HIV+HEP
POLICY INSTITUTE

November 12, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Comments on *Notice of Benefits and Payment Parameters for 2026* Proposed Rule [CMS-9888-P]

Dear Administrator Brooks-LaSure:

The **HIV+Hepatitis Policy Institute**, a leading national HIV and hepatitis policy organization promoting quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions, is pleased to offer comments on the *Notice of Benefits and Payment Parameters* for 2026 Proposed Rule (Proposed NBPP Rule).

On November 4, 2024, we submitted comments on the 2026 Draft Letter to Issuers, which can be found **here**. In those comments, we reiterate our profound disappointment with CCIIO and state regulators for not enforcing the strong ACA nondiscrimination patient protections, including a prohibition on adverse tiering in drug formularies and the requirement to cover the drugs included in widely accepted national treatment guidelines. We also outline a number of recent examples by insurers that CCIIO and state insurance regulators are permitting to operate that discriminate against people living with HIV by using benefit designs that discourage their enrollment.

While we appreciate the many steps that you are taking to make healthcare more accessible and affordable for beneficiaries, the majority of this comment on the Proposed NBPP Rule focuses on the need for CMS and related federal agencies to take the necessary steps to increase access and affordability of prescription drugs that should have been included in the Draft NBPP Rule but were not.

Risk Adjustment for PrEP & Hepatitis C

Before we address these issues, we want to voice our strong support for the proposal to include PrEP in the risk adjustment model. The **HIV+Hepatitis Policy Institute** has signed on to a community letter in support of the proposal that we hope will begin for the 2026 plan

year. As CMS correctly noted in the proposed rule, use of PrEP is not fully reflected in the current risk adjustment model since PrEP users do not have an active health condition with a diagnosis code. However, recognizing that insurers must cover all forms of PrEP without cost-sharing, PrEP use should be adequately reflected in the risk adjustment model.

We also do not believe the use of low-cost generic PrEP should be included in the same factor as brand name PrEP. There is a substantial price difference between newer branded name and older generic forms of PrEP and insurers should not be rewarded at the same rate for both. Additionally, newer and more effective long-acting PrEP drugs, which will undoubtedly be more expensive than daily generic PrEP, will likely be the predominant form of PrEP in the future. Therefore, we support excluding generic PrEP from the Affiliated Cost Factor (ACF).

We also support the proposal to begin to phase out the market pricing adjustment to the plan liability associated with Hepatitis C drugs in the HHS risk adjustment models and start treating Hepatitis C drugs consistent with other drugs. CMS rightfully concluded that the expected costs of Hepatitis C drugs have declined for many years and have stagnated due to the introduction of new and generic drugs and will only rise alongside the expected cost of other specialty drugs. We believe the phase out should progress as quickly as possible.

The remainder of the comment letter will focus on the following three issues:

1) It has been over a year since the District Court for D.C. in *HIV and Hepatitis Policy Institute et al. v. HHS et al.* struck down the section of the *2021 Notice of Benefits and Payment Parameters* rule that allowed issuers to decide if copay assistance can count or not, and that same Court clarified, at the government's request, that the *2020 Notice of Benefits and Payment Parameters* rule is now in effect. Therefore, issuers must count copay assistance, in most instances, and not implement copay accumulators. Instead of upholding the court's decision, CMS has ignored it and stated that it will issue a new rule regarding cost-sharing. Doing great harm to patients, the federal agencies have yet to issue that rule and did not include it in the Proposed NBPP Rule, but indicated it would do so in the future. **We urge the federal government to uphold the Court's decision, and, if a new rule is proposed, it must ensure that copay assistance count as cost-sharing.**

2) We are pleased that CMS codified in the 2025 NBPP Rule for the small group and individual markets the policy that prescription drugs covered in excess of the state's benchmark plan are considered essential health benefits (EHB) and are therefore subject to EHB protections, including annual cost-sharing limits. The 2025 NBPP Rule indicated that the federal government intends to propose a rule to apply this regulation to large group and self-insured plans. **We are disappointed that this proposal was not included in the draft 2026 NBPP rule and urge the departments to issue a rule in the very near future to close this loophole for all plans.**

3) Employers are teaming up with vendors that force beneficiaries that use certain medications to enroll in an alternative program, which is not insurance, in order to bypass ACA laws and regulations relative to patient cost-sharing limits and other patient protections. They then find alternative funding mechanisms, such as patient assistance programs or imported drugs, to pay for the drugs. If the patient does not comply, they will be left paying the full cost of the drug. **The federal government must take steps to prohibit the use of alternative funding programs.**

Copay Assistance & Definition of Cost-sharing

More than a year ago, on September 29, 2023, the District Court for D.C. in *HIV and Hepatitis Policy Institute et al. v. HHS et al.* struck down the section of the *2021 Notice of Benefits and Payment Parameters* rule that allowed issuers to decide if copay assistance can count or not (see Attachment 1). That same Court clarified, at the government's request, that the *2020 Notice of Benefits and Payment Parameters* rule is now in effect (see Attachment 2). That means that issuers must count copay assistance in most instances and not implement copay accumulators.

The rule states:

> Notwithstanding any other provision of this section, and to the extent consistent with state law**, amounts paid toward cost sharing using any form of direct support offered by drug manufacturers** to enrollees to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that **have an available and medically appropriate generic equivalent are not required to be counted toward the annual limitation on cost sharing** (as defined in paragraph (a) of this section). 45 C.F.R. § 156.130(h)(1)

As HHS explained in adopting the rule: "Where there is no generic equivalent available or medically appropriate," manufacturer assistance "must be counted toward the annual limitation on cost sharing" (84 Fed. Reg. at 17,545).

Instead of complying with the Court's ruling and issuing guidance to insurers of their legal obligation, CMS is ignoring it, and instead, said it would issue a new rule regarding cost-sharing. However, to date, that rule has yet to be proposed and, much to the disappointment of the patient community, was not included in the Draft NBPP Rule. The Draft NBPP Rule merely states:

> HHS and the Departments of Labor and Treasury intend to issue a future notice of proposed rulemaking [to] address the issues arising out of *HIV and Hepatitis Policy Institute et al.* v. *U.S. Department of Health and Human Services et al.,* Civil Action No. 22-2604 (D.D.C. Sept. 29, 2023), namely, the applicability of drug manufacturer support to the annual limitation on cost sharing.

Every day that this rule is delayed is another day that patients are forced to pay more for their prescription drugs while insurers and PBMs continue to pocket billions of dollars meant for patients who are struggling to afford their drugs.

Not only does this inaction increase the cost patients must pay for their drugs, it creates confusion in the states and instability in the prescription drug market.

While a new rule is not necessary, if one were to be issued, it must require copay assistance to count as cost-sharing. Since the federal government sided against patients and defended the insurers and PBMs in our litigation, we are very concerned about which direction the proposed rule may take. We cannot imagine how the government can rule differently. The Court concluded what patient groups have long maintained: copay accumulators increase patient costs, increase drug manufacturer payments, increase insurer revenues, and are not drug discounts.

Counting cost-sharing towards the out-of-pocket (OOP) maximum is consistent with Congressional intent of the Affordable Care Act (ACA) and is consistent with the plain language of the statute itself.

Title 42 USC Section 18022 both establishes the out-of-pocket maximum and defines the "cost sharing" that must be counted towards that OOP. That section of the ACA unambiguously provides that the "cost sharing" required to be recognized includes "deductibles, coinsurance, copayments, or similar charges."

The plain language meaning of the statute is clear, with no carve-out to its broad applicability. The source of the funds used to satisfy these amounts is irrelevant to the statutory mandate that they must be counted. Any such "charge" to a patient, regardless of the source of the funds then used to satisfy that "charge," must be recognized for purposes of the OOP maximum. It does not matter if the source of the funds used to satisfy any of those "charges" is a parent, a sibling, a family friend, a charity, or a drug manufacturer sponsoring a copayment card. The statutory text, along with the structure and purpose of the statute, speak directly and decisively to the question. They must be counted.

We urge the agencies to adopt, by regulation, that reading of the statute, as it is the only reading of the term "cost sharing" that CMS can lawfully adopt.

Patient Stories

The **HIV+Hepatitis Policy Institute** receives countless stories from patients and their families who have been victims of copay accumulator policies forced upon them, usually without their knowledge, by their insurer and PBMs. They read press coverage of our court victory and wonder, if we won the lawsuit, why isn't the copay assistance they have received not being counted as cost-sharing, and why do they have to come up with thousands of additional dollars to pay for their prescriptions. These people are desperate, wondering why

the government is not enforcing the Court's decision, and want to know what they can do and are willing to hire lawyers to help them out.

Below are just a couple of these real-life patient stories we received this year:

South Carolina Family, Husband w/Stage 4 Colon Cancer:

> *We are currently in the awful situation where we had a co-pay coupon/assistance from a drug manufacturer to help relieve the burden for our medical bills for a drug which has no generic option.*
>
> *My husband is fighting stage 4 colon cancer, and has been for 6 years and counting. You can imagine the burden of year after year deductibles having to be met. So, when we came across what seemed to be a HUGE blessing from drug manufacturer Taiho for chemo drug Lonsurf in January 2024, we were soooo thankful! Only to be surprised SC BCBS did NOT apply this to our deductible. As best as I can tell, Lonsurf is still patent protected which means a generic version is NOT available. By my understanding of the ruling in late 2023, BCBS should be applying this to our deductible since there is no generic version available, but BCBS is NOT doing this.*
>
> *I am not even sure you can help, but I'm just a wife/mom/caregiver trying to get some relief for my family. My husband is only 46 and my son is 7, and this deductible relief means so much to us as we battle this awful disease holding on to any time we have left as a family. It's just so appalling the insurance companies would take this away from people in a fight for their life!*

Crohn's Disease Patient:

> *My husband has been prescribed Stelara, which does not have a generic equivalent, to treat severe Crohn's disease. In January of this year we used a copay assistance card to fill the first dose for the year. Optum pharmacy was paid by the manufacturer the cost of our out of pocket maximum. However, they reported to United Healthcare only the $5.00 payment that we made. We were unaware that UHC was using a copay accumulator which makes us still responsible for the over $5,000 out of pocket max on our insurance. We have appealed to the 2nd level of UHC stating the federal findings regarding drugs that do not have a generic form. We just received the 2nd denial.*

Couple, Both Living with HIV:

> *I wanted to follow up with both of you and let you know that both [NAME REDACTED] and I are falling under the situation where we each have had our copay cards drained for 2024, and now both insurance companies are coming after us for the full deductible amounts ($1750 for mine, $3000 for [NAME REDACTED]).*

I sincerely hope that the HHS comes out with updated guidelines that firmly state, once and for all, that copay assistance must apply to deductibles.

Person Living with HIV

I'm on the last two weeks of my 90-day HIV meds, and for an additional 30 days, CVS is looking to bill me nearly $4,200. I do not have enough money for more HIV meds, and at this point in time, I had anticipated my Gilead co-pay coupon to fully cover my deductible and, in turn, cover my meds. My insurer, United Healthcare, continues to say they will not apply my co-pay coupon toward my deductible. Now, I'm unsure how to proceed.

Patient Scenarios: Copay Accumulators and Maximizers

There has been some confusion, perpetuated by the payer community, as to the patient, drug manufacturer, and payer impact of copay accumulators and maximizers. Payers have repeatedly contended, even to the Court, that they do not collect the copay assistance and are not double billing and collecting more than they should under the ACA. While they are correct that they do not collect the copay assistance but rather the pharmacy does, they fail to mention what the pharmacy does with the copay assistance after they receive it. It flows back to the payers.

If it did not flow back to the payers, why would they be implementing copay accumulator programs and why are they defending them and working so hard to make sure the copay assistance does not count? It is clear that they are doing this to increase their revenues and profits, and at a great expense to patients. We are extremely disappointed that the federal agencies continue to take the side of the insurers and PBMs to the detriment of patients who depend on copay assistance to afford their medications.

As clearly described in the patient scenarios below, the patient pays much more in cost-sharing under the copay accumulator scenario compared to a patient whose copay assistance counts. Also, for both accumulators and maximizers the payers collect much more money than they should under the ACA when copay assistance counts.

Comparing Plans: Traditional vs Maximizer vs Accumulat

Patient Insurance Max Out of Pocket: $6,500

Copay Program: $0 copay up to $20,000 Annually

Traditional	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
Cost Share	$4,500	$2,500	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$6,500
Copay Funds	$4,500	$2,500	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	**$6,500**
Patient ROOP	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	**$0**

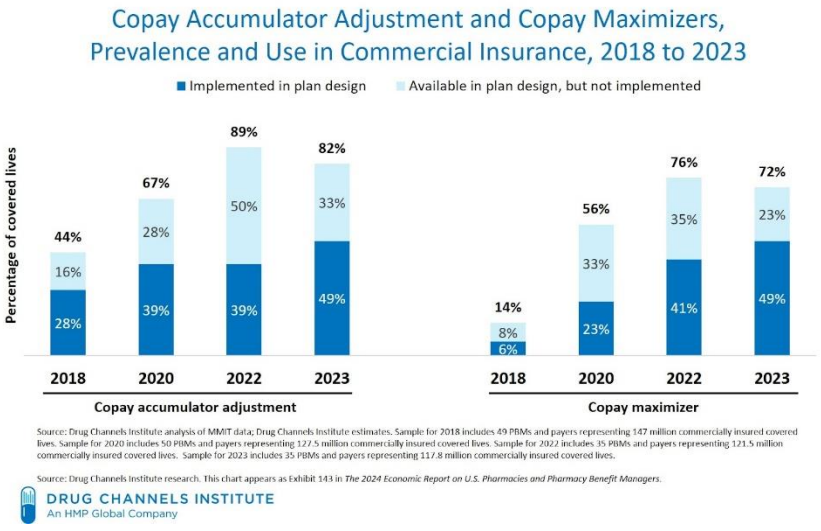
Maximizer	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
Cost Share	$1,666.67	$1,666.67	$1,666.67	$1,666.67	$1,666.67	$1,666.67	$1,666.67	$1,666.67	$1,666.67	$1,666.67	$1,666.67	$1,666.67	$20k
Copay Funds	$1,666.67	$1,666.67	$1,666.67	$1,666.67	$1,666.67	$1,666.67	$1,666.67	$1,666.67	$1,666.67	$1,666.67	$1,666.67	$1,666.67	**$20k**
Patient ROOP	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0

Accumulator	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
Cost Share	$4,500	$4,500	$4,500	$4,500	$4,500	$2,000	$2,000	$0	$0	$0	$0	$0	$26,500
Copay Funds	$4,500	$4,500	$4,500	$4,500	$2,000	$0	$0	$0	$0	$0	$0	$0	$20k
Patient ROOP	$0	$0	$0	$0	**$2,500**	$2,000	$2,000	$0	$0	$0	$0	$0	$6,500

Proliferation of Copay Accumulators & Copay Maximizers

The use of copay accumulators and copay maximizer programs will continue to increase, due to the federal government's inaction in issuing rules to stop them and their lack of enforcement of our favorable Court decision.

As illustrated in the graph below, in 2023, 49 percent of commercial plans had implemented copay accumulators. This compares to 39 percent in 2022. For copay maximizers, 49 percent of commercial plans had implemented copay maximizers in 2023, compared to 41 percent in 2022.



According to IQVIA, copay accumulator and maximizer programs accounted for $4.8 billion of copay assistance in 2023, more than double the amount attributed to these programs in 2019.[1]

Increased Out-of-Pocket Expenses for Patients & Their Impact

There is no doubt that patients need copay assistance in order to afford their prescription drugs, particularly due to high deductibles and high cost-sharing, often expressed in term of co-insurance based on the list price of a drug.

While there has been much attention to the list price of medications, patient out-of-pocket costs—the amount of money people actually pay for their drugs—are set by the insurers. Due to insurance benefit design, as described below, issuers are forcing beneficiaries to pay high costs, especially when compared to other healthcare services.

CMS has already announced that the maximum annual out-of-pocket cost will be increasing in 2026 by 10.3 percent from 2025. For an individual it will be **$10,150 and for a family $20,300.** The 2025 limits are $9,200 and $18,400, respectively. This is a great deal of money, which most people do not have, and it is on top of the cost of monthly premiums.

Due to the proliferation of high deductible plans, depending on the drug, an individual may be required to pay the total amount of $10,150 all at once for their medication at the beginning of the year.

According to CMS, the 2025 silver plan median deductible will be $4,928 while the bronze plan median deductible will be $7,323.[2]

That is why patients who rely on prescription medications rely on copay assistance. As illustrated in the graph below, according to IQVIA, in 2023 patient out-of-pocket costs for medicines in 2023 were $91 billion. That was an increase of $5 billion from 2022.

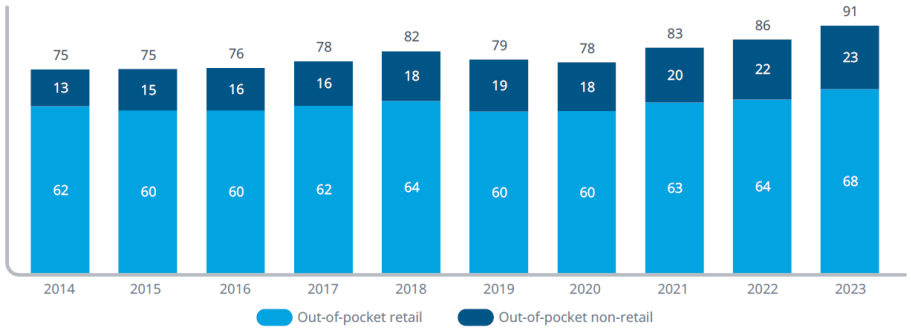
[1] Source: IQVIA LAAD 3.0 claims data, IQVIA US Market Strategy Consulting Analysis, December 2023.

[2] "Plan Year 2025 Qualified Health Plan Choice and Premiums in HealthCare.gov Marketplaces," CMS, October 25, 2024, https://www.cms.gov/files/document/2025-qhp-premiums-choice-report.pdf, page 14.

PATIENT OUT-OF-POCKET COSTS

Out-of-pocket costs in aggregate reached $91Bn in 2023, an increase of $5Bn, with most of the increases in retail drugs

Exhibit 19: Aggregate patient out-of-pocket cost for medicines dispensed in retail and non-retail settings, US$Bn

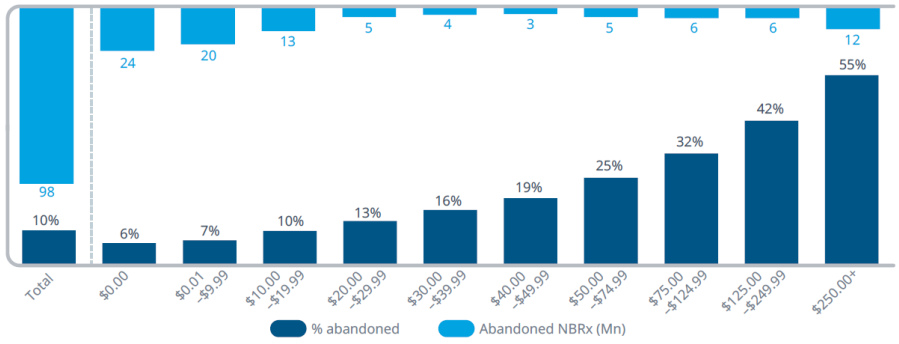


Source: IQVIA LAAD Sample Claims Data, CMS National Health Expenditures, Dec 2023; IQVIA Institute, Mar 2024.

Due in part to high patient out-pocket costs, patients do not always pick up their prescription drugs. As detailed below, according to an IQVIA analysis, an estimated 98 million prescriptions were abandoned at the pharmacy in 2023 (compared to 92 million in 2022), with an abandonment rate of one in three for prescriptions with out-of-pocket costs above $75. For prescriptions with a final out-of-pocket cost above $250, 55 percent are not picked up by patients, as compared with 7 percent of patients who do not fill when the cost to them is less than $10.

Patients starting new therapy abandoned 98Mn prescriptions at pharmacies in 2023 with increasing frequency as costs rise

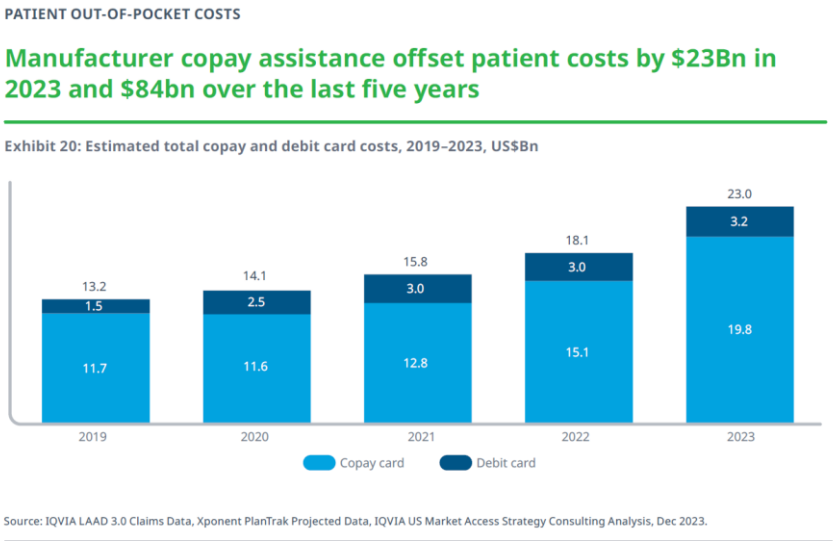
Exhibit 26: 14-day abandonment share of new-to-product prescriptions by final out-of-pocket cost in 2023, all payers, all products



Source: IQVIA National Prescription Audit: New to Brand, LAAD Sample Claims Data, Dec 2023; IQVIA Institute, Mar 2024.

In order to afford their prescription medications, patients and families rely on copay assistance. **In 2023, manufacturer copay assistance brought down patient costs by nearly $23 billion and accounted for 25 percent of out-of-pocket costs.** Over the last five years, copay assistance

accounted for $84 billion. Without copay assistance, the American people would have had to come up with all this money, which most people do not have.

