IN THE 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.	No. 1:22-cv-2604 (JDB)

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Federal Rule of Civil Procedure 56 and Local Rule 7(h)(2), Plaintiffs HIV and Hepatitis Policy Institute, Diabetes Patient Advocacy Coalition, Diabetes Leadership Council, Alyssa Dykstra, Katherine Mertens, and Cynthia Regan respectfully request that the Court issue an order granting summary judgment to them on all claims in their First Amended Complaint and setting aside Defendants' rule, *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. 29,163 (May 14, 2020) (the 2021 NBPP), to the extent it authorizes insurers and other parties not to count manufacturer assistance amounts against patients' cost-sharing responsibilities. Plaintiffs also respectfully request an opportunity to present oral argument on this motion.

As set forth in greater detail in the accompanying memorandum of points and authorities, Plaintiffs are entitled to summary judgment on their claims because: (1) the 2021 NBPP's authorization of copay accumulator programs conflicts with the statutory text of the Affordable Care Act; (2) that authorization conflicts with the text of the existing regulatory definition of cost-sharing,

which the 2021 NBPP does not purport to rescind or interpret; and (3) Defendants' authorization of copay accumulators in the 2021 NBPP is arbitrary and capricious for multiple reasons, including that the agencies' reasoning (a) is based on a misunderstanding of the law, (b) is irrational in several respects, (c) failed to grapple with the agencies' earlier contrary findings or the existence of reliance interests, and (d) treats like cases differently.

For these reasons, summary judgment and vacatur are appropriate.

Dated: February 2, 2023

Respectfully submitted,

/s/ *Paul W. Hughes*

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MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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GLOSSARY

2020 NBPP	*Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020*, 84 Fed. Reg. 17,454 (Apr. 25, 2019), the preexisting rule amended by the rule challenged in this case.
2021 NBPP	*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. 29,163 (May 14, 2020), the rule challenged in this case.
ACA	Patient Protection and Affordable Care Act
CMS	Defendant Centers for Medicare and Medicaid Services
DLC	Plaintiff Diabetes Leadership Council
DPAC	Plaintiff Diabetes Patient Advocacy Coalition
HDHP	High deductible health plan
HHS	Defendant U.S. Department of Health and Human Services
HSA	Healthcare savings account

INTRODUCTION

It cannot be denied that pharmaceutical innovations have transformed the lives of countless Americans. But patients in need, even when they have insurance coverage, frequently struggle to access these lifesaving and life-enhancing drugs, in large part due to insurance benefit design: Ever-increasing deductibles and co-insurance requirements, among other provisions, leave individuals and families facing higher and higher out-of-pocket bills for drugs.

In light of escalating healthcare prices and the unavailability of quality, affordable healthcare to millions of Americans, Congress enacted the Patient Protection and Affordable Care Act (ACA). The ACA aimed to curtail the maximum out-of-pocket expenditures that would attach to those plans regulated by the ACA, yet these sums remain high, and millions of American families simply cannot afford their cost-sharing obligations. One recent study explained that "[a]bout half of households could not afford a typical employer plan deductible and almost two in three households do not have enough resources to cover a higher-end deductible of private health plans," and "[m]ost households do not have enough liquid assets to meet the typical out-of-pocket maximum." Gregory Young, *et al*., *Peterson-KFF Health System Tracker* (Mar. 10, 2022), https://perma.cc/BP27-EC4Z.

This sets up an impossible circumstance for many Americans with urgent medical needs. When their doctors prescribe the most effective medications to treat their conditions, many patients simply cannot afford the copays. To take just one striking example, a recent study reported that "69 percent of commercially insured patients did not fill their new prescriptions when they had to pay more than $250 out of pocket." AR002324; *see also, e.g.*, AR001058 ("Nearly one in five workers with a chronic condition in the family had trouble meeting copays for prescription drugs."). Meanwhile, prescription drug "[n]onadherence is estimated to cause approximately 125,000 deaths and at least 10 percent of hospitalizations, and to cost the U.S. health care system between $100 billion and $289 billion a year." AR002762; *accord, e.g.*, AR002583.

Patients in these circumstances are faced with limited choices. Many go into debt to acquire medications, but this is generally not a sustainable path. Some patients will seek assistance

to help pay for their necessary drugs—including charity from family, friends, churches, and non-profits. Yet too many others will go without the innovative therapies that could improve and extend their lives.

Recognizing these dire circumstances, many drug manufacturers have created programs to offer assistance to patients in need. Many drug innovators provide direct financial assistance to patients, known variously as copay assistance programs, copay coupons, and copay cards. These programs enable millions of Americans to afford the copays and deductibles for their physician-prescribed—and often critically important—medications. Indeed, the scope of these programs, and the relief they provide to patients, is enormous: In 2018, for example, manufacturer assistance programs provided $13 billion to enable patients to access their needed medications. AR001346; *see also, e.g.*, AR002252-002253 (17 percent of cancer-patient respondents reported using manufacturer assistance to help pay for prescription medications).

Insurance companies, however, have resisted these programs. Through schemes generally called copay accumulator adjustment programs, many insurers now refuse to count assistance provided by a manufacturer towards patients' deductibles and out-of-pocket maximums. If patients can find assistance funds to pay for their medications, insurers often recover far more money—collecting *both* from the patient and from the copay assistance provided by the manufacturer, often until the patient exhausts any available copay assistance program benefits. Patients are thus left where they started—financially unable to obtain medically necessary treatments. And if patients cannot pay, they may take less effective treatments or entirely forego the prescribed therapy.

Regrettably, the federal agencies charged with implementing the ACA have endorsed the efforts of large insurers and pharmacy benefit managers to impede access to innovative medicine by denying patients the benefit of contributions provided by drug manufacturers when calculating patient payment obligations. In particular, the U.S. Department of Health and Human Services (HHS), along with its component agency the Centers for Medicare and Medicaid Services (CMS), issued a rule in 2020 expressly permitting insurance companies and pharmacy benefit managers to utilize copay accumulators across the board. *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. 29,164 (May 14, 2020) (the 2021 NBPP). The federal agencies responsible for regulating health insurers thus sided explicitly with insurance companies and pharmaceutical benefit managers, allowing them to disregard any such manufacturer assistance when calculating whether a patient has met his or her deductible or out-of-pocket maximum.

But the 2021 NBPP is plainly unlawful. As laid out below, the agencies' approval of copay accumulator programs conflicts with the plain language of the Affordable Care Act that it purports to implement; it is irreparably inconsistent with the agencies' existing regulations; and it is arbitrary and capricious for a whole host of reasons. The Court should set it aside, restoring patients' ability to access lifechanging—and often lifesaving—medications.

BACKGROUND

A. The Affordable Care Act's cost-sharing provisions.

1. Among its patient-benefitting provisions, the Affordable Care Act sets an annual cap on the amounts that insured individuals can be forced to pay out of pocket for their healthcare, exclusive of their insurance premiums. For 2021, for example, that cap was set at $8,550 for an individual plan and $17,100 for a family plan (AR000066), and for 2023 those numbers have risen to $9,100 and $18,200, respectively (*Glossary: Out-of-pocket maximum/limit*, HealthCare.gov, https://www.healthcare.gov/glossary/out-of-pocket-maximum-limit/). The result is that, once a patient hits that maximum, *all* of her medical costs for the remainder of the year must be covered by her insurer at 100%.

Which expenses count toward that annual cap is therefore critically important to patients. For example, if a patient manages to come up with $1,000 to pay for an expensive specialty drug, but her insurer is permitted not to count that $1,000 toward the annual cap on out-of-pocket expenses, she will remain just as far away from the annual cap—and therefore from accessing her full insurance benefits—as she was when she started. In effect, this example results in the insurer gaining $1,000 and the patient losing $1,000, by delaying (by $1,000) the point at which the insurer will be forced to cover 100% of the patient's medical costs.

In general, amounts that a patient is able to raise from third parties, through family, charity, crowdfunding, or other mechanisms, must be counted toward the annual cap on a patient's out-of-pocket expenses.

2. As a technical matter, the ACA brings this structure about by mandating that "cost-sharing"—that is, the portion of an insured patient's annual healthcare costs for which the patient himself is responsible—"shall not exceed" the result of a statutory formula. 42 U.S.C. § 18022(c)(1). The statute then 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).

The text of the ACA thus sets an annual limit on the "deductibles, coinsurance, copayments," and "other expenditure[s]" that may be "required of an insured individual" by that person's health insurance plan. 42 U.S.C. § 18022(c)(3).

B. Insurance companies impose substantial cost-sharing on drugs, and manufacturers respond with copay assistance.

Meanwhile, insurers have increasingly erected barriers, in the form of increased deductibles[1] and co-insurance requirements[2]—that shift the cost of drugs from the insurer to the patient.

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[1] A deductible is, "[u]nder an insurance policy, the portion of the loss to be borne by the insured before the insurer becomes liable for payment." Deductible, *Black's Law Dictionary* (11th ed. 2019). In non-technical terms, therefore, it is "[t]he amount you pay for covered health care services before your insurance plan starts to pay." *Glossary: Deductible,* HealthCare.gov, https://www.healthcare.gov/glossary/deductible/.

[2] As opposed to a copayment—which is a flat, usually low fee that an insurer may require of a patient when he or she picks up a prescription even after the deductible is met—a co-insurance payment represents a percentage of the cost of the drug (often as high as 50%). *Compare, e.g.*, *Glossary: Coinsurance*, HealthCare.gov ("The percentage of costs of a covered health care service you pay (20%, for example) after you've paid your deductible."), https://www.healthcare.gov/glossary/co-insurance/, *with Glossary: Copayment*, HealthCare.gov ("A fixed amount ($20, for example) you pay for a covered health care service after you've paid

For example, the median deductible for an individual-market silver plan—the most popular level of plan—rose to $5,388 for the 2023 plan year, a 21% increase from 2019.[3] The increases over time are even greater: Deductibles in employer-provided plans increased by 212% between 2008 and 2018, while workers' earnings increased only 26%. AR001057.

Insurers also frequently divide their drug formularies into tiers, with specialty drugs (that is, the drugs commonly required for chronic conditions like HIV and hepatitis) placed into higher tiers, with correspondingly high cost-sharing imposed on patients. *See, e.g.*, AR001598; AR001863; AR002207. Indeed, coinsurance for expensive specialty drugs can frequently be as high as 30-50%—meaning that insurance plans require their enrollees to pay 30-50% of the list price of the drug out of pocket, even after their deductible is met. AR002207. That can easily translate to thousands of dollars of out-of-pocket costs per month—a burden that many patients cannot afford.

For this reason, many drug manufacturers have begun to provide copay assistance to patients. In one common setup, the drug manufacturer issues a coupon to an insured individual to present at the pharmacy; when he or she does so, the pharmacy will bill all or most of the individual's copayment or coinsurance—which he or she would otherwise have to pay to the pharmacy directly—to the drug manufacturer. *See, e.g.*, AR002768-002769. In essence, the drug manufacturer assists the patient in meeting his or her cost-sharing obligations by supplying the money that the insured individual would otherwise need to pay directly in order to receive his or her medication.

Manufacturer copay assistance thus lessens the financial burdens of drug costs on needy patients and their families, particularly those with chronic conditions, like HIV and hepatitis, that

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your deductible. . . . [S]ometimes called 'copays.'"), https://www.healthcare.gov/glossary/co-payment/. Thus, when a drug is expensive, the difference between a flat copayment and a percentage-based co-insurance payment may be enormous.

[3] U.S. Dep't of Health & Human Servs., *Plan Year 2023 Qualified Health Plan Choice and Premiums in Healthcare.gov Marketplaces* at 12 (Oct. 26, 2022), https://perma.cc/M2F7-637P.

require expensive specialty medications. Indeed, millions of Americans currently rely on copay assistance to afford their critical prescriptions.[4]

C. Copay accumulator programs.

While these forms of copay assistance help make innovative drugs affordable to everyday Americans despite increasingly hostile insurance benefit design, insurance companies seek to recognize a windfall, accepting copay assistance funds as a benefit to the insurer *without* crediting those funds to the patients' out-of-pocket obligations, through programs known as copay accumulators or copay accumulator adjustment programs. *See, e.g.*, 2021 NBPP, 85 Fed. Reg. at 29,233 ("'[A]ccumulator adjustment programs' . . . are utilization management tools pharmacy benefit managers and health plans may use that exclude copay assistance from counting toward a patient's deductible or annual limitation on cost sharing."). These programs thus force patients to pay out of pocket *regardless* of copay assistance provided by manufacturers.

