IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
950 F Street NW, Suite 300
Washington, DC 20004,

Plaintiff,

v.

XAVIER BECERRA, SECRETARY OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue SW
Washington, DC 20201,

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue SW
Washington, DC 20201,

ELIZABETH "LIZ" RICHTER, ACTING ADMINISTRATOR OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES,
7500 Security Boulevard
Baltimore, MD 21244,

CENTERS FOR MEDICARE & MEDICAID SERVICES,
7500 Security Boulevard
Baltimore, MD 21244,

Defendants.

Civil Action No. 1:21-cv-1395

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Pharmaceutical Research and Manufacturers of America (PhRMA) alleges as follows:

INTRODUCTION

1. In this action, Plaintiff challenges portions of a final rule issued by the Centers for Medicare & Medicaid Services (CMS) that penalize pharmaceutical manufacturers simply for providing financial assistance to patients to help them afford the medicines prescribed by their doctors. CMS's final rule contradicts the plain text of the Medicaid rebate statute by improperly requiring manufacturers to treat financial assistance that they provide to *patients* to help defray their co-pays and other out-of-pocket costs as part of the "price" a manufacturer offers to *commercial health insurers*. Because this portion of the rule is inconsistent with the statute's plain text and would be harmful to patient health, it is unlawful and invalid under the Administrative Procedure Act.

2. Pharmaceutical manufacturers have long made a regular practice of offering financial assistance to patients with commercial health insurance to help those patients afford the out-of-pocket costs their insurers set for the purchase of medicines prescribed by their doctors. Such manufacturer assistance to patients has only grown in importance over time. On top of higher premiums, patients today face greater out-of-pocket costs than ever before because health plans are imposing ever-increasing deductibles, co-pays, coinsurance, and other costs, particularly with respect to prescription medications.

3. These health-plan-imposed costs have a rationing effect. They deter patients from purchasing drugs that their doctors have prescribed, including in situations when no alternative treatment exists or when a specific drug is working safely and effectively for the patient. Studies confirm that manufacturer assistance helps patients adhere to prescribed treatment regimens and

receive the full medical benefits their doctors intend for them. *E.g.*, Matthew Daubresse *et al.*, *Effect of Prescription Drug Coupons on Statin Utilization and Expenditures: A Retrospective Cohort Study*, 27 Pharmacotherapy 12-24 (2017).

4. Because manufacturer assistance helps patients overcome the rationing effect of high out-of-pocket costs, health plans have taken steps to blunt the beneficial effects of such assistance for patients. Specifically, health plans have partnered with Pharmacy Benefits Managers (PBMs)—companies that manage prescription drug benefits on behalf of health insurers—to implement so-called "accumulator adjustment programs." Through these programs, health plans and PBMs unfairly siphon the benefits of manufacturer assistance from the patients for whom it is intended.

5. Manufacturer assistance provides financial help to patients at the pharmacy counter. Historically, this financial help not only defrayed a patient's out-of-pocket cost at the point of sale, but also assisted patients in meeting their plans' cost-sharing obligations such as the patient's annual deductible or maximum for out-of-pocket drug costs. Accumulator adjustment programs, however, allow health plans and PBMs *not* to count the amount of manufacturer assistance toward those patient deductibles or out-of-pocket maximums—often unbeknownst to either the patient or the manufacturer. This forces patients to pay *again* the amounts paid by a manufacturer before their deductibles or out-of-pocket maximums are satisfied.

6. Accumulator adjustment programs achieve their pernicious goal, first, by determining whether a patient is using assistance from a manufacturer to pay their out-of-pocket costs. If so, health plans and PBMs refuse to count the amount of manufacturer assistance toward satisfaction of the patient's annual deductible or maximum for out-of-pocket drug costs. Consequently, it could take longer for patients who use manufacturer assistance to satisfy their

deductibles or out-of-pocket maximums in a plan year. Patients may not even know about an accumulator adjustment program until after the manufacturer assistance is exhausted, at which point the patient faces a surprise at the pharmacy counter. For example, in the final rule challenged here, CMS itself described a scenario in which a patient who would pay just $25 per month without an accumulator adjustment program would instead get hit with a surprise bill of $2,400. 85 Fed. Reg. 87,000, 87,048-49 (Dec. 31, 2020). Bills of this nature can cause patients to cut back on drugs prescribed by their doctors, including drugs with important health benefits for treatment of serious medical conditions. *See, e.g.*, Amitabh Chandra, et al., *The Health Costs of Cost-Sharing*, National Bureau of Economic Research Working Paper 28439 35 (Feb. 2021).

7. Instead of attacking accumulator adjustment programs at their source, CMS has acquiesced to the efforts of health plans and PBMs to undermine manufacturer assistance to patients through a rulemaking under the Medicaid rebate statute, in contravention of Congress's intent. The Medicaid rebate statute enables state Medicaid programs to receive the same price discounts that manufacturers provide to commercial purchasers of prescription drugs. It does so by requiring manufacturers to pay statutorily-calculated rebates to state Medicaid programs. For innovator medicines, these rebates are calculated in part based on the manufacturer's "Best Price"—defined in the law as "the lowest price available from the manufacturer to" specifically-enumerated entities (hereinafter, "Best Price"). 42 U.S.C. § 1396r(c)(1)(C).

