IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HIV AND HEPATITIS POLICY INSTITUTE, *et al.*,	)	
Plaintiffs,	)	
v.	)	Case No.: 1:22-cv-02604-JDB
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES *et al.*,	)	
Defendants.	)	

UNOPPOSED MOTION OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA FOR LEAVE TO FILE AN AMICUS CURIAE BRIEF IN SUPPORT OF PLAINTIFFS

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Pursuant to this Court's Civil Local Rule ("LCvR") 7(o), Pharmaceutical Research and Manufacturers of America ("PhRMA") respectfully moves for leave to file a brief as *amicus curiae* in the above captioned case in support of Plaintiffs' Motion for Summary Judgment. The proposed *amicus* brief is attached hereto as Exhibit A. Plaintiffs consent to the filing of the *amicus* brief; Defendants do not oppose.

District courts have "broad discretion" to permit *amicus* participation. *Nat'l Ass'n of Home Builders v. U.S. Army Corps of Eng'rs*, 519 F. Supp. 2d 89, 93 (D.D.C. 2007). *Amicus* participation is appropriate where "the *amicus* has unique information or perspective that can help the court beyond the help that the lawyers for the parties are able to provide," *Jin v. Ministry of State Sec.*, 557 F. Supp. 2d 131, 137 (D.D.C. 2008) (quoting *Ryan v. Commodity Futures Trading Comm'n*, 125 F.3d 1062, 1063 (7th Cir. 1997)), or where the *amicus* has "relevant expertise and a stated concern for the issues at stake in [the] case," *District of Columbia v. Potomac Elec. Power Co.*, 826 F. Supp. 2d 227, 237 (D.D.C. 2011); *see also Ellsworth Assocs., Inc. v. United States*, 917 F. Supp. 841, 846 (D.D.C. 1996) (allowing non-party with special interest in and knowledge of issues to participate as *amicus curiae*); *Priests for Life v. Dep't of Health & Hum. Servs.*, No. 1:13-cv-01261-EGS (D.D.C. Oct. 25, 2013); *Jin*, 557 F. Supp. 2d at 137–38.

PhRMA has a strong interest in the matter before the Court and can offer a unique perspective that it believes would aid the Court's consideration of the issues in this litigation and that the Court would not otherwise obtain from the parties. PhRMA is an association that represents the nation's leading biopharmaceutical research companies and manufacturers. PhRMA therefore works to ensure that biopharmaceutical therapies remain accessible and affordable for all patients. Indeed, many of PhRMA's members offer cost-sharing assistance programs to commercially insured patients to help them afford treatments—like coupons, copay cards, or rebates applied to

patients' out-of-pocket expenses. PhRMA can offer insights into how accumulator programs work from the manufactures' perspective, and into how the recent rule from the Department of Health and Human Services ("HHS") and the Centers for Medicare and Medicaid Services ("CMS") (collectively "the agencies") threatens to undermine the benefits of cost-sharing assistance for patient health and the healthcare system. Given PhRMA's stake in its members' ability to operate successful cost-sharing assistance programs, district courts have recently granted PhRMA leave to file *amici* in a case about cost-assistance programs, *Pfizer Inc. v. HHS*, No. 1:20-CV-4920, 2021 WL 4523676, at *1 n.1 (S.D.N.Y. Sept. 30, 2021), and in a case about a program similar to an accumulator program, *Johnson & Johnson Health Care Sys. v. SaveOnSP LLC*, No. 22-cv-2632, slip op. at 16 n.5 (D.N.J. Jan. 25, 2023).

PhRMA is familiar with the agencies' 2020 and 2021 rules relating to accumulator programs. In February 2019, PhRMA commented on the first rule that limited the use of accumulator programs, *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020*, 84 Fed. Reg. 17,454, 17,545 (April 25, 2019) (2020 NBPP).[1] And in March 2020, PhRMA commented on the rule at issue here, which allowed accumulators in all circumstances, *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, 29,234 (May 14, 2020) (2021 NBPP).[2]

[1] PhRMA, Comment Letter on Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020 (February 19, 2019), https://www.thecppc.org/_files/ugd/1859d0_00a54a71454a49ab8c83d8e277e8dccd.pdf.

[2] PhRMA, Comment Letter on Proposed Rule, Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans (March 2, 2020), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/0-9/2021-NBPP-Comment-Letter_FINAL.pdf.