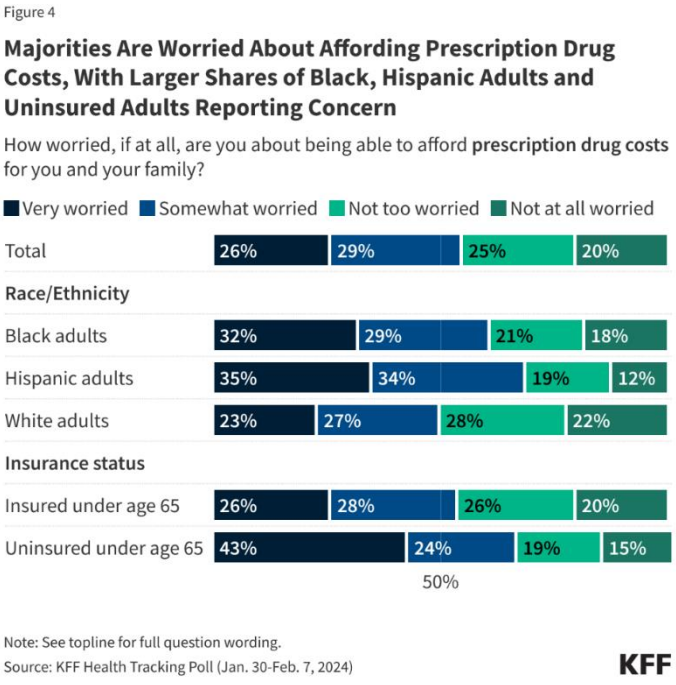


Consider some of the other following studies and surveys regarding patient affordability of prescription drugs:

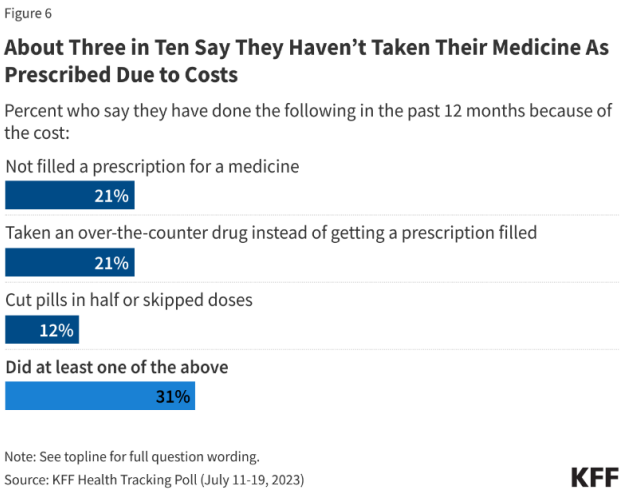
- In October 2024, **KFF** released a survey titled *Public Opinion on Prescription Drugs and Their Prices.*[3] According to the survey:

  over half (55%) of adults are worried about being able to afford their family's prescription drug costs, including a quarter (26%) who are "very" worried. Larger shares of Black and Hispanic adults report being worried about affording prescription drug costs (61% and 69% respectively) compared with White adults, half of whom report being worried. A somewhat larger share of adults under the age of 65 without insurance (67%) report being worried about affording prescription drug costs, but still *more than half (54%) of those who have insurance* say they worry about these costs.

[3] https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/



The survey also found "about three in ten adults report not taking their medicines as prescribed at some point in the past year because of the cost. This includes about one in five who say they have not filled a prescription (21%) or took an over-the counter drug instead (21%), and 12% who say they have cut pills in half or skipped a dose because of the cost."



- According to the **Commonwealth Fund 2023 Health Care Affordability Survey**:

  Many insured adults said they or a family member had delayed or skipped needed health care or prescription drugs because they couldn't afford it in the past 12 months: 29 percent of those with employer coverage and 37 percent covered by Marketplace or individual-market plans.

Insurance coverage didn't prevent people from incurring medical debt. Thirty percent of adults with employer coverage were paying off debt from medical or dental care, as were 33 percent of those in Marketplace or individual-market plans.

Medical debt is leading many people to delay or avoid getting care or filling prescriptions: more than one-third (34 percent) of people with medical debt in employer plans while 39 percent in Marketplace or individual-market plans.[4]

- According to **CMS' 2023 National Health Expenditures** report, while overall healthcare spending grew at 4.1 percent in 2022, the increase in out-of-pocket spending was substantially higher at 6.6 percent to $471.4 billion. For prescription drugs, out-of-pocket spending totaled $56.7 billion, or 14 percent of the total spending on prescription drugs. This represents an increase of 11.6 percent in 2022 after slower growth of 6.4 percent in 2021.

  However, for hospital care, which accounts for over three times more of total spending than prescription drugs, patients were responsible for paying only 2.6 percent. Despite the much smaller total amount of spending for prescription drugs, the out-of-pocket spending for prescription drugs ($56.7 billion) was higher than all the out-of-pocket spending for hospitals ($35.1 billion).[5]

- The **Centers for Disease Control and Prevention (CDC)** reported that the high cost of prescription drugs caused more than 9 million adults between the ages of 18 and 64 to not take their medications as instructed. Women were most likely to skip or delay taking prescribed drugs and 20 percent of people with disabilities rationed their medications because of cost.[6]

- An analysis of patient cost-sharing for prescription drugs in the commercial insurance market by staff of the **Bureau of Economic Affairs** found that between 2016 and 2020, out-of-pocket prices experienced faster growth than prices faced by insurers, after commercial rebates were accounted for. Through the period 2007–20, the authors found that "although retail pharmacy prices increased 9.1 percent annually, negotiated prices grew by a mere 4.3 percent, highlighting the importance of rebates in price measurement. Surprisingly, consumer out-of-pocket prices diverged from

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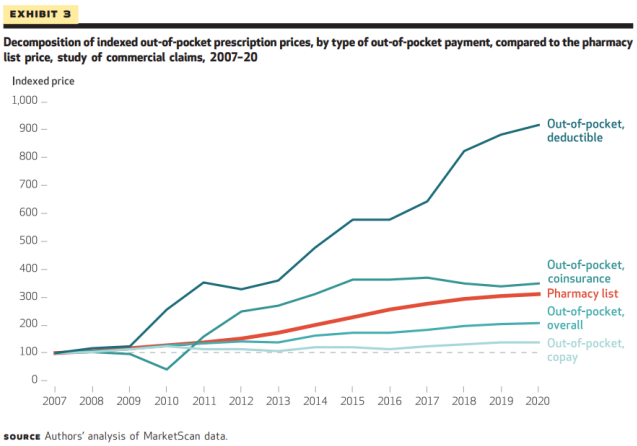
[4] Sara R. Collins, Shreya Roy, Relebohile Masitha. "Paying for It: How Health Care Costs and Medical Debt Are Making Americans Sicker and Poorer," *Findings from the Commonwealth Fund 2023 Health Care Affordability Survey*, October 26, 2023, https://www.commonwealthfund.org/publications/surveys/2023/oct/paying-for-it-costs-debt-americans-sicker-poorer-2023-affordability-survey?check_logged_in=1&utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top.

[5] "National Health Expenditure Data," CMS, last modified 12/13/23, https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet#:~:text=NHE%20grew%204.1%25%20to%20%244.5,18%20percent%20of%20total%20NHE.

[6] Mykyta L, Cohen RA. Characteristics of adults aged 18–64 who did not take medication as prescribed to reduce costs: United States, 2021. *NCHS Data Brief*. 2023;(470). doi:10.15620/cdc:127680.

negotiated prices after 2016, *growing 5.8 percent annually* while negotiated prices remained flat."[7]



Copay Accumulator State Bans Lead to Lower Patient Costs & Greater Adherence

A recent study (see Attachment 3) conducted by Oxford PharmaGenesis examined the impact of copay accumulator adjustment program (CAAP) bans in five states (Arizona, Georgia, Illinois, Virginia, and West Virginia) and patient cost and adherence of autoimmune or multiple sclerosis drugs between January 1, 2017, and December 31, 2021. The study found that

> states that implemented a CAAP ban had relative reductions in patient liability after the first 2 months, which ranged from 41% to 63%, with monthly savings ranging from $128 to $520. Patients in states with a CAAP ban had 14% greater odds of being adherent to their treatment after policy implementation than patients in states without a CAAP ban and a 13% reduction in risk of discontinuing.

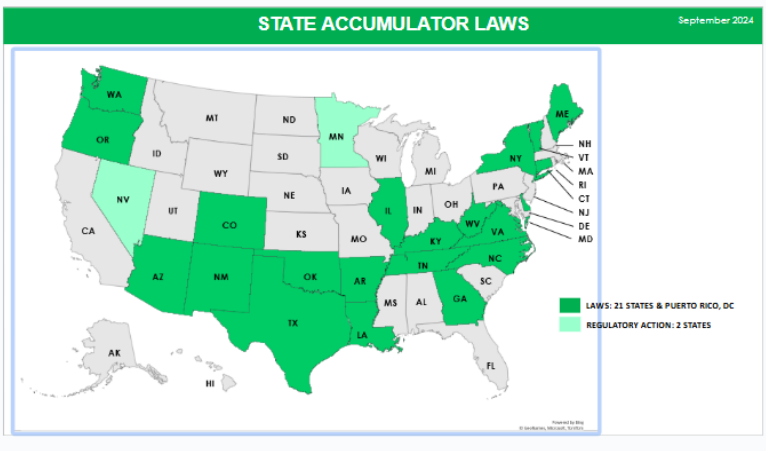
Looking at patient liability,

> in states without a CAAP ban increased from a range of $930 (January) to $88 (November) before the policy effective date to a range of $930 (January) to $103 (November) after the policy effective date. In contrast, in the states that implemented a CAAP ban, the mean monthly patient liability reduced from a range of $2,781 (January) to $303 (November) before the policy effective date to a range of $2,460 (January) to $164 (November) after the policy effective date. For states with a CAAP ban, relative reductions in patient liability were similar to those of states without a CAAP ban in January and February, whereas relative reductions were greater from March through December, ranging from 41% to 63% and monthly savings ranging from $128 to $520.[8]

[7] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2023.01344
[8] https://www.jmcp.org/doi/epdf/10.18553/jmcp.2024.30.9.909

Confusion in the States

While the federal government is allowing insurers and PBMs to implement copay accumulators, 21 states, Puerto Rico, and DC have banned them legislatively for state regulated plans. Two additional states, Nevada and Minnesota, require, as they should, plans to abide by the federal Court decision. This patchwork is creating great confusion throughout the country for patients, regulators, payers, and drug manufacturers and is another reason why the federal government should issue a rule requiring copay assistance to count.



<u>Covered Drugs Must be Included as Essential Health Benefits</u>

The federal government is finally taking steps to clamp down on insurers and employers that abuse the Affordable Care Act by covering drugs without including them as part of essential health benefits. We are pleased that CMS did codify in the *2025 Notice of Payment and Parameters Rule* the policy that prescription drugs covered in excess of the state's benchmark plan are to be considered essential health benefits (EHB) in the small group and individual markets, and therefore, are subject to EHB protections, including annual cost-sharing limits. However, it did not make the same clarification for the large group and self-funded markets but said it would do so in the future.

Unfortunately, the 2026 Proposed Rule failed to include that important clarification. In order to close this loophole, we urge the federal agencies to issue a rule that applies this same principle to all plans.

Due to the federal government's inaction, payers and vendors who use this scheme are able to continue to implement copay maximizers by exploiting copay assistance from drug manufacturers far in excess of the annual amount payers are entitled to.

In our comments on the proposed *2025 Notice of Benefits and Payment Parameters Rule*, we described how certain entities are working with employers and insurers to implement schemes that designate certain prescription drugs as "non-essential health benefits." The drugs selected just happen to be the ones whose manufacturers offer copay assistance. The copay assistance

does not accumulate toward the beneficiaries' deductible or out-of-pocket maximum and the vendors then extract all the copay assistance for themselves and split it with the payers. To accomplish this, they force the beneficiaries to sign up for copay assistance programs but if they do not, require them to pay a high cost, such as 30 percent co-insurance.

As we wrote last year, it is rather ironic that while there are entities (including insurers) that voice strong opposition to copay assistance, at the same time they are working with others that are taking advantage of the copay assistance programs and extracting as much as they can for themselves.

To make matters worse, the federal government is allowing these schemes to continue and grow.

While stopping the use of "non-EHB" schemes will end the practice of copay maximizers, doing so without also requiring copay assistance to count will force patients from copay maximizers into copay accumulators. This is because maximizers drain copay assistance from drug manufacturers while they set the copay at the level of the copay assistance which allows patients to pick up their drug without cost (although it does not apply to their deductible or out-of-pocket costs). As described in the patient scenarios above, accumulators have a much greater financial impact on patients. Therefore, it is necessary for the federal government to end the "non-EHB" loophole *and* make copay assistance count.

Also, in our comments last year, the **HIV+Hepatitis Policy Institute** provided many examples of the employers using these "non-EHB" schemes. Since then, we have updated that research and as of August 2024, we have identified 128 employers and 25 issuers that utilize outside vendors that designate certain drugs as "non-EHB" to evade ACA cost-sharing requirements (see Attachment 4). The list includes thirty private sector employers including the Bank of America, Chevron, Citibank, Hilton, Target and United Airlines; nine states such as Connecticut, Kentucky, and New Mexico; thirteen counties; five cities; eleven school districts and teacher retirement plans; 44 universities including Brown, Columbia, Dartmouth, Duke, Harvard, Loyola, Penn State, Texas A&M, and the University of California; and eleven unions including the New York Teamsters and the Screen Actors Guild. Our research also identified 25 issuers exploiting the EHB loophole, most of them part of the Blue Cross Blue Shield network in such states as Illinois, Massachusetts, Michigan, and Minnesota.

We also provided, in Attachment 5, a sample list of the "non-EHB" drugs that the vendor SaveOnSP selected for Network Health in Wisconsin. We also noted the many drugs selected that treat HIV and hepatitis.

Alternative Funding Programs (AFPs)

In addition to entities that designate "non-EHB drugs" in order to extract manufacturer copay assistance to implement a copay maximizer, there are other vendors that also use "non-EHB drug" designations to implement alternative funding programs. In these programs, patients who use certain medications are directed to enroll in an alternative program, which is not

insurance, in order to bypass ACA laws and regulations relative to patient cost-sharing limits and other patient protections. They then find alternative funding mechanisms to pay for the drugs. If the patient does not comply, they will be left paying the full cost of the drug.

In our comments on the 2025 proposed rule, we described in more detail some of these companies and how they work. We described that for alternative funding one vendor uses "manufacturer free programs, grants/charities, our International Mail Order Pharmacy partner, domestic wholesale pharmacy and occasionally a copay card." Another vendor forces patients to sign up for drug manufacturers patient assistance programs, which are free drug programs meant for people who are *uninsured*.

There are a growing number of other vendors that are working with insurers, employers, and PBMs around the country.

According to Laura Huff, vice president of Gallagher Research and Insights, at a presentation at Academy of Managed Care Pharmacy Nexus 2024, 5 percent of employers are using alternative funding programs. Huff also reported that in 2023, 64 percent of employers were not familiar or have not looked into them, but in 2024, 30 percent did look into them, but did not adopt them. While 5 percent are using them now, 7 percent are planning to implement them in the next two years.[9]

The impact on patients is profound. In a recent study published in the *Journal of Managed Care and Specialty Pharmacy* (see attachment 6) that sampled 227 patients who had to use AFPs, they found:

> Most patients (61% [136/223]) first heard of the AFP as part of their health benefit when trying to obtain their medication. Of 198 patients, 88% reported being stressed because of the medication coverage denial and the uncertainty of obtaining their medication. More than half of patients (54% [115/213]) reported being uncomfortable with the benefits manager from the AFP vendor. On average, patients reported waiting to receive their medication for 68.2 days (approximately 2 months); 24% (51/215) reported the wait for the medication worsened their condition and 64% (138/215) reported the wait led to stress and/or anxiety.[10]

The federal government must investigate and prohibit these harmful schemes.

We thank you for the opportunity to share these comments and look forward to working with you as you seek to make healthcare more affordable and accessible for more

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[9] https://www.managedhealthcareexecutive.com/view/use-of-copay-offset-programs-expected-to-rise-amcp-nexus-2024

[10] Wong, W.B., Yermilov, I., Dalglish, H., Bienvenu, L., James, J., Gibbs, S.N. (2024). A descriptive survey of patient experiences and access to specialty medicines with alternative funding programs. *Journal of Managed Care & Specialty Pharmacy, 30*(11), https://www.jmcp.org/doi/10.18553/jmcp.2024.30.11.1308.

Americans. Should you have any questions or comments, please feel free to contact me at cschmid@hivhep.org. Thank you very much.

Sincerely,

Carl E. Schmid II
Executive Director

Attachments (6)

Attachment 1

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HIV AND HEPATITIS POLICY INSTITUTE et al.,
Plaintiffs,
v.
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES et al.,
Defendants.

Civil Action No. 22-2604 (JDB)

MEMORANDUM OPINION

Plaintiffs, three individuals and three patient advocacy groups, challenge a rule promulgated by defendants, the U.S. Department of Health and Human Services ("HHS"), its component agency the Centers for Medicare and Medicaid Services ("CMS"), and the leadership of those agencies (collectively, the "agencies"). This rule affirmatively permits, but does not require, health insurance issuers and group health plans (collectively, "insurers") to decline to credit certain financial assistance provided to patients by drug manufacturers when calculating whether those patients have met their cost-sharing obligations under the Affordable Care Act. See Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans, 85 Fed. Reg. 29164, 29230–35, 29261 (May 14, 2020) (codified at 45 C.F.R. § 156.130(h)) ("2021 NBPP").[1] Plaintiffs allege that the rule conflicts with the Affordable Care Act's statutory definition of "cost sharing," conflicts with the agencies' preexisting regulatory definition of "cost sharing," and is arbitrary and capricious.

[1] The full "Notice of Benefit and Payment Parameters for 2021" spans ninety-nine pages in the Federal Register. References to the "2021 NBPP" throughout this opinion are only to the portion challenged by plaintiffs.

Before the Court are the parties' cross-motions for summary judgment. For the reasons that follow, the Court concludes that the 2021 NBPP must be set aside based on its contradictory reading of the same statutory and regulatory language and the fact that the agencies have yet to offer a definitive interpretation of this language that would support the rule. The Court will thus grant plaintiffs' motion, deny the agencies' cross-motion, and vacate the challenged rule.

Background

I. Statutory and Factual Background

In 2010, Congress enacted the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) ("ACA"), in an effort to "increase the number of Americans covered by health insurance and decrease the cost of health care." Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519, 538 (2012). Among its various provisions, the ACA sets an annual cap on the amount that insurers can require insured individuals to pay out of pocket for their medical expenses. See 42 U.S.C. § 18022(c)(1); see also id. § 300gg-6(b); 2021 NBPP, 85 Fed. Reg. at 29229 (setting cost-sharing cap for 2021 at $8,550 for individual plans and $17,100 for family plans). Once this annual "cost sharing" cap is reached, the insurer is solely responsible for covering the insured individual's remaining medical expenses that year. See 42 U.S.C. § 18022(c)(1). The statute defines "cost sharing" as follows:

> The term "cost-sharing" includes—(i) deductibles, coinsurance, copayments, or similar charges; and (ii) any other expenditure required of an insured individual which is a qualified medical expense (within the meaning of section 223(d)(2) of Title 26) with respect to essential health benefits covered under the plan.

Id. § 18022(c)(3)(A).

A deductible is "the portion of the loss [under an insurance policy] to be borne by the insured before the insurer becomes liable for payment." Deductible, Black's Law Dictionary (9th ed. 2009). Coinsurance is "[i]nsurance under which the insurer and insured jointly bear

responsibility." Coinsurance, id. And a copayment is "[a] fixed amount that a patient pays to a healthcare provider according to the terms of the patient's health plan." Copayment, id. Copayments are typically low, flat fees required when picking up a prescription drug or accessing medical care, while coinsurance payments are assessed as a percentage of the overall cost and thus may be much higher. See Pls.' Mem. Supp. Summ. J. [ECF No. 13-1] ("Pls.' Mot.") at 4 n.2 (citing public-facing agency guidance).

Some drug manufacturers offer direct "manufacturer assistance"—financial support to patients to pay for specific prescription drugs. See, e.g., 2021 NBPP, 85 Fed. Reg. at 29230. In one common setup, a drug manufacturer may provide a patient with a coupon that, when presented to a pharmacy or other point of sale, directs the pharmacy to bill all or part of the patient's copayment or coinsurance obligations to the drug manufacturer instead of the patient. See id. at 29234 (providing example of patient paying a $50 copay with $30 cash and a $20 coupon); Admin. R. App. [ECF No. 40-2] ("AR") at 2790–91 (describing the typical billing process as (1) the pharmacy submitting an electronic claim to the insurer for the drug, (2) the insurer processing the claim and sending a response indicating what portion of the payment is to be paid by the patient as cost-sharing, (3) the pharmacy billing the third-party assistance provider for all or part of that cost-sharing obligation, and (4) the patient paying any remaining balance); id. at 2768–69 ("The pharmacy receives the same payment it would for each drug dispensed, regardless of whether cost-sharing assistance is applied."). Other direct manufacturer assistance programs include "pre-paid debit cards for the payment of cost-sharing . . . and cash or check reimbursement to patients for their cost-sharing for a specific drug." AR at 2270 n.4; see id. at 2791 (similar). The through-line is some payment by the drug manufacturer to subsidize the patient's purchase of the drug at the

point of sale. See, e.g., id. at 2790–91; see also id. at 2270 n.4 (comment from national insurers' organization describing these programs as "funded by drug manufacturers").

Supporters of manufacturer assistance argue that these programs help patients—particularly those suffering from rare or costly conditions—afford drugs, which improves health outcomes by promoting adherence to existing medication regimens. See, e.g., 2021 NBPP, 85 Fed. Reg. at 29234; AR at 3569–71. Critics contend that manufacturer assistance can be used by drug manufacturers to artificially inflate demand for their drugs, thus distorting the market and increasing overall healthcare costs. See, e.g., 2021 NBPP, 85 Fed. Reg. at 29234; AR at 2271–72.

In response to manufacturer assistance, some insurers have instituted "copay accumulator" programs. Under these programs, patients are still able to utilize manufacturer assistance to pay for medications, but the value of this assistance is not credited toward patients' deductibles and annual cost-sharing maximums. See, e.g., 2021 NBPP, 85 Fed. Reg. at 29233. Take this stylized example, with assumptions of a $6,000 cost-sharing maximum, $4,000 in manufacturer assistance available, and a $2,000 monthly drug cost:

	Without Copay Accumulator		With Copay Accumulator	
Month	Paid by Patient	Paid by Mfr. Assistance	Paid by Patient	Paid by Mfr. Assistance
January	$0	$2,000	$0	$2,000
February	$0	$2,000	$0	$2,000
March	$2,000	$0	$2,000	$0
April	$0	$0	$2,000	$0
May	$0	$0	$2,000	$0
Rest of Year	$0	$0	$0	$0
Total	**$2,000**	**$4,000**	**$6,000**	**$4,000**

Cf. AR at 1348 (providing similar example). With the copay accumulator program, the patient pays $4,000 more—the value of the non-credited manufacturer assistance—before reaching the $6,000 cost-sharing cap and having the insurer cover all costs for the remainder of the year. The

insurer thus collects $10,000 in cost-sharing payments as opposed to the $6,000 it would have collected in the absence of the copay accumulator.

II. Regulatory Background

Prior to 2019, the agencies had not directly addressed the permissibility of copay accumulator programs. See 2021 NBPP, 85 Fed. Reg. at 29232 (noting that prior to the 2019 rulemaking, "federal rules did not explicitly state whether issuers and group health plans had the flexibility to determine how to factor in direct drug manufacturer support amounts towards the annual limitation on cost sharing"). The agencies had, however, defined the term "cost sharing" by regulation as follows:

> Cost sharing means any expenditure required by or on behalf of an enrollee with respect to essential health benefits; such term includes deductibles, coinsurance, copayments, or similar charges, but excludes premiums, balance billing amounts for non-network providers, and spending for non-covered services.