Under a copay accumulator program, the insurer simply does not count any manufacturer-provided copay assistance against an insured individual's deductible or out-of-pocket maximum in the insurer's internal accounting systems. Accordingly, when a patient presents a copay card at a pharmacy—meaning that a patient is obtaining assistance from a manufacturer to pay for the patient's cost-sharing obligation for the dispensed drugs—the insurance plan accepts the payment but the assistance amount of that payment is not counted toward the patient's deductible or maximum out-of-pocket-costs. This provides a windfall to the insurer, allowing the insurer to collect full deductible and copayment amounts from each patient for each prescription fill, but then disregard any portion of those payments that came from manufacturer assistance on future prescription

[4] According to IQVIA data, 14% of commercially insured patients taking branded medications used copay assistance to reduce their out-of-pocket costs in 2020. IQVIA Institute for Human Data Science, *The Use of Medicines in the U.S.: Spending and Data Trends and Outlook to 2025* 46 (May 2021), https://perma.cc/3CCS-2EVD; *accord, e.g.*, *e.g.*, AR002252-002253 (17 percent of cancer-patient respondents reported using manufacturer assistance to help pay for prescription medications).

fills. This allows the insurance company to collect far in excess of the statutory cost-sharing obligation that would apply if the patient obtained assistance from another source.

These accumulator programs also mean that the patient is no closer to reaching his or her deductible. Reaching that deductible is important because it would allow the patient to obtain more affordable drugs and other healthcare for the rest of the year. The accumulator programs therefore deny patients the benefit of satisfying the deductible amount.

The following numerical example illustrates the financial impact of a copay accumulator program on the patient, the manufacturer attempting to provide copay assistance, and the insurer:

CASE STUDY 2: PrEP – Silver Level High Deductible Plan (Co-insurance)

Plan annual OOP maximum: $6,000
Deductible (combined medical and Rx): $3,000
Drug cost sharing for preferred brand: 20% after deductible
Industry co-pay assistance program (CAP) annual maximum: $4,800
WAC monthly drug price: $1,676

	Medication Costs *Counting Industry Co-pay Card Toward Deductible and OOP Max.*		**Medication Costs** *Not Counting Industry Co-pay Card Toward Deductible and OOP Max.*	
	Consumer Pays	**Industry Co-pay Card Pays**	**Consumer Pays**	**Industry Co-pay Card Pays**
January	$0	$1,676	$0	$1,676
February	$0	$1,394	$0	$1,676
		Plan deductible hit		
March	$0	$335	$228	$1,448
			Industry CAP max. hit	
April	$0	$335	$1,676	$0
May	$0	$335	$1,212	$0
			Plan deductible hit	
June	$0	$335	$335	$0
July	$0	$335	$335	$0
August	$280	$55	$335	$0
		Industry CAP max. hit		
September	$335	$0	$335	$0
October	$335	$0	$335	$0
November	$250	$0	$335	$0
December	$0	$0	$335	$0
		Plan annual OOP max. hit		
Annual Consumer Cost	**$1,200**		**$5,461**	
Total Amount Collected by Insurance Plan	**$6,000**		**$10,261**	

AR004150. As this example illustrates, the end result of a copay accumulator program is two-fold: The patient is required to pay significantly more money to obtain his or her drugs, and the insurer correspondingly pockets more money. *See also* AR001348 (similar graphical example); AR004138-4140 (same); AR004149-004152 (additional examples). Studies have shown that co-pay accumulators are associated with reductions in patient adherence to their specialty pharmaceutical prescriptions. AR002324; *see also* AR002384.

While insurers may assert that such programs encourage the use of less expensive generics, experts estimate that "the overwhelming majority (87 percent) of co-pay assistance programs are for drugs that have no generic equivalent." AR003538 (comment letter on 2021 NBPP, citing study reporting this percentage) *see also* AR002865 (same); AR002583 (same); AR002763 (another comment letter, citing studies reporting that "[i]n 2017, less than one percent of all commercial market medicine claims were filled with costsharing assistance for a branded medicine where a generic equivalent was available."). Copay accumulators, accordingly, frequently penalize needy patients without any prospect of incentivizing more economically efficient care decisions.

D. The agencies permit insurers to exclude manufacturer assistance from patient cost-sharing calculations where a generic alternative is available.

In 2019, Defendants HHS and CMS—the federal agencies responsible for implementing the Affordable Care Act—issued a rule entitled *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020*, 84 Fed. Reg. 17,454 (Apr. 25, 2019) (the 2020 NBPP). In that rule, the agencies expressly permitted the use of copay accumulator programs by insurers—but only with respect to drugs for which a generic alternative was available and medically appropriate. *Id.* at 17,544-17-545; *see* 45 C.F.R. § 156.130(h)(1) (version effective from June 24, 2019 to July 12, 2020) (providing that "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") (emphasis added).

As the 2020 NBPP explained, the agencies "recognize[d] that copayment support may help beneficiaries by encouraging adherence to existing medication regimens, particularly when copayments may be unaffordable to many patients." 2020 NBPP, 84 Fed. Reg. at 17,544. But the agencies took the view that "the availability of a coupon may cause physicians and beneficiaries to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available," thus "distort[ing] the market and the true cost of drugs." *Id.* Critically, the agencies understood that the possibility of market distortion exists *only* "when a less expensive and equally effective generic is available": "Where 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 17,545; *see also id.* ("[W]hen an enrollee is determined . . . to require a brand drug because the generic or other alternative may not be available or medically appropriate, the use of the manufacturer coupon would not disincentivize a less expensive choice.").

Thus, the 2020 NBPP explicitly rejected comments suggesting that copay accumulators should be permitted regardless of generic availability, explaining that "[w]here 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." 2020 NBPP, 84 Fed. Reg. at 17,545 (emphasis added).

E. The agencies expand the exclusion, permitting insurers to disregard manufacturer assistance even where a generic alternative is not available.

Not even a year later, however, the agencies abruptly reversed course. First, HHS issued a guidance document in August 2019 stating that, pending additional rulemaking, "the Departments *will not initiate an enforcement action* if an issuer . . . 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," purportedly on the basis of a potential conflict with IRS guidance. AR004321 (emphases added).

Then, in the rule challenged here—*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. 29,164 (May 14, 2020) (the 2021 NBPP)—the agencies expressly removed the limitation that copay accumulator programs are permitted only with respect to branded prescriptions where a generic is available.

In the final rule, the agencies again emphasized that the underlying justification for approving copay accumulator programs was a "concern that market distortion can exist when a consumer selects a higher-cost brand name drug *when an equally effective generic drug is available.*" 2021 NBPP, 85 Fed. Reg. at 29,231 (emphasis added). Yet the agencies went on to expand the approval of copay accumulators to *all* situations, whether or not a generic is available, apparently based solely on a legal concern that *not* allowing such programs could conflict with provisions of the tax code and IRS guidance. *Id.* at 29,231, 29,233.

Many advocacy groups, companies, and concerned citizens submitted comments on the proposed rule, expressing grave doubts about the wisdom and legality of permitting copay accumulator programs where no generic is available. For one thing, "numerous commentors" explained "that the proposal is in direct opposition to the administration's stated goals of reducing drug prices for patients," and that "patient costs would increase dramatically [under the 2021 NBPP], which could lead to greater non-adherence to medications and ultimately impact the life and health of patients." 2021 NBPP, 85 Fed. Reg. at 29,232. In response, the agency made a curious contention:

> We appreciate commenters' concerns that the proposal could raise out-of-pocket costs for consumers who use brand name drugs. However, we believe the impact of such costs may be limited if issuers that currently allow these amounts to be counted toward enrollees' deductibles or their annual limitation on cost sharing continue their current behavior, which we believe will be the case.

Id. In other words, the agencies' sole explanation for why their rule would not raise out-of-pocket costs for patients was essentially that insurance companies would not change their behavior to take advantage of the new rule's legalization of copay accumulators. That is, the agencies predicted that insurers would act against their economic interests.

The agencies had also proposed in the notice of proposed rulemaking "to interpret the [statutory] definition of cost sharing to exclude expenditures covered by direct drug manufacturer support." 2021 NBPP, 85 Fed. Reg. at 29,230; *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. 7,088, 7,136 (Feb. 6, 2020) (notice of proposed rulemaking, discussing proposed interpretation of the statutory definition).

In the final rule, in response to the concerns of "[m]ultiple commenters" that this proposed interpretation conflicted with the statute and the existing regulatory definition, the agencies explicitly determined not to adopt the interpretation they had proposed: "After consideration of comments, we are not finalizing the proposed interpretation to exclude expenditures covered by drug manufacturer coupons and other drug manufacturer direct support from the definition of cost sharing at 45 C.F.R. 155.20." 2021 NBPP, 85 Fed. Reg. at 29,234.

Instead, the agencies did something very bizarre. After acknowledging both sides of the interpretive question—that is, whether manufacturer copay assistance falls within the statutory and regulatory definitions of "cost sharing," meaning that those amounts must count toward the annual limitation on patients' out-of-pocket costs—the agencies announced that "[w]e have . . . determined that the term 'cost sharing' is subject to interpretation regarding whether these amounts fall under this definition." 2021 NBPP, 85 Fed. Reg. at 29,234 (emphasis added). The result, apparently, is that each individual insurer is *free to choose* whether the definition of cost-sharing includes or excludes manufacturer copay assistance, for purposes of that insurer's plans:

> For issuers who elect to include these amounts [that is, manufacturer copay assistance] 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 [and therefore within the cost-sharing definition]. For 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 [and therefore outside the cost-sharing definition].

Id. That is, the agencies' ultimate conclusion appears to be that the identical legal text (the statutory and regulatory definitions of cost sharing) will have a different meaning (either including or excluding manufacturer copay assistance) depending on what each individual regulated party wants the law to mean.

In the end, the 2021 NBPP revised 45 C.F.R. § 156.130(h) to read as follows:

> 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 29,261.

Though the agencies later issued annual notice of benefit and payment parameter rules for 2022 and 2023, and have proposed a corresponding rule for 2024, none has made any changes to the approval of copay accumulators (or even discussed the issue) despite repeated requests from affected communities during the respective comment periods. *Compare, e.g.*, Comment of All Copays Count Coalition, https://perma.cc/8VFJ-JFC3 (urging the agencies to address the copay accumulator issue during the comment process on the 2023 rule), *with Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023*, 87 Fed. Reg. 27,208 (May 6, 2022) (2023 rule, not addressing the issue).

ARGUMENT

"In an APA case, 'the district judge sits as an appellate tribunal,' and 'the entire case on review is a question of law.'" *Hurry v. FDIC*, 589 F. Supp. 3d 100, 115 (D.D.C. 2022) (quoting *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001)). Thus, in an APA challenge like this one, "[s]ummary judgment serves as a mechanism for deciding, as a matter of law, whether the agency action is consistent with the APA standard of review." *Id.* (quotation marks omitted; alteration incorporated).

Applying that standard of review here, the 2021 NBPP is unlawful several times over. Its authorization for insurance plans to employ copay accumulator programs is flatly inconsistent with

both the statutory text of the ACA and the text of the agencies' existing regulations. And the reasoning the agencies used to reach that unlawful result is arbitrary and capricious on multiple grounds, including that (1) it was based on an incorrect belief that other options were foreclosed by tax law; (2) it dismisses the obvious, predictable result of approving accumulator programs—increased costs to patients—by assuming that profit-motivated insurance companies would act contrary to their economic interests; (3) it fails either to distinguish prior contrary factual findings or to consider legitimate reliance interests, both of which are required when an agency changes course; and (4) it treats similarly situated cases differently without adequate explanation. For all these reasons, and more, the 2021 NBPP's approval of copay accumulator programs must be set aside.

I. THE 2021 NBPP IS CONTRARY TO BOTH STATUTE AND EXISTING REGULATION.

To begin, the 2021 NBPP's authorization for insurers to refuse to count funds provided by drug manufacturers towards an individual's annual cost-sharing cap conflicts with both the text of the ACA and the agencies' existing regulations—both of which include copays and other amounts required of an insured individual within the definition of cost-sharing, regardless of whether the individual turns to a third party to come up with the money.

A. The approval of copay accumulators conflicts with the statutory text.

Most fundamentally, the agencies' authorization of copay accumulators conflicts with the text of the ACA, and therefore cannot stand. *See, e.g.*, *Decker v. Nw. Envtl. Def. Ctr.*, 568 U.S. 597, 609 (2013) ("It is a basic tenet that 'regulations, in order to be valid, must be consistent with the statute under which they are promulgated.'") (quoting *United States v. Larionoff*, 431 U.S. 864, 873 (1977)); *Texas v. EPA*, 726 F.3d 180, 195 (D.C. Cir. 2013) (Kavanaugh, J.) ("A valid statute always prevails over a conflicting regulation, and a regulation can never trump the plain meaning of a statute.") (quotation marks and citation omitted; alteration incorporated).

1. 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).

