**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

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| PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,<br><br>*Plaintiff*,<br><br>v.<br><br>XAVIER BECERRA, *et al.*,<br><br>*Defendants*. | Civil Action No. 1:21-cv-1395 (CJN) |

**MEMORANDUM OPINION**

Pharmaceutical Research and Manufacturers of America (PhRMA) challenges a final rule promulgated by the Department of Health and Human Services on the grounds that the rule violates the Administrative Procedure Act. *See generally* Compl. ("Compl."), ECF No. 1. At the motion to dismiss stage, the Court rejected the government's contention that PhRMA lacks Article III standing. *See Pharm. Rsch. & Mfrs. of Am. v. Becerra*, No. 1:21-CV-1395 (CJN), 2021 WL 5630798 (D.D.C. Dec. 1, 2021). PhRMA has now moved for summary judgment, arguing that the rule exceeds the agency's authority under the relevant statute. *See* PhRMA's Motion for Summary Judgment ("PhRMA's Mot."), ECF No. 26. The government has cross-moved for summary judgment. *See* HHS's Cross-Motion for Summary Judgment ("HHS's Cross-Mot."), ECF No. 31. For the reasons that follow, the Court grants PhRMA's motion and denies the government's cross-motion.

## I. Factual and Procedural Background

### A. Prescription Drug Best Prices and Accumulator Adjustment Programs

Medicaid is a "cooperative federal-state program that provides federal funding for state medical services to the poor." *Frew ex rel. Frew v. Hawkins*, 540 U.S. 431, 433 (2004); *see also* 42 U.S.C. § 1396 *et seq.* When a state decides to participate in the Medicaid program it must offer Medicaid plans that meet certain federal statutory and regulatory requirements. *See Cookeville Reg'l Med. Ctr. v. Leavitt*, 531 F.3d 844, 845 (D.C. Cir. 2008). Among the regulatory requirements include those promulgated by the Secretary of Health and Human Services, as the Secretary has been tasked with "mak[ing] and publish[ing] such rules and regulations . . . as may be necessary to the efficient administration" of the Medicaid program. 42 U.S.C. § 1302.

A state may offer outpatient prescription drug coverage as part of its Medicaid plan. *See* 42 U.S.C. § 1396d(a)(12); *Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 652 (2003). To manage the costs of covering prescription drugs, Congress has conditioned receipt of federal funds on a cost-saving measure that requires drug manufacturers to participate in something called the Medicaid Drug Rebate Program. *See Walsh*, 538 U.S. at 649. That program requires drug manufacturers to enter into rebate agreements. *See id.*

Under those agreements, manufacturers rebate to states a portion of a drug's cost purchased through the state's Medicaid plan. 42 U.S.C. § 1396r-8(a)(1), (b)(1)(A). In particular, the Medicaid rebate statute requires manufacturers, as a condition of having their drugs eligible for payment with federal Medicaid funds, to provide their drugs to state Medicaid programs at prices at least as favorable as the prices offered to certain commercial purchasers. *See id.*; *see also id.* § 1396r-8(a)(1) (providing that "for payment to be available [from federal Medicaid funds] for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in

effect a rebate agreement . . . with [the agency] on behalf of States"). That provision strives to ensure that the Medicaid program does not pay more for drugs than private entities in the commercial market.

The Medicaid rebate statute calculates the amount of the rebates for innovator drugs based in part on the manufacturer's "best price." The statute defines "best price" as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States." *Id.* § 1396r-8(c)(1)(C)(i); *see also id.* § 1396r-8(c)(1)(C)(ii) (providing "special rules" that further define the term). The statute's listed entities to whom the manufacturer offers the lowest price are known as the "best-price-eligible purchasers." HHS's Cross-Mot. at 11. The statute also requires manufacturers to report their best price to the agency within thirty days after the end of each rebate period. 42 U.S.C. § 1396r-8(b)(3)(A).