45 C.F.R. § 155.20; see Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers, 77 Fed. Reg. 18310, 18445 (March 27, 2012) ("2012 Rule").

In April 2019, the agencies published the following rule regarding copay accumulators:

> Notwithstanding any other provision of this section, and to the extent consistent with state law, amounts paid toward cost sharing using any form of direct support offered by drug manufacturers to enrollees to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have an available and medically appropriate generic equivalent are not required to be counted toward the annual limitation on cost sharing (as defined in paragraph (a) of this section).

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020, 84 Fed. Reg. 17454, 17568 (April 25, 2019) (codified at 45 C.F.R. § 156.130(h); version effective from June 24, 2019 to July 12, 2020) ("2020 NBPP"). In the preamble to the rule, the agencies explained that it was motivated by the market-distortive effect of manufacturer assistance

when a less expensive generic drug is available and expressed the view that "the overall intent of the [ACA] was to establish annual limitations on cost sharing that reflect the actual costs that are paid by the enrollee." Id. at 17544.

In response to commenters who recommended that all manufacturer assistance be excluded from counting toward the cost-sharing limit, the agencies explained that the rule was specifically intended to address market distortion in the generic-drug context and that "[w]here there is no generic equivalent available or medically appropriate, it is less likely that the manufacturer's coupon would disincentivize a lower cost alternative and thereby distort the market." Id. at 17545. The agencies further stated:

> Where there is no generic equivalent available or medically appropriate . . . amounts paid toward cost sharing using any form of direct support offered by drug manufacturers must be counted toward the annual limitation on cost sharing. We have added language to the regulation text to address this clarification.

Id. (emphasis added). But no such language was in fact added to the text of the final regulation. Compare Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020, 84 Fed. Reg. 227, 290–91 (proposed Jan. 24, 2019) ("Proposed 2020 NBPP"), with 2020 NBPP, 84 Fed. Reg. at 17568.

In short order, the agencies received "feedback . . . indicat[ing] there [was] confusion about whether the 2020 NBPP Final Rule require[d] plans and issuers to count the value of drug manufacturers' coupons toward the annual limitation on cost sharing, other than in circumstances in which there is a medically appropriate generic equivalent available." AR at 4320. The agencies, along with the Departments of Labor and the Treasury, issued a guidance document in August 2019 acknowledging this confusion. See id. at 4319–21. The guidance document also explained that, if read to apply outside the generic-drug context, the 2020 NBPP might conflict with certain IRS guidance regarding high deductible health plans. Id. at 4320. The agencies noted their intent

to address this issue in the 2021 NBPP and explained that, until then, they "[would] not initiate an enforcement action if an [insurer] excludes the value of drug manufacturers' coupons from the annual limitation on cost sharing, including in circumstances in which there is no medically appropriate generic equivalent available." Id. at 4321; see id. at 4320–21.

In May 2020, the agencies published the 2021 NBPP regulation at issue in this case:

> Notwithstanding any other provision of this section, and to the extent consistent with State law, amounts paid toward reducing the cost sharing incurred by an enrollee using any form of direct support offered by drug manufacturers for specific prescription drugs may be, but are not required to be, counted toward the annual limitation on cost sharing, as defined in paragraph (a) of this section.

2021 NBPP, 85 Fed. Reg. at 29261 (emphasis added); see 45 C.F.R. § 156.130(h). The preamble to the rule explained that it was motivated by the "confusion" engendered by the 2020 NBPP, the potential conflict with IRS guidance, and the desire to provide insurers with "flexibility." 2021 NBPP, 85 Fed. Reg. at 29231. The agencies stressed that the 2021 NBPP was intended to leave insurers "free to continue longstanding policies" and that the agencies "[did] not require and are not directing [insurers] to any specific practice with regards to how [manufacturer assistance is] treated with respect towards accumulators." Id. at 29233; see also, e.g., id. at 29232 ("[Insurers] need not make changes to how they have historically handled direct drug manufacturer support amounts.").

In the notice of proposed rulemaking for the 2021 NBPP, the agencies had "proposed to interpret the definition of cost sharing to exclude expenditures covered by drug manufacturer coupons." Id. at 29231; see also Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans, 85 Fed. Reg. 7088, 7136 (proposed Feb. 6, 2020). The agencies opted not to finalize this proposed interpretation, due at least in part to commenters who argued that the interpretation was

inconsistent with the existing regulatory definition of "cost sharing" at 45 C.F.R. § 155.20. See 2021 NBPP, 85 Fed. Reg. at 29230, 29234. Instead, the agencies concluded that "the term 'cost sharing' is subject to interpretation":

> For [health insurance] issuers who elect to include these amounts towards a consumer's annual limitation on cost sharing, the value of direct drug manufacturer support would be considered part of the overall charges incurred by the enrollee. For [health insurance] issuers who elect to not count these amounts towards the consumer's annual limitation on cost sharing, the value of the direct drug manufacturer support would be considered a reduction in the amount that the enrollee incurs or is required to pay.

Id. at 29234.

The agencies also responded to other comments expressing concern about aspects of the rule. As to the purported conflict with IRS guidance, the agencies explained their reasoning as to why this conflict "may exist." Id. at 29233. As to comments questioning why the rule was limited to direct support provided by drug manufacturers (as opposed to other forms of third-party support, such as amounts raised via crowdfunding), the agencies explained that they "currently ha[d] no evidence" that these other types of support had "similar distortive effects." Id. at 29234. And as to comments expressing concern that the affirmative authorization of copay accumulators would increase patients' out-of-pocket costs, the agencies noted that this cost impact would be limited if insurers not currently utilizing copay accumulators "continue[d] their current behavior," which the agencies "believe[d] [would] be the case." Id. at 29232. The agencies "acknowledge[d] the possibility" that the 2021 NBPP might lead some insurers to adopt copay accumulator programs but concluded that they could not "project this burden with sufficient certainty." Id.

III. Procedural History

On August 30, 2022, the three organizational plaintiffs—the HIV and Hepatitis Policy Institute, the Diabetes Patient Advocacy Coalition, and the Diabetes Leadership Council—filed a

complaint challenging the 2021 NBPP and naming as defendants HHS, CMS, Xavier Becerra, in his official capacity as Secretary of HHS, and Chiquita Brooks-Lasure, in her official capacity as Administrator of CMS. Compl. [ECF No. 1]. The agencies moved to dismiss for lack of standing. Defs.' Mot. to Dismiss [ECF No. 8]. In response, plaintiffs filed an amended complaint adding three individual plaintiffs: Alyssa Dykstra, Katherine Mertens, and Cynthia Regan. Am. Compl. [ECF No. 10] ¶¶ 18–20.

On February 2, 2023, plaintiffs moved for summary judgment. Pls.' Mot. Plaintiffs advance three central arguments as to why the 2021 NBPP is unlawful and must be set aside. First, they argue that the 2021 NBPP conflicts with the ACA's statutory definition of "cost sharing" and that the new rule is not entitled to Chevron deference. See id. at 13–18. Second, plaintiffs contend that the 2021 NBPP "clashes even more starkly" with the agencies' preexisting regulatory definition of "cost sharing" at 45 C.F.R. § 155.20. Id. at 18; see id. at 18–21. Third, plaintiffs offer a host of reasons why the 2021 NBPP is arbitrary and capricious: (1) it gives the same statutory and regulatory language different meanings, (2) the "sole justification" for the rule is based on an erroneous view of the law, (3) the rule's analysis of costs to patients is irrational, (4) the agencies failed to explain their "reversal" from the 2020 NBPP and failed to take reliance interests on that earlier rule into account, and (5) the rule treats similarly situated cases differently without adequate justification. See id. at 21–38.

The agencies filed a cross-motion for summary judgment and opposed plaintiffs' motion. Defs.' Mem. Supp. Cross-Mot. Summ. J. & Opp'n to Pls.' Mot. [ECF No. 27-1] ("Defs.' Mot."). The agencies argue that the 2021 NBPP is not reviewable both because it is not "final agency action," 5 U.S.C. § 704, and because it is "agency action committed to agency discretion by law," id. § 701(a)(2). Defs.' Mot. at 12–16. They further contend that each of plaintiffs' challenges

lacks merit. See id. at 16–38. And the agencies assert that, even if the Court ultimately sets aside the 2021 NBPP as arbitrary and capricious, it should decline to interpret the statutory definition of "cost sharing" in the first instance. See id. at 39.

Plaintiffs filed a combined reply in support of their motion and opposition to the agencies' cross-motion, Reply Supp. Pls.' Mot. & Opp'n to Defs.' Cross-Mot. [ECF No. 32] ("Pls.' Reply"), and the agencies filed a reply in support of their cross-motion, Reply Supp. Defs.' Cross-Mot. [ECF No. 38] ("Defs.' Reply"). The Court also received three amicus curiae briefs supporting plaintiffs—one from Aimed Alliance and other healthcare policy and patient advocacy organizations, one from drug assistance coupon administrator TrialCard Incorporated, and one from Pharmaceutical Research and Manufacturers of America—and an amicus curiae brief supporting the agencies from America's Health Insurance Plans, Inc.

Both motions are now fully briefed and ripe for decision.

Legal Standard

A moving party is entitled to summary judgment where it shows "that there is no genuine dispute as to any material fact and [that it] is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In an Administrative Procedure Act ("APA") challenge such as this, the "'entire case' . . . is a question of law," Am. Bioscience, Inc. v. Thompson, 269 F.3d 1077, 1083 (D.C. Cir. 2001), and "[s]ummary judgment is the proper mechanism for deciding, as a matter of law, whether an agency action is supported by the administrative record and consistent with the APA standard of review," Hosp. for Special Surgery v. Becerra, Civ. A. No. 22-2928 (JDB), 2023 WL 5448017, at *4 (D.D.C. Aug. 24, 2023) (quoting Styrene Info. & Rsch. Ctr., Inc. v. Sebelius, 944 F. Supp. 2d 71, 77 (D.D.C. 2013)). Under the APA, a reviewing court will set aside final agency action that

is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); see id. § 704.

Analysis

I. Justiciability

A. Standing

The agencies concede that at least one of the individual plaintiffs added in plaintiffs' amended complaint has standing because she "takes a biologic medication . . . that currently has no generic equivalent." Defs.' Mot. at 10 n.1; see Am. Compl. ¶¶ 20, 81–82; Regan Decl. [ECF No. 13-4] ¶ 3. This plaintiff, Cynthia Regan, attests that due to her insurer's copay accumulator, manufacturer assistance she utilized in both 2022 and 2023 was not credited toward her cost-sharing maximum and she was required to pay additional money out of pocket before reaching the maximum. Regan Decl. ¶¶ 4–9.

To establish standing, "a plaintiff must show (i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief." TransUnion LLC v. Ramirez, 141 S. Ct. 2190, 2203 (2021). Here, the monetary harm suffered by Regan is a quintessential injury in fact. See id. at 2204. The agencies' authorization of the insurer's conduct satisfies the causation element, because "injurious private conduct is fairly traceable to the administrative action contested in the suit if that action authorized the conduct or established its legality." Animal Legal Def. Fund, Inc. v. Glickman, 154 F.3d 426, 441 (D.C. Cir. 1998) (en banc) (quoting Tel. & Data Sys., Inc. v. F.C.C., 19 F.3d 42, 47 (D.C. Cir. 1994)); see also, e.g., Consumer Fed'n of Am. v. F.C.C., 348 F.3d 1009, 1012 (D.C. Cir. 2003). And "[i]t follows that the injury is also redressable." Consumer Fed'n of Am., 348 F.3d at 1012. Even assuming the

2020 NBPP does not prohibit the challenged conduct—such that vacatur of the 2021 NBPP would render the conduct unregulated as opposed to unlawful—"[o]n remand, the [agencies] could adopt [plaintiffs'] position and force [insurers] to change [their] practices." Id. While "remand would not entitle [plaintiffs] to such relief, it 'would constitute a necessary first step.'" Id. (some internal quotations omitted) (quoting Tel. & Data Sys., Inc., 19 F.3d at 47).

Hence, Regan has standing. Because she does, the Court "need not consider the standing of the other plaintiffs." Carpenters Indus. Council v. Zinke, 854 F.3d 1, 9 (D.C. Cir. 2017) (quoting Mountain States Legal Found. v. Glickman, 92 F.3d 1228, 1232 (D.C. Cir. 1996)).[2]

B. Administrative Reviewability

The agencies argue that the 2021 NBPP is unreviewable either as agency action that is not "final," 5 U.S.C. § 704, or as "agency action committed to agency discretion by law," id. § 701(a)(2). Neither contention is ultimately persuasive.

Under the APA, judicial review is limited to "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. To be "final," agency action must generally meet two requirements: (1) it "must mark the consummation of the agency's decisionmaking process" rather than being "of a merely tentative or interlocutory nature" and (2) it "must be one by which rights or obligations have been determined, or from which legal consequences will flow." U.S. Army Corps of Eng'rs v. Hawkes Co., 578 U.S. 590, 597 (2016) (quoting Bennett v. Spear, 520 U.S. 154, 177–78 (1997)). The agencies concede that the first of these requirements is met. Defs.' Mot. at 12.

[2] The agencies moved to dismiss plaintiffs' original complaint for lack of standing. Plaintiffs have since filed the amended complaint adding Dykstra, Mertens, and Regan as individual plaintiffs. The Court will thus deny the motion to dismiss as moot. See, e.g., Bowe-Connor v. Shinseki, 923 F. Supp. 2d 1, 3 n.1 (D.D.C. 2013).

The agencies argue that the second requirement is not satisfied because the 2021 NBPP "is essentially a decision to decline to set rules" and "does not require regulated entities to make any changes to prior practices or impose any consequences on the choices regulated parties make in this regard." Id. at 12–13. They highlight the rule preamble's explanation that regulated parties "need not make changes," remain free to "continue longstanding policies," and are afforded "flexibility." Id. at 13 (quoting 2021 NBPP, 85 Fed. Reg. at 29231–32). And they invoke case law noting that this requirement is commonly met where an agency action "impose[s] 'obligations, prohibitions or restrictions on regulated entities'" or subjects them to "the risk of 'significant criminal and civil penalties'"—conditions that are not present here. Id. (quoting Sierra Club v. Env't Prot. Agency, 955 F.3d 56, 63 (D.C. Cir. 2020)); see also, e.g., Nat'l Min. Ass'n v. McCarthy, 758 F.3d 243, 252 (D.C. Cir. 2014).

The agencies are correct, but only to a point. They miss an important strand of case law: agency action may also have "legal consequences" (and thus be final) where it meaningfully circumscribes regulators' discretion and affords a safe harbor to regulated parties. See Scenic Am., Inc. v. United States Dep't of Transp., 836 F.3d 42, 56 (D.C. Cir. 2016) (concluding that guidance memorandum had legal consequences, and thus was final agency action, because it "withd[rew] some of the discretion . . . [regulators] previously held," thus "creat[ing] a safe harbor" such that the agency could not disapprove of conduct authorized by the memorandum); see also, e.g., POET Biorefining, LLC v. Env't Prot. Agency, 970 F.3d 392, 405 (D.C. Cir. 2020) ("The Guidance carries legal consequences because it withdraws some of the discretion [a prior rule] afforded EPA . . . ."); cf. Cal. Cmtys. Against Toxics v. Env't Prot. Agency, 934 F.3d 627, 637–38 (D.C. Cir. 2019) (distinguishing case from the "circumstance where the action at issue may be legally consequential because its binds agency staff").

Here, the 2021 NBPP affirmatively authorizes the use of copay accumulator programs. See 85 Fed. Reg. at 29261. In so doing, it bars the agencies from instituting enforcement actions against insurers who utilize these programs so long as the rule is in effect. This "legal consequence[]" satisfies Bennett's second requirement, and thus the 2021 NBPP is a final agency action. Hawkes Co., 578 U.S. at 597 (quoting Bennett, 520 U.S. at 178).

The fact that the 2021 NBPP was published in the Code of Federal Regulations ("CFR") following notice and comment reinforces this conclusion. While publication in the CFR is not dispositive in the finality inquiry, see Am. Tort Reform Ass'n v. Occupational Safety & Health Admin., 738 F.3d 387, 394 (D.C. Cir. 2013), it is another indicator that the rule has legal effect and thus constitutes final agency action, see Ass'n of Flight Attendants-CWA, AFL-CIO v. Huerta, 785 F.3d 710, 717 (D.C. Cir. 2015); see also 44 U.S.C. § 1510(a) (designating for publication in the CFR "documents . . . having general applicability and legal effect").

The agencies also argue that the 2021 NBPP is unreviewable because it is "agency action . . . committed to agency discretion by law." 5 U.S.C. § 701(a)(2). They contend that the rule "represents an exercise of [their] discretion not to regulate in certain situations," Defs.' Mot. at 15, and that the Court has "no meaningful standard against which to judge [this] exercise of discretion," id. (quoting Webster v. Doe, 486 U.S. 592, 600 (1988)). But, as plaintiffs observe and as discussed above, the 2021 NBPP is not merely a decision not to regulate. See Pls.' Reply at 7. Rather, it affirmatively authorizes two courses of conduct and permits regulated parties to choose between them. Plaintiffs are not challenging the agencies' decision whether or not to regulate, but rather the product of the agencies' decision to regulate. And as to the agencies' affirmative authorization of copay accumulators, there is clearly a "meaningful standard" against which to

judge the action's legality: the statutory and regulatory definitions of "cost sharing," as well as the APA's well-established arbitrary and capricious test.

The Court thus concludes that the 2021 NBPP is reviewable under the APA.

II. Merits

Plaintiffs contend that the 2021 NBPP must be vacated because (1) it conflicts with the ACA's statutory definition of "cost sharing," (2) it conflicts with the agencies' preexisting regulatory definition of "cost sharing," and (3) it is arbitrary and capricious for a variety of reasons, including that it defines the same statutory and regulatory language in two conflicting ways. As discussed below, the Court will set aside the 2021 NBPP based on both its contradictory reading of the same statutory and regulatory language and the fact that the agencies have yet to offer a definitive interpretation of this language that would support their authorization of copay accumulators. The Court declines to reach plaintiffs' remaining arguments as to why the 2021 NBPP is arbitrary and capricious.

A. Contradictory Textual Interpretation

The agencies have yet to adopt a single interpretation of either the statutory or regulatory definition of "cost sharing" as applied to manufacturer assistance. See 2021 NBPP, 85 Fed. Reg. at 29234. Rather, the 2021 NBPP authorizes insurers to either count, or not count, such assistance "toward the annual limitation on cost sharing"—that is, to treat it as either within or without the definitions of "cost sharing." Id. at 29261. The agencies justified these dual authorizations based on two different, and contradictory, readings of the same statutory and regulatory text:

> For [health insurance] issuers who elect to include these amounts towards a consumer's annual limitation on cost sharing, the value of direct drug manufacturer support would be considered part of the overall charges incurred by the enrollee. For [health insurance] issuers who elect to not count these amounts towards the consumer's annual limitation on cost sharing, the value of the direct drug

> manufacturer support would be considered a reduction in the amount that the enrollee incurs or is required to pay.

Id. at 29234.

Plaintiffs challenge as arbitrary and capricious this interpretation of the same statutory and regulatory provisions as having two different meanings, to be chosen at the discretion of regulated parties. See Pls.' Mot. at 21; Pls.' Reply at 14–16. The Court agrees. The Supreme Court has rejected the "dangerous principle that . . . the same statutory text" can be given "different meanings in different cases." Clark v. Martinez, 543 U.S. 371, 386 (2005); accord United States v. Santos, 553 U.S. 507, 522–23 (2008) (plurality opinion); cf. Walter O. Boswell Mem'l Hosp. v. Heckler, 749 F.2d 788, 798–99 (D.C. Cir. 1984) (noting that "[i]t would be arbitrary and capricious for HHS to bring varying interpretations of the statute to bear" based "on mere expedience"). This is not a case where the agency has interpreted a term differently when it appears in different sections of a statute; here, the dueling authorizations are based on the very same provision. Cf. Verizon California, Inc. v. F.C.C., 555 F.3d 270, 276 (D.C. Cir. 2009).

The agencies offer little in the way of pushback to this conclusion, not even addressing the argument in their reply brief. They first assert that they "are permitted to promulgate regulations interpreting ambiguous statutes without having to resolve all possible ambiguity." Defs.' Mot. at 25 (quoting Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives, 920 F.3d 1, 34 (D.C. Cir. 2019)). But the issue here is not that the agencies have not yet definitively interpreted the definition of "cost sharing": it is that they have authorized two courses of conduct based on two fundamentally contradictory readings of that definition. The agencies also generally invoke the importance of choice in the health insurance context and the role of state-level regulation, and claim that the 2021 NBPP "merely extends this provision of choice to the question of whether to

count manufacturer financial assistance as cost sharing." Id. at 26. Again, this is not responsive to the fact that the rule rests on contradictory interpretations of the same text.

Hence, the Court concludes that the 2021 NBPP is arbitrary and capricious in its authorization of conduct (at the insurer's choice) based on contradictory interpretations of the same statutory and regulatory provisions and must be set aside on that basis.

B. Statutory Definition

Plaintiffs urge the Court to conclude that the ACA's definition of "cost sharing" unambiguously encompasses manufacturer assistance. See Pls.' Mot. at 13–18. The agencies, for their part, do not offer a preferred interpretation of the statute but rather defend their prior conclusion that the statute is ambiguous. See Defs.' Mot. at 16–23. The agencies concede that, because they have not offered an authoritative interpretation of the statute, Chevron "step two" deference is not warranted. Defs.' Mot. at 23 n.2; see also Pls.' Mot. at 17.

In assessing whether the statutory language is ambiguous—such that remand to the agencies to interpret it in the first instance would be warranted—the Court begins, as it must, with the text. See, e.g., Bartenwerfer v. Buckley, 143 S. Ct. 665, 671 (2023). The ACA defines "cost sharing" as follows:

> The term "cost-sharing" includes—(i) deductibles, coinsurance, copayments, or similar charges; and (ii) any other expenditure required of an insured individual which is a qualified medical expense (within the meaning of section 223(d)(2) of Title 26) with respect to essential health benefits covered under the plan.

42 U.S.C. § 18022(c)(3)(A). This definition does not expressly speak to the treatment of manufacturer assistance, so the Court will employ the traditional tools of statutory construction.

The Court will interpret the three enumerated terms in the first clause in light of their "plain meaning at the time of enactment." Tanzin v. Tanvir, 141 S. Ct. 486, 491 (2020). Both parties cite Black's Law Dictionary as reflective of this meaning. See Pls.' Mot. at 14; Defs.' Mot. at 19.