Amounts that patients are required to pay providers in order to access healthcare are encompassed by clause (i) of this definition, regardless of whether the patient turns to outside sources in order to fulfil that financial obligation. While "deductibles," "coinsurance," and "copayments" are not defined by statute, the terms' ordinary meanings place no limitation on the ultimate source of the funds. A deductible, for example, is "the portion of the loss *to be borne* by the insured before the insurer becomes liable for payment" (Deductible, *Black's Law Dictionary* (11th ed. 2019) (emphasis added)), thus placing the focus on the legal *responsibility* for payment, not where the insured gets the money to satisfy that responsibility. *See also* Insurance, *Black's Law Dictionary* (11th ed. 2019) (defining "coinsurance" to mean "[i]nsurance under which the insurer and insured jointly bear *responsibility*") (emphasis added). Similarly, the final item in the statutory list is "similar charges," indicating an emphasis throughout the whole list on the amount "charg[ed]" to the patient, not the provenance of the funds ultimately paid to the provider. *Cf.* Charge, *Black's Law Dictionary* (11th ed. 2019) ("To demand a fee; to bill").

This reading is confirmed by the complementary language in clause (ii). *See, e.g.*, *Murphy v. Smith*, 138 S. Ct. 784, 789 (2018) (looking to "[t]he surrounding statutory structure" to "reinforce[]" an interpretive "conclusion"). First, that clause follows the enumerated categories of charges in clause (i) with "any other expenditure required of an insured individual" (42 U.S.C. § 18022(c)(3)(A)(ii)), indicating that the clause (i) categories, too, are types of "expenditures *required of* an insured individual." (emphasis added); *see, e.g.*, *Dong v. Smithsonian Inst.*, 125 F.3d 877, 880 (D.C. Cir. 1997) ("[T]he phrase 'A, B, or any other C' indicates that A is a subset of C.") (quoting *United States v. Williams-Davis*, 90 F.3d 490, 508-509 (D.C. Cir. 1996)). And again, the phrase "required of an insured individual" places the statute's focus squarely on the responsibility

imposed on the insured; the text looks not to where the money used for a copay originates, but whether the insurer "require[s]" the insured individual to come up with the money *somewhere* before the insurer will pay for the remainder of the treatment.

Second, clause (ii) also contains a limitation—not present in clause (i)—that the charge must be "a qualified medical expense (within the meaning of section 223(d)(2) of Title 26)." 42 U.S.C. § 18022(c)(3)(A)(ii). The cross-referenced section in turn limits "qualified medical expense" to "amounts paid by [a] beneficiary for medical care . . . but only to the extent such amounts are not compensated for by insurance or otherwise." 26 U.S.C. § 223(d)(2)(A). Thus, clause (ii)—unlike clause (i)—*does* look to whether the beneficiary is "compensated" for an expense or instead pays it out of pocket. Under well-settled principles of construction, Congress's choice to include this limitation only in clause (ii) indicates that no such restriction is present in clause (i). *See, e.g.*, *Badgerow v. Walters*, 142 S. Ct. 1310, 1318 (2022) ("'When Congress includes particular language in one section of a statute but omits it in another section of the same Act,' we generally take the choice to be deliberate.") (quoting *Collins v. Yellen*, 141 S. Ct. 1761, 1782 (2021)); *Jama* v. *ICE*, 543 U.S. 335, 341 (2005) ("We do not lightly assume that Congress has omitted from its adopted text requirements that it nonetheless intends to apply, and our reluctance is even greater when Congress has shown elsewhere in the same statute that it knows how to make such a requirement manifest.").

The statutory text accordingly sweeps within the definition of "cost-sharing" any "deductibles, coinsurance, copayments, or similar charges" that are "required of" the insured individual in order to access her healthcare, *regardless* of whether the individual turns to manufacturer assistance to fulfil that "require[ment]." 42 U.S.C. § 18022(c)(3)(A). As the agencies acknowledge, if interpreted with this focus on the requirement placed on the patient, the statutory definition would be inconsistent with the use of copay accumulators to exclude such amounts. *See* 2021 NBPP, 85 Fed. Reg. at 29,234 ("[I]f a consumer is responsible for a $50 co-pay for a brand name drug, the consumer cannot obtain the drug at the point of sale without providing the full $50 (whether with $50 cash, or $30 cash with [a] $20 coupon."). And the statute then places an annual cap on the

amount of "cost-sharing incurred under a health plan," based on the result of a statutory formula. *Id.* § 18022(c)(1)(A), (B).[5]

The 2021 NBPP, by contrast, expressly permits insurers to exclude payments from the annual statutory cap on cost-sharing—notwithstanding that those payments are "required of" the insured in order to obtain treatment—just because the insured obtains assistance from the drug manufacturer in satisfying that obligation: "[A]mounts paid toward reducing the cost sharing incurred by an enrollee using any form of direct support offered by drug manufacturers for specific prescription drugs . . . are not required to be[] counted toward the annual limitation on cost sharing." 45 C.F.R. § 156.130(h) (as amended by the 2021 NBPP, *see* 85 Fed. Reg. at 29,261). That provision is in direct conflict with the statutory text, and therefore cannot stand. *See, e.g.*, *Decker*, 568 U.S. at 609; *Texas*, 726 F.3d at 195. The Court should set it aside.

2. To the extent the agencies' contrary decision to authorize copay accumulators reflects an interpretation of—rather than a decision to disregard—the statutory text, that interpretation is not entitled to any deference. First, the statute is not ambiguous to begin with, so formal deference does not come into play. *See, e.g.*, *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1358 (2018) ("[U]nder *Chevron*, we owe an agency's interpretation of the law no deference unless, after 'employing traditional tools of statutory construction,' we find ourselves unable to discern Congress's meaning.") (quoting *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 843 n.9 (1984)); *cf. Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) ("[B]efore concluding that a rule is genuinely ambiguous, a court must exhaust all the 'traditional tools' of construction," meaning that the "legal toolkit is empty and the interpretive question still has no single right answer."). Because "Congress's meaning"—that a patient's payment obligation does not lose its status as cost-sharing just because she satisfies it by obtaining funds from a manufacturer—is apparent from the application

[5] The use of the term "incurred" in this phrase again emphasizes that cost-sharing is concerned with liabilities imposed on an insured individual, not her means of satisfying those liabilities. *See, e.g.* Incur, *Black's Law Dictionary* (11th ed. 2019) ("To suffer or bring on oneself (a liability or expense).").

of the "traditional tools of statutory construction" discussed above (*SAS Inst.*, 138 S. Ct. at 1358), deference does not come into play here.

Second, even if the statute were ambiguous, deference would still not be proper. *Chevron* deference is only even potentially available "when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 227 (2001).

Here, while the 2021 NBPP as a whole was enacted through notice-and-comment rulemaking, which is generally sufficient to satisfy *Mead* (*see* 533 U.S. at 227), the agency expressly *declined* to interpret the statutory cost-sharing definition in a way that would make it reconcilable with the agency's approval of copay accumulators. *See* 85 Fed. Reg. at 7,136 (proposed rule, proposing "to interpret the definition of cost sharing" in "Section 1302(c)(3)(A) of the PPACA" "to exclude expenditures covered by drug manufacturer coupons"); 2021 NBPP, 85 Fed. Reg. at 29,232 ("[W]e are generally finalizing this policy as proposed, except we . . . are not finalizing the proposed interpretation of the definition of cost sharing to exclude expenditures covered by direct drug manufacturer support."); *see also* pages 11-12, *supra*, and 20-21, *infra*.

Thus, the agency made a considered decision *not* to issue the sort of "authoritative interpretation that triggers *Chevron* deference" as to the proper interpretation of the statutory cost-sharing definition when it issued the 2021 NBPP. *Park v. C.I.R.*, 722 F.3d 384, 386 (D.C. Cir. 2013) (citing *Mead*, 533 U.S. 228-232); *see also, e.g.*, *N. Air Cargo v. U.S. Postal Serv.*, 674 F.3d 852, 860 (D.C. Cir. 2012) (rejecting agency's claim to *Chevron* deference where it "never actually advanced any interpretation, let alone an authoritative one," instead issuing "conclusory" documents in which "no attempt was made to parse or reconcile the ambiguous statutory language"); *cf. Kisor*, 139 S. Ct. at 2415 (explaining that courts will not extend *Auer* deference when "an interpretation does not reflect an agency's authoritative, expertise-based, fair, or considered judgment," and describing the *Mead* inquiry as "similar"). And "[w]hen [an agency's] decision does not derive primarily from its interpretation of part of its enabling statute . . . its interpretation is not

entitled to deference." *Ass'n of Civilian Technicians v. Fed. Labor Relations Auth.*, 250 F.3d 778, 783 (D.C. Cir. 2001) (quotation marks omitted).

Indeed—and quite to the contrary of any suggestion of deference—as discussed in the next section, when the agencies *did* authoritatively interpret the statutory definition of cost sharing, they chose an interpretation that plainly includes amounts paid by third parties "on behalf of" insured individuals. 45 C.F.R. § 155.20; *see* pages 19-20, *infra*.

Given the agencies' considered choice not to issue a *Chevron*-eligible authoritative interpretation of the ACA's cost-sharing definition when promulgating the 2021 NBPP, the agencies will not now be heard to argue that their adoption of a rule in conflict with that statute constitutes such an interpretation. For this reason, too, deference does not save the 2021 NBPP from its conflict with the statutory text.[6]

B. The approval of copay accumulators conflicts with existing regulation.

If the conflict with the statute were not clear enough, the 2021 NBPP's approval of copay accumulators clashes even more starkly with the agencies' own regulatory definition of cost-sharing, and is therefore arbitrary and capricious. *See, e.g.*, *Nat'l Envt'l Dev. Ass'n's Clean Air Project v. EPA*, 752 F.3d 999, 1009 (D.C. Cir. 2014) ("Although it is within the power of an agency to amend or repeal its own regulations, an agency is not free to ignore or violate its regulations while they remain in effect.") (quotation marks omitted; alterations incorporated); *Policy Research, LLC v. HHS*, 313 F. Supp. 3d 62, 72 (D.D.C. 2018) (Jackson, J.) ("It is also clear beyond cavil that an agency acts arbitrarily and capriciously if it acts in a manner that is contrary to its own regulations."); *S. Cal. Edison Co. v. FERC*, 415 F.3d 17, 22-23 (D.C. Cir. 2005) ("[O]f course, agencies may alter regulations. . . . But agencies may not keep regulations in place and then disregard them

[6] Plaintiffs recognize that the Supreme Court and D.C. Circuit cases applying *Chevron* deference are binding on this Court, but argue here for preservation purposes that the doctrine should be overturned or reconsidered. *See, e.g.*, *Buffington v. McDonough*, 143 S. Ct. 14, 14-22 (2022) (Gorsuch, J., dissenting from denial of certiorari) ("We should acknowledge forthrightly that *Chevron* did not undo, and could not have undone, the judicial duty to provide an independent judgment of the law's meaning in the cases that come before the Nation's courts.").

in order to disapprove actions taken by regulated entities to conform with those regulations. Doing so is perhaps the essence of 'arbitrary and capricious.'").

1. The pre-existing regulatory definition provides:

> 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).

If there were any doubt that manufacturer copay assistance payments are "required of" the insured individual under the statute (42 U.S.C. § 18022(c)(3)), that doubt would be resolved by the regulation: Copay assistance payments from drug manufacturers are unassailably made "on behalf of" the patient beneficiary, even though they do not come out of the patient's own pocket (45 C.F.R. § 155.20). *See, e.g.*, 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.'"). No reasonable speaker of English would think that when a patient presents a copay card to a pharmacy, and the pharmacist therefore bills a drug manufacturer for some portion of the patient's copayment obligation, that payment from the manufacturer to the pharmacist is something other than made "on behalf of" the patient. *See, e.g.*, *Kisor*, 139 S. Ct. at 2441 (Gorsuch, J., concurring) ("When judges interpret a regulation, what we are trying to get at, as Justice Holmes explained long ago, is . . . 'what its words would mean to a normal speaker of English in the circumstances in which they were used.'") (quoting Oliver Wendell Holmes, *The Theory of Legal Interpretation*, 12 Harv. L. Rev. 417, 417-418 (1899)).

The 2021 NBPP's assertion that funds provided through manufacturer assistance "are not required to be[] counted toward the annual limitation on cost sharing" (45 C.F.R. § 156.130(h)) is flatly inconsistent with this existing regulatory definition, which provides that "any expenditure . . . *on behalf of* an enrollee" counts as cost-sharing and therefore counts toward the annual cap (45 C.F.R. § 155.20 (emphasis added)). And because the agencies have chosen not to "amend or repeal" that existing "regulation[]," they are "not free to ignore" the regulation when promulgating

a new one. *Clean Air Project*, 752 F.3d at 1009. The agencies are "[them]sel[ves] bound by" their own prior regulatory definition "until that rule is amended or revoked" (*Clean Air Council v. Pruitt*, 862 F.3d 1, 9 (D.C. Cir. 2017)), with the result that the irreconcilable copay-accumulator provision of the 2021 NBPP must be set aside. *See also Huntington Hosp. v. Thompson*, 319 F.3d 74, 75 (2d Cir. 2003) (where an agency has promulgated "two separate [and concurrently effective] regulations construing the same act of Congress in a totally inconsistent manner[,] [s]uch administrative rulemaking cannot stand.").

