EXHIBIT A

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.	Case No. 1:22-cv-2604

AMICUS CURIAE BRIEF OF TRIALCARD INCORPORATED IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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CORPORATE DISCLOSURE STATEMENT

TrialCard Incorporated is a wholly-owned subsidiary of TC Holdings, LLC, which is in turn owned by TCH Group, LP. No publicly traded company owns 10% or more of its stock.

IDENTITY AND INTEREST OF *AMICUS CURIAE*[1]

Amicus Curiae TrialCard Incorporated ("TrialCard") is a biopharmaceutical services organization whose mission is to help make medications more accessible and affordable for patients. To that end, TrialCard delivers fully integrated solutions that simplify access to care for patients, healthcare providers, pharmacies, and payers. As most relevant here, its solutions include patient assistance coupon programs sponsored by manufacturers—the very coupon programs subject to the regulation challenged in this case. TrialCard is the leading administrator of such patient assistance programs and has worked with more than 400 life-science customers and helped nearly 36 million patients benefit from over billions of dollars in savings to date. It has led working groups for the National Council on Prescription Drug Programs, which sets claims and data standards for pharmacy transactions, and has helped inform efforts to standardize and operationalize the delivery of assistance to patients.

The core of TrialCard's mission is ensuring that patients are aware of and can access the assistance programs that can be used at pharmacies to pay the coinsurance obligations required under many commercial, private health insurance plans. When a patient presents a prescription to a pharmacy, after a physician has prescribed the

[1] Pursuant to Local Civil Rule 7(o)(5) and consistent with Federal Rule of Appellate Procedure 29(a)(4)(E), TrialCard states that no counsel for any party authored this brief in whole or in part; no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief; and no person other than *amicus curiae*, its members, or its counsel made such a monetary contribution. Plaintiffs have consented to the timely filing of this *amicus* brief, and Defendants do not oppose it.

medication that best meets the patient's clinical needs, TrialCard facilitates the distribution of patient assistance to satisfy patients' out-of-pocket responsibility. As a result, patients are able to secure the prescription medications that have been selected for them as the best available therapy by their providers.

Plaintiffs' Administrative Procedure Act ("APA") lawsuit challenges Defendants' 2020 rule that permits insurers and for-profit pharmacy benefit managers ("PBMs") to exclude manufacturer-sponsored patient assistance from "the annual limitation on cost sharing." *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, 29,234, 29,261 (May 14, 2020) ("Patient Assistance Rule" or "Rule"); *see also* 45 C.F.R. § 156.130(h). The Patient Assistance Rule is unlawful. Even though the text of the Affordable Care Act ("ACA") plainly requires that third-party patient assistance be counted toward a patient's cost-sharing obligations, the Rule unlawfully authorizes insurance plans and PBMs[2] to disregard such assistance when calculating the annual federal limit on cost-sharing under health plans regulated by the ACA. The upshot is that insurers, PBMs, and their agents can now demand—from some of the most vulnerable patients—

[2] PBMs are typically large entities that act to negotiate and administer pharmaceutical benefits on behalf of insurers. Indeed, the largest PBMs, which dominate their competitors, are themselves owned by the three largest health care insurers in the United States.

massive co-share payments that vastly exceed the limits imposed by the Affordable Care Act.[3]

Insurers and PBMs achieve this unlawful outcome by adopting so-called "accumulator" or "maximizer" programs, which the Patient Assistance Rule has sanctioned and encouraged. These programs allow insurers to ***accept*** patient assistance provided by drug manufacturers but nevertheless ***exclude*** such amounts from patients' annual cost-sharing obligations. As a result, despite the amounts the insurer has received through patient assistance programs, patients are forced to pay the full out-of-pocket maximum ***in addition to*** what has been paid through patient assistance—a total that frequently violates the ACA's cost-sharing limits and can run into the tens of thousands of dollars. Meanwhile, the insurer pockets the full out-of-pocket maximum ***plus*** the amounts received through manufacturer assistance, resulting in a substantial windfall for the insurers while harming patients for whose benefit the assistance was intended.

By sanctioning these programs, the Patient Assistance Rule systematically harms vulnerable patients who are suffering from such debilitating conditions as cancer, hemophilia, and immune disorders. These programs force patients to pay crushing deductibles, copayments, and coinsurance payments that are prohibited by the Act. The coupon programs that TrialCard administers are often the only way for

[3] The ACA was the seminal legislation that made significant changes in the health care coverage offered by most insurers in the United States in order to make that coverage both more meaningful and affordable. *See Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 538 (2012).

these patients to afford essential (often life-saving) therapies. Accumulator and maximizer programs rob patients of the benefits of such assistance, surprising patients with devastating financial burdens when, as far as the patients know, their cost-sharing obligations have already been met. The inevitable result is that many critically-ill patients are forced to abandon medically necessary services—services that become, through conduct sanctioned and encouraged by the Patient Assistance Rule, cost-prohibitive. And because, notwithstanding applicable nondiscrimination provisions of the ACA and other laws, these programs target those with the most serious health conditions and disabilities, their discriminatory effects are often felt by the most vulnerable patients. TrialCard's data demonstrate the harms that patients are experiencing from both accumulator and maximizer programs.

