IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

601 Pennsylvania Avenue, N.W., Suite 740
Washington, D.C. 20004

Plaintiff,

v.

Case No. _____

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

200 Independence Avenue, S.W.
Washington, D.C. 20201;

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES – OFFICE OF INSPECTOR GENERAL,

330 Independence Avenue, S.W.
Washington, D.C. 20201;

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES – OFFICE OF COUNSEL TO THE INSPECTOR GENERAL,

330 Independence Avenue, S.W.
Washington, D.C. 20201;

UNITED STATES DEPARTMENT OF JUSTICE,

950 Pennsylvania Avenue, N.W.
Washington, D.C. 20530;

ALEX M. AZAR, II, in his official capacity as Secretary of Health and Human Services,

200 Independence Avenue, S.W.
Washington, D.C. 20201;

JEFFREY A. ROSEN, in his official capacity as Acting Attorney General of the United States,

950 Pennsylvania Avenue, N.W.
Washington, D.C. 20530;

CHRISTI A. GRIMM, in her official capacity as Acting Inspector General of the Department of Health and Human Services,

330 Independence Avenue, S.W.
Washington, D.C. 20201; and

GREGORY E. DEMSKE, in his official capacity as Chief Counsel to the Inspector General of the Department of Health and Human Services,

330 Independence Avenue, S.W.
Washington, D.C. 20201

Defendants.

COMPLAINT AND PRAYER FOR DECLARATORY AND INJUNCTIVE RELIEF

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GLOSSARY

Term	Definition
CBO	Congressional Budget Office
CMS	Centers for Medicare & Medicaid Services
DIR	Direct and Indirect Remuneration
HHS	U.S. Department of Health and Human Services
HHS-OIG	U.S. Department of Health and Human Services – Office of Inspector General
Medicare Act	Tit. XVIII, 42 U.S.C. § 1395 *et seq.*
OACT	CMS Office of the Actuary
OIRA	Office of Information & Regulatory Affairs
OMB	Office of Management and Budget
PBM	Pharmacy benefit manager
PCMA	Pharmaceutical Care Management Association
Proposed Rule	84 Fed. Reg. 2340 (Feb. 6, 2019)
Rebate Rule	85 Fed. Reg. 76666 (Nov. 30, 2020)

Plaintiff Pharmaceutical Care Management Association ("PCMA"), for its complaint against Defendants the UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES ("HHS"); the DEPARTMENT OF HEALTH AND HUMAN SERVICES – OFFICE OF INSPECTOR GENERAL ("HHS-OIG"); the UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES – OFFICE OF COUNSEL TO THE INSPECTOR GENERAL ("HHS-OCIG"); the DEPARTMENT OF JUSTICE ("DOJ"); ALEX M. AZAR, II, in his official capacity as Secretary of Health and Human Services (the "Secretary"); JEFFREY A. ROSEN, in his official capacity as Acting Attorney General of the United States; CHRISTI A. GRIMM, in her official capacity as Acting Inspector General of the Department of Health and Human Services; and GREGORY E. DEMSKE, in his official capacity as Chief Counsel to the Inspector General of the Department of Health and Human Services, alleges, by and through its attorneys, as follows:

INTRODUCTION

1. This case is about the "Rebate Rule"—a final order issued by the Department of Health and Human Services Office of Inspector General ("HHS-OIG") in the waning days of the Trump Administration that radically transforms the way prescription drugs are priced and paid for in the Medicare Part D program. *See Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals*, 85 Fed. Reg. 76666 (Nov. 30, 2020) (the "Rebate Rule"). The Rebate Rule is the product of an erratic and highly irregular administrative process. When HHS-OIG proposed the Rule in 2019, the proposal provoked a tsunami of concern about increased premiums for enrollees and skyrocketing federal spending. HHS's *own* actuaries estimated the cost of the proposed rule to be as high as ***$196 billion*** over ten years—making it one of the most expensive regulations in history—and predicted that seniors' prescription drug ***premiums would go up by as much as 25%***. HHS-OIG then withdrew the proposal, and the

matter seemed to be over. In July 2020, however, the proposal was abruptly revived by President Trump's Executive Order directing Secretary Azar to finalize the Rule—so long as Secretary Azar could confirm that it would not adversely affect premiums or federal spending. Less than four months later, HHS-OIG adopted the Rebate Rule, with an accompanying certification by Secretary Azar making the exact findings demanded by the President based on nothing more than "experience." The Rule reflects a total lack of coordination between HHS-OIG and HHS's own Centers for Medicare & Medicaid Services ("CMS"), which administers Medicare Part D and issues critical implementing rules and guidance for program participants. Not surprisingly, given this tumultuous and rushed procedural history, the Rebate Rule suffers from numerous fatal legal flaws and is already producing chaos and confusion in the planning process for the 2022 contract year in which the Rule is scheduled to take effect.

2. This action under the Administrative Procedure Act, 5 U.S.C. §§ 551-706 ("APA"), and the Declaratory Judgment Act, 28 U.S.C. § 2201, accordingly challenges and seeks declaratory relief from the Rebate Rule because it exceeds HHS-OIG's statutory authority, violates the APA's notice-and-comment-rulemaking requirement, and departs from settled principles of agency rulemaking. The Rule is unlawful, arbitrary, and irrational, and will undermine critical aspects of the Medicare Part D prescription drug program, upend preparations for the 2022 contract year, and increase prescription drug premiums, federal spending, and aggregate spending on prescriptions—ultimately harming the American seniors and disabled citizens the Rule purports to help.

3. Medicare Part D is a federal prescription drug benefit program that uses market-based mechanisms to offer affordable drug coverage to millions of seniors and disabled Americans through privately operated, federally subsidized drug plans. Since Congress enacted

the program in 2003 and the program became operational in 2006, sponsors of Part D plans have emulated the commercial insurance market—just as Congress intended—in negotiating with drug manufacturers and pharmacies to control the cost of prescription drugs and compete for enrollees. As commercial insurers have done for decades, Part D plan sponsors typically employ pharmacy benefit managers ("PBMs") to administer their drug plans and negotiate rebates from manufacturers' nominal "list" prices. By offering rebates that lower the net cost of a drug, manufacturers can potentially increase their market share because lower net costs incentivize PBMs and plan sponsors to offer or adopt formularies—tiered lists of covered drugs—that include or prefer the drug under plan utilization management rules. Since the mid-1990s and through the earliest days of Part D, PBMs and manufacturers in both the commercial and Part D contexts have converged around a business model in which manufacturers pay retrospective rebates to PBMs after the product is dispensed to the enrollee, and PBMs pass rebates on to plan sponsors—including 99.6% of rebates in the Medicare Part D context. Plan sponsors under Part D are then required to report the full amount of the rebates (including any portion that may be retained by the PBM pursuant to the contract between the PBM and plan sponsor) to CMS as drug price reductions, and pass the savings on to the government and plan enrollees in the form of reduced subsidies and premiums. This widely adopted and longstanding model has proved critical to the tremendous success of the Medicare Part D program.

4. The Rebate Rule breaks with this established business model and seeks to radically transform the way that prescription drugs offered by manufacturers are typically priced and paid for, at a significant cost to the federal government and the large majority of Part D sponsors and enrollees. The Rule pursues this result by threatening manufacturers, PBMs, and plan sponsors with significant criminal and civil liability under the federal anti-kickback statute,

42 U.S.C. § 1320a-7b, simply for engaging in the same rebate practices that they have followed since the start of the Medicare Part D program, consistent with the commercial insurance market that Congress intended for Part D plans to emulate.

5. The anti-kickback statute makes it a felony for any person to "knowingly and willfully" pay or receive "remuneration" in exchange for, among other things, recommending items or services reimbursed by federal healthcare programs. 42 U.S.C. § 1320a-7b(b)(1)-(2). An important statutory exception clarifies, however, that remuneration does *not* include any "discount or other reduction in price" that is "properly disclosed and appropriately reflected" in the costs for which reimbursement could be claimed under a federal healthcare program. *Id.* § 1320a-7b(b)(3)(A). For decades, a more specific regulatory safe harbor has also protected any "rebate" for which "the terms" are "disclosed in writing to the buyer at the time of the initial sale" and the buyer, if requested by the Secretary, discloses certain information provided by the seller. 42 C.F.R. § 1001.952(h)(1)(iii). PBMs, plans, and manufacturers have relied on this regulatory safe harbor since the start of Medicare Part D to conduct their retrospective rebate practices.

6. The Rebate Rule uses the threat of liability under the anti-kickback statute to bring an end to retrospective manufacturer rebates for plans and PBMs. The Rule modifies the regulatory safe harbor for discounts so that it no longer applies to rebates paid by manufacturers to plan sponsors or PBMs under Medicare Part D. Instead, the Rule seeks to channel manufacturer price concessions into a new regulatory safe harbor that applies only when the discount is applied at the point of sale (*e.g.*, when the enrollee is filling the prescription at the pharmacy counter), passed through to the enrollee, and paid to the pharmacy through a

chargeback; in other words, the manufacturer effectively pays the pharmacy directly or indirectly.

7. The Rebate Rule is purportedly aimed at reducing the enrollee's out-of-pocket contribution toward the price of the particular prescription drug through cost-sharing payments such as deductible, copayment, and coinsurance. But multiple government and commercial actuarial analyses of the Rule—including analyses performed by HHS's own actuaries and the nonpartisan Congressional Budget Office ("CBO")—confirm that in practice it will serve mainly to reinforce the ability of the pharmaceutical industry to raise prices, and thus will ultimately have the counterproductive effect of *increasing* the cost of prescription drugs. PBMs' ability to maximize price concessions from manufacturers depends on keeping negotiations confidential so that no one manufacturer knows what price any other manufacturer has agreed to accept. That is why HHS treats price information as confidential and therefore protected under the federal Trade Secrets Act. Mandating that discounts apply at the point of sale will undercut those protections and make it easy for manufacturers to discern each other's prices and discounts. As both CBO and the Federal Trade Commission ("FTC") have recognized, disclosure of this sensitive information will allow manufacturers to tacitly collude in their negotiations and avoid the deepest discounts, driving up the net price paid for prescription drugs after all discounts and rebates, resulting in more profits for manufacturers.

8. Even if net prices remained constant, moreover, government and commercial actuaries have uniformly recognized that lowering enrollees' cost share at the point of sale will increase their premiums unless plan sponsors reduce coverage. Increased premiums, in turn, will increase federal spending on subsidies, which are tied by law to the costs incurred by plan sponsors. Lower cost sharing by enrollees will also drive up utilization of less cost-effective

drugs as enrollees become less sensitive to their true costs, further increasing the cost of providing coverage and therefore premiums and federal spending. And implementing the Rule will require massively overhauling the current system through which price concessions are delivered, resulting in implementation costs that will further drive up premiums and federal subsidies.

9. These obvious and colossal costs of the Rebate Rule doomed HHS-OIG's first attempt to promulgate it through notice-and-comment rulemaking in 2019. While drug manufacturers welcomed the Proposed Rule as a way to limit PBMs' bargaining power, PBMs, Part D sponsors, and independent and academic commentators widely condemned it. And after the close of the comment period, other agencies and administration officials joined in the condemnation. HHS-OIG submitted the Rule to the Office of Management and Budget ("OMB"), where the Rule met widespread opposition from within the administration and was accordingly withdrawn. More than a year later, however, President Trump resuscitated the Rule by Executive Order, directing HHS-OIG to complete the rulemaking, but only if the Secretary reached the conclusion—unsupportable in light of the evidence on costs according to HHS's own actuarial analysis—that the Rule would not increase premiums or federal spending. Predictably, the Secretary drew that very conclusion. He did so without evidentiary support based on little more than his personal speculation that PBMs are sophisticated negotiators, and that plan sponsors would never settle for increased premiums irrespective of the underlying market dynamics. HHS-OIG then rushed the Rule out the door, shortly before the end of the Trump Administration, improperly dispensing with the new comment period required by the APA for the new rulemaking.

10. The result of this herky-jerky, last-minute rulemaking process is an unlawful rule that rests on flawed and widely rejected economic assumptions. HHS lacks authority to subject retrospective manufacturer rebates under Medicare Part D to liability under the anti-kickback statute because—irrespective of the regulatory safe harbor for discounts—the original statutory exception for discounts continues to protect retrospective rebates. At the time Medicare Part D was enacted, moreover, the regulatory safe harbor already reflected HHS-OIG's understanding that properly disclosed manufacturer rebates were *not* remuneration within the meaning of the federal anti-kickback statute. As reflected in multiple provisions of the Medicare Act, therefore, Congress clearly understood that retrospective manufacturer rebates paid to PBMs—the dominant form of price concessions in the private market at the time, as today—were not illegal kickbacks but publicly beneficial financial arrangements. Indeed, the entire point of Medicare Part D was to create a federally subsidized program that would simulate commercial market practices. HHS-OIG's repeal of the regulatory safe harbor for discounts thus undermines the fundamental premises of the Medicare Act, is contrary to law, and is arbitrary and capricious. In the alternative, should this Court uphold the Rebate Rule, PCMA seeks a declaratory judgment that its members' rebate practices are protected by the statutory exception, which HHS-OIG cannot and did not seek to repeal.