8. Critically, *patients* have *never* been included on the list of Best-Price-eligible purchasers, presumably because Congress did not want to discourage manufacturers from offering discounts or other assistance to patients. CMS, which administers the Medicaid rebate program, has long recognized this Congressional imperative to exclude patient discounts and assistance from the calculation of Best Price. In 2007, CMS promulgated regulations excluding manufacturer-

sponsored drug discount card programs, coupons, and co-pay assistance from the Best Price calculation, so long as the benefits go to the patient. 42 C.F.R. § 447.505(c)(8)-(10). Similarly, in 2016, CMS revised its Best Price regulations to recognize that "[d]irect sales to patients" are excluded from Best Price, *id.* § 447.505(c)(19), because "patients are not one of the entities described in the statutory definition of Best Price," 81 Fed. Reg. 5,170, 5,253-54 (Feb. 1, 2016).

9. Now, however, though the statutory text remains unchanged, CMS has reversed course and adopted a new regulation that treats financial assistance manufacturers provide to *patients* as if such assistance were a price discount that the manufacturer instead provided to the patients' *health plans*, unless the manufacturer somehow "ensures" that no health plan retroactively takes the benefits that the manufacturer intended for and provided to patients through the imposition of an accumulator adjustment program. This change, found in the rule's amendments to 42 C.F.R. § 447.505(c)(8)-(11), 85 Fed. Reg. at 87,102-03, is referred to here as "the Accumulator Rule."

10. If treated as a price discount to health plans, financial assistance provided to patients must be included in a manufacturer's Best Price determination. That, in turn, may lower the manufacturer's Best Price and increase the rebates owed to state Medicaid programs. In effect, by using patient assistance to increase manufacturers' Medicaid rebate liability, the Accumulator Rule penalizes pharmaceutical manufacturers for the assistance they provide to *patients*.

11. The Accumulator Rule contradicts the Medicaid rebate statute's plain text. The statute defines Best Price as "the lowest price available from a manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States," subject to certain exclusions. 42 U.S.C. § 1396r-8(c)(1)(C). By its plain meaning, "price" is the consideration a seller and buyer agree upon for the

sale of an item. The seller offers a price, the buyer accepts it, the price is paid, and the item is exchanged. A "price" thus is an amount that the seller intentionally offers and voluntarily agrees to accept. If the buyer unilaterally recaptures part of the consideration from either the seller or some third party, the "price" between the seller and the buyer remains unchanged.

12. Manufacturer assistance to patients is not part of the "price" available from the manufacturer to any Best-Price-eligible purchaser, with or without an accumulator adjustment program. Accumulator adjustment programs deploy only after a drug has been paid for and dispensed and diverts the assistance that the manufacturer provided to the patient, against the manufacturer's will and often without its knowledge. That diversion does not and cannot transform the manufacturer assistance provided to patients into part of the "price" the manufacturer intends and agrees to offer to health plans. Such assistance provided to patients is not part of any "price available from a manufacturer … to" any Best-Price-eligible purchaser. It therefore must be excluded from the calculation of Best Price under the plain language of the statute.

13. If the Accumulator Rule stands, it will harm patients and manufacturers alike. The upshot for patients is that manufacturer assistance—a crucial and growing source of support for patients who meet their premium obligations yet struggle to pay the out-of-pocket costs increasingly imposed on them by health plans—may dry up, leaving patients without the ability to afford essential medications. And manufacturers will be required—contrary to the statute—to pay significantly higher Medicaid rebates on the basis of financial assistance they provide to patients.

14. For these reasons, and as explained below, Plaintiff seeks a declaration that the Accumulator Rule is invalid, an injunction preventing the Defendants from implementing or enforcing the Accumulator Rule, and other relief as the Court deems appropriate.

JURISDICTION AND VENUE

15. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 (action arising under the laws of the United States), *id.* § 1346 (United States as a defendant). An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, and other relief pursuant to 28 U.S.C. §§ 2201–02 and 5 U.S.C. §§ 705–06.

16. Defendants' publication of the final rule on December 31, 2020 constitutes a final agency action that is judicially reviewable under the APA. 5 U.S.C. §§ 704, 706.

17. Venue is proper in this Court under 28 U.S.C. § 1391(e) because this action seeks relief against federal agencies and officials acting in their official capacities, some Defendants are located in this district, Plaintiff resides in this district, and a substantial part of the events or omissions giving rise to the claim occurred in this district.

PARTIES

18. PhRMA is a non-profit corporation organized and existing under the laws of the State of Delaware, with offices located in Washington, D.C. PhRMA members are the country's leading manufacturers of innovative medicines and other biotechnology products, which are devoted to discovering and developing new medications that allow people to live longer, healthier, and more productive lives. PhRMA serves as the industry's principal policy advocate, representing its members' interests in matters before Congress, the Executive Branch, state regulatory agencies and legislatures, and the courts. PhRMA is committed to advancing public policies that foster continued medical innovation and educating the public about the drug development and discovery process. Numerous PhRMA members provide patients with assistance in purchasing their medicines, and therefore will be adversely affected by the Accumulator Rule. A list of PhRMA members can be found at www.phrma.org.

19. Defendant Xavier Becerra is the Secretary of the United States Department of Health and Human Services (HHS). He oversees, among other things, CMS and the Medicaid program. He is sued in his official capacity.