2. As the agencies themselves explained, "multiple commenters" participating in the 2021 NBPP rulemaking process highlighted the inconsistency of the agencies' proposed action with respect to the regulatory cost-sharing definition. 2021 NBPP, 85 Fed. Reg. at 29,234. Indeed, the agencies responded to this inconsistency by "not finalizing [their] proposed interpretation to exclude [manufacturer-provided] amounts from the definition of cost sharing." *Id.*

Instead, as noted above, the agencies appear to have interpreted the regulatory definition of cost-sharing to simultaneously mean two different things—that is, to both include and simultaneously exclude funds provided by manufacturers for the benefit of insured individuals, depending on the preferences of each individual insurer:

> For issuers who elect to include these amounts [that is, manufacturer copay assistance] 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 [and therefore within the cost-sharing definition]. For 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 [and therefore outside the cost-sharing definition].

2021 NBPP, 85 Fed. Reg. at 29,234; *see* pages 11-12, *supra*.

But this maneuver does not solve the agencies' problems, for two reasons. First, even under this Schrodinger's-cat approach to interpretation, the agencies have authorized insurers to utilize copay accumulator programs if they want to, and that authorization—even if optional—conflicts

with the regulatory cost-sharing definition, which provides that amounts paid "on behalf of" beneficiaries unequivocally *are* "cost sharing," thus rendering copay accumulators unlawful. 45 C.F.R. § 155.20.

Second, the agencies' announcement that the statutory and regulatory cost-sharing definitions mean something different depending on *what each individual insurer wants them to mean* is itself independently arbitrary and capricious, requiring vacatur. The Supreme Court has "forcefully rejected" "the dangerous principle that . . . the same statutory text" can be given "different meanings in different cases" (*United States v. Santos*, 553 U.S. 507, 522 (2008)) (quoting *Clark v. Martinez*, 543 U.S. 371, 386 (2005)))—yet that is precisely what the agencies' approach would do: Manufacturer assistance "would be considered" either to be within the cost-sharing definition or outside of it, depending on whether "issuers . . . elect to include these amounts toward a consumer's annual limitation on cost sharing." 2021 NBPP, 85 Fed. Reg. at 29,234. But if the rule of law means anything, it means that regulated parties do not get to decide, on a case by case basis, whether a duly promulgated law applies to them. *Cf.*, *e.g.*, *Chrysafis v. Marks*, 141 S. Ct. 2482, 2482 (2021) (applying "the Court's longstanding teaching that ordinarily no man can be a judge in his own case consistent with the Due Process Clause") (quotation marks omitted).

Because the 2021 NBPP would "giv[e] the same word, in the same statutory [and regulatory] provision, different meanings in different factual contexts" (*Santos*, 553 U.S. at 522)—and, indeed, would permit that meaning to change based on the wishes of each individual entity subject to that law—it is grossly arbitrary and capricious. *Cf., e.g.*, *Walter O. Boswell Mem. Hosp. v. Heckler*, 749 F.2d 788, 799 (D.C. Cir. 1984) ("It would be arbitrary and capricious for HHS to bring varying interpretations of the statute to bear, depending on whether the result helps or hurts Medicare's balance sheets."). Far from saving the 2021 NBPP's authorization of copay accumulators from a clear conflict with the preexisting regulatory cost-sharing definition, therefore, the agencies' bizarre interpretive maneuver is an independent basis for setting aside the rule.

II. THE 2021 NBPP IS ARBITRARY AND CAPRICIOUS.

In addition to its plain inconsistency with both statute and regulation, the agencies' decision to authorize the use of copay accumulators in the 2021 NBPP is arbitrary and capricious for several independent reasons. "Under the [APA], agency action must be 'reasonable and reasonably explained'" to satisfy the arbitrary and capricious standard. *E.g. Advocates for Highway & Auto Safety v. Fed. Motor Carrier Safety Admin.*, 41 F.4th 586, 595 (D.C. Cir. 2022) (quoting *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021)); *see also id.* ("In particular, we must ensure that the agency drew a 'rational connection between the facts found and the choice made,' and that it 'reasonably considered the relevant issues.'") (first quoting *Motor Vehicles Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983), then quoting *Prometheus Radio Project*, 141 S. Ct. at 1158) (citations omitted).

An agency can run afoul of that standard either by simply failing to "articulate" the requisite "rational connection between the facts found and the choice made" (*State Farm*, 463 U.S. at 43)—that is, by offering an explanation that is irrational or unreasonable—or by violating one of the more specialized applications of the standard, such as those "requir[ing] an agency to treat like cases alike" (*Nat'l Weather Service Emps. Org. v. Fed. Labor Relations Auth.*, 966 F.3d 875, 883 (D.C. Cir. 2020)), or mandating "a more detailed explanation" when an agency changes course and "disregard[s] facts and circumstances that underlay or were engendered by [its] prior policy" (*FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)).

The agencies here have violated all of these doctrines. Their sole policy justification for the expansion of accumulator authorization beyond situations where a generic equivalent is available—a purported conflict with IRS tax guidance—is legally incorrect; their analysis of the costs of their action to patients is naive to the point of irrationality; they have performed an abrupt about-face without acknowledging their earlier findings or considering potential reliance interests; and their rule arbitrarily treats manufacturer assistance differently from other forms of third-party funding, without adequate justification. The agencies' action must be set aside for each of these independent failings.

A. The agencies' sole justification for the rule—a purported conflict with tax law—is baseless.

1. The sole affirmative policy justification offered by the agencies for their across-the-board authorization of copay accumulators was the "possibility" of "a conflict" between the prior agency policy—which permitted copay accumulators only where a generic substitute drug was available and medically appropriate—and "certain [tax] rules for [high deductible health plans]." 2021 NBPP, 85 Fed. Reg. at 29,231 (discussing regulatory history of agencies identifying this purported conflict); *id.* at 29,233 ("In the proposed rule and this final rule, we seek to clarify the HHS policy and address the confusion, including the potential conflict identified by stakeholders.").

That purported conflict, however, does not exist. The agencies' concerns to the contrary are based upon a misreading of the tax statutes and guidance—and the decision made on that basis must therefore be set aside. *See, e.g.*, *Sea-Land Serv., Inc. v. Dep't of Transp.*, 137 F.3d 640, 646 (D.C. Cir. 1998) ("An agency action, however permissible as an exercise of discretion, cannot be sustained 'where it is based not on the agency's own judgment but on an erroneous view of the law.'") (quoting *Prill v. NLRB*, 755 F.2d 941, 947 (D.C. Cir. 1985)); *see also, e.g.*, *NAACP v. Trump*, 298 F. Supp. 3d 209, 238 (D.D.C. 2018) (Bates, J.) (same); *SEC v. Chenery Corp.*, 318 U.S. 80, 94 (1943) ("[A]n order may not stand if the agency has misconceived the law."); *Jacoby v. NLRB*, 233 F.3d 611, 618 (D.C. Cir. 2000) (applying this principle, "[t]he Board's reliance on its mistaken analysis of [particular case law] compels a remand.").

a. The supposed conflict is between the cost sharing definition (interpreted to encompass manufacturer assistance amounts) and the tax statute governing healthcare savings accounts (HSAs), 26 U.S.C. § 223. *See* 2021 NBPP, 85 Fed. Reg. at 29,233. As the agencies see it, under Section 223, for an individual covered by a high deductible health plan (HDHP) to remain eligible for a healthcare savings account, "the HDHP is not permitted to credit the deductible in a manner that does not reflect the actual cost of medical care to the individual." *Id.*; *see also id.* ("[T]o meet the requirements of section 223 of the Code, an HDHP may only take into account" "the true economic cost to the individual . . . when determining whether the individual has satisfied the

deductible."). Thus, the agencies assert, "a conflict between the HHS policy finalized in the 2020 [NBPP] and the provisions of section 223 of the Code and IRS guidance may exist for issuers who elect to include drug manufacturer support amounts towards the consumer's deductible and annual limitation on cost sharing if the consumer is enrolled in an HDHP coupled with an HSA." *Id.*

The problem for the agencies, however, is that Section 223 does not actually say any of these things. Notably, the agency's interpretation (such as it is) cites no specific statutory language within the rather lengthy Section 223 for its claim that manufacturer assistance cannot be counted toward a deductible without rendering the enrollee ineligible for an HSA. This, alone, is sufficient reason to vacate the agencies' decision and remand for further explanation. *See, e.g.*, *Constellation Mystic Power, LLC v. FERC*, 45 F.4th 1028, 1056 (D.C. Cir. 2022) ("Ordinarily, 'we will uphold an agency decision where the agency's path may be reasonably discerned, even if the decision is of less than ideal clarity.' But when an agency 'fail[s] to provide an intelligible explanation' for its decision, it has 'fail[ed] to engage in reasoned decisionmaking,'" and its action cannot be upheld) (first quoting *Epsilon Elecs., Inc. v. U.S. Dep't of Treasury*, 857 F.3d 913, 924 (D.C. Cir. 2017), then quoting *FPL Energy Marcus Hook, L.P. v. FERC*, 430 F.3d 441, 448 (D.C. Cir. 2005)); *Epsilon Elecs.*, 857 F.3d at 928 ("[W]e 'may not supply a reasoned basis for the agency's action that the agency itself has not given.'") (quoting *State Farm*, 463 U.S. at 43); *NAACP*, 298 F. Supp. 3d at 238 (agency's "legal judgment was virtually unexplained, . . . and so it cannot support the agency's decision.").

But even if the Court could "reasonably discern[]" the agencies' interpretive "path" from a handful of sentences discussing no specific statutory language (*Constellation Mystic Power*, 45 F.4th at 1056), that interpretation fails. The only conceivable path for manufacturer assistance to render an HDHP beneficiary ineligible for an HSA under the statute is through Section 223(c)(1)(A)(ii), which requires that the beneficiary "not, while covered under a high deductible health plan, [be] covered under any health plan-- (I) which is not a high deductible health plan, and (II) which provides coverage for any benefit which is covered under the high deductible health plan." 26 U.S.C. § 223(c)(1)(A)(ii)(I), (II). That is, the beneficiary cannot be covered by a *different*

"health plan," other than her HDHP, "which provides coverage for any benefit which is covered" by the HDHP—essentially requiring that the beneficiary not be double-covered.

For this reasoning to work, however, a manufacturer copay assistance program must *be* a "health plan." 26 U.S.C. § 223(c)(1)(A)(ii)(I), (II). And the agencies have given no indication why that would be the case, particularly given that such programs—unlike typical health insurance arrangements—do *not* require a beneficiary to pay premiums in exchange for an insurer's agreement to pay for healthcare costs. Instead, manufacturers provide copay assistance without any requirement of consideration from the patient, in order for the patient to be able to access the manufacturer's drugs.

More, even if manufacturer assistance programs *were* "health plan[s]" under the statute—as required to make the agencies' interpretation work—that still would not disqualify amounts provided by such programs. The statutory language rendering a beneficiary ineligible for an HSA if she has multiple "health plan[s]" "shall be applied without regard to . . . coverage for any benefit provided by *permitted insurance*," which is in turn defined to include "insurance for a specified disease or illness." 26 U.S.C. § 233(c)(1)(B)(i), (c)(3)(B) (emphasis added). And the agencies' authorization for insurers to utilize copay accumulators is expressly aimed at "direct support offered by drug manufacturers for *specific* prescription drugs" (45 C.F.R. § 156.130(h) (emphasis added)), which are approved by the FDA only for the treatment of specified diseases (*see generally* 21 U.S.C. § 355).

Thus—although Plaintiffs submit that the best reading of the statute is that manufacturer assistance programs are not statutory "health plan[s]" at all, due to the major differences between them and traditional health insurance—if manufacturer assistance programs *are* health plans, then they are also "permitted insurance" because they are limited to the "specified disease or illness" (26 U.S.C. § 233(c)(3)(B)) for which the "specific prescription drugs" (45 C.F.R. § 156.130(h)) included in the manufacturer assistance program are indicated and prescribed. Accordingly, insofar as the Court is even able to "reasonably discern[]" its basis (*Constellation Mystic Power*, 45

F.4th at 1056), the agencies' interpretation of Section 223 of the Tax Code is incorrect, and cannot support the agencies' action.[7]

b. To the extent the agencies relied on a 16-year-old IRS guidance document in support of their position, that reliance is misplaced. *See* 2021 NBPP, 85 Fed. Reg. at 29,233 (referencing "Q&A 9 of IRS Notice 2004-50"); AR004250 (reproducing the guidance in question).[8] For one thing, agency guidance documents are by definition not binding statements of law or even interpretations meriting deference, so even if it were relevant, the Q&A document could not overcome the lack of any support for the agencies' position in the text of Tax Code Section 223. *See, e.g.*, *Sierra Club v. EPA*, 873 F.3d 946, 951 (D.C. Cir. 2017) (explaining that for a "purported guidance document" to avoid running afoul of the APA's notice-and-comment rulemaking requirement for legislative rules, it must be "binding on neither the public nor the agency") (quoting *Ass'n of Flight Attendants v. Huerta*, 785 F.3d 710, 716 (D.C. Cir. 2015)); *Orton Motor, Inc. v. U.S. Dep't of Health & Human Servs*., 884 F.3d 1205, 1211 (D.C. Cir. 2018) ("[I]nterpretations contained in policy statements, agency manuals, and enforcement guidelines . . . lack the force of law [and] do not warrant *Chevron*-style deference.") (quoting *Christensen v. Harris Cty*., 529 U.S. 576, 587 (2000)).

