IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HIV AND HEPATITIS POLICY INSTITUTE
1602 Belmont Street NW, Unit B
Washington, D.C. 20009,

DIABETES PATIENT ADVOCACY COALITION
229 Tahoma Road
Lexington, KY 40503,

and

DIABETES LEADERSHIP COUNCIL
229 Tahoma Road
Lexington, KY 40503,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CENTERS FOR MEDICARE AND MEDICAID SERVICES; XAVIER BECERRA, in his official capacity as Secretary of HHS,

and

CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of CMS,

Defendants.

No. 1:22-cv-2604

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. Pharmaceutical innovations have transformed our lives. Groundbreaking pharmaceuticals can enable a person with HIV and hepatitis B to live a normal lifespan; there are now drugs that prevent new HIV infections; and individuals infected with hepatitis C can be cured in a matter of weeks. New therapies in diabetes management that provide significant protection

against heart and kidney failure, two of the most common and devastating complications of the disease, are now available to patients. Certain medications have proven remarkably successful in treating—and, in some cases, curing—various forms of cancer. Other new therapeutics are vastly improving outcomes for patients with heart disease and other chronic conditions. In all, hundreds of innovative drugs now enable millions of Americans to lead healthier, better, and—ultimately—longer lives.

2. 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 bills for drugs.

3. In light of escalating healthcare prices and the unavailability of quality, affordable healthcare to millions of Americans, in 2010 Congress enacted the Patient Protection and Affordable Care Act (ACA). In creating an individual insurance market, the ACA sought to ensure that premiums were affordable to everyday Americans. It also aimed to curtail the maximum out-of-pocket expenditures that would attach to those plans regulated by the ACA. Yet these sums remain high. In 2022, for example, the out-of-pocket maximum for an individual is $8,700 for an individual and $17,400 for a family.

4. Even with the ACA's limits, millions of American families simply cannot afford these out-of-pocket maximums. 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." Gregory Young, *et al*., *Peterson-KFF Health System Tracker* (Mar. 10, 2022), https://perma.cc/BP27-EC4Z. That is, "about a third (32%) of single-person households with private insurance in 2019 could not pay a $2,000 bill, and half (51%) could not pay a $6,000 bill." *Id*. Though many private health plans set the out-of-pocket maximum lower than the ACA's upper boundary—the study suggests that the average is $4,272 for a single person—"[m]ost households do not have enough liquid assets to meet the typical out-of-pocket maximum." *Id*.

5. Due to prevailing insurance benefit design, including high deductibles and the use of co-insurance, many drugs come with patient costs that easily reach the annual maximum, frequently in the first few months of the plan year.

6. 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. In a recent survey of patients with chronic conditions and their caregivers, for example, a full 46% of respondents reported that they or someone in their household has been unable to afford their out-of-pocket costs (copays and/or coinsurance) in the last year.[1]

7. 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 nonprofits. Yet too many others will go without the innovative therapies that could improve and extend their lives.

8. 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. This assistance is 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.

9. Insurance companies, however, have resisted these programs. Many insurers now attempt to forbid a patient from counting assistance provided by a manufacturer as part of his or her co-payment obligation. If patients can find assistance funds to pay for their medications, insurers often recover far more money—collecting *both* from the patient as well as from the copay assistance provided by the manufacturer, often until the patient exhausts any available copay

[1] National Hemophilia Foundation, *Press Release: National Patient & Caregiver Survey Shows that COVID-19 Has Exacerbated Treatment Affordability Challenges & Health Inequities for Vulnerable Americans* (May 19, 2021), https://perma.cc/YZK4-XSJ8.

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.

10. Under these schemes, generally called copay accumulator adjustment programs, a patient who pays, for example, the $250 copay for a month's supply of medication using a $250 manufacturer copay card is no closer to reaching her deductible than she was before making the payment. Although the patient has held up her end of the bargain by obtaining funds to satisfy her copay obligation, the insurer is permitted to disregard that payment, leaving full benefits just as far out of reach as before. Unsurprisingly, copay accumulator adjustment programs can thus be expected to result in increased out-of-pocket costs to needy patients, decreased adherence to now-unaffordable prescription drug regimens, and greater systemic costs to the healthcare system and to the Nation's health.[2] At worst, these programs create a two-tiered system of healthcare, where needy Americans are simply foreclosed from accessing the most promising therapeutics, thus undercutting the basic tenets of the Affordable Care Act.