20. Defendant HHS is an executive department of the United States Government headquartered in Washington, D.C., and responsible for CMS and the Medicaid program.

21. Defendant Elizabeth "Liz" Richter is the Acting Administrator of CMS. She administers the Medicaid program on behalf of the Secretary and oversees CMS's activities. She is sued in her official capacity.

22. Defendant CMS is an administrative agency within HHS headquartered in Baltimore, MD that administers the Medicaid program. CMS promulgated the Accumulator Rule at issue.

BACKGROUND

Manufacturers Must Give Medicaid the Same Discounts They Give Commercial Purchasers

23. In 1990, Congress enacted the Medicaid rebate statute, which requires drug manufacturers to provide prescription drugs to state Medicaid programs at prices at least as favorable as those given to commercial purchasers in return for Federal Financial Participation ("FFP") being made available to the States for the company's products. *See* Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388 (1990) (codified as amended at 42 U.S.C. § 1396r-8); H.R. Rep. 101-881, at 96 (1990). These reduced prices take the form of rebates paid by manufacturers to state Medicaid programs. 42 U.S.C. § 1396r-8(b)(1)(A). In particular, as a condition of having their drugs eligible for FFP, a manufacturer "must have entered into and have in effect a rebate agreement … with [HHS], on behalf of States." *Id.* § 1396r-8(a)(1). That rebate agreement, in

turn, must "require the manufacturer to provide[] to each State plan … a rebate for a rebate period in an amount specified" by the statute. *Id.* § 1396r-8(b)(1)(A).

24. Under the statutory provisions governing innovator drugs (as opposed to generic drugs), the amount of the "basic rebate" manufacturers are required to pay is calculated in part based on the manufacturer's Best Price. In general, for each quarterly rebate period, a manufacturer's basic rebate amount is calculated as: (1) the total number of units reimbursed by the state's Medicaid program, multiplied by; (2) the greater of (a) the difference between the manufacturer's Average Manufacturer Price and its Best Price, or (b) a statutorily-specified percentage of the Average Manufacturer Price plus, if applicable, an additional rebate based on price changes in excess of inflation. *Id.* § 1396r-8(c)(1)(A).

25. The statute requires manufacturers to report the Best Price for relevant drugs to CMS. *See id.* § 1396r-8(b)(3)(A). Failure to timely and accurately report Best Price is subject to penalties, including a civil fine of $10,000 for each day the report is late and a fine of up to $100,000 for each knowingly false "item of information" reported. *Id.* § 1396r-8(b)(3)(C).

26. When first enacted, the rebate statute defined Best Price as "the lowest price available from the manufacturer to any wholesaler, retailer, nonprofit entity, or governmental entity within the United States," with certain exclusions. Pub. L. No. 101-508, § 4401(a)(3) (1990). Congress also specified that Best Price "shall be inclusive of cash discounts, free goods, volume discounts, and rebates (other than rebates under this section)." *Id.*

27. In the original Medicaid rebate statute, as well as subsequent amendments, Congress took care to ensure that the definition of Best Price does not have the unintended consequence of discouraging manufacturers from offering discounts to certain non-Medicaid buyers. The original 1990 definition of Best Price, for example, excluded depot prices and prices

negotiated under single-award contracts with federal agencies. *See* Pub. L. No. 101-508, § 4401(a)(3). These procurement methods were used by the VA for certain drugs, and they were excluded from Best Price to avoid effectively forcing manufacturers to raise prices on drugs sold through these methods. *See* S. Rep. 102-401, at 61-62 (1992).

28. Similarly, in the years following the rebate statute's initial enactment, Congress became concerned that the statute was forcing manufacturers to reduce the discounts they offered to the VA and certain other Best-Price-eligible purchasers to avoid having to pay those discounts to the entire Medicaid program through increased rebates. *See* H.R. Rep. 102-384(I), at 1, 4 (1991); Stefanie Berman, *A Legislative History of the Medicaid Drug Rebate Law: The Drug Industry and the Crusade of Senator David Pryor* 52-54 (2004). For example, in 1992, Congress amended the statute to exclude from Best Price discounts manufacturers offer to the VA, the Indian Health Service, the Department of Defense, and certain other governmental or safety-net entities, as well as "any prices charged under the Federal Supply Schedule." Pub. L. No. 102-585, Title VI, § 601(a)-(c) (1992). Congress has never included patients as Best-Price-eligible entities.

CMS Addresses Discounts to Pharmacy Benefit Managers and Assistance to Patients

29. In 2006, CMS proposed comprehensive regulations governing the Medicaid rebate calculation, including the Best Price determination. In pertinent part, the proposed regulations addressed the treatment of certain payments to PBMs. As relevant here, CMS proposed to include *all* discounts, rebates, and price concessions to PBMs in Best Price, even though manufacturers had reported that they did not know the extent to which PBMs pass those price concessions on to health plans, employers, pharmacies, or other entities. 71 Fed. Reg. 77,174, 77, 179, 77,183 (Dec. 22, 2006). The agency's initial view was that *any* adjustment that affects the "net" amount realized by a manufacturer for a drug should count toward Best Price. *Id.* at 77,183.