Beyond its devastating consequences, the Patient Assistance Rule is also plainly contrary to the ACA and arbitrary and capricious. Patients' copay obligations (irrespective of whether or not those obligations are covered by patient assistance programs) unquestionably constitute "cost-sharing" as the ACA defines that term, which must then be counted toward the ACA's out-of-pocket maximum. 42 U.S.C. § 18022(c)(3)(A). Defendants' rationales for declining to apply the plain language of the statute are irrational and arbitrary. Equally arbitrary—and unquestionably unlawful—was Defendants' decision to delegate *to the insurers themselves* whether, in a given instance, patient assistance should qualify as "cost-sharing" under the ACA. This unlawful agency subdelegation to private parties constitutes an independent reason to set the Rule aside.

In sum, as a service provider interacting with patients, pharmacies, and manufacturers, TrialCard has valuable insights into the operation of patient assistance programs. These insights afford TrialCard a unique vantage point that may assist the Court in understanding the Patient Assistance Rule's disturbing ramifications. Accordingly, TrialCard submits this *amicus curiae* brief to aid the Court's disposition of Plaintiffs' motion for summary judgment. For the reasons that follow, TrialCard respectfully urges the Court to set aside the Rule as contrary to law and arbitrary and capricious under the APA.

SUMMARY OF ARGUMENT

I. Patient assistance programs are vital for creating affordable access to medicines for patients suffering from debilitating conditions like cancer, HIV, or Hepatitis C. The Patient Assistance Rule permits insurers and PBMs to deny patients the benefits of that assistance by implementing copay accumulator and maximizer programs. The pernicious effect of these programs is that patients abandon medically necessary services, putting their health and lives at risk. Because these programs target patients based on their health condition or disability, they unlawfully discriminate against those most in need of the ACA's protections.

II. Not only are the effects of the Patient Assistance Rule disastrous and discriminatory, but the Rule itself is also flatly contrary to the text, structure, and purpose of the ACA's cost-sharing and out-of-pocket maximum provisions. Interpreted using the standard tools of statutory construction, these provisions make clear that patient costs covered by manufacturer assistance qualify as "cost-sharing"

and must be included when calculating whether a patient has satisfied his or her maximum allowable cost-sharing obligation under the ACA.

III. The Patient Assistance Rule is also arbitrary and capricious. The Rule (i) fails to offer a rational justification for Defendants' decision, (ii) leaves unexplained a stark departure from prior agency findings, (iii) responds with illogical *ipse dixit* to concerns raised by commenters, and (iv) treats similarly situated parties differently. The Rule is a case study in arbitrary and capricious agency action.

IV. The Patient Assistance Rule must also be set aside because it unlawfully subdelegates to insurers the authority to implement and interpret the ACA's cost-sharing provision. Without any statutory authority, insurers have been delegated the power to dictate whether and when manufacturer assistance should constitute "cost-sharing" under the statute.

ARGUMENT

I. The Patient Assistance Rule Harms Vulnerable Patients.

A. Accumulator and Maximizer Programs Rob Patients of Vital Assistance.

Defendants themselves have acknowledged the importance of patient assistance programs, recognizing that such programs "encourag[e] adherence to existing medication regimens, particularly when copayments may be unaffordable to many patients." *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020*, 84 Fed. Reg. 17,454, 17,544 (Apr. 25, 2019); *see also Revising Medicaid Drug Rebate and Third Party Liability Requirements*, 85 Fed. Reg. 87,000, 87,003 (Dec. 31, 2020) ("Manufacturer-sponsored patient assistance

programs can be helpful to patients in obtaining necessary medications."). It is not hard to see why this is so, especially as insurers have dramatically increased deductibles, copays, and coinsurance in recent years. Those increased healthcare costs have forced many patients to abandon medically necessary services.

Given these costs, many patients have come to rely on copayment support from manufacturers to afford their medications. This is especially true for those with serious conditions that require specialty therapies that do not have generic alternatives or clinically appropriate substitutes. *See, e.g.*, IQVIA, *Fact Sheet: An Evaluation of Co-Pay Card Utilization in Brands After Generic Competitor Launch* (2018).[4] These medications are quite literally the difference between life and death for many patients, such as those "living with HIV, hepatitis, … cancer, multiple sclerosis, and hemophilia." *E.g.*, Carl Schmid, *New Insurance Proposal Would Hurt Americans with HIV*, Wash. Blade (Feb. 28, 2020).[5] For these patients, adherence to their prescribed medications is critical—"[m]issing just a few doses can have disastrous consequences." *Id.*; *see also* Mass. Health Pol'y Comm'n, *Prescription Drug Coupon Study: Report to the Massachusetts Legislature* 14 (July 2020) (noting that increasing medication adherence can "reduce emergency department visits, hospitalizations, and overall health care costs for patients managing chronic conditions") (footnotes omitted).