Moreover, the IRS FAQ document in question is plainly inapposite on its merits. As numerous commenters explained, the FAQ document dealt with "[d]iscount cards that entitle holders to obtain discounts for health care services or products" (AR004250), not manufacturer assistance

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[7] This interpretation, too, is ineligible for *Chevron* deference. *Cf.* pages 16-18, *supra*. First, it is an interpretation of the tax code (*i.e.*, Title 26) by healthcare agencies, and "[u]nder the law of this circuit, when an agency interprets a statute other than that which it has been entrusted to administer, its interpretation is not entitled to deference." *U.S. Air Tour Ass'n v. FAA*, 298 F.3d 997, 1016 (D.C. Cir. 2002) (quotation marks omitted). Second, and even more fundamentally, the so-called interpretation does not engage whatsoever with the statutory text. *See N. Air Cargo*, 674 F.3d at 860 (rejecting *Chevron* deference for "conclusory" documents in which "no attempt was made to parse or reconcile the ambiguous statutory language").

[8] It is unclear from the Federal Register text whether the agencies viewed IRS Notice 2004-50 as support for their legal position, or simply as a historical explanation for the supposed "confusion" that led to the agencies' change in position on copay accumulators. *See generally* 2021 NBPP, 85 Fed. Reg. at 29,233.

that leaves unchanged the amount the pharmacist must be paid before dispensing the drug and simply supplies some of the money to meet that requirement. *See also* AR004250 (FAQ document, giving an "example" in which "[a]n employer provides its employees with a pharmacy discount card. For a fixed annual fee (paid by the employer), each employee receives a card that entitles the holder to . . . discounts of 15 percent to 50 percent off the usual and customary fees charged by the providers").

As multiple commenters pointed out in response to the agencies' proposed rulemaking, this arrangement functions quite differently from the manufacturer assistance that is targeted by copay accumulators. In the accurate portrayal of one commenter on the 2021 NBPP, for example:

> Under the IRS example, an employer purchases a discount card for employees in order to access discounted rates for prescription drugs from pharmacies, and only the amount actually paid to the pharmacy is counted toward the patient's deductible and annual limitation on cost sharing. Under this example, the discount card essentially lowers the rate that the pharmacy charges. This lower rate . . . is then applied towards the patient's deductible or annual maximum.
>
> This process bears little if any semblance to the way manufacturer copay coupons work in the market today. . . . Manufacturer assistance offsets the cost-sharing that the employee is still obligated to pay—it does not entitle the policyholder to purchase healthcare services or products at managed market rates. Manufacturer assistance also does not change the rate the pharmacy charges, nor the amount the pharmacy receives pursuant to a negotiated rate with the issuer. . . . In these scenarios, the full negotiated rate should count toward the deductible and annual maximum.

AR003575; *accord, e.g.*, AR002674 ("The cited Q&A addresses discount cards that actually reduce the amount the pharmacy receives in payment from the patient and plan. Cost-sharing assistance, on the other hand, does not reduce the amount due. Instead, cost-sharing assistance offers an alternative source of payment for the amount that the patient is required to pay. Given this difference, we do not agree that the existing IRS Q&A creates a barrier to the application of the 2020 [NBPP] final rule's requirement to count manufacturer assistance towards patients' out-of-pocket maximums except when a medically appropriate generic equivalent was available."); AR002768-002769 ("The facts described in this Q&A . . . bear no similarity to what occurs when

a patient uses manufacturer assistance to help pay cost sharing under a health plan at the pharmacy."); AR002260 (similar); AR002574 (similar); AR002769 (providing helpful graphic contrasting the two scenarios).

Thus, the 2004 IRS guidance—like the statute itself—is entirely consistent with insurers counting manufacturer assistance against patient deductibles and out-of-pocket maximums. It sensibly explains that when an employer pays a pharmacy to lower the rates the pharmacy charges to its employees, only that lower rate should be counted against the employee's deductible and out-of-pocket maximum in order to maintain HSA eligibility. Indeed, such employer-provided discount cards "traditionally are used *in lieu of health insurance*, so it would naturally follow that such cards were excluded from the calculation of an annual deductible when the [IRS guidance] was released in 2004." AR00439 (emphasis added). The guidance says nothing about the situation here, where manufacturers unilaterally provide funds to pay for drugs at the pharmacist's existing and unchanged rates.

2. Finally, even if all of the above were wrong, and the agencies were correct that crediting manufacturer assistance toward a deductible would render a high deductible health plan beneficiary ineligible to contribute to an HSA, its decision would *still* be arbitrary and capricious for failure to consider obvious alternatives in light of that legal conclusion. *See, e.g.*, *Spirit Airlines, Inc. v. U.S. Dep't of Transp.*, 997 F.3d 1247, 1255 (D.C. Cir. 2021) ("An agency is required to consider responsible alternatives to its chosen policy and to give a reasoned explanation for its rejection of such alternatives.") (quoting *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 242 (D.C. Cir. 2008)); *id.* ("[T]he failure of an agency to consider obvious alternatives has led uniformly to reversal.") (quoting *Yakima Valley Cablevision, Inc. v. FCC*, 794 F.2d 737, 746 n.36 (D.C. Cir. 1986)); *Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 59 (D.C. Cir. 2015) ("Nor do we uphold agency action if it fails to consider significant and viable and obvious alternatives.") (quotation marks omitted).

Here, where the agencies have permitted *all* insurance plans to disregard manufacturer assistance amounts through copay accumulator programs, on the basis of a purported conflict with

tax rules that apply only to a *subset* of insurance plans, at least one possible alternative is strikingly "obvious" (*Spirit Airlines*, 997 F.3d at 1255): permit plans to utilize copay accumulator programs *only* with respect to patients who actually present the supposed conflict—those "enrolled in an HDHP coupled with an HSA." 2021 NBPP, 85 Fed. Reg. at 29,233. But the agencies do not appear to have "consider[ed]" this "responsible alternative," much less given "a reasonable explanation for [their] rejection" of it. *Spirit Airlines*, 997 F.3d at 1255. In other words, instead of even considering whether to narrowly tailor their action to the specific purported conflict that formed the sole basis for that action, they have thrown the baby out with the bathwater by applying that action to all insurers across the board. That failure to consider, and explain their rejection of, a clearly obvious alternative independently renders the agencies' decision arbitrary and capricious—quite apart from the agencies' underlying legal error in interpreting the tax code. *Id.*

B. The agencies' analysis of costs to patients is also flatly irrational.

Next, the agencies' dismissive analysis of the costs that will be imposed on patients as a result of the agencies' approval of copay accumulators is also irrational, and thus arbitrary and capricious. *See, e.g.*, *Advocates for Highway & Auto Safety*, 41 F.4th at 595 (agency must draw "a rational connection between the facts found and the choice made") (quoting *State Farm*, 463 U.S. at 43).

Specifically, in response to the "concerns" of "[n]umerous commentators" that "the proposal could raise out-of-pocket costs for consumers who use brand name drugs," (2021 NBPP, 85 Fed. Reg. at 29,232), the agencies made an unsupported and illogical assumption that for-profit insurance companies would eschew a newly provided opportunity to make more money: "[W]e believe the impact of such costs [on patients] may be limited if issuers that currently allow [manufacturer assistance] to be counted towards enrollees' deductibles or their annual limitation on cost sharing continue their current behavior, which we believe will be the case." *Id.*; *see also id.* ("We do not expect any significant increases in patient costs or non-adherence to medications *if* issuers choose to continue their current behavior" of not employing copay accumulators in the absence of

generic alternatives.) (emphasis added). In other words, the agencies "believe[d]"—without substantive discussion—that insurers would simply not take advantage of a newly legalized opportunity to pad their profits.[9]

That assumption runs contrary to basic economic realities, and is therefore irrational. *See, e.g.*, *WildEarth Guardians v. U.S. Bureau of Land Mgmt.*, 870 F.3d 1222, 1236 (10th Cir. 2017) (holding an agency action based on an economic assumption "arbitrary and capricious because the assumption itself is irrational (i.e., contrary to basic supply and demand principles)"); *cf. Am. Trucking Ass'ns, Inc. v. Fed. Motor Carrier Safety Admin.*, 724 F.3d 243, 248 (D.C. Cir. 2013) ("[W]e think it 'a hardly-speculative exercise in naked capitalism' to suggest motor carriers would respond to the hours-increasing provisions by requiring their drivers to use them and work longer days.") (quoting *Abigail Alliance for Better Access to Dev. Drugs v. Eschenback*, 469 F.3d 129, 135 (D.C. Cir. 2006)). *Of course* profit-motivated insurers, when provided with a new tool that allows them to extract additional profits (*see, e.g.*, page 7, *supra*) will utilize that tool.

What is more, as one commenter explained to the agencies, the incentives are even stronger than merely an opportunity to capture additional profits: "[A]ny health plan that *doesn't* implement an accumulator policy will fear attracting a disproportionate number of expensive patients who rely on high cost drugs," thus *reducing* the insurer's profits. AR002701 (emphasis added). In this way, the opportunity for *any* insurers to implement across-the-board accumulators incentivizes *all* insurers to do so as a matter of self-preservation, to avoid being saddled with expensive patients fleeing other plans that do use accumulators—it is a classic race to the bottom.

Not only is the agencies' contrary conclusion illogical as a matter of economic interests, it is contradicted by evidence in the comment record. Multiple commenters informed the agency that, even in the six months between the agencies' August 2019 FAQ document informing the

[9] The agencies' only observation on this point was that, "[i]n fact, no comments submitted by the health insurance industry . . . expressed a desire to change their current practices" with respect to copay accumulators. 2021 NBPP, 85 Fed. Reg. at 29,232 n.150. When requesting comment on whether to open the door to the henhouse, a farmer would do well not to construe the foxes' silence on their intentions to mean that they will forgo their newfound opportunity for an easy lunch.

public that it would not "initiate an enforcement action" against issuers applying copay accumulators in the absence of a "medically appropriate generic equivalent" (AR004321) and the February 2020 comment period on the 2021 NBPP, many insurers had *already* instated new copay accumulators, therefore raising patients' out-of-pocket costs. *See* AR002209 (comment letter: "Following the Tri-Agency FAQ issued in August 2019 indicating HHS would delay enforcement of the final rule, an issuer that had previously aligned its policy to comply with the requirements of the 2020 NBPP [that is, using copay accumulators only where a medically appropriate generic equivalent is available] promptly issued an addendum, reverting to broadly banning all copay assistance without exception."). Indeed, "following the Tri-agencies' announced change in policy for the 2020 plan year, *all but one* of Florida's nine marketplace participants included accumulator adjuster provisions in their health plans." AR002701 (another comment letter).[10]

Thus, the agency had before it not only the logic of the incentives created by its proposed action, but actual evidence that insurers were, in fact, following those incentives to their logical conclusion: instituting copay accumulators, and thereby increasing out-of-pocket costs to patients. Yet the agency simply "acknowledge[d]" those concerns and brushed them aside, rather than engaging with their sound logic and evidentiary support. That, too, renders the agencies' action arbitrary and capricious. *See Carlson v. Postal Reg. Comm'n*, 938 F.3d 337, 344 (D.C. Cir. 2019) (agency "must respond to comments that can be thought to challenge a fundamental premise underlying the proposed agency decision"); *Gresham v. Azar*, 950 F.3d 93, 103 (D.C. Cir. 2020) ("Nodding to concerns raised by commenters only to dismiss them in a conclusory manner is not a hallmark of reasoned decisionmaking."), *vacated as moot*, 142 S.Ct. 166 (2022); *Citizens for Resp. & Ethics in Wash. v. Nat'l Archives & Records Admin.*, 2022 WL 2064831, at *3 (D.D.C. June 8, 2022) (where agency "summarily responded" to comments "without explaining *how* the agency came to [its] conclusion," "[g]iving such short shrift to substantive comments about a key

[10] *See also, e.g.*, AR000404 ("In other markets, insurers have enthusiastically embraced copay accumulator programs, so it seems unlikely that they will choose *not* to use this authority in exchange plans."); AR002719 ("The Network believes this policy would result in more plans utilizing copay accumulators, which in turn, would increase the out-of-pocket exposure of patients.").

factor in the agency's decisionmaking flew in the face of well-established precedent"); *Cigar Ass'n of Am. v. FDA*, 480 F. Supp. 3d 256, 279 (D.D.C. 2020) ("The requirement that agency action not be arbitrary and capricious includes a requirement that the agency respond to relevant and significant public comments, and an agency cannot meet this burden by nodding to concerns raised by commenters only to dismiss them in a conclusory manner.") (quotation marks and citation omitted; alterations incorporated).[11]

In sum, the agency's analysis of increased costs to patients both (1) is irrational on its face for assuming that economic entities will not act in their economic interests; and (2) disregarded comments demonstrating that insurers already were, in fact, acting in accord with those interests by instituting copay accumulators. The agency's action—based, as it is, on that irrational analysis—must be set aside.

