PIONEER HEALTH

Out-of-Pocket Pirates:

Pharmacy Benefit Managers (PBMs) and the Confiscation of Out-of-Pocket Assistance Programs

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Introduction

PBMs are diverting billions of dollars intended for patients and using that money to offset their own drug costs as well as to reward shadowy companies who arrange for the confiscation of those funds. While many business practices in healthcare can shock the conscience when they are exposed, the accumulator and maximizer issues stand out, as one group of companies is quite literally pilfering billions from another group of companies that were intended to assist patients in managing their out-of-pocket (OOP) costs.

PBMs are diverting billions of dollars intended for patients and using that money to offset their own drug costs as well as to reward shadowy companies who arrange for the confiscation of those funds.

Historically, drug manufacturers have set up assistance programs to offset the patient's out-of-pocket cost so they will not abandon their drug. That assistance would be applied towards a patient's deductible and out-of-pocket responsibility.

Accumulator programs are a financial mechanism used by PBMs and insurers to draw down additional assistance program dollars and not apply the dollars to a patient's out-of-pocket obligations. When the manufacturer assistance runs out, the patient's out-of-pocket costs kick in. As a result, patients pay more out-of-pocket, drug manufacturers pay more out in assistance, and PBMs and insurers pay less in total.

Maximizer programs are similar but draw down all of the manufacturer's assistance for a particular drug over the course of a year. This reduces the patient's out-of-pocket obligations *for that particular drug*, but it does not eliminate a patient's (sometimes significant) out-of-pocket obligations. A patient's out-of-pocket obligations may simply be pushed to another drug or to the costs of a medical procedure.

The confiscation of these funds causes higher out-of-pocket obligations for the patient, which in turn causes patients to forgo care. Our estimate is that delayed or forgone care in the maximizer population could increase annual healthcare cost by between $1.3 billion and $2.5 billion.

These confiscations have not garnered the kind of media attention they deserve, possibly because the pilfered funds originate with pharmaceutical manufacturers, a sector that gets little media sympathy. On the other hand, the resources are inarguably intended for a noble purpose, to help patients pay for their medicine and help them to meet health plans' growing out-of-pocket cost requirements. A recent American Cancer Society survey of cancer patients and their caregivers pointed out that 83 percent of respondents felt that the manufacturer assistance program enabled "them to get the medication they otherwise couldn't afford."[1]

This is not an obscure policy issue impacting a small universe of patients. According to the Drug Channels Institute, 80 percent of commercial insurance plans offered accumulator programs in their plan design by 2021, while 61 percent offered maximizer programs.[2] For maximizer programs, 45 percent of plans do not simply offer maximizers as an option for employers but implement maximizer programs in the plan's benefit design. There is new data to suggest that this growth has continued unabated. A January 2023 report from Avalere[3] indicates that 83 percent of "commercial market enrollees" belong to health plans that have implemented accumulator programs while 73 percent belong to plans that have implemented maximizer programs.

The goal of this paper is to highlight the plight of patients, particularly those who may find themselves prescribed an expensive drug, who struggle to meet out-of-pocket requirements that are the result of PBM insurance benefit design. We chose to highlight patient out-of-pocket (OOP) costs for three conditions: Multiple Sclerosis (MS), Oncology, and Psoriatic Arthritis. As a recent paper[4] from IQVIA demonstrates, PBM programs that keep OOP costs high for therapies of these three conditions have seen consistent growth from 2019 to 2022.

Understanding How Out-of-Pocket Costs are Impacted by Accumulators and Maximizers

To understand the origins of the maximizer program, one needs to understand that maximizers are the progeny of accumulator programs, a PBM tactic that generated enormous controversy and led to multiple states banning the practice.

What are Out-of-Pocket Costs?

This paper discusses the impact of accumulator and maximizer programs upon patient OOP costs. However, there are different types of OOP costs, so it is important to define how OOP costs generally work.

There are three terms that require definition: annual deductible, coinsurance, and out-of-pocket maximum. The annual deductible is that amount of money a patient must pay for healthcare before the patient's insurance will pay anything. So, if a patient has a $3,000 deductible and the patient's drug costs $3,000, the patient's insurance will pay nothing for the patient's first prescription unless the patient had paid something previously toward their healthcare.

Coinsurance, on the other hand, is a percentage of the cost of a healthcare therapy or service that a patient must pay regardless of whether the patient has met their deductible. So, let's say the patient's deductible has been met and the patient's health plan has a coinsurance amount of 20% for hospital care, and then the patient gets a hospital bill for $10,000. The patient will then owe $2,000 that they must pay themselves even if they have met their deductible.

Finally, most insurance plans have an out-of-pocket maximum. Using the two examples above, if a patient has an out-of-pocket maximum of $5,000, and that patient has already paid their $3,000 deductible and paid a $2,000 hospital bill, then that patient has met their $5,000 out-of-pocket maximum and their insurance company will pay every dime moving forward with no more OOP liability for the patient.

Examining the Current Biopharmaceutical Market Context

Before examining accumulator or maximizer programs, it is important to understand what is happening in the biopharmaceutical marketplace. The new drugs emerging from biopharmaceutical labs are more expensive therapies that treat small niches of the patient population. These new drugs are often classified as "specialty drugs" because they require special handling, or they may be infused or injected. Specialty drugs now make up the majority of biopharmaceutical spending.

The profile of medicines being approved by the Food and Drug Administration is increasingly composed of specialty medicines, many for rare diseases (e.g., orphan drugs), that tend to be more expensive because they treat a smaller universe of patients. During 2020, 58 percent of FDA's approvals were for orphan drugs and that figure was 52 percent for 2021.[5] Policymakers can argue about the pricing practices of pharmaceutical companies and whether, in individual cases, prices for some of these orphan drugs are too high. Sound economic theory, however, would estimate that newly launched orphan drugs for a smaller universe of patients will always be more expensive than small molecule drugs that treat millions.

Specialty medicines are not typically lifestyle drugs for conditions such as hair loss or erectile dysfunction. Specialty drugs treat some of the most serious conditions, such as cancer, rheumatoid arthritis, hemophilia, H.I.V., psoriasis, inflammatory bowel disease and hepatitis C. It is disconcerting that companies that offer health insurance benefits have an increasing bias against these valuable therapies.

With advice from their PBMs, payers have reacted aggressively against this trend toward specialty medicines. In short, have limited patient access over cost concerns. The most common tactic employed by PBMs to deny patients' access to specialty medicines is to increase a patient's out-of-pocket costs. A foreshadowing of this health plan tactic is found in the Medicare Part D

program. It is well understood that health plans and PBMs lobbied successfully for the part D benefit to contain a "specialty tier" where specialty medicines exhibit much larger cost-sharing requirements.

The campaign against specialty medicines by PBMs then bled into insurance benefit designs for commercial insurance products. Patients in these plans found that their out-of-pocket costs for specialty drugs might total thousands of dollars, particularly if patients found themselves in "high deductible" health plans — plans that are increasingly common in the employer-based health insurance market.

For obvious commercial, as well as philanthropic reasons, pharmaceutical manufacturers did not want patients to abandon their specialty prescriptions because of high out-of-pocket costs. Therefore, drug companies began offering assistance to patients that could defray their out-of-pocket costs. These programs made patients' drugs more affordable by contributing drug company funds toward meeting a patient's deductible or coinsurance requirements. This financial assistance to patients came in two forms. First, charitable foundations were formed to provide "out-of-pocket assistance" funds for certain patients based upon financial need. Drug manufacturers also created out-of-pocket assistance programs that were made available to a broader set of patients to help them meet payer out-of-pocket requirements. For the purposes of this paper, "out-of-pocket assistance" refers to these drug manufacturer programs where drug company-provided funds can be used to offset copays, deductibles, and coinsurance obligations.

Using drug company funds to offset OOP requirements was an enormous benefit to patients. If a patient utilized $5,000 in drug company assistance to meet their deductible requirement, for example, out-of-pocket costs for the patient's second or third drug, as well as other medical services such as MRIs or surgeries, would be substantially mitigated at no cost to the patient.

While out-of-pocket assistance programs from drug companies were quite popular with patients, they were very unpopular with health plans and PBMs. A press release from the Pharmaceutical Care Management Association (PCMA), the lobby for PBMs, included criticism of these programs that was typical of health plans: "Drug coupons and out-of-pocket assistance programs undermine employers' ability to use utilization management tools, such as varying copay amounts for different-priced drugs, to reduce drug costs."[6] While technically true, it fails to acknowledge the benefits of these programs for patients. Although the press release does make one unwitting concession: these out-of-pocket assistance programs "increase product uptake among insured patients." In short, with these programs, patients are more likely to receive the drug prescribed by their doctor which, from the PBM perspective, is seen as a concerning thing.

The most common tactic employed by PBMs to deny patients' access to specialty medicines is to increase a patient's out-of-pocket costs.

Accumulator Programs

How do accumulator programs work?

Health plans and PBMs did not tolerate these manufacturer assistance programs for long. To drive down the utilization of specialty drugs, PBMs instituted accumulator programs. Accumulator programs allowed the patients to utilize manufacturer out-of-pocket assistance; however, PBMs don't count the use of that assistance toward the patient's OOP obligations, as it previously had. Here is how the well-respected blog *Drug Channels* describes accumulator programs: "The (drug) manufacturer funds prescriptions until the maximum value of the copayment program is reached. After that point, the patient's out-of-pocket spending then begins counting toward their annual deductible and out-of-pocket maximum. Accumulators reduce the plan's cost by shifting more drug costs to patients and manufacturers."[7]

Case Study: Accumulators

To illustrate, let's explain what would happen to a patient in the real world who was subjected to an accumulator program. For simplicity's sake, let's say that a patient is prescribed a specialty

drug that costs $3,333.33 per month, and the patient is enrolled in a health plan that has a $5000 deductible requirement. Let's also postulate that the patient's drug is sold by a manufacturer who offers $20,000 in out-of-pocket assistance to qualifying patients.

Prior to the implementation of accumulator programs, the out-of-pocket assistance from the manufacturer would count toward the patient's deductible and, sometime in the middle of the second month when $5,000 had been spent on the drug, the patient's deductible would be met, and the patient's insurance would begin paying for the drug. For the manufacturer providing the out-of-pocket assistance, this would mean that the patient would only use $5,000 of the $20,000 available, allowing the unspent $15,000 to be used by other patients or for other purposes.

How would an accumulator program change this scenario? Under accumulator programs, none of the out-of-pocket assistance provided by the drug manufacturer can be used toward the patient's deductible. At $3,333 for the drug, the out-of-pocket assistance from the manufacturer can still offset almost six months of drug costs for the patient since the drug company offers $20,000 in total assistance.