Building on these comment letters, PhRMA's proposed *amicus* supplements the information provided by the parties on the operation of cost-sharing assistance programs, their benefits for patient health and across the healthcare system, and their interactions with accumulator programs. In particular, PhRMA can provide the Court with a well-developed analysis of the benefits of the cost-sharing assistance programs provided by PhRMA members. And PhRMA can detail the likely negative effects of the agencies' rule permitting accumulators in all circumstances.

PhRMA's *amicus* brief also is "timely." LCvR 7(o)(2). Plaintiffs initiated this litigation in August last year, and Plaintiffs submitted their motion for summary judgment on February 2, 2023. According to the Court's briefing schedule, Defendants have until March 2, 2023 to response—affording Defendants an entire month to respond to the *amicus* brief. Defendants will suffer no prejudice, and PhRMA's *amicus* brief will not delay—let alone "unduly delay," LCvR 7(o)(2)—the Court's consideration of the Plaintiffs' motion. *Cf. Pratt v. Indian River Cent. Sch. Dist.*, No. 7:09-CV-0411, 2010 WL 11681606, at *4 (N.D.N.Y. Dec. 6, 2010) (motion for leave to participate as *amicus* was not too late, because it was filed before the court had rendered a decision on the relevant motion). PhRMA respectfully requests that the Court grant its motion for leave to file the proposed *amicus* brief.

For these reasons, the PhRMA respectfully requests that the Court grant its motion for leave to file the proposed *amicus* brief.

Dated: February 9, 2023

Respectfully submitted,

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Exhibit A

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BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFFS

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STATEMENT OF COUNSEL

No party's counsel authored this brief in whole or in part; no party or party's counsel contributed money intended to fund the preparation or the submission of this brief; and no person other than the *amicus curiae*, its members, and its counsel contributed money intended to fund the preparation or the submission of this brief.

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INTRODUCTION

Amicus Pharmaceutical Research and Manufacturers of America ("PhRMA") is an association that represents the country's leading innovative biopharmaceutical research companies and manufacturers. PhRMA devotes its resources to discovering and developing medicines that enable patients to live longer and healthier lives. PhRMA has a strong interest in promoting affordable and accessible prescription drug coverage. To that end, many of PhRMA's members offer cost-sharing assistance programs to reduce patients' out-of-pocket burdens, allowing them to more readily access and adhere to their prescribed treatments while improving patients' health outcomes and creating savings for the healthcare system.

"Accumulator adjustment programs" undermine these essential manufacturer cost-sharing assistance programs by redirecting manufacturer financial assistance intended for patients to insurers. Under an accumulator adjustment program, insurers prevent the value of manufacturer cost-sharing assistance from accruing toward the patient's deductible or the statutorily required annual limitation on cost-sharing. This allows for the collection of the manufacturer's cost-sharing assistance, *as well as* the full amount of the patient's deductible or out-of-pocket maximum. In the end, commercially insured patients who use manufacturer cost-sharing assistance subject to an accumulator adjustment program can have substantially higher out-of-pocket costs over the course of a year than they would have without the manufacturer assistance—contrary to the manufacturer's intent and worsening the very problems associated with high out-of-pocket expenses that manufacturer assistance programs were designed to ameliorate.

To address these concerns, the Department of Health and Human Services ("HHS") and the Centers for Medicare and Medicaid Services ("CMS") (collectively "the agencies") issued a rule prohibiting insurers' accumulator adjustment programs except in limited circumstances. In so

doing, the agencies acknowledged the value of manufacturer cost-sharing assistance programs, and therefore permitted accumulators *only* when a generic medicine was available. *See Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020*, 84 Fed. Reg. 17,454, 17,545 (April 25, 2019) ("2020 NBPP"). Unfortunately, the agencies quickly and arbitrarily reversed course. Less than a year later, they adopted the rule at issue here, allowing accumulators in *all* circumstances. *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, 29,233–34 (May 14, 2020) ("2021 NBPP").

