresponded to an 8.4 percent decrease in DALYs in 2015 creating an elasticity of -0.73. Our drug utilization estimate range applied to this elasticity results in a decrease of 3.5 to 12.2 percent of DALYs.

Using extensive prior research, copay assistance leads to out-of-pocket savings on drug therapies leading to an increase in utilization which ultimately has positive health outcomes, including an increase in life expectancy. Patients benefit from copay cards and public policies need to continue to encourage their use.

## Section 4: Policy Implications

Despite the benefits of copay assistance on patient affordability, access, and health outcomes as outlined above, in recent years, insurance plans and policymakers have taken steps to limit the use of manufacturer copay assistance to the detriment of patients. Insurance plans have adopted what are known as accumulator adjustment and maximizer programs to mitigate the patient benefit of copay cards.<sup>23</sup> Copay cards traditionally have counted towards patients' deductibles and out-of-pocket maximums; the most insurance plans can require patients to pay in a given year before the insurer steps in and covers the rest. Accumulator adjustment and maximizer programs, however, don't count these copay cards towards a patient's out-of-pocket maximum or deductible.<sup>24</sup> As a result, their full insurance coverage may never kick in, and their out-of-pocket health costs remain high throughout the year. Accumulator adjustment and maximizer programs thus cancel out the financial benefits of copay assistance by shifting the cost burden of medication back onto patients.<sup>25</sup> It essentially amounts to patients paying twice to qualify for plans to cover them, first through the cards and then again on their own.

To put these programs into context, first the cost burden was shifted onto patients through high-deductible plans. In response, the use of manufacturer copay cards increased. Now, accumulator adjustment and maximizer programs are growing in prominence to counteract the uptake of manufacturer copay assistance shifting the cost burden back onto patients. Copay assistance has been an effective tool to ease the out-of-pocket cost burden on patients, so limiting their use without giving patients a new way to address their affordability issues will negatively impact patients.

As the prevalence of accumulator adjustment programs grows, recent research illustrates the harms of these programs as they raise the out-of-pocket costs for patients leading to less medication adherence. After one large insurer imposed an accumulator adjustment program for autoimmune medications, refill rates dropped 12 percentage points and treatment discontinuation increased 20 percentage points within just one year (Sherman et al, 2019). RxCrossroads (2019) show adherence for specialty drug therapy fell 13 percent after copay accumulators were introduced for patients with high-deductible health plans as once patients under copay accumulators hit the annual savings cap of their copay assistance, patients stopped taking their medication. PhRMA and IQVIA (2020) conducted a joint analysis finding accumulator adjustment programs can also create a “copay surprise” where patients suddenly hit their copay assistance maximum leaving them with a substantial increase in their monthly cost for their medication. The discontinuation rate of medication rises to a range of 25 to 36 percent for

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<sup>23</sup> Accumulator adjustment and maximizer programs are also known as copay accumulator or copay maximizer programs. Insurers each have their own names like Express Script's “Out-of-Pocket Protection Program” or UnitedHealthcare's “Coupon Adjustment: Benefit Plan Protection Program” (Brooks 2020).

<sup>24</sup> Though slight differences exist between copay accumulators and copay maximizers, they both still shift the cost burden to patients. Copay accumulators do not allow the copay card to be applied to out-of-pocket maximums or deductibles. Copay maximizers also do not apply copay cards to the out-of-pocket maximums or deductibles, but they do spread the copay card benefit over the entire benefit year.

<sup>25</sup> See Fein (2018) for an example to illustrate how the cost burden shifts from insurance plans to patients.

patients who face a copay surprise of more than \$1,500 due to accumulator programs (PhRMA and IQVIA, 2020).

Despite this evidence and the harm of accumulator adjustment and maximizer programs on patients, survey data has tracked the growth of these programs since 2018. Surveys by MMIT find insurance policies that have adopted copay accumulator programs has grown from 44 percent of covered lives in 2018 to 68 percent in 2020 and is expected to continue growing (Fein 2020b). The numbers for copay maximizer programs are 14 percent and 56 percent, respectively (Fein 2020b).<sup>26</sup> These numbers are considered an upper bound for beneficiaries enrolled in these programs because while a policy can have these programs written in them, the choice to implement the policy is still up to the individual plan sponsor. In March 2021, the National Alliance of Healthcare Purchaser Coalitions found only 36 to 37 percent of employers are currently using copay accumulator or maximizer programs (National Alliance of Healthcare Purchaser Coalitions, 2021).<sup>27</sup> Patterson et al (2021) of MME Advisors released results showing hesitancy in adopting these programs is tied to beliefs that these programs shift the cost burden to patients from plan sponsors and that these programs could lower medication adherence.<sup>28</sup> Accumulator adjustment and maximizer programs are continuing to be adopted even though they negatively impact patients.

One of the main claims used to justify accumulator programs is that they prevent drug companies from incentivizing patients to take brand-name drugs instead of cheaper bioequivalent generics.<sup>29</sup> However, this argument belies the fact that copay cards are used primarily for brand drugs without a generic substitute. IQVIA (2018) found that copay cards used on brand-name medicines that have generic competitors represent just 0.4 percent of all commercially insured medication dispensed in 2017. Van Nuys et al (2018) evaluated copay card drug use on the top 200 drugs in 2014 by drug spending finding 79 percent of drugs with copay cards available have no direct generic equivalent.<sup>30</sup> This result is consistent yet slightly smaller

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<sup>26</sup> These numbers are expected to increase to just under 70 percent by the end of 2021. The 2020 survey asked 50 managed care plans covering 127.5 million covered lives about their adoption of copay accumulator and maximizer programs. This is for the 2020 results and the expected 2021 results. The results for 2018 come from a similar sample.