C. The agencies have failed to adequately justify their abrupt reversal.

Next, the agencies have also failed to follow the procedures required of an agency that reverses its previous position. *See generally Fox*, 556 U.S. at 515-516 ("It would be arbitrary and capricious [for an agency] to ignore" either the fact that "its new policy rests upon factual findings that contradict those which underlay its prior policy" or that "its prior policy has engendered serious reliance interests that must be taken into account.").

1. Here, the agencies determined in the 2020 NBPP that the authorization for plans to employ copay accumulators should be limited to situations where a generic alternative is available and medically appropriate: "Where there is no generic equivalent available or medically appropri-

[11] While it would be inappropriate to judge the agencies' reasoning based on hindsight (*see, e.g.*, *Univ. of Colo. Health v. Azar*, 486 F. Supp. 3d 185, 218 (D.D.C. 2020)), the latest data confirms the information the agencies had before them at the time: Insurers continue to act in accordance with their economic incentives by adopting more and more copay accumulator programs. For example, for patients requiring specific specialty medications, "exposure to or prevalence of accumulator and [related] maximizer plans grew from 14% of commercially-insured patients in 2019 to 33% in 2022." IQVIA, Five Years and Counting: Deductible Accumulators and Copay Maximizers in 2022, https://perma.cc/F3SG-4KR4.

ate . . . 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." 2020 NBPP, 84 Fed. Reg. at 17,545.

This restriction was premised on a factual finding that the entire basis for permitting accumulators in the first place—combating supposed market distortions—applies only when a generic is available. As the agencies explained at the time, "the availability of a coupon may cause physicians and beneficiaries to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available," thus "distort[ing] the market and the true cost of drugs"—but that possibility exists *only* "when a less expensive and equally effective generic is available": "Where 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." 2020 NBPP, 84 Fed. Reg at 17,545; *see also id.* ("[W]hen an enrollee is determined . . . to require a brand drug because the generic or other alternative may not be available or medically appropriate, the use of the manufacturer coupon *would not disincentivize a less expensive choice*.") (emphasis added).

In the 2021 NBPP, the agencies reversed this policy, expanding the approval of copay accumulators even beyond situations where a medically appropriate generic alternative is available. *See* 2021 NBPP, 85 Fed. Reg. at 29,261. Yet the agencies did not even attempt to distinguish or rebut their prior factual finding that accumulators are justified by market forces only "when a less expensive and equally effective generic *is* available." 2020 NBPP, 84 Fed. Reg at 17,545 (emphasis added); *see generally* 2021 NBPP, 85 Fed. Reg. at 29,230-29,235 (not meaningfully discussing this finding); *cf. id.* at 29,234 ([T]he availability of . . . direct support may cause physicians and enrollees to choose an expensive brand-name drug *when a less expensive and equally effective generic . . . is available*.") (emphasis added). That head-in-the-sand approach to changing agency policy is precisely what *Fox* and its progeny do not allow. *See Fox*, 556 U.S. at 515-516 ("[A] reasoned explanation is needed for disregarding facts and circumstances that underlay . . . the prior policy."); *Mozilla Corp. v. FCC*, 940 F.3d 1, 55 (D.C. Cir. 2019) ("[A]n agency cannot simply

disregard contrary or inconvenient factual determinations that it made in the past, any more than it can ignore inconvenient facts when it writes on a blank slate.") (quoting *Fox*, 556 U.S. at 537 (Kennedy, J., concurring)).

For example, the Fifth Circuit recently vacated an agency action under *Fox* because it "rested upon factual findings that contradict those which underlay" the agency's prior policy, "[y]et [the agency] didn't address its own prior factual findings at all when it terminated" that prior policy. *Texas v. Biden*, 20 F.4th 928, 990-991 (5th Cir. 2021), *rev'd on other grounds*, 142 S. Ct. 2528 (2022); *see also id.* at 991 ("When a 'new policy rests upon factual findings that contradict those which underlay [the agency's] prior policy," the agency must "address its prior factual findings—explaining why they were mistaken, misguided, or the like.") (quoting *Fox*, 556 U.S. at 515). As the court explained, under *Fox*, if an agency "fail[s] to give a 'detailed' (or any) discussion of the prior findings" that contradict its current approach, "[t]hat's that": the action is arbitrary and capricious. *Id.*

Just so here. Because the 2021 NBPP "simply disregard[s]" the "contrary or inconvenient factual determinations that [the agencies] made in the past" (*Mozilla*, 940 F.3d at 55)—specifically, that copay accumulators do not serve a socially beneficial economic purpose when applied in the absence of generic equivalents—rather than "explaining why [those findings] were mistaken, misguided or the like" (*Texas*, 20 F.4th at 991), it is arbitrary and capricious under *Fox*.

2. The agency also failed to consider reliance interests that may have accreted around its prior policy, another violation of the *Fox* doctrine. "When an agency changes course, as [HHS and CMS] did here, it must 'be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account.' 'It would be arbitrary and capricious to ignore such matters.'" *DHS v. Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020) (quoting *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016)) (citation omitted).

Here, important reliance interests are upset by the agencies' approval of copay accumulators. For example, it is entirely foreseeable that patients may have started on chronic medications with the help of manufacturer copay assistance, only to be undercut by the agencies' approval of

copay accumulators even where no generic alternative is available. Indeed, numerous commenters highlighted precisely this situation. *See, e.g.*, AR000760 (comment from leukemia survivor with chronic graft-versus-host disease, blindsided by a copay accumulator); AR001943 (comment from patient who would be unable to afford the medication that "has changed [her] life" without copay assistance); AR002184 (comment of the American Medical Association in opposition to the 2021 NBPP, explaining that "[w]hen the copay coupon expires or runs out . . . the patient is faced with a sudden—and often massive—increase in financial responsibility for a drug, as the coupons have not counted toward his/her deductible. This could result in some patients deciding not to take or continue taking their medications with severe adverse health consequences."); AR002337 ("[I]f HHS finalizes its proposal, HIV and [hepatitis] patients could learn—perhaps as soon as this summer or fall depending on how quickly plans implement this new direction from HHS—that they are required to pay hundreds or thousands of dollars more at the pharmacy counter to remain adherent to their life-saving therapies.").[12]

[12] *Accord, e.g.*, AR002463 (Comment of the American College of Rheumatology: "Without the assistance of manufacturer copay coupons, our patients will be forced to delay treatment, ration their medication, forfeit treatment entirely, or experience incredible financial hardships to pay for their treatment."); AR002575 ("Imposing copay accumulator programs on consumers who have no other choice but an expensive brand-name medication not only does nothing to bring down drug costs, but pose significant individual and public health harms by cutting off access to lifesaving medications."); AR002671 (commenter "cautions against" the change because it would "cause[] lower adherence due to higher costs to patients and/or patient confusion due to having to switch medications the patient might already be acclimated to."); AR002696 ("Patients who are stable on a medication regimen depend on uninterrupted access to their prescribed therapies."); AR002701 ("[P]roposals to restrict coupons should ensure that patients who currently rely on them are not harmed."); AR002719 ("Excluding copay coupons from patients' annual maximum out-of-pocket or deductible amounts would compound their financial burden, threatening treatment adherence and potentially altering outcomes."); AR002846 (This policy could . . . lead[] to the possibility of [not only] unforeseen mid-year *affordability* challenges but also *health* challenges for the patient."); AR003279 ("If finalized, this policy will leave cancer patients at risk for exorbitant bills—or worse, without access to lifesaving treatment."); AR003536-3537 ("If HHS implements this rule as proposed, many patients will no longer be able to access potentially lifesaving medication because they cannot afford it. The consequences of HHS' proposal are entirely predictable. Fewer prescriptions will be filled, leading to disruptions in treatment and worse health outcomes. Gaps in treatment can have deadly consequences for some, including people living with HIV/AIDS where 'even short interruptions of care can threaten health and undermine prevention effects.'"); AR003616-3617 (similar).

The agencies, however, did not analyze these reliance interests at all. *See generally* 2021 NBPP, 85 Fed. Reg. at 29,230-29,235. As the Supreme Court explained in *Regents*, because the agencies were "not writing on a blank slate" in the 2021 NBPP, they were "required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." 140 S. Ct. at 1915. Just as in *Regents*, performing that assessment and "[m]aking that difficult decision was the agency's job, but the agency failed to do it." *Id.* at 1914. Just as in *Regents*, therefore, "[t]hat failure was arbitrary and capricious in violation of the APA." *Id.* at 1915.

D. The rule treats similarly situated cases differently, without adequate justification.

Finally, the 2021 NBPP's approval of copay accumulator programs targeting manufacturer assistance is also arbitrary and capricious for its failure "to treat like cases alike." *Nat'l Weather Service Emps. Org.*, 966 F.3d at 883. Robust case law provides that "if an agency treats similarly situated parties differently, its action is arbitrary and capricious in violation of the APA." *E.g.*, *Wilhelmus v. Geren*, 796 F. Supp. 2d 157, 162 (D.D.C. 2011) (quoting *El Rio Santa Cruz Neighborhood Health Ctr., Inc. v. HHS*, 300 F. Supp. 2d 32, 42 (D.D.C. 2004)); *see also id.* ("Government is at its most arbitrary when it treats similarly situated people differently.") (quoting *Etelson v. Office of Personnel Management*, 684 F.2d 918, 926 (D.C. Cir. 1982)); *Indep. Petroleum Ass'n of Am. v. Babbitt*, 92 F.3d 1248, 1260 (D.C. Cir. 1996) ("The treatment of cases A and B, where the two cases are functionally indistinguishable, must be consistent. That is the very meaning of the arbitrary and capricious standard.").

Here, the 2021 NBPP permits insurers to exclude manufacturer assistance from individuals' annual cost-sharing caps, but does not similarly disfavor other forms of third-party copay assistance, such as "crowdfunding amounts, waived medical debt, or support toward the purchase of [durable medical equipment]." 2021 NBPP, 85 Fed. Reg. at 29,234. But there is no basis, as a matter of statutory and regulatory interpretation, to conclude that amounts paid using these other forms of third-party support *are* "cost sharing," while amounts paid using manufacturer support

are not. *Cf.* pages 13-21, *supra*; AR003577 ("[T]he statutory definition of cost-sharing never delineates a carve-out or exception for manufacturer support—in the same way that it does not carve out support provided to a patient by any other third party, such as a bona fide charity, parent, relative, friend, or a charitable stranger. . . . Treating manufacturer support to patients differently from other sources of funding would retroactively impose a new cost sharing limitation on patients that cannot be found anywhere in the plain text of PPACA."); *see also* AA002328.

As for policy, the agencies rely again on the supposedly market-distorting qualities of manufacturer assistance when cheaper generic alternatives are available, and note that they "currently have no evidence that the other types of support . . . ha[ve] similar distortive effects on the market." 2021 NBPP, 85 Fed. Reg. at 29,234. But that is no answer at all—as the agency previously explained, those distortive effects can exist only when generics are available: "[W]hen an enrollee is determined . . . to require a brand drug because the generic or other alternative may not be available or medically appropriate, the use of the manufacturer coupon would not disincentivize a less expensive choice." 2020 NBPP, 84 Fed. Reg at 17,545. And the agencies were presented with significant evidence indicating that this problematic circumstance—the use of manufacturer assistance when a generic *is* available—is extremely rare. *See, e.g.*, AR002865 (comment letter explaining that "Prescription payment claims analyzed by IQVIA from 2013 to 2017 revealed that of the total commercial market, copay cards for products that had lost exclusivity (meaning a generic equivalent exists) *made up only 0.4 percent of the volume of claims*.") (emphasis added); *see also, e.g.*, AR002583 ("87% of manufacturer copay assistance is used for drugs that have no generic equivalent.").

Therefore, the agencies' proffered explanation for treating facially similar cases differently—that manufacturer assistance can cause unique market distortions when generics are available—does not actually explain the action they have taken: permitting insurers to exclude manufacturer assistance from cost-sharing even when generics are *not* available. To adapt the D.C. Circuit's illustration (*Indep. Petroleum Ass'n*, 92 F.3d at 1260), if an agency includes categories A and B in a policy but excludes category C, it is no justification for that arrangement to say that A

is different from C—that may be so, but it does not explain the agency's decision to include *B* but not C. That is the circumstance here: The agencies are treating manufacturer assistance *absent* generic competition differently from other forms of third-party assistance, even though there is no evidence that either of those two categories creates the sort of market distortions the agency has cited from manufacturer assistance where generic competition *is* present. Because the agencies' decision thus fails to proffer a reasoned explanation for its failure "to treat like cases alike" (*Nat'l Weather Service Emps. Org.*, 966 F.3d at 883), it must be set aside for this reason, too.