30. The final rule, promulgated in 2007, rejected this approach. CMS instead excluded PBM discounts, rebates, and price concessions from Best Price unless they are "*designed* to adjust prices at the retail or provider level." 72 Fed. Reg. 39,142, 39,198 (July 17, 2007) (emphasis added); *see also* 42 C.F.R. § 447.505(c)(17). CMS reasoned that "discounts, rebates, chargebacks and other forms of price concessions may reduce the *amount received* by the manufacturer for drugs" and yet not actually "reduce *prices*." 72 Fed. Reg. at 39,171 (emphases added).

31. The 2007 regulation also confirmed that, consistent with the statute, the Best Price calculation should exclude assistance to patients, including "[m]anufacturer-sponsored drug discount card programs," "[m]anufacturer coupons to a consumer," "[m]anufacturer copayment assistance programs," "[m]anufacturer-sponsored patient refund or rebate programs," and "[m]anufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs." 42 C.F.R. § 447.505(c)(8)-(12). CMS concluded that these programs should be excluded from the Best Price calculation "to the extent that … [any] other entity does not receive any price concession." *Id.* The Best Price exclusion for manufacturer assistance to patients remained unchanged at all points until the Accumulator Rule in December 2020. *See also* 81 Fed. Reg. 5,170, 5,253-54 (Feb. 1, 2016) (reiterating that "patients are not one of the entities described in the statutory definition of Best Price").

As Financial Burdens on Patients Rise, Manufacturers Provide Patient Assistance

32. Manufacturer-sponsored patient assistance programs are an increasingly important source of financial support for patients who need prescription drugs, as patient burdens are rising disproportionately for such medications. More and more, health plans and PBMs have imposed high out-of-pocket costs on patients in the form of large deductibles, co-payments, and co-insurance. *See, e.g.*, Katie Devane, *et al.*, *Patient Affordability Part One: The Implications of*

Changing Benefit-Designs and High Cost-Sharing, IQVIA (2018), https://bit.ly/3hNw89s. From 2007 to 2017, for example, spending on deductibles rose by 205% among enrollees in large employer health plans, outpacing wage growth significantly. *Tracking the Rise in Premium Contributions and Cost-sharing for Families with Large Employer Coverage*, Peterson-Kaiser Family Foundation (August 2019), https://bit.ly/3v7JzFb. Higher patient burdens are often also the result of markups by hospitals and other participants in the healthcare system. One analysis found an average hospital markup on medicines of 487% over the price charged by the manufacturer. *Hospital Charges and Reimbursement for Medicines* (Sept. 2018), https://bit.ly/33ZFozh.

33. Higher patient out-of-pocket costs all too frequently mean that patients cannot afford the medications that their doctors have prescribed and their health plans have promised to cover. A growing scholarly consensus demonstrates that even "small increases in cost cause patients to cut back on drugs with large benefits, ultimately causing their death." Amitabh Chandra, et al., *The Health Costs of Cost-Sharing*, National Bureau of Economic Research Working Paper 28439 35 (Feb. 2021). An increase in cost of just $10.40 per drug can lead to a 22.6% drop in total drug consumption and a 32.7% increase in mortality. *Id.* at 1. In 2017, for example, 69% of commercially insured patients did not fill new prescriptions when they had to pay more than $250 out of pocket. Katie Devane, et al., *Patient Affordability Part Two: Implications for Patient Behavior & Therapy Consumption*, IQVIA (2018), https://bit.ly/3hNwkWe. The comparable figure for patients with out-of-pocket costs of $30 or less was just 11 percent. *Id.*

34. Manufacturer assistance is an important safety net for patients who need financial support to help them pay for medications that their doctors have determined will benefit them. In

2019, for example, 70 percent of patients taking innovative medicines to treat multiple sclerosis used cost-sharing assistance to help them pay the high out-of-pocket costs set by their plan. Without cost-sharing assistance, these patients would have paid over five times more out of pocket ($2,238 more, on average). *IQVIA Analysis for PhRMA*, U.S. Market Access Strategy Consulting Analysis (2020). Similarly, patients taking diabetes medicines would have paid more than twice as much out of pocket if they were prevented from using cost-sharing assistance. *Id.*

35. Manufacturer assistance is particularly important for specialty drugs. A 2017 study of cancer patients using specialty drugs, for example, found that patient assistance programs reduced out-of-pocket expenses by a median of $411 for each prescription. *See* Leah L. Zullig et al., *The Role of Patient Financial Assistance Programs in Reducing Costs for Cancer Patients*, 23 J. Manag. Care Spec. Pharm. 407-411 (2017).

36. When manufacturers help patients pay their out-of-pocket costs, patients are more likely to get the medicines they need and to adhere to their treatment regimens. *See, e.g.*, Jonas B. Daugherty, *et al.*, *The Impact of Manufacturer Coupon Use in the Statin Market*, 19 J. Managed Care & Specialty Pharmacy 765 (2013); Matthew Daubresse *et al.*, *Effect of Prescription Drug Coupons on Statin Utilization and Expenditures: A Retrospective Cohort Study*, 27 Pharmacotherapy 12-24 (2017). Patients receiving such assistance have proven much less likely to abandon needed treatments. Catherine I. Starner, *et al.*, *Specialty Drug Coupons Lower Out-of-Pocket Costs and May Improve Adherence at the Risk of Increasing Premiums*, 33 Health Affairs 1761 (2014). And "[p]atient nonadherence to prescribed medications is associated with poor therapeutic outcomes, progression of disease, and an estimated burden of billions per year in avoidable direct health care costs." Aurel O. Iuga & Maura J. McGuire, *Adherence and Healthcare Costs*, 7 Risk Management Healthcare Policy 35 (February 2014).