PhRMA submits this brief in support of plaintiffs' motion for summary judgment because the 2021 NBPP violates the ACA's plain terms, is arbitrary and capricious, and harms patients. Permitting accumulator adjustment programs without restriction will increase out-of-pocket costs for commercially insured patients who rely on manufacturer cost-sharing assistance to access and adhere to their prescription medications. These increased costs will be felt especially by commercially insured patients who rely on specialty medications for which no generic equivalent exists. PhRMA thus respectfully urges the Court to vacate the challenged provisions of the 2021 NBPP that undermine commercially insured patients' access to their critical medications.

ARGUMENT

I. The 2021 NBPP Harms Patients by Permitting the Exclusion of All Cost-Sharing Assistance from Patients' Out-of-Pocket Maximums.

A. Cost-Sharing Assistance Programs Help Patients Access and Afford Essential Medications and Improve Health Outcomes.

Patients with commercial insurance often face high out-of-pocket expenses for prescription medications, creating a financial barrier to accessing life-saving medication. Between 2012 and 2017, the share of employer-sponsored health plans requiring a deductible for prescription drugs increased by more than 200%. *See* PhRMA, *Faced with High Cost Sharing for Brand Medicines,*

Commercially Insured Patients with Chronic Conditions Increasingly Use Manufacturer Cost-Sharing Assistance 3 (Jan. 29, 2021) ("PhRMA 2021").[1] And actual deductible amounts have grown. The median deductible for an individual-market silver plan (the most popular level of plan under the ACA) increased by 21% between 2019 and 2023. *See* Dep't of Health & Human Servs., *Plan Year 2023 Qualified Health Plan Choice and Premiums in Healthcare.gov Marketplaces* at 11 (Oct. 26, 2022).[2] These multiple payment obligations impair out-of-pocket spending predictability for patients. Coinsurance for many branded medicines can be as high as 30% to 50% of the total cost. *See* PhRMA 2021 at 3. Based on a recent study, patients with deductibles or coinsurance spent six times more, on average, in out-of-pocket costs than patients with only copays. *See* PhRMA, *Deductibles and Coinsurance Drive High Out-Of-Pocket Costs For Commercially Insured Patients Taking Brand Medicines* 2 (Nov. 14, 2022) ("PhRMA 2022").[3]

High out-of-pocket costs make patients more likely to abandon their medicines and lead to poorer health outcomes. According to one study mentioned in the complaint, over half of patients who learned that they would owe between $125 and $250 for a prescription medication did not start the therapy; and 69% of patients did not even begin taking medication if the patient's own spending exceeded $250. *See* Katie Devane et al., *Patient Affordability Part Two: Implications for Patient Behavior & Therapy Consumption*, IQVIA 1 (May 18, 2018); *see also* Compl. ¶ 10 n.2. Another study found that 44% of cancer patients abandoned their medications when their cost-

[1] https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/Faced-with-High-Cost-Sharing-for-Brand-Medicines.pdf.

[2] https://www.cms.gov/cciio/resources/data-resources/downloads/2023qhppremiumschoicereport.pdf. This trend matches last year's increase. *See* Compl. ¶ 28 (describing the 23% increase in the median deductible for an individual-market silver plan between 2018 and 2022 (citation omitted)).

[3] https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/G-I/IQVIA-Report-High-OOP-for-Brand-Medicines_November-2022_v2.pdf.

share reached $500. *See* 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. CLIN. ONCOL. 476, 481 tbl. 3 (Feb. 2018). These costs have a rationing effect; they deter patients from purchasing drugs their doctors have prescribed, including in situations when no alternative treatment exists or when a specific drug is working safely and effectively for a patient.

Patient nonadherence to medication has serious adverse consequences for public health. By one estimate, nonadherence could be responsible for more than 100,000 deaths and 10% of all hospitalizations in the United States every year. *See* Aurel O. Iuga & Maura J. McGuire, *Adherence and Health Care Costs*, 7 RISK MANAG. HEALTHC. POLICY 35 (Feb. 2014); Lisa Rosenbaum & William H. Shrank, *Taking Our Medicine—Improving Adherence in the Accountability Era*, 369 N. ENG. J. MED. 694 (2013). Nonadherence is also associated with hundreds of billions of dollars in costs per year to the U.S. healthcare system through avoidable disease progression, doctor's visits, and hospitalizations. *See* Iuga & McGuire, *Adherence and Healthcare Costs* 37.