11. In fact, co-pay accumulator programs affirmatively harm patient health. As one recent study found, patients subjected to a copay accumulator program fill their prescriptions—again, prescriptions that are frequently for life-saving medications—1.5 times less than patients in

[2] Non-adherence to prescription medications—for which cost is perhaps the largest driving factor—"is estimated to cause approximately 125,000 deaths and at least 10 percent of hospitalizations, and to cost the American health care system between $100 billion and $289 billion a year. Jane E. Brody, *The Cost of Not Taking Your Medicine*, New York Times (Apr. 17, 2017), https://perma.cc/SLZ2-77RN. For example, one study estimates that up to 69% of patients will abandon medications if cost sharing exceeds $250. *See* Katie Devane, Katie Harris, & Kevin Kelly, *Patient Affordability Part Two: Implications for Patient Behavior & Therapy Consumption*, IQVIA (May 18, 2018) (explaining that "69% of commercial patients did not start therapy when faced with out-of-pocket costs exceeding $250") (downloadable at https://www.iqvia.com/locations/united-states/library/case-studies/patient-affordability-part-two). Another recent study found that 44% of commercially insured cancer patients abandoned their medications when the out-of-pocket costs reached $500; for those whose out-of-pocket costs exceeded $2000, the abandonment rate was 67%. Jalpa A. Doshi et al., *Association of Patient Out-of-Pocket Costs With Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents*, 36 J. Clinical Oncology 476, 481 tbl. 3 (2018), https://perma.cc/5XKQ-WM25.

high deductible health plans.[3] The injuries caused by copay accumulator programs are real and concrete.

12. 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. 29,163 (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.

13. Since promulgation of the 2021 NBPP, insurance companies and pharmaceutical benefit managers have enhanced their use of copay accumulator adjustment programs, to the detriment of patients across the country.

14. But the 2021 NBPP is plainly unlawful. 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.

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[3] Steve Mink, *Driving Persistence among Patients Affected by Copay Accumulators with Patient-Centric Support*, American Journal of Managed Care (Oct 18, 2020), https://perma.cc/T42V-YFMJ.

PARTIES

15. The HIV and Hepatitis Policy Institute is a leading national policy and advocacy organization working to promote quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions. Those patient populations are often reliant on expensive specialty drugs, and the Institute therefore has a distinct interest in ensuring that the Affordable Care Act's provision for an annual limit on cost-sharing is fully implemented and not violated by HHS and CMS regulations. The Institute is a 501(c)(3) tax-exempt nonprofit headquartered in Washington, D.C.

16. The Diabetes Patient Advocacy Coalition (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.

17. The Diabetes Leadership Council (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.

18. Defendant United States Department of Health and Human Services (HHS) is the federal agency charged with enhancing the health of all Americans by providing for effective health and human services, and co-signed the 2020 Rule challenged here. HHS is headquartered in Washington, D.C.

19. Defendant Xavier Becerra is the Secretary of HHS. He is sued in his official capacity.

20. Defendant Centers for Medicare and Medicaid Services (CMS) is a component of HHS; the agency co-signed the 2020 Rule challenged here along with HHS. CMS is headquartered in Baltimore, Maryland.

21. Defendant Chiquita Brooks-LaSure is the Administrator of CMS. She is sued in her official capacity.

JURISDICTION AND VENUE

22. Plaintiffs bring this suit under the Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and this Court's inherent equitable powers.

23. The court's jurisdiction over is invoked under 28 U.S.C. § 1331, as this case arises under the laws of the United States.

24. Venue is proper in this district under 28 U.S.C. § 1391(e) because Defendant HHS resides in this district. Venue is also proper under 28 U.S.C. § 1391(e) because Plaintiff HIV and Hepatitis Policy Institute resides in this district, and no real property is involved in this action.