37. CMS itself has acknowledged that "copayment support may help beneficiaries by encouraging adherence to existing medication regimens, particularly when copayments may be unaffordable to many patients." 84 Fed. Reg. 17,454, 17,544 (Apr. 25, 2019). Indeed, CMS has recognized that patient assistance is crucial for "consumers whose drug costs would otherwise be extremely high due to a rare or costly condition." 84 Fed. Reg. at 17,544.

Health Plans and PBMs Penalize Patients for Using Manufacturer Assistance

38. Because manufacturer assistance mitigates the rationing effects of high patient out-of-pocket costs, health plans and PBMs have begun to deploy "accumulator adjustment programs." Accumulators are systems that have traditionally been used by insurers to track patients' spending towards deductibles and annual out-of-pocket maximum. However, under an accumulator adjustment program, if a patient uses manufacturer assistance to pay their out-of-pocket costs at the pharmacy counter, the patient's health plan does not count such manufacturer assistance toward satisfaction of a patient's annual deductible or out-of-pocket maximum. This effectively keeps patients in the deductible period longer or keeps them from satisfying out-of-pocket maximums—effectively extending the amount of time before the insurance benefit kicks in. As a result, it could take longer for the patient to satisfy their deductible or out-of-pocket maximum, which they may not realize until the manufacturer assistance is exhausted. At that point, the patient may be required to meet a portion or all of their deductible again, with the end result that patients either abandon their prescribed medications or pay more than they would have otherwise, while the health plans may pay less. *See* 85 Fed. Reg. 37,286, 37,298 (June 19, 2020).

39. Accumulator adjustment programs harm patients. They force patients to pay more for drugs and cause exactly the problems that manufacturer co-pay assistance programs are designed to ameliorate: prescription abandonment, non-adherence to prescribed medication

regimens, poor health outcomes, and unnecessary medical spending by patients. Patients who pay their premiums but cannot afford their out-of-pocket costs at the pharmacy often leave without the medicine their doctor prescribed. For example, after the implementation of an accumulator adjustment program, high deductible health plan enrollees taking autoimmune specialty drugs had a 20 percent higher level of treatment discontinuation. Bruce W. Sherman, et al., *Impact of a Co-pay Accumulator Adjustment Program on Specialty Drug Adherence*, 25 Am. J. Managed Care 335 (2019). As an AIDS Institute report noted: "Copay accumulator programs put patients with chronic conditions in a tough position—forcing them to choose between their health and other financial obligations." *Copay Accumulator Adjustment Programs*, AIDS Institute 5 (June 2020), https://bit.ly/3bGCS5v. CMS itself has observed that accumulator adjustment programs can harm patients by making them pay "a significantly larger bill for" a medicine. 85 Fed. Reg. at 37,298.

CMS Promulgates the Accumulator Rule

40. On June 19, 2020, CMS published a proposed rule addressing, among other things, the impact of accumulator adjustment programs on the Best Price determination. 85 Fed. Reg. 37,286.

41. CMS recognized that patient assistance by manufacturers is "helpful to patients in obtaining necessary medications," and that accumulator adjustment programs dilute the benefit of such assistance "to the detriment of the patient." *Id.* at 37,289, 37,298. But rather than proposing solutions to limit the negative impact of accumulator adjustment programs, CMS did exactly the opposite by reversing its longstanding approach to Best Price and requiring inclusion of manufacturer assistance to patients unless the manufacturer somehow "ensures" that the patient's health plan does not use an accumulator adjustment program. *Id.* at 37,299.

42. On July 17, 2020, recognizing the severe negative consequences that this proposed rule would have on its members and on patients who receive manufacturer assistance, PhRMA submitted comments to CMS. PhRMA stressed that the proposed rule violated the plain terms of the statute, rested on unsupported assumptions, and, if finalized, could leave manufacturers with no choice but to pull back assistance they currently offer to patients. *See* PhRMA, Comment Letter (July 17, 2020), https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/V-Z/VBP-Proposed-Rule-Comment-Letter-7172020.pdf.

43. On December 31, 2020, CMS nonetheless published the final Accumulator Rule, which adopts the amended regulations as proposed with respect to the effect of accumulator adjustment programs on Best Price, effective January 1, 2023. 85 Fed. Reg. 87,000, 87,102-03 (Dec. 31, 2020) (amending, as relevant here, 42 C.F.R. §§ 447.505(c)(8)-(11)).

44. In its response to the many comments received sounding the alarm about the Accumulator Rule, CMS attempted to explain why it adopted the Rule as proposed, but none of those explanations justifies CMS's decision. CMS first addressed the Rule's "Impact on Patients." *Id.* at 87,049. In that discussion, CMS fully admitted and agreed that accumulator adjustment programs harm patients by "shift[ing] costs back to the patient prematurely by not applying the full value of the manufacturer-sponsored assistance to a patient's health plan deductible." *Id.* And "[u]pon exhaustion of the value of the manufacturer's assistance …[,] the beneficiary of the manufacturer-sponsored assistance must pay the remaining amount of their deductible for the drug before the plan's benefit begins." *Id.* "When this happens," CMS recognized, "the patient may be forced to stop taking the drug, switch to an alternative offered by the plan, or pay the full bill for the non-formulary drug, none of which are patient-friendly, especially for those patients with rare and life threatening conditions." *Id.* at 87,050.