In response to high out-of-pocket expenses and the barriers they cause for patient access to medicines, manufacturers have invested significant resources in cost-sharing assistance programs for patients enrolled in commercial insurance. One estimate found that pharmaceutical companies offered $14 billion in assistance in 2020 alone for cost-sharing assistance programs. *See* Tomas J. Philipson et al., *The Patient Impact of Manufacturing Copay Assistance in an Era of Rising Out-of-Pocket Costs*, U. CHI., Dec. 2021, at 2.[4] These programs are designed to help patients start and continue taking their prescribed medications. Assistance comes in the form of coupons or copay cards applied at the point of sale to the patient's cost-sharing obligations. *See, e.g.*, IQVIA, *An*

[4] https://cpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2021/12/2021_12_15-Copay-Assistance-Final-Draft-Clean.pdf.

Evaluation of Co-Pay Card Utilization In Brands After Generic Launch (Feb. 2018); Compl. ¶ 30. The manufacturer-provided cost-sharing assistance does not reduce the amount the patient owes to the pharmacy; the funds are simply another source of financial support that a patient may rely on to pay for his or her cost-sharing obligations related to the medication. They operate in much the same way as other sources of cost-sharing assistance, like help from a family member or an individual's fundraiser.

Cost-sharing assistance programs help millions of commercially insured patients every year. In 2021 alone, they helped patients reduce their annual out-of-pocket costs by roughly $500, which amounts to a nearly 60% decrease from the amount set by a health plan. *See* PhRMA 2022, at 7. And while reduced out-of-pocket spending benefits all commercially insured patients eligible for manufacturer assistance, it is particularly helpful to those with complex or chronic illnesses. Patients suffering from conditions like multiple sclerosis, HIV, and cancer rely on manufacturer cost-sharing assistance to meet their increasingly higher cost-sharing obligations and access their medication throughout the year. *See* PhRMA 2021, at 6–7.

Across all patients, cost-sharing programs improve medication adherence. The programs are associated with higher prescription medication compliance and lower rates of therapy discontinuation. *See, e.g.*, Matthew Daubresse et al., *Effect of Prescription Drug Coupons on Statin Utilization and Expenditures: A Retrospective Cohort Study*, 37 PHARMACOTHERAPY 12 (Jan. 2017); Jones Daugherty, et al., *The Impact of Manufacturer Coupon Use in the Statin Market*, 19 J. MANAG. CARE PHARM. 765 (2013). One study found that, for patients at an increased risk of prescription drug abandonment because of high out-of-pocket spending, cost-sharing assistance

programs lowered their abandonment rate between 12 and 19%. *See* IQVIA, *Patient Affordability Part Two* (May 2018).[5]

In short, by helping commercially insured patients afford and access their prescription medications, manufacturer cost-sharing assistance programs help patients adhere to their prescribed treatments—improving their health outcomes and avoiding the unnecessary health costs and financial pressures on the healthcare system that result from patients abandoning necessary medical treatments.

B. Accumulator Adjustment Programs Increase Patients' Out-of-Pocket Costs, With Predictable Harmful Consequences for Health Outcomes.

Accumulator adjustment programs (or accumulator programs) unravel the many benefits of manufacturer cost-sharing assistance. These programs "prevent manufacturer cost-sharing assistance from accumulating toward patient deductibles and annual out-of-pocket limits." PhRMA 2021 at 8; *see also* Compl. ¶ 33 ("[T]he 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."). Instead, when a patient presents a manufacturer coupon or copay card at the pharmacy and the pharmacy processes the payment, the financial assistance from the manufacturer is applied at the point of sale but does not count toward the patient's deductible or out-of-pocket maximum. *See* PhRMA 2021 at 8; Pls. Mot. for Sum. J. at 7, Dkt. 13-1 (displaying a chart that illustrates the financial impact of an accumulator adjustment program).