The problem arises in month 7. Since none of the drug company's funding support is permitted by the PBM to offset the patient's deductible requirement, when the patient visits the pharmacy in month seven, they will face a shocking out-of-pocket bill for $3,333 since the $20,000 in manufacturer assistance will have been exhausted in the previous six months.

With out-of-pocket costs totaling $3,333 in month 7, there is substantial academic research to suggest that most patients will abandon their prescriptions at that point. For example, one study from IQVIA concluded that when out-of-pocket drug costs top $500, 60 percent of patients abandon their prescriptions (assuming the deductible hasn't been met through other patient incurred cost).[8]

PBMs are likely familiar with this academic literature and would privately acknowledge that the entire goal of the accumulator programs is to prod patients into abandoning expensive prescriptions, especially for specialty drugs. PBMs emphasize that these tactics are part of their efforts to assist employers in controlling costs.

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However, accumulator programs generated enormous backlash from patients, patient advocates and policy makers. Elected leaders heard swiftly and loudly from patients who had experienced that month seven sticker shock. Why, patients asked, had I been experiencing very little out-of-pocket spending in the first few months of the year, only to be handed a bill I could not pay in month seven?

According to Avalere, as of May 2022, 14 states have banned the use of accumulators by PBMs. These bans impact 10 percent of patients enrolled in commercial health plans, or 14.8 million patients.[9]

While there are 143 million patients enrolled in commercial health plans in the U.S. and PBMs could secure substantial profits by instituting accumulator programs for all these patients, PBMs seem to have decided that the "handwriting is on the wall" and that accumulator programs will not survive the wrath of the public and policy makers.

Case Study: Maximizer Programs

Given this pushback on accumulators, maximizers were introduced. Maximizers share common elements with accumulator programs. First, they seek to draw down every dollar of out-of-pocket assistance available to patients from drug companies. Second, they also do not apply out-of-pocket assistance toward a patient's out-of-pocket obligations for either deductibles or coinsurance.

However, maximizers differ from accumulators by their mitigation of the "month seven problem." Maximizer programs draw down every dime of available patient out-of-pocket assistance and spread that out over 12 months, eliminating any spending for that particular drug. So, for example, if a drug manufacturer offers out-of-pocket assistance capped at $20,000 annually, the

maximizer program would draw down all $20,000 and create a new patient payment level of $1666.66 per month ($20,000 divided by 12 months). Yet, since the payment amount is funded by the drug manufacturer's out-of-pocket assistance program, the patient would pay nothing each month for that particular drug.

Under federal law and regulations, however, the maximizer programs require certain benefit design gymnastics. For example, if a patient's health plan requires out-of-pocket costs of $5,000 due to the deductible, the maximizer program is essentially raising this out-of-pocket requirement to $20,000. In essence, the health plan is avoiding payment for the patient's drug even as $20,000 is being shelled out for the drug by other entities. This means that the maximizer program is, de facto, raising the payment obligation for this drug to $20,000.

Let's walk through the patient experience with a maximizer program. A patient is prescribed an expensive oncology drug for their cancer. The patient has not enrolled in the maximizer program in advance, so she travels to the pharmacy to fill her prescription. At the pharmacy counter, the patient is told that their drug is not covered by their health plan, and she would need to pay thousands of dollars out-of-pocket to fill the prescription.

Then, the pharmacist tells the patient that they can enroll in a program that will provide the drug at little or no out-of-pocket cost. The pharmacist puts the patient on the phone with one of the PBM's partner companies that manages the maximizer program. The opaque company tells the patient that, if they were to enroll in the company's program, they would pay nothing for their drug.

The PBM Express Scripts, for example, partners with Accredo specialty pharmacy to steer patients into their maximizer program, and they partner with SaveonSP to manage their maximizer program. Patients enrolled in a health plan that uses Express Scripts are required to fill their prescriptions at Accredo.

Here is how Express Scripts describes the enrollment process: "If a member has not spoken to SaveonSP and attempts to fill one of the select specialty medications, an Accredo representative will make outreach prior to the processing of the prescription and assist with enrollment into the program by transferring the member to SaveonSP." This is a confusing description as, if a patient is attempting to fill a prescription, how is the outreach made "prior" to "processing the prescription." A simpler way to describe the process would be that the patient is denied the prescription at Accredo, and then told that they must enroll in SaveonSP or face a large out-of-pocket cost for their drug.

Once enrolled in the program, the patient's oncology drug is labeled a "non-essential health benefit," meaning under the Affordable Care Act, that drug is exempt from any of the out-of-pocket costs limits that federal law imposes upon essential health benefits. This means that, even if the patient has satisfied their deductible for the year, the maximizer program can exempt the health plan from paying for the patient's drug and put those costs onto the drug company's out-of-pocket assistance program.

Once the patient's drug has been classified as "non-essential," the patient (or the PBM's partner company on the patient's behalf) can be enrolled in a drug manufacturer's out-of-pocket assistance program that provides funds intended to defray the patient's out-of-pocket costs. Since the drug manufacturer is told that the patient has no insurance coverage for this drug, these patients are generally approved for assistance.

Once approved, the PBM's partner company draws down every dollar from the drug manufacturer's out-of-pocket assistance program over the course of 12 months. As described earlier, if the out-of-pocket assistance maximum is $20,000, the patient's payment obligation is set at $1,666.66 per month, far above the maximum out-of-pocket obligation allowed by the ACA. This out-of-pocket requirement placed upon the patient is likely far higher than the out-of-pocket deductibles and coinsurance contained in their health plan. However, the patient is ultimately required to pay

nothing, as the drug company's out-of-pocket assistance program then meets all of the patient's obligations.

Importantly, as with accumulator programs, none of this $20,000 in spending counts towards the patient's out-of-pocket obligations in their health plan, so the patient will still be on the hook for out-of-pocket spending if they are prescribed a second or third drug, or if they require other medical services such as an MRI, a surgery, or a physician visit. While the accumulator programs create a problem for the patient in "month seven," patients in a maximizer program could be hit with sticker shock for OOP obligations at any time of the year when they try to access any other medical therapy or service besides the drug in the maximizer program.

In summary, here is how the *Drug Channels* blog describes the maximizer program: "The maximum value of the manufacturer's out-of-pocket assistance program is applied evenly throughout the benefit year. The patient's out-of-pocket obligations aren't based on the list or net price of the drug—but are instead set to equal the maximum value of a manufacturer's OOP assistance program. To avoid these extraordinary costs, the beneficiaries must enroll in a separate maximizer program. To implement a maximizer, plans will deem many specialty drugs "non-essential health benefits." Non-essential drugs are still covered by the plan, but they are not subject to the Affordable Care Act (ACA) Essential Health Benefit requirements and can be removed from the out-of-pocket maximums required by the ACA."[10]

The "Gray Areas" of Maximizer Programs

While the mechanics of most maximizer programs are opaque, Express Scripts' maximizer partner, SaveOnSP, has a video circulating on the Internet explaining to employers how their program works.[11]

Speakers in the video point out that there are a number of "gray areas" for maximizer programs that may raise "compliance" issues. And that employers who embrace maximizer programs must have an "appetite for risk." In short, the speakers seem to be implying that there may be aspects of maximizer programs that could be illegal.

Here is list of the potential gray areas:

1. Are false statements being made during the enrollment process? For patients who do not pre-enroll in the maximizer program, they may have the experience of arriving at the pharmacy counter and being told that their drug is not covered. As the SaveOnSP video explains, the prescription is "rejected" by the pharmacy. The question must be asked: are patients being told the truth? Are there cases in which the patients are told that their health plan does not cover a drug when indeed it does? Yet patients may be told the drug is not covered because that particular drug comes with generous OOP assistance, revenue that SaveOnSP and Express Scripts wishes to capture by making a false statement to the patient.

2. Is SaveOnSP running a health plan? After all, the maximizer program has a formulary and a benefit design. It insures patients against health care costs that may arise from healthcare therapies. If maximizer programs are indeed health plans, then they may be violating many federal rules on essential health benefits, out-of-pocket limits and other rules governing health plans. Would federal or state regulators approve a health plan's formulary that is completely based upon which drugs come with the most "lucrative" out-of-pocket assistance program, as some maximizer programs do? Would federal and state regulators allow a health plan to "manage a patient out" of the health plan if out-of-pocket assistance were no longer available, as SaveOnSP claims to do?

3. Is SaveOnSP violating the contract between patient and drug manufacturer? When a patient applies for out-of-pocket assistance from a drug company, typically the agreement is that the company's funds will be provided to *the patient*. Yet under maximizer programs, funds from

the manufacturers are not provided to the patient but are captured by the PBM to offset the health plan's drug costs. Moreover, in the case of SaveOnSP, their video makes clear that a full 25 percent of the drug manufacturer's out-of-pocket assistance funds are diverted to SaveOnSP as a "fee" for their services. Is it legal for maximizer companies to pocket these funds?

4. Are patients fully informed about the implications of maximizers for their out-of-pocket obligations? One can understand why patients enroll in maximizer programs. They are told that they can avoid huge out-of-pocket spending for their drug and obtain their prescription for free. Yet what may not be clear to patients is that their deductible, coinsurance, and other out-of-pocket obligations are simply being applied to their use of other healthcare services. For example, since none of the out-of-pocket assistance used up by the maximizer program applies to the patient's deductible, a patient with a $5,000 deductible, who then undergoes elective surgery, may face a $5,000 bill upon their recovery. Are patients made aware of the shifting of their OOP obligations when they enroll in a maximizer program? Most importantly, when OOP costs are pushed to the patient's other drugs or medical services, do patients forgo needed medical care? The third and fourth sections of this paper seek to answer that question.

Out-of-pocket assistance programs offered by manufacturers may indeed allow drug companies to retain market share for their products. However, patient surveys indicate that these programs are also invaluable in allowing patients to afford drugs. Because accumulator programs, and especially maximizer programs, draw down every dollar of funds, drug companies are seeing exponential growth in their out-of-pocket assistance program budgets. Patient advocates must ask if the draw down of these funds by PBMs might lead to substantial reductions in the amount of financial assistance drug companies provide to patients.

Out-of-Pocket Assistance is Threatened by Accumulators and Maximizers

Manufacturer out-of-pocket assistance programs have two goals that are different but not conflicting. First, and most importantly, out-of-pocket assistance programs help patients access drugs they otherwise may not be able to afford. There is considerable academic research to suggest that when patients face out-of-pocket costs above $500, the majority of patients abandon their prescription.[12] Yet, it is also obvious that manufacturer assistance programs have a second goal: allowing manufacturers to sell more medicine. Since these programs lessen patient out-of-pocket costs, patients are less likely to abandon that prescription and manufacturers are more likely to secure a sale. However, the goals of patients and those of manufacturers are not in conflict. In fact, they are compatible. (Although, the authors of this study agree that it is not appropriate to offer out-of-pocket assistance for a branded drug when there is a generic equivalent available. Most out-of-pocket assistance programs help patients afford drugs with no generic equivalent.)