11. The Rebate Rule is arbitrary and capricious in numerous other respects. On the merits, the Rebate Rule rests on a central premise—that the changes imposed will not increase premiums or federal spending—that is recognized as irrational by the consensus of independent analyses, as well as the government's own studies, which show that the rule will *increase* both premiums and federal spending. For that reason, the Rule will not achieve its intended purpose of lowering costs for seniors, but will instead only harm the vast majority of Medicare Part D

enrollees. The Rule will also critically undermine HHS's publicly stated goal of promoting value-based arrangements to reward healthcare providers with incentive payments based on the quality of care provided, because many of those arrangements will now be subject to criminal prosecution due to their falling outside of the new, narrowed safe harbors. Moreover, HHS-OIG violated the APA's procedural requirements to provide notice and an opportunity for comment on the Rebate Rule, which was abruptly issued in November 2020 without any new notice or comment period—well over a year after the Proposed Rule was publicly listed as withdrawn in July 2019.

12. To make matters worse, the January 1, 2022 effective date of the Rebate Rule's key provision puts PBMs and the Part D sponsors they support in an impossible practical situation. The work that goes into estimating net drug prices, premiums, and the information necessary for potential enrollees to choose the right plan for them is a long, complex, and highly regulated endeavor. Part D sponsors must submit their bids for 2022 by early June of *this* year. Those bid submissions, in turn, require months of preparation and negotiation, and depend in significant part on regulations and guidance governing bid requirements issued by CMS well in advance of the bid deadline. Numerous commenters explained why market participants would need substantial lead time to restructure their affairs in light of the Rebate Rule and to allow CMS to weigh in on how the Rebate Rule would affect bid and other Part D regulatory requirements. HHS-OIG, however, did not view these timing concerns as its problem. It simply declared, 37 separate times, that the comments pointing out these practical problems were "outside the scope" of the Rebate Rule. Because of the timing of the adoption of the Rebate Rule, CMS lacked any meaningful opportunity to issue guidance accounting for the Rebate Rule's impact on Part D for contract year 2022. As a result, manufacturers will be unwilling to

lock in binding rebate offers to PBMs and plan sponsors, threatening plan sponsors' ability to effectively design their plans and complete the bidding process. To adopt an effective date for the Rebate Rule that is completely out of alignment with the CMS schedule for implementing Part D program bid requirements is the definition of arbitrary and capricious action.

13. For all of these reasons, even if this Court were to conclude that HHS-OIG had statutory authority to regulate in this manner, the Rebate Rule must be vacated as arbitrary and capricious and contrary to the APA. At the very least, the Rule's January 1, 2022 effective date must be vacated to ensure adequate time to implement the Rule during a subsequent bid cycle. In addition, the Court should issue a declaration that retrospective rebates paid to Part D plan sponsors and PBMs are protected by the statutory exception for discounts.

PARTIES

14. Plaintiff PCMA is a non-profit § 501(c)(6) corporation duly organized under the laws of the State of Delaware, with its principal place of business in Washington, D.C. PCMA is the national trade association representing America's PBMs, which administer prescription drug plans for more than 270 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and the health insurance marketplaces. Many PBMs also own and operate home delivery and specialty pharmacies.

15. PBMs are the only entities in the supply chain whose mission is to lower drug costs for plan sponsors. Plan sponsors engage PBMs to maximize the value of prescription drug benefits by negotiating price concessions from drug manufacturers and pharmacies, in addition to providing numerous other services. PBMs also lower costs in other ways, such as by encouraging the use of generics, offering specialty pharmacy services, and helping patients with adherence to the prescribed plan of care. Two 2020 studies estimated that PBMs helped

beneficiaries and payers save on average $962 per beneficiary per year in prescription drug costs, equaling more than $1 trillion over the ensuing decade. Visante, Inc., *The Return on Investment (ROI) on PBM Services* (Feb. 2020), https://www.pcmanet.org/wp-content/uploads/2020/02/ROI-on-PBM-Services-FINAL_.pdf; Visante Inc., *Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers* (Feb. 2020), https://www.pcmanet.org/wp-content/uploads/2020/02/Pharmacy-Benefit-Managers-Generating-Savings-for-Plan-Sponsors-and-Consumers-2020-1.pdf. PBMs would not serve 270 million beneficiaries through all types of health plans if they did not bring down costs.

16. PCMA's members include the following PBMs: Abarca Health, CerpassRx, CVS Health, Envolve Pharmacy Solutions, Express Scripts, Humana Pharmacy Solutions, IngenioRx, Integrated Prescription Management, Magellan Rx Management, Maxor Plus, MedImpact Healthcare Systems, OptumRx, PerformRx, Prime Therapeutics, Serve You Rx, and WellDyneRx (collectively, the "members"). PCMA's members each administer prescription drug benefits on behalf of health plans and their enrollees, including enrollees who reside or purchase pharmaceuticals in Washington, D.C.

17. Each of PCMA's members has Article III standing because they rely on the regulatory safe harbor eliminated by the Rebate Rule in negotiating price concessions in the Medicare Part D context. As explained herein, by eliminating this safe harbor, the Rule will force PCMA's members to modify their current price concession practices; renegotiate agreements with manufacturers, pharmacies, plans, and other parties; and restructure business models that have existed for decades, to avoid exposing themselves to potential civil and criminal liability under the anti-kickback statute. Even to continue to implement price concessions under the new point-of-sale safe harbor adopted by the Rebate Rule, PCMA's

members will be forced to publicly reveal valuable trade secret information regarding the terms of their contracts, drastically undercutting their bargaining power in negotiating those agreements, and thus reducing their ability to secure valuable price concession that lower the cost of prescription drugs for Medicare Part D drug plan sponsors, enrollees, and the federal government. In any event, the system configurations and other implementing action required to come within this safe harbor are practically impossible under the current effective date of the Rule. Those injuries are directly and immediately traceable to the challenged rule and would be remedied by a judgment vacating the Rule or its effective date or declaring that the current price concession practices of PCMA's members are otherwise protected from liability under the federal anti-kickback statute.

18. PCMA has associational standing to bring this lawsuit on behalf of its members because at least one of its members has Article III standing, the interests that PCMA seeks to protect are germane to its organizational purpose of promoting PBMs and the proven tools they utilize to lower prescription drug prices, and neither the claims asserted nor the relief requested in this lawsuit requires the participation of individual PCMA members.

19. Defendant HHS is an executive department of the United States federal government that is headquartered in Washington, D.C. HHS is responsible for administering federal health and social services program including Medicare, and for civil enforcement of the federal anti-kickback statute.

20. Defendant HHS-OIG is an administrative agency within HHS that is headquartered in Washington, D.C. HHS is responsible for combating waste, fraud, and abuse within HHS programs, including through civil enforcement of the federal anti-kickback statute

and referring violations of that statute to the Attorney General for criminal enforcement. HHS-OIG promulgated the Rebate Rule challenged in this lawsuit.

21. Defendant HHS-OCIG is an administrative agency within HHS-OIG that is headquartered in Washington, D.C. HHS-OCIG is responsible for providing legal advocacy and counsel to the Inspector General and other components of HHS-OIG, including in civil enforcement matters under the federal anti-kickback statute.

22. Defendant DOJ is an executive department of the United States federal government that is headquartered in Washington, D.C. DOJ is responsible for criminal enforcement of the federal anti-kickback statute.

23. Defendant Alex M. Azar, II is Secretary of Health and Human Services. The Secretary is a signatory to the Rebate Rule and oversees enforcement of the federal anti-kickback statute. He is sued in his official capacity.

24. Defendant Jeffrey A. Rosen is Acting Attorney General of the United States. The Attorney General oversees criminal enforcement of the federal anti-kickback statute. He is sued in his official capacity.

25. Defendant Christi A. Grimm is Acting Inspector General of HHS. The Inspector General is a signatory to the Rebate Rule and shares responsibility for civil enforcement of the federal anti-kickback statute and for referring violations of that statute to the Attorney General for criminal enforcement. She is sued in her official capacity.

26. Defendant Gregory E. Demske is Chief Counsel to the Inspector General of HHS. The Chief Counsel is head of HHS-OCIG and shares responsibility for civil enforcement of the federal anti-kickback statute and for referring violations of that statute to the Attorney General for criminal enforcement. He is sued in his official capacity.

JURISDICTION AND VENUE

27. This action arises under the Medicare Act, the federal anti-kickback statute, the APA, and the Declaratory Judgment Act. This Court has subject-matter jurisdiction over this action under 28 U.S.C. § 1331. The Court is authorized to issue the nonmonetary relief sought herein pursuant to the APA, 5 U.S.C. §§ 702, 705, and 706, and the Declaratory Judgment Act.

28. Venue is proper in this Court under 28 U.S.C. § 1391(e)(l) because this is an action against agencies of the United States and several officers of the United States. Defendants HHS, HHS-OIG, HHS-OCIG, and DOJ reside in this judicial district; Defendants Azar, Rosen, Grimm, and Demske perform their official duties in this judicial district; a substantial part of the events or omissions giving rise to this action occurred in this judicial district; Plaintiff resides in this judicial district; and no real property is involved in the action.

FACTUAL ALLEGATIONS

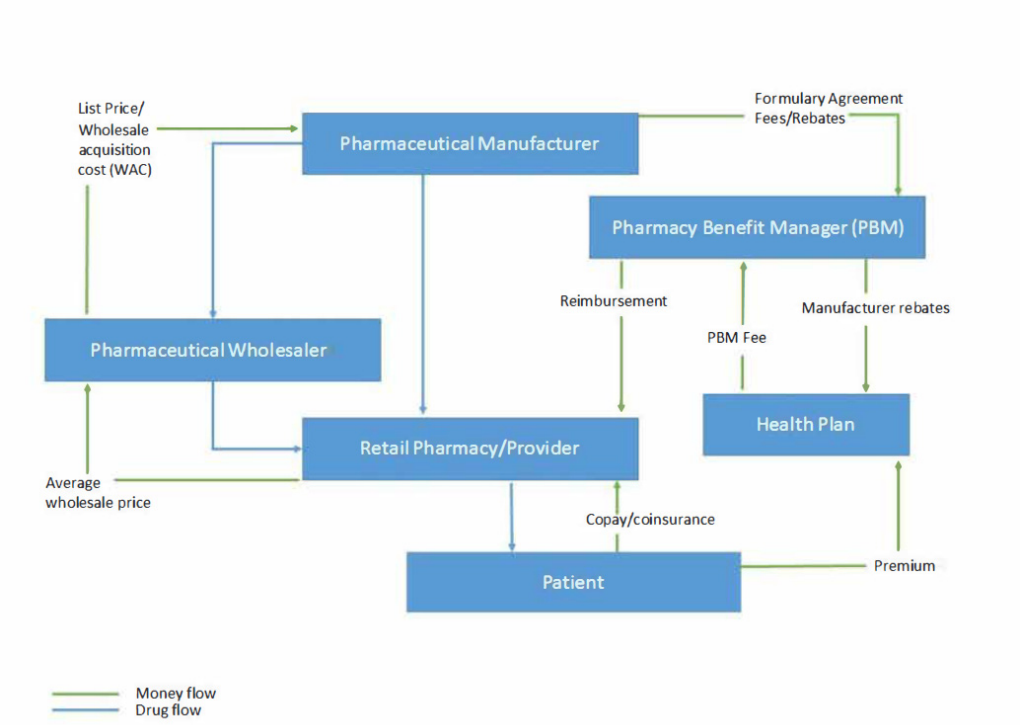
I. LEGAL AND FACTUAL BACKGROUND

A. Retrospective Rebates Play A Critical Role In Controlling Prescription Drug Prices

29. Prescription drug prices in the private insurance market and a variety of federal programs are set through negotiations between drug manufacturers, wholesalers, pharmacies, PBMs, and plan sponsors based on discounts and rebates from the nominal "list" prices (or "wholesale acquisition cost") at which manufacturers sell drugs to wholesalers and other larger purchasers.

30. For decades, the market has coalesced around a business model driven by retrospective manufacturer rebates to plan sponsors and PBMs. Plan sponsors hire PBMs to administer their drug plans and negotiate price concessions from manufacturers. Manufacturers offer these price concessions because lowering the net cost of the drug incentivizes PBMs and

plan sponsors to offer or adopt formularies—the tiered lists of drugs covered by the plan—that include or prefer the drug under plan utilization management rules. Manufacturers typically pay rebates to PBMs *after* the point of sale—rather than, *e.g.*, at the pharmacy counter—and PBMs then pass rebates on to plan sponsors.



Baylor Scott & White Health Comment Letter at 9 (July 16, 2018), https://www.regulations.gov/document?D=CMS-2018-0075-2999.

31. This practice of manufacturers paying "retrospective" rebates after the point of sale originated in the mid-1990s in response to antitrust litigation challenging the prior practice of paying rebates at the point of sale. *See infra* ¶¶ 230-31. The PBM industry emerged around the same time, experiencing "[e]xplosive growth . . . into the mid-1990s as managed care organizations, insurers and later self-insured employers sought to reduce the cost of their pharmacy benefit by contracting with PBMs to receive manufacturer rebates and pharmacy network discounts." Health Care Financing Administration, *Study of the Pharmaceutical Benefit*

Management Industry, at 5 (June 2001), attached as Ex. 1 to the Declaration of Matthew S. Rozen attached hereto. By 2001, PBMs—and the retrospective rebate model they administer—had "emerged as the national standard for the administration of prescription drug insurance in the United States." *Id*.

32. In a typical drug transaction under the current model, a wholesaler acquires a drug from the manufacturer at the list price, possibly with a discount negotiated between the wholesaler and the manufacturer. The wholesaler then sells the drug to the pharmacy at a rate negotiated between the wholesaler and the pharmacy.