According to health plans and pharmacy benefit managers ("PBMs"), accumulator programs help to control drug costs by discouraging the use of expensive brand drugs when a generic equivalent is available. But in practice, manufacturer cost-sharing assistance is frequently used for

[5] https://www.iqvia.com/locations/united-states/library/case-studies/patient-affordability-part-two.

medicines *without* a generic equivalent. For example, in 2017, only 0.4% of all commercial-market claims filled with cost-sharing assistance were for brand medicines with a generic equivalent. *See* IQVIA, *An Evaluation of Co-Pay Card Utilization*. Another study found that a majority of the "highest expenditure drugs" with manufacturer assistance had no generic substitute. *See* Karen Van Nuys et al. *A Perspective on Prescription Drug Copayment Coupons*, USC SCHAEFFER, Feb. 2018, at 1.[6]

Predictably, the use of accumulator programs has negative impacts on medication adherence. Again, when a patient's out-of-pocket spending increases, medication adherence decreases. *See* PhRMA 2022 at 6; Compl. ¶ 10 n.2. If a patient goes to the pharmacy to pick up a prescription but faces an unexpectedly high cost-sharing obligation, the patient may often walk away. Researchers have confirmed that this is what happens when a health plan or PBM implements an accumulator program. One study found that patients taking an autoimmune specialty drug experienced a 20% higher level of treatment discontinuation following the application of an accumulator program. *See* Bruce W. Sherman, *Impact of a Co-Pay Accumulator Adjustment Program on Specialty Drug Adherence*, 25 AM. J. MANAG. CARE 335 (2019).

C. The Agencies' Blanket Approval of Accumulator Adjustment Programs Puts Patients' Health At Risk.

The agencies' initial rule recognized the value of cost-sharing assistance programs. Understanding that "high and rising out-of-pocket costs for prescription drugs" present a "challenge to consumers," the agencies found 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. At the same time, they observed that the

[6] https://healthpolicy.usc.edu/wp-content/uploads/2018/02/2018.02_Prescription20Copay20Coupons20White20Paper_Final-1.pdf.

availability of cost-sharing assistance "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." *Id.* But, the agencies noted, any purported price "distortion" effects are significantly less likely where there is no generic equivalent on the market because "the use of the manufacturer coupon would not disincentivize a less expensive choice." *Id.* at 17,545. Thus, the agencies concluded that, except in limited circumstances where a medically appropriate generic equivalent was available, "amounts paid toward cost sharing using any form of direct support offered by drug manufactures *must* be counted toward the [ACA's] annual limitation on cost sharing." *Id.* (emphasis added); *see also id.* at 17,568.

Not even a year later, in May 2020, the agencies arbitrarily reversed course. Under the new regulation, at issue here, "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"—regardless of the availability of a generic equivalent. *See* 45 C.F.R. § 156.130(h).

The agencies again expressed concern that manufacturer cost-sharing assistance programs could "[i]n some cases … increas[e] overall drug costs." 2021 NBPP, 85 Fed. Reg. at 29,234. But the agencies failed to explain how their speculation makes any sense as applied to manufacturer assistance for brand-name drugs without a less expensive generic alternative. *See infra*, at 13. And the agencies never mentioned that plans and PBMs have alternative ways to control costs. For instance, they can rely on utilization management techniques to evaluate the necessity of medical treatments or control access to brand medicines by excluding them from their formularies. *See, e.g.*, PhRMA, Comment Letter on Proposed Rule, Patient Protection and Affordable Care Act;

HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans 7 (March 2, 2020).[7]

Most puzzlingly, the agencies predicted that their about-face would not result in a proliferation of accumulator programs, because insurers would "choose to continue their current behavior" of basing the allowance of cost-sharing assistance on the availability of generics. 2021 NBPP, 85 Fed. Reg. at 29,232. The agencies provided no economic analysis or data in support of their position. *See id.*; *see also id.* at 29,253 (offering no meaningful economic analysis in analyzing the rule's regulatory impact). And that wishful thinking has already proven false. In 2021, almost a quarter of firms with 500 or more employees instituted accumulator programs. *See Employer Health Benefits: 2021 Annual Survey* 189–191, Kaiser Family Foundation (2021);[8] *see also* Compl. ¶ 71 n.13. Thus, despite the Department's self-professed goal of combatting "high and rising out-of-pocket costs from prescription drugs," the 2021 NBPP does the exact opposite: increase out-of-pocket expenses, thereby decreasing medication adherence. *See* 2021 NBPP, 85 Fed. Reg. at 29,232. These harmful effects fall most severely on patients relying on specialized drugs without any generic equivalents—circumstances where cost-sharing assistance can provide effective financial aid without implicating the agencies' concern about distorted market prices.

At bottom, the agencies' blanket blessing of accumulator programs harms patients by threatening to undo the many benefits of cost-sharing assistance programs already outlined.