Manufacturer out-of-pocket assistance programs have two goals that are different but not conflicting. First, and most importantly, out-of-pocket assistance programs help patients access drugs they otherwise may not be able to afford.

While most manufacturers keep their spending on out-of-pocket assistance programs confidential, there is evidence to suggest that accumulator and maximizer programs are making out-of-pocket assistance less financially attractive to manufacturers. This is because accumulator and maximizer programs can draw down all the funds available in an out-of-pocket assistance program. For example, a patient in a traditional out-of-pocket assistance program who is also enrolled in a high deductible health plan can draw down only $5,000 or so in manufacturer assistance when $20,000 may be available. This patient need not draw down the full amount available as, once they meet their deductible and coinsurance, the health plan begins paying for their drug.

However, in the case of an accumulator or maximizer program, the PBM may draw down the entire amount of funds available from the manufacturer. While in the traditional out-of-pocket

assistance program, the manufacturer will only have liability until out-of-pocket obligations are met, accumulators and maximizers draw down the entire balance of out-of-pocket assistance. So, in the above example, manufacturer financial liability rises from $5,000 to $20,000 once a patient is enrolled in an accumulator or maximizer program.

Since overall manufacturer spending on out-of-pocket assistance programs is confidential, we cannot measure the overall increase in manufacturers' budgets for these programs. However, anecdotal evidence suggests it is significant.

In May, Johnson & Johnson (J&J) filed suit against SaveOnSP, a company that contracts with Express Scripts, a large PBM, to manage their maximizer program. In their complaint, J & J says that SaveOnSP's program has increased their out-of-pocket assistance liability by $100 million.[13] The complaint further alleges that the average amount of out-of-pocket assistance provided for their immunosuppressive drug, STELARA, rose from $1,171 for patients not enrolled in SaveOnSP's programs to $4,301 for those who were enrolled. J&J pointed to numerous other drugs that had seen out-of-pocket assistance liability skyrocket with the advent of accumulators and maximizers.[14]

Johnson & Johnson is one of the largest pharmaceutical companies, with drug revenues of $52 billion in 2021.[15] But this $52 billion is only a fraction of the overall revenues of the industry. So if J&J's out-of-pocket assistance liability rose by $100 million, one can surmise that accumulators and maximizers are costing the overall industry billions of dollars.

This gives rise to an important question: will manufacturer out-of-pocket assistance programs be ended or significantly reduced? After all, with accumulators and maximizers, for-profit PBMs are confiscating all the manufacturer revenue while patients are still saddled with high deductibles and coinsurance amounts for their overall healthcare. Why would manufacturers continue the programs?

Our models, later in the paper, suggest that manufacturers would not need to abandon these programs altogether, as this would create the appearance that they were abandoning patients. If manufacturers were to simply make their programs less generous, e.g. pegged to the individual patient's out-of-pocket obligations, suddenly these programs would become less financially attractive to PBMs. For example, if a patient's out-of-pocket obligations — deductible and coinsurance — were $5,000, a manufacturer might reduce its out-of-pocket assistance cap from $20,000 to $5,000 for that patient, reducing PBM revenue for that patient by $15,000. In many cases, reductions of this magnitude would make accumulator and maximizer programs unprofitable for PBMs.

There is some evidence that this is already happening. Vertex recently reduced the amount of out-of-pocket assistance available for its cystic fibrosis treatments from $100,000 to $20,000, an 80 percent reduction.[16]

We are not suggesting that manufacturers make their out-of-pocket assistance programs less generous. However, our analysis suggests that, given the rising abuse of these programs by PBMs, the financial realities make less generous out-of-pocket assistance programs more likely in the future. We explain later in the paper how reductions in the manufacturer's out-of-pocket assistance cap makes these programs unprofitable for PBMs.

The Costs of Accumulators and Maximizers: Examples

(Authors' note: In the financial models used below, payer financial liabilities are certainly overestimated as rebate and fee payments are proprietary, so we cannot know the levels of discounts provided to PBMs and health plans.)

Working through the implications based on actual cost data and the average benefit design for an ACA-compliant plan demonstrates the consequences of implementing accumulator and

maximizer programs. These programs enable payers and PBMs to expropriate the resources that manufacturers dedicate to out-of-pocket assistance programs to the detriment of manufacturers and patients. We demonstrate these outcomes using three conditions, starting with a psoriatic arthritis patient. For the record, we chose these conditions because we were able to find reliable, up-to-date data on the medical and drug costs for patients with these conditions, and because there is evidence that these therapeutic areas continue to display PBM accumulator and maximizer programs.

According to Maksabedian Hernandez et al. (2020), the per patient per month costs for a psoriatic arthritis patient prescribed Adalimumab (a standard biologic treatment) is $4,811, comprised of $3,947 in outpatient pharmacy costs and $864 in medical costs.[17] These monthly figures equate to total annual pharmaceutical costs of $47,364 and medical expenses of $10,368 for a grand total of $57,732.

When evaluating the impact of a maximizer program, it is crucial to account for the $10,368 in medical costs in addition to the $47,364 in pharmaceutical costs due to the widespread use of a combined deductible that merges the OOP obligations of pharmacy and medical spending. According to the Kaiser Family Foundation (KFF), 83 percent of silver plans in 2022 (the most popular ACA plan choice) have a combined deductible.[18] Accounting for the medical costs demonstrates how the maximizer plans do not provide the assumed patient cost benefits.

Before reviewing the calculations, it is essential to note that while this analysis proceeds by evaluating the medical cost implications, a similar logic holds for other expenses. For instance, according to Haddad and Zisman (2017)

> *"studies have shown that patients with psoriatic disease suffer also from associated comorbidities, including cardiovascular disease, obesity and metabolic syndrome, diabetes, osteoporosis, malignancy, fatty liver disease, depression, and anxiety."*[19]

Managing these other diseases requires additional spending on pharmaceuticals and medical services that will similarly eliminate the patient savings the maximizer program allegedly creates. Therefore, the logic of the analysis performed below also applies to these other medical and pharmaceutical costs.

Based on the KFF's evaluation of the benefit design,[20] ACA silver insurance plan deductibles, co-insurance, and out-of-pocket maximum used for this evaluation are summarized in Table 1. According to KFF, the average combined deductible (or the amount a person must cover before insurance coverage begins) for a silver plan in 2022 is $4,753; the average out-of-pocket maximum is $6,436; the average specialty drug coinsurance rate (the share of the drug costs covered by the patient) is 34 percent; and the average specialty doctor coinsurance rate is 24 percent.

Table 1 Insurance Benefit Design: Average ACA Silver Plan

General annual deductible	$4,753
Out-of-pocket maximum	$6,436
Specialty drug coinsurance	34%
Specialty doctor coinsurance	24%

Assuming a psoriatic arthritis patient requires Xeljanz throughout the entire year beginning in January, then the benefit design described in Table 1 would require the outlays from patients and insurers, as summarized in Table 2.[21]

Table 2 Annual Cost Breakdown for Typical Psoriatic Arthritis Patient Based on Average ACA Silver Plan Benefit Design

	Drug Cost	Patient Deductible Payment	Patient Coinsurance	Total Patient Payment	Payer Payment
January	$3,947	$3,947	$-	$3,947	$-
February	$3,947	$806	$1,068	$1,874	$2,073
March	$3,947	$-	$615	$615	$3,332
April	$3,947	$-	$-	$-	$3,947
May	$3,947	$-	$-	$-	$3,947
June	$3,947	$-	$-	$-	$3,947
July	$3,947	$-	$-	$-	$3,947
August	$3,947	$-	$-	$-	$3,947
September	$3,947	$-	$-	$-	$3,947
October	$3,947	$-	$-	$-	$3,947
November	$3,947	$-	$-	$-	$3,947
December	$3,947	$-	$-	$-	$3,947
Full Year	**$47,364**	**$4,753**	**$1,683**	**$6,436**	**$40,928**
Total Patient Payment	**$6,436**				
Total Payer Payment	**$40,928**				

(numbers may not add due to rounding)

Table 2 illustrates that, based on the average benefit design of a silver plan, patients with $3,947 in monthly outpatient psoriatic arthritis drug costs will meet their annual deductible in a bit more than one month. Since the patients' deductible is met during the second month, the drug's costs are then split between the patients' co-insurance costs and payer costs up to the patients' out-of-pocket maximum. Once this maximum is met, which happens in March, payers are responsible for covering all remaining costs. In total, given the drug costs and benefit design, patients will spend their out-of-pocket maximum for the year ($6,436) and payers will pay $40,928.

Maximizer programs do not, on net, reduce patient costs.

This point is pivotal concerning the impact of the maximizer program. Since patients reach their out-of-pocket maximum paying for their psoriatic arthritis drugs, they are not responsible for any other healthcare expenditures. Since psoriatic arthritis patients incur many other healthcare expenditures, maximizer programs simply switch where the patients spend their money as the following calculations demonstrate. Maximizer programs do not, on net, reduce patient costs. This outcome starkly contrasts with the impact of manufacturer out-of-pocket assistance.

As described earlier in this paper, the manufacturer's out-of-pocket assistance aims to help alleviate the $6,436 cost that patients must cover. Typical manufacturer out-of-pocket assistance has a maximum value of around $15,000,[22] but most assistance does not require patients to receive the full value. For instance, under the benefit designs described in Table 1, out-of-pocket assistance only needs to cover $6,436 (see Table 3).

Table 3 demonstrates the value of out-of-pocket assistance which transfers patients' drug costs to the manufacturer, freeing them of these obligations. Importantly with respect to psoriatic arthritis, these costs are typically high enough to fulfill their out-of-pocket maximums, so patients' out-of-pocket burdens on all other medical expenditures have similarly been eliminated.