33. At the point of sale—*e.g.*, at the pharmacy counter—the pharmacy dispenses the drug to plan enrollees under a contract between the pharmacy and the PBM, usually at a rate negotiated in advance and often tied to the manufacturer's list price—referred to as the "negotiated price." Payment to the pharmacy for the drug is then shared between the enrollee and the PBM, which reimburses the pharmacy according to the terms of contact between the PBM and the pharmacy. PBMs thus act as buyers, paying network pharmacies for drugs dispensed to enrollees of PBMs' plan sponsor customers.

34. The enrollee's out-of-pocket payment at the point of sale is determined by the terms of his or her plan. This payment typically includes 100% of costs up to a set deductible, then when the deductible is reached, a fixed copayment or coinsurance equal to a percentage of any additional costs, but terms vary from plan to plan, and enrollees are encouraged to select the plan with the terms most favorable to them. PBMs pay the pharmacy the difference between the negotiated price and the enrollee's contribution. Deductibles, copayments and coinsurance help control drug spending by ensuring that enrollees internalize some of the cost of their medication and are incentivized to make cost-effective decisions between competing treatment options.

These cost-sharing payments also offset plan sponsors' spending, leading to savings that plan sponsors can use to lower premiums.

35. After the point of sale—on a periodic, predetermined basis—manufacturers typically pay PBMs rebates negotiated in advance between the manufacturer and the PBM. PBM-negotiated drug rebates are the only proven and practical method to obtain pricing concessions from manufacturers. Drug manufacturers facing competition for their products are usually willing to negotiate rebates from the list price they initially set to incentivize favorable formulary placement and utilization management rules by PBMs and their plan sponsor clients.

36. As part of their services in administering drug plans, PBMs typically handle the negotiations with manufacturers, make payments to pharmacies, and collect manufacturer rebates, but plan sponsors ultimately bear the cost of paying drug prices in excess of the enrollee's share. Plan sponsors reimburse PBMs for the drug, and the PBMs pass manufacturer rebates on to the plan. In certain contexts, some PBMs may retain a fee, as negotiated by contract with the plan sponsor, to compensate for the PBM's services; plan sponsors may alternatively choose to pay PBMs separately on a per-claim or per-enrollee basis. In general, however, PBMs pass through to plan sponsors the vast majority of negotiated rebates—ranging from 90% in the commercial context, to 99.6% in the Medicare context—and plan sponsors then use the rebates to lower enrollees' and their own health spending. *See*, *e.g.*, Written Testimony of Joanna Shepherd, Ph.D, Emory University for the ERISA Advisory Council Hearing on PBM Compensation and Fee Disclosure at 5 (June 19, 2014) (citing J.P. Morgan, *Pharmacy Benefit Management, Takeaways from Our Proprietary PBM Survey* (May 21, 2014)), https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure-shepherd-06-19.pdf ("Shepherd Testimony");

Government Accountability Office, *MEDICARE PART D Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization* (July 2019), https://www.gao.gov/assets/710/700259.pdf ("GAO Study").

B. Confidentiality Is Essential To The Functioning Of The Retrospective Rebate System

37. The retrospective rebate system depends on PBMs' ability to effectively negotiate rebates from manufacturers. PBMs' success in negotiations in turn depends critically on their ability to negotiate confidentially, maintaining the details of their rebate contracts as trade secrets that are not available to other manufacturers.

38. The retrospective rebate system preserves confidentiality by ensuring that the terms of any particular rebate are not publicly disclosed or discernible to third parties, including the pharmacy at the point of sale. Confidentiality, in turn, allows PBMs to bargain from a position of strength to reduce drug prices. The rebate system depends on the exercise of bargaining power by PBMs acting on behalf of plan sponsors to counteract the pricing power of manufacturers.

39. By contrast, public disclosure of sensitive pricing information negotiated between PBMs would make it harder to negotiate and, thus, to save costs for plans and federal health care programs. Generally, when a competitor's best offer is known, discounts offered by other manufacturers will decrease. And because the pharmaceutical market is highly concentrated in terms of sellers (drug manufacturers) and buyers (PBMs), a supplier can gain the upper hand with only a few data points. In effect, the public availability of pricing information allows tacit collusion between manufacturers, who would find it more difficult to set prices below their competitors' prices without detection. Without the leverage afforded by the existing system of confidential rebate contracts, the ability of PBMs to extract price concessions from

manufacturers would be significantly weakened, and the total net cost paid by plan sponsors and their enrollees would therefore increase.

40. Common sense, historical evidence, and expert opinion all point to the negative effects of increased disclosure on PBM bargaining power. Leading academic economists are clear on this question: Tacit collusion is real, and the availability of final net cost information leads to *higher* net costs overall. Testimonies of Drs. Fiona Scott-Morton and Craig Garthwaite to the House Judiciary Committee, Subcommittee on Regulatory Reform, Commercial and Antitrust Law (Mar. 7, 2019), https://judiciary.house.gov/calendar/eventsingle.aspx?EventID=1976.

41. This consensus view—that government-enforced disclosure will raise costs by reducing PBMs' ability to maintain affordable drug prices—is also the considered opinion of several federal agencies with expertise in market analysis. These agencies include the CBO, a "strictly nonpartisan" office that produces "independent analyses of budgetary and economic issues to support the Congressional budget process," CBO, *Introduction to CBO*, https://www.cbo.gov/about/overview, and the FTC, which independently enforces federal antitrust laws.

42. The CBO, in a landmark paper on the advantages and disadvantages of price transparency in healthcare, recognized that "[t]he markets for some health care services are highly concentrated, and increasing transparency in such markets could lead to higher, rather than lower, prices." CBO, *Increasing Transparency in the Pricing of Health Care Services and Pharmaceuticals*, at 4 (June 2008), https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/06-05-pricetransparency.pdf ("CBO Transparency Study"). In "highly concentrated" markets like the prescription drug market, "where only a small number of firms

operate, increased transparency would make it easier for those firms to observe the prices charged by their rivals, which could lead to reduced competition between them." *Id.* Hence, "reduced competition might result if more transparent pricing revealed the prices negotiated between insurers and providers." *Id.*

43. The FTC shares the CBO's view of the negative effect of disclosure of drug prices. Based on "extensive . . . experience with PBMs," the FTC has explained that "[i]f pharmaceutical manufacturers learn the exact amount of rebates offered by their competitors . . . then tacit collusion among manufacturers is more feasible," so that government-mandated disclosures "may lead to higher prices for . . . pharmaceuticals." FTC, *Letter to Assemblyman Aghazarian* at 3, 9 (Sept. 7, 2004), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-comment-hon.greg-aghazarian-concerning-ca.b.1960-requiring-pharmacy-benefit-managers-make-disclosures-purchasers-and-prospective-purchasers/v040027.pdf ("FTC Letter"). Rules requiring such disclosure thus "may have the unintended consequences of limiting competition, thus increasing the cost of pharmaceuticals" by "mak[ing] it more difficult for PBMs to generate cost savings (including rebates)," and thus "result in an increase in health insurance premiums and reduced availability of insurance coverage for pharmaceuticals." *Id.* at 2.

C. Medicare Part D Provides Subsidized Access To Prescription Drug Coverage Through A Market-Based Program Modeled On Longstanding Rebate Practices

44. Congress deliberately drew on these established drug pricing and rebating practices when it significantly expanded prescription drug access by establishing Medicare Part D in 2003.

45. Medicare is a federal government program enacted in 1965 and administered by CMS—an agency within HHS—that provides health insurance for seniors and disabled Americans.

46. Medicare Part D is a critical component of the Medicare program that provides subsidized access to prescription drug coverage on a voluntary basis for all enrollees, and premium and cost-sharing subsidies for low-income enrollees. Congress created Medicare Part D as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, and the program went into effect in 2006. In 2019, Medicare Part D covered 47.2 million Americans—including the great majority of the 61.2 million total Medicare enrollees—and paid benefits of $97.6 billion on their behalf. Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, *2020 Annual Report* at 10 (Apr. 22, 2020), https://www.cms.gov/files/document/2020-medicare-trustees-report.pdf ("Medicare Trustees Report").

47. Congress designed Part D as a private-sector solution that draws on competitive market forces to help provide drugs to America's seniors and disabled in an affordable and efficient manner. The Part D benefit is accordingly administered by private drug plan sponsors that contract with the federal government to offer subsidized prescription drug coverage to enrollees. Congress intended for drug plan sponsors to use their "bargaining power" and their existing business relationships to "negotiate discounts" from drug manufacturers and pharmacies and "drive down the cost of prescription drugs" through "competition," and then pass those savings on to enrollees and the government in the form of lower premiums and thus lower government subsidies. Conference Report, Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 108 Cong. Rec. S15670, S15761-72 (Nov. 24, 2003) (Statement of

Sen. Bill Frist), https://www.congress.gov/congressional-record/2003/11/24/senate-section/article/S15670-2. Through these negotiations, plan sponsors craft the most competitive products they can within the parameters established by Congress and CMS and compete with each other for enrollees in a highly competitive marketplace.

48. Pursuant to its market-based mandate "to promote competition" under Medicare Part D, the government is forbidden from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and [plan] sponsors," and from "requir[ing] a particular formulary [list of covered drugs] or institut[ing] a price structure for the reimbursement of covered part D drugs." 42 U.S.C. § 1395w-111(i)(1)-(2). Congress chose this market-based approach because other solutions would have had a harmful effect on employers currently providing prescription drug coverage.

49. Predictably—and as intended by Congress—Part D plans have long emulated the private market practices extant at the inception of the program, with great success in containing costs. Consistent with longstanding practice in the private market, Part D plan sponsors contract with PBMs to administer their plans and negotiate price concessions from manufacturers and pharmacies. From the start of the Part D program, price concessions from manufacturers have typically taken the form of retrospective rebates paid to PBMs after the point of sale, just as in the private commercial market.

50. That approach has produced one of the most efficient and successful government programs in recent history. Since its implementation in 2006, Part D has operated well under its initial projected costs. By 2012, Part D was costing the federal government less than half of what the CBO initially projected for that year. That was not a one-year "blip": From 2006 to 2011, the program cost half as much as projected in total. Douglas Holtz-Eakin & Robert Book,

Competition and the Medicare Part D Program (Sept. 11, 2013), https://www.americanactionforum.org/research/competition-and-the-medicare-part-d-program/. The Medicare Trustees projected spending level for 2021 finally matches the amount projected by the CBO for 2012: $112 billion. Medicare Trustees Report, *supra*, at 145 tbl. IV.B10. And the program is working well for enrollees. According to a recent survey, 83% of seniors enrolled in Part D plans are satisfied with the program, finding that plans cover the drugs they need, are easy to use, provide sufficient pharmacy access, and protect them against high out-of-pocket costs. North Star Opinion Research, *National Survey of Senior Voters Enrolled in Medicare Part D*, at 1 (Mar. 2019), https://www.pcmanet.org/wp-content/uploads/2019/03/NSO-PCMA-Senior-Part-D-Survey-Memo-March-6.pdf.

51. As in the private market, rebates under Part D depend on PBMs' ability to maintain confidentiality with respect to their rebate agreements, which enjoy protection as trade secrets, in order for PBMs effectively to negotiate with drug manufacturers to lower prices. The Medicare Act treats information reported by a Part D sponsors to the Secretary as confidential under federal law if that information allows a member of the public to derive "prices charged for drugs." 42 U.S.C. § 1396r-8(b)(3)(D). The federal Trade Secrets Act prohibits HHS officers and other United States officers from disclosing such confidential information. 18 U.S.C. § 1905.

52. CMS—the agency whose expertise in administering Part D is most relevant to this issue—has likewise recognized the central importance of PBM confidentiality to this system for well over a decade. In a 2008 rulemaking, CMS explained that Part D "is based on a competitive business model," and "releas[ing] commercially or financially sensitive data to the public could negatively impact Part D sponsors' ability to negotiate for better prices, and ultimately affect the

ability of sponsors to hold down prices for beneficiaries and taxpayers." *Medicare Program; Medicare Part D Claims Data*, 73 Fed. Reg. 30664, 30668 (May 28, 2008). Accordingly, CMS recognized the strong "need to protect the sensitive data under the Part D program." *Id.*; *see also Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs*, 79 Fed. Reg. 29844 (May 23, 2014) (declining to include pharmacy price concessions in definition of "negotiated prices" because such disclosures would harm competition among pharmacies).

53. The CBO also shares CMS' longstanding view that confidentiality is critical to the retrospective rebates upon which Medicare Part D depends to lower drug prices. The CBO's landmark 2008 paper on the effects of disclosure specifically addressed Medicare, concluding that in the highly concentrated prescription drug market, "requiring the disclosure of discounts made to prescription drug plans in the Medicare program could set in place conditions for tacit collusion, as manufacturers would find it more difficult to set prices below their competitors' without detection." CBO Transparency Study, *supra*, at 6. These views echoed a prior CBO letter, specific to Part D rebates, arguing that disclosure "would create pressure to reduce those rebates, which would tend to increase costs for both the Medicare program and, on average, for enrollees." CBO, *Letter to the Honorable Joe Barton and Jim McCrery* at 3 (Mar. 12, 2007), https://www.cbo.gov/system/files?file=2018-10/03-12-drug-rebates.pdf.