FACTUAL ALLEGATIONS

A. Manufacturer copay assistance and the Affordable Care Act's cost-sharing cap.

25. Among its patient-benefitting provisions, the Affordable Care Act mandates 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).

26. In turn, the statute defines "cost-sharing" as follows: "The term 'cost-sharing' includes—(i) deductibles, coinsurance, copayments, or similar charges; and (ii) any other expenditure required of an insured individual which is a qualified medical expense . . . with respect to essential health benefits covered under the plan." 42 U.S.C. § 18022(c)(3).

27. The statute thus sets an annual cap on the "expenditure[s] required of an insured individual" by that person's health insurance plan. 42 U.S.C. § 18022(c)(3).

28. Meanwhile, insurers have increasingly erected barriers, in the form of increased deductibles and co-insurance requirements[4]—that shift the cost of drugs from the insurer to the patient. For example, the median deductible for an individual-market silver plan—the most popular level of plan—has increased by 23% between 2018 and 2022, from $3,939 to $5,155.[5]

29. 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. Indeed, as many as 81% of silver plans require co-insurance for specialty drugs, and the median coinsurance amount is 40%—meaning that these plans require their enrollees to pay 40% of the list price of the drug out of pocket, even after their deductible is met.[6] That can easily translate to thousands of dollars of out-of-pocket costs per month—a burden that many patients simply cannot afford.

30. 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. In essence, the drug manufacturer assists the patient in meeting their 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.

31. 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,

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[4] 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—a co-insurance payment represents a percentage of the cost of the drug (often as high as 50%). Thus, when a drug is expensive, the difference between a flat copayment and a percentage-based co-insurance payment may be enormous.

[5] Dep't of Health & Human Servs., *Plan Year 2022 Qualified Health Plan Choice and Premiums in Healthcare.gov States* at 10 (Oct. 25, 2021), https://perma.cc/VU8L-2XFX.

[6] *See* AIDS Institute, *Discriminatory Copay Policies Undermine Coverage for People with Chronic Illnesses*, at 10 (Jan. 2022), https://perma.cc/ZU8T-N7SF.

that require expensive specialty medications. Indeed, millions of Americans currently rely on copay assistance to afford their critical prescriptions.[7]

B. Copay accumulator programs.

32. While these forms of copay assistance help make innovative drugs affordable to everyday Americans, insurance companies seek to recognize a windfall, accepting copay assistance funds as a benefit to the insurer *without* crediting it to the patients' out-of-pocket obligations. These programs thus force patients to pay out of pocket *regardless* of copay assistance provided by manufacturers.

33. In response to copay programs offered by manufacturers, insurers have developed schemes known as copay accumulator adjustment programs. 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. Thus, 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 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.

34. 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

[7] 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.

more affordable drugs for the rest of the year. The accumulator programs thus deny patients the benefit of satisfying the deductible amount.

35. Consider the following example:[8]

- Plan deductible: $4,600
- Annual out-of-pocket maximum: $8,550
- Cost-sharing for specialty tier prescription: 50% after deductible is met
- Monthly medication cost: $1,680
- Copay assistance total: $7,200

Scenario 1: Plan ***Without*** a Copay Accumulator Program

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total	Insurer collects
Copay Assistance	$1,680	$1,680	$1,240	$840	$840	$840	$80	$0	$0	$0	$0	$0	$7,200	
Remaining Deductible	$2,920	$1,240	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0		$8,550
Consumer Pays	$0	$0	$0	$0	$0	$0	$760	$590	$0	$0	$0	$0	$1,350	

Deductible is met — Copay assistance limit is met — Out-of-Pocket maximum is met

Scenario 2: Plan ***With*** a Copay Accumulator Program

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total	Insurer collects
Copay Assistance	$1,680	$1,680	$1,680	$1,680	$480	$0	$0	$0	$0	$0	$0	$0	$7,200	
Remaining Deductible	$4,600	$4,600	$4,600	$4,600	$3,400	$1,720	$40	$0	$0	$0	$0	$0		$15,160
Consumer Pays	$0	$0	$0	$0	$1,200	$1,680	$1,680	$40	$840	$840	$840	$840	$7,960	

Deductible is met — Copay assistance limit is met — Out-of-Pocket maximum is met

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 that money goes directly into the insurer's pocket.