[4] https://www.iqvia.com/locations/united-states/library/fact-sheets/evaluation-of-co-pay-card-utilization.

[5] https://www.washingtonblade.com/2020/02/28/new-insurance-proposal-would-hurt-americans-with-hiv/.

Before the advent of accumulators and maximizers, patient assistance programs facilitated medication adherence. *See, e.g.*, Diana Brixner et al., *Patient Support Program Increased Medication Adherence with Lower Total Health Care Costs Despite Increased Drug Spending*, 25 J. Managed Care & Specialty Pharm. 770, 770 (July 2019) (patients receiving support had 29% higher adherence and 22% lower discontinuations, with disease-related medical costs lower by 35%). Patients could access assistance via the sort of coupon programs TrialCard administers, and their insurers would recognize the assistance paid in calculating outstanding deductibles or out-of-pocket maximums. By thus helping patients meet their cost-sharing obligations, patient assistance programs saved patients from having to abandon prescriptions or discontinue therapy.

But patient accumulator and maximizer programs have now, because of the Rule, become the norm and they systematically rob patients of the benefits of assistance. As this Court (in another case involving accumulators and maximizers) recently recognized, these programs are nothing more than "schemes" devised to allow commercial health insurers "to pocket for themselves" patient assistance. *PhRMA v. Becerra*, No. 1:21-cv-1395 (CJN), 2022 WL 1551924, at *2 (D.D.C. May 17, 2022). Devised by PBMs, accumulators and maximizers "seek to shift drug costs from insurers to patients and manufacturers." *Id.* at *2 n.1.

How these programs accomplish this cost-shifting is well documented. Under an accumulator program, for instance, a PBM designs and implements a back-end system to identify situations where a patient has paid deductibles and copayments

on medically necessary medicines by using a prescription drug coupon or other financial assistance. Once those payments are identified, the PBM prevents them from counting toward the annual deductible or out-of-pocket maximum provided for in the patient's insurance plan. However, because the accumulator's operation is not apparent, patients believe the payments have satisfied (or reduced) their deductibles or out-of-pocket maximums. Later, when manufacturer assistance runs out or the patient tries to access other health care items or resources, patients discover that they are no closer to reaching their deductibles or out-of-pocket maximums and must still pay thousands of dollars to continue on the drug therapy or obtain those other products or services.

Maximizer programs work essentially in the same way, except that they are specifically designed to exhaust all available patient assistance drug manufacturers offer to patients. They accomplish this by setting a patient's cost-sharing obligation at dramatically high amounts and then spreading the full value of the manufacturer's copay assistance evenly throughout the benefit year, such that the increased copay matches the patient assistance maximum. *See* Drug Channels, *Copay Maximizers Are Displacing Accumulators—But CMS Ignores How Payers Leverage Patient Support* (May 19, 2020).[6] While slightly different from accumulators, the outcome is the same. Maximizers allow insurers to ***accept*** patient assistance provided by manufacturers on behalf of patients but then ***exclude*** those amounts from those patients' cost-sharing obligations. Patients believe they have satisfied their cost-sharing

[6] https://perma.cc/AT8B-DKKA.

obligations, only to be shocked[7] by massive costs when they seek additional healthcare items or services. In this way, both accumulator and maximizer programs "negate the intended benefit of patient assistance programs—and remove a safety net for patients who need expensive specialty medications but cannot afford them." ASCO, *Copay Accumulators and Copay Maximizers - Policy Brief*, at 1–2 (Jan. 2021) ("ASCO, Policy Brief").[8]

B. Accumulator and Maximizer Programs Harm Patients' Health and Safety.

The adverse public health consequences of copay accumulators and maximizers are well-known and pervasive, and they are not merely financial. To the contrary, they undermine the health and safety of many of the nation's sickest patients.

Just as patient assistance programs can facilitate medication adherence, *see supra* at 6-8, robbing patients of the benefits of that assistance inevitably leads to medication abandonment. Numerous studies have established that abandonment

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[7] That patients are surprised by the operation of these programs is understandable—a number of insurers have consistently failed to adequately disclose information regarding these programs in customer-facing materials. And when insurers' materials address accumulator or maximizer programs, they frequently describe them in positive terms—as *benefits* to the insured. ASCO, *Copay Accumulators and Copay Maximizers - Policy Brief*, at 2 (Jan. 2021), www.asco.org/files/content-files/advocacy-and-policy/documents/2021-AccumulatorsPolicyBrief.pdf ("ASCO Policy Brief"); *see also* Patients Rising Now, *Telling the Truth About Copay Accumulators*, https://patientsrisingnow.org/truth-about-copay-accumulators/ (last visited Feb. 7, 2023) (calling "for an end" to accumulators "without proper consumer notice," including "disclos[ure of] their copay card policies clearly in plain documents and formularies, notify[ing] health providers and patients explicitly").