<sup>27</sup> An additional 22-32 percent are considering adopting these programs, and 32-41 percent are not currently considering these programs. They conducted an online survey asking 151 employers or health insurance purchasers across industries and company size about pharmacy drug policy strategies. These programs are being adopted at faster rates in companies with more than 5,000 employees.

<sup>28</sup> This was an online survey of 24 pharmacy and medical directors covering 229 million covered lives. When asked if these programs could potentially shift costs onto patients from plan sponsors, about 60 percent of payers strongly agreed and 54 percent of payers also agreed these programs could lower medication adherence.

<sup>29</sup> Dafny et al (2017) finds after a direct generic equivalent enters the market, a branded drug's share of dispensed prescriptions falls to about 5 percent, and copay cards add at least an additional 3 percentage points to the use of branded drugs, an about 60 percent increase in brand drug use.

<sup>30</sup> In their sample, 51 percent of brand drugs with copay cards available had no bioequivalent generic competition, and an additional 28 percent of brand drugs with copay cards available only have a generic close therapeutic substitute.

than a prior finding that 92 percent of drugs with copay cards available have no direct generic substitute (Ross and Kesselheim, 2013).<sup>31</sup>

Despite the low prevalence of copay assistance when generic substitutes are available, two states adopted policies designed to limit the use of manufacturer copay assistance where copay cards can only be used on brand name drugs with no generic equivalent (Massachusetts since 2012, California beginning 2018).<sup>32</sup> Rome et al (2021) found no statistically significant increase in generic uptake occurred in California in the first year after the law took effect compared to 10 surrounding states.<sup>33</sup> If copay assistance caused substitution away from generics, California generic uptake should have risen at a faster pace than surrounding states due to the new law. In contrast, since 2019, twelve states, Arizona, Arkansas, Connecticut, Georgia, Illinois, Kentucky, Louisiana, North Carolina, Oklahoma, Tennessee, Virginia, and West Virginia, plus Puerto Rico took decisive action by restricting or outright banning accumulator adjustment programs giving patients the full benefit of copay assistance (HFA 2021a; HFA 2021b).<sup>34</sup> This suggests a growing recognition within states about the importance of protecting copay assistance.

On the Federal level, policies have been advanced that may make it more difficult for patients to benefit from copay assistance. Specifically, in the 2020 "Notice of Benefits and Payment Parameters" that sets the standards for many of the health insurance plans sold across the country, HHS formally allowed insurers to shift costs onto America's most vulnerable patients through the use of accumulator adjustment programs for any brand-name drug. In addition, at the end of 2020, CMS finalized a rule – set to go into effect in January 2023 – that could make it more difficult for manufacturers to offer copay assistance, by incorporating this assistance into the calculation of Medicaid Best Price in certain circumstances where accumulators are in place.<sup>35</sup>

Copay assistance is a necessary innovation that helps patients to afford and adhere to their medications when plans fail to provide sufficient coverage. Accumulator adjustment and maximizer programs operate to prevent these benefits from being fully realized by patients – with real impacts on patient access and affordability which will lead to worse patient outcomes based on the data presented above. The federal government still has time to modify the NBPP rule and revisit the Medicaid Rule to curtail the use of these accumulator programs and protect

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<sup>31</sup> 54 percent of total drugs in Ross and Kesselheim's (2013) sample had a lower-cost generic alternative within their drug class but these are not bioequivalent generics.

<sup>32</sup> Prior to this change in 2012, Massachusetts banned all copay card use, the last state with such a ban.

<sup>33</sup> They investigated 15 brand drugs with copay cards and 26 without copay cards that faced first-time generic competition a few years before the California law took effect. When comparing generic uptake in these drugs in California and 10 surrounding states in the first year, generic uptake for brand drugs with copay cards increased from 91 to 96 percent in California versus 92 to 97 percent in the surrounding states. Similar results occurred in brand drugs without copay cards.

<sup>34</sup> The following 7 states and Puerto Rico outright ban the use of accumulator programs: Connecticut, Illinois, Louisiana, Oklahoma, Tennessee, Virginia, and West Virginia. The remaining 5 states, Arizona, Arkansas, Georgia, Kentucky, and North Carolina, do not allow accumulator adjustment programs for brand drugs with no generic alternative available.

<sup>35</sup> CMS published their final rule titled "Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements" at the end of December 2020 (CMS 2020b).

continued use of copay assistance. This will lead to improved patient health that benefits the entire healthcare system. Policymakers should be taking steps to protect the availability of copay assistance, not continue to promote policies that put that use in jeopardy.

## **Section 5: Concluding Remarks**

This paper illustrates the full effect of copay assistance programs. These programs increase the affordability of drugs, especially specialty drugs, for patients who otherwise would not be able to afford them. This affordability increases medical adherence as patients choose to fill their prescriptions and continue to refill them because they now can afford to follow their prescribed amount. When patients increase their medical adherence, they improve their health outcomes saving the overall healthcare system money by avoiding worse health outcomes and leading to longer and a higher quality of life.

The full effect of copay assistance programs needs to be considered when debating policy around them. The initial cost exposure for patients continues to rise leading patients to rely on copay assistance programs to lower the out-of-pocket cost burden on patients. Patients have indeed seen a decrease in their out-of-pocket costs due to the continued adoption of copay assistance. This leads to positive health benefits. Programs like accumulator adjustment programs and other policies that aim to get rid of or lower the use of copay assistance do so at the detriment of patients' finances and health. This paper shows the importance of helping all patients afford their medications. Manufacturer sponsored copay assistance programs do not necessarily need to be the only system available to patients, but for now, they are the best option and provide major benefits to patients.

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