This analysis yields competing inferences. On the one hand, Black's defines "deductible" as "the portion of the loss to be borne by the insured." Deductible, Black's Law Dictionary (9th ed. 2009) (emphasis added). This language is most naturally read as speaking to "loss"—i.e., costs—actually "borne" by the insured herself. Such a reading is reinforced by the definition of "copayment" as "[a] fixed amount that a patient pays to a healthcare provider." Copayment, id. (emphasis added). On the other hand, Black's defines "coinsurance" as "[i]nsurance under which the insurer and insured jointly bear responsibility." Coinsurance, id. (emphasis added). This lends support to plaintiffs' central argument that these terms and the overall statutory definition of "cost sharing" speak only to "the legal responsibility for payment, not where the insured gets the money to satisfy that responsibility." Pls.' Mot. at 14. The phrase "any other expenditure required of an insured individual" in the second statutory clause—which plaintiffs argue should read back to define the terms in the first clause—also supports this theory. Id. (citing Dong v. Smithsonian Inst., 125 F.3d 877, 880 (D.C. Cir. 1997)); see id. at 14–15; Pls.' Reply at 11.

Plaintiffs also argue that the second clause's definition of the other types of expenditures that count toward "cost sharing" supports their position. The clause cross-references 26 U.S.C. § 223(d)(2), which defines "qualified medical expenses," in relevant part, as amounts paid for medical care "but only to the extent such amounts are not compensated for by insurance or otherwise." Id. (emphasis added). Plaintiffs argue that the presence of this limitation (which would presumably exclude manufacturer assistance) in the second clause but not the first clause evinces Congress's intent that the first clause of the definition not be so limited. Pls.' Mot. at 15. Plaintiffs are correct that when "'Congress includes particular language in one section of a statute but omits it in another section' . . . [courts] generally take the choice to be deliberate." Bartenwerfer, 143 S. Ct. at 673 (quoting Badgerow v. Walters, 142 S. Ct. 1310, 1318 (2022)). But

this exclusionary presumption "is not absolute": "[c]ontext counts, and it is sometimes difficult to read much into the absence of a word that is present elsewhere in a statute." Id. "The more apparently deliberate the contrast, the stronger the inference." Field v. Mans, 516 U.S. 59, 75 (1995). Here, the potentially limiting language is present in a cross-reference to another statute, weakening the inference. And there is also a tension inherent in plaintiffs' argument: they argue that the "required of" language in the second clause must reflect back on the terms in the first clause, but offer no explanation as to why, under that logic, the limiting language from § 223(d)(2) should not also reflect back.

To add to the mix, the agencies contend that manufacturer assistance may not even be a "cost" within the statutory definition in the first place, because "the value of the direct drug manufacturer support could be viewed as not representing costs incurred by or charged to enrollees" but rather "a reduction . . . in the amount that the enrollee is required to pay . . . to obtain the drug." Defs.' Mot. at 17 (quoting 2021 NBPP, 85 Fed. Reg. at 29234); see also Defs.' Reply at 3–4.

Finally, plaintiffs contend that "the patient-benefitting purpose of the ACA" should serve as "an interpretive tie-breaker." Pls.' Reply at 10 n.4. But while benefiting individual patients is no doubt one purpose of the statute, the statute was also intended to "decrease the cost of health care." Nat'l Fed'n of Indep. Bus., 567 U.S. at 538. And the agencies undertook the 2021 NBPP rulemaking in part due to concern that manufacturer assistance may distort the market and "add significant long-term costs to the health care system." 2021 NBPP, 85 Fed. Reg. at 29234.

Having considered these arguments and the statutory text, the Court concludes that the ACA's definition of "cost sharing" does not speak clearly as to the treatment of manufacturer assistance. And "[i]n a suit challenging agency action, 'it is not for the court to choose between

competing meanings' of an ambiguous statute when the agency charged with its administration has not weighed in first." Teva Pharms. USA, Inc. v. Food & Drug Admin., 441 F.3d 1, 4 (D.C. Cir. 2006) (some internal quotations omitted) (quoting PDK Labs., Inc. v. D.E.A., 362 F.3d 786, 798 (D.C. Cir. 2004)); see also, e.g., Prill v. N.L.R.B., 755 F.2d 941, 942 (D.C. Cir. 1985); Hosp. of Barstow, Inc. v. N.L.R.B., 820 F.3d 440, 445 (D.C. Cir. 2016) (collecting cases).

The Court rejects plaintiffs' contention that this principle does not apply here. See Pls.' Reply at 24. While the agencies have offered potential interpretations of the statute, they have not made a final judgment between these competing meanings so as to "tee[] up" that interpretive question for the Court's review. Id. And while the original rationale for the doctrine—remand "when an agency incorrectly concludes that Congress mandated a particular regulatory interpretation of a statute"—is not implicated here, subsequent case law makes clear that the underlying principle applies more broadly. Noble Energy, Inc. v. Salazar, 671 F.3d 1241, 1246 n.5 (D.C. Cir. 2012); see also, e.g., Child.'s Hosp. & Rsch. Ctr. of Oakland, Inc. v. N.L.R.B., 793 F.3d 56, 59 (D.C. Cir. 2015).

Hence, the Court will vacate the 2021 NBPP and remand to permit the agencies to interpret the statutory definition in the first instance. Vacatur is appropriate here. An "inadequately supported rule . . . need not necessarily be vacated," because an "agency may be able to rehabilitate its rule on remand, and the consequences of vacatur 'may be quite disruptive.'" Shands Jacksonville Med. Ctr., Inc. v. Azar, 959 F.3d 1113, 1118 (D.C. Cir. 2020) (quoting Allied-Signal, Inc. v. U.S. Nuclear Regul. Comm'n, 988 F.2d 146, 150–51 (D.C. Cir. 1993)). But here, whatever interpretation the agencies adopt on remand cannot conceivably "rehabilitate" the 2021 NBPP, because the 2021 NBPP rests on two contradictory interpretations of the statute. Tellingly, the

agencies do not even argue for remand without vacatur. See Defs.' Mot. at 39; see generally Defs.' Reply.

C. Regulatory Definition

Building on their statutory arguments, plaintiffs contend that the 2021 NBPP must be set aside because its approval of copay accumulators "clashes even more starkly" with the agencies' preexisting regulatory definition of "cost sharing." Pls.' Mot at 18; see id. at 18–20; Pls.' Reply at 12–14. The Court agrees that, based on the arguments presented by the parties, the 2021 NBPP would conflict with the regulatory definition. But there are difficult interpretive questions as to this definition that were not raised by the parties.

"[A]n agency action may be set aside as arbitrary and capricious if the agency fails to 'comply with its own regulations.'" Nat'l Env't Dev. Ass'ns Clean Air Project v. E.P.A., 752 F.3d 999, 1009 (D.C. Cir. 2014) (quoting Environmentel, LLC v. F.C.C., 661 F.3d 80, 85 (D.C. Cir. 2011)); see also, e.g., Pol'y & Rsch., LLC v. U.S. Dep't of Health & Hum. Servs., 313 F. Supp. 3d 62, 67 (D.D.C. 2018). Here, the agencies defined "cost sharing" under the ACA by regulation as follows:

> Cost sharing means any expenditure required by or on behalf of an enrollee with respect to essential health benefits; such term includes deductibles, coinsurance, copayments, or similar charges, but excludes premiums, balance billing amounts for non-network providers, and spending for non-covered services.

45 C.F.R. § 155.20 (emphasis added). This regulation, enacted in 2012, predated the 2021 NBPP. See 2012 Rule, 77 Fed. Reg. at 18445.

Both parties appear to read the regulation as defining cost sharing as an "expenditure" by or on behalf of an enrollee. Pls. Mot. at 19; see Defs.' Mot. at 23–25 (not challenging plaintiffs' characterization). So read, the definition squarely encompasses manufacturer assistance: such assistance is an "expenditure" by drug manufacturers made "on behalf of an enrollee." 45 C.F.R.

§ 155.20; see Expenditure, Black's Law Dictionary (9th ed. 2009) ("A sum paid out."); Behalf, Black's Law Dictionary (11th ed. 2019) ("[O]n behalf of means 'in the name of, on the part of, as the agent or representative of.'"). The use of the term "any" lends further support to that conclusion. See, e.g., Lissack v. Comm'r, 68 F.4th 1312, 1320 (D.C. Cir. 2023) ("The Supreme Court has 'repeatedly explained' that 'the word "any" has an expansive meaning.'" (quoting Patel v. Garland, 142 S. Ct. 1614, 1622 (2022))).

The agencies' three rejoinders are not persuasive. First, the agencies argue that the 2021 NBPP's affirmative authorization of copay accumulators does not run afoul of this definition because the value of manufacturer assistance could "be viewed as representing a reduction, by drug manufacturers, in the amount that the enrollee is required to pay at the point of sale in order to obtain the drug." Defs.' Mot. at 24 (quoting 2021 NBPP, 85 Fed. Reg. at 29234). But regardless of whether manufacturer assistance represents a reduction in the amount a patient is required to pay (under the statutory definition), it would still be an "expenditure" by the drug manufacturer "on behalf of" that patient (under the regulatory definition).

The agencies further contend that the preexisting regulatory definition could be viewed as speaking to the "actual economic impact" on the drug manufacturer. Id. at 25. On this view, manufacturer assistance may be more easily characterized as a reduction in the price of the drug rather than a "cost" or an "expenditure" on behalf of a patient. But nothing in the regulatory definition indicates that "cost sharing" should be defined with reference to its underlying economic impact on third-party drug manufacturers. To the contrary, the text of the regulation—"any expenditure required by or on behalf of an enrollee"—makes clear that the locus of the inquiry is the patient. 45 C.F.R. § 155.20 (emphasis added). The statutory language—"any other

expenditure required of an insured individual"—is to the same effect. 42 U.S.C. § 18022(c)(3)(A) (emphasis added).

Finally, the agencies assert that manufacturer assistance "may not involve any 'expenditure[s]' on anyone's behalf" because "at least in some cases, the drug manufacturer may merely reduce the amount required to be paid by the purchaser." Defs.' Reply at 7. The agencies offer no factual support for this assertion regarding the mechanics of manufacturer assistance. And it is in tension with the 2021 NBPP and the administrative record, which indicate that manufacturer assistance involves a payment—an expenditure—by the drug manufacturer to a pharmacy or other point of sale. See, e.g., 2021 NBPP, 85 Fed. Reg. at 29234; AR at 2270 & n.4, 2768–69, 2790–91. But even accepting the agencies' premise, the 2021 NBPP would still conflict with the preexisting regulatory definition with respect to many forms of manufacturer assistance that do involve "expenditure[s]" by drug manufacturers.

Hence, on these arguments, the Court would conclude that the regulatory definition unambiguously requires manufacturer assistance to be counted as "cost sharing."

But the parties' reading is not the only, and perhaps not the best, literal reading of the text of the regulation. The Court agrees with the parties' implicit assumption that the likely intent of the regulation was to define "cost sharing" as costs that are (1) required of an enrollee and (2) paid by "or on behalf of" that enrollee. But that is not what the text of the regulation actually says. Instead, it defines cost sharing as "any expenditure required by or on behalf of an enrollee." 45 C.F.R. § 155.20. On the parties' reading, this means any expenditure either "required by" or "on behalf of" an enrollee. But an equally plausible reading of the language is any expenditure "required by" or "required . . . on behalf of" an enrollee.[3] This raises thorny questions about what

[3] Indeed, this may be the best reading of the words. See, e.g., Wronke v. Marsh, 787 F.2d 1569, 1574–75 (Fed. Cir. 1986) (concluding that, under rules of English grammar, the phrase "judicial proceedings resulting in an

it might mean for an expenditure to be "required"—whether by law, by an insurance plan, by contractual arrangement, or otherwise—"on behalf of" an enrollee. And there is a further wrinkle: the regulation defines cost sharing as an expenditure "required by" an enrollee, instead of the statutory "required of." It would be odd to think of the enrollee as the one "requiring" the expenditure, but that is what the word "by" implies. In sum, there are interpretive depths to this regulation that have yet to be plumbed.

These questions further support the Court's decision to remand to the agencies. Plaintiffs do not challenge this preexisting regulatory definition, and the parties have not briefed any of these questions. The Court will thus leave these questions to the agencies to grapple with in the first instance on remand.

D. Remaining Arguments

Because the Court will set aside the 2021 NBPP for the reasons stated above, it declines to reach plaintiffs' remaining arguments as to why the agencies acted arbitrarily and capriciously in promulgating the 2021 NBPP.[4]

acquittal based on the merits of the case or in an action having the same effect" must be read as "judicial proceedings resulting in an acquittal . . . or judicial proceedings resulting in an action having the same effect as an acquittal" (emphasis omitted)); cf. A. Scalia & B. Garner, Reading Law: The Interpretation of Legal Texts 147 (2012) ("When there is a straightforward, parallel construction that involves all nouns or verbs in a series, a prepositive . . . modifier normally applies to the entire series.").

[4] Plaintiffs' amended complaint seeks vacatur, a declaratory judgment, and an injunction. Am. Compl. at 28–29. In their summary judgment briefing, plaintiffs request only vacatur of the rule. Pls.' Mot. at 42; Pls.' Reply at 25. In light of that limited request and in the absence of any indication that the agencies will not abide by the Court's ruling, issuance of an injunction is not warranted at this juncture. See O.A. v. Trump, 404 F. Supp. 3d 109, 153–54 (D.D.C. 2019).

III. Conclusion

For the foregoing reasons, the Court will grant plaintiffs' motion for summary judgment and will deny the agencies' cross-motion for summary judgment.[5] An accompanying Order will issue on this date.

/s/
JOHN D. BATES
United States District Judge

Dated: September 29, 2023

[5] The Court will vacate the 2021 NBPP to the extent that it amends 42 C.F.R. § 156.130(h). See 85 Fed. Reg. at 29261. Should the agencies need further clarification as to what rule is in effect while they consider the matter on remand, they may seek guidance from the Court.

Attachment 2

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HIV AND HEPATITIS POLICY INSTITUTE et al.,
Plaintiffs,
v.
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES et al.,
Defendants.

Civil Action No. 22-2604 (JDB)

MEMORANDUM OPINION & ORDER

Plaintiffs, three individuals and three patient advocacy groups, challenged a rule promulgated by defendants, the U.S. Department of Health and Human Services ("HHS"), its component agency the Centers for Medicare and Medicaid Services, and the leadership of those agencies (collectively, the "agencies"). That rule, the "2021 NBPP," affirmatively permitted, but did not require, health insurance issuers and group health plans to decline to credit certain financial assistance provided to patients by drug manufacturers when calculating whether those patients have met their cost-sharing obligations under the Affordable Care Act. On September 29, 2023, this Court granted plaintiffs' motion for summary judgment, denied the agencies' cross-motion for summary judgment, vacated the challenged rule, and remanded the matter to the agencies. See HIV & Hepatitis Pol'y Inst. v. U.S. Dep't of Health & Hum. Servs., Civ. A. No. 22-2604 (JDB), 2023 WL 6388932 (D.D.C. Sept. 29, 2023) [ECF No. 42] ("SJ Op."); Summ. J. Order [ECF No. 41]. The agencies now move for clarification of the scope of the Court's decision. For the reasons that follow, the Court will grant the motion.

Background

The Court assumes familiarity with its prior opinion and the factual and procedural history set forth therein. As relevant here, the Court vacated the rule challenged by plaintiffs and remanded to the agencies for further consideration. Summ. J. Order; SJ Op. at *14.[1] The Court also noted that "[s]hould the agencies need further clarification as to what rule is in effect while they consider the matter on remand, they may seek guidance from the Court." SJ Op. at *14 n.5.

On November 27, 2023, the agencies filed a motion to clarify the scope of the Court's order. Defs.' Conditional Mot. to Clarify [ECF No. 43] ("Mot."). The agencies indicate their intent "to address, through rulemaking, the issues left open by the Court's opinion" and to refrain from "tak[ing] any enforcement action against issuers or plans based on their treatment of such manufacturer assistance" pending the issuance of a new final rule. Id. at 2. They seek to "clarif[y]" their understanding of the Court's decision as "vacat[ing] the relevant portion of the 2021 NBPP but . . . not order[ing] any additional relief." Id. In particular, they seek confirmation that the Court's order does not "require HHS to take enforcement action." Id.

The next day, the agencies filed a notice of appeal to the D.C. Circuit. Notice of Appeal [ECF No. 44].

On December 11, 2023, plaintiffs filed their own notice of appeal. Notice of Appeal [ECF No. 46]. They also opposed the agencies' motion to clarify. Pls.' Resp. to Mot. [ECF No. 47] ("Opp'n"). Plaintiffs argue that the Court's vacatur of the 2021 NBPP restores the prior rule and that the agencies' newly announced nonenforcement policy is unlawful. See id. at 3–10.

The agencies filed a reply in support of their motion, Defs.' Reply in Further Supp. of Mot. [ECF No. 49] ("Reply"), and plaintiffs filed a motion for leave to file a surreply, Mot. for Leave

[1] Citations to the Court's prior opinion follow the Westlaw pagination.

to File Surreply & Surreply [ECF No. 50]. The agencies have indicated that they oppose plaintiffs' motion for leave to file a surreply but will not file a separate opposition. Id. at 1. The agencies' motion to clarify is thus fully briefed and ripe for decision.

Legal Standard

"A 'motion for clarification' is not a formal creature of civil procedure; it appears nowhere in the Federal Rules." All. of Artists & Recording Cos. v. Gen. Motors Co., 306 F. Supp. 3d 413, 418 (D.D.C. 2016). Even so, courts generally "permit parties to tender motions that beseech the court 'to explain or clarify something ambiguous or vague' about a ruling." Id. (quoting United States v. Philip Morris USA, Inc., 793 F. Supp. 2d 164, 168 (D.D.C. 2011)). Such motions "have a limited role," and are not a proper vehicle for "seek[ing] to alter or modify the result" of the prior ruling. Steele v. United States, Civ. A. No. 14-1523 (RCL), 2023 WL 6215790, at *5 (D.D.C. Sept. 25, 2023) (quoting Sai v. Transp. Sec. Admin., Civ. A. No. 14-403 (RDM), 2015 WL 13889866, at *3 (D.D.C. Aug. 19, 2015)).

Analysis

I. Jurisdiction

The Court will first consider whether it has jurisdiction to entertain the agencies' request. Neither party disputes the Court's jurisdiction—plaintiffs address this issue briefly in a footnote, while the agencies do not address it at all. See Opp'n at 3 n.1; see generally Mot.; Reply.[2]

An appeal generally "divests the district court of its control over those aspects of the case involved in the appeal." Coinbase, Inc. v. Bielski, 143 S. Ct. 1915, 1919 (2023) (quoting Griggs v. Provident Consumer Discount Co., 459 U.S. 56, 58 (1982) (per curiam)); see also 16A Wright

[2] Because the Court will conclude that it has jurisdiction, it need not reach the question whether jurisdiction is waivable or forfeitable in this situation.

& Miller, Federal Practice and Procedure § 3949.1 (5th ed. April 2023 update) ("Wright & Miller").[3] However, this is "not a per se rule," but rather "a judicially crafted rule rooted in the interest of judicial economy, designed 'to avoid confusion or waste of time resulting from having the same issues before two courts at the same time.'" United States v. Rodgers, 101 F.3d 247, 251 (2d Cir. 1996) (quoting United States v. Salerno, 868 F.2d 524, 540 (2d Cir. 1984)). Hence, "its application is guided by concerns of efficiency and is not automatic." Id. District courts generally retain jurisdiction to act "in aid of the appeal," including by clarifying an ambiguity in the appealed-from decision. See, e.g., United States v. Viola, 555 F. App'x 57, 59–60 (2d Cir. 2014); Lytle v. Griffith, 240 F.3d 404, 407 n.2 (4th Cir. 2001); Barnstead Broad. Corp. v. Offshore Broad. Corp., 869 F. Supp. 35, 38–39 (D.D.C. 1994); see generally Wright & Miller. Applying that principle to the particular circumstances here—where the Court specifically invited the agencies to seek clarification if necessary, the agencies did so prior to noticing their appeal, the relief sought is clarification of ambiguity rather than a substantive alteration, and the appeal is still in its infancy—the Court concludes that it may properly consider the agencies' motion.

II. Merits

A. Effect of Vacatur of 2021 NBPP

The Court's prior decision vacated the 2021 NBPP but did not explicitly specify what rule was in effect on remand. See SJ Op. at *14 n.5; cf. id. at *6 (alluding to fact that prior rule would

[3] Had the agencies filed their motion to clarify within 28 days of entry of the Court's judgment, the Court could arguably have construed the motion as made under Federal Rule of Civil Procedure 59 or 60 so as to retain jurisdiction pending the disposition of the motion. Federal Rule of Appellate Procedure 4(a)(4)(B)(1) provides that "[i]f a party files a notice of appeal after the court . . . enters a judgment—but before it disposes of [certain timely post-judgment motions]—the notice becomes effective to appeal . . . when the order disposing of the last such remaining motion is entered." Fed. R. App. P. 4(a)(4)(B)(1). These post-judgment motions include timely filed motions under Federal Rules of Civil Procedure 59 and 60 (the latter if "filed within the time allowed for filing a motion under Rule 59"). Id. 4(a)(4)(A). The relevant time period under Rule 59 is 28 days. Fed. R. Civ. P. 59(b), (e). Here, however, the agencies filed their motion outside of this 28-day window so the motion cannot toll the effective date of their notice of appeal.

govern on remand). Clarification of this ambiguity is warranted. See, e.g., All. of Artists & Recording Cos., 306 F. Supp. 3d at 418.

The effect of vacatur is to "reinstate the rules previously in force." Georgetown Univ. Hosp. v. Bowen, 821 F.2d 750, 757 (D.C. Cir. 1987) (cleaned up) (quoting Action on Smoking & Health v. CAB, 713 F.2d 795, 797 (D.C. Cir. 1983)), aff'd, 488 U.S. 204 (1988); see also, e.g., Am. Great Lakes Ports Ass'n v. Zukunft, 301 F. Supp. 3d 99, 103–04 (D.D.C. 2018), aff'd sub nom. Am. Great Lakes Ports Ass'n v. Schultz, 962 F.3d 510 (D.C. Cir. 2020); Nat'l Parks Conservation Ass'n v. Jewell, 62 F. Supp. 3d 7, 21 (D.D.C. 2014). As the Court has previously noted, there is some tension in D.C. Circuit case law on this point. See AFL-CIO v. Chao, 496 F. Supp. 2d 76, 83 n.1 (D.D.C. 2007) (discussing Small Refiner Lead Phase-Down Task Force v. U.S. E.P.A., 705 F.2d 506, 545 (D.C. Cir. 1983)). But the weight of circuit precedent favors the reinstatement-on-vacatur principle, and this principle is also "consistent with the unanimous body of law from other circuits." Id. In any event, here the agencies never argued that vacatur did not restore the prior rule.

The prior (and thus reinstated) rule is the "2020 NBPP." See Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020, 84 Fed. Reg. 17454, 17568 (April 25, 2019) (previously codified at 45 C.F.R. § 156.130(h) from June 24, 2019 to July 12, 2020).[4] The Court expresses no view on plaintiffs' proffered interpretation of this rule. See Opp'n at 4–5.