D. Part D Plan Sponsors Compete For Enrollees Based On Coverage, Premiums, And Out-Of-Pocket Costs At The Point Of Sale

54. Plan sponsors participating in Part D determine which benefits to offer and how to structure the benefits offered to and cost-sharing required from enrollees, within limits set by law and regulation. In advance of each contract year, the sponsors of Part D plans submit "bids" to the government detailing drugs they will cover and the estimated cost per enrollee (including any

rebates). 42 C.F.R. §§ 423.265, .272. For plans that meet the program requirements and are approved to participate, the government pays each plan sponsor a direct subsidy, for each enrollee, approximately equal to the average bid received. *Id.* §§ 423.279, .315(b), .329. Medicare Part D enrollees choose which plan in which to enroll, and each non-low-income enrollee pays that plan sponsor a premium that is set using a formula based on the difference between the individual plan sponsor's bid and the average bid. *Id.* §§ 423.286, .293(a). (The federal government subsidizes all or most of the premium for each low-income enrollee. *Id.* §§ 423.315(d), .329(d), .773, .780, .800.)

55. This bidding system serves to encourage competition among plans to reduce drug prices because if a plan sponsor bids too high, premiums for the plan will rise accordingly, and Part D enrollees will avoid or abandon it for other plans with lower premiums. *See*, *e.g.*, Senate RPC, *Medicare Part D Prescription Drug Coverage* (2019), https://www.rpc.senate.gov/policy-papers/medicare-part-d-prescription-drug-coverage. Plan sponsors therefore have incentives to keep costs down in order to attract enrollees. Plan sponsors compete for enrollees based on the total mix of coverage, premiums, and out-of-pocket costs at the point of sale, allowing enrollees to choose the plan that works best for them. Increases in net prices paid to drug manufacturers are ultimately borne by either the enrollee or the government (or both).

56. In general, Part D plans must provide "[s]tandard" coverage with specified cost-sharing phases, 42 C.F.R. § 423.104(d), or "alternative" coverage that is actuarially equivalent to standard coverage, *id.* §§ 423.100, .104(e), .265(d)(2). Plans may also voluntarily offer enhanced plans including supplemental coverage, above and beyond these levels, paid for by higher premiums that the federal government generally does not subsidize. *Id.* §§ 423.104(f),

.272(e), .286(d)(2). The standard cost-sharing phases for non-low-income enrollees, with inflation adjusted amounts for 2021, are as follows:

a. Deductible Phase: The enrollee pays 100% of the total allowed drug costs up to a deductible of $445. 42 C.F.R. § 423.104(d)(1).

b. Initial Coverage Phase: After the $445 deductible, the enrollee pays 25% in coinsurance, while the plan sponsor is responsible for 75%, until the enrollee and the plan sponsor have spent $4,130 combined in total allowed drug costs (including the deductible). 42 C.F.R. § 423.104(d)(2)-(3).

c. Coverage Gap Phase: After the enrollee and the plan sponsor have spent $4,130 combined, the enrollee pays 25% in coinsurance for brand drugs and generic drugs, the plan sponsor pays 5% for most brand drugs and 75% for generic drugs, and the manufacturer is required by statute to pay the remaining 70% for most brand drugs. This phase continues until certain qualifying costs known as True Out-of-Pocket Costs—which include the enrollee's payments and the manufacturer's share—reach $6,550. 42 C.F.R. §§ 423.100, .104(d)(3)-(4), .2310, .2315, .2325; 42 U.S.C. § 1395w-114a(g)(4)(A).

d. Catastrophic Phase: After the enrollee's True Out-of-Pocket Costs reach $6,550, the enrollee pays approximately 5% in coinsurance and CMS reimburses plans for 80% in the form of reinsurance, leaving approximately 15% to be covered by the plan. 42 C.F.R. §§ 423.104(d)(5), .315(c), .329(c).

See generally Medicare.gov, *Costs for Medicare Drug Coverage*, https://www.medicare.gov/drug-coverage-part-d/costs-for-medicare-drug-coverage.

57. For low-income enrollees, cost-sharing is set by law at reduced or nominal amounts, supported by government cost-sharing subsidies. 42 C.F.R. §§ 423.315(d), .343(d), .773, .782, .800. The low-income enrollee pays reduced coinsurance or nominal copay depending on income, with no deductible and no coverage gap. *Id.* § 423.782. The plan sponsor is responsible for the remaining amounts (which the federal government ultimately covers). *Id.* § 423.800(b), (c).

58. Under Part D, manufacturer rebates are considered part of Direct and Indirect Remuneration ("DIR")—payments after the point of sale to help reduce the final price of a medication paid by the PBM or plan sponsor, also including pharmacy rebates and price concessions. The plan sponsor must report DIR to the government, including retrospective rebates, regardless of whether the PBM retains a portion of the rebates as compensation for its services or passes the full rebate through to the plan. 42 C.F.R. §§ 423.308, .322(a), .343(c).

59. Within six months of the end of each contract year, the DIR reports are due to CMS, and then the government reconciles its interim payments to amounts actually paid after accounting for DIR, including rebates. 42 C.F.R. §§ 423.308, .315(c), (d)-(f), .329(c)-(d), .343(c)-(d), .2320(b). As part of this process, plan sponsors pass approximately 35% of rebates and all other DIR on to the government, proportionate to the share of the costs covered by the federal government in reinsurance. *Id.* § 423.308. This reconciliation process incentivizes plan sponsors to bid accurately in the first instance, including by accounting for rebates and other DIR.

60. The Medicare Part D construct described above contains several mechanisms to control costs and ensure that savings from rebates are passed on to the government and to enrollees. These mechanisms include:

a. Bidding Process/Competition. As described above, plan sponsors must submit bids for the following contract year to CMS each year reflecting the drugs they will cover and the estimated costs per member. Enrollee premiums are set based on the average bid received. If a plan sponsor's costs are too high, its premiums will rise and fewer people will sign up. Plan sponsors therefore have incentives to keep costs down in order to attract enrollees.

b. Bid Approval and Audits. Plan sponsors must report information including actual vs. expected margin for a three-year period as part of their bid submission. CMS reviews this information and will not approve a bid if a sponsor is consistently off with its projections. 42 C.F.R. §§ 423.265, .272(b), .322(a). CMS also performs audits to ensure proper bid protocols are followed. *Id.* § .504(d)(iii).

c. Reconciliation. As described above, subsidies are reconciled after the end of each year based on actual expense and revenue, including rebates and other DIR. Plan sponsors therefore have incentives to bid accurately in the first instance.

d. Risk Adjustment. The direct subsidy paid to plan sponsors, as described above, is risk-adjusted by CMS to deter selection behavior by plans (*i.e.*, to counteract incentives for sponsors to try to avoid enrollees who have higher utilization of covered drugs). Plan sponsors therefore have incentives to keep costs down for all enrollees, including those who are higher utilizers.

e. Risk Corridors. Through the risk corridors program, the government makes payments each year to plans that experience higher-than-expected costs, and collects payments from plans that experience lower-than-expected costs, limiting each plan's potential losses (or gains). 42 C.F.R. §§ 423.315(e), .336. CMS thus

recoups plan profits that exceed a certain threshold each year, preventing plans from reaping unexpected windfalls.

f. Medical Loss Ratio rebates. Plan sponsors must submit data on the proportion of premium revenues spent on administrative costs and profits, and provide rebates to enrollees if the plan sponsor does not spend at least 85% of premium dollars on prescription drug costs. *See* 45 C.F.R. pt. 423. Sponsors therefore have incentives to keep administrative costs down.

g. Prescription Drug Plan Margin Requirement. CMS requires the gain/loss margin on a company's Part D business to be within 1.5% of the plan sponsor's corresponding Medicare Advantage (Part C) margin. This limits the amount of profit a sponsor can make from Part D relative to other programs.

61. These mechanisms ensure that PBMs in the Medicare Part D context pass on to plan sponsors 99.6% of all manufacturer rebates paid under Medicare Part D, ensuring that rebates do not represent a major source of PBM revenue. PCMA Supplemental Comment Letter to HHS-OIG at 6 (Aug. 3, 2020), attached as Ex. 2 to the Declaration of Matthew S. Rozen attached hereto ("PCMA Suppl. Comment Letter") (citing GAO Study, *supra*).

E. Designing Part D Plans, Submitting Bids For Each Contract Year, And Coming Into Compliance With New Program Rules Is A Complex, Lengthy, And Highly Regulated Process That Begins More Than A Year In Advance Of A Contract Year

62. Part D plan sponsors develop their bids during a complex process spanning many months, culminating each year in final bid submissions on the first Monday of June of the year before the bids will take effect (*e.g.*, June 2021 for the 2022 contract year), as required by CMS regulations. *See* 42 C.F.R. §§ 423.265(b)(1), 423.272(b). The June deadline ensures that CMS has time to review the bids, negotiate with plan sponsors, and approve the bids by late August—

and enter into contracts with plan sponsors by early September—so plan sponsors can complete materials describing their plans for potential enrollees and take all steps necessary to implement required systems changes by October—the beginning of the annual open enrollment period—when the public begins selecting which plan to enroll in. *See*, *e.g.,* CMS, *CY2021 Medicare Parts C and D Annual Calendar* 5-6 (Feb. 13, 2020), https://go.cms.gov/3bhoGjU. Plan sponsors and their PBMs and other contractors then have until January, when coverage starts, to take any remaining steps to ensure they are in full compliance with all Part D requirements for the forthcoming contract year.

63. To meet the June bid deadline, PBMs "[s]tart . . . the bid planning process" a full year in advance—*e.g.*, the preceding June or July—then typically "begin negotiating with manufacturers and developing preliminary formularies" in "October", and finalize their formulary structure by March. American Academy of Actuaries Comment Letter at 2-3 (Apr. 3, 2019), https://www.regulations.gov/document?D=HHSIG-2019-0001-19122. Once formularies are set, plan sponsors must design their plans and send them to actuaries for certification as required by law. *See* 42 C.F.R. § 423.265(c)(3). "[A]ctuaries seek to lock down all assumptions in the first week in May," so that plan sponsors have a full month to finalize their bids and compile the necessary "documentation that accompanies the bids" submitted by the first Monday in June. Kaiser Permanente Comment Letter at 33 (Apr. 8, 2019), https://www.regulations.gov/document?D=HHSIG-2019-0001-19838; *see also* BlueCross BlueShield Association Comment Letter at 16 (Apr. 8, 2019), https://www.regulations.gov/document?D=HHSIG-2019-0001-19775.

Example: Timeline of Bid Process for Contract Year 2019	
Date	**Action**
June-October 2017	Plan sponsors start the bid planning process.
October-November 2017	Plan sponsors and PBMs typically begin to negotiate contracts with manufacturers.
March 2018	Plan sponsors finalize the formulary structures for upcoming bids.
March-May 2018	Plan sponsors design their plans.
First week in May 2018	Actuaries lock down all plan assumptions and certify plan sponsors' bids.
May-June 2018	Plan sponsors finalize bids and all accompanying documentation.
First Monday in June 2018	Plan sponsors submit bids for the upcoming 2019 contract year.
June-August 2018	CMS reviews and approves bids and negotiates with plan sponsors.
Early September 2018	Plan sponsors enter into contracts with CMS.
September-October 2018	Plan Sponsors complete materials describing their plans for potential enrollees and take all steps necessary to implement required system changes.
October 2018	Plan enrollment opens.
October 2018- January 2019	Plan sponsors, PBMs, and other contractors take any remaining steps needed to ensure full compliance with all Part D requirements for the forthcoming contract year.
January 2019	Plan coverage begins.

64. Plans need a host of information from CMS in order to complete their negotiations, finalize plan design, submit bids, and meet the Part D requirements for providing coverage under accepted bids. In a typical year, that information may include Part D benefit parameters for deductibles, initial coverage limits, cost-sharing payments, and formulary tier

thresholds; formulary guidance (*e.g.*, allowing for coverage by specific indications); changes in Part D payment methodologies; updates to CMS's Bid Pricing Tool, which is the approved data-entry format through which plan sponsors submit information for their bids; updates to opioid use disorder programs mandated by Congress; and updates to tools that enrollees use to select plans, such as CMS's Star Ratings system and the Medicare Plan Finder Tool. In addition, and just as important, CMS must advise plan sponsors and their PBMs and other contractors of any policy or technical changes that could influence the bid submission process, including any changes that may be necessary in response to legislative changes or applicable HHS regulations.

65. CMS has historically provided the information that plan sponsors need through a combination of subregulatory guidance and notice-and-comment rulemaking.

66. The Part D bid process was built off the existing Part C process. Since the start of Medicare Part D, CMS has issued an annual, two-part Advance Notice providing information that sponsors of Part C and Part D plans "need to take into consideration in preparing their [upcoming] bids." CMS, *Advance Notice of Methodological Changes for Calendar Year (CY) 2020* at 100 (Jan. 30, 2019), https://go.cms.gov/2MG08H2 ("2020 Advance Notice Part II").

67. Part I of the Advance Notice, which primarily concerns Medicare *Part C*, is historically issued in December or January. CMS, *Advance Notice of Methodological Changes for Calendar Year (CY) 2019 – Part I* at 1 (Dec. 27, 2017), https://go.cms.gov/3s9KrrZ; CMS, *Advance Notice of Methodological Changes for Calendar Year (CY) 2020 – Part I* (Dec. 20, 2018), https://go.cms.gov/3ooBHf8. CMS is required by law to provide a 60-day comment period for this content. 42 U.S.C. § 1395w-23(a)(1)(I).