In recent years, pharmaceutical manufacturers have started providing financial assistance to patients. *See* PhRMA's Mot. at 7. The financial assistance can help patients—including those with commercial health insurance—shoulder high out-of-pocket costs and obtain needed medications that their doctors have prescribed. *See* McKesson Corporation's Amicus Brief ("McKesson's Brief"), ECF No. 27-3 at 6–7. Insured patients might be priced out of certain drug markets without a manufacturer's financial assistance. *See* HHS's Cross-Mot. at 7. And the agency has recognized that financial assistance from a manufacturer "encourage[s] adherence to existing medication regimens, particularly when copayments may be unaffordable to many patients." *Patient Protection and Affordable Care Act*, 84 Fed. Reg. 17,454, 17,544 (Apr. 15, 2019); *see also Revising Medicaid Drug Rebate and Third Party Liability Requirements*, 85 Fed.

Reg. 87,000, 87003 (Dec. 31, 2020) ("Manufacturer-sponsored patient assistance programs can be helpful to patients in obtaining necessary medications.").

Commercial health insurers have caught on to these offerings. *See* Compl. ¶ 4. Seeking to pocket for themselves at least some of the assistance, commercial health insurers have devised schemes known as "accumulator adjustment programs." *Id.* Accumulator adjustment programs enable insurers, working with companies that manage prescription drug benefits on behalf of health insurers, to refuse to count toward satisfaction of an insured's annual deductible and co-payment a pharmaceutical manufacturer's financial assistance to that patient. *Id.* ¶¶ 4–5.[1]

**B. Regulatory Background and the Accumulator Adjustment Rule**

HHS has throughout the years utilized its authority under the Medicaid rebate statute to issue regulations regarding the calculation of the "best price." *See* 42 U.S.C. § 1396r-8. In 2006, the agency proposed comprehensive regulations governing the calculation. In a final rule promulgated in July 2007, the agency stated that the best price excludes, among other things, "[g]oods provided free of charge under a manufacturer's patient assistance programs," as well as "[m]anufacturer coupons redeemed by a consumer, agent, pharmacy or another entity acting on behalf of the manufacturer; but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agency, or other entity does not receive any price concession." *See Medicaid Program & Prescription Drugs,* 72 Fed. Reg. 39142, 39242 (July 17, 2007).

[1] The mechanics undergirding accumulator adjustment programs are complex. In essence, though, commercial health insurers use an "accumulator" to track an insured patient's payments toward that patient's annual out-of-pocket costs. *See* PhRMA's Mot. at 13. Using the data, commercial health insurers exclude from the patient's out-of-pocket costs any financial assistance received from a manufacturer. *See id.* In effect, then, an accumulator adjustment programs seek to shift drug costs from insurers to patients and manufacturers. *Id.*

The agency revisited the Medicaid rebate regulations in 2016. That year, the agency revised the regulations to provide that "[b]est price excludes" "[m]anufacturer-sponsored patient refund or rebate programs, to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other entity does not receive any price concession." *See Medicaid Program & Covered Outpatient Drugs*, 81 Fed. Reg. 5170, 5352 (Feb. 1, 2016). The revision also clarified that best price includes "all prices, including applicable discounts, rebates, or other transactions that adjust prices either directly or indirectly to the best price-eligible entities." *Id.* at 5351. The 2016 version retained the policy that the "[m]anufacturer-sponsored . . . patient assistance programs" do not fall within the best-price calculation so long as the assistance "is passed on to the consumer; and the pharmacy, agent, or other AMP eligible entity does not receive any price concession." *Id.* at 5350.

Four years later, the agency proposed regulations addressing the effect of accumulator adjustment programs on best price calculations. *See Revising Medicaid Drug Rebate and Third Party Liability Requirements*, 85 Fed. Reg. 37286 (June 19, 2020). In particular, the agency proposed revising its regulations to provide that a manufacturer's financial assistance "apply only to the extent the manufacturer ensures the full value of the assistance or benefit is passed on to the consumer or patient." *Id.* at 37299. The agency also stated that it believed that "manufacturers have the ability to establish coverage criteria around their manufacturer assistance programs to ensure the benefit goes exclusively to the consumer or patient." *Id.*