[8] https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2021-AccumulatorsPolicyBrief.pdf.

increases alongside out-of-pocket costs. *See, e.g.*, Katie Devane et al., IQVIA, *Patient Affordability Part Two: Implications for Patient Behavior & Therapy Consumption*, at 1 (May 2018) (52% of new patients abandoned treatment when out-of-pocket cost was between $125 and $250, and 69% of new patients with an out-of-pocket cost above $250 abandoned treatment).[9] Patient abandonment of prescribed medication is a serious—potentially *fatal*—problem, associated with "poor therapeutic outcomes, progression of disease, and an estimate burden of billions per year in avoidable direct health care costs." *See* Aurel Iuga & Maura McGuire, *Adherence and Healthcare Costs*, 7 Risk Mgmt. Healthcare Pol'y 35, 35 (Feb. 20, 2014).

Beyond reducing medication adherence, higher out-of-pocket costs are also associated with an increase in patient mortality. *See, e.g.*, Amitabh Chandra et al., Nat'l Bureau of Econ. Rsch., *The Health Costs of Cost-Sharing* (Feb. 2021).[10] One study found that for every one percent increase in a patient's coinsurance obligation, there is a three percent increase in mortality attributable to not initiating, limiting,

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[9] *See also* Jalpa 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, 480 & tbl. 2 (Dec. 20, 2017), https://ascopubs.org/doi/abs/10.1200/JCO.2017.74.5091 (abandonment of oral cancer treatment increased from 10% for patients with a $10 out-of-pocket cost or less to 31.7% for patients with a $100.01 to $500 out-of-pocket cost, 41% for patients with a $500.01 to $2,000 out-of-pocket cost, and 49.4% for patients with an out-of-pocket cost exceeding $2,000); Michael Eaddy, *How Patient Cost-Sharing Trends Affect Adherence and Outcomes*, 37 Pharmacy & Therapeutics 45, 45 (Jan. 2012) (literature review of 160 articles from 1974 to 2008 finding that "85% showed that an increasing patient share of medication costs was significantly associated with a decrease in adherence").

[10] https://www.nber.org/system/files/working_papers/w28439/w28439.pdf.

or discontinuing drug therapy. *See* Amitabh Chandra, Law & Econ. Symposium, *Health Consequences of Patient Cost-Sharing* (Apr. 28, 2021).[11]

For these reasons, a broad range of critics of accumulators and maximizers have spoken out against their "devastating effects on patients." Amanda Brooks, GoodRx, *Copay Accumulator Programs: What Patients Should Know* (June 18, 2020) (explaining that these programs result in patients "leaving … condition[s] untreated," where "[d]rops in adherence could be fatal").[12] Critics have thus highlighted that these programs "jeopardize health outcomes, as patients may decide to forego, discontinue or alter their treatment for non-medical reasons based on the negative financial impact from such programs." ASCO, Policy Brief, *supra*, at 2; *see also* Coal. of Texans with Disabilities, *Healthcare Costs*, https://www.txdisabilities.org /healthcare-costs (last visited Feb. 7, 2023) (accumulators lead to "unnecessary disease progression, hospitalizations, or life-threatening ramifications").

On this point the evidence is overwhelming. Studies have repeatedly shown the direct, negative, and substantial effects that these programs have on patients' healthcare. One patient group study, for example, found that patients subject to an accumulator were 1.5 times *less* likely to fill their prescriptions. *See* 105 Patient Groups' Comment Letter to FTC, at 7 (May 24, 2022).[13] The group also found that

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[11] https://laweconomicssymposium.com/wp-content/uploads/2021/05/les_webinar_ health-consequences-of-patient-cost-sharing.pdf.

[12] https://www.goodrx.com/insurance/health-insurance/copay-accumulator-programs -cms-ruling.

[13] https://hivhep.org/wp-content/uploads/2022/05/FTC-Public-Comments-on-PBM-Practices-5.24.22-1.pdf.