68. Part II of the Advance Notice covers CMS payment and policy updates for both Parts C and D. Until the most recently completed bid cycle (for the 2021) contract year, Part II

included a Call Letter containing "information . . . plan sponsor organizations will find useful as they prepare their bids for the new contract year" and "draft bid and operational guidance for plans." CMS, *Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter* at 2 (Feb. 1, 2018) ("CY 2019 Advance Notice Part II"), https://go.cms.gov/3nucf6A. That information includes "changes in the Part D payment methodology," "annual adjustments . . . to the Medicare Part D benefit parameters for the defined standard benefit," information on "formulary submissions," "tier composition," "utilization review controls," and more. *Id.* at 1-2, 193-220. CMS historically provided a 30-day public comment period for this content.

69. CMS historically considers comments submitted on the Advance Notices and finalizes its payment and policy updates in a final Rate Announcement issued in early April. *See* CMS, *Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* (Apr. 2, 2018), https://go.cms.gov/3q2hegz; *Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* (Apr. 1, 2019), https://go.cms.gov/3q4a7V6. CMS is required by law to finalize the part of this Rate Announcement—corresponding to Part I of the Advance Notice—60 days before bids are due, 42 U.S.C. § 1395w-23(b)(1)(B); 42 C.F.R. § 422.312(a)(1), and CMS historically issues the entire Rate Announcement together during that same time frame.

70. CMS also historically issues a Policy and Technical Changes rule for upcoming contract years through notice-and-comment rulemaking, with final rules published no later than April or May. *See Medicare Program; Contract Year 2015 Policy and Technical Changes to the*

Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29844 (May 23, 2014); *Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program*, 83 Fed. Reg. 16440 (Apr. 16, 2018). The issues addressed may range from major changes in policy, such as changes to the Part D program's policy on "protected classes" of drugs that plans are generally required to cover, to minor "technical" issues such as contract termination notification requirements and requirements related to the release of Part D data. *See Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs*, 79 Fed. Reg. 1918, 1936 (Jan. 10, 2014) (proposed rule); *see also* 79 Fed. Reg. at 29844 (final rule).

Example: Timeline of CMS Guidance for Contract Year 2019	
Date	**Action**
November 27, 2017	CMS issues Policy and Technical Changes proposed rule.
December 27, 2017	CMS issues Part I of the Advance Notice.
February 1, 2018	CMS issues Part II of the Advance Notice, including a Call Letter.
April 2, 2018	CMS considers comments on Advance Notices and issues Rate Announcement finalizing payment and policy updates.
April 16, 2018	CMS publishes Policy and Technical Changes final rule.
June 3, 2018	Plan sponsors submit bids for the upcoming 2019 contract year.

71. Following the Supreme Court's decision in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019), CMS changed its approach for the 2021 contract year and presumably future years. *Allina* held that the Medicare Act's notice-and-comment requirement, 42 U.S.C.

§ 1395hh(a)(2), applies more broadly than the APA's requirement, and can apply to statements of policy that establish or change a substantive legal standard, 139 S. Ct. at 1811-14. In the wake of *Allina*, CMS declined to include a Call Letter in Part II of its Advance Notice, which was issued on February 5, 2020. *See Advance Notice of Methodological Changes for Calendar Year (CY) 2021 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies – Part II* (Feb. 5, 2020), https://go.cms.gov/3osPilJ; CMS, *2021 Medicare Advantage and Part D Advance Notice Part II Fact Sheet* (Feb. 5, 2020) ("CMS will not be publishing a Call Letter for 2021"), https://go.cms.gov/2XwGZti. Instead, CMS shifted much of the information that would be "typically included in the annual Call Letter" into the Policy and Technical Rule, CMS, *2021 Medicare Advantage and Part D Advance Notice Part II Fact Sheet*, *supra*, which CMS issued as a proposed rule published shortly after the Advance Notices, *see Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly*, 85 Fed. Reg. 9002 (Feb. 18, 2020); *see also id.* at 9003 (noting that CMS was "codify[ing] in regulation several CMS interpretive policies previously adopted through the annual Call Letter"). CMS thus solicited public comments due April 6, 2020, *id.* at 9002, and completed the rulemaking on May 22, 2020, with barely enough time for the upcoming bids to account for it. *See Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program*, 85 Fed. Reg. 33796 (June 2, 2020); CMS, *Contract Year 2021 Medicare Advantage and Part D Final Rule (CMS-4190-F1) Fact Sheet* (May 22, 2020) (noting that CMS "issued" the final rule on "May 22, 2020"), https://go.cms.gov/3sflATt.

Timeline of CMS Guidance for Contract Year 2021	
Date	**Action**
January 6, 2020	CMS issues Part I of the Advance Notice.
February 5, 2020	CMS issues Part II of the Advance Notice, without including a Call Letter.
February 18, 2020	CMS issues Policy and Technical Changes proposed rule.
May 22, 2020	CMS issues Policy and Technical Changes final rule.
June 1, 2020	Plan sponsors submit bids for the upcoming 2021 contract year.

72. *Allina* thus appears to constrain CMS's ability to quickly make critical determinations and provide critical information to plan sponsors through subregulatory guidance (i.e., the Call Letter). Particularly in light of *Allina*, CMS must begin the process of providing critical information to plan sponsors earlier in the bid cycle to allow for notice-and-comment rulemaking and ensure that the necessary determinations and information can be finalized with sufficient time for plan sponsors to negotiate with manufacturers, design their plans, finalize their bids by the bid deadline, and bring their plans into compliance prior to the start of the contract year.

F. A Statutory Exception And Regulatory Safe Harbor For Manufacturer "Discounts" Protect Price Concessions To Pharmacy Benefit Managers From Liability Under The Federal Anti-Kickback Statute

73. From the outset of Medicare Part D, the current Part D pricing system has always been protected by statutory exception and regulatory safe harbor from liability under the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b.

74. Congress enacted the Anti-Kickback Statute in 1972 to address "concern that decisions of health care providers can be improperly influenced by a profit motive, and in order to protect federal health care programs from additional costs and overutilization." Jennifer A.

Staman, Cong. Research Serv., RS22743, Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid 4 (2014), https://fas.org/sgp/crs/misc/RS22743.pdf. That statute bars "certain practices" that have "long been regarded by professional organizations as unethical." H.R. Rep. No. 92-231 (1971), *reprinted in* 1972 U.S.C.C.A.N. 4989, 5093; *accord* H.R. Rep. 95-393(II) (1977), *reprinted in* 1977 U.S.C.C.A.N. 3039, 3055; *see, e.g.*, Social Security Amendments of 1972, Pub. L. No. 92-603, § 242, 86 Stat. 1329, 1419. Specifically, the statute makes it unlawful for any person to "knowingly and willfully" pay or receive "remuneration" in exchange for, among other things, recommending items or services reimbursed by federal health care programs. 42 U.S.C. § 1320a-7b(b)(1)-(2).

75. Penalties under the anti-kickback statute are severe. Violations are classified as a felony, and are punishable with criminal fines of up to $100,000 and imprisonment of up to 10 years. 42 U.S.C. § 1320a-7b(b)(1)-(2). In addition, the Secretary has civil authority to impose civil monetary penalties of up to $100,000 per kickback, *id.* § 1320a-7a(a)(7), and exclude from participation in any federal health care program any individual or entity that "the Secretary determines" has violated the statute, *id.* § 1320a-7(b)(7).

76. Given the serious criminal and civil sanctions at stake, Congress has long recognized that the anti-kickback statute could chill "legitimate" "commercial arrangements." S. Rep. 100-109 (1987), *reprinted in* 1987 U.S.C.C.A.N. 682, 707. Accordingly, over the years, Congress has enacted eleven statutory exceptions and instructed HHS-OIG to promulgate additional regulatory safe harbors, all designed to insulate ordinary, everyday business activity from the threat of criminal prosecution. 42 U.S.C. § 1320a-7b(b)(3); 42 C.F.R. § 1001.952(h). "The clear congressional intent behind the development of these safe harbor provisions is to

define innocuous arrangements that should not be prosecuted." *Medicare and State Health Care Programs*, 56 Fed. Reg. 35952, 35957 (July 29, 1991).

77. Congress enacted the pertinent statutory exception here—the discount exception, 42 U.S.C. § 1320a-7b(b)(3)(A)—in 1977 as part of the first set of exceptions under the statute. As the name implies, the discount exception "specifically exclude[s] the practice of discounting or other reductions in price from the range of financial transactions to be considered illegal under [M]edicare and [M]edicaid." H.R. Rep. 95-393(II), *reprinted in* 1977 U.S.C.C.A.N. at 3056. The exception thus broadly protects any "discount or other reduction in price" that is "properly disclosed and appropriately reflected" in the costs for which reimbursement could be claimed under a federal healthcare program. 42 U.S.C. § 1320a-7b(b)(3)(A). Congress added the discount exception "to ensure that the practice of discounting the normal course of business transactions would not be deemed illegal." H.R. Rep. 95-393(II), *reprinted in* 1977 U.S.C.C.A.N. at 3056. Indeed, in enacting the exception, Congress expressly "*encourage*[*d*] providers [of medical products and services] to seek discounts as a good business practice which results in savings to [M]edicare and [M]edicaid program costs." *Id.* (emphasis added).

78. PBMs and other buyers rely on the statutory exception for discounts to protect retrospective rebates received from drug manufacturers. The rebates that PBMs negotiate with drug manufacturers meet the requirements of this exception:

a. Rebates operate as "discount[s] or other reduction[s] in price," 42 U.S.C. § 1320a-7b(b)(3)(A), from the price ordinarily paid by plans and PBMs for covered drugs. HHS has repeatedly recognized the rebates are a type of discount. *See Medicare and State Health Care Programs*, 59 Fed. Reg. 37202, 37206 (July 21, 1994) (defining "'rebate'" as "any discount which is not given at the time of sale");

Medicare and State Health Care Programs, 56 Fed. Reg. at 35987 ("The term *discount* may include a rebate check." (emphasis added)); and

b. The amount of these discounts is "properly disclosed and appropriately reflected." 42 U.S.C. § 1320a-7b(b)(3)(A). PBMs disclose aggregate discounts to plan sponsors, who, in turn, disclose them to the Secretary as direct and indirect remuneration, as required by the Medicare Act. *See id.* § 1395w-102(d)(1)(B), (2) (requiring plan sponsors to "disclose to the Secretary . . . the aggregate negotiated price concessions," including any "rebates," "made available to the sponsor . . . by the manufacturer"). Sponsors factor the expected rebates and other DIR into their plan bids, and the amounts ultimately disclosed are "factored into CMS's calculation of final Medicare payments to Part D plans." CMS, *Medicare Part D - Direct and Indirect Remuneration (DIR)*, (Jan. 19, 2017), https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir.

79. In 1987, Congress also instructed the Secretary to promulgate regulatory safe harbors specifying additional "payment practices that shall not be treated as a criminal offense" under the anti-kickback statute. Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, § 14(a), 101 Stat. 680, 697. HHS-OIG may modify these regulatory safe harbors in light of a number of factors. *See* Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 205, 110 Stat. 1936, 2000 (codified at 42 U.S.C. § 1320a-7d(a)(2)). Congress made clear that the regulatory safe harbors were "in addition to" the statutory exceptions to liability, Pub. L. No. 100-93, § 14(a), 101 Stat. at 697, and were aimed at resolving lingering "uncertainty among healthcare providers as to which commercial arrangements [were] legitimate, and which [were] proscribed," S. Rep. 100-109, *reprinted in*

1987 U.S.C.C.A.N. at 707. *See also* 42 U.S.C. § 1320a-7b(b)(3)(E) (excluding from the anti-kickback statute "any payment practice specified by the Secretary in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987"). Thus, a "regulatory safe harbor both incorporates and enlarges upon the statutory exception." *Medicare and State Health Care Programs*, 64 Fed. Reg. 63518, 63528 (Nov. 19, 1999).

80. HHS-OIG promulgated the first set of regulatory safe harbors in 1991. *See Medicare and State Health Care Programs*, 56 Fed. Reg. 35952. From the beginning, these safe harbors protected "discount[s]," including "rebates." *Id.* at 35978. And at minimum, the original version of the regulatory safe harbor for discounts protected "*all* the discounts or reductions in price that Congress intended to protect under the statutory exception for discounts." *Medicare and State Health Care Programs*, 59 Fed. Reg. at 37206 (emphasis added).

81. In its current form, the regulatory safe harbor for discounts includes any "rebate" for which (A) "the terms" are "disclosed in writing to the buyer at the time of the initial sale" and (B) the buyer, if requested by the Secretary, discloses certain information provided by the seller. 42 C.F.R. § 1001.952(h)(1)(iii). The regulation defines "rebate" to include "any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale." *Id.* § 1001.952(h)(4).

82. PBMs and other buyers rely on the regulatory safe harbor for discounts to protect retrospective rebates received from drug manufacturers. The rebates that PBMs negotiate with drug manufacturers meet the requirements of this safe harbor because the "[t]erms" of the rebates—meaning the "methodology that will be used to calculate the rebate[s]"—are disclosed at the time of the sale, *Medicare and State Health Care Programs*, 64 Fed. Reg. at 63529, and (if

asked to do so) the buyer would disclose requested information to the Secretary, for example, through DIR reporting on behalf of the plan sponsor. PBMs have therefore long relied on the regulatory safe harbor for discounts to protect their role in setting Part D drug prices from federal anti-kickback liability. *See* PCMA Comment Letter at 24 (Apr. 8, 2019), https://www.regulations.gov/document?D=HHSIG-2019-0001-19773 ("PCMA Comment Letter"); Anthem Comment Letter at 12 (Apr. 8, 2019), https://www.regulations.gov/document?D=HHSIG-2019-0001-19832.