On December 31, 2020, HHS finalized its revisions and promulgated the "accumulator adjustment rule." *See Revising Medicaid Drug Rebate and Third Party Liability Requirements*, 85 Fed. Reg. 87000 (Dec. 31, 2020). The rule codified the proposed language requiring that manufacturers "ensure[] the full value of the assistance or benefit is passed on to the consumer or

patient" for any financial assistance to an insured patient not to count toward the best price. *Id.* at 87102. The agency, however, delayed the effective date of the change until January 1, 2023, because manufacturers had voiced "concern[s] that they may not be able to ensure their manufacturer assistance is going to the patient and not being passed through to the health plan via an electronic means right away." *Id.* at 87053. The delayed effective date, as the agency put it, "will give manufacturers time to implement a system that will ensure the full value of assistance under their manufacturer-sponsored assistance program is passed on to the patient." *Id.*

### C. Procedural History

In May 2021, PhRMA filed this action. *See* Compl. PhRMA's Complaint asserts a single cause of action, alleging that the accumulator adjustment rule violates the APA because it conflicts with the text, structure, history, and purpose of the Medicaid rebate statute. *See id.* ¶¶ 68–71. The government moved to dismiss, arguing that PhRMA lacked Article III standing. *See* HHS's Mot. to Dismiss, ECF No. 10. The Court denied that motion. *See* Court's Order, ECF No. 20. PhRMA has now moved for summary judgment, *see* PhRMA's Mot., and the government has cross-moved for summary judgment. *See* HHS's Cross-Mot. As the government sees it, the rebate statute expressly authorizes the accumulator adjustment rule; at most, the government argues, the statute is ambiguous and the Court should defer to its reasonable interpretation. *Id.* The government also asserts, for the first time at the summary judgment stage, an Article III standing argument separate and distinct from the arguments made in its motion to dismiss. *Id.*

## II. Standard of Review

The Administrative Procedure Act provides that a court must set aside agency action that is "not in accordance with law[,] . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C). "[W]hen a party seeks review of agency

action under the APA, the district judge sits as an appellate tribunal." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). The district court applies the "appropriate APA standard of review to the agency decision based on the record the agency presents to the reviewing court." *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743–44 (1985) (quotation omitted).

An agency's rule promulgated through the notice-and-comment rule-making process may in some instances receive *Chevron* deference. Step one of the *Chevron* framework requires courts to explore whether "Congress has spoken directly to the precise question at issue," and if so, courts "must give effect to [Congress's] unambiguously expressed intent." *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984). The analysis ends at step one unless a court, "employing traditional tools of statutory construction, is left with an unresolved ambiguity." *Epic Sys. Corp. v. Lewis*, 138 S. Ct. 1612, 1630 (2018) (quotation omitted). Assuming that the statute is sufficiently ambiguous, *Barnhart v. Walton*, 535 U.S. 212, 218 (2002), step two of the *Chevron* framework directs courts to consider whether the agency's interpretation "is based on a permissible construction of the statute," *Chevron*, 467 U.S. at 843. If so, courts will defer to the agency's interpretation. *See Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 696 (D.C. Cir. 2014).

## III. The Court Possesses Article III Jurisdiction

Before reaching the merits, the Court must again address whether it has Article III jurisdiction. *See Bridgeport Hosp. v. Becerra*, No. 1:20-CV-01574 (CJN), 2022 WL 612658, at *5 (D.D.C. Mar. 2, 2022). A plaintiff, of course, must demonstrate injury in fact, causation, and

redressability. *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016); *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021).

The government contends (for the second time, but for a different reason) that PhRMA lacks standing.[2] *See* HHS's Cross-Mot. at 15. In the government's view, the alleged injuries of PhRMA's members stem not from HHS's recent rulemaking, but from the 2007 and 2016 regulations, which means that no PhRMA member has suffered a harm traceable to the 2020 accumulator adjustment rule. *Id.* Put differently, the government argues that manufacturers have long had a duty to include in their best price calculations the effects of accumulator adjustment programs, and thus any harm to PhRMA's members is traceable to the 2007 and 2016 regulations and not the accumulator adjustment rule (which is the only agency action challenged here). *Id.*