45. Having identified these major and unacceptable problems, however, CMS then proceeded not to tackle them. CMS instead deflected concern about the massive negative impacts on patients by speculating that the Accumulator Rule "will ensure that the full value of the manufacturer-sponsored assistance programs is passed on to the patient." *Id.* That unsupported guess by CMS, however, presupposes that manufacturers will be able to structure their assistance to patients in a manner that can avoid misappropriation by accumulator adjustment programs. CMS offered no evidence to support this assumption.

46. In fact, the available evidence contradicts CMS's assumption that manufacturers can render accumulator adjustment programs ineffective. Manufacturers are not involved in the development or implementation of accumulator adjustment programs, and as PhRMA pointed out in its comments, outside analysts have determined that "there is *not currently a reliable method* by which manufacturers can ensure in all cases that the assistance they offer is applied exclusively to the benefit of the patient." Rich Fry, *Co-Pay Programs: The CMS Best Price Revision* (June 30, 2020), https://bit.ly/3f1WWkA; *see* PhRMA, Comment Letter at 9 (July 17, 2020), https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/V-Z/VBP-Proposed-Rule-Comment-Letter-7172020.pdf. Again, manufacturers are often not even aware that an accumulator adjustment program is in place.

47. CMS also responded to comments raising concerns that the Rule would force manufacturers to pull back on patient assistance. *Id.* at 87,050. But CMS's response again deflected this concern, this time by positing, without elaboration, that manufacturers "will improve their oversight of these manufacturer assistance programs," which "could actually lead to lower drug prices." *Id*. But that deflection only addressed prices, and did not address, much less refute, the substantial risk that manufacturers would need to reduce or withdraw their assistance programs.

48. CMS also addressed the Rule's "Legal Authority." *Id.* at 87,051. But CMS's discussion of that topic was entirely contradictory. On the one hand, CMS asserted that, even before the final Rule's adoption, CMS's existing regulations "already provide that manufacturers can only exclude manufacturer-sponsored assistance if it is being passed through to the patient." *Id.* at 87,052. That is because, according to CMS, "[i]n cases where the PBM accumulator programs do not allow any manufacturer-sponsored assistance to apply to the beneficiary'[s] deductible, the health plan is receiving a price concession in the form of delaying the health plan's obligation to provide coverage of the drug under the patient's health plan benefit." *Id.* On the other hand, CMS simultaneously admitted that the Rule imposes *new* requirements. For that reason, CMS "delay[ed] the effective date until January 1, 2023," to "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.* at 87,053.

The Accumulator Rule Is Inconsistent with the Plain Text of the Medicaid Rebate Statute

49. The Accumulator Rule is inconsistent with the text, structure, and purpose of the Medicaid rebate statute.

50. The statute defines Best Price as the "lowest price available from a manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States," subject to certain exclusions. 42 U.S.C. § 1396r-8(c)(1)(C). Notably, patients are not included on this list, meaning the lower price available to patients is *not* considered part of the Best Price calculation. *See Jennings v.*

Rodriguez, 138 S. Ct. 830, 844 (2018) (noting that under the negative implication canon, "[t]he expression of one thing implies the exclusion of others").[1]

51. On this point, CMS agrees. In its 2016 rulemaking, CMS "agree[d]" with commenters that "Best Price excludes direct sales to patients because patients are not one of the entities described in the statutory definition of Best Price." 81 Fed. Reg. 5,170, 5,253-54 (Feb. 1, 2016). For that reason, CMS excluded "[d]irect sales to patients" from the Best Price calculation. 42 C.F.R. § 447.505(c)(19); *see also* 81 Fed. Reg. at 5,252 (agreeing to revise proposed rule's definition of Best Price to resolve "ambiguity regarding the treatment of prices and associated discounts or other price concessions to customers, such as patients, that are not included in the statutory definition of Best Price").

52. Manufacturer assistance to patients does not become a "price" concession offered to health plans just because those plans or PBMs use an accumulator adjustment program to misappropriate the benefit of the assistance from the patient to the plan, against the will and often without the knowledge of the manufacturers that offered it or the patients who received it.

53. The statutory term "price" is the starting point for this analysis. Because the word "price" is "undefined in [the] statute," it must be given "its ordinary meaning." *Taniguchi v. Kan Pac. Saipan, Ltd.*, 566 U.S. 560, 566 (2012). In ordinary use, "price" is generally defined as "the amount of money given or set as consideration for the sale of a specified thing." *Price*, Merriam-Webster, https://www.merriam-webster.com/dictionary/price; *see Price*, Black's Law Dictionary (11th ed. 2019) (similar). As this definition suggests, the "price" of an item must result from a

[1] We note that the interpretation of the statutory term "price" set forth herein should also apply consistently to the use of that term throughout the Medicaid rebate statute, including with respect to the calculation of "average manufacturer price" (another component of determining manufacturers' Medicaid rebate obligations under the statute).

meeting of the minds between the buyer and the seller; it is the amount a seller has *voluntarily* agreed to accept in exchange for transferring the good to the buyer.