Table 3 Annual Cost Breakdown for Typical Psoriatic Arthritis Patient Based on Average ACA Silver Plan Benefit Design with Out-of-pocket Assistance

	Drug Cost	Out-of-pocket Assistance	Patient Deductible Payment	Patient Coinsurance	Total Patient Payment	Payer Payment
January	$3,947	$3,947	$-	$-	$-	$-
February	$3,947	$1,874	$-	$-	$-	$2,073
March	$3,947	$615	$-	$-	$-	$3,332
April	$3,947		$-	$-	$-	$3,947
May	$3,947		$-	$-	$-	$3,947
June	$3,947		$-	$-	$-	$3,947
July	$3,947		$-	$-	$-	$3,947
August	$3,947		$-	$-	$-	$3,947
September	$3,947		$-	$-	$-	$3,947
October	$3,947		$-	$-	$-	$3,947
November	$3,947		$-	$-	$-	$3,947
December	$3,947		$-	$-	$-	$3,947
Full Year	**$47,364**	**$6,436**	**$-**	**$-**	**$-**	**$40,928**
Total Patient Payment	**$-**					
Out-of-pocket Assistance Program	**$6,436**					
Total Payer Payment	**$40,928**					

(numbers may not add due to rounding)

Patients and policymakers resist co-pay accumulators because they undermine these patient benefits. Table 4 details how accumulators work under the assumption that the entire value of manufacturer out-of-pocket assistance is tapped prior to any patient payment obligations—it is a best-case scenario for the patient and is directly comparable to how the maximizer programs work. Column 3 in Table 3 tracks the expenditures of typical out-of-pocket assistance. Thanks to the accumulator program, none of the out-of-pocket assistance expenditures are credited to the patient to meet their annual deductibles or coinsurance obligations. Therefore, when the support runs out, in this case during April, patients must start paying their deductibles and then, beginning in June and through July, their required coinsurance costs. Patients' payment obligations are met only when the out-of-pocket maximum is fulfilled in July.

Table 4 demonstrates the value of accumulator programs to payers. Since the $15,000 in out-of-pocket assistance does not count toward patients' deductibles or coinsurance, patients must also spend $6,436 when accumulator programs are in effect. The net effect is to reduce payers' costs from $40,928 previously to just $25,928. Table 4 also demonstrates that accumulators transfer benefits meant for patients to payers, which is consistent with the strong push-back these programs have received.

Enter maximizer programs, see Table 5.

Table 4 Annual Cost Breakdown for Typical Psoriatic Arthritis Patient with an Accumulator Program Based on Average ACA Silver Plan Benefit Design and $15,000 Total Out-of-pocket Assistance Value

	Drug Cost	OOP assistance	Patient Deductible Payment	Patient Coinsurance	Total Patient Payment	Payer Payment
January	$3,947	$3,947	$-	$-	$-	$-
February	$3,947	$3,947	$-	$-	$-	$-
March	$3,947	$3,947	$-	$-	$-	$-
April	$3,947	$3,159	$788	$-	$788	$-
May	$3,947	$-	$3,947	$-	$3,947	$-
June	$3,947	$-	$18	$1,336	$1,354	$2,593
July	$3,947	$-	$-	$347	$347	$3,600
August	$3,947	$-	$-	$-	$-	$3,947
September	$3,947	$-	$-	$-	$-	$3,947
October	$3,947	$-	$-	$-	$-	$3,947
November	$3,947	$-	$-	$-	$-	$3,947
December	$3,947	$-	$-	$-	$-	$3,947
Full Year	**$47,364**	**$15,000**	**$4,753**	**$1,683**	**$6,436**	**$25,928**
Total Patient Payment	**$6,436**					
Total Out-of-pocket Assistance Program	**$15,000**					
Total Payer Payment	**$25,928**					

(numbers may not add due to rounding)

Table 5 Annual Cost Breakdown for Typical Psoriatic Arthritis Patient for a Maximizer Program Based on Average ACA Silver Plan Benefit Design and $15,000 Total Out-of-pocket Assistance Value

	Drug Cost	Maximizer Program	Payer Payment
January	$3,947	$1,250	$2,697
February	$3,947	$1,250	$2,697
March	$3,947	$1,250	$2,697
April	$3,947	$1,250	$2,697
May	$3,947	$1,250	$2,697
June	$3,947	$1,250	$2,697
July	$3,947	$1,250	$2,697
August	$3,947	$1,250	$2,697
September	$3,947	$1,250	$2,697
October	$3,947	$1,250	$2,697
November	$3,947	$1,250	$2,697
December	$3,947	$1,250	$2,697
Full Year	**$47,364**	**$15,000**	**$32,364**
Total Patient Payment	**$-**		
Total Out-of-pocket Assistance Program	**$15,000**		
Total Payer Payment	**$32,364**		

(numbers may not add due to rounding)

Table 5 demonstrates how a typical maximizer program works based on the earlier description. Column 3 in Table 5 assumes that the maximum value for the out-of-pocket assistance program is $15,000 per patient. This assumption is critical. Based on this assumption, the maximizer program would essentially cover $1,250 of psoriatic arthritis patients' monthly costs, with the payer covering the remaining $2,697. Consequently, the program "maximizes" the extraction from manufacturer out-of-pocket assistance programs. The manufacturer assistance, by definition, covers $15,000 of the drug's costs, and the payer is only responsible for $32,364.

Manufacturers can upend the financial viability of the maximizer programs by limiting the maximum value of their assistance. As stated earlier, the assumed maximum value of the program is critical. For instance, under the same financial assumptions, assistance with a $6,436 maximum value would increase the payers' costs to $40,928, or the same costs as would have occurred under a scenario of out-of-pocket assistance without any maximizers or accumulators. As Table 6 demonstrates, limiting the out-of-pocket assistance to a lower $3,000 value would cause payers to lose money from implementing a maximizer program. Under a $3,000 out-of-pocket assistance limit, payers would be required to cover $44,364 in drug costs, which is higher than the costs associated with out-of-pocket assistance without an accumulator or maximizer program in effect ($40,928) as in Table 2 or 3.

Table 6 Annual Cost Breakdown for a Maximizer Program for Typical Psoriatic Arthritis Patient Based on Average ACA Silver Plan Benefit Design and $3,000 Total Out-of-pocket Assistance Value

	Drug Cost	Maximizer Program	Payer Payment
January	$3,947	$250	$3,697
February	$3,947	$250	$3,697
March	$3,947	$250	$3,697
April	$3,947	$250	$3,697
May	$3,947	$250	$3,697
June	$3,947	$250	$3,697
July	$3,947	$250	$3,697
August	$3,947	$250	$3,697
September	$3,947	$250	$3,697
October	$3,947	$250	$3,697
November	$3,947	$250	$3,697
December	$3,947	$250	$3,697
Full Year	**$47,364**	**$3,000**	**$44,364**
Total Patient Payment	**$-**		
Total PA Payment	**$3,000**		
Total Payer Payment	**$44,364**		

(numbers may not add due to rounding)

Beyond the incentives to limit the generosity of out-of-pocket assistance, which can reduce the benefits patients receive, maximizer programs do not reduce patients' overall healthcare costs once other medical care costs are considered.

Patients with rheumatoid arthritis require other medical care that costs, on average, $864 a month, or $10,368 annually. Patients receiving manufacturer out-of-pocket assistance without an accumulator or maximizer program have met their out-of-pocket maximums and are not required to cover any of these costs, which are fully covered by their payers. Even patients with accumulator

programs will not face additional costs because the out-of-pocket maximums have been met. However, patients subject to maximizer programs still must pay their deductibles and coinsurance costs associated with these other healthcare services up to their out-of-pocket maximums. Table 7 applies the benefit design from the average silver plan described in Table 1 to these costs.

It is important to note that, unlike monthly drug costs, patients may incur their medical expenses in an irregular pattern. Further, the costs associated with healthcare visits to receive an MRI will be more expensive than a consultation with a physician. However, while the allocation of patients' expenditures will change, the total costs will be similar. Consequently, an average monthly expense is estimated for simplicity of presentation.

Table 7 — Annual Medical Cost Breakdown for Psoriatic Arthritis Patient Subject to a Maximizer Program and Benefit Design Based on Average ACA Silver Plan

	Medical Costs	Patient Deductible Payment	Patient Coinsurance	Total Patient Payment	Payer Payment
January	$864	$864	$-	$864	$-
February	$864	$864	$-	$864	$-
March	$864	$864	$-	$864	$-
April	$864	$864	$-	$864	$-
May	$864	$864	$-	$864	$-
June	$864	$433	$103	$536	$328
July	$864	$-	$207	$207	$657
August	$864	$-	$207	$207	$657
September	$864	$-	$207	$207	$657
October	$864	$-	$207	$207	$657
November	$864	$-	$207	$207	$657
December	$864	$-	$207	$207	$657
Full Year	**$10,368**	**$4,753**	**$1,348**	**$6,101**	**$4,267**
Total Patient Payment	**$6,101**				
Total Payer Payment	**$4,267**				

(numbers may not add due to rounding)

Table 7 demonstrates that the maximizer program does not eliminate patients' costs; it simply shifts the costs to other areas. In the case of psoriatic arthritis, patients must pay their deductibles and coinsurance costs associated with their medical costs throughout the entire year when a maximizer program is applied to their medicine, which they would not otherwise have to pay. For many other disease areas, the costs will hit the out-of-pocket maximum. In the case of psoriatic arthritis, the average medical costs of $6,101 are essentially the maximum out-of-pocket costs of $6,436.

For ease of comparison, Table 8 summarizes the expenditures of patients, manufacturer out-of-pocket assistance, and payers under the four alternative scenarios — without any assistance, with a typical out-of-pocket assistance, with a payer accumulator program in place, and with a payer maximizer program in place. Several trends are evident,

- Out-of-pocket assistance without payers imposing accumulators or maximizers is the only option that eliminates patients' out-of-pocket costs
- Accumulator programs are a means for payers to transfer resources from manufacturers to payers without helping patients
- Maximizer programs create the appearance of patient savings when only the costs of drugs for

the relevant condition — in this case, psoriatic arthritis — are considered; the apparent savings disappear once the broader healthcare landscape is considered.

Table 8 Summary of Expenditures by Patient, Out-of-pocket Assistance and Payer Typical Psoriatic Arthritis Drug and Medical Costs

	Results Summary for Drug Costs for Treating Psoriatic Arthritis Alone			
	No Out-of-pocket assistance Program	Out-of-pocket Assistance Program	Accumulator Program	Maximizer Program
Total Patient Payment	$6,436	$-	$6,436	$-
Total Out-of-pocket assistance Payment	$-	$6,436	$15,000	$15,000
Total Insurer/Payer Payment	$40,928	$40,928	$25,928	$32,364
	Results Summary for Medical Costs for Treating Psoriatic Arthritis Alone			
Total Patient Payment	$-	$-	$-	$6,101
Total Out-of-pocket assistance Payment	$-	$-	$-	$-
Total Insurer/Payer Payment	$10,368	$10,368	$10,368	$4,267
	Results Summary for Drug & Medical Costs for Treating Psoriatic Arthritis Alone			
Total Patient Payment	$6,436	$-	$6,436	$6,101
Total Out-of-pocket assistance Payment	$-	$6,436	$15,000	$15,000
Total Insurer/Payer Payment	$51,296	$51,296	$36,296	$36,631

(numbers may not add due to rounding)

Multiple Sclerosis

As a second example the following tables estimate the cost breakdowns for patients living with Multiple Sclerosis (MS) under the same scenarios. According to Bebo et. al. (2022), the per person direct medical costs for a person living with MS were $65,612 including $35,154 for disease-modifying therapies (DMT), $4,143 in other prescriptions, and $26,315 for other medical services.[23]

MS provides an important comparison to the psoriatic arthritis example because while the main therapy is less expensive, there are higher expenses for other drugs and medical services. The following series of tables demonstrates that the accumulator and maximizer programs still leave MS patients exposed to the out-of-pocket costs for the other drugs patients must take and their required medical services. Consequently, patients will still reach their out-of-pocket maximum even when a maximizer program appears to alleviate these costs for their DMT drugs.