The Court disagrees. The accumulator adjustment rule of 2020 imposes new regulatory requirements on manufacturers, and it is the alleged harms from those new requirements (among others) that PhRMA's Complaint seeks to redress. Recall that the 2007 and 2016 rules provided that manufacturer assistance must both be "passed on to the consumer" and that a best-price eligible purchaser must "not receive any price concession" for the manufacturer's assistance to be excluded from the best price calculation. *See* 72 Fed. Reg. 39142, 39242; 81 Fed. Reg. 5170, 5254. The accumulator adjustment rule of 2020, by contrast, provides that a manufacturer can exclude from its best price calculation assistance it provides to patients "only to the extent *the*

[2] PhRMA has provided, for the first time at the summary judgment stage, declarations from multiple senior officers of four PhRMA members. *See* PhRMA's Mot. at 40, 40 n.8. Those declarations eliminate any doubt that at least one member of PhRMA would have standing if the government's newest argument is incorrect—meaning that PhRMA has associational standing. *See id.* Ex. A, Ex. B, Ex. C, & Ex. D.

*manufacturer ensures* the full value of the assistance or benefit is passed on to the consumer or patient." 85 Fed. Reg. 37286, 37299 (emphasis added).

This new language places the burden on manufacturers to "ensure" that patients receive the full benefit of assistance programs; otherwise, any financial assistance cannot be excluded from the calculation of the best price. Under the new rule, then, no longer will it be enough that the manufacturer's financial assistance "passes on" to the patient and that the best-price-eligible purchaser receives no "price concession." Rather, starting on January 1, 2023, manufacturers must "ensure" that the full value of the assistance stays with the patient. That new obligation will impose on the manufacturers numerous compliance requirements that will affect pocketbooks. Indeed, even assuming that commercial health insurers share all relevant information with the drug companies, those companies must now adopt mechanisms to ensure that no financial assistance to patients passes off to commercial health insurers (or that, if it does, it is included in the best price calculation). As one amicus noted, establishing "coverage criteria" to identify whether an accumulator program applies to a particular prescription transaction would prove costly. *See* McKesson's Brief at 6–7.

The government argues that the 2020 rule just "clarified the preexisting requirements" and did not create "a significant new regulatory burden." HHS's Cross-Mot. at 15 n.3, 16. That contention falls flat for at least two reasons. First, the language of the 2020 rule does more than just clarify: manufacturers now must "ensure" any assistance passes in-full to the patient. Second, HHS delayed the effective date of the new rule until January 1, 2023. *See* 85 Fed. Reg. 87000, 87053. Why delay the effective date if the rule imposed no additional obligations? In the government's own words, the delay "will give manufacturers time to implement a system that will ensure the full value of assistance under their manufacturer-sponsored assistance program is

passed on to the patient." *Id.* Having to implement systems that the manufacturers would otherwise not have to create is an injury that is traceable to the rule, and PhRMA therefore has Article III standing.

## IV. The Accumulator Adjustment Rule of 2020 Fails Under *Chevron* Step One

Turning to the merits, the Court starts and ends with the statutory text. Recall that the Medicaid rebate statute defines "best price" as the "lowest price available from the manufacturer . . . to any [best-price-eligible purchaser]." 42 U.S.C. § 1396r-8(c)(1)(C). Best-price eligible purchasers include wholesalers, retailers, providers, health maintenance organizations, nonprofit entities, or governmental entities within the United States. *Id.* Patients, as the government acknowledges, do not qualify as "best price eligible entities." *See* 85 Fed. Reg. 87000, 87052 ("This regulation does not treat patients as best price eligible entities."). The dispositive question in the case, then, is whether a manufacturer's financial assistance to a patient—at least in the context of an accumulator adjustment program—can count as the "lowest price available from the manufacturer . . . to any [best-price-eligible purchaser]?" The answer is no.

A manufacturer's financial assistance to a patient does not qualify as a price made available *from* a manufacturer *to* a best-price-eligible purchaser. Rather, a manufacturer's financial assistance is available *from* the manufacturer *to* the patient. And a patient is not a best-price-eligible purchaser. As a result, HHS lacks the statutory authority to adopt the accumulator adjustment rule. That conclusion holds true even though commercial health insurers have developed accumulator adjustment programs intended to capture some (or all) of a manufacturer's financial assistance to a patient. To the extent that a manufacturer's financial assistance is "available . . . to [an insured patient's health insurer]," it is available only from (or at least as a result of a contractual relationship with) the patient, not "from the manufacturer." Indeed,

commercial health insurers cannot capture any portion of a manufacturer's financial assistance to a patient unless and until that patient first obtains the assistance from the manufacturer independent of the insured patient's health plan.