54. On this understanding, a payment reduction counts as part of a "price" only if the seller agreed and intended to make that reduction available to the buyer. If the payment reduction instead results from conduct unrelated to the parties' voluntary transaction, it is not part of the "price." For example, if a buyer takes some of the payment amount back from a seller, one would not describe the amount taken as a reduction in the "price." The same would be true if the seller were to provide a gift to a third party, and the buyer were to take that gift from the third party and pocket it—the amount the buyer took would not qualify as a "price concession" from the seller.

55. The same logic holds here: A reduction in the amount health plans pay for a drug is part of the drug's "price" only to the extent the manufacturer *agrees* to accept the reduced payment from the health plan. Manufacturer-sponsored patient assistance appropriated by a health plan's or PBM's accumulator adjustment program does not meet this standard. Manufacturers offer financial assistance exclusively to patients, who are Best-Price-ineligible, and manufacturers intend for patients to be the sole beneficiaries of their assistance programs. Any payment reduction that a plan or PBM unilaterally achieves through an accumulator adjustment program occurs *against the will of and without the consent of the manufacturer*.

56. CMS previously accepted that the statutory term "price" includes an intent requirement. In 2006, CMS proposed a regulation that would have included *all* discounts, rebates, and price concessions that manufacturers provide to PBMs in the Best Price calculation. 71 Fed. Reg. at 77,179, 77,183. In the 2007 final rule, however, CMS instead determined that PBM discounts, rebates, and price concessions should be included in Best Price only to the extent they are "*designed* to adjust prices at the retail or provider level." 72 Fed. Reg. are 39,198 (emphasis

added); *see also* 42 C.F.R. § 447.505(c)(17). By making the inclusion of discounts turn on a manufacturer's "design," CMS agreed that, consistent with the statute, intent governs: only discounts that manufacturers *intend* to reduce the amount a Best Price-eligible buyer pays should affect Best Price.

57. Applying this commonsense, ordinary meaning of "price" here, manufacturer-sponsored assistance to patients is not part of a drug's "price" offered to a health plan because it is not a discount that manufacturers intend and agree to provide to plans.

58. Other portions of the Best Price definition reinforce that Best Price does not include manufacturer assistance that plans and PBMs misappropriate through accumulator adjustment programs. In particular, the definition provides that Best Price is the lowest price "available from a manufacturer … to any … provider." 42 U.S.C. § 1396r-8(c)(1)(C). Manufacturer-sponsored patient assistance misappropriated by accumulator adjustment programs, however, is not "available from a manufacturer … to any … provider"; rather, it is available from manufacturers to *patients*.

59. Yet another aspect of the rebate program further reinforces that conclusion. In particular, the statute requires each manufacturer to report its Best Price to the Secretary and subjects them to steep penalties for providing false information. 42 U.S.C. § 1396r-8(b)(3)(A), (C). Under the Accumulator Rule, however, the only apparent way to avoid these steep penalties would be for the manufacturer to conduct extensive investigation, along with cooperation from health plans, into whether and how each and every single health plan is using accumulator adjustment programs to reduce its costs. But given that health plans and their PBMs control accumulator adjustment programs, manufacturers may not be able to reach such a determination for every health plan. After all, manufacturers do not have full visibility into the total extent to

which health plans are adopting behind-the-scenes accumulator adjustment programs or—equally important—the actual extent to which those programs reduce the total amount paid by the plan for a specific product for each and every patient. Had Congress intended an accurate Best-Price determination to require such an extraordinary compliance burden, it would have spoken more clearly. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) (Congress "does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes."); *cf. United States v. Data Translation Inc.*, 984 F.2d 1256 (1st Cir. 1992) (declining to interpret government contract with a most-favored-customer provision as requiring the disclosure of "*every price discount* [the contractor] provided *any* of its customers *ever*," since that would "ask[] a business to shoulder a compliance burden which will often seem inordinately difficult or impossible to carry out").

60. The history of the Medicaid rebate statute further confirms that Best Price includes only those discounts that manufacturers *intend* and *agree* to make available to Best-Price-eligible entities. Congress drew the term Best Price directly from a voluntary rebate program that Merck had previously established with state Medicaid programs prior to enactment of the Medicaid rebate statute. Stefanie Berman, *A Legislative History of the Medicaid Drug Rebate Law: The Drug Industry and the Crusade of Senator David Pryor* 52-54 (2004). All parties understood that manufacturers would be in control of their Best Price. *See* H.R. Rep. 102-384(I) at 3 (1991) (the program "provides a vehicle for providing Medicaid programs with the same 'Best Price' discounts which other large-buying entities secured through negotiation").

61. All of the available "traditional tools of statutory interpretation" show that the statute is not ambiguous and a manufacturer's Best Price is not reduced by manufacturer-sponsored assistance that a third-party payer misappropriates through use of accumulator adjustment

programs. *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 843 n.9 (1984). CMS's contrary interpretation in the Accumulator Rule accordingly is owed no deference.