II. THE REBATE RULE

83. The Rebate Rule upends this established practice by eliminating the regulatory safe harbor for discounts in the Medicare Part D context and threatening PBMs, manufacturers, and plan sponsors with significant criminal and civil liability unless they fundamentally alter the way in which price concessions are negotiated and applied under Medicare Part D. HHS-OIG rushed the Rule out the door in the final days of the Trump Administration through an erratic and highly irregular rulemaking process at the urging of the pharmaceutical industry, over objections from PBMs, Plan D sponsors, independent and academic commentators, and multiple federal agencies and officials that the Rule exceeded HHS's authority, would not achieve its objectives, and would only enhance the ability of drug manufacturers to increase prices at the expense of increased Part D premiums, federal spending, and total spending on prescription drugs.

A. HHS Introduces The Rebate Rule By Issuing A Request For Information And A Notice Of Proposed Rulemaking

84. HHS first floated the concept that became the Rebate Rule in a 2017 CMS request for information, which sought comments on the possibility of requiring plan sponsors to "include at least a minimum percentage of manufacturer rebates and all pharmacy price concessions received for a covered Part D drug" in calculating the "negotiated price" used to determine

enrollee deductibles and coinsurance payments. *Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program*, 82 Fed. Reg. 56336, 56419 (Nov. 28, 2017). CMS acknowledged that if this proposal were adopted, "[p]lan premiums would likely increase," and "government costs . . . would increase overall." *Id.* at 56424-25.

85. These predictions understandably generated significant concerns, including from PCMA and its members. PCMA "agree[d] with CMS's assessment" that applying price concessions "to drug prices at the point-of-sale . . . would raise premiums for beneficiaries, expose taxpayers to higher costs, and offer a significant windfall to brand manufacturers." PCMA Comment Letter on 2017 RFI at 1 (Jan. 16, 2018), https://www.regulations.gov/document?D=CMS-2017-0156-1512; *accord* Express Scripts Comment Letter at 6 (Jan. 16, 2018) (noting proposal's "far reaching impacts on the very fundamentals" of Part D and cautioning CMS against making point-of-sale discounts mandatory), https://www.regulations.gov/document?D=CMS-2017-0156-1510; CVS Health Comment Letter on 2017 RFI at 69 (Jan. 16, 2018) (agreeing that the proposal "would increase costs to Part D plans, beneficiaries, and taxpayers") (heading), https://www.regulations.gov/document?D=CMS-2017-0156-1457. PCMA thus warned CMS that "[b]oth the noninterference provision and the prohibition against setting a benefit structure bar[red]" CMS from adopting the policy of "requiring that all price concessions be applied at" the point of sale. PCMA Comment Letter on 2017 RFI at 177-78. CMS declined to adopt the proposal; its final rule did not include any point-of-sale requirement. *Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the*

Medicare Prescription Drug Benefit Programs, and the PACE Program, 83 Fed. Reg. 16440, 16616 (Apr. 16, 2018).

86. HHS nonetheless revisited the proposal in May 2018 when HHS-OIG published a "blueprint" to lower list prices and out-of-pocket costs at that point of sale, and issued a Request for Information that asked questions and solicited comments regarding HHS-OIG's priorities in tackling the problem of rising prescription drug prices. *HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, 83 Fed. Reg. 22692 (May 16, 2018) ("HHS Blueprint"). HHS-OIG's blueprint identified four goals: Improving competition in the regulatory process; supporting better negotiation of drug discounts; creating incentives for pharmaceutical companies to lower list prices; and reducing out-of-pocket spending for patients at the pharmacy. *Id.* at 22692.

87. In considering how to incentivize lower list prices, HHS-OIG raised the prospect of restricting or reducing the use of rebates in contracts between Part D plan sponsors and drug manufacturers. *HHS Blueprint*, 83 Fed. Reg. at 22698. HHS-OIG asked whether "removing the discount safe harbor" would affect list prices; the behavior of drug manufacturers, PBMs, and insurers; or formulary design, premium rates, and the overall structure of the Part D system. *Id.*

88. From the start, HHS's suggestion that the discount safe harbor might be eliminated met immediately with harsh criticism from multiple stakeholders. For example, insurers who serve as Part D plan sponsors "strongly oppose[d]" a mandatory shift away from the existing system of confidential retrospective rebates, because such a change would raise costs for both enrollees and the government while "not address[ing] the core issue of making prescription drugs more affordable." Blue Cross & Blue Shield Association Comment Letter on Blueprint RFI at 2, 12-15 (July 16, 2018), https://www.regulations.gov/document?D=CMS-

2018-0075-2916; *see also* UnitedHealth Group Comment Letter on Blueprint RFI at 2-3, 6-8 (July 16, 2018), https://www.regulations.gov/document?D=CMS-2018-0075-2989; America's Health Insurance Plans (AHIP) Comment Letter on Blueprint RFI at 6-15 (July 16, 2018) ("strongly disagree[ing]" with HHS's premise that rebates "cause high list prices and price increases," because in fact, "[r]ebates are a market-based response to drug company practices of setting high prices," and in Part D, "have been effective in reducing costs for beneficiaries through low premiums"), https://www.regulations.gov/document?D=CMS-2018-0075-2581. CVS Health, which both operates a large national chain of pharmacies and serves as a PBM, explained that the replacement of confidential retrospective rebate with mandated disclosure at the point of sale "will not lead to better health care or lower health care costs," as confirmed by previous government studies. CVS Health Comment Letter on Blueprint RFI at 20-21 (July 16, 2018), https://www.regulations.gov/document?D=CMS-2018-0075-2853. Other PBMs echoed concerns that "HHS's focus on the removal of rebates is misplaced and will do little to lower list prices or overall cost of drugs." AmeriHealth Caritas Family of Companies Comment Letter on Blueprint RFI at 6-8 (July 16, 2018), https://www.regulations.gov/document?D=CMS-2018-0075-2995.

89. PCMA submitted a comment letter to HHS-OIG "commend[ing] the Administration for addressing the issue of high drug prices," but like other critics, cautioned that eliminating negotiated rebates on brand drugs would harm the drug market and result in higher drug spending—the opposite of HHS-OIG's intended effect. PCMA Comment Letter on Blueprint RFI at i (July 16, 2018), https://www.regulations.gov/document?D=CMS-2018-0075-2579. PCMA explained that rebates are the only proven way for PBMs to negotiate lower drug costs with manufacturers, that HHS-OIG lacked the statutory authority to subject rebates to

federal anti-kickback statute scrutiny, and that the contemplated policy would raise a host of concerns under the Part D non-interference clause, the APA, and federal antitrust laws. *See id.* at ii.

90. Despite these objections, HHS-OIG proceeded with its proposal to pare back the regulatory safe harbor for discounts. In February 2019, the agency issued a notice of proposed rulemaking commencing notice-and-comment rulemaking with regard to the Rebate Rule. *Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals*, 84 Fed. Reg. 2340, 2340 (Feb. 6, 2019) ("Proposed Rule"). HHS-OIG proposed for the amendment to be "effective on January 1, 2020." *Id.* at 2348.

91. HHS-OIG proposed to amend the existing discount safe harbor "so that it would no longer protect price reductions from manufacturers to plan sponsors under Medicare Part D . . . , either directly or through PBMs acting under contract with plan sponsors under Medicare Part D . . . , in connection with the sale or purchase of prescription pharmaceutical products." *Proposed Rule*, 84 Fed. Reg. at 2347. HHS-OIG proposed for the amendment to be "effective on January 1, 2020." *Id.* at 2348. (The Proposed Rule would have applied the same amendment to Medicaid managed care organizations, but this portion of the Proposed Rule was not codified and is not at issue in this rule challenge.)

92. HHS-OIG also proposed two new safe harbors:

a. The "point-of-sale safe harbor" would "protect point-of-sale price reductions offered by manufacturers on certain prescription pharmaceutical products . . . that meet certain criteria." *Proposed Rule*, 84 Fed. Reg. at 2348.

b. The "PBM service fee safe harbor" would "protect fixed fees that manufacturers pay to PBMs for services rendered to the manufacturers that meet specified

criteria," such as "utilization management, medical education, medication monitoring," and "data management." *Proposed Rule*, 84 Fed. Reg. at 2344, 2349.

93. The Proposed Rule's intended effect was to channel rebates through the new point-of-sale safe harbor—"replacing rebates with discounts"—so that these price concessions "would be passed on to beneficiaries at the point of sale" instead of reducing premiums. *Proposed Rule*, 84 Fed. Reg. at 2352, 2355.

94. HHS-OIG presented the Proposed Rule as a solution to the problem of "drug price inflation." *Proposed Rule*, 84 Fed. Reg. at 2340. But the Proposed Rule did not seek to control the "net prices" actually collected by manufacturers after rebates or other discounts. Nor did the Proposed Rule purport to constrain the aggregate spending on prescription drugs by consumers, drug plans, and the federal government. Instead, the Proposed Rule targeted only a narrow component of prescription drug prices: the nominal "list prices" or "wholesale acquisition cost" that manufacturers set unilaterally, before the application of rebates. *Id*.

95. HHS-OIG explained that in its view, "list prices" were rising faster than "net prices," creating a "widening ga[p] between gross and net prescription drug costs" called the "'gross to net bubble.'" *Proposed Rule*, 84 Fed. Reg. at 2340-41, 2353. Though manufacturers set list prices unilaterally, HHS-OIG blamed the growth in list prices and the gross to net bubble on PBMs. HHS-OIG claimed without any evidentiary support that PBM compensation is "derived from … the gap between the list price and 'net price,'" so that PBMs somehow profit when rebates increase, *id.* at 2341—even though PBMs pass 99.6% of rebates through to plan sponsors, *see supra* ¶¶ 36, 61. HHS-OIG thus posited that PBMs had an incentive to favor drugs with higher list prices and larger rebates to drugs with lower list prices and smaller

rebates—even when the net price was the same. *Proposed Rule*, 84 Fed. Reg. at 2341. According to HHS, this supposed dynamic explained the growth in list prices and thus the need for regulation.

96. To justify its focus on list prices rather than net prices, HHS isolated a single component of prescription drug spending—the "out-of-pocket" payment by enrollees at the point of sale, in the form of deductibles and coinsurance. *Proposed Rule*, 84 Fed. Reg. at 2341. Deductible and coinsurance payments are calculated based on the negotiated price charged by the pharmacy at the point of the sale—*i.e.*, *before* manufacturer rebates are applied. According to HHS, therefore, if list prices increase, and the pharmacy's negotiated prices increase in response, deductible and coinsurance payments will increase too. *Id.* By forcing PBMs and plan sponsors to pass rebates on to the enrollee at the point-of-sale, HHS thus sought to align out-of-pocket payments with the net prices paid to manufacturers after rebates are applied.

B. Governmental And Commercial Actuarial Studies Of The Rebate Rule Predict Troubling Economic Consequences

97. Over the course of the rulemaking, multiple federal agencies and outside commercial firms performed actuarial analyses seeking to estimate the Proposed Rule's likely effect on prescription drug spending. Before issuing a notice of proposed rulemaking, HHS-OIG itself commissioned actuarial studies from the CMS Office of the Actuary ("OACT")—which directs the actuarial program for CMS, including the development of and methodologies for economic analyses of health care financing issues—and from two outside commercial firms, Milliman and Wakely Consulting Group. *Proposed Rule*, 84 Fed. Reg. at 2356 & nn.86-87. And the nonpartisan CBO published an additional analysis of the Proposed Rule shortly after the comment period closed. *See* CBO, *Incorporating the Effects of the Proposed Rule on Safe Harbors for Pharmaceutical Rebates in CBO's Budget Projects—Supplemental Material for*

Updated Budget Projections: 2019 to 2019 (May 2019), https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf ("CBO Analysis").

98. Each of these studies cast serious doubt on the efficacy of the Proposed Rule and indicated that it could have perverse effects on Part D premiums, net prices, or total spending on prescription drugs.

99. OACT: The predictions of CMS's own actuaries were dire. Even assuming that reducing out-of-pocket costs for enrollees at the point of sale would not lead to "changes in [drug] utilization"—an assumption other agencies ultimately questioned, *see infra* ¶¶ 105-07, 211—OACT predicted that implementing the Proposed Rule would increase "overall drug spending net of rebates and . . . discounts" by "approximately $137 billion" over ten years, largely driven by federal "spending on premium subsidies for Medicare beneficiaries," which would increase by $196 billion. OACT, Analysis of Proposed Safe Harbor Regulation at 2, 4 (Aug. 30, 2018), https://www.regulations.gov/document?D=HHSIG-2019-0001-0004 ("OACT Analysis"); *see also Proposed Rule*, 84 Fed. Reg. at 2356-57, 2360. Further, OACT predicted that although "average beneficiary costs would decrease, the majority of beneficiaries would see" the opposite effect—"an increase in their total [out-of-pocket] and premium costs"—and "the costs to the Federal Government would more than offset [any] savings." OACT Analysis, *supra*, at 5, 8. OACT predicted that the Proposed Rule would primarily benefit drug manufacturers, who would face less price competition under the Proposed Rule and would therefore reduce their current rebates by up to 15% with no corresponding reduction in their list prices. *Id.* at 3, 8. As a result, manufacturers would reap a disproportionate amount of the increased federal spending. *Id*. at 8.