[4] The Court agrees with plaintiffs' position (uncontested by the agencies) that, by its own terms, the nonenforcement policy announced in August 2019 expired upon issuance of the 2021 NBPP. See Opp'n at 5 n.2; Admin. Rec. [ECF No. 40-2] at 4321 ("Until the 2021 NBPP is issued and effective, the Departments will not initiate an enforcement action . . . .").

B. Nonenforcement Policy

The Court's prior decision vacated the 2021 NBPP. It did not purport to interpret the 2020 NBPP or to rule on the legality of any nonenforcement policy. And for good reason: these issues were not before the Court. Plaintiffs' amended complaint challenges only the 2021 NBPP. See Am. Compl. [ECF No. 10] at 28–29; see also, e.g., Reply Supp. Pls.' Mot. for Summ. J. & Opp'n to Defs.' Cross-Mot. [ECF No. 32] at 11 ("[T]he statutory validity of the pre-existing regulations [i.e., the 2020 NBPP] is simply not at issue in this case.").

Plaintiffs take issue with the agencies' apparent announcement, in their motion to clarify, of a new nonenforcement policy. See Mot. at 2; Opp'n at 6–9. The lawfulness of any such policy is not properly before the Court on the present motion to clarify. A ruling on this issue would go far beyond merely "clarify[ing] something ambiguous or vague" in the Court's prior decision. All. of Artists & Recording Cos., 306 F. Supp. 3d at 418 (quoting Philip Morris USA, Inc., 793 F. Supp. 2d at 168); see Steele, 2023 WL 6215790, at *5. Hence, the Court declines to reach this question, and expresses no view on it.

* * *

For the foregoing reasons, and upon consideration of the entire record herein, it is hereby

ORDERED that [50] plaintiffs' motion for leave to file a surreply is **GRANTED**; and it is further

ORDERED that [43] defendants' motion to clarify [41] [42] the Court's September 29, 2023 order and memorandum opinion is **GRANTED**.

/s/
JOHN D. BATES
United States District Judge

Dated: December 22, 2023

Patient liability, treatment adherence, and treatment persistence associated with state bans of copay accumulator adjustment programs

Achal Patel, PhD; Danny Sheinson, PhD; William B. Wong, PharmD, MS

Plain language summary

Drug companies and foundations help patients afford medications by covering their cost. However, some health insurance providers have copay accumulator adjustment programs (CAAPs) that do not allow this money to count against what patients owe for medication. This study found that in states that banned CAAPs, patients in most months paid 41%-63% less for their medicine. They were also more likely to keep taking their medicine correctly and less likely to stop taking it.

Implications for managed care pharmacy

The findings from this study offer insights on the impact of restricting the use of CAAP in states that have enacted legislation, as well as in states that may be considering implementing similar legislation in the future. Restricting the use of CAAPs may improve access to medication for patients in state-regulated plans, particularly those for whom high patient costs can be a barrier to remaining on treatment.

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J Manag Care Spec Pharm.
2024;30(9):909-16

ABSTRACT

BACKGROUND: Health insurers have increased the use of copay accumulator adjustment programs (CAAPs) to control costs; however, some states within the United States have banned the use of CAAPs to protect patients from rising out-of-pocket expenses.

OBJECTIVE: To assess the impact of state CAAP bans on patient liability, treatment adherence, and treatment persistence.

METHODS: This was a retrospective cohort study using administrative claims recorded in the IQVIA PharMetrics Plus database. Data were extracted for patients with fully insured commercial plans receiving autoimmune or multiple sclerosis drugs between January 1, 2017, and December 31, 2021. Patient liability was defined as the difference in insurer allowed and paid amounts. Treatment adherence was measured as the proportion of days covered over a 1-year period, with "adherent" defined as a proportion of days covered greater than or equal to 80%. Treatment persistence was defined as time from treatment initiation to discontinuation (a period of 60 days without supply of treatment). The analysis compared differences in outcomes in states that implemented a CAAP ban during the study period (Arizona, Georgia, Illinois, Virginia, West Virginia) with states that did not, for before and after the date of ban.

RESULTS: States that implemented a CAAP ban had relative reductions in patient liability after the first 2 months, which ranged from 41% to 63%, with monthly savings ranging from $128 to $520. Patients in states with a CAAP ban had 14% greater odds of being adherent to their treatment after policy implementation than patients in states without a CAAP ban and a 13% reduction in risk of discontinuing.

CONCLUSIONS: The implementation of state legislation to restrict the use of CAAPs in state-regulated plans was associated with reductions in patient liability and improvements in treatment adherence and persistence for the 5 states that were early implementers of a CAAP ban. These results may offer insights for states that have recently implemented a CAAP ban, as well as for those considering enacting similar legislation.

Cost sharing in health care is a strategy used by insurers to reduce costs, with the idea that patients will be more considerate of whether they should consume care if they are required to cover a larger proportion of the cost of the service.[1] Cost-sharing requirements, such as deductibles and out-of-pocket (OOP) maximums, have risen over time,[2] with patients being required to cover more costs being associated with poorer treatment adherence.[3] One option for patients to alleviate the financial burden of greater cost sharing is the use of copay assistance. Copay assistance, commonly through manufacturer sponsored programs or nonprofit foundations, helps to offset the OOP cost of prescriptions to patients by reducing their cost-sharing requirements. Furthermore, copay assistance has been shown to reduce prescription abandonment while also potentially having an equity impact, thereby increasing access to medicines for patients.[4]

Commercial insurers have a skeptical view of copay assistance, mostly viewing such programs as "marketing tools"[5] by manufacturers to circumvent formulary management tools. Although most evidence of copay assistance suggests that use of coupons does improve patient adherence,[6,7] there is mixed evidence on whether copay assistance encourages higher-cost drugs over less expensive generics.[8,9] Nonetheless, in response to the use of copay assistance programs, copay accumulator adjustment programs (CAAPs) have been used by commercial insurers to encourage patients to choose lower-cost drug options by restricting the amount of copay assistance (for higher-cost drugs) that can count toward a patient's annual deductible and OOP limit, thereby increasing a patient's OOP exposure.[10] Furthermore, as CAAPs have grown in use, insurers have increasingly viewed copay assistance programs as a source of revenue to help to save the plan sponsor's money,[11] with insurers reporting specialty drug–spend savings with copay adjustment programs.[12] CAAPs were initially focused in specific specialty therapeutic areas, such as autoimmune diseases or multiple sclerosis; however, their use has expanded to other disease areas as well.[13] Reports have suggested that CAAPs may raise patient OOP expenses[14] and decrease patient adherence to treatment.[15]

Despite the potential negative impact to patient's OOP costs and outcomes, the 2021 Notice of Benefit and Payment Parameters confirmed the ability of commercial insurers to use CAAPs.[16] On the other hand, states have taken a different approach toward CAAPs, with 20 states having passed legislation banning the use of CAAPs, although these legislations are limited to state-regulated health plans and do not apply to Employee Retirement Income Security Act (ERISA)–regulated plans.[17] The policies of the first states to enact legislation on CAAPs went into effect between 2019 and 2021. Therefore, there has been little empirical data thus far to understand the real-world impact of CAAP bans. The purpose of this study was to assess whether there is an association between the implementation of a CAAP ban and patient liability and treatment adherence and persistence.

Methods

STUDY DESIGN

This was a retrospective cohort study using administrative claims from the IQVIA PharMetrics Plus database for patients with commercial plans receiving autoimmune or multiple sclerosis drugs between January 1, 2017, and December 31, 2021. To assess the impact of the state CAAP bans, we limited our patient population to those with fully insured health plans, which fall under state regulations (whereas self-funded health plans would be ERISA regulated). We compared differences in patient liability and treatment adherence and persistence in states that implemented a CAAP ban during the study period (Arizona, Georgia, Illinois, Virginia, West Virginia) with states that did not, for before and after the date of ban. The policy effective dates for the states that implemented a CAAP ban can be found in Supplementary Table 1 (available in online article). For states not implementing a CAAP ban, a pseudopolicy effective date was set to January 1, 2020. Autoimmune and multiple sclerosis drugs were chosen because of the early focus of CAAPs on these specialty drugs. We included autoimmune and multiple sclerosis drugs that were available both before and after the policy effective date. Included drugs were required to not have a generic or biosimilar available during the study period to minimize confounding in patient liability and treatment persistence due to potential switching from branded to generic/biosimilar products (Supplementary Table 2).

PATIENT LIABILITY

The study design for the patient liability analyses can be found in Supplementary Figure 1. Previously treated patients were included in the patient liability analyses to minimize any potential imbalance in the amount of costs already contributed toward a deductible as a result of patients initiating treatment at various points during the calendar year. First and last drug use had to cover January of any calendar year within the study period (2017-2021), with January 1st after first drug use defined as the index date. Additional criteria included continuous enrollment in medical and pharmacy benefits for at least 1 year before the index date (defined as the baseline period) and at least 1 month

of drug use between the index date and end of continuous enrollment (Supplementary Table 3). Only months for which the patient was continuously enrolled since the index date were included. Because copay assistance is not captured by the data source used for this study, overall financial liability to the patient, which is inclusive of both OOP costs spent by the patient and manufacturer copay assistance spent on behalf of the patient, was examined as the outcome instead. Patient liability was thus defined as the difference in allowed costs and plan-paid amounts. Costs were adjusted to 2021 US dollars using the medical care component of the consumer price index.

TREATMENT ADHERENCE AND PERSISTENCE

The study design for the treatment adherence and persistence analyses is depicted in Supplementary Figure 2. Because time since treatment initiation for previously treated patients could bias adherence and persistence results, newly treated patients were used for these analyses, with drug initiation during the study period defined as the index date. Patients across both adherence and persistence analyses were required to have at least 1 year of continuous enrollment in medical and pharmacy benefits before the index date (patient attrition can be found in Supplementary Tables 4 and 5).

For the adherence analyses, patients were required to have additional continuous enrollment of at least 1 year after the index date. Patients in the adherence analysis were grouped into cohorts according to whether most of the 1-year follow-up time fell before or after the policy effective date. Treatment adherence was measured as the proportion of days covered (PDC), defined as the number of days with drug on hand, over a 1-year continuous enrollment period after the index date.

In the persistence analyses, patients were required to have additional continuous enrollment of at least 3 months after the index date and were categorized into cohorts based on the index date. Treatment persistence was measured as the time from treatment initiation to discontinuation, defined as a period of 60 days without supply of treatment.

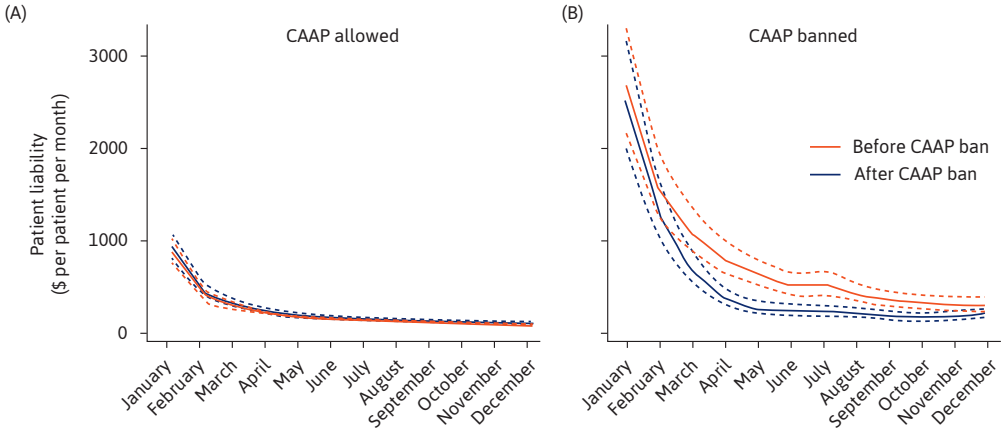
STATISTICAL METHODS

Three separate statistical models were used for analyzing the effect of state CAAP bans on patient liability, treatment adherence, and treatment persistence, with separate cohorts for each outcome, for ease of interpretation of results. Multivariate difference-in-difference models with year-month as the unit of analysis were fit to mean monthly patient liability, weighted by the number of patients with drug claims per year-month, to assess differences in patient liability between states with and without a CAAP ban. Mean monthly patient liability was modeled using a log-linked gamma generalized linear model with a 4-way interaction between drug, calendar month, CAAP status, and before vs after the policy effective date. Parallel trends in patient liability before the policy effective date were assessed by fitting generalized linear models to data from only before the policy effective date. To account for composition effects, patient characteristics whose relative distributions were different before compared with after the policy effective date, in states with or without a CAAP ban, were included in the generalized linear model as adjustment variables. Composition effects for each patient characteristic were tested for by an overall F-test (for continuous variables) or likelihood ratio test (categorical) from fitting a linear (continuous) or logistic (categorical) regression model for each variable as a function of CAAP status and before vs after the policy effective date, comparing models with and without an interaction term. Estimates of the overall mean monthly patient liability across drugs were weighted by the number of patients in each factor combination in the model to reflect OOP costs best in the patient sample (R package *emmeans*[18]).

One-year adherence was estimated as a weighted mean and was assessed using a weighted logistic regression (defined as PDC ≥0.8). In adherence analyses, patients were followed up for 1 year (1-year continuous enrollment). Patients who initiated before the policy effective date and had follow-up time across both policy periods were assigned to either the before or after policy period according to when most of the follow-up time (ie, >6 months) occurred. Weights for both persistence and adherence analyses were computed using propensity score methods, in which the propensity of being in a state with a CAAP ban vs not was modeled according to baseline characteristics that included demographic factors, health care resource utilization, and disease status (rheumatoid arthritis, multiple sclerosis, psoriasis). All analyses were conducted using R version 4.1.0.[19]

Persistence was assessed as time to treatment discontinuation using weighted Kaplan-Meier methods. Given that persistence, unlike adherence, tends toward a variable follow-up design, we decided to maximize our patient population for the persistence analyses by requiring a less restrictive minimum of 3 months (as opposed to the minimum of 1 year for adherence) of post-index continuous enrollment. Patients who initiated treatment before the policy effective date and did not discontinue were censored at the end of continuous enrollment or policy effective date, whichever was the earlier date. Patients who initiated after the policy effective date and did not discontinue were censored at the end of continuous enrollment.

FIGURE 1 Patient Liability for States With a CAAP (A) and With a CAAP Ban (B)



Dashed lines indicate 95% CIs. Model included covariates for the proportion of patients on preferred provider organization plans, on health maintenance organization plans, residing in the South, residing in the Midwest, and with any diagnosis of rheumatoid arthritis
CAAP = copay accumulator adjustment program.

Results

PATIENT CHARACTERISTICS

Overall, 95,519 patients were included for the patient liability analyses, 44,969 for the treatment adherence analyses, and 65,990 for the treatment persistence analyses. Baseline characteristics were similar pre-policy vs post-policy within each analytic cohort, with a mean (SD) age ranging from 45 (14) to 48 (13) years and with female patients constituting 57% to 64% of each cohort (Supplementary Tables 6, 7, and 8). The relative proportions of patients before vs after the policy effective date on preferred provider organization plans or health maintenance organization plans, residing in the South or the Midwest, and with any diagnosis of rheumatoid arthritis during the baseline period differed in states with or without a CAAP ban; therefore, they were added as covariates to the difference-in-difference models of patient liability. With the exception of baseline pharmacy costs, baseline outpatient costs, and baseline total costs, which were higher/lower in the persistence analysis cohort, there were no significant differences among the cohorts for individual drug use, baseline health care resource utilization, and costs.

PATIENT LIABILITY

Patient liability in states without a CAAP ban increased from a range of $930 (January) to $88 (November) before the policy effective date to a range of $930 (January) to $103 (November) after the policy effective date (Figure 1A). In contrast, in the states that implemented a CAAP ban, the mean monthly patient liability reduced from a range of $2,781 (January) to $303 (November) before the policy effective date to a range of $2,460 (January) to $164 (November) after the policy effective date (Figure 1B). For states with a CAAP ban, relative reductions in patient liability were similar to those of states without a CAAP ban in January and February, whereas relative reductions were greater from March through December, ranging from 41% to 63% and monthly savings ranging from $128 to $520 (Table 1).

TREATMENT ADHERENCE AND PERSISTENCE

Before the policy effective date, PDC was not significantly different between states with and without a ban (mean [SD], 0.66 [0.31] vs 0.66 [0.31]; $P = 0.7$), and there was no difference in the odds of being adherent to their medication (odds ratio 0.99 [95% CI = 0.91-1.08]; $P = 0.9$) (Table 2). After the policy effective date, mean PDC was greater in those states with a CAAP ban (mean [SD], 0.69 [0.31] vs 0.66 [0.31]; $P < 0.01$), and patients in these states had a 14% greater odds of being adherent to their treatment (odds ratio 1.14 [95% CI = 1.03-1.27]; $P < 0.01$) compared with patients in states without a CAAP ban.

Before the policy effective date, there was no significant difference in the risk of patients discontinuing treatment between states that had a CAAP ban or not (hazard ratio 0.99 [95% CI = 0.94-1.04]; $P = 0.6$) (Figure 2A). After the policy effective date, states with a CAAP ban had a 13% reduction in risk of patients discontinuing treatment compared with states without a CAAP ban (hazard ratio 0.87 [95% CI = 0.82-0.93]; $P < 0.01$) (Figure 2B). The median persistence was 4 months longer for states with a CAAP ban than those without.

TABLE 1 Relative Patient Liability Before and After CAAP Ban, by CAAP Status

Month	Ratio of patient liability before and after ban		Adjusted ratio (ratio of CAAP allowed/ratio of CAAP banned)	Effect of CAAP ban on patient liability, % ($)
	CAAP allowed	CAAP banned		
January	1.00 (0.91, 1.10)	1.13 (0.85, 1.50)	0.89 (0.66, 1.20)	–12% ($320)
February	0.93 (0.84, 1.02)	1.24 (0.93, 1.65)	0.75 (0.56, 1.01)	–25% ($399)
March	0.91 (0.82, 0.997)	1.68 (1.27, 2.24)	0.54 (0.40, 0.73)	–46% ($520)
April	0.90 (0.82, 0.99)	2.17 (1.62, 2.90)	0.42 (0.31, 0.57)	–58% ($472)
May	0.96 (0.86, 1.06)	2.55 (1.89, 3.44)	0.37 (0.27, 0.51)	–63% ($415)
June	0.90 (0.81, 0.99)	2.26 (1.66, 3.06)	0.40 (0.29, 0.55)	–60% ($317)
July	0.88 (0.80, 0.98)	2.36 (1.77, 3.14)	0.38 (0.28, 0.51)	–63% ($336)
August	0.87 (0.78, 0.97)	2.07 (1.55, 2.76)	0.42 (0.31, 0.57)	–58% ($255)
September	0.86 (0.77, 0.96)	2.09 (1.55, 2.81)	0.41 (0.30, 0.57)	–59% ($217)
October	0.97 (0.87, 1.08)	1.84 (1.36, 2.49)	0.53 (0.38, 0.72)	–47% ($161)
November	0.86 (0.77, 0.96)	1.85 (1.36, 2.50)	0.47 (0.34, 0.64)	–53% ($162)
December	0.88 (0.79, 0.98)	1.49 (1.09, 2.03)	0.59 (0.43, 0.82)	–41% ($128)

Model included covariates for the proportion of patients on preferred provider organization plans, on health maintenance organization plans, residing in the South, residing in the Midwest, and with any diagnosis of rheumatoid arthritis.

CAAP = copay accumulator adjustment program.

TABLE 2 Treatment Adherence Before and After CAAP Ban, by CAAP Status

	N	Mean PDC (SD)	*P* value	Adherence (PDC ≥ 0.8), %	*P* value	IPTW-weighted OR (95% CI) for adherence (PDC ≥ 0.8)	*P* value
Before CAAP ban							
CAAP allowed	25,643	0.66 (0.31)	0.7	46.4	0.6	Reference	0.9
CAAP banned	2,865	0.66 (0.31)		46.9		0.99 (0.91–1.08)	
After CAAP ban							
CAAP allowed	14,613	0.66 (0.31)	<0.01	47.9	<0.01	Reference	0.01
CAAP banned	1,848	0.69 (0.31)		52.9		1.14 (1.03–1.27)	

Weighting was performed for propensity of a patient in a state with a CAAP ban vs a patient in a state without a CAAP ban according to age, sex, drug type, patient region, psoriasis status at baseline period, rheumatoid arthritis status at baseline period, multiple sclerosis status at baseline period, total baseline costs, number of prescription fills at baseline, and quarter of drug start.

CAAP = copay accumulator adjustment program; IPTW = inverse probability of treatment weighting; OR = odds ratio; PDC = proportion of days covered.

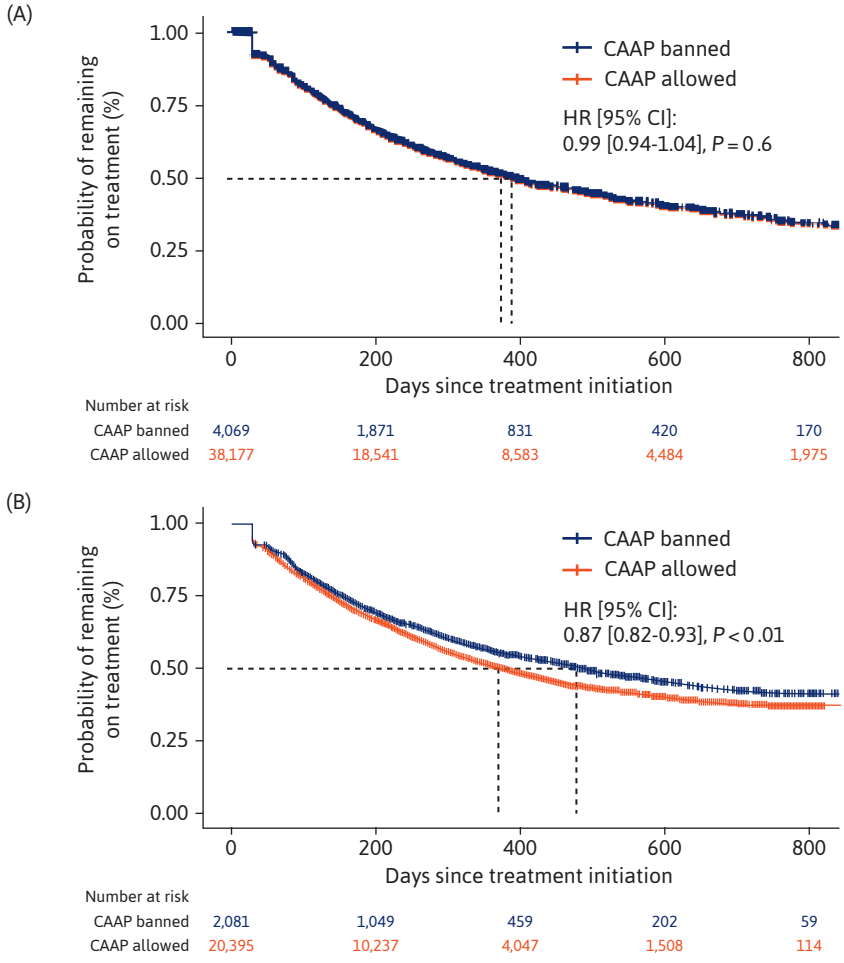
Discussion

This study demonstrated that states that had implemented a ban on CAAPs had lower patient liability than before the ban went into effect and better treatment adherence and persistence among patients treated with autoimmune and multiple sclerosis medications. To our knowledge, this is the first study to assess the real-world implications of state legislation prohibiting the use of CAAPs for state-regulated health plans. The findings here have implications for both policymakers and patients.