Feasibility concerns support this conclusion. The accumulator adjustment rule would make the calculation of the best price turn on information often in the sole possession of commercial health insurers. Under the proposed rule, manufacturers would need to conduct transaction-by-transaction investigations into the operations of accumulator adjustment programs even though manufacturers have no control over (and sometimes no information concerning) those programs. Such a requirement makes it infeasible for manufacturers to report the best price to the agency in a timely fashion as the statute requires. *See* 42 U.S.C. § 1396r-8(b)(3)(A) (requiring that manufacturers report their best price to the agency within thirty days after the end of each quarterly rebate period).

In the government's view, a manufacturer's financial assistance to an insured patient meets the statutory requirement of being "available from the manufacturer to [the commercial health plan]" because manufacturers "offer patient assistance in a way that a health plan may be apprised of [it]" and then may "apply the [financial assistance] towards the patient's deductible through an accumulator adjustment program." HHS's Cross-Mot. at 25; *see also id.* at 20 ("There is no doubt that discounts offered by manufacturers through patient assistance programs lower the 'price' of their drugs, and that those discounted prices are 'available to' health plans, which often capture the discounts at the expense of patients."). Stated differently, the government argues that a manufacturer's financial assistance to an insured patient in all practical effect counts as a price made available *from* the manufacturer *to* the commercial health plan. That interpretation, however, stretches the statutory text too thin. A manufacturer's financial assistance to an insured patient is

not available from the manufacturer to the commercial health insurer, even if the insurer's health plan has devised a way to capture that financial assistance. The government's position is, in essence, that the best price calculation must take account of a price made available *from* the manufacturer *to* the commercial health plan *through* an insured patient. But the statute does not sanction the last leg of this journey (*i.e.*, *through an insured patient*). Plus, manufacturers have no involvement with accumulator adjustment programs. In fact, manufacturers, as the amicus briefs make clear, oppose the programs and in no way negotiate with commercial health insurers over how rebate capture occurs under them. *See* McKesson's Brief at 27-3; TrialCard Incorporated's Amicus Brief, ECF No. 28-1.

The government also argues that best price can include "all prices, including applicable discounts, rebates, or other transactions, that adjust prices either *directly or indirectly* to . . . best-price-eligible entities." 81 Fed. Reg. 5170, 5252 ("[W]e are finalizing under notice and comment rulemaking, that best price includes prices and associated rebates, discounts, or other price concessions that adjust prices either directly or indirectly."); *see also* 85 Fed. Reg. 87000, 87052 ("We believe the reference to 'other transactions that adjust prices either directly or indirectly' to the best price eligible entities in paragraph (a) includes the transactions made by the manufacturer indirectly to health plans via manufacturer-sponsored assistance programs should be included."). A manufacturer's financial assistance to an insured patient, from the government's perspective, often results in an *indirect* price concession to commercial health insurers. *See* HHS's Cross-Mot. at 21.

This is something of a shift from the agency's prior position. In 2016, the agency stated that the direct-indirect language in the regulation was "designed to require that manufacturers include those adjustments made *to an eligible entity* but not to require an accumulation of

adjustments provided to all entities." 81 Fed. Reg. 5170, 5252 (emphasis added). The agency, in other words, recognized that the direct-indirect language ensured that it was capturing both direct and indirect transactions *from* a manufacturer *to* a best-price eligible entity. The agency never suggested that the revised language swept in best-price *ineligible* entities like patients. In any event, for the reasons already discussed, Congress enacted a statute that covers only prices available *from* a manufacturer *to* a best-price eligible entity, not prices available from a manufacturer to a patient.

## V. Conclusion

For the foregoing reasons, PhRMA's Motion for Summary Judgment is **GRANTED**. The agency's Cross-Motion for Summary Judgment is **DENIED**. The Court **VACATES** and **SETS ASIDE** the accumulator adjustment rule of 2020. An Order will be entered contemporaneously with this Memorandum Opinion.

DATE: May 17, 2022

CARL J. NICHOLS
United States District Judge