100. Milliman: The Milliman analysis covered seven different scenarios reflecting a range of assumptions about how the Rule would affect price concessions from manufacturers and pharmacies. In the baseline scenario ("Scenario 1"), Milliman assumed that manufacturers would shift 100% of their price concessions to the point of sale, whether by reducing list prices, negotiating equivalent discounts, or some combination thereof. Milliman, *Impact of Potential Changes to the Treatment of Manufacturer Rebates* 7, 12 (Jan. 31, 2019), https://beta.regulations.gov/document/HHSIG-2019-0001-0002 ("Milliman Report"). Milliman also considered scenarios in which PBMs responded to the Proposed Rule by tightening "formulary controls"—*i.e.*, reducing access to expensive drugs (Scenarios 2 and 3)—or manufacturers responded by reducing price concessions, driving up the net price of drugs (Scenario 4). *Id.* at 12-13. Milliman also considered three other scenarios (Scenarios 5, 6, and 7), involving other theoretically possible behavioral responses to the Proposed Rule, *id.* at 13-14, that HHS-OIG did not consider likely enough to include in its analysis, *see Proposed Rule*, 84 Fed. Reg. at 2357; *Rebate Rule*, 85 Fed. Reg. 76725.

101. Milliman did not opine on whether any of these scenarios were likely or even realistic based on actuarial principles or reasonable assumptions about stakeholder behavior. Instead, all indications are that HHS-OIG itself came up with a series of scenarios that it expected would justify the Proposed Rule, and instructed Milliman to include those scenarios in its analysis.

102. Despite HHS-OIG's efforts to contrive favorable scenarios, all seven scenarios analyzed by Milliman predicted that the Proposed Rule would result in an increase in Medicare Part D premiums, ranging from $4 billion over ten years if PBMs and plan sponsors covered fewer drugs *and* manufacturers increased priced concessions (Scenario 3), to $44.9 billion if

manufacturers reduced price concessions (Scenario 4). Milliman Report, at 14, Table 4. These scenarios reflected a premium increase of between 12% (Scenario 3) and 22% (Scenario 4) per enrollee for the 2022 contract year. *Proposed Rule*, 84 Fed. Reg. at 2357-58, Table 2.A. Milliman also found that if manufacturers kept their price concessions constant (Scenario 1) or decreased them—meaning higher net prices for drugs (Scenario 4)—federal spending could increase by $34.8 billion (Scenario 1) to $139.9 billion (Scenario 4) over ten years. Milliman Report, at 14, Table 4. Milliman also suggested that government spending *could* decrease several of HHS-OIG's contrived scenarios, but only if PBMs and plan sponsors reduced drug coverage (Scenarios 2 and 3) or in the scenarios that HHS-OIG ultimately declined to analyze (Scenario 5, 6, and 7). *Id.* Finally, Milliman concluded that if manufacturers decreased their price concessions, *aggregate* spending on prescription drugs would increase by $135.1 billion.

103. Wakely: The Wakely analysis stipulated to the assumption—without any supporting analysis—that manufacturers would continue to provide the same discount at the point of sale under the Proposed Rule that they currently provide through retrospective rebates. Wakely Consulting Group, *Estimates of the Impact on Beneficiaries, CMS, and Drug Manufacturers in CY2020 of Eliminating Rebates for Reduced List Prices at Point-of-Sale for the Part D Program* at 1 (Aug. 30, 2018), https://beta.regulations.gov/document/HHSIG-2019-0001-0005 ("Wakely Report"). Like Milliman, Wakely did not offer any support for that stipulated assumption, and instead appeared to have adopted the assumption pursuant to the instructions in its contract with HHS-OIG. Even accepting this questionable premise, however, Wakely concluded that the Proposed Rule would increase premiums—albeit less than the average reduction in enrollee's out-of-pocket spending at the point of sale. *Id.* And not every enrollee would save. Seventy percent of non-low-income enrollees would "experience a net

increase in out of pocket expenses," as increases in their premiums would outpace savings at the point of sale. *Id.* at 2. On the government side, Wakely concluded that "CMS will see its Part D payments increase by 3%." *Id.* at 3.

104. HHS-OIG summarized the results of the OACT, Milliman, and Wakely studies in the Proposed Rule:

TABLE 2.A.—BENEFICIARY IMPACTS, PER MEMBER PER MONTH, NON-LOW INCOME SUBSIDY ENROLLEES, CY 2020—Continued

	OACT	Milliman, Scenario 1	Milliman, Scenario 2	Milliman, Scenario 3	Milliman, Scenario 4	Wakely
Impact on Beneficiary Premium.	+$5.64, (+19%)[89]	+$3.15, (+14%)[90]	+$2.70, (+12%)	+$2.77, (+12%)	+$5.11, (+22%)	+$3.73, (+8%).[91]
Impact on Beneficiary Cost sharing.	−$8.01, (−14%)	−$4.85, (−11%)	−$5.44, (−13%)	−$5.22, (−12%)	−$3.86, (−9%)	−$5.75, (−10%).
Total	−$2.37, (−3%)	−$1.70, (−3%)	−$2.74, (−4%)	−$2.44, (−4%)	+$1.25, (+2%)	−$2.02, (−2%).

TABLE 2.B.—BENEFICIARY IMPACTS, PER MEMBER PER MONTH, NON-LOW INCOME SUBSIDY ENROLLEES, CY 2020–CY 2029

	OACT	Milliman, Scenario 1	Milliman, Scenario 2	Milliman, Scenario 3	Milliman, Scenario 4	Wakely
Premium[92]	+25%	+$4.03, +13%	+$1.27, +4%	+$0.61, +2%	+$6.84, +21%	N/A.
Cost sharing	−18%	−$6.23, −12%	−$9.85, −19%	−$9.68, −19%	−$4.97, −10%	N/A.
Total	−4%	−3%	−18%	−11%	+2%	N/A.

Proposed Rule, 84 Fed. Reg. at 2357-58.

TABLE 4.A.—GOVERNMENT SPENDING IMPACTS, CY 2020—Continued
[$billions]

	OACT	Milliman, Scenario 1	Milliman, Scenario 2	Milliman, Scenario 3	Milliman, Scenario 4	Wakely
Direct subsidy	+$20.1, (+128%)	+$15.1, (+149%)	+$14.5, (+144%)	+$14.8, (+146%)	+$15.6, (+154%)	Not avail., (+146%[94]).
Low income premium subsidy.	+$0.9, (+20%)	+$0.8, (+14%)	+$0.7, (+12%)	+$0.7, (12%)	+$1.4, (+22%)	Not avail., (+8%).
Low income cost sharing subsidy.	−$1.8, (−6%)	−$5.8, (−18%)	−$6.2, (−20%)	−$6.1, (−20%)	−$4.4, (−14%).	Not avail., (−12%).
Reinsurance	−$5.9, (−12%)	−$7.3, (−16%)	−$7.9, (−17%)	−$8.0, (−17%)	−$3.0, (−6%)	Not avail., (−14%).
Total	+$13.4, (+14%)	+$2.8, (+3%)	+$1.1, (+1%)	+$1.5, (+1%)	+$9.5, (+10%)	Not avail., +3%.

TABLE 4.B.—GOVERNMENT SPENDING IMPACTS, CY 2020 THROUGH 2029
[$billions]

	OACT	Milliman, Scenario 1	Milliman, Scenario 2	Milliman, Scenario 3	Milliman, Scenario 4	Wakely
Direct subsidy	+$258.7, (+119%)	+$215.4, (+193%)	+$174.7, (+157%)	+$180.3, (+162%)	+$221.1, (+199%)	Not avail.
Low income premium subsidy.	+$15.4, (+24%)	+$12.0, (+13%)	+$3.8, (+4%)	+$1.9, (+2%)	+$20.5, (+21%)	
Low income cost sharing subsidy.	−$57.7, (−15%)	−$89.5, (−20%)	−$118.3, (−26%)	−$118.5, (−26%)	−$71.4, (−16%)	
Reinsurance	−$20.3, (−3%)	−$103.1, (−13%)	−$139.1, (−18%)	−$163.2, (−18%)	−$30.2, (−4%)	
Total	+$196.1, (+14%)	+$34.8, (+2%)	−78.8, (−5%)	−$99.6, (−7%)	+$139.9, (+10%)	N/A.

Id. at 2359-60.

105. CBO: The CBO's analysis further undermined the foundation on which the Proposed Rule was built because it predicted increased Federal spending and increased premiums. "Implementing the rule as proposed would, CBO estimates, increase federal spending by about $177 billion over the 2020-2029 period," including $170 billion in increased spending on Medicare Part D premiums. CBO Analysis, *supra*, at 1, 3. The CBO explained that "[u]nder current rules, plans may use manufacturers' rebates to reduce premiums for all beneficiaries. If those rebates were no longer paid directly to plans"—as the CBO predicted—"*Part D premiums would rise*." *Id.* at 3 (emphasis added). The resources needed to implement the chargeback systems required by the new point-of-sale safe harbor would further "increase premiums." *Id.* at 4.

106. The CBO's analysis reflected a careful evaluation of how the industry would respond to the Proposed Rule. The CBO "consulted with stakeholders and outside experts to understand the likely effects of implementing the rule," and concluded that "manufacturers would withhold some of the discounts they previously negotiated that could no longer be used under the rule." CBO Analysis at 2. Contrary to the Proposed Rule's premise that manufacturers would lower list prices, the "CBO expects that rather than lowering list prices, manufacturers would offer the renegotiated discounts in the form of chargebacks." *Id.* at 2-3.

107. The CBO observed that its assessment of the Proposed Rule's effects was in line with OACT's estimate that the Proposed Rule would increase Federal spending for Medicare Part D by about $196 billion on net over a ten-year period. CBO Analysis at 7. The CBO also noted that Milliman had "also estimated the effects of the proposed rule" and analyzed "several scenarios" that led to estimates "spann[ing] a wide range, from a reduction in federal spending of

almost $100 billion to an increase of about $139 billion." *Id.* The CBO provided no further analysis of Milliman's (or Wakely's) analysis.

108. In sum, the government's own data said the Proposed Rule would increase federal spending, that most individuals would see their premiums increase, and that list prices would not decrease as HHS-OIG hoped. A private group drew no firm conclusions, but presented an array of options ranging from huge increases in Federal spending (and premiums) to decreases in Federal spending (and premiums) depending on different variables. A second private group predicted that even on assumptions favorable to the Proposed Rule, premiums and federal spending would increase, and a majority of enrollees would see an increase in their spending on prescription drugs.

C. The Proposed Rule Draws Praise From Drug Manufacturers And Broad Concerns From PBMs, Plan Sponsors, Pharmacies, And Others About Higher Premiums And Federal Spending

109. HHS-OIG received more than 25,000 comment letters on the Proposed Rule.

110. Unsurprisingly, the pharmaceutical industry—which stood to gain billions from the reduction in rebates by the estimates of HHS's own actuaries, *see supra* ¶ 90—praised the Proposed Rule. On behalf of the industry, the Pharmaceutical Research and Manufacturers of America ("PhRMA") wrote to support the proposed "fundamental policy changes," whose "transformative impact on Medicare Part D" PhRMA considered "too important to delay," necessitating an "aggressive" implementation timeline. PhRMA Comment Letter at 2-3 (Apr. 8, 2019), https://www.regulations.gov/document?D=HHSIG-2019-0001-19764. The Biotechnology Innovation Organization, another industry trade association, likewise "welcom[ed]" and "support[ed]" the proposal. Biotechnology Innovation Organization Comment Letter at 1-2 (Apr. 8, 2019), https://www.regulations.gov/document?D=HHSIG-2019-0001-19736. Numerous individual drug manufacturers also submitted comments to echo that

support and "urge OIG to finalize the proposed rule as quickly as possible." *E.g.*, GlaxoSmithKline Comment Letter at 1 (Apr. 8, 2019), https://www.regulations.gov/document?D=HHSIG-2019-0001-19984. These drug manufacturers asserted that "the current rebate system is broken" and that government intervention was "urgently needed" in order to combat "[t]he ability of PBMs and plans to extract significant rebates from manufacturers" in price negotiations. Novartis Comment Letter at 2-3, 5 (Apr. 8, 2019) (heading), https://www.regulations.gov/document?D=HHSIG-2019-0001-19763. These manufacturers accordingly supported HHS's proposal to undercut PBMs' ability to negotiate pricing arrangements that manufacturers "do not want and which are imposed on the manufacturer by a PBM." Bayer Comment Letter at 8 (Apr. 8, 2019), https://www.regulations.gov/document?D=HHSIG-2019-0001-19791.

111. By contrast, other stakeholders submitted comments raising serious concerns about the Proposed Rule, including that it would not serve HHS's purported goal of lowering drug prices for enrollees and the government. Insurers that serve as Part D plan sponsors explained why the proposed rule would in fact "ultimately result in higher drug costs and higher premiums for tens of millions of Medicare beneficiaries," contrary to HHS's goals and the public interest. AHIP Comment Letter at 2 (Apr. 8, 2019), https://www.regulations.gov/document?D=HHSIG-2019-0001-19788; *see also*, *e.g.*, Anthem Comment Letter, *supra*, at 1 (expressing "strong concerns that the reforms in this proposed regulation . . . fall well short of meeting these objectives and would actually increase the net price of drugs in government programs, significantly increasing costs for consumers and taxpayers"). Other stakeholders, including those who operate pharmacy chains and PBMs, submitted additional "comments [to] demonstrate that any potential positive impact of the proposed rule is far outweighed by the

negative impacts on Medicare Part D beneficiaries and taxpayers." CVS Health Comment Letter at 2 (Apr. 8, 2019), https://www.regulations.gov/document?D=HHSIG-2019-0001-19777; *see also*, *e.g.*, Magellan Health Comment Letter at 6-7 (Apr. 8, 2019) ("net prices will rise under the proposed rule for several reasons," including that "[a]nalyses from numerous sources demonstrate list prices, not rebates, drive drug spending"), https://www.regulations.gov/document?D=HHSIG-2019-0001-19694. Stakeholders also wrote to highlight the extensive administrative hurdles to the proposal implementation that HHS ignored or overlooked, given the numerous "program and legal requirements that Part D sponsors . . . must comply with." National Council for Prescription Drug Programs ("NCPDP") Comment Letter at 2 (Apr. 8, 2019), https://www.regulations.gov/document?D=HHSIG-2019-0001-19807; *see also* AHIP Comment Letter, *supra*, at 2 (detailing "concerns about the likelihood of significant operational challenges associated with moving to a new system with little time to rigorously test the system").