"patients subject to these programs experience a 13 percent drop in persistence between months 3 and 4 … and terminate their therapies." *Id.* Another study found that between 25 percent and 36 percent of patients abandoned medication after manufacturer assistance is exhausted and costs exceed a certain threshold during the middle of a plan year (as commonly occurs with accumulators). *See* PhRMA, *Accumulator Adjustment Programs from Payers Lead to Surprise Out-of-Pocket Costs and Nonadherence* (Nov. 13, 2020)[14] Other studies have demonstrated that even when accumulators and maximizers do not cause outright abandonment, they often lead to patients "not taking their medicines as prescribed (e.g., pill splitting, skipping doses)." Rachel Galloway, RJW & Partners, *How Copay Accumulators and Maximizers Are Shifting Drug Costs to Patients and Manufacturers* (July 29, 2022).[15]

TrialCard's own internal data bear out these concerns. The data indicate that patients cease using drugs when accumulator programs are in effect. In particular, they highlight that accumulators and maximizers are harming increasing numbers of patients each year. Simply stated, these programs "put[] patients' health at risk." Patients Rising Now, *supra*.

[14] https://phrma.org/resource-center/Topics/Cost-and-Value/Accumulator-Adjustment-Programs-from-Payers-Lead-to-Surprise-Out-of-pocket-Costs-and-Nonadherence.

[15] https://www.rjwpartners.com/post/how-copay-accumulators-and-maximizers-are-shifting-drug-costs-to-patients-and-manufacturers.

C. Accumulator and Maximizer Programs Unlawfully Discriminate Against the Most Vulnerable Patients.

Accumulators and maximizers have their greatest and most adverse effects on patients suffering debilitating health conditions and disabilities. By targeting such patients, accumulator and maximizer programs contravene numerous federal nondiscrimination provisions.

As so many patient groups have recognized, "the sickest, most vulnerable patients" are "hardest hit by copay accumulators." *See* Patients Rising Now, *supra*. Those who represent vulnerable patient groups have thus been particularly fierce opponents of these programs. For instance, ASCO, the professional society dedicated to fighting cancer, has attacked these programs because they "lead to poorer health outcomes" for vulnerable oncology patients. ASCO, *Position Statement: Copay Accumulators and Copay Maximizers*, at 2 (Jan. 21, 2021) (highlighting the "harm patients [experience] by discouraging the appropriate utilization of specialty therapies and reducing adherence to recommended treatment").[16] Multiple other disease groups have made the same points in compelling discussions of their concerns about the accumulator or maximizer programs permitted by the Patient Assistance Rule. Speaking on behalf of HIV and AIDS patients, for example, the AIDS Institute has explained that these programs create "financial hardship and potentially life-threatening treatment interruptions for patients." *See* Insurance Newsnet, *AIDS Institute, 'Copay Accumulator Adjustment Programs - Putting Insurance Company*

[16] https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2021-CopayAccumulatorsStatement.pdf.

Profits Over Patients' (Aug. 31, 2020).[17] For those suffering from HIV or AIDS, treatment interruptions may lead to irreversible disease progression and render certain drugs no longer viable as treatment options. *Id.* Similarly, because of these harmful effects, the "All Copays Count Coalition," which is made up of more than 60 groups representing patients with serious and chronic health conditions, has campaigned to stop the use of harmful accumulators and maximizers. *See* Nat'l Hemophilia Found., *New Insurance Policies Are Targeting Vulnerable Patients with High Copays* (2023).[18]

Patient groups are engaged in a concerted effort to end the use of accumulators and maximizers because these programs "disproportionately target the most financially vulnerable patients with serious chronic health conditions, creating an affordability crisis and essentially undermining pre-existing condition protections." *Id.* Put differently, patients are subject to those programs precisely because they have serious health conditions—like cancer, HIV, or rare genetic diseases—which are typically only treatable with medications for which patient assistance is available. Such discrimination, however, violates federal nondiscrimination protections under the ACA and other laws, which prohibit discrimination against patients based on their disabilities or medical conditions. *See* 45 C.F.R. § 156.200(e) (prohibiting discrimination on the basis of disability in connection with qualified health plans under the ACA); 45 C.F.R. §§ 146.121(a), 147.110 (prohibiting discrimination against

[17] https://insurancenewsnet.com/oarticle/aids-institute-copay-accumulator-adjustment-programs-putting-insurance-company-profits-over-patients.

[18] https://www.hemophilia.org/advocacy/federal-priorities/make-all-copays-count.

"participants, beneficiaries, and individuals based on a health factor," including "[h]ealth status," "[m]edical condition," "[r]eceipt of health care," "[m]edical history," or "[d]isability"); *see also* 45 C.F.R. §§ 146.121(b), 147.110 (prohibiting discrimination based on a health factor in any "rules for eligibility," which "include, but are not limited to, rules relating to … [b]enefits (including rules relating to covered benefits, benefit restrictions, and cost-sharing mechanisms such as coinsurance, copayments, and deductibles)").

In sum, the significant adverse—and discriminatory—consequences of accumulator and maximizer programs are well-documented and opposed by those who advocate for vulnerable patient groups. Nonetheless, the Defendants, contrary to their statutory duties to protect patients against discrimination, are actively encouraging these harmful and discriminatory programs by sanctioning them through the Patient Assistance Rule. This is unacceptable.