The real-world findings from our study on patient liability support previous reports that have illustrated the potential increase in OOP costs for CAAP patients in hypothetical examples.[14] Despite the potential patient OOP savings, critics of proposed CAAP ban legislation often cite that offsetting increases patient premiums. However, other analyses have found no evidence that state CAAP bans increase premiums,[20,21] which, taken in consideration with the present study, suggests that CAAP bans may alleviate the financial burden for patients.

The improved treatment adherence and persistence associated with the legislation prohibiting CAAPs found in

FIGURE 2 Treatment Persistence Before (A) and After (B) CAAP Ban, by CAAP Status



Weighting was performed for propensity of a patient in a state with a CAAP ban vs a patient in a state without a CAAP ban according to age, sex, drug type, patient region, psoriasis status at baseline period, rheumatoid arthritis status at baseline period, multiple sclerosis status at baseline period, total baseline costs, number of prescription fills at baseline period, and quarter of drug start.

CAAP = copay accumulator adjustment program; HR = hazard ratio.

this study is also consistent with previous research that found that CAAPs are associated with lower adherence and higher rates of treatment discontinuation for specialty drugs.[15] Despite the improvement, the mean adherence observed in both states with and without CAAP bans was less than ideal, and additional efforts beyond legislative action are needed to improve adherence overall. Given the importance of medication adherence in treating serious and chronic diseases, the implementation of state CAAP bans may potentially have an impact on the overall health outcomes for patients in the states with a CAAP ban, and further research is needed. With the observed potential impacts on patient OOP costs, adherence, and persistence, patients and plan sponsors should consider these when choosing health plan benefits. However, to aid patients in deciding whether to choose a plan with a CAAP, additional transparency is needed on the presence of CAAPs in a plan's benefit design[14] to enable patients to make the most informed choice of their health coverage.

These results could provide insight for future policy regarding CAAPs. State policymakers who are debating legislation on CAAPs should consider the findings here and

whether the outcomes observed in the early implementers of CAAP bans may also apply to their own state if similar legislation were to be passed. It should be noted, however, that state CAAP bans are limited in their impact both in terms of geography (limited to that state) and the plan types that they affect (state-regulated health plans), with estimates of the proportion of commercially insured lives affected by the current 19 states banning CAAPs being approximately 19%.[22]

Given the limited scope of the state CAAP legislation, an additional consideration is the health equity impact of such legislation, because previous research has suggested that CAAPs may disproportionately impact historically marginalized patients.[23] Although states that prohibit CAAPs may alleviate health disparities exacerbated by CAAPs among patients on state-regulated health plans through a reduction in patient liability and improvement in adherence and persistence, this may also widen differences between those on ERISA-regulated health plans and state-regulated health plans, as well as for patients in states without legislation that prohibits the use of CAAPs. Recently, the US Department of Health and Human Services (HHS) dropped its appeal challenging a US district court decision to strike down a federal rule that allowed plans to omit manufacturer copay assistance from cost-sharing calculations. Although this would limit the use of copay accumulators in federally regulated plans, HHS has stated that it will not enforce the previous rule and instead will enter into new rulemaking on the topic. Thus, close attention should be paid to the potential impact of this, as well as other federal-level legislation, such as the HELP Copays Act, in addressing the use of CAAPs and reducing the variation in access to medicines for patients across the United States.

There are several limitations to consider when interpreting the results of this study. First, the database is not able to detect the use of copay cards or coupons, and thus we were not able to distinguish between copay assistance being used and patient OOP costs. That being said, the results observed are in line with expectations, as patients were expected to have higher patient liability with CAAPs (owing to the full deductible amount plus the value of the copay cards accounting for the patient liability) and CAAP bans were expected to reduce patient liability (copay card value accounting for some of the deductibles). Given that patients are required to cover their entire deductible once their copay assistance is exhausted, it is likely that their OOP expenses have increased as demonstrated by other studies that have conducted modeling exercises,[14] although further research is warranted to measure the extent of the increased financial burden. Furthermore, our results could potentially be conservative because this analysis was not restricted to only patients with copay assistance, and the reductions in patient liability associated with the CAAP bans could be greater if patients without copay assistance were to have similar patient liability irrespective of the state CAAP laws. Second, the 5 states that implemented a CAAP ban in this study started out with higher patient liability in January of calendar years before the ban relative to states that did not implement bans. Thus, these 5 states had more room to decrease patient liability after the bans went into effect, and it is possible that other states with lower patient liability to start off with may not realize the same level of savings by implementing a CAAP ban. Third, although parallel trends in OOP costs between states with and without a CAAP ban before the policy effective date provides confidence in the estimated effect on patient liability after the bans were implemented, other confounding factors that might differ before and after policy implementation (such as COVID-19) could potentially impact the results. Lastly, even though the claims database used for the analysis covers multiple insurers and plans, not all US insurers were included in the data and we did not include all specialty medicines impacted by CAAPs. Further research would be needed to understand whether similar findings are observed in other insurers and health plans, as well as generalizable to other therapeutic areas.

Conclusions

The implementation of state legislation to restrict the use of CAAPs in state-regulated plans was associated with reductions in patient liability and greater treatment adherence and persistence for the 5 states that were early implementers of a CAAP ban. These results may offer insights to those states that have recently implemented a CAAP ban, as well as those considering enacting similar legislation. Given the variation in state adoption of CAAP bans, additional considerations should be given to the health equity impact of CAAPs, as well as potential federal solutions to address the variation in access for patients across the United States.

ACKNOWLEDGMENTS

The authors acknowledge Vikte Lionikaite, PhD, and Rebecca Hornby, PhD, of Oxford PharmaGenesis, Oxford, UK, for medical writing support funded by Genentech, Inc.

DISCLOSURES

This study was funded by Genentech, Inc. Genentech, Inc., had a role in the study design, data analysis and interpretation, manuscript writing, submission, and approval. All authors are employed by the study sponsor and are shareholders in Roche.

DATA SHARING STATEMENT

This claims database analyses used IQVIA PharMetrics Plus closed claims data obtained under license from IQVIA, Inc., as per signed agreement between Genentech, Inc., and IQVIA, Inc., and thus data cannot be publicly shared. Interested researchers can reach out to IQVIA Inc. to request access to the data.

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Attachment 4

HIV+HEP
POLICY INSTITUTE

Employers & Issuers Using "Non-Essential Health Benefit" Prescription Drug Vendors

Updated August 2024

The following **128 employers and 25 issuers** utilize outside vendors as part of the prescription drug benefit of their health insurance policy. These vendors designate certain drugs as "non-essential health benefits" to evade ACA cost-sharing requirements.

Some vendors implement a practice known as a **copay maximizer**, under which they exhaust all available copay assistance from drug manufacturers and keep that money for themselves and the employer. The employee may not pay anything for their drug, but copay assistance or any amount paid by the employee does not count toward their deductible or out-of-pocket maximum. If the employee does not participate, they are forced to pay co-insurance (often 30 percent of the list price of the drug).

Other schemes implement a practice known as an **alternative funding program**, in which the carved-out drugs are sourced from patient assistance programs meant for the uninsured or by drug importation. The federal government has indicated it will issue a rule that would prohibit the designation of "non-EHB" drugs for the large group and self-funded markets, but no rule has been promulgated to date.

For an example of what drugs are impacted by one of these vendors, which include the most popular HIV and hepatitis drugs, click here:

- **Private sector employers** (30)
  - Amedisys https://mybenefits.aon.com/getmedia/de61620c-caa7-4231-a6df-a2e74f39c293/2024-Benefits-Guide.pdf (PrudentRx)
  - BAE Systems https://info.caremark.com/oe/baesystems (PrudentRx)
  - Bank of America https://www.bankofamerica.com/content/documents/employees/abe_aug_2024_announcement_article.pdf (PrudentRx)
  - Carolina Therapy Services (NC) https://www.carolinatherapy.net/wp-content/uploads/Who-Is-Payer-Matrix.pdf (Payer Matrix*)
  - Chevron https://hr2.chevron.com/-/media/hr2/document-library/smm/smm_2023_rxexpressscripts_saveonsp_medppo_final.pdf (SaveOnSP)
  - Comcast https://www.prudentrx.com/Comcast/ (PrudentRx)
  - Coast Property Management (AK, ID, OR, WA) https://coastrealestate.weebly.com/payer-matrix.html (Payer Matrix*)
  - Citibank https://www.citibenefits.com/Health/Prescription-Drugs (PrudentRx)

- Delta Airlines https://deltabenefits.com/# (PrudentRx)
- DuPont https://dupontbenefits.com/wp-content/uploads/2023/09/Archimedes-Specialty-Medication-FAQs.pdf (Archimedes)
- ExxonMobil https://saveonsp.com/exxonmobil/ (SaveOnSP)
- Hertz https://hertzbenefits.com/wp-content/uploads/UMR-SPD-2020-2021.pdf (Archimedes*)
- Hilton https://cache.hacontent.com/ybr/R516/01250_ybr_ybrfndt/downloads/HiltonUSSPDEnglish.pdf (PrudentRx)
- Home Depot https://www.caremark.com/portal/asset/HomeDepot_Base_BAAG.pdf (PrudentRx)
- JCPenney https://d19dicv3xxhmze.cloudfront.net/pdfs/2024/JCP-2024-Benefits-Guide.pdf (no vendor listed)
- J. M. Huber (NJ) https://mybenefits.huber.com/-/media/Mercer/Huber/Documents/SaveON-drug-list.pdf (SaveOnSP)
- Marathon Petroleum Company https://www.mympcbenefits.com/Documents/MPC-2023-Saveon-Program-Medication-List-Classic-Plan.pdf (SaveOnSP)
- MGM https://docs.mgmbenefits.com/external.aspx?DocID=10150973&InBrowser=1 (SHARx*)
- Montana's Credit Unions https://www.mcun.coop/wp-content/uploads/2023/04/MCULSmithRx_Connect-Patient_Assistance_Program.pdf (Smith Rx*)
- Moog https://mybenefits.aon.com/getmedia/1f9e42df-98ba-4b43-a6c6-0f0861dd89df/Moog-2024-FT-Benefits-Guide-FINAL.pdf (PrudentRx)
- NewsCorp https://mynewscorpbenefits.com/news-corp/prudentrx-opportunities-to-save-on-specialty-rx/ (PrudentRx)
- Old National Bank (IN) https://www.oldnational.com/globalassets/onb-site/onb-documents/onb-about-us/onb-team-member-handbook/2024-benefits-guide.pdf (PaydHealth*)
- Potlatch #1 Financial Credit Union (Idaho) https://fliphtml5.com/nwekg/uawj/basic (Payer Matrix*)
- Publicis Group https://www.publicisconnections.com/Health-Benefits/-/media/Mercer/Publicis/Documents/PrudentRx_Specialty_Medication_Copay_Program_FAQs.pdf (Prudent Rx)
- Ruby Tuesday https://benefits.rubytuesday.com/pdf/PayerMatrixMemberLeaveBehind_100122_vF.pdf (Payer Matrix*)
- Samsung https://mybenefits.aon.com/getmedia/6913dd3c-92af-4b8c-9ea5-0e189665da3e/Samsung-SRA-2024-Guide.pdf (PrudentRx)
- Southwest Airlines https://cdn.phenompeople.com/CareerConnectResources/SOUTUS/documents/2024-Enrollment-Benefits-and-Perks-Guide-1700585780081.pdf (PrudentRx)
- Target https://www.express-scripts.com/files/hub/art/open_enrollment/TargetBenOverview.pdf (SaveOnSP)
- Truist Financial https://benefits.truist.com/benefits/pharmacy (PrudentRx)

* Vendor likely implementing an alternate funding program

    - United Airlines https://cache.hacontent.com/ybr/R516/00245_ybr_ybrfndt/downloads/254455.pdf (PrudentRx)
- **States** (9)
    - Connecticut https://carecompass.ct.gov/wp-content/uploads/2024/04/2024_2025_ActiveEmployees_Healthcare_Planner.pdf (PrudentRx)
    - Delaware https://dhr.delaware.gov/benefits/cvs/documents/prudentrx/faq.pdf (PrudentRx)
    - Iowa https://das.iowa.gov/media/3883/download?inline= (PrudentRx)
    - Kansas https://sehp.healthbenefitsprogram.ks.gov/media/cms/2024_Enrollment__Presentation__09_d17de44190c92.pptx (PrudentRx)
    - Kentucky https://extranet.personnel.ky.gov/KEHP/PrudentRx%20Overview.pdf (PrudentRx)
    - Nevada https://pebp.nv.gov/uploadedFiles/pebpnvgov/content/Plans/2025/PY25_Rx_LDPPO_BenefitSummary.pdf (SaveOnSP)
    - New Mexico https://www.mybenefitsnm.com/documents/CVS_and_HR_Reminders.pdf (Prudent Rx replacing SaveOnSP)
    - South Dakota https://bhr.sd.gov/BenefitsGuide.pdf (PrudentRx)
    - West Virginia Public Employees Insurance Agency https://peia.wv.gov/forms-downloads/prescription-drug-benefits/Pages/default.aspx (SaveOnSP)
- **Counties** (13)
    - Cherokee County GA https://cherokeecountyga.gov/Human-Resources/_resources/documents/US-Rx%20Care_Prescription%20Drug%20Navigation%20Guide%20-%20SS%20w%20International%202023_v.1.pdf (Script Sourcing, importation)
    - Clermont County OH https://hr.clermontcountyohio.gov/prescription-plan/ (Payd Health*)
    - Cole County MO https://www.colecounty.org/DocumentCenter/View/8488/SmithRx-Welcome-Letter (Smith Rx)
    - Dunn County WI https://vendornet.wi.gov/Download.aspx?type=bid&Id=54a11329-5ad2-ed11-9043-00505684483d&filename=Appendix+B+-+2023+Dunn+County+Benefit+Booklet.pdf (Scout Rx*)
    - King County WA https://kcemployees.com/2023/12/18/save-100-on-specialty-medications-with-prudentrx/ (PrudentRx)
    - Mendocino County CA https://www.mendocinocounty.org/government/executive-office/health-insurance-plan/prescription-coverage (SaveOnSP)
    - Orange County FL https://www.orangecountyfl.net/Portals/0/resource%20library/employment%20-%20volunteerism/2024MedicalBenefits/SaveOnSP.pdf (SaveOnSP)
    - Sanilac County MI https://www.sanilaccounty.net/Handlers/File.ashx?ID=204727 (SHARx*)

* Vendor likely implementing an alternate funding program

- San Luis Obispo County CA https://www.slocounty.ca.gov/Departments/Human-Resources/Employee-Benefits/Pharmacy/Pharmacy-Benefits/SaveOnSP.aspx (SaveOnSP)
- Summit County OH https://hreb.summitoh.net/files/6519/meeting_file/openenrollmentguide.pdf (SaveOnSP, ImpaxRx*)
- Tehama County CA https://www.co.tehama.ca.us/wp-content/uploads/2022/04/Save-on-SP.pdf (SaveOnSP)
- Tulare County CA https://tularecounty.ca.gov/hrd/benefits-wellness/pharmacy/variable-co-pay-assistance-program/ (EmpiRx Variable Copay Assistance Program*)
- Waukesha County WI https://www.waukeshacounty.gov/globalassets/administration/human-resources/benefits/true-rx-spd-waukesha-county-002.pdf (ShaRx*)

- **Cities and other local jurisdictions** (5)
  - Akron Metropolitan Housing Authority (OH) https://digital.nfp.com/vlp/AMHA%20Benefits%20Page%20-%20NB (SaveOnSP/ImpaxRx*)
  - Cheyenne WI https://cheyenne.granicus.com/MetaViewer.php?view_id=5&event_id=1142&meta_id=123138 (Payd Health*)
  - Columbus GA https://www.columbusga.gov/Portals/HR/pdfs/DPS%20Flyer.pdf (ImpaxRx*)
  - New Jersey State League of Municipalities https://www.njlm.org/DocumentCenter/View/8097/111919-0345-rxcostdriverspart2 (SaveOnSP)
  - Village of Lake Zurich IL https://lakezurich.org/DocumentCenter/View/11785/SaveonSP-Overview-and-FAQs?bidId= (SaveOnSP)
- **School Districts and Teacher Retirement Plans** (11)
  - Albuquerque Public Schools (NM) https://www.aps.edu/human-resources/benefits/documents/2023-summary-of-benefits/Express-Scripts-Summary-of-Benefits-a.pdf (SaveOnSP)
  - Arizona School Boards Association Insurance Trust https://content.myconnectsuite.com/api/documents/72c88ea8876746b7b21a1b51edeb43a1.pdf (PrudentRx)
  - Clovis Unified School District https://www.cusd.com/Prescriptions1.aspx (PrudentRx)
  - Menasha Joint School District WI https://doa.wi.gov/School%20District%20Health%20Ins%20Attachments/2021-22%20Menasha%20Joint%20Benefits%20Summary.pdf (ScoutRx*)
  - Missouri Educators Unified Health Plan (MEUHP) http://meuhp.com/media/20100/saveonsp%20broker%20client%20flyer.pdf (SaveOnSP; Cigna Plan)
  - Osceola County FL School District https://www.osceolaschools.net/cms/lib/FL50000609/Centricity/Domain/156/ElectRx%20International%20Mail%20Order%20Program.pdf (Elect RX, importation*)
  - Pinellas County Schools FL https://www.pcsb.org/Page/37275 (PrudentRx)

* Vendor likely implementing an alternate funding program

- Ripon Area School District (WI) https://www.ripon.k12.wi.us/cms_files/resources/2023%20Benefit%20Guide%20(5).pdf (Scout Rx*)
- Sarasota County Schools https://core-docs.s3.us-east-1.amazonaws.com/documents/asset/uploaded_file/4647/SCS/4034242/Low_HMOBlueCare_60_RX_SBC_1-1-2024_Rev._FINAL.pdf (SaveOnSP)
- State Teachers Retirement System of Ohio https://www.strsoh.org/_pdfs/health-care/saveonsp.pdf (SaveOnSP)
- Teacher Retirement System of Texas https://www.trs.texas.gov/TRS%20Documents/faq-prudentrx.pdf (PrudentRx)

- **Universities** (44)
  - Barton Community College https://docs.bartonccc.edu/humres/HRBenefits%20and%20Discounts/Benefits/Health%20Plan%20Open%20Enrollment%20Links/BCCC%20Payer%20Matrix%20Overview%20%20FAQs%20-Combined%20(002).pdf (Payer Matrix*)
  - Baylor University https://hr.web.baylor.edu/sites/g/files/ecbvkj1046/files/2023-03/prudentrx_copay_optimization.pdf (PrudentRx)
  - Brown University https://www.brown.edu/about/administration/human-resources/benefits/health-and-wellbeing/prescription-drug-coverage (Pillar Rx)
  - Butler University https://www.butler.edu/wp-content/uploads/sites/14/2022/01/paydhealth_select_drugs_and_products_program_member_mrx1346_0420-3.pdf (Payd Health*)
  - Carnegie Mellon University https://www.cmu.edu/hr/benefits/health-welfare/prescription/prudent-rx.html (PrudentRx)
  - Columbia University https://humanresources.columbia.edu/content/ipc-copay-assistance-program (PillarRx)
  - Concordia University (WI) https://blog.cuw.edu/high-cost-prescription-assistance/ (Payer Matrix/EmpiRx*)
  - Dartmouth University https://www.dartmouth.edu/hr/benefits_compensation/benefits/2023_benefits/pharmacy.php (Pillar Rx)
  - Duke University https://hr.duke.edu/benefits/medical/pharmacy/ (SaveOnSP)
  - George Washington University https://hr.gwu.edu/prudent (Prudent Rx)
  - Harvard University https://hughp.harvard.edu/prescriptions (Pillar Rx)
  - Hendrix College https://www.hendrix.edu/uploadedFiles/Campus_Resources/Human_Resources/Benefits_Info/2024%20Health%20Benefit%20Overview.pdf (Payer Matrix*)
  - Illinois Institute of Technology https://www.iit.edu/sites/default/files/2021-07/prudent-rx-participant-qa.pdf (PrudentRx)
  - Iona University https://www.iona.edu/offices/human-resources/employee-benefits/health-insurance/saveonsp-variable-copayments-certain (SaveOnSP)
  - Iowa State University https://hr.iastate.edu/files/documents/2024-01/SaveonSP%20Overview%20and%20FAQs.crpf_.pdf (SaveOnSP)

* Vendor likely implementing an alternate funding program

- Ithaca College https://www.ithaca.edu/intercom/2023-11-03-prudent-rx-update-and-open-enrollment-resources (use of Prudent Rx paused)
- Kent State University https://www.kent.edu/people-and-culture/benefits/prescription-cvs-health (PrudentRx)
- Loyola University of New Orleans https://finance.loyno.edu/sites/default/files/2023-10/2024%20Loyola%20Benefits%20Guide.pdf (Payer Matrix*)
- Massachusetts Institute of Technology https://hr.mit.edu/benefits/prescriptions/saveonsp (SaveOnSP)
- Missouri Southern State University https://www.mssu.edu/business-affairs/human-resources/2023-MSSU_Benefit-Guide_FULL-TIME_20230101.pdf (Payer Matrix*)
- Mount Holyoke College https://offices.mtholyoke.edu/sites/default/files/hr/docs/Mount_Holyoke_Guide_2025.pdf (Pillar Rx)
- Northwestern University https://hr.northwestern.edu/benefits/health-insurance/health-insurance-plans/prescription-drug-benefits/ (SaveOnSP)
- New York University https://www.nyu.edu/employees/benefit/full-time/staff/benefits-guide-2024/prescription-drug-plan/prudentrx-specialty-medication-program.html (PrudentRx)
- Northwestern University https://hr.northwestern.edu/benefits/health-insurance/health-insurance-plans/prescription-drug-benefits/ (SaveOnSP)
- Oakland University https://www.oakland.edu/Assets/Oakland/uhr/files-and-documents/2022-Benefits/2022%20OU%20Guide%20Faculty_final.pdf (Pillar Rx)
- Ohio University https://www.ohio.edu/hr/benefits/prescription-drug-coverage (PrudentRx)
- Ohio State University https://hr.osu.edu/wp-content/uploads/rx-saveonsp-list.pdf (SaveOnSP)
- Penn State University https://hr.psu.edu/current-employee/benefits/health/prescription-coverage (Pillar Rx)
- Princeton University https://hr.princeton.edu/sites/g/files/toruqf1976/files/documents/2022-SPD-prescription-drug-plan.pdf (OptumRx Variable Copay Solution)
- Purdue University https://www.purdue.edu/hr/Benefits/prescription/ (Archimedes*)
- Texas A&M University https://www.tamus.edu/business/prescription-programs-and-your-am-system-prescription-drug-benefits/ (SaveOnSP)
- University of Alaska https://www.alaska.edu/hr/benefits/documents-and-forms/pharmacy/2021saveonsp-drug-list.pdf (SaveOnSP)
- University of California https://ucnet.universityofcalifornia.edu/forms/pdf/2023_uchsp-rx-booklet.pdf (Lumicera/Navitus)
- University of Connecticut https://hr.uconn.edu/wp-content/uploads/sites/1421/2022/05/2022-SEBAC-Agreement.pdf (PrudentRx)
- University of Pittsburgh https://www.hr.pitt.edu/sites/default/files/PrescriptionDrugFAQ.pdf (SaveOnSP)
- University of Richmond https://hr.richmond.edu/benefits/insurance/medical-plans/pdf/SaveonSP.pdf (SaveOnSP)