III. PLAINTIFFS HAVE STANDING.

Plaintiffs plainly enjoy Article III standing to bring this case. "[T]he 'irreducible constitutional minimum' of standing consists of three elements[:] The plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-561 (1992)).

a. As laid out in greater detail in their respective declarations, each of the individual plaintiffs has suffered—and continues to suffer—direct financial harms from copay accumulators, which would be unlawful but for the 2021 NBPP. *Compare* 2021 NBPP, 85 Fed. Reg. at 29,261 (adopting rule that manufacturer assistance amounts "are not required to be[] counted toward the annual limitation on cost sharing") *with* 2020 NBPP, 84 Fed. Reg. at 17,545 (under the prior rule, "[w]here 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.") (emphasis added).

Specifically, each individual plaintiff is harmed in precisely the manner that commenters explained to the agencies would be the logical result of their action: Each patient receives manufacturer copay assistance for lifechanging drugs, yet each plaintiff's insurance plan includes a copay accumulator that excludes manufacturer assistance from her deductible and/or out-of-pocket maximum. *See* Dykstra Decl. ¶¶ 3-5; Mertens Decl. ¶¶ 4-6; Regan Decl. ¶¶ 3-4. As a result, each plaintiff was forced to pay more out of pocket during the 2022 plan year than would be the case

without the copay accumulator included in her plan, and these harms are continuing into the 2023 plan year. *See* Dykstra Decl. ¶¶ 5-10; Mertens Decl. ¶¶ 7-10; Regan Decl. ¶¶ 5-10. Such monetary or "pocketbook injury is a prototypical form of injury in fact" for standing purposes (*Collins v. Yellen*, 141 S. Ct. 1761, 1779 (2021)), irrespective of the magnitude of the financial loss. *Czyzewksi v. Jevic Holding Corp*, 580 U.S. 451, 464 (2017) ("For standing purposes, a loss of even a small amount of money is ordinarily an 'injury.'") (citing *McGowan v. Maryland*, 366 U.S. 420, 430-431 (1961), in which a fine of "$5 plus costs" was sufficient to confer standing);[13] *see also, e.g.*, *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2204 (2021) ("[T]raditional tangible harms, such as . . . monetary harms" "readily qualify as concrete injuries under Article III").

These injuries in fact are also "fairly traceable to the challenged conduct of the defendant" (*Spokeo*, 578 U.S. at 338), under "the well-established principle that standing will lie where a plaintiff demonstrates that the challenged agency action authorizes the conduct that allegedly caused the plaintiff's injuries, if that conduct would allegedly be illegal otherwise" (*Am. Trucking Ass'ns*, 724 F.3d at 248 (quotation marks omitted)). *See also*, *e.g.*, *Animal Legal Def. Fund, Inc. v. Glickman*, 154 F.3d 426, 440-441 (D.C. Cir. 1998) (en banc) ("This circuit's case law confirms the proposition that a plaintiff satisfies the causation prong of constitutional standing by establishing that the challenged agency rule permitted the activity that allegedly injured her, when that activity would allegedly have been illegal otherwise.") (collecting authorities). Just so here: Plaintiffs challenge the agencies' decision to "permit[]" copay accumulators, which plaintiffs allege "would . . . be illegal otherwise" because of the statutory and existing regulatory definitions of cost-sharing. *See* pages 13-21, *supra*.[14]

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[13] The magnitude of the financial harms imposed on the individual plaintiffs here is far from minor. For example, plaintiff Alyssa Dykstra was forced to pay roughly an additional $4,500 out of pocket in 2022 due to the copay accumulator in her insurance plan. Dykstra Decl. ¶ 5.

[14] Whether that allegation of illegality is correct is a merits inquiry, and need not be resolved at the standing stage. *See, e.g.*, *Parker v. District of Columbia*, 478 F.3d 370, 377 (D.C. Cir. 2007) ("[W]hen considering whether a plaintiff has Article III standing, a federal court must assume *arguendo* the merits of his or her legal claim.") (collecting authorities).

And finally, plaintiffs' injuries are redressable by a favorable decision in this case; such a decision would set aside the 2021 NBPP's authorization of copay accumulators in the absence of a medically appropriate generic alternative, and the individual plaintiffs' insurance plans would no longer be permitted to impose them. The individual plaintiffs therefore have standing to challenge the agencies' action. *Spokeo*, 578 U.S. at 338; *cf., e.g.*, *Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Human Servs.*, 485 F. Supp. 3d 1, 18 (D.D.C. 2020) ("[I]f constitutional standing 'can be shown for at least one plaintiff, we need not consider the standing of the other plaintiffs to raise that claim.'") (quoting *Carpenters Indus. Council v. Zinke*, 854 F.3d 1, 9 (D.C. Cir. 2017)).

b. The organizational plaintiffs, too, are harmed by the agencies' action here, and therefore have standing on their own behalf. *See, e.g.*, *Scenic Am., Inc. v. U.S. Dep't of Transp.*, 983 F. Supp. 2d 170, 175-179 (D.D.C. 2013) (discussing organizational standing, and explaining that D.C. Circuit and Supreme Court "precedent . . . is quite generous in defining harm to an organizational plaintiff's 'activities.' Such a plaintiff is said to suffer an injury in fact if it 'undertakes expenditures in response to, and to counteract, the effects of a defendant's challenged conduct.") (quoting *Equal Rights Ctr. v. Post Properties, Inc.*, 633 F.3d 1136, 1140 (D.C. Cir. 2011)) (alterations incorporated).

As explained in their respective declarations, each organization has been forced to divert its resources away from its ordinary activities and toward education and advocacy to combat the rise in, and mitigate the effects of, copay accumulator programs in the wake of the 2021 NBPP. *See* Schmid Decl. ¶¶ 4-10; Huntley Decl. ¶¶ 4-10. These activities include efforts to increase health-insurance literacy within patient populations; direct analysis of insurance plan documents for evidence of accumulators and communication to patients of those findings and their impacts; and training of patients and family members to advocate for their own rights. Schmid Decl. ¶¶ 5-8; Huntley Decl. ¶¶ 5-6, 9-10. These educational and awareness activities are exactly the kind of "expenditures . . . to counteract[] the effect of a defendant's challenged conduct" that give rise to standing. *Scenic Am.*, 983 F. Supp. 2d at 179 (finding that plaintiff's diversion of resources to "educating local communities about the legal, policy, safety, and administrative issues related to

[the practice authorized by the challenged agency action]" was sufficient to confer organizational standing).

Thus, while the organizational plaintiffs certainly do engage in issue advocacy, they also perform "non-lobbying activities" (*Ctr. for Law & Educ. v. Dep't of Educ.*, 396 F.3d 1152, 1161 (D.C. Cir. 2005)), the impairment of which, through diversion of resources, constitutes Article III injury. *See, e.g.*, *Scenic Am.*, 983 F. Supp. 2d at 176-179. And for the same reasons as discussed above with respect to the individual plaintiffs, these cognizable harms are also traceable to the 2021 NBPP and redressable by judicial action in this case. *See Am. Trucking Ass'ns*, 724 F.3d at 248. The organizational plaintiffs, too, have standing.[15]

c. Finally, Plaintiff DPAC also enjoys associational standing on behalf of its members—individuals with diabetes—who are directly harmed by copay accumulators authorized by the 2021 NBPP. *See generally, e.g.*, *Wash. Alliance of Tech. Workers v. DHS*, 50 F.4th 164, 175-176 (D.C. Cir. 2022) (party seeking associational standing "must show that (1) at least one of its members has standing to sue in his or her own right, (2) that the interests it seeks to protect are germane to its purpose, and (3) neither the claim asserted nor the relief requested requires the participation of an individual member in the lawsuit."). For example, Plaintiff Katherine Mertens is a member of DPAC (Mertens Decl. ¶ 2); her injuries, and resulting entitlement to standing, are detailed above, and other DPAC members are similarly situated and thus have suffered similar, corresponding

[15] Defendants' approval of copay accumulators also conflicts with Plaintiffs' respective organizational missions. *See, e.g.*, *Nat'l Treasury Emps. Union v. United States*, 101 F.3d 1423, 1430 (D.C. Cir. 1996) ([W]here an organization alleges that a defendant's conduct has made the organization's activities more difficult, the presence of a direct conflict between the defendant's conduct and the organization's mission is necessary—though not alone sufficient—to establish standing."). The HIV and Hepatitis Policy Institute's "Mission Statement" is that "[t]he HIV+Hepatitis Policy Institute promotes quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions." Schmid Decl. ¶ 3. The "Mission and Vision Statement" of DPAC is "[t]o ensure quality of and access to care, medications and devices for people living with diabetes; and to educate, inspire and empower patient advocates as well as lawmakers toward meaningful action on diabetes." Huntley Decl. ¶ 8. And DLC is "dedicated to securing effective, affordable health care and a discrimination-free environment for every person with diabetes." *Id.* ¶ 3.

harms. Huntley Decl. ¶¶ 7, 9. Because the interests at stake in this case are also germane to DPAC's purpose (*see* note 15, *supra*), and nothing about this APA claim requires participation of individuals rather than associations, DPAC has associational standing as well as organizational standing to bring this case.

CONCLUSION

For the foregoing reasons, the Court should grant summary judgment in favor of Plaintiffs, and set aside the 2021 NBPP's authorization of copay accumulator programs.

Dated: February 2, 2023

Respectfully submitted,

/s/ *Paul W. Hughes*

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IN THE 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.	No. 1:22-cv-2604

DECLARATION OF ALYSSA DYKSTRA

I, Alyssa Dykstra, hereby declare as follows:

1. I am above 18 years of age, and have personal knowledge of the following facts.

2. I have suffered direct monetary harm as a result of the copay accumulator program instituted by my health insurance plan, which I understand was authorized by the United States Department of Health and Human Services and Centers for Medicare and Medicaid Services in a rule titled *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. 29,164 (May 14, 2020).

3. Specifically, I take a prescription biologic medication called Cimzia, which costs about $3,000 for a one-month supply. I receive copay assistance from the manufacturer of Cimzia, UCB, through an assistance program called CIMplicity, which covers my entire out-of-pocket cost for the medication.

4. In mid-2022, I switched health insurance plans and, as I now know, the new plan included a copay accumulator program, which prevents the assistance I receive through the CIMplicity program from counting toward my annual deductible or out of pocket maximum. For 2022, my deductible was $2,800 and my out-of-pocket maximum was $4,500.

5. As a result of my insurance plan's copay accumulator, the funds I obtained through the CIMplicity program to cover my out-of-pocket Cimzia expenses for September through December of 2022 were not counted toward either my deductible or my out-of-pocket maximum. I therefore ultimately paid $4,500 dollars in other, out-of-pocket medical expenses before my insurer decided I had met my out-of-pocket maximum, and started covering my expenses at 100%.

6. Had my insurer not had a copay accumulator in place—and therefore had to count the roughly $3,000 per month I obtained from the CIMplicity program toward my deductible and out-of-pocket maximum, I would have reached my deductible within one month, and my out-of-pocket maximum within two months, and thus would not have had to pay that extra $4,500 out of pocket for my other, non-Cimza medical expenses in 2022.

7. The fact that my insurance plan includes a copay accumulator therefore directly caused me to pay roughly $4,500 out of pocket that I would not have had to pay, absent the copay accumulator.

8. I attempted to work with my husband's employer (through which I have my coverage) to find a plan for 2023 that did not contain a copay accumulator—but the employer reported that it was unable to find any plan that does not have one. I therefore remain on a plan with a copay accumulator in 2023.

9. Because I will continue to take Cimzia, with its ongoing cost of $3,000 per month, and will continue to receive manufacturer assistance through CIMplicity, this same situation will continue in 2023: I will again be required to pay additional money to reach my deductible and out-of-pocket maximum that I would not have to pay if the insurer counted the funds I obtain through the CIMplicity program against my deductible and out-of-pocket maximum.

10. The monetary harm to me from my plan's copay accumulator is therefore likely to continue indefinitely, so long as the plan continues to maintain and apply the copay accumulator.

I declare under penalty of perjury that the foregoing facts are true and correct to the best of my knowledge.

Executed this 30 day of January (month), 2023, at Lake Forest, California (city and state)

Alyssa R. Dykstra

Alyssa Dykstra

IN THE 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.	No. 1:22-cv-2604

DECLARATION OF KATHERINE MERTENS

I, Katherine Mertens, hereby declare as follows:

1. I am above 18 years of age, and have personal knowledge of the following facts.

2. I am a member of the Diabetes Patient Advocacy Coalition, or DPAC.

3. I have suffered direct monetary harm as a result of the copay accumulator program instituted by my health insurance plan, which I understand was authorized by the United States Department of Health and Human Services and Centers for Medicare and Medicaid Services in a rule titled *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. 29,164 (May 14, 2020).