II. The Patient Assistance Rule Violates The ACA's Text, Structure, and Purpose.

In contending that the Patient Assistance Rule violates the ACA, Plaintiffs have it exactly right. The fact that amounts paid via patient assistance coupons or other payments qualify as "cost-sharing" is a straightforward question of statutory interpretation for which there is only one plain language answer.[19] By permitting

[19] Of course, Defendants did not take a final position on whether such assistance does or does not constitute "cost-sharing" under the statute, instead leaving this question for insurers to decide on a case by case basis. *See* 85 Fed. Reg. at 29,234. But that indecision is still unlawful because the text, context, and purpose of the ACA's cost-sharing provision make clear that a patient's insurance obligations covered by direct patient assistance *do* qualify as "cost-sharing."

insurers to adopt accumulator and maximizer programs that refuse to treat such assistance as "cost-sharing"—and violate the statutory caps—Defendants violated the statute and their Rule must be set aside as "not in accordance with law." 5 U.S.C. § 706(2)(A). The text, purpose, and structure of the ACA clearly show that patient assistance supporting deductibles, coinsurance, and copays constitute "cost-sharing" that must count toward the statutory maximum.

"As with all questions of statutory interpretation, [this Court] start[s] with the text." *PhRMA v. FDA*, 957 F.3d 254, 260 (D.C. Cir. 2020). The ACA defines "cost-sharing" to include "deductibles, coinsurance, copayments, or similar charges." 42 U.S.C. § 18022(c)(3)(A)(i). Nothing in this clause restricts or limits the type of "deductibles, coinsurance, copayments, or similar charges" that qualify as "cost-sharing." Congress did not limit the scope of these terms so as to make them contingent on whether or not the charges were satisfied with monies from a third-party—whether from a friend, a relative, or, as here, a drug manufacturer. And so the plain text of the ACA's cost-sharing definition offers no basis for limiting the scope of these terms so as to *exclude* "deductibles, coinsurance, copayments, or similar charges" satisfied by third-party payments.

Holding otherwise would rewrite the ACA's definition, supplementing it with additional terms and qualifications contrary to bedrock principles of statutory interpretation. *See United States v. Stevens*, 559 U.S. 460, 481 (2010) (rejecting construction of statute that would "require[] rewriting, not just reinterpretation"); *see also Util. Air Regul. Grp. ("UARG") v. EPA*, 573 U.S. 302, 328 (2014) ("We reaffirm

the core administrative-law principle that an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate.").

Statutory context confirms that direct patient assistance provided by drug manufacturers to satisfy patient "deductibles, coinsurance, copayments, or other similar charges" qualifies as "cost-sharing" under the ACA. Although the statute places no restrictions on *these* forms of "cost-sharing," a different clause addressing *other* forms of cost-sharing—*i.e.*, "any other expenditure required of an insured," 42 U.S.C. § 18022(c)(3)(A)(ii)—does contain additional restrictions and limitations. This second clause specifies that these "*other* expenditure[s] required of an insured" qualify as cost-sharing *only if* they also meet two conditions: (1) they must constitute "qualified medical expense[s] (within the meaning of section 223(d)(2) of Title 26)" and (2) they must relate "to essential health benefits covered under the plan." *Id.* (emphasis added). Congress was thus well aware how to impose restrictions and limitations on the type of payments that qualify as "cost-sharing." Had Congress intended to impose limitations on when or whether "deductibles, coinsurance, copayments, or similar charges" count as "cost-sharing" under the ACA, "it easily could have drafted language to that effect." *Miss. ex rel. Hood v. AU Optronics Corp.*, 571 U.S. 161, 169 (2014). But Congress did not do so.[20]

[20] What is more, the second restricted clause, in referring to the term "qualified medical expense[s]," is defined to limit what is recognized to "amounts [that] are *not compensated for by insurance or otherwise*." 26 U.S.C. § 223(d)(2)(A) (emphasis added). In other words, the distinct "qualified medical expenses" clause cannot include amounts compensated by patient assistance programs—*i.e.*, "amounts … compensated for … otherwise." *Id.* Again, no such restriction applies for "deductibles, coinsurance, copayments or similar charges."

The upshot of these definitions is that the ACA's clause referring to "other expenditures" "contains precisely the limitation that [Defendants] would read into the" provision covering "deductibles, coinsurance, copayments, or similar charges." *See Gallardo ex rel. Vassallo v. Marstiller*, 142 S. Ct. 1751, 1758 (2022). However, "[h]ad Congress intended to restrict" that provision to exclude amounts compensated by third parties, it "would have done so expressly as it did in" qualifying the "other expenditures" that count as "cost-sharing." *Russello v. United States*, 464 U.S. 16, 23 (1983). This Court "must give effect to, not nullify, Congress' choice to include limiting language in some provisions but not others." *Gallardo*, 142 S. Ct. at 1759. In allowing insurers and PBMs to restrict which amounts paid to satisfy "deductibles, coinsurance, copayments, or similar charges" count as "cost-sharing," Defendants have nullified that choice.