[7] https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/0-9/2021-NBPP-Comment-Letter_FINAL.pdf.

[8] https://files.kff.org/attachment/Report-Employer-Health-Benefits-2021-Annual-Survey.pdf.

II. The 2021 NBPP Is Unlawful.

A. The Rule Conflicts with the ACA's Definition of Cost Sharing.

"It is a basic tenet that regulations, in order to be valid, must be consistent with the statute under which they are promulgated." *Decker v. Nw. Env't. Def. Ctr.*, 568 U.S. 597, 609 (2013) (quoting *United States v. Larionoff*, 431 U.S. 864, 873 (1977)). Here, the 2021 NBPP violates the statutory text of the ACA in two ways: it flouts the ACA's clear definition of cost sharing; and it improperly ascribes two simultaneous and contradictory meanings to the statute, leaving it up to insurers to decide on their preferred interpretation.

The ACA provides that "[t]he cost-sharing incurred under a health plan … for a plan year … shall not exceed" a calculated amount. 42 U.S.C. § 18022(c)(1)(A). The statutory definition of "cost sharing" includes "deductibles, coinsurance, copayments, or similar charges" and does not qualify "deductibles, "coinsurance," or "copayments" based on whether a patient receives compensation for them. *Id.* § 18022(c)(3)(A)(i). "Cost sharing" also includes certain "other expenditures" for medical expenses, *id.* § 18022(c)(3)(A)(ii) (incorporating 26 U.S.C. § 223(d)(2)), provided that these particular expenses are "not compensated by insurance or otherwise," 26 U.S.C. § 223(d)(2). Because all provisions of a statute must be considered together, the presence of language in clause (ii) describing the limitation of expenses that are compensated by "insurance or otherwise," and the absence of such language in clause (i), dictates that clause (i) expenses must be included in cost sharing even if the insured individual is compensated for them. *See Russello v. United States*, 464 U.S. 16, 23 (1983) ("Where Congress includes particular language in one section of a statute but omits it in another, … it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion."); *cf. Motion Picture Ass'n of Am., Inc. v. FCC*, 309 F.3d 796, 802 (D.C. Cir. 2002). Accordingly, the statute does not permit the agencies to exclude from the annual limitation on cost sharing deductibles, coinsurance, copayments, or

similar charges for any essential health benefits—whether paid by manufacturer cost-sharing assistance or not.

The 2021 NBPP squarely conflicts with the statutory definition of "cost sharing." As already explained, these programs do not reduce the amount owed by the patient (*i.e.*, the "cost incurred" under a health plan); they provide a separate source of funds to assist patients in paying out-of-pocket prescription costs. Like donations from a family member or fundraising accounts, manufacturer cost-sharing assistance simply helps patients pay the deductible or out-of-pocket expenses set by the health plan.

The agencies appeared to misunderstand this basic feature of manufacturer cost-sharing assistance. According to HHS, this assistance might be viewed as "reducing the costs incurred by an enrollee under the health plan" because the assistance would "reduce the amount that the enrollee is required to pay in order to obtain coverage for the drug." 2021 NBPP, 85 Fed. Reg. at 29,231. But these cost-sharing assistance programs do not reduce the total amount the patient owes to the pharmacy; they operate as an additional funding source to pay for a patient's medication.

Making matters worse, the agencies improperly gave the ACA's definition of "cost sharing" two separate and contradictory meanings. They "determined that the term 'cost sharing' is subject to interpretation regarding whether" the amount covered by manufacturer assistance falls under § 18022(c)(1)(A). *See* 2021 NBPP, 85 Fed. Reg. at 29,234. But even if that were true, it was the agencies' job to interpret the statute. *See PDK Labs. Inc. v. DEA*, 362 F.3d 786, 798 (D.C. Cir. 2004) (before exercising discretion agency "necessarily had to decide what [statute] meant"). Instead, they left it to insurers to *pick* which definition of cost sharing they prefer—one that includes patient assistance programs or one that excludes such programs. 85 Fed. Reg. at 29,234 (noting that insurers may "elect" to count manufacturer assistance towards annual limitations on cost

sharing). According to the 2021 NBPP, then, a single statutory and regulatory term *can have different meanings for different parties*, with each individual insurer deciding what the statute means.