The Final Rule Is Internally Contradictory, Reinforcing The Accumulator Rule's Invalidity

62. In the final rule itself, CMS recognized that Best Price does not include benefits that Best-Price-eligible purchasers obtain from parties other than manufacturers. In a separate section of the rule, CMS addressed "'warranty-type' insurance models," in which a manufacturer might pay a premium to a third-party insurer in exchange for the insurer's agreement to pay claims to a Best Price-eligible payer in the event that the manufacturer's product did not perform as warranted. 85 Fed. Reg. at 87,020. In addressing how payments under that third-party warranty model should be treated for purposes of Best Price determinations, CMS explained that, while manufacturer premium payments would be Best-Price-eligible, the "benefits paid by [a] third party [insurer] in the event the drug did not meet certain clinical or performance measures are exempt from 'best price' because *payments made from the third party to the payer do not represent a price available from the manufacturer to any best price eligible entity*." *Id.* (emphasis added).

63. CMS's conclusion in the warranty section of the rule correctly applies the statutory requirement that a price must be "available from a manufacturer … to [a Best-Price-eligible purchaser]" in order to affect Best Price. But CMS inexplicably failed to follow this same commonsense analysis when addressing accumulator adjustment programs. Applying CMS's logic from the warranty section here, manufacturer-sponsored assistance that plans and PBMs misappropriate from patients "do not represent a price available from the manufacturer to any best price eligible entity," but rather an amount that a health plan obtains from elsewhere (namely from patients). Like the payment from the third-party insurance company to the payer in the warranty

context, the assistance amount that payers take from the patient in the accumulator adjustment program context also should be excluded from Best Price.

PhRMA Has Standing To Challenge the Accumulator Rule

64. PhRMA has standing to challenge the Accumulator Rule because "(a) its members would otherwise have standing to sue in their own right; (b) the interest it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Pharm. Research & Mfrs. of Am. v. D.C.*, 406 F. Supp. 2d 56, 62 (D.D.C. 2005), *aff'd sub nom. Biotechnology Indus. Org. v. D.C.*, 496 F.3d 1362 (Fed. Cir. 2007) (finding PhRMA has standing to challenge a D.C. pricing ordinance).

65. The Accumulator Rule "directly impose[s] regulatory restrictions, costs, or other burdens" on PhRMA's members. *Grocery Mfrs. Ass'n v. EPA*, 693 F.3d 169, 174-75 (D.C. Cir. 2012). As detailed herein, the Accumulator Rule directly affects the rights and obligations of PhRMA members by altering the rules for determining Best Price. In so doing, the Accumulator Rule puts PhRMA members to a Hobson's choice—either risk paying higher Medicaid rebates (i.e., "costs") or forego offering financial assistance to patients (i.e., "other burdens"). *Id.* Again, either side of that dilemma inflicts a cognizable harm that confers standing.

66. The Rule also imposes an extraordinary new compliance burden on manufacturers, requiring them to investigate, every quarter and beyond, whether and how health plans are using accumulator adjustment programs to increase their own profits. Because the Accumulator Rule excludes manufacturer-sponsored assistance from Best Price only if manufacturers "ensure[] the full value of the assistance or benefit is passed on to the consumer or patient," 85 Fed. Reg. 37,299, manufacturers who offer such assistance must conduct regular investigations and persuade PBMs

and plans to share information that will impact their ability to continue to appropriate the assistance provided by the manufacturers to the patient in order for the manufacturer to report accurate Best Price information. Even with such investigation, there is no guarantee that the relevant information will be available to manufacturers.

67. The interests at stake here are germane to PhRMA's mission as the industry's principal policy advocate, representing its members' interests in matters before Congress, the Executive Branch, state regulatory agencies and legislatures, and the courts. *Biotechnology Indus. Org. v. D.C.*, 496 F.3d 1362, 1370 (Fed. Cir. 2007) (Plaintiffs are "industry organizations who seek to shape policy in a manner favorable to member pharmaceutical and biotechnology companies, so the subject matter of this case is highly germane to their respective purposes.").

CLAIM FOR RELIEF

Declaratory/Injunctive Relief Under Section 706 (A), (C) of the Administrative Procedure Act - the Accumulator Rule Exceeds CMS's Statutory Authority Under 42 U.S.C. § 1396r-8

68. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

69. The APA requires courts to "hold unlawful and set aside" agency action that is "not in accordance with law" or is "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(A), (C).

70. The Accumulator Rule is contrary to statutory requirements on what may be considered as part of the Best Price calculation under 42 U.S.C. § 1396r-8(c)(1)(C), which 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 government entity within the United States," with certain exceptions. Contrary to the Accumulator Rule,

assistance provided by a manufacturer to a patient is not part of the "price available from the manufacturer … to any [Best-Price-eligible purchaser]."

71. The Accumulator Rule is thus "not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations," and must be set aside under 5 U.S.C. § 706(2)(A), (C).

PRAYER FOR RELIEF

NOW, THEREFORE, Plaintiff PhRMA requests a judgment in its favor against Defendants as follows:

1. Declare that the Accumulator Rule, 42 C.F.R. § 447.505(c)(8)-(11), is not in accordance with law and is therefore invalid under the Administrative Procedure Act;
2. Set aside and vacate the Accumulator Rule;
3. Issue an injunction preventing Defendants from implementing or enforcing the Accumulator Rule;
4. Award Plaintiff reasonable attorneys' fees and costs; and
5. Grant such other and further relief as the Court may deem appropriate.

DATED: May 21, 2021.

Respectfully submitted,

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* *Motion for admission forthcoming*