36. While insurers may assert that this encourages use of less expensive generics, some experts estimate that as many as "87% of medications for which co-pay assistance is available

[8] *Discriminatory Copay Policies*, *supra* note 6, at 7.

have no generic substitute."[9] To receive the medication that the provider prescribes, many patients must first go through cumbersome prior authorizations and step therapy processes, in which insurers attempt to push patients toward alternative drugs, even if it is not the best clinical option. Copay accumulators, accordingly, simply penalize needy patients without any prospect of incentivizing more economically efficient care decisions.

37. Copay accumulator programs are also harmful to patients in additional ways. For one thing, insurance plan documents often lack transparency about whether the plan will include a copay accumulator—meaning that patients will be surprised by unexpected prescription-drug bills that they thought they had already paid through copay assistance. And when a prescription drug expense is unexpected, it can lead to prescription abandonment even in cases where the patient *could* have afforded the drug, if he or she had notice and time to prepare for the expense.

38. These "copay accumulator adjustment policies"—which "contribute to insurance company profit while shifting the cost of expensive prescription drugs back to the patients who most rely on them"—"have become more common in recent years."[10]

39. Insurers and pharmacy benefit managers also have instituted other schemes that result in more flagrant violations of the ACA cost-sharing limits, for example using so-called copay maximizers. Under these programs, the amount of patient cost-sharing is set at a uniquely high amount, designed to result in the patient needing to access the full limits of the manufacturer assistance program. Although the copay assistance still does not count towards the beneficiary's cost-sharing obligation, the insurer nonetheless continues to collect that amount each month from the drug manufacturer resulting in insurers collecting payments far exceeding the out-of-pocket maximum.[11]

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[9] Terry Wilcox & Stacey Worthy, *How a Quiet Co-Pay Rule Change Could Mean Massive Drug Cost Increases*, Fortune (July 22, 2020) (emphasis added), https://perma.cc/Y97B-5F5T.

[10] The AIDS Institute, *Double Dipping* (March 2021), at 3, https://perma.cc/QAA2-7MXC.

[11] *See* Drug Channels, *Copay Maximizers Are Displacing Accumulators—But CMS Ignores How Payers Leverage Patient Support* (May 19, 2020), https://perma.cc/AT8B-DKKA.

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

40. In 2019, 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 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).

41. 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.").

42. 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.

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

43. 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. U.S. Department of Health & Human Servs. et al., *FAQs About Affordable Care Act Implementation Part 40* (Aug. 26, 2019) (emphases added), https://perma.cc/JC3X-RSEF.

44. 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.

45. 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 would conflict with provisions of the tax code and IRS guidance. *Id.* at 29,231, 29,233.

46. 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.

47. In fact, the use of copay accumulators is growing in view of this regulatory change. As one study found, "copay accumulator adjustment policies" have "grown in the wake of HHS's changing policy."[12]

48. 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).

[12] *Double Dipping*, supra note 10, at 18, https://perma.cc/QAA2-7MXC.

49. 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.

50. 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.

51. 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*.

52. Perhaps unsurprisingly, the agencies supplied no legal authority for the proposition that the same legal text can simultaneously mean two different things, never mind the further proposition that a regulated party gets to choose what the law means as applied to itself.

53. 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.

E. The 2021 NBPP is unlawful.

54. Insofar as it permits insurers to exclude manufacturer assistance from the definition of cost-sharing, the agencies' 2021 NBPP is contrary to statute, inconsistent with existing regulations, and arbitrary and capricious for multiple independent reasons.