Table 9 applies the benefit design summarized in Table 1 to the annual costs of the DMT modifying therapy of $35,154 without any out-of-pocket assistance, accumulators, or maximizers.

Table 9 illustrates that, based on the average benefit design of a silver plan, patients with $2,930 in monthly outpatient DMT drug costs will meet their annual deductible in just under two months. Since the patients' deductible is met during the second month, the drug's costs are then split between the patients' coinsurance costs and payer costs up to the patients' out-of-pocket maximum. Once this maximum is met, which happens in April, payers are responsible for covering all remaining costs. In total, given the drug costs and benefit design, patients will spend their out-of-pocket maximum for the year ($6,436) and payers will pay $28,718.

Table 9 Annual Cost Breakdown for DMT Therapy for Typical MS Patient Based on Average ACA Silver Plan Benefit Design

	Drug Cost	Patient Deductible Payment	Patient Coinsurance	Total Patient Payment	Payer Payment
January	$2,930	$2,930	$-	$2,930	$-
February	$2,930	$1,824	$376	$2,200	$730
March	$2,930	$-	$996	$996	$1,933
April	$2,930	$-	$311	$311	$2,619
May	$2,930	$-	$-	$-	$2,930
June	$2,930	$-	$-	$-	$2,930
July	$2,930	$-	$-	$-	$2,930
August	$2,930	$-	$-	$-	$2,930
September	$2,930	$-	$-	$-	$2,930
October	$2,930	$-	$-	$-	$2,930
November	$2,930	$-	$-	$-	$2,930
December	$2,930	$-	$-	$-	$2,930
Full Year	**$35,154**	**$4,753**	**$1,683**	**$6,436**	**$28,718**
Total Patient Payment	**$6,436**				
Total Payer Payment	**$28,718**				

(numbers may not add due to rounding)

If manufacturer's out-of-pocket assistance was provided, then, just as in the case of psoriatic arthritis patients, the $6,436 out-of-pocket maximum is covered by the out-of-pocket assistance program. Table 10 demonstrates this value to patients.

Table 11 demonstrates that accumulators have the same negative impact on MS patients as they do for patients living with psoriatic arthritis. The accumulator program prevents any expenditures from the out-of-pocket assistance to be credited toward patients' annual deductibles or coinsurance obligations. When the out-of-pocket assistance support runs out, in this case during June, patients must start paying their deductibles and then, beginning in July through September, their required coinsurance costs. Patients' payment obligations are met only when the out-of-pocket maximum is fulfilled in September. Therefore, the accumulator program only changes when MS patients must pay their out-of-pocket expenditures, not the total amount of expenditures. Payers benefit, however, by transferring the value of the assistance programs toward their own cost obligations, which are reduced to $13,718.

Table 10 Annual Cost Breakdown for DMT Therapy for MS Patient Based on Average ACA Silver Plan Benefit Design with Out-of-pocket Assistance Program

	Drug Cost	Out-of-pocket Assistance	Patient Deductible Payment	Patient Coinsurance	Payer Payment
January	$2,930	$2,930	$-	$-	$-
February	$2,930	$2,200	$-	$-	$730
March	$2,930	$996	$-	$-	$1,933
April	$2,930	$311	$-	$-	$2,619
May	$2,930	$-	$-	$-	$2,930
June	$2,930	$-	$-	$-	$2,930
July	$2,930	$-	$-	$-	$2,930

August	$2,930	$-	$-	$-	$2,930
September	$2,930	$-	$-	$-	$2,930
October	$2,930	$-	$-	$-	$2,930
November	$2,930	$-	$-	$-	$2,930
December	$2,930	$-	$-	$-	$2,930
Full Year	**$35,154**	**$6,436**	**$-**	**$-**	**$28,718**
Total Patient Payment	**$0**				
Total Out-of-pocket Assistance	**$6,436**				
Total Payer Payment	**$28,718**				

(numbers may not add due to rounding)

Table 11 Annual Cost Breakdown for DMT Therapy for MS Patient with an Accumulator Program Based on Average ACA Silver Plan Benefit Design and $15,000 Total Out-of-pocket Assistance Program Value

	Drug Cost	OOP assistance	Patient Deductible Payment	Patient Coinsurance	Total Patient Payment	Payer Payment
January	$2,930	$2,930	$-	$-	$-	$-
February	$2,930	$2,930	$-	$-	$-	$-
March	$2,930	$2,930	$-	$-	$-	$-
April	$2,930	$2,930	$-	$-	$-	$-
May	$2,930	$2,930	$-	$-	$-	$-
June	$2,930	$353	$2,577	$-	$2,577	$-
July	$2,930	$-	$2,176	$256	$2,432	$497
August	$2,930	$-	$-	$996	$996	$1,933
September	$2,930	$-	$-	$431	$431	$2,499
October	$2,930	$-	$-	$-	$-	$2,930
November	$2,930	$-	$-	$-	$-	$2,930
December	$2,930	$-	$-	$-	$-	$2,930
Full Year	**$35,154**	**$15,000**	**$4,753**	**$1,683**	**$6,436**	**$13,718**
Total Patient Payment	**$6,436**					
Total Out-of-pocket Assistance	**$15,000**					
Total Insurer Payment	**$13,718**					

(numbers may not add due to rounding)

Just as with the psoriatic arthritis patients, the maximizer programs — a response to the negative feedback from patients regarding the accumulator programs — allow patients to not pay any out-of-pocket expenditures on their DMT drugs at the expense of slightly higher costs for payers relative to the accumulator programs, see Table 12.

Table 12 Annual Cost Breakdown for DMT Therapy for MS Patient for a Maximizer Program Based on Average ACA Silver Plan Benefit Design and $15,000 Total Out-of-pocket Assistance Program Value

	Drug Cost	Maximizer Program	Payer Payment
January	$2,930	$1,250	$1,680
February	$2,930	$1,250	$1,680
March	$2,930	$1,250	$1,680
April	$2,930	$1,250	$1,680
May	$2,930	$1,250	$1,680
June	$2,930	$1,250	$1,680
July	$2,930	$1,250	$1,680
August	$2,930	$1,250	$1,680
September	$2,930	$1,250	$1,680
October	$2,930	$1,250	$1,680
November	$2,930	$1,250	$1,680
December	$2,930	$1,250	$1,680
Full Year	**$35,154**	**$15,000**	**$20,154**
Total Patient Payment	**$-**		
Total Out-of-pocket Assistance	**$15,000**		
Total Payer Payment	**$20,154**		

(numbers may not add due to rounding)

As with the previous example, the out-of-pocket assistance program, by definition, covers $15,000 of the drug's costs, and the payer is responsible for $20,154—more than with an accumulator program but less than without an accumulator.

As demonstrated earlier, the assumed maximum value of the out-of-pocket assistance is critical and lowering that assistance to $3,000 would cause payers to lose money from implementing a maximizer program. Under a $3,000 limit, payers would be required to cover $32,154 in drug costs, which is higher than the costs associated with an out-of-pocket assistance program without an accumulator or maximizer program in effect ($28,718).

Table 13 Annual Cost Breakdown for DMT Therapy for MS Patient for a Maximizer Program Based on Average ACA Silver Plan Benefit Design and $3,000 Total Out-of-pocket Assistance Program Value

	Drug Cost	Maximizer Program	Payer Payment
January	$2,930	$250	$2,680
February	$2,930	$250	$2,680
March	$2,930	$250	$2,680
April	$2,930	$250	$2,680
May	$2,930	$250	$2,680
June	$2,930	$250	$2,680
July	$2,930	$250	$2,680
August	$2,930	$250	$2,680
September	$2,930	$250	$2,680
October	$2,930	$250	$2,680
November	$2,930	$250	$2,680
December	$2,930	$250	$2,680
Full Year	**$35,154**	**$3,000**	**$32,154**
Total Patient Payment	**$-**		
Total Out-of-pocket Assistance	**$3,000**		
Total Payer Payment	**$32,154**		

(numbers may not add due to rounding)

The problem of maximizers shifting patients' out-of-pocket costs to other medical care services is just as applicable to MS patients as it is for psoriatic arthritis patients.

The problem of maximizers shifting patients' out-of-pocket costs to other medical care services is just as applicable to MS patients as it is for psoriatic arthritis patients. Patients living with MS require other medical care that costs, on average, $2,193 a month or $26,315 annually. There are also the non-DMT pharmaceuticals that total, on average, $4,143 annually. Patients subject to maximizer programs must pay their deductibles and coinsurance costs for these other healthcare services up to their out-of-pocket maximums. Table 14 applies the benefit design from the average silver plan described in Table 1 to just the medical costs, assuming a constant expenditure pattern, demonstrating that a maximizer program applied to MS DMT medicines does not prevent patients from hitting their out-of-pocket maximums.

Table 14 - Annual Medical Cost Breakdown for MS Patient Subject to a Maximizer Program and Benefit Design Based on Average ACA Silver Plan

	Medical Costs	Patient Deductible Payment	Patient Coinsurance	Total Patient Payment	Payer Payment
January	$2,193	$2,193	$-	$2,193	$-
February	$2,193	$2,193	$-	$2,193	$-
March	$2,193	$367	$438	$805	$1,388
April	$2,193	$-	$526	$526	$1,667
May	$2,193	$-	$526	$526	$1,667
June	$2,193	$-	$192	$192	$2,001
July	$2,193	$-	$-	$-	$2,193
August	$2,193	$-	$-	$-	$2,193
September	$2,193	$-	$-	$-	$2,193
October	$2,193	$-	$-	$-	$2,193
November	$2,193	$-	$-	$-	$2,193
December	$2,193	$-	$-	$-	$2,193
Full Year	**$26,315**	**$4,753**	**$1,683**	**$6,436**	**$19,879**
Total Patient Payment	**$6,436**				
Total Out-of-pocket Assistance	**$-**				
Total Payer Payment	**$19,879**				

(numbers may not add due to rounding)

When a maximizer program is applied to MS patients' DMT medicine, their deductibles and coinsurance costs for medical services are so expensive that they will still hit their out-of-pocket maximums by June. Therefore, the maximizer program does not save patients any out-of-pocket health expenditures once other medical costs are considered.