* Vendor likely implementing an alternate funding program

- University of Texas https://www.utsystem.edu/sites/default/files/documents/publication/2023/ut-select-medical-plan-guide-prescription-drug-coverage/ut-select-plan-guide-2024.pdf (SaveOnSP)
- University of Wisconsin https://www.wisconsin.edu/ohrwd/benefits/health/pharmacy-benefits/ (Navitus/Lumicera)
- University System of New Hampshire https://www.usnh.edu/sites/default/files/hr/resources/benefits/pdf/benefits-guide-2024.pdf (Pillar Rx)
- Villanova University https://www1.villanova.edu/content/dam/villanova/hr/documents/SBC-23-24%20PPO%20Villanova%20University.docx (SaveOnSP)
- Washington University in St. Louis https://hr.wustl.edu/benefits/medical-dental-life/prescription-drug-benefit/ (SaveOnSP)
- Western Michigan University https://wmich.edu/sites/default/files/attachments/u7712/2024/WMU-2024-Benefit-Guide-ACA-Rev-2024-04-29.pdf (Pillar Rx)
- Yale University https://your.yale.edu/work-yale/benefits/benefits-enrollment-2024/managerial-and-professional-benefits-2024 (PrudentRx)
- Yeshiva https://www.yu.edu/sites/default/files/inline-files/Yeshiva%202021%20OE%20Presentation_Final%20%28003%29.pdf (PrudentRx)

- **Unions** (11)
  - ATU 1181 (NY) https://atu1181.org/wp-content/uploads/2019/04/Active-SBC-4-15-19-12-31-19.pdf (Payer Matrix*)
  - Electrical Industry Board of Nassau and Suffolk Counties (NY) https://www.eibofli.com/wp-content/uploads/2024/05/payer-matrix-20230501.pdf (Payer Matrix*)
  - Food Employers Labor Relations Association and United Food and Commercial Workers VEBA Fund https://www.associated-admin.com/images/pdf/FELRA/FELRA%20SMM%20re%20COVID-19%20and%20SaveOn%203.23.2020.pdf (SaveOnSP)
  - International Association of Machinists and Aerospace Workers https://www.iambtf.org/medical-prescriptions/prudentrx-copay-program (PrudentRx)
  - New York Teamsters https://nytfund.org/media/jdedv5pz/20211122-saveonsp-drug-list-effective-01012022.pdf (SaveOnSP)
  - Screen Actors Guild https://www.sagaftraplans.org/health/cvs-specialty (PrudentRx)
  - Sprinkler Fitters of Chicago https://sprinklerfitterchicago.org/ULWSiteResources/ualocal281_v2/Resources/file/health-welfare/documents/smm-21.pdf (Payd Health*)
  - Tri-County Building Trades Health Fund (MI, OH, WV) https://www.ourbenefitoffice.com/SheetMetalWorkers33/Benefits/Module/Member/MaintFileUploadPopup.aspx?fileUploadID=zLAQ7vZg2Rs%3D (Payd Health*)
  - United Food and Commercial Workers

* Vendor likely implementing an alternate funding program

  - Vancouver Firefighters Union (WA) https://www.vanfiretrust.org/payer-matrix.html (Payer Matrix*)
  - Writers Guild https://www.wgaplans.org/saveonsp/ (SaveOnSP)
- **Other non-profit organizations** (5)
  - Broward Health, FL https://employee.browardhealth.org/-/media/broward-health/employee/benefits/prudentrx-frequently-asked-questions.pdf (PrudentRx)
  - Catholic Diocese of Columbus https://columbuscatholic.org/system/resources/W1siZiIsIjIwMjEvMTAvMTkvMWxrM2diNjFkeV9BRVROQV9QcnVkZW50X1J4X0FtZW5kbWVudF85LjEuMjEucGRmIl1d/AETNA%20Prudent%20Rx%20Amendment%209.1.21.pdf (PrudentRx)
  - Cleveland Clinic https://employeehealthplan.clevelandclinic.org/Home/Resources/Specialty-Drug-Copay-Card-Assistance-Programs (PrudentRx)
  - Nemours Children's Health https://nemoursbenefitsguide.com/wp-content/uploads/2022/12/2023-Rx-Plan-overview-Nemours.pdf (SaveOnSP)
  - Lake Metropolitan Housing Authority https://digital.nfp.com/vlp/Lake%20Metropolitan%20Housing%20Authority%20Landing%20Page (ImpaxRx*)

- **Issuers** (25)
  - Advantage Health Plans (TX, OK) https://www.advantagehealthplans.com/pdf/AHP%20Southern%20Scripts%20Variable%20Copay.pdf (Southern Scripts Variable Copay Program)
  - Blue Cross Blue Shield of Alabama https://www.bcbsal.org/web/documents/1511503/511278633/FlexAccess+Drug+List.pdf (FlexAccess)
  - Blue Cross Blue Shield of Illinois https://www.bcbsil.com/employer/our-products/product/pharmacy (FlexAccess)
  - Blue Cross Blue Shield of Kansas https://benefits-direct.com/ottawa290/wp-content/uploads/sites/81/2023/09/FlexAccess-member-flyer-2023.pdf (FlexAccess)
  - Blue Cross Blue Shield of Massachusetts https://home.bluecrossma.com/collateral/sites/g/files/csphws1571/files/acquiadam-assets/Cost%20Share%20Assistance%20Medication%20List.pdf (Pillar Rx)
  - Blue Cross Blue Shield of Michigan https://www.bcbsm.com/amslibs/content/dam/public/employers/documents/share-resources-employees/individual-files/high-cost-drug-discount-program.pdf (Pillar Rx)
  - Blue Cross Blue Shield of Minnesota https://www.bluecrossmn.com/sites/default/files/DAM/2022-09/2023_RX-Fact-Sheet_AGCS%2BMedsYourWay_91922.pdf (FlexAccess)
  - Blue Cross Blue Shield of Nebraska https://www.nebraskablue.com/-/media/Files/NebraskaBlueDotCom/Shop-Plans/Group-Health-Plans/Large-Group-Plans/PremierBlue_Plan_Options_92106.pdf (FlexAccess)

* Vendor likely implementing an alternate funding program

- Blue Cross Blue Shield of Western New York https://www.bcbswny.com/content/dam/BCBSWNY/broker-group/public/pdf/group/computer-task-group/Saveon-Member-Flyer.pdf (SaveOnSP)
- Capital Blue Cross (PA) https://capbluecross.mediaroom.com/news-releases?item=122564 (FlexAccess)
- Chorus Community Health Plans (W) https://chorushealthplans.org/getmedia/87931284-9823-4cef-b6b0-75fba6b587ec/Chorus-Gold-SOB-2024-(Rev-2023-06-12).pdf (SaveOnSP)
- Christian Brother Services https://www.cbservices.org/assets/images/health/health_benefit_flyers/H&B_SaveonSP%20Program.pdf (SaveOnSP)
- EMI Health (offers medical insurance to corporate, government, public education, and higher education groups in AZ, GA, TX & UT) https://emihealth.com/pdf/saveon.pdf (SaveOnSP)
- Guidestone Health Insurance https://www.guidestone.org/-/media/Insurance/LifeConversionForms/Express-Scripts-SaveonSP-Medication-List (SaveOnSP)
- Health Alliance Plan (MI) https://www.hap.org/-/media/project/hap/hap/files/hap/prescription/2024/2024-copay-assistance-program-for-hap-members-flyer.pdf (SaveOnSP)
- Johns Hopkins https://www.hopkinsmedicine.org/johns-hopkins-health-plans/providers-physicians/our-plans/ehp/pharmacy-formulary (PrudentRx)
- Medical Mutual of Ohio https://www.medmutual.com/-/media/88221371697746DA9E847850C2B8754A.ashx?h=16&thn=1&w=16 and https://www.buaweb.com/files/63123/the_file/saveonsp_flyer_c3116rxx_422.pdf (SaveOnSP)
- Members Health Plan NJ https://membershealthplannj.com/wp-content/uploads/2019/12/2019-SaveOn-list.pdf (SaveOnSP)
- Network Health Insurance Plans (Wisconsin) https://networkhealth.com/__assets/pdf/pharmacy/saveon-drug-list.pdf (SaveOnSP)
- Pacific Source Health Plans (MT, OR, ID, WA) https://pacificsource.com/sites/default/files/2024-02/LRG726_0224_PrudentRx%20Member%20Flier.pdf (PrudentRx)
- Premera Blue Cross https://www.premera.com/documents/052560_07-01-2024.pdf (SaveOnSP)
- Priority Health (MI) https://www.priorityhealth.com/individual-family-health-insurance/learning-center/mypriority-plan-benefits (SaveOnSP)
- University of Pittsburgh Medical Center Plans: https://www.upmchealthplan.com/aon/pharmacy.aspx (SaveOnSP)
- Wellmark BlueCross Blue Shield (Iowa and South Dakota) https://www.wellmark.com/-/media/sites/public/files/member/prudentrx-drug-list.pdf?sc_lang=en&hash=D71214E333698A85351498D5E6CB4D57 (PrudentRx)
- Wisconsin Physicians Service Insurance Corporation https://secure.wpsic.com/sales-materials/files/35618-wps-aso-esi-specialty-drug-program.pdf (SaveOnSP)

* Vendor likely implementing an alternate funding program

Attachment 5

SaveOnSP Drug List

Effective as of July 1, 2024.

The specialty medications included in the copay assistance benefit drug list are specific to your plan's prescription drug benefit and subject to change at any time. Prescription drug benefit plan terms will always take precedence. Medications with prior authorization criteria must be approved in advance by the plan and follow applicable laws and/or regulations. The specialty medications included on this list will have a 30 percent coinsurance, which may be subject to change. By completing the manufacturer copay assistance program's enrollment process and consenting to SaveOnSP monitoring your pharmacy account, your final cost will be reduced. Specialty medications will be filled through your approved specialty pharmacy.

Please call 800-683-1074 to participate. Once you've completed the manufacturer copay assistance program's enrollment process and consented to SaveOnSP monitoring your pharmacy account, your responsibility will be reduced.

A
Abrilada
Actemra
Adalimumab-adaz
Adbry
Adstiladrin
Alecensa
Alunbrig
Alymsys
Arcalyst
Austedo
Avonex
Ayvakit

B
Bafiertam
Balversa
Benlysta
Betaseron
Biktarvy
Bimzelx
Bosulif
Braftovi
Brixadi
Brukinsa
Bylvay

C
Cabometyx
Calquence
Camzyos
Cayston
Cerdelga
Cholbam
Cibinqo
Cimzia
Columvi
Cometriq
Complera
Copaxone
Copiktra
Cosentyx
Cotellic
Crysvita
Cuvrior
Cyltezo
Cystadrops

D
Daybue
Dojolvi
Doptelet
Dovato
Dupixent

E
Edurant
Egrifta
Elrexfio
Empaveli
Enbrel
Entyvio
Epkinly
Erivedge
Exkivity

F
Fasenra
Filspari
Fintepla
Firdapse
Fotivda
Fulphila
Fylnetra
Fylnetra

G
Galafold
Gattex
Gavreto
Genotropin
Genvoya
Gilotrif
Glatopa
Gocovri
Granix

H
Haegarda
Halaven
Harvoni
Hulio
Hyrimoz

I
Ibrance
Iclusig
Idacio
IDHIFA
Ilaris
Ilumya
Imbruvica
Imcivree
Increlex
Ingrezza
Inlyta
Inqovi
Inrebic
Intelence
Iwilfin

J
Jakafi
Jaypirca
Joenja
Juluca
Juxtapid
Jynarque

K
Kalbitor
Kalydeco
Kesimpta
Keveyis
Kevzara
Kineret
Kisqali
Kisqali Femara Co-Pack
Koselugo

L
Ledipasvir/Sofosbuvir
Lenvima
Litfulo
Livmarli
Lonsurf
Loqtorzi
Lorbrena
Lumakras
Lumryz
Lupkynis
Lynparza
Lytgobi

M
Mayzent
Mekinist
Mektovi

N
Nerlynx
Neulasta
Neupogen
Ngenla
Ninlaro
Nivestym
Nourianz
Nplate
Nubeqa
Nucala
Nuplazid
Nutropin
Nyvepria

SaveOnSP Drug List

https://networkhealth.com/__assets/pdf/pharmacy/saveon-drug-list.pdf

O
Ocaliva
Odefsey
Odomzo
Ogsiveo
Ojjaara
Olpruva
Olumiant
Omnitrope
Omvoh
Onureg
Opsumit
Orencia
Orenitram
Orfadin
Orgovyx
Orladeyo
Orserdu
Otezla
Oxbryta
Oxervate
Ozurdex

P
Palynziq
Pemazyre
Phesgo
Pifeltro
Piqray
Plegridy
Ponvory
Prezcobix
Procysbi
Prolia
Promacta
Pulmozyme
Pyrukynd

Q
Qinlock

R
Radicava
Ravicti
Rebif
Retevmo
Rinvoq
Rolvedon
Rozlytrek
Rukobia
Rydapt

S
Scemblix
Selzentry
Serostim
Signifor
Siliq
Simponi
Skyclarys
Skyrizi
sodium oxybate
Sofosbuvir/Velpatasvir
Somavert
Sotyktu
Sovaldi
Sprycel
Stelara
Stimufend
Stivarga
Strensiq
Stribild
Sublocade
Sucraid
Syfovre
Symdeko
Symtuza
Synagis

T
Tabrecta
Tadliq
Tafinlar
Tagrisso
Takhzyro
Taltz
Talzenna
Tasigna
Tavalisse
Tavneos
Tazverik
Tecentriq
Tegsedi
Thalomid
Tibsovo
Tobi
Tremfya
Trikafta
Triumeq
Truqap
Tukysa
Turalio
Tymlos

U
Udenyca

V
Valchlor
Vanflyta
Vegzelma
Venclexta
Verzenio
Vijoice
Viracept
Vistogard
Vitrakvi
Vizimpro
Vosevi
Votrient
Vowst
Voxzogo
Vumerity
Vyjuvek
Vyleesi
Vyndamax
Vyndaqel

W
Welireg

X
Xalkori
Xeljanz
Xembify
Xermelo
Xolair
Xospata
Xpovio
Xtandi

Y
Yuflyma
Yusimry

Z
Zarxio
Zejula
Zelboraf
Zeposia
Ziextenzo
Zokinvy
Ztalmy
Zynyz

HIV drugs

Hepatitis C drugs

Attachment 6

A descriptive survey of patient experiences and access to specialty medicines with alternative funding programs

William B. Wong, PharmD, MS; Irina Yermilov, MD, MPH, MS; Hannah Dalglish, MPH; Lori Bienvenu, MS, LPC; Jonathan James, BEd; Sarah N. Gibbs, MPH

Plain language summary

Patients who have used alternative funding programs (AFPs) to access their medication were surveyed to understand their experiences. We found that using AFPs may lead to delays in patients receiving their medication, which may lead to worsening of their disease and add to their stress/anxiety. Employers should be mindful that, because of AFPs, patients reported considering leaving their jobs to find a role with better insurance coverage.

Implications for managed care pharmacy

AFPs may potentially disrupt patient access to specialty medications and be associated with a negative member experience. Further research is needed to understand the longer-term impacts on patients and health plan sponsors.

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J Manag Care Spec Pharm.
2024;30(11):1308-316

ABSTRACT

BACKGROUND: Alternative funding programs (AFPs) seek to reduce health plan sponsor costs, for example by excluding specialty drugs from a beneficiary's plan coverage and requiring patients to obtain medications through alternative sources (typically, the manufacturer's patient assistance programs) via an AFP vendor as a third-party.

OBJECTIVE: To describe patients' experiences and specialty medication access with AFPs.

METHODS: A survey method consisting of 26 optional single-choice and multiple-choice questions with branching logic divided across 5 sections (related to patient challenges with AFPs) was administered to patients recruited from an experienced AFP online patient panel and a patient advocacy group. The survey assessed patients' awareness of AFPs from their employers, experience with the patient assistance program application process via the AFP vendor, timeliness of medication access (if granted), and/or the health impact of delay in access. All descriptive and exploratory subgroup analyses were conducted by disease area and reported income levels; statistical analyses were carried out for the exploratory analyses.

RESULTS: The final sample included 227 patients. Most patients (61% [136/223]) first heard of the AFP as part of their health benefit when trying to obtain their medication. Of 198 patients, 88% reported being stressed because of the medication coverage denial and the uncertainty of obtaining their medication. More than half of patients (54% [115/213]) reported being uncomfortable with the benefits manager from the AFP vendor. On average, patients reported waiting to receive their medication for 68.2 days (approximately 2 months); 24% (51/215) reported the wait for the medication worsened their condition and 64% (138/215) reported the wait led to stress and/or anxiety. Patients who indicated the wait time negatively affected them had considered a job change or left their job at a 3–5-fold higher rate than those who reported no impact from wait time. A significantly higher proportion of patients with hemophilia and other bleeding disorders reported receiving their prescribed medication less often than patients with other conditions (63% [19/30] vs 81% [52/64]; $P=0.022$), whereas more patients with lower incomes (<$50,000 vs >$50,000) reported not receiving any medication (12% [7/57] vs 5% [7/129]; $P=0.657$), although these differences were not significant.

CONCLUSIONS: Most patients who obtain their specialty medicines via AFPs reported being uncomfortable with the process and experiencing treatment delays, which may have been linked to disease progression, worsened mental well-being, and consideration of a job change. Employers should be aware of the potential downstream impacts on employee health, retention, and the employee–employer relationship when considering implementing an AFP into their health plan.

Specialty medications have traditionally been defined as those that treat chronic, complex, or serious conditions.[1] Although many of these medications improve clinical outcomes, concerns have arisen about their affordability. Consequently, pharmaceutical manufacturers may offer copay assistance to improve affordability and reduce the out-of-pocket cost burden for commercially insured patients.[2] Alternatively, patient assistance programs (PAPs; free drug programs) or charitable foundations, which can be funded by manufacturers or other private sources, are aimed at supporting patients who are uninsured or underinsured (insured patients with significant financial burden).[3,4] Although PAPs and charitable foundations generally provide medications free of charge, income restrictions are typically in place, and patients with higher incomes are usually excluded from these programs.

In recent years, alternative funding programs (AFPs) have emerged as a new way to limit plan sponsors' exposure (ie, employers) to the cost of specialty medications. These programs are operated by vendors who work on behalf of plan sponsors to exclude certain specialty medications from a beneficiary's health plan coverage.[5-7] The AFP vendors then seek alternative sources to obtain the patient's medication. Typically, the alternative sources are PAPs or foundations, or they may include sources outside of the United States.[5,7] The use of AFPs thus far has been limited, with 14% of employers and 7% of health plans reporting using AFPs in 2023. However, there is potential for these programs to grow, with an additional 14% of employers and 33% of health plans reporting exploring their use.[8]

Some concerns have been raised around these programs. There are ethical considerations of diverting limited resources from PAPs and charitable foundations away from patients without insurance, who rely on these programs as a critical safety net and instead give them to insured patients. Furthermore, the AFP process of coverage denial and subsequently applying for aid can take time leading to potential treatment delays and disruption.[4-6] Lastly, there is additional administrative complexity for patients to obtain their medication via the AFP process, as well as privacy concerns, which may result in a negative experience for plan beneficiaries.[4,9] Although these concerns are potentially alarming, there has been no systematic research to support these hypotheses to date. To further understand the impact of AFPs, we conducted a patient survey to gather patients' experiences with the AFP process and their medication access through AFPs.

Methods

A cross-sectional survey was conducted between October and December 2023. This study used convenience sampling to concurrently recruit participants from the Rare Patient Voice (RPV) patient panels and the Hope Charities (HOPE) patient advocacy group. In previous studies, RPV patient panels have been used across multiple disease areas,[10-12] and in the present study they were included to survey patients across conditions that may be treated with specialty medications. The HOPE patient advocacy group was used primarily to survey patients with hemophilia because there have been anecdotes of these patients being impacted by AFPs.[13,14] RPV used a panel method to prevent duplicate responses, and duplicate responses from HOPE were mitigated via internet protocol (IP) tracking from Qualtrics, which prevented respondents from the same IP address completing the survey twice. Additionally, patient demographic responses were evaluated for potential duplicative participation from each data source. Respondents received financial compensation for their participation.

To identify patients who had experience with AFPs, we developed a 4-item screening tool (Supplementary Table 1 and Supplementary Exhibit 1, available in online article). Patients were required to have employer-sponsored or union-sponsored health insurance and a chronic condition requiring a specialty medication. The specialty medication had to be excluded from their insurance coverage (but not if it was part of step therapy), and patients had to acquire it by contacting an AFP vendor to help them enroll in a PAP. Only adults (aged >18 years) were eligible to complete the survey, including caregivers who completed the survey on behalf of patients aged younger than 18 years.

Eligible patients were invited to complete a survey comprising 26 single-choice and multiple-choice, closed-ended questions, any of which patients could opt out of answering (Supplementary Exhibit 2). The survey was developed by the Partnership for Health Analytic Research in collaboration with HOPE and Genentech. The questions aimed to explore patient challenges with AFPs, including potential impacts on access to therapies. The questions were developed following conversations with individuals familiar with AFPs, in order to better understand the interactions between patients and AFPs and to obtain examples of challenges patients commonly face with AFPs, including those associated with treatment access and added costs. The survey was divided into the following 5 sections: "Change in specialty medication coverage," "Patient assistance program application process," "Medication access," "Other challenges," and "Demographics." Although the survey was not formally pilot tested, the content was reviewed by HOPE for comprehension from a patient perspective and was updated based on the input received. The study protocol, screening tool, and survey were reviewed and approved by the Western Institutional Review Board.

The survey was administered via Qualtrics, and data were analyzed descriptively (proportions, means, and medians)

using SAS version 9.4 (SAS Institute Inc); no statistical analyses were conducted for the primary analysis. Where a participant skipped optional questions, this was considered missing data and excluded. Statistical analyses were carried out for exploratory subgroup analyses, which were conducted by disease area (for those subgroups with ≥30 respondents) and annual income (<$50,000 vs >$50,000). All tests were 2-sided and *P* less than 0.05 was considered significant.