55. ***First***, the 2021 NBPP is contrary to the statutory text of the ACA. The statute defines "cost-sharing" to include "(i) deductibles, coinsurance, copayments, or similar charges; and (ii) *any other expenditure required of an insured individual* which is a qualified medical expense." 42 U.S.C. § 18022(c)(3) (emphasis added). The text thus looks not to where the money used for a copay originates, but simply 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. That is, the copayments set out in a health insurance policy remain "required of" the beneficiary even if the beneficiary seeks outside assistance in fulfilling that financial "require[ment]": If the beneficiary cannot produce the money—whether from her own bank account, from a family member or a GoFundMe page, or from manufacturer copay assistance—the insurer will not cover the remainder of the treatment.

56. Yet the 2021 NBPP expressly permits insurers to exclude payments from the annual statutory cap on cost-sharing—notwithstanding that the insurer "requires [those payments] of" the insured—just because the insured obtains assistance from the drug manufacturer in satisfying that obligation. It must therefore be set aside as contrary to the statute. *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); *Pub. Serv. Elec. & Gas. Co. v. FERC*, 989 F.3d 10, 19 (D.C. Cir. 2021) ("[A] regulation can never trump the plain meaning of a statute.") (quotation marks omitted).

57. Similarly, the statute serves to define the maximum amount of funds that an insurer may receive as compensation beyond premiums for the provision of healthcare to patients. The accumulator programs, however, unlawfully allow an insurer to collect *more* money than the ACA cap authorizes. That is, payments are made both by the patient and other sources up to the ACA out-of-pocket maximum *and* co-payment assistance is provided by the drug manufacturer. In all, the insurer winds up with more payments received than the statute allows.

58. ***Second***, the 2021 NBPP's approval of copay accumulator programs conflicts even more starkly with the definition of "cost sharing" in the agencies' existing regulations. Those regulations provide that "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." 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 form drug manufacturers are unassailably made "on behalf of" the patient beneficiary (45 C.F.R. § 155.20).

59. Moreover, while agencies' *interpretation* of their existing regulations may in some circumstances be entitled to deference (*cf. Kisor v. Wilkie*, 139 S. Ct. 2400 (2019)), the agencies here expressly *declined* to either amend or interpret the regulatory cost-sharing definition to accommodate copay accumulator programs. *See* 2021 NBPP, 85 Fed. Reg. at 29,232 ("[W]e . . . are not finalizing the proposed interpretation of the definition of cost sharing to exclude expenditures covered by direct drug manufacturer support."); *id.* at 29,234. The agencies' approval of copay accumulator programs thus cannot be supported on this basis.

60. The agencies—and the regulated industry of insurers—therefore remain bound by the plain meaning of the definitional regulation, and their actions in contravention of that regulation must be set aside. *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) ("[A]n agency is not free to ignore or violate its regulations while they remain in effect," and "an agency action may be set aside as arbitrary and capricious if the agency fails to comply with its own regulations.") (quotation marks omitted).

61. ***Third***, the 2021 NBPP's approval of copay accumulator programs is arbitrary and capricious for myriad reasons.

62. Perhaps most obviously, the agencies' bizarre decision to interpret 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 (*see* 2021 NBPP, 85 Fed. Reg. at 29,234)—is contrary both to fundamental principles of interpretation and to the rule of law itself. *See, e.g.*, *Clark v. Martinez*, 543 U.S. 371, 386 (2005) (rejecting "the dangerous principle that . . . the same statutory text" can be given "different meanings in different cases."). What is more, leaving the decision up to the insurers themselves is, by definition, arbitrary.

63. The agencies' policy reasoning also fails the APA's requirement that the agency "articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicles Mfrs. Ass'n of U.S. Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The sole reason the agencies gave in the 2021 NBPP for expanding their approval of copay accumulators beyond situations in which generic alternatives are available was that the prior rule allegedly conflicted with certain provisions of the tax code and IRS guidance. *See* 2021 NBPP, 85 Fed. Reg. at 29,231. But this argument fails for many reasons.