For ease of comparison, Table 15 summarizes the expenditures of patients, manufacturer out-of-pocket assistance, and payers under the four alternative scenarios — without any out-of-pocket assistance, with typical out-of-pocket assistance, with a payer accumulator program in place, and with a payer maximizer program in place. The same trends are evident,

- Out-of-pocket assistance programs without payers imposing accumulators or maximizers are the only option that eliminates patients' out-of-pocket costs
- Accumulator programs are a means for payers to transfer resources from manufacturers to payers without helping patients
- Maximizer programs create the appearance of patient savings when only the costs of drugs for the relevant condition are considered, the apparent savings completely disappear once the broader healthcare landscape is counted.

Table 15 Summary of Expenditures by Patient, Out-of-pocket Assistance Program, and Payer for Typical MS DMT Drug and Medical Costs

	Results Summary for Drug Costs			
	No Out-of-pocket assistance Program	Out-of-pocket Assistance Program	Accumulator Program	Maximizer Program
Total Patient Payment	$6,436	$-	$6,436	$-
Total Out-of-pocket assistance Payment	$-	$6,436	$15,000	$15,000
Total Payer Payment	$28,718	$28,718	$13,718	$20,154
	Results Summary for Medical Costs			
Total Patient Payment	$-	$-	$-	$6,436
Total Out-of-pocket assistance Payment	$-	$-	$-	$-
Total Payer Payment	$26,315	$26,315	$26,315	$19,879
	Results Summary for Drug & Medical Costs			
Total Patient Payment	$6,436	$-	$6,436	$6,436
Total Out-of-pocket assistance Payment	$-	$6,436	$15,000	$15,000
Total Payer Payment	$55,033	$55,033	$40,033	$40,033

(numbers may not add due to rounding)

Breast Cancer

As the third example, we evaluate the implications from maximizer and accumulator programs on the expensive breast cancer treatment Ibrance. The average monthly price for Ibrance is currently about $15,886.[24] The therapy's duration is based on patients' tolerability and individual effectiveness. Patients who tolerate the medicine well and for whom the drug is effective may receive treatment throughout an entire year.

Due to high monthly costs, patients will hit the annual out-of-pocket maximum of $6,436 in the first month of treatment based on the benefit design for an average ACA silver plan (see Table 16). Payers/insurers cover the remainder of the annual costs, with a total cost exposure of $184,200.

Table 16 Annual Cost Breakdown for Ibrance for Breast Cancer Patient Based on Average ACA Silver Plan Benefit Design

	Drug Cost	Patient Deductible Payment	Patient Coinsurance	Total Patient Payment	Payer Payment
January	$15,886	$4,753	$1,683	$6,436	$9,450
February	$15,886	$-	$-	$-	$15,886
March	$15,886	$-	$-	$-	$15,886
April	$15,886	$-	$-	$-	$15,886
May	$15,886	$-	$-	$-	$15,886
June	$15,886	$-	$-	$-	$15,886
July	$15,886	$-	$-	$-	$15,886
August	$15,886	$-	$-	$-	$15,886
September	$15,886	$-	$-	$-	$15,886
October	$15,886	$-	$-	$-	$15,886

November	$15,886	$-	$-	$-	$15,886
December	$15,886	$-	$-	$-	$15,886
Full Year	**$190,636**	**$6,436**	**$-**	**$-**	**$184,200**
Total Patient Payment	**$6,436**				
Total Out-of-pocket Assistance	**$-**				
Total Payer Payment	**$184,200**				

(numbers may not add due to rounding)

Assistance programs cover the out-of-pocket maximum that patients would otherwise pay, creating a benefit for patients, without impacting the costs for payers/insurers, see Table 17.

Table 17 Annual Cost Breakdown for Ibrance for Breast Cancer Patient Based on Average ACA Silver Plan Benefit Design with Out-of-pocket Assistance Program

	Drug Cost	Out-of-pocket Assistance	Patient Deductible Payment	Patient Coinsurance	Payer Payment
January	$15,886	$6,436	$-	$-	$9,450
February	$15,886	$-	$-	$-	$15,886
March	$15,886	$-	$-	$-	$15,886
April	$15,886	$-	$-	$-	$15,886
May	$15,886	$-	$-	$-	$15,886
June	$15,886	$-	$-	$-	$15,886
July	$15,886	$-	$-	$-	$15,886
August	$15,886	$-	$-	$-	$15,886
September	$15,886	$-	$-	$-	$15,886
October	$15,886	$-	$-	$-	$15,886
November	$15,886	$-	$-	$-	$15,886
December	$15,886	$-	$-	$-	$15,886
Full Year	**$190,636**	**$6,436**	**$-**	**$-**	**$184,200**
Total Patient Payment	**$-**				
Total Out-of-pocket Assistance	**$6,436**				
Total Payer Payment	**$184,200**				

(numbers may not add due to rounding)

As in the previous examples, the accumulator and maximizer programs transfer resources from out-of-pocket assistance to payers without benefiting patients, see Table 18. In the case of Ibrance, the maximum value of manufacturer assistance is $25,000 annually,[25] which is sufficient to cover approximately 1.5 months of costs before patients must start making payments. Due to the expense, patients will hit their out-of-pocket maximum by March, in which case the payer covers the remaining costs. However, the $25,000 out-of-pocket assistance has lowered the payer's costs from $184,200 to $159,200.

As in the previous examples, the accumulator and maximizer programs transfer resas in ources from out-of-pocket assistance to payers without benefiting patients.

Table 18 Annual Cost Breakdown for Ibrance for Breast Cancer Patient with an Accumulator Program Based on Average ACA Silver Plan Benefit Design and $25,000 Total Out-of-pocket Assistance Program Value

	Drug Cost	Out-of-pocket Assistance	Patient Deductible Payment	Patient Coinsurance	Total Patient Payment	Payer Payment
January	$15,886	$15,886	$-	$-	$-	$-
February	$15,886	$9,114	$4,753	$687	$5,440	$1,333
March	$15,886	$-	$-	$996	$996	$14,890
April	$15,886	$-	$-	$-	$-	$15,886
May	$15,886	$-	$-	$-	$-	$15,886
June	$15,886	$-	$-	$-	$-	$15,886
July	$15,886	$-	$-	$-	$-	$15,886
August	$15,886	$-	$-	$-	$-	$15,886
September	$15,886	$-	$-	$-	$-	$15,886
October	$15,886	$-	$-	$-	$-	$15,886
November	$15,886	$-	$-	$-	$-	$15,886
December	$15,886	$-	$-	$-	$-	$15,886
Full Year	**$190,636**	**$25,000**	**$4,753**	**$1,683**	**$6,436**	**$159,200**
Total Patient Payment	**$6,436**					
Total Out-of-pocket Assistance	**$25,000**					
Total Insurer Payment	**$159,200**					

(numbers may not add due to rounding)

The takeaway from the Ibrance example is the same: once subject to an accumulator program, patient savings enabled by out-of-pocket assistance are eliminated and patients must once again pay their out-of-pocket maximum — $6,436 — to receive their Ibrance prescription.

Just as with psoriatic arthritis and MS, the maximizer program appears to alleviate these costs for patients, but this outcome only applies to their drug costs with respect to the specific condition, however. Once other medical costs are considered, the patient savings enabled by maximizers disappears. Tables 19 and 20 demonstrate these outcomes with respect to patients prescribed Ibrance.

Table 19 Annual Cost Breakdown for Ibrance Patient for a Maximizer Program Based on Average ACA Silver Plan Benefit Design and $25,000 Total Out-of-pocket Assistance Program Value

	Drug Cost	Maximizer Program	Payer Payment
January	$15,886	$2,083	$13,803
February	$15,886	$2,083	$13,803
March	$15,886	$2,083	$13,803
April	$15,886	$2,083	$13,803
May	$15,886	$2,083	$13,803
June	$15,886	$2,083	$13,803
July	$15,886	$2,083	$13,803
August	$15,886	$2,083	$13,803

September	$15,886	$2,083	$13,803
October	$15,886	$2,083	$13,803
November	$15,886	$2,083	$13,803
December	$15,886	$2,083	$13,803
Full Year	**$190,636**	**$25,000**	**$165,636**
Total Patient Payment	**$-**		
Total Out-of-pocket Assistance	**$25,000**		
Total Payer Payment	**$165,636**		

(numbers may not add due to rounding)

Table 19 demonstrates that the maximizer program eliminates any patient costs with respect to Ibrance. What has not been covered yet, however, are the medical costs associated with breast cancer. As Ibrance is prescribed for advanced stage breast cancer, Table 20 estimates the non-pharmaceutical medical costs associated with stage III breast cancer or $125,546.[26] Based on the benefit design for the average ACA silver plan, patients' share of the expenditures will hit the annual out-of-pocket maximum of $6,436 indicating that payers' costs are $119,100.

Table 20 - Annual Medical Cost Breakdown for Breast Cancer Patient Prescribed Ibrance Subject to a Maximizer Program and Benefit Design Based on Average ACA Silver Plan

	Medical Costs	Patient Deductible Payment	Patient Coinsurance	Total Patient Payment	Payer Payment
January	$10,462	$4,753	$1,370	$6,123	$4,339
February	$10,462	$-	$313	$313	$10,149
March	$10,462	$-	$-	$-	$10,462
April	$10,462	$-	$-	$-	$10,462
May	$10,462	$-	$-	$-	$10,462
June	$10,462	$-	$-	$-	$10,462
July	$10,462	$-	$-	$-	$10,462
August	$10,462	$-	$-	$-	$10,462
September	$10,462	$-	$-	$-	$10,462
October	$10,462	$-	$-	$-	$10,462
November	$10,462	$-	$-	$-	$10,462
December	$10,462	$-	$-	$-	$10,462
Full Year	**$125,546**	**$4,753**	**$1,683**	**$6,436**	**$119,110**
Total Patient Payment	**$6,436**				
Total Payer Payment	**$119,110**				

(numbers may not add due to rounding)

Table 21 compares the four payment scenarios for Ibrance. As with psoriatic arthritis patients and MS patients, once the full drug and medical costs are considered, maximizer programs do not reduce patients' expenditures.

Table 21 Summary of Expenditures By Patient, Out-of-pocket Assistance Program, and Payer for Typical Ibrance Patient and Medical Costs

	Results Summary for Drug Costs			
	No Out-of-pocket assistance Program	Out-of-pocket Assistance Program	Accumulator Program	Maximizer Program
Total Patient Payment	$6,436	$0	$6,436	$0
Total Out-of-pocket Assistance	$0	$6,436	$25,000	$25,000
Total Payer Payment	$184,200	$184,200	$159,200	$165,636
	Results Summary for Medical Costs			
Total Patient Payment	$0	$0	$0	$6,436
Total Out-of-pocket Assistance	$0	$0	$0	$0
Total Payer Payment	$125,546	$125,546	$125,546	$119,110
	Results Summary for Drug & Medical Costs			
Total Patient Payment	$6,436	$0	$6,436	$6,436
Total Out-of-pocket Assistance	$0	$6,436	$25,000	$25,000
Total Payer Payment	$309,746	$309,746	$284,746	$284,746

(numbers may not add due to rounding)

Maximizers' Can Adversely Impact Treatment Adherence

One important issue not considered in the above scenarios is the impact accumulator and maximizer programs can have on medication adherence and use of necessary healthcare services. The value created by out-of-pocket assistance programs arises, in part, because there is a negative relationship between high out-of-pocket expenditures and faithful adherence to patients' prescribed healthcare regimen.