That is not how statutory interpretation works. An agency cannot "interpret" a statutory text to have two contradictory meanings at the same time, let alone meanings that change at the option of regulated parties. The Supreme Court has warned against "the dangerous principle" that "the same statutory text" could carry "different meanings in different cases." *Clark v. Martinez*, 543 U.S. 371, 386 (2005). And basic logic dictates that a single statutory phrase cannot simultaneously mean both "A" and "*not* A," depending on how the agency or a regulated party wants to read it in a particular circumstance. *See United States v. Santos*, 553 U.S. 507, 522 (2008) (plurality opinion) ("[T]he meaning of words in a statute cannot change with the statute's application."). Even if the ACA's definition of cost sharing were ambiguous—and it is not—the agencies cannot delegate the task of resolving the ambiguity to regulated parties, allowing them to choose the interpretation that best suits them. "A single law should have one meaning;" full stop. *Carter v. Welles-Bowen Realty, Inc*, 736 F.3d 722, 730 (6th Cir. 2013) (Sutton, J., concurring) ("[A] statute is not a chameleon. Its meaning does not change from case to case.").

B. The Rule Is Arbitrary and Capricious.

The 2021 NBPP is also arbitrary and capricious, for at least three reasons.

First, the 2021 NBPP violates HHS's own regulation. An existing HHS regulation defines "cost sharing" as "any expenditure required by or on behalf of an enrollee with respect to essential health benefits." 45 C.F.R § 155.20. This definition contains no exclusion for payments from third parties. Indeed, the definition expressly *allows* for third-party payments, through the phrase "expenditure[s] … *on behalf of* an enrollee." *Id.* (emphasis added). "An agency action may be set aside as arbitrary and capricious if the agency fails" to follow "its own regulations." *Nat'l Env't Dev. Assoc.'s Clean Air Project v. EPA*, 752 F.3d 999, 1009 (D.C. Cir. 2014).

Second, the agencies' justification for the 2021 NBPP relied on an erroneous premise. The agencies identified a purported conflict between counting manufacturer assistance toward patients' cost-sharing obligations and an IRS guidance document from 2004. *See* 2021 NBPP, 85 Fed. Reg. at 29,231. Under that guidance, a high-deductible plan must disregard certain drug discounts when determining if the deductible has been satisfied. *See* Notice 2004-50, Q&A-9.[9] Crucially, that guidance applies to "discount cards" that *lower the total amount received* by a pharmacy. In contrast, manufacturer cost-sharing assistance programs provide a separate source of funds to pay prescription costs; they do not lower the amount received by a pharmacy or the amount required to be paid for the patient to receive the medication. Because the IRS guidance simply does not apply to cost-sharing assistance programs, the agencies' purported justification that the prior rule could conflict with that guidance was arbitrary and capricious. *See Jacoby v. NLRB*, 233 F.3d 611, 617 (D.C. Cir. 2000) ("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 *Sea-Land Serv., Inc. v. Dep't of Transp.*, 137 F.3d 640, 646 (D.C. Cir. 1998)).

Third, the agencies failed to consider "an important aspect of the problem" when they failed to explain how manufacturer cost-sharing assistance could cause market distortion when applied to brand drugs without medically appropriate generic alternatives. *See Am. Clinical Lab'y Ass'n v. Becerra*, 40 F.4th 616, 624 (D.C. Cir. 2022) (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). In that circumstance, "the availability of a coupon or other direct support" cannot "cause physicians and enrollees to choose an expensive brand name drug" over "a less expensive and equally effective … alternative," because no equivalent alternative is available. 2021 NBPP, 85 Fed. Reg. at 29,234. Although the majority of cost-

[9] https://www.irs.gov/pub/irs-drop/n-04-50.pdf.

sharing assistance programs target prescriptions that do not have a generic alternative, *see supra* at 6–7, the 2021 NBPP nowhere grapples with this reality or its implications for the agencies' rule. The 2021 NBPP rests on speculation, rather than meaningful economic analysis. *See id*. at 9.

CONCLUSION

For these reasons, PhRMA respectfully urges the Court to set aside the provisions of the 2021 NBPP that unlawfully allow for the exclusion of manufacturer cost-sharing assistance from qualifying as statutory cost sharing for commercially insured patients.

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Respectfully submitted,

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Exhibit B