Defendants' nullification of Congress's choice to restrict one but not another form of cost-sharing is especially egregious because it repudiates the deliberate legislative choice inherent in the ACA's limits on cost-sharing. In 42 U.S.C. § 18022(c)(1), Congress expressly limited the maximum cost-sharing obligations under the ACA, which resulted, in 2022, in maximum cost-sharing amounts of $8,700 for an individual and $17,400 for a family. By permitting insurers to exclude cost-sharing paid by drug manufacturers from this amount via accumulator and maximizer programs, the Patient Assistance Rule allows patients to incur additional cost-sharing obligations over and above the amount specifically identified as a maximum limit by Congress. This plainly contravenes Congress's unambiguous

intention in setting the limit in the first place. *Cf. UARG*, 573 U.S. at 326 ("It is hard to imagine a statutory term less ambiguous than the[se] precise numerical thresholds[.]").

Finally, the purpose of the ACA likewise confirms that patient assistance provided by drug manufacturers qualifies as cost-sharing applicable to annual maximum limits because it helps to ensure that meaningful access to coverage is secured for patients who, otherwise, would have coverage in name only. As the Supreme Court has recognized, Congress enacted the ACA "to increase the number of Americans covered by health insurance and decrease the cost of health care." *Nat'l Fed'n of Indep. Bus.*, 567 U.S. at 538. Here, allowing insurers to exclude patient assistance provided by drug manufacturers from the definition of basic cost-sharing would make insurance prohibitively expensive for many with limited means, thereby undermining Congress' intent to increase the number of Americans covered by *meaningful* health insurance.

In sum, when Defendants authorized insurers to disregard the maximum cost-sharing dictated by Congress—in violation of the ACA's plain text, structure, and purpose—they acted contrary to law and "went well beyond the 'bounds of [their] statutory authority.'" *UARG*, 573 U.S. at 326 (citation omitted).

III. The Patient Assistance Rule Is Arbitrary And Capricious.

The Patient Assistance Rule is also arbitrary and capricious on multiple grounds. Specifically, Defendants (i) failed to offer a rational justification for their Rule, (ii) did not explain their abrupt departure from prior reasoning, (iii) offered illogical responses to problems raised by commenters, and (iv) treated similarly

situated parties differently. The Rule is a classic example of arbitrary and capricious agency action.

First, Defendants based their decision permitting insurers and PBMs to exclude patient assistance from a patient's cost-sharing obligation by pointing to a purported conflict with a 2004 IRS guidance document relating to the treatment of drug discounts in the context of high deductible health plans ("HDHPs") with health savings accounts ("HSAs"). *See* 85 Fed. Reg. at 29,231, 29,233. That 2004 guidance indicates that an HDHP must take into account only those costs an individual has actually paid—rather than the undiscounted amount—when determining whether the individual has satisfied the HDHP deductible. *See* Q&A-9 of IRS Notice 2004-50.[21] But the 2004 IRS guidance regarding drug discounts can neither explain nor excuse Defendants' arbitrary and capricious adoption of the Rule.

To begin with, the IRS guidance does not purport to interpret the ACA. Nor could it, considering that the guidance *predates* the ACA by almost a decade. In fact, the guidance does not even involve the sort of patient assistance coupon programs at issue here—drug *discounts* offered by providers are a discrete issue. Even if the guidance *were* relevant to the interpretation of the ACA's cost-sharing provision, another agency's nonbinding guidance document could not override the plain language of a subsequently enacted statute. Defendants' suggestion that the 2004 IRS guidance controls its analysis of the subsequently enacted ACA is utterly meritless.

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

Second, the Patient Assistance Rule contains an unexplained reversal of Defendants' prior rule about when accumulators or maximizers might be justified. Previously, Defendants had concluded that those programs could generally not be justified, except under the very narrow situation "when a less expensive and equally effective generic is available." 84 Fed. Reg. at 17,545. In the Patient Assistance Rule, however, Defendants concluded that insurers and PBMs broadly could exclude patient assistance, regardless whether a generic alternative was available. The Defendants' failure to explain this about-face was unreasonable. *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

Third, Defendants' responses to the concerns of commentors were illogical. Commentors explained—and Defendants ***agreed***—that the Patient Assistance Rule threatened to "raise out-of-pocket costs" and cause medication nonadherence. 85 Fed. Reg. at 29,232. Nonetheless, Defendants asserted that they did "not expect any significant increases in patient costs or non-adherence to medications *if issuers choose to continue their current behavior*"—*i.e.*, continue to apply accumulators or maximizers only when generic alternatives are available. *Id.* (emphasis added). Defendants then expressed the "belie[f]" that insurers might "continue their current behavior," thereby "limit[ing]" the adverse effects of the Patient Assistance Rule. *Id.*