64. To start with, as many commenters explained to the agency during the notice and comment process, that supposed legal conflict was illusory. *See generally id.* at 29,233 (discussing comments). The straightforward text of the relevant statute, 26 U.S.C. § 223, makes plain that allowing manufacturer cost-sharing assistance to count toward a high deductible health plan's

deductible does not disqualify the participant (or the participant's employer) from contributing to a health savings account. Section 223 contains no restriction on *who* pays the deductible, and such an understanding would be contrary to the plain and ordinary meaning of the language used in the statute. The contrary conclusion in the 2021 NBPP is thus straightforward legal error, and it is black-letter law that agency action "cannot be sustained where it is based … on an erroneous view of the law." *Sea-Land Serv., Inc. v. Dep't of Transp.*, 137 F.3d 640, 646 (D.C. Cir. 1998) (quotation marks omitted).

65. More, the IRS guidance at issue is neither a statute nor a regulation, and thus it cannot be a basis to overcome the ACA. At issue here is Q&A 9 of IRS Notice 2004-50—which is merely regulatory guidance. If there were any conflict between the ACA and earlier IRS statutes (to be clear, there is not), the specific mandates in the ACA would govern over predecessor laws.

66. Yet more, the discount cards discussed by Q&A 9 of the IRS Notice 2004-50 are materially different than the manufacturer assistance that is at issue here. The manufacturer assistance at issue here results in the same payments being made to the pharmacist. By contrast, the issue discussed by the IRS guidance addresses a discount card that changes the *rates* the pharmacist charges the patient, resulting a pharmacist receiving less compensation for the drug. The issue in the IRS notice is thus a different one entirely from that present here.

67. Further, the agencies inexplicably failed to consider alternative courses of action that would have been compatible even with their erroneous view of the IRS guidance, short of allowing copay accumulators in *all* circumstances. Because, as commentators robustly underscored, the agencies had options far short of blanket authorization of copay accumulators, the reasoning here—even if credited—cannot supply a non-arbitrary basis for the action. The 2021 NBPP is arbitrary and capricious for this reason, as well. *See, e.g.*, *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).

68. Similarly, the agencies appear to have abandoned, without discussion, their earlier finding that copay accumulators are only justified "when a less expensive and equally effective

generic is available," because in the absence of a medically appropriate generic or otherwise lower-cost drug, "the use of the manufacturer coupon would not disincentivize a less expensive choice" and therefore would not cause the supposed market distortions that formed the entire basis for allowing copay accumulators in the first place. 2020 NBPP, 84 Fed. Reg. at 17,545. Such an unexplained departure from past findings is arbitrary and capricious. *See, e.g.*, *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (requiring a "detailed justification" when an agency's "new policy rests upon factual findings that contradict those which underly its prior policy.").

69. What is more, the agency's change in position disregarded the legitimate reliance interests of patients who 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. This, too, was arbitrary and capricious. *See, e.g. DHS v. Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020) ("When an agency changes course," its "fail[ure] to address whether there was 'legitimate reliance' on the [prior policy] . . . would be arbitrary and capricious.").

70. Relatedly, the only explanation the agencies gave in response to comments demonstrating that their proposed expansion of copay accumulators would increase out-of-pocket costs to patients was essentially that the agencies did not believe insurers would actually apply accumulators in the absence of a generic alternative: "[W]e believe the impact of such [out-of-pocket] costs may be limited if issuers that currently allow these amounts [that is, amounts provided through manufacturer assistance] to be counted toward enrollees' deductibles or their annual limitation on cost sharing continue their current behavior, which we believe will be the case." 2021 NBPP, 85 Fed. Reg. at 29,232; *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.).

71. That is, the agencies' sole justification for why their action would not result in increased costs to patients was a naked assumption that profit-motivated insurance companies

(many of which are publicly traded) would voluntarily forgo a mechanism to increase their profits. That unsupported assumption is flatly irrational, and a rule based upon it therefore cannot stand. *Cf., 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)"). And unsurprisingly, the agencies' economically irrational assumption has turned out to be wrong in practice, with more insurance plans instituting copay accumulators than ever.[13]

72. Indeed, commenters pointed out that some plans had *already* adopted new copay accumulators in response to HHS's 2019 non-enforcement guidance[14]—but the agencies completely failed to respond. That failure forms yet another independent basis to set aside the 2021 NBPP. *See, e.g.*, *City of Columbus v. Cochran*, 523 F. Supp. 3d 731, 745-746 (D. Md. 2021) ("An agency also violates the APA if it fails to respond to significant points and consider all relevant factors raised by the public comments.") (quotation marks omitted) (collecting cases). For this reason, too, the agencies' rule cannot stand.