4. Specifically, my 4-year-old son was diagnosed with type 1 diabetes as a baby; he now takes Novolog fast-acting insulin as a part of his treatment regimen, among other medications. Insulin is a necessary treatment to manage the effects of diabetes; he will therefore continue to require insulin injections indefinitely.

5. I utilize a copay card—that is, manufacturer copay assistance—from the manufacturer of Novolog to help pay for my son's ongoing insulin expenses.

6. My employer-provided health insurance plan does not count the manufacturer assistance I obtain through the copay card against my annual deductible; I understand that this is the result of the plan utilizing a copay accumulator. For 2022, the deductible for my family plan was $2,800; after we hit the deductible, we pay $20% coinsurance until we hit our out-of-pocket maximum of $7,900.

7. In 2022, we ultimately reached the $2,800 deductible, even though the insurer was not counting funds provided through manufacturer assistance against that tally. Because the insurer was not counting manufacturer assistance funds, however, we reached the deductible later than we otherwise would have, and therefore had to pay 100% for certain other, non-insulin medical expenses out of pocket—whereas we would have only had to pay the 20% coinsurance for those expenses had our deductible been deemed already met.

8. The fact that my insurance plan includes a copay accumulator therefore directly caused me to pay money out of pocket that I would not have had to pay, absent the copay accumulator.

9. Because my son will continue to require fast-acting insulin, with its associated ongoing costs, and because we will continue to obtain manufacturer assistance, this same situation will continue in 2023: We will again be required to pay additional money to reach our deductible that we would not have to pay if the insurer counted the funds I obtain through the insulin copay card program against the plan's deductible. Indeed, I have already used manufacturer copay assistance to pay for my son's Novolog multiple times in 2023, and my insurer continues not to count that assistance toward my deductible.

10. The monetary harm to me from my plan's copay accumulator is therefore likely to continue indefinitely, so long as the plan continues to maintain and apply the copay accumulator.

I declare under penalty of perjury that the foregoing facts are true and correct to the best of my knowledge.

Executed this 1 day of February, 2023, at Columbia, MD
(month) (city and state)

Katherine Mertens

IN THE 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.	No. 1:22-cv-2604

DECLARATION OF CYNTHIA REGAN

I, Cynthia Regan, hereby declare as follows:

1. I am above 18 years of age, and have personal knowledge of the following facts.

2. I have suffered direct monetary harm as a result of the copay accumulator program instituted by my health insurance plan, which I understand was authorized by the United States Department of Health and Human Services and Centers for Medicare and Medicaid Services in a rule titled *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. 29,164 (May 14, 2020).

3. Specifically, in mid-2022, I was prescribed and began taking Humira, an advanced biologic medication, for psoriasis and psoriatic arthritis.

4. When I attempted to pay for my Humira in part with a $500 manufacturer coupon, however, I discovered that my insurance plan has a copay accumulator that prevented that $500 from counting toward my deductible or out-of-pocket maximum.

5. For 2022, the deductible and out-of-pocket maximum for my employer-provided plan were both set at $6,350.

6. Thus, as a result of my plan's copay accumulator—which prevented the $500 of manufacturer coupon assistance from counting toward my deductible or out-of-pocket maximum—I was required to pay an extra $500 to other healthcare providers before my insurer considered the out-of-pocket maximum met for 2022, and began paying for my care at 100%.

7. The fact that my insurance plan includes a copay accumulator therefore directly caused me to pay money out of pocket that I would not have had to pay, absent the copay accumulator.

8. Because I expect to continue taking Humira, with its associated ongoing costs, for my health conditions, and because I will continue to obtain manufacturer assistance, this same situation will continue in 2023: I will again be required to pay additional money to reach my deductible and out-of-pocket maximum that I would not have to pay if the insurer counted the funds I obtain through manufacturer coupons against the plan's deductible and out of pocket maximum. For 2023, my deductible is $4,000; after I reach that deductible my plan covers expenses at 80% until I hit my out-of-pocket maximum of $6,550.

9. Indeed, in January of 2023 I paid for a fill of Humira using manufacturer assistance, and the explanation of benefits document issued by my insurer explicitly stated that the manufacturer assistance—which in this instance amounted to multiple thousands of dollars—would not be counted toward my deductible or out of pocket maximum. If these amounts counted toward my deductible and out-of-pocket maximum, I would reach the deductible in a matter of a few months based on my Humira prescription alone, after which my insurer would have to cover all of my medical expenses at 80%—and I would reach the out of pocket maximum in a few months more, after which the insurer would have to cover 100% of my medical expenses. But because the assistance is not being credited, I will instead be forced to pay fully out of pocket for any other medical expenses, just as was the case in 2022.

10. The monetary harm to me from my plan's copay accumulator is therefore likely to continue indefinitely, so long as the plan continues to maintain and apply the copay accumulator.

I declare under penalty of perjury that the foregoing facts are true and correct to the best of my knowledge.

Executed this 1st day of February (month), 2023, at Newtown, PA (city and state)

Cynthia H Regan

Cynthia Regan

IN THE 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.	No. 1:22-cv-2604

DECLARATION OF CARL SCHMID

I, Carl Schmid, hereby declare as follows:

1. I am above 18 years of age, and have personal knowledge of the following facts.

2. I am the Executive Director of the HIV and Hepatitis Policy Institute, which I formed in 2020. I have been a national policy and advocacy leader in the HIV community for over 20 years.

3. The HIV and Hepatitis Policy Institute is a nonprofit organization headquartered in Washington, D.C. Its official mission statement is that "[t]he HIV+Hepatitis Policy Institute promotes quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions." *See About Us*, HIV and Hepatitis Policy Institute, https://hivhep.org/about-us/.

4. The expanding use of copay accumulators in insurance plans imposes significant harms on patients with chronic conditions, like HIV and hepatitis, requiring often-expensive specialty medications. Copay accumulators thus pose an issue of considerable importance to the HIV and Hepatitis Policy Institute.

5. To that end, in addition to extensive policy advocacy at the state and national levels seeking to stop this unfair and exploitative practice, the HIV and Hepatitis Policy Institute has diverted significant resources towards direct educational services and awareness campaigns aimed at countering the harmful effects of copay accumulators on affected patient populations in the wake of HHS's and CMS's explicit approval of copay accumulators, regardless of generic availability, in the 2021 NBPP challenged in this lawsuit.

6. Specifically, the HIV and Hepatitis Policy Institute has devoted countless hours of staff time to researching insurance plans throughout the country in order to determine how each plan addresses cost-sharing obligations and copay assistance. This information is usually buried in byzantine plan documents, and it takes significant staff time and expertise to unravel each plan's policies. The Institute has then directly educated patients and patient groups throughout the country on these findings and their impact on patients, enabling patients to make more informed coverage and care decisions.

7. This work has occurred both within the HIV and hepatitis communities and other patient communities, including those impacted by cancer, mental illness, autoimmune diseases, arthritis, hemophilia, cardiovascular illnesses, Lupus, psoriasis, and many others, including those with rare diseases.

8. The HIV and Hepatitis Policy Institute has also devoted resources toward public awareness campaigns, frequently working with the media and reporters throughout the country, making the general public aware of copay accumulators and the current regulations impacting them, so that patients can make better decisions both in selecting their insurance and in accessing and affording their medications once they have insurance.

9. Because the Institute has finite staff and financial resources, devoting time, money, and energy towards these educational efforts to combat the worst effects of copay accumulators necessarily decreases the Institute's ability to pursue its other organizational goals, including efforts related to HIV and hepatitis-specific programs and policies. For example, this has been a particularly challenging period for combating HIV and hepatitis due to the COVID-19 crisis. Not only did the Institute work to educate its patient communities and stakeholders on how to carry out and adopt its operations during the crisis, but since HIV and hepatitis are both infectious diseases, many resources and expertise in the field were devoted to COVID-19 and therefore unavailable for other diseases like HIV and hepatitis, making the Institute's efforts in this area all the more necessary. Yet the Institute instead had to divert much of its resources toward copay accumulators.

10. Were it not for the 2021 NBPP's explicit approval of copay accumulators in all circumstances (not limited to situations with available generics), the Institute would not have to make these expenditures—and certainly not at the levels it is required to make now. The 2021 NBPP is therefore responsible for this diversion of the Institute's resources.

I declare under penalty of perjury that the foregoing facts are true and correct to the best of my knowledge.

Executed this _1st__ day of _February ___, 2023, at ___Washington DC_____
(month) (city and state)

Carl Schmid

IN THE 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.	No. 1:22-cv-2604

DECLARATION OF GEORGE HUNTLEY

I, George Huntley, hereby declare as follows:

1. I am above 18 years of age, and have personal knowledge of the following facts.

2. I am the Chief Executive Officer (CEO) of the Diabetes Patient Advocacy Council (DPAC). I am also the CEO and a founding member of the Diabetes Leadership Council (DLC). I myself have been living with type 1 diabetes since 1983, and have been a formal advocate for the interests of people with diabetes for over thirty years.

3. DLC unites former leaders of national diabetes organizations, dedicated to securing effective, affordable health care and a discrimination-free environment for every person with diabetes. DLC is comprised of people with diabetes, parents of children with diabetes, allies and tireless volunteers dedicated to improving the lives of all people impacted by diabetes. DLC is "dedicated to securing effective, affordable health care and a discrimination-free environment for every person with diabetes." *See Who We Are*, DLC, https://diabetesleadership.org/who-we-are.

4. The expanding use of copay accumulators in insurance plans imposes significant harms on patients with chronic conditions, like diabetes, requiring regular use of often-expensive brand and specialty medications to manage their blood glucose levels and delay or prevent the onset of the devastating complications of diabetes including blindness, heart disease, kidney failure and amputations. Copay accumulators thus pose an issue of considerable importance to DLC.

5. To that end, in addition to extensive policy advocacy seeking to stop this unfair and exploitative practice, DLC has diverted significant resources towards direct services and awareness campaigns aimed at countering the harmful effects of copay accumulators on affected patient populations in the wake of HHS's and CMS's explicit approval of copay accumulators, regardless of generic availability, in the 2021 NBPP challenged in this lawsuit.

6. For example, Plaintiff DLC works to increase health-insurance literacy both within and outside the diabetes patient population, ensuring patients are better able to understand their options and plan their healthcare spending, including with respect to copay accumulators. DLC also works with individual employers, employer organizations, and benefit consultants to incorporate plan features beneficial to the diabetes community, such as deductible exemptions for insulin. This direct service activity, too, now focuses on copay accumulators.

7. DPAC is an alliance of people with diabetes, caregivers, patient advocates, health professionals, diabetes organizations and companies working collaboratively to promote and support public policy initiatives to improve the health of all 37 million Americans with diabetes. Its members include patients with diabetes who utilize manufacturer assistance and are harmed by copay accumulator programs.

8. The "Mission and Vision Statement" of DPAC is "[t]o ensure quality of and access to care, medications and devices for people living with diabetes; and to educate, inspire and empower patient advocates as well as lawmakers toward meaningful action on diabetes." *See About*, DPAC, https://www.diabetespac.org/about.

9. The expanding use of copay accumulators in insurance plans imposes significant harms on patients with chronic conditions, like diabetes, requiring regular use of often-expensive

brand and specialty medications to manage their blood glucose levels and delay or prevent the onset of the devastating complications of diabetes including blindness, heart disease, kidney failure and amputations. Copay accumulators thus pose an issue of considerable importance to DPAC.

10. To that end, in addition to extensive policy advocacy seeking to stop this unfair and exploitative practice, DPAC has diverted significant resources towards direct services and awareness campaigns aimed at countering the harmful effects of copay accumulators on affected patient populations in the wake of HHS's and CMS's explicit approval of copay accumulators, regardless of generic availability, in the 2021 NBPP challenged in this lawsuit. In particular, DPAC has developed a training program for its constituents on the impact of copay accumulators on diabetes patients and trains diabetes patients and family members to take charge and effectively advocate for their own interests at the state government level, including with respect to copay accumulator programs.

11. Plaintiff Katherine Mertens is a member of DPAC.

I declare under penalty of perjury that the foregoing facts are true and correct to the best of my knowledge.

Executed this 1st day of February, 2023, at Orlando, FL

George Huntley (Feb 1, 2023 16:17 EST)

George Huntley

IN THE 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.	No. 1:22-cv-2604 (JDB)

[PROPOSED] ORDER

Having considered Plaintiffs' Motion for Summary Judgment, the statements of points and authorities filed in support thereof and opposition thereto, and the arguments of the parties, the Court hereby:

ORDERS that Plaintiffs' Motion for Summary Judgment is GRANTED; and the Court further

ORDERS that Defendants' rule, *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. 29,163 (May 14, 2020), is hereby VACATED to the extent it authorizes insurers and other parties not to count manufacturer assistance amounts against patients' cost-sharing responsibilities.

IT IS SO ORDERED.

Dated this ____ day of _____, 2023

_____
John D. Bates
United States District Judge