Starting with the impact on drug adherence, a 2020 report by IQVIA found that the drug abandonment rate was below 5 percent when patients did not face any out-of-pocket costs, but was 45 percent when patients' out-of-pocket costs were over $125 and 60 percent when patients' costs exceeded $500.[27]

Confirming IQVIA's results, Reynolds et. al. (2020) found that "higher out-of-pocket costs were associated with lower medication adherence in 3 common neurologic conditions."[28] A comprehensive review of the medicine adherence literature similarly concluded

> *that reducing patients' out-of-pocket costs improves medication adherence. Compared with other effective interventions, such as case management and collaborative care, which are relatively complex and labor-intensive, reducing copayments can potentially improve adherence for large numbers of geographically diverse patients.*[29]

Eaddy et al. (2012) quantified these impacts finding that

> *for each dollar increase in patient copays, adherence (as measured by these studies) would be expected to decrease by 0.4%. Thus, a $10 change would be expected to result in a 3.8% drop in adherence overall; however, as evidenced by the wide range of results included in the chart, the actual result of such a change might be larger or smaller, depending on the population and intervention affected.*[30]

Large out-of-pocket obligations have a similar impact on patients' use of needed medical services. A study by the Employee Benefit Research Institute (EBRI), for instance, found that higher out-of-pocket costs were associated with decreases in the use of inpatient healthcare and primary care physician visits.[31] The EBRI results are consistent with findings from other analyses as well. For instance, a 2001 study in the American Journal of Public Health found that patients with high out-of-pocket costs were less likely to seek medical care for serious symptoms compared to patients that did not face a significant out-of-pocket requirement.[32]

The reduction in their out-of-pocket expenditures leads to an improved patient adherence to their prescribed healthcare regimen and, consequently, to better health outcomes.

By helping patients with large drug expenditures meet their out-of-pocket maximums, out-of-pocket assistance programs can eliminate annual out-of-pocket expenditures. The reduction in their out-of-pocket expenditures leads to an improved patient adherence to their prescribed healthcare regimen and, consequently, to better health outcomes. A 2021 IQVIA analysis examined adherence rates between two groups of patients over time — those on a patient support group (referred to as the test group) and those not participating in a patient support program (referred to as the control group).[33] The analysis concluded that

> *69 percent of the patients in the test group, compared to 55 percent in the combined control groups, remained on their medication at the one-year mark. And, after two years, 46 percent of those in the program remained on therapy, versus 34 percent in the control group.*[34]

Patients' out-of-pocket costs for medicines and medical services are covered when out-of-pocket assistance is utilized for conditions treated with high-cost drugs. Accumulator and maximizer programs prevent these out-of-pocket savings from being counted toward their out-of-pocket contributions. As the numerical cost models demonstrated, patients are, consequently, still responsible to pay their entire (or nearly entire) out-of-pocket maximums when payers adopt either an accumulator or maximizer program. As a result, accumulators and maximizers should be expected to reduce patients' adherence to their medicines or their use of required medical services.

Health outcomes suffer when patients do not adhere to their prescribed drugs or fail to seek necessary medical services. Poor adherence is also associated with greater long-term expenditures as avoidable and more costly medical interventions such as hospitalizations and surgeries become necessary. With respect to medications, lack of adherence

> *is estimated to cause approximately 125,000 deaths, at least 10% of hospitalizations, and a substantial increase in morbidity and mortality. Nonadherence has been estimated to cost the U.S. healthcare system between $100 billion and $289 billion annually.*[3]

With respect to medical services, a 2019 study examined the impact from foregone and delayed medical care among heart patients.[35] Their analysis found that,

> *in general, those reporting foregone/delayed care had more hospitalizations, ED [emergency department] visits and expenditures. Among the elderly, those reporting forgone/delayed care had more ED visits (43% v. 58%, $p < 0.05$). Additionally, elderly HF [heart failure] patients reporting foregone/delayed care had higher annual inpatient, and total health care costs compared to those not foregoing care (Difference: $7,548, & $10,581, respectively, all $p < 0.05$). Among non-elderly HF patients, total annual out-of-pocket costs were higher for those who reported foregone/delayed care.*[36]

Since there is a strong relationship between higher out-of-pocket costs and patients' proclivity to forgo or delay care, and since accumulator and maximizer programs will increase patients' out-of-pocket costs, accumulators and maximizers will cause some patients to forgo or delay necessary care. The forgone or delayed care will reduce patients' health outcomes and increase

overall healthcare expenditures. These additional costs are additional negative consequences these programs impose on the healthcare sector.

Table 22 provides a sense of the potential impact maximizer programs could have on increasing total healthcare expenditures. It is important to note upfront that there are data limitations, so the estimates are intended to provide an approximation of costs. To the extent that data certainty can be improved, more precise estimates could be calculated. To account for the uncertainty, conservative assumptions are used in the following methodology.

The first step in valuing these impacts is to estimate the total number of people using out-of-pocket assistance programs that are subject to maximizer programs. According to *Drug Channels*, 78 percent of the eligible population (e.g., people with commercial insurance) are subject to maximizer programs.[37] Since 54.6 percent of the population has commercial insurance,[38] 42.6 percent of the population are subject to maximizer programs.

According to Phreesia, 3 percent of the eligible population are currently using an out-of-pocket assistance program,[39] indicating that 1.3 percent of the population are currently using assistance. Relative to the 332 million Americans,[40] the percentages imply that there are 4.2 million people currently using an out-of-pocket assistance program who are also subject to a maximizer program.

Due to the maximizer program, deductible, coinsurance, and copay obligations for patients with a combined plan will need to be applied against the costs for their medical services. These costs will discourage some patients from seeking treatment, either in a timely manner or at all. According to the Kaiser Family Foundation, 9 percent of patients "said that they either delayed or did not receive medical care due to cost reasons in 2020."[41] Should 9 percent of the patients using an. out-of-pocket assistance program that are subject to a maximizer program delay or skip care, then there are nearly 382,000 patients who would not be receiving their proper medical care due to the maximizer program.

Since these patients are using out-of-pocket assistance programs, they presumably are living with expensive illnesses. Average expenditures for a high-cost patient, according to the Commonwealth Fund, are $21,021.[42] Across the nearly 382,000 patients, these figures imply total medical costs of $8 billion. Delaying, or missing, their necessary care will increase these expenditures. A study in the Journal *Circulation* estimated that the excess costs created when heart patients delay or forgo necessary care increases total healthcare expenditures for non-elderly patients by 31.4 percent.[43]

Applying this estimate and one-half of this estimate, for conservative purposes because it was based on heart disease only, to the total current healthcare costs indicate that delayed or forgone care in the maximizer population could increase annual healthcare cost by between $1.3 billion and $2.5 billion.

Table 16 Potential Drug Non Adherence Costs Caused by Maximizer Programs

		($'s in billions)		
		Low	High	
1	Percentage of Patients with Commercial Insurance (eligible population)	54.6%		https://www.k ff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D
2	Percentage of Eligible Population Subject to Maximizer Programs	78.0%		https://www.drugchannels.net/2020/11/copay-accumulator-and-maximizer-update.html
3	*Percentage of Population Subject to Maximizer Programs*	*42.6%*		*1 * 2*
4	Percentage Eligible Population Using Out-of-pocket assistance Programs	3.0%		https://engage.phreesia.com/rs/867-GML-252/images/Phreesia_Industry_Perspectives_Patient_Support_Programs.pdf
5	*Percentage Population Using Out-of-pocket assistance Program*	*1.3%*		*3 * 4*
6	Total U.S. Population	331,893,745		https://www.census.gov/quickfacts/fact/table/US/PST045221
7	*Population Subject to Maximizer Program Using Out-of-pocket assistance Program*	*4,240,407*		*5 * 6*
8	Abandonment Rate Due to Maximizer Program	9%		https://www.healthsystemtracker.org/chart-collection/cost-affect-access-care/#Percent%20of%20adults%20who%20reported%20delaying%20or%20going%20without%20medical%20care%20due%20to%20costs,%202020
9	*Abandoned Population*	*381,637*		*7 * 8*
10	Hospital & Physician Costs (in dollars)	$21,021		https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_issue_brief_2016_aug_hayes_who_are_high_need_high_cost_patients_appendix_tables.pdf
11	*Expenditures by Abandoned Population (in billions)*	*$8.02*		*9 * 10*
12	Patient Expenditure Premium from Missed Care*	15.7%	31.4%	https://www.ahajournals.org/doi/10.1161/circ.140.suppl_1.13991
13	**Excess Expenditures (in billions)**	**$1.26**	**$2.52**	11 * 12

* High assumes premium for heart patients, low assumes 50 percent of that level.

The potential of an additional $1.3 billion to $2.5 billion in extra medical costs arises because the maximizer program simply shifts patients' out-of-pocket obligations from the medicines impacted by the program to medical services or other pharmaceuticals.

The potential of an additional $1.3 billion to $2.5 billion in extra medical costs arises because the maximizer program simply shifts patients' out-of-pocket obligations from the medicines impacted by the program to medical services or other pharmaceuticals.

Public Policy Around Accumulators and Maximizers

Both state and federal legislators have expressed concerns about accumulators and maximizers which has led to a number of legislative proposals.

1. **State Laws That Require Any OOP Support to Count Towards a Patient's Deductible and OOP Maximum**

Sixteen states have enacted laws requiring that OOP financial support—from any source—count toward a patient's OOP obligations. The problem with these laws is that they only apply to smaller, state-regulated health plans, not large, multistate ERISA plans. According to recent data from Avalere,[44] 83 percent of commercial market enrollees belong to plans that feature accumulator programs, while 73 percent belong to plans with maximizers programs. Due to the OOP cost challenges that these programs create for patients, in recent years state legislatures have enacted

bans on accumulator programs. The broad language of these statutes may also ban the use of maximizer programs. As of January 2023, 16 states have passed such bans and, according to Avalere, when those state laws take effect, 13 percent of the total U.S. market will have passed requirements that third party payments for patients count toward those patients' OOP requirements, representing 18.8 million individuals who are helped by these bans. So while sixteen states have enacted these laws, only 13 percent of patients are impacted by these laws. Federal legislation is required to reach a broader set of patients.