Results

PATIENT DEMOGRAPHICS

Across RPV patient panels, 23,584 patients were invited to complete the screening tool, of whom 6,828 were screened (29% response rate). Meanwhile, the HOPE patient advocacy group advertised the survey via quick response code at a conference, sent it to their blast e-mail groups, and posted it on their website, resulting in 718 patients being screened (response rate could not be calculated). In total, 7,546 patients were screened and 231 of these patients had experience with AFPs and therefore were eligible to complete the survey. Of 231 patients, 227 provided consent and answered at least 1 question in the survey, resulting in a response rate of 98% (Supplementary Table 1). Most patients were aged at least 18 years (90% [190/211]), were male (70% [144/207]), were non-Hispanic White (71% [150/211]), and lived in a suburb near a large city (43% [89/209]) (Table 1). The most common health conditions reported were multiple sclerosis (22% [47/211]), cancer (15% [32/211]), and hemophilia/bleeding disorders (14% [30/211]). Around a quarter of patients (27% [57/211]) reported an annual income of less than $50,000, 61% (129/211) more than $50 000, and 12% (25/211) did not wish to report or did not know their income.

PATIENT AWARENESS OF AFPs AS PART OF HEALTH INSURANCE COVERAGE

Most patients (61% [136/223]) reported that they first learned about AFPs when they attempted to obtain their specialty medication and discovered it was excluded from their health plan (Figure 1). Overall, 28% (62/223) of patients reported being told about AFPs by their employer, including 19% (42/223) of patients who reported their employer let them know an AFP would automatically be applied to all their employees' health plan, or were strongly encouraged or required to enroll in the AFP. Among patients encouraged or forced to enroll in AFPs, more than half (51% [20/39]) reported being uncomfortable with the pressure from their employer (Figure 2). Furthermore, more than half of patients (54% [115/213]) were uncomfortable discussing their medication needs or financial challenges accessing their medication with their employer.

TABLE 1 Survey Sample Demographics

Patient characteristics	n (%)[a]
Total	227 (100)
Age, years	211
<18	21 (10)
18-34	61 (28.9)
35-44	46 (21.8)
45-54	50 (23.7)
≥55	32 (15.2)
Do not wish to report	1 (0.5)
Unknown	16
Gender	207
Female	61 (29.5)
Male	144 (69.6)
Do not wish to report	2 (1.0)
Unknown	20
Race and ethnicity, n	211
Asian/Pacific Islander/American Indian or Alaska Native[b]	5 (2.4)
Black[b]	18 (8.5)
Hispanic, Latino, or Spanish origin of any race	22 (10.4)
Race and ethnicity not listed or do not wish to report	12 (5.7)
Two or more races[b]	4 (1.9)
White[b]	150 (71.1)
Unknown	11
Yearly income, n	211
<$25,000	19 (9.0)
$25,000-$50,000	38 (18.0)
$50,000-$75,000	44 (20.9)
$75,000-$100,000	46 (21.8)
>$100,000	39 (18.5)
Do not wish to report or do not know	25 (11.8)
Unknown	16
Type of community, n	209
Large city	46 (22.0)
Suburb near a large city	89 (42.6)
Small city or town	49 (23.4)
Rural area	24 (11.5)
Do not wish to report	1 (0.5)
Unknown	18
Health condition, n[c]	211
Arthritis	21 (10.0)
Cancer	32 (15.2)

continued on next page

TABLE 1 Survey Sample Demographics *(continued)*

Crohn's disease, ulcerative colitis, or other GI disease	18 (8.5)
Hemophilia or other bleeding disorder	30 (14.2)
Multiple sclerosis	47 (22.3)
Skin condition (such as psoriasis or eczema)	10 (4.7)
Other rare disease not mentioned above	38 (18.0)
Other nonrare disease not mentioned above	9 (4.3)
Do not wish to report	6 (2.8)
Unknown	16

"Unknown" are respondents who did not answer the question.
[a]*Proportions may not total 100 because of rounding.*
[b]*Not Hispanic, Latino, or Spanish origin.*
[c]*Condition that a patient's excluded specialty medication was intended to treat.*
GI = gastrointestinal.

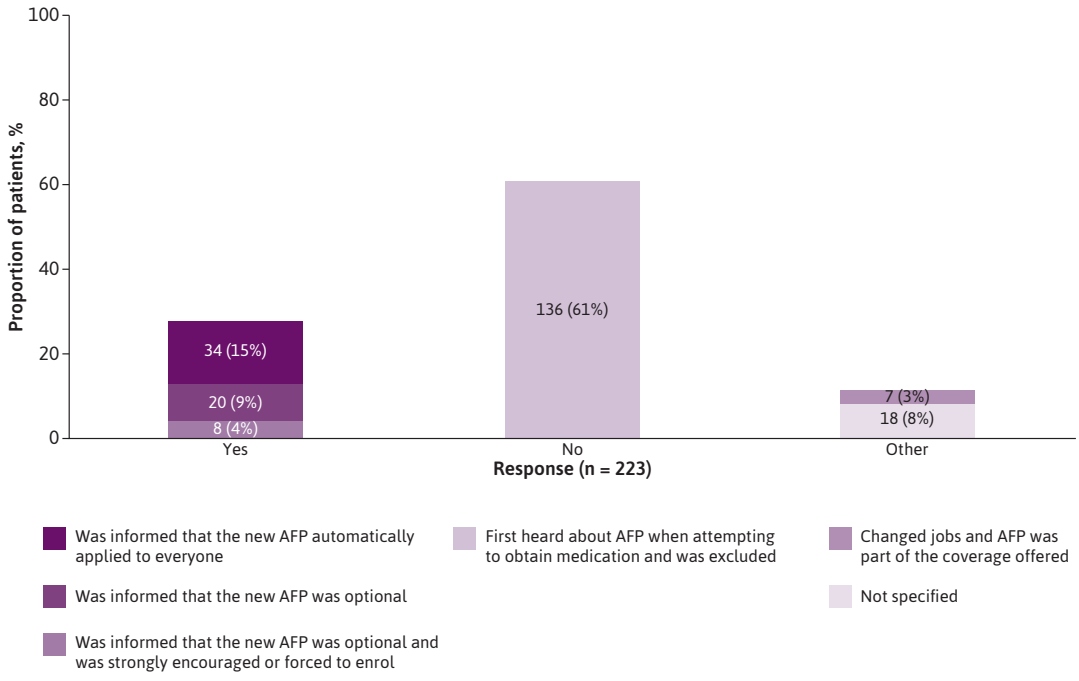
PATIENT EXPERIENCES WITH THE AFP VENDOR AND PAP APPLICATION PROCESS

Almost 9 out of 10 patients (88% [174/198]) reported being stressed by their medication coverage being denied and the uncertainty of obtaining their medication. Additionally, 71% (143/201) of patients reported confusion over why their coverage was denied and why they needed to sign up with the AFP vendor to obtain their medication. More than half of patients (54% [115/213]) reported being uncomfortable with the benefits manager (person who is employed by the AFP vendor and in direct contact with patients) from the AFP vendor for 1 or more reasons, including medication needs (26% [30/115]), financial challenges (27% [31/115]), providing sensitive information (31% [36/115]), and confusion as to who they were (40% [46/115]). Lastly, 44% (94/213) of patients reported paying an out-of-pocket expense related to the AFP process, including 34% (72/213) who paid the full cost of the medication and 24% (51/213) who paid fees related to the AFP vendor (including fees to enroll in the PAP).

PATIENTS' ACCESS TO SPECIALTY MEDICATION

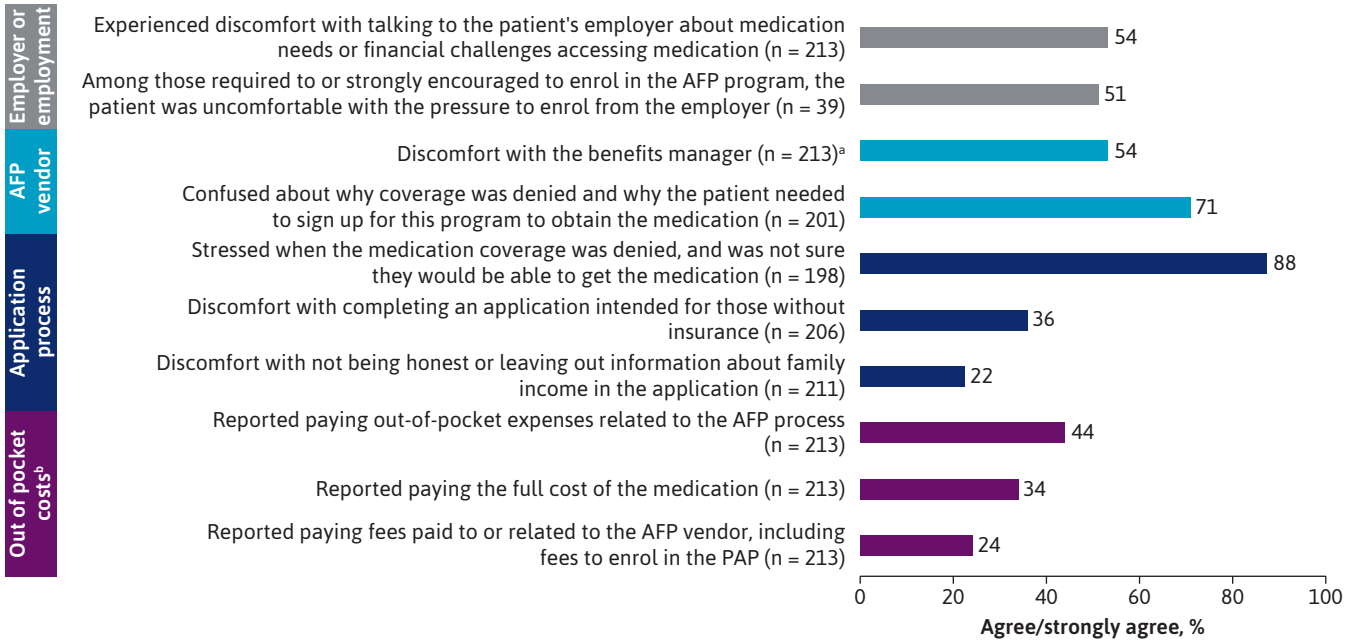
On average, patients reported a mean±SD waiting time to receive their medication of approximately 68.2±72.7 days (median 45.0 days). Patients indicated that the delay in receiving medication had negative impacts, with 24% (51/215) reporting that their condition worsened and 64% (138/215) reporting that the wait led to stress and/or anxiety (Table 2). The mean±SD wait time was approximately 2

FIGURE 1 Patient Awareness of AFP Program Which Would Impact Their Specialty Medication Coverage



Values shown in the graph are the number and proportion of patients.
AFP = alternative funding program.

FIGURE 2 Patient-Reported Experiences with Employer, AFP Vendor, and PAP Application Process



[a]*Talking to them about medication needs or financial challenges, providing them with sensitive information, or were confused about who they were.*
[b]*These statements were multiple choice, and all that were true could be selected.*
AFP = alternative funding program; PAP = patient assistance programs.

TABLE 2 Impact of Waiting for Specialty Medication Among Patients Who Answered Whether the Wait for Their Medication Had a Negative Impact on Their Health

Measure	Overall	Impact of wait for specialty medication[a]		
		Worsened condition	Stressed/anxious	No impact
Impact of wait for specialty medication, n (%)	215 (100)	51 (24)	138 (64)	49 (23)
Time to receiving or waiting for medication, n	200	48	129	44
Mean ± SD, days	68.2±72.7	95.3±96.2	71.3±76.5	43.0±41.7
Considered leaving their job because of health insurance,[b] n	198	48	128	43
n (%)	59 (29)	18 (38)	44 (34)	3 (7)
Left their job because of health insurance[b]	202	46	128	48
n (%)	26 (13)	9 (20)	16 (13)	2 (4)

[a]*Proportions are based on respondents who answered whether the wait for their medication had a negative impact on their health (respondents possible responses were: "Yes, not having the medication has made my/the patient's condition worse," "Yes, I and/or the patient have been stressed or anxious," and "No") and the subsequent question of interest in the table rows.*
[b]*Number of respondents who "strongly agreed" or 'agreed' with the relevant statement.*

times longer for patients with worsened condition or stress and/or anxiety resulting from wait time than patients who reported no impact (95.3±96.2 and 71.3±76.5 days vs 43.0±41.7 days, respectively). The patients who experienced a negative impact from the delay in receiving medication also reported considering a job change or leaving their job at 3-fold to 5-fold higher rates than those who reported no impact from the wait time (considered leaving job or left their job owing to health insurance, respectively: worsened condition, 38% [18/48] and 20% [9/46]; stress and/or anxiety, 34% [44/128] and 13% [16/128]; no impact, 7% [3/43] and 4% [2/48]).

EXPLORATORY ANALYSES BY DISEASE AREA AND INCOME

Compared with all other respondents, a significantly lower proportion of patients with hemophilia reported receiving their originally prescribed medication (81% [52/64] vs 63% [19/30], respectively; $P = 0.022$) and having their initial PAP application approved (67% [35/64] vs 26% [5/30]; $P < 0.001$) (Table 3). Additionally, compared with all other patients, a significantly greater proportion of patients with hemophilia reported being stressed and/or anxious as a result of waiting for their medication (61% [35/57] vs 90% [27/30], respectively; $P = 0.001$). Compared with all other patients, a greater proportion of patients with hemophilia reported not receiving any medication (5% [3/64] vs 23% [7/30]; $P = 0.955$) and reported longer mean±SD waiting times to receive their medication (66.0 ± 72.2 vs 83.7 ± 78.7 days, respectively; $P = 0.222$); however, these results were not significant.

Exploratory analyses showed differences between patient groups according to the level of income, although no results reached statistical significance. Compared with patients reporting an income greater than $50,000, a slightly greater proportion of patients with incomes less than $50,000 reported not receiving their medication at all (5% [7/129] vs 12% [7/57]; $P = 0.657$) (Table 3). Furthermore, patients with lower incomes waited longer mean±SD times for their medication than patients with higher incomes (81.0±94.8 vs 67.7±67.9 days; $P = 0.367$) and reported considering leaving or having left their jobs because of their insurance coverage at a higher rate (44% [14/32] vs 33% [21/63]; $P = 0.147$).

Discussion

In this cross-sectional descriptive survey, we found that the AFP process added confusion and complexity for some respondents seeking to obtain their medication. Some patients reported experiencing prolonged wait times to obtain their medicine, causing them additional stress and worsening their health conditions. These findings have implications for both employers and their employees.

Our findings detailing the delays in patients accessing their specialty medication aligns with previous commentaries that have hypothesized that AFPs might result in treatment delays and/or disruption.[4,5] We found that the average time to receipt of therapy because of medication delay was 68.2 days, approximately 2 months (median 45.0 days or 1.5 months), which is considerably longer than the wait time reported in the literature to obtain cancer medications without AFP involvement (median 6-15 days)[15,16] or specialty medications within specialty pharmacies (means of 2-7 days).[17-19] Given the seriousness of the conditions treated by specialty medications, delays in accessing medication may have significant clinical consequences. In metastatic nonsmall cell lung cancer, previous research has shown that a delay in treatment initiation of as little as 3 weeks may be associated with a greater than 2-fold higher risk of death.[20] In early stage cancers, delays in adjuvant treatment may be associated with up to a 13% higher risk of death.[21] Overall, 24% of respondents within our survey self-reported that their condition worsened as a result of waiting for their medication. Additionally, it should be noted that across all conditions reported in this study, most patients reported greater stress and/or anxiety, and many patients with chronic illnesses already have preexisting or develop mental health conditions as a result of their disease.[22] Therefore, close attention should be paid to supporting the mental health of patients using AFPs.

In exploratory subgroup analyses, we found trends suggesting that patients' experiences may vary by disease state. In particular, based on the survey responses, patients with hemophilia experienced more challenges accessing their medicine and heightened stress and/or anxiety. Delays or interruption in hemophilia treatment are impactful because regular treatment prophylaxis is associated with lower risk of bleeding compared with on-demand treatment.[23] Furthermore, compared with the general population, patients with hemophilia have been shown to have an increased risk of mental health conditions such as depression and anxiety.[24] Additional stress and/or anxiety among patients with hemophilia may worsen quality of life and be associated with an increased risk of bleeding and hospital visits.[25]

Findings in the study have several implications in addition to the need for employers and plan sponsors to support their beneficiaries' or employees' mental health. First, most patients reported a lack of awareness regarding the changes in their health plan that require them to use an AFP vendor to obtain their medication. This suggests that there is a continued need for employers to be more mindful about sharing

TABLE 3 Exploratory Analyses by Disease Area and Income Levels

	Disease area							Income			
Accessing medication[a]	Overall	Cancer	Hemophilia, or other bleeding/ blood disorder	Multiple sclerosis	Other rare disease	Other/NR	*P* value[b]	<$50,000	>$50,000	NR	*P* value[c]
Receipt of medication, n (%)	211 (100)	32 (15)	30 (14)	47 (22)	38 (18)	64 (30)	0.024	57 (27)	129 (61)	25 (12)	0.255
Received originally prescribed medication	167 (79)	25 (78)	19 (63)	36 (77)	35 (92)	52 (81)		43 (75)	103 (80)	21 (84)	
Switched medications	29 (14)	5 (16)	4 (13)	8 (17)	3 (8)	9 (14)		7 (12)	19 (15)	3 (12)	
Did not receive any medication by the time of the survey	15 (7)	2 (6)	7 (23)	3 (6)	0 (0)	3 (5)		7 (12)	7 (5)	1 (4)	
Method by which the medication was received, n[d]	167	25	19	36	35	52	0.0225	43	103	21	0.05
Initial application to PAP approved	104 (62)	15 (60)	5 (26)	27 (75)	22 (63)	35 (67)		25 (58)	69 (67)	10 (48)	
≥2 applications to PAP or different PAP approved	26 (16)	6 (24)	7 (37)	3 (8)	3 (9)	7 (13)		13 (30)	10 (10)	3 (14)	
Other method[e]	37 (22)	4 (16)	7 (37)	6 (17)	10 (29)	10 (19)		5 (12)	24 (23)	8 (38)	
Average wait time for medication, days, n	196	29	29	43	34	61		51	122	23	
Mean±SD	68.6±73.3	59.7±67.4	83.7±78.7	57.5±48.6	70.1±89.4	72.6±78.4	0.590	81.0±94.8	67.7±67.9	46.0±30.4	0.367
Median (interquartile range)	45 (28-84)	28 (28-112)	56 (28-112)	43 (25-84)	48 (28-84)	45 (28-84)		56 (28-84)	45 (28-84)	35 (21-56)	
Range	(4-504)	(4-305)	(5-336)	(7-197)	(7-504)	(10-364)		(7-504)	(4-364)	(7-112)	
Patients reporting stress/ anxiety because of wait for medication, n	211	32	30	47	38	64		57	129	25	
n (%)	136 (64)	23 (72)	27 (90)	25 (53)	25 (66)	36 (56)	0.008	35 (61)	83 (64)	18 (72)	0.701
Patients considering leaving or have left their job because of the insurance coverage[f]	207	32	29	45	38	63		56	126	25	
n (%)	67 (32)	14 (43.8)	16 (55.2)	7 (15.6)	9 (23.7)	21 (33.3)	0.003	24 (43)	40 (32)	3 (12)	0.147

Data are presented for only patients who responded to the disease area or income question and the question of interest.
[a]Proportions may not total 100 because of rounding.
[b]P value across the 5 groups.
[c]P value for less than $50,000 vs more than $50,000.
[d]Originally prescribed medication.
[e]Patient paid directly, employer made an exception, or patient changed jobs.
[f]Agreed or strongly agreed with this statement.
NR=not reported; PAP=patient assistance program.

these updates with their employees. Furthermore, patients reported being uncomfortable with several topics related to the AFP process, including discussing personal information (such as health or finances) with their employer, feeling pressure to enroll in the AFP, and the AFP vendor themselves. Taken together, these findings suggest that AFPs may negatively impact the employee–employer relationship. To further support this statement, a proportion of patients reported that they considered leaving or actually left their job, especially among those whose condition worsened or who reported stress and/or anxiety because of the wait for their medication. This may have particularly important implications in job markets with high competition for talent or where employee retention is critical. Lastly, stratified

by income, although the results were not statistically significant, there were trends suggesting differences between higher and lower wage employees regarding the experiences with obtaining their medications via AFP vendors. Although these findings are exploratory and should be interpreted with caution, it may be important for employers to consider whether the addition of AFPs into their health benefits could lead to disparities in access to specialty medication for their employees. Moreover, the findings in this study are based on a small sample size of respondents, thereby limiting the generalizability of the results. Additional research is warranted to further explore any potential discriminatory effect AFPs may have for patients, because research into AFPs is lacking. The findings from our study may be the basis for future research into these programs and their impacts.

LIMITATIONS

The survey methodology used in this study has a number of limitations to consider, including being self-reported (therefore prone to bias), using a convenience sample from 2 different sources, and having a limited sample size. The inclusion of a control group to enable comparisons and understand potential biases would have been ideal; however, this was not possible in this study in part because of the lack of prior information available on potential sample size, because there were no previous studies at the time with a similar design. Direct comparisons in the primary analysis were not possible in this study, but for some metrics (such as time to obtaining treatment), we were able to reference the literature to contextualize our results. Nonetheless, future research examining the impact of AFPs should consider the inclusion of a control group to better understand differences in delays in medication access and its effects. In addition, as mentioned, our study was limited in sample size because of the relatively low prevalence of AFPs, despite attempting to maximize the sample size by screening more than 7,500 patients from 2 data sources. Additionally, the branching and optional questions led to smaller response numbers for certain questions. Because subgroup analyses were limited in sample size, with only 30 patients with hemophilia participating, these should be considered exploratory. Despite the sample size limitations, this study offers the first insights into patients' experiences with AFPs and can therefore be considered foundational for other research to leverage and expand upon. Lastly, given that a convenience sample of self-reporting patients was used, the generalizability of the results may be limited and only be applicable to those who answered the survey. Because this is the first study surveying patients who had experience with AFPs, the direction of any potential bias is unknown. Further research with additional populations is needed to be able to compare these findings.

Conclusions

Among patients participating in this survey study, most who obtain their specialty medicines via AFPs reported being uncomfortable with the process and experienced treatment delays, which may lead to disease progression, additional stress and/or anxiety, and consideration of a job change. Employers should be aware of the potential downstream impacts on employee retention and the employee–employer relationship when considering implementing an AFP into their health plan.

DISCLOSURES

This study was funded by Genentech, Inc. Genentech, Inc. were involved in conducting the study. Dr Wong is an employee of Genentech, Inc. and has Roche stock/stock options. Dr Yermilov, Ms Dalglish, and Ms Gibbs are employees of Partnership for Health Analytic Research, which was paid by Genentech, Inc., to conduct the research described in this manuscript.

ACKNOWLEDGMENTS

Medical writing support was provided by Rebecca Spencer Martín, MSci, and Rebecca Hornby, PhD, of Oxford PharmaGenesis, Oxford, UK, with funding from Genentech, Inc.

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