CLAIMS FOR RELIEF

Count I
Administrative Procedure Act – conflict with statute

73. Plaintiffs incorporate and re-allege the foregoing paragraphs as though fully set forth herein.

[13] For example, a 2021 Kaiser Family Foundation survey found that 24% of medium and large employers utilized copay accumulators in the health plans offered to their employees. *See* KFF, *Employer Health Benefits: 2021 Annual Survey* 189-191 & fig. 13.19. The true number of employers using copay accumulators is likely much higher, as more than 60% of the respondent firms did not know whether their plans used a copay accumulator or not. *Id.*

[14] *See* Comment from All Copays Count Coalition (Mar. 2, 2020), https://www.regulations.gov/comment/CMS-2020-0009-0877.

74. The APA empowers courts to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

75. It likewise authorizes courts to set aside agency action "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(C).

76. The 2021 NBPP violates these APA requirements. It conflicts with the provisions of the Affordable Care Act and is therefore in excess of statutory authority and not in accordance with law. *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.'").

77. The 2021 NBPP must therefore be set aside. 5 U.S.C. § 706(2).

Count II
Administrative Procedure Act – conflict with existing regulations

78. Plaintiffs incorporate and re-allege the foregoing paragraphs as though fully set forth herein.

79. The APA empowers courts to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Under this standard, "[a]n agency of the government must scrupulously observe rules, regulations, or procedures which it has established," and "[w]hen it fails to do so, its action cannot stand and courts will strike it down." *Chen Zhou Chai v. Carroll*, 48 F.3d 1331, 1340 (4th Cir. 1995) (quotation marks omitted).

80. The 2021 NBPP is unlawful because it conflicts with HHS's and CMS's existing regulations, thus abdicating the agencies' responsibility "to comply with [their] own regulations" "while they remain in effect. *Nat'l Envt'l Dev. Ass'n's Clean Air Project v. EPA*, 752 F.3d 999, 1009 (D.C. Cir. 2014).

81. The 2021 NBPP must therefore be set aside. 5 U.S.C. § 706(2).

Count III
Administrative Procedure Act – arbitrary and capricious

82. Plaintiffs incorporate and re-allege the foregoing paragraphs as though fully set forth herein.

83. The APA empowers courts to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

84. The 2021 NBPP fails under the arbitrary and capricious standard in myriad ways: It fails to "articulate . . . a 'rational connection between the facts found and the choice made,'" it "fail[s] to consider . . . important aspect[s] of the problem," and it "offer[s] an explanation for its decision that runs counter to the evidence before the agency." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). It also "misconceive[s] the law" and therefore "may not stand" (*SEC v. Chenery Corp.*, 318 U.S. 80, 94 (1943)) and reverses course without adequate explanation or consideration of reliance interests (*see DHS v. Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020)).

85. For all these reasons, too, the 2021 NBPP must be set aside. 5 U.S.C. § 706(2).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs HIV and Hepatitis Policy Institute, Diabetes Patient Advocacy Coalition, and Diabetes Leadership Council respectfully request that the Court enter judgment in their favor and that the Court:

(a.) "[S]et aside" the 2021 NBPP to the extent it amends 42 C.F.R. § 156.130(h) to permit copay accumulator programs, pursuant to the Administrative Procedure Act, *see* 5 U.S.C. § 706(2);

(b.) Issue a declaratory judgment declaring that the 2021 NBPP is unlawful and void the 2021 NBPP to the extent it amends 42 C.F.R. § 156.130(h) to permit copay accumulator programs;

(c.) Enjoin Defendants from enforcing or otherwise carrying out the 2021 NBPP's approval of copay accumulator programs; and

(d.) Award Plaintiffs such other and further relief as the Court may deem just and proper.

Dated: August 30, 2022

Respectfully submitted,

/s/ *Paul W. Hughes*

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