Defendants unexplained assertion that insurers were unlikely to expand their use of accumulator and maximizer programs was nothing more than "*ipse dixit*"—the paradigm of arbitrary agency action. *Music Choice v. Copyright Royalty Bd.*, 970 F.3d 418, 429 (D.C. Cir. 2020) (emphasis added). It is also illogical in that it assumes

insurers and PBMs will act contrary to their economic self-interest by forgoing the increased profits they could extract by *increasing* their use of those programs. Of course, this illogical assumption has proven entirely incorrect. TrialCard's own internal data indicate that increasing numbers of patients are being harmed by maximizers and accumulators.

Lastly, even though "[g]overnment is at its most arbitrary when it treats similarly situated people differently," *Etelson v. Off. of Personnel Mgmt.*, 684 F.2d 918, 926 (D.C. Cir. 1982), the Patient Assistance Rule does precisely that in at least two respects. First, the Rule treats assistance one patient receives from a drug manufacturer differently from the assistance another patient receives from any other third party—*e.g.*, a relative or friend. Both patients are equally receiving third-party assistance, yet the former may be forced to pay additional sums to satisfy applicable cost-sharing obligations while the latter is not. Defendants' offered no reason to justify this unequal treatment. Further, by allowing *insurers and PBMs* to choose whether manufacturer assistance will count toward a patient's cost-sharing obligations, the Patient Assistance Rule will lead to situations where similarly situated patients receiving manufacturer assistance will be treated differently. One may have the manufacturer assistance disregarded, while another may not—all based on the subjective policies of their respective insurers or PBMs. Because the Rule treats similarly situated patients differently, the Patient Assistance Rule must be set aside. *W. Deptford Energy, LLC v. FERC*, 766 F.3d 10, 20 (D.C. Cir. 2014).

IV. The Patient Assistance Rule Constitutes An Unlawful Subdelegation By Defendants.

The Patient Assistance Rule must also be set aside because it unlawfully subdelegates to insurers the authority to decide whether patient assistance from drug manufacturers qualifies as cost-sharing under the ACA. In the Patient Assistance Rule, Defendants expressly declined to "finaliz[e]" any fixed interpretation of the term "cost sharing." *See* 85 Fed. Reg. at 29,232. Instead, Defendants granted *insurers* "flexibility to determine whether to include or exclude amounts of direct support provided by drug manufacturers from the annual limitation on cost sharing." *Id.* at 29,231.

But Congress authorized *Defendants*—and only Defendants—to implement and interpret the ACA. Under federal law, this kind of "subdelegation" of agency authority "to outside parties [is] assumed to be improper absent an affirmative showing of congressional authorization." *U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 565 (D.C. Cir. 2004); *see also Shook v. D.C. Fin. Resp. & Mgmt. Assistance Auth.*, 132 F.3d 775, 783–84 & n.6 (D.C. Cir. 1998) (subdelegation to outside party is "*ultra vires*"). It is not difficult to understand why an agency's subdelegation of authority to outside parties is presumptively unlawful. When it occurs, "lines of accountability may blur, undermining an important democratic check on government decision-making." *U.S. Telecom Ass'n*, 359 F.3d at 565. Likewise, outside parties likely will "not share the agency's 'national vision and perspective,' and may pursue goals inconsistent with those of the agency and the underlying statutory scheme," *id.* at 565–66 (citation omitted), such, as here, maximizing their own profits.

Nothing in the ACA provides the "affirmative showing of congressional authorization" necessary to make Defendants' subdelegation to insurers permissible. *Id.* at 565. Nevertheless, Defendants subdelegated to insurers the authority to implement ACA's cost-sharing provision and determine whether to exclude expenditures covered by manufacturer assistance with "no standards to guide the [insurers'] decisionmaking." *Sofco Erectors, Inc. v. Trustees of Ohio Operating Eng'rs Pension Fund*, 15 F.4th 407, 428 (6th Cir. 2021).[22] Here, there is no basis whatsoever to assume Congress intended to do anything of the kind.

CONCLUSION

For these reasons, Plaintiffs' motion for summary judgment should be granted and the Patient Assistance Rule should be vacated as unlawful.

[22] Indeed, it is questionable whether "even Congress[] could delegate such [standardless] discretion" to private parties, allowing them free rein to interpret and apply a critical provision of federal law. *Id.*

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Local Rule 7(o)(4) and Federal Rule of Appellate Procedure 29(a)(4), because it does not exceed 25 pages and uses 12-point Century Schoolbook font.

Dated: February 9, 2023

/s/ William A. Sarraille
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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing will be served this 9th day of February, 2023, electronically through the Court's CM/ECF system on all registered counsel.

/s/ William A. Sarraille
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