2. **Federal Law to Require that ERISA plans Count Any OOP Support Toward a Patient's Deductible and OOP Maximum**

As discussed, state laws that require health plans to count third party financial assistance toward a patient's OOP obligations cannot legally regulate large, multistate ERISA plans**.** According to some legal analyses, the language in these statutes may only apply the ban to individual or small group health plans. Large group health plans — so-called ERISA plans — for unions and corporations may be exempt from these bans because they are federally regulated under ERISA law. A congressional bill, H.R. 830, would complement state laws by requiring large ERISA plans to count any third party financial OOP assistance toward a patient's deductible and OOP maximums.[45]

3. **Anti-Steering Legislation**

When patients are prescribed a specialty drug, those patients' pharmacy benefit is managed by a PBM. Typically, if that PBM wishes to enroll a patient into an accumulator or maximizer program, the patient must be "steered" into that PBM's specialty pharmacy. Once a patient is provided with a specialty prescription, he or she is told that they "must" use the PBM's specialty pharmacy to fill their prescription or their OOP costs will skyrocket. When that patient appears on the radar of that PBM's specialty pharmacy, the patient is told that they will be enrolled into an accumulator or maximizer program and that the patient will be helped to apply for any patient financial assistance that may be available from the drug's manufacturer. (If the drug manufacturer has no financial assistance available, the patient may be told that they will be put on another drug that does.) IQVIA has documented[46] that the growth in accumulator and maximizer programs has been aided by PBM-affiliated specialty pharmacies: "PBM-affiliated specialty pharmacies had a particularly large growth in maximizer prevalence from 4% in 2019 to 17% in 2022 while maximizer prevalence in other specialty pharmacies remained relatively stable."

Typically, if that PBM wishes to enroll a patient into an accumulator or maximizer program, the patient must be "steered" into that PBM's specialty pharmacy.

IQVIA goes on to report that the future success of accumulator and maximizer programs will be related to the PBMs continued ability to steer patients into affiliated specialty pharmacies: "Current prevalence trends suggest there could be a limit to how pervasive these plans, particularly accumulators, can be outside of PBM affiliated pharmacies."

In short, the ability of PBMs to enroll patients into these programs that keep OOP costs high is predicated on the PBM's ability to steer patients into its specialty pharmacy. Without this "steering" ability, enrollment in these accumulator/maximizer programs would be difficult. Therefore, state legislators that wish to limit the ability of PBMs to keep OOP costs high can ban the requirement that patients use the specialty pharmacy designated by their PBMs. These laws are called "anti-steering" laws. The most recent was enacted in Texas and became effective September 1, 2021.

The Texas law is very straightforward. Its major provisions include:

1. PBMs are prohibited from steering patients toward their PBM-owned pharmacy in any verbal or written communications.

2. PBMs are prohibited from forwarding certain patient information to their affiliated providers.

3. PBMs may not offer reduced cost-sharing or full benefits to patients as means to induce them into their provider's plans.

While the legal loophole for larger group plans may offer PBMs a temporary period in which they can enforce accumulator and maximizer programs for these health plans, one can surmise that time is not on the side of PBMs. The clear intent of all 16 state laws was to make certain that the third parties could assist patients in meeting their OOP obligations. The spirit of these laws, therefore, represents a philosophy that would look askance at any programs that seek to prevent third party benefactors from assisting patients in meeting their OOP obligations.

Drug Manufacturer Business Options to Limit Accumulators and Maximizers

It is a lamentable development PBMs are confiscating funds intended for patients and, for that reason, some drug manufacturers are scaling back their financial assistance to patients for OOP costs.

When manufacturers first began their OOP assistance programs, they were indifferent to individual patient's OOP requirements or OOP maximums. Manufacturers would simply offer assistance up to a certain maximum that typically could cover the OOP costs for most patients. Now that PBMs are pilfering these funds, manufacturers may wish to consider a more individualized approach.

While it is certainly more labor intensive, manufacturers may wish to look at the OOP maximums for the health plans of individual patients and tailor their financial assistance to meet that OOP maximum and no more. In short, manufacturers can say to patients and their PBMs, "we will provide financial assistance up to the OOP maximum in this patient's plan, and no more."

Such a strategy would allow drug makers to keep their commitment to patients in helping with their OOP costs, and would also make accumulator and maximizer programs far less attractive to PBMs and the third party contractors, such as SaveOnSP, who typically take a fee of 20–25% of the drug maker's assistance.

While the authors of this report are not endorsing this strategy of scaling back OOP assistance programs, every company needs to decide for themselves based upon the commitments they have made to patients, from an economic perspective, we feel this individualized approach is the strategy most likely to be adopted by the industry.

Are Accumulator/Maximizer Programs Necessary?

Accumulator and maximizer programs can inflict significant OOP costs upon patients, many of whom suffer from serious chronic conditions. The question that must be asked: are payers and PBMs so inundated with rising drug costs and drug prices that they are being forced to offload many of their costs onto patients? Would the solvency of health plans be threatened if they scrapped these accumulator and maximizer programs and simply allowed patients to utilize out-of-pocket assistance from drug manufacturers?

When looking at the financial impact of prescription drug costs upon payers, three sets of data are important. First, how do prescription drug costs contribute to health plan premiums? Obviously, if rising prescription drug costs were forcing major premium increases, this would be a significant threat to the business model of commercial payers.

The overall growth in drug costs is the second important data set. If payers are witnessing tremendous growth in drug price increases, as well as utilization growth, then overall drug costs would be placing financial pressure upon their business.

Finally, average drug prices are also an important data set to consider. Even if utilization of prescription drugs were dropping, huge price increases could put pressure on payers and they might be left with no choice but to adopt accumulators and maximizers.

One of the most comprehensive data sets related to the impact of prescription drug costs on healthcare premiums is found in California's "Prescription Drug Cost Transparency Report,"

data which health plans must file each year under California law. In the most recent report for 2021, the data indicates that prescription drug expenses make up only 11.2 percent of health plan premiums (net of manufacturer rebates and discounts). Moreover, it seems clear that health plans and PBMs are reaping huge profits from drug manufacturer rebates, which increased by 16.5 percent between 2020 and 2021. Total rebate payments to the health plans that filed with the state rose from $1.4 billion in 2020 to $1.7 billion in 2021.

From this data, it seems clear that prescription drug costs represent only a fraction of the medical expenses incurred by health plans, and do not contribute significantly to premium growth, especially when drug rebate revenues are considered.

Moreover, nothing in the data on drug costs would suggest that payers will face an avalanche of drug cost growth in the coming years. According to the well-respected consulting firm IQVIA[47], "(R)eal net per capita medicine spending growth is expected to grow at 0-3%, about a percentage point lower than the 2.8% growth seen over the prior five years when adjusted for population, economic growth, and manufacturer concessions." IQVIA and other prescription drug cost analysts attribute the modest cost growth predictions to the many looming patent cliffs for high-revenue medicines that will occur in the coming years.[48]

Are average prescription drug prices "skyrocketing" so significantly that payers must turn to patient OOP obligations to make up the financial shortfall? While many datasets could be brought to bear to lay out recent drug price trends, we will point to one quote from *Drug Channels*: "For 2022, brand-name drugs' net prices dropped for an unprecedented fifth consecutive year. What's more, after adjusting for overall inflation, brand-name drug net prices plunged by almost 9%."[49]

In short, are accumulators and maximizers a financial necessity for payers? The firm and conclusive answer is no. Prescription drug costs are a small factor in healthcare premiums; prescription drug costs are growing at very modest rates, and: average prescription drug prices are dropping, not rising. Given these financial realities, it is hard to see how payers, including employers, can continue to inflict these devastating OOP costs upon patients and employees.

Conclusion

The use of maximizers and accumulators in commercial health plans is a lamentable development. For decades, commercial health plans were the most reliable payers for innovation. Because commercial health plans compete in a market-based system, there were market incentives in place for them to cover the most innovative, effective and popular drugs. Employers, for example, who were providing healthcare as an employee benefit, sought to ensure that their employees had access to a generous drug formulary that covered the drugs that they were most likely to be prescribed by doctors.

With the advent of specialty medicines, these market-based incentives are breaking down. Specialty medicines and orphan drugs are generally taken by a smaller subset of the population. While specialty medicines remain some of the most innovative therapies ever brought to market, denials of access to specialty therapies by health plans and employers generally do not generate the market backlash that denial of a popular statin drug would have because the patient population taking a certain specialty drug may be only 1 percent to 2 percent of patients in the employee pool.

Because the market power of patients taking specialty drugs is so much less than patients who are prescribed drugs taken by millions of patients, health plans and employers are far less reluctant to restrict access to specialty drugs.

This is highly lamentable, as commercial payers are now in the position of discouraging innovation in an area of biopharmaceutical research that is most promising. If specialty drugs, such as cell therapies for rare cancers, are not reimbursed by payers and employers, one can be certain that research budgets for those therapies will be reduced.

While the impact of maximizers and accumulators on innovation can be significant, their use also calls into question the overall value of private health insurance. What maximizers and accumulators do is to invert the purpose of health insurance.

While the impact of maximizers and accumulators on innovation can be significant, their use also calls into question the overall value of private health insurance. Insurance, after all, has as one of its primary goals the prevention of fiscal disaster for sick patients. What maximizers and accumulators do is to invert the purpose of health insurance. The goal of maximizers and accumulators is to keep OOP costs high for patients who are experiencing an illness or otherwise require a specialty drug while, at the same time, reducing the healthcare premiums of healthy people enrolled in that health plan. In short, tax the sick to keep premiums low for the healthy. While the inversion of the purpose of insurance may help, short-term, with the balance sheets of health plans and employers, over the long run it is bound to taint the entire health insurance industry with a reputation for punishing sick patients for profit.

However, by far the worst aspect of maximizers and accumulators is the financial and health impacts upon patients. Health plans are making a deliberate choice to make it very challenging for middle- and lower-income patients to access the latest cutting-edge therapies for cancer, arthritis, MS, cystic fibrosis and many other devastating diseases — all with the goal of keeping premiums low for healthy enrollees.

The regrettable irony of commercial health plans and employers turning away from innovative medicines is that a degradation in the quality of commercial insurance will increase demand for government health plans, where rationing innovative therapies is commonplace. Patients who turn to the government may find their access to high quality therapies even more limited.

Our central recommendation is that commercial health plans and employers return to the commonsense goal of insurance programs: protect the patient if they fall ill. It is perfectly reasonable to expect patients to bear some cost-sharing burden, but inflicting OOP cost obligations so significant that they are intended to cause the abandonment of prescriptions seems a complete inversion of the purpose of insurance. Policy makers who wish to protect the market-based commercial insurance industry would be wise to enact reforms that limit the use of accumulator and maximizer programs.

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