112. Independent and academic commentators also submitted comments documenting the many problems with the Proposed Rule. Professor Craig Garthwaite—whose work HHS-OIG relied on in its NPRM, *see Proposed Rule*, 84 Fed. Reg. at 2342 & n.14—wrote that the Proposed Rule "will cause more harm than good." Garthwaite Comment Letter at 1 (Apr. 8, 2019), https://www.regulations.gov/document?D=HHSIG-2019-0001-19671. As Professor Garthwaite explained, "for many reasons," the existing system of rebate-contracts "improves market efficiency," "increases price competition," and "leads to lower net prices—which overall is good for consumers"—whereas HHS's proposed disclosure regime "can facilitate tacit collusion" among drug manufacturers. *Id.* at 2-4. And the Medicare Payment Advisory Commission (MedPAC), a nonpartisan legislative branch agency that provides Congress with

analysis and policy advice on the Medicare Program, submitted comments expressing "substantial concerns about the proposed changes" and the "undesirable outcomes" they could create, such as "set[ting] in place conditions for tacit collusion among manufacturers of competing drugs" to raise prices. MedPAC Comment Letter at 1-2 (Apr. 5, 2019), https://www.regulations.gov/document?D=HHSIG-2019-0001-19346.

113. Multiple commenters also identified significant challenges that were likely to arise if HHS-OIG moved forward with the Proposed Rule and, accordingly, recommended that the agency build in substantial lead time for market participants to restructure their affairs before the Rule went into effect.

114. As proposed in February 2019, the Rebate Rule was to become effective within one year, on January 1, 2020. *Proposed Rule*, 84 Fed. Reg. at 2348. Multiple commenters expressed concern that such a compressed timeline was "unworkable and likely to cause significant disruption to [Medicare plan] beneficiaries." BlueCross BlueShield Association Comment Letter, *supra*, at 16. BlueCross BlueShield, for example, explained that Medicare Part D bids for each contract year are due in the first week of June in the previous year. *Id.* Those "[b]id submission[s] represen[t] the culmination of a complex development process" that begins long before June and "would be severely disrupted by the proposed changes." *Id.* Specifically, "[p]lans generally try to complete formulary structures for their bids in March and have their bids certified by third-party actuaries in May for early June submission." *Id.* And once a rule were finalized, "plan sponsors would need to essentially begin the process again, including renegotiation of contracts and re-pricing of bids." *Id.*

115. Commenters explained that this renegotiation and re-pricing process could not commence without further guidance from CMS. Due to a "multitude of implementation

challenges" identified by commenters, CMS would need to initiate "additional rulemaking and guidance on a host of Medicare and Medicaid issues" to resolve ambiguities arising from the Rebate Rule. Magellan Health Comment Letter, *supra*, at 5; *see also* CVS Health Comment Letter, *supra*, at 13 ("A final rule released without sufficient lead time to provide definitive direction for plan bids before they are due cannot impact the 2020 plan year."). Issues requiring CMS guidance would include "whether discounted prices count towards a patients' true out-of-pocket costs (TrOOP) or toward the negotiated price for purposes of the Coverage Gap Discount Program." BlueCross BlueShield Association Comment Letter, *supra*, at 16-17. CMS would "also likely need to reissue guidance, including those related to plan sponsor reporting (e.g. the out-of-pocket cost (OOPC) tool, total beneficiary cost (TBC), prescription drug event (PDE) and direct and indirect remuneration (DIR) reporting) and beneficiary-facing communications (e.g. Plan Finder, Explanation of Benefits, and any future Real Time Benefit Tools)." *Id.* at 17. Moreover, CMS would "likely also need to recalibrate the Part D risk adjustment model (RxHCC) to reflect these changes and ensure the model compensates for any meaningful selection bias resulting from the change from rebates to discounted prices." *Id.* As for the timing of this regulatory guidance "[e]ven if CMS immediately began expedited rule-making, it is unlikely that [the] process could be completed in time to provide necessary clarity prior to bid submission." *Id.*

116. Indeed, commenters advised that once the industry received the needed regulatory clarity, more work would *still* be needed. For instance, the National Council for Prescription Drug Programs, a non-profit standards development organization for information exchanges related to healthcare, outlined a few approaches that it would potentially need to take to update its standards in light of the Proposed Rule. *See* NCPDP Comment Letter, *supra*, at 3-5; *Rebate*

Rule, 85 Fed. Reg. at 76699. And it estimated that the process would take about 10-12 months from publication of any final rule—plus additional time for the industry to modify its operations accordingly. NCPDP Comment Letter, *supra*, at 6, 10; *Rebate Rule*, 85 Fed. Reg. at 76699.

117. PCMA submitted a comment letter on April 8, 2019. PCMA explained that it was "wholly aligned with the Administration goals of reducing drug prices and beneficiary out-of-pocket costs, by increasing competition and improving negotiation," but that the Proposed Rule was unlikely to achieve those objectives. PCMA Comment Letter, *supra*, at 4.

118. PCMA raised several specific concerns, including that: (1) the Proposed Rule would lead to improper disclosure of sensitive pricing information, increased utilization of less cost-effective drugs, and increased net drug costs, premiums, and federal spending, reducing access to plans and plan choice, and costing most enrollees more in overall out-of-pocket costs, PCMA Comment Letter, *supra*, at 13, 29-65; (2) without additional safe harbor protections that PCMA proposed, the Proposed Rule would undermine HHS-OIG's push to encourage "value-based arrangements"—which tie compensation to quality of care—by exposing those arrangements to federal anti-kickback liability, *id.* at 22-28; and (3) the Proposed Rule exceeded HHS-OIG's authority, including because the statutory exception protects rebates and HHS-OIG thus lacks authority to subject them to federal anti-kickback liability, *id.* at 80-100.

119. The comment period on the Proposed Rule closed on April 8, 2019.

D. HHS-OIG Withdraws The Proposed Rule

120. The Proposed Rule met with similar criticism from officials throughout the Executive branch.

121. In May 2019, HHS-OIG listed the Rule in the Spring 2019 Unified Agenda, with an anticipated publication date of November 2019. *See* Office of Information & Regulatory Affairs ("OIRA"), *Removal of Safe Harbor Protection for Rebates to Plans or PBMs Involving*

Prescription Pharmaceuticals and Creation of New Safe Harbor Protection, RIN 0936-AA08 (Spring 2019), https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201904&RIN=0936-AA08. The Unified Regulatory Agenda is a semiannual publication of "regulatory and deregulatory activities under development throughout the Federal Government." OIRA, *About the Unified Agenda*, https://www.reginfo.gov/public/jsp/eAgenda/UA_About.myjsp.

122. On June 10, 2019, HHS-OIG submitted the Proposed Rule to the Office of Management and Budget ("OMB") for review.

123. The Proposed Rule was not well received at OMB. Public reports point to "pretty wide consensus" among Executive Branch officials who reviewed the Proposed Rule that it "was a terrible idea" because the "cost was exorbitant and it was perceived as a bailout to Big Pharma." Yasmeen Abutaleb, et al., *Trump kills key drug price proposal he once embraced*, WASH. POST (July 11, 2019), https://www.washingtonpost.com/business/economy/white-house-kills-key-drug-pricing-rule-to-eliminate-hidden-rebates/2019/07/11/ff595192-a3de-11e9-bd56-eac6bb02d01d_story.html (quoting a "senior administration official"). OMB Acting Director Russ Vought "was chief among those" who believed the Proposed Rule was a bad idea, and while OMB was "leading on the charge" in that respect, there was broad agreement about the Proposed Rule's lack of merit. *Id.*

124. Upon information and belief, President Trump met with several advisers in the Oval Office to discuss the Proposed Rule in July 2019. Azar and White House Domestic Policy Council Director Joe Grogan were among the attendees.

125. On July 10, 2019—shortly after the Oval Office meeting and a month after HHS-OIG submitted the Proposed Rule to OMB—HHS-OIG withdrew the Proposed Rule.

126. The withdrawal was reflected in multiple government publications, including the OIRA's regulatory review of the Proposed Rule, and OMB's listing of the Proposed Rule's status. *See* OIRA, *OIRA Conclusion of EO 12866 Regulatory Review* ("Concluded Action: Withdrawn"), https://www.reginfo.gov/public/do/eoDetails?rrid=129208; OMB, *Removal of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection*, RIN 0936-AA08 (Fall 2019) (listing rule as "Withdrawn" and dated "7/26/2019"), https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201910&RIN=0936-AA08. The Proposed Rule's official government docket—at which all rulemaking materials can be viewed by the public—also listed the rule as "Withdrawn" as of June 26, 2019, but that information no longer appears on the docket. *See* U.S. Gen. Services Admin., *Fraud and Abuse Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals*, Dkt. HHSIG-2019-0001 (listing rule as "Withdrawn" and dated "7/26/2019"), https://www.regulations.gov/docket?D=HHSIG-2019-0001.

127. The White House confirmed that the Proposed Rule had been withdrawn. Judd Deere, Special Assistant to the President and Deputy Press Secretary, issued a statement on July 11, 2019 that said: "Based on careful analysis and thorough consideration, the President has decided to withdraw the rebate rule. The Trump administration is encouraged by continuing bipartisan conversations about legislation to reduce outrageous drug costs imposed on the American people, and President Trump will consider using any and all tools to ensure that prescription drug costs will continue to decline." Shira Stein, *Trump Kills Drug Rebate 'Safe Harbor' Rule That Favored Pharma*, BLOOMBERG LAW (July 11, 2019) (quoting statement), https://news.bloomberglaw.com/health-law-and-business/trump-kills-drug-rebate-safe-harbor-rule-that-favored-pharma.

128. Secretary Azar told reporters at a press briefing that the Proposed Rule was withdrawn in part because President Trump "does not want any risk that our actions could cause seniors' premiums to increase." Peter Sullivan, *White House withdraws controversial rule to eliminate drug rebates*, THE HILL (July 11, 2019), https://thehill.com/policy/healthcare/452561-white-house-withdraws-controversial-rule-to-eliminate-drug-rebates.

129. The Proposed Rule's withdrawal was widely reported in the press. *See, e.g.*, Sullivan, *White House withdraws controversial rule to eliminate drug rebates*, *supra*; Abutaleb, et al., *supra* (quoting White House statement); Angelica LaVito, *White House drops proposal to eliminate drug rebates. Health stocks soar*, CNBC (July 11, 2019) (same), https://www.cnbc.com/2019/07/11/white-house-pulls-proposal-to-eliminate-drug-rebates-politico.html; Susan Morse, *Trump administration withdraws drug rebate rule*, HEALTHCARE FIN. (July 11, 2019) (quoting same statement), https://www.healthcarefinancenews.com/news/trump-administration-withdraws-drug-rebate-rule.

130. The Proposed Rule's withdrawal caused real-world effects. For example, the "reversal caused [stock market] investors to recalibrate their expectations" and change their investment strategies related to the pharmaceutical industry. Anna Edney, *Trump Administration Abandons Plan to Overhaul Drug Rebates*, TIME (July 11, 2019) (describing HHS-OIG's "about-face" as a "[s]ubstantial [s]hift" in policy), https://time.com/5624425/trump-abandons-drug-rebates/.

131. Following the Proposed Rule's withdrawal, regulated entities and stakeholders including PCMA's members reasonably viewed HHS-OIG as having abandoned its rulemaking to revise the discount safe harbor and had no reason to anticipate that HHS-OIG would issue

final, binding regulations revising the discount safe harbor without addressing the myriad Part D regulatory uncertainties still outstanding or providing any additional opportunity to comment.

E. President Trump Issues An Executive Order Directing HHS-OIG To Promulgate A Rule

132. More than a year after HHS-OIG withdrew the Proposed Rule, President Trump suddenly reversed course and signed an Executive Order providing that Secretary Azar "shall complete the rulemaking process he commenced." Exec. Order 13939 of July 24, 2020, *Lowering Prices for Patients by Eliminating Kickbacks to Middlemen*, 85 Fed. Reg. 45759, 45759 (July 29, 2020).

133. In an apparent effort to protect the President from election-year criticism that the Proposed Rule would hurt seniors and increase federal spending, the Executive Order imposed conditions on the rulemaking. It directed HHS-OIG to complete the rulemaking process only if the "action is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs." *Exec. Order 13939*, 85 Fed. Reg. at 45759.

134. By the time the President issued this requirement, it was already impossible to achieve. Multiple federal agencies and commercial studies had *already* projected that the Rule would increase federal spending, Medicare enrollee premiums, or both. No agency or actuarial study at the time supported the Executive Order's condition on proceeding with the rulemaking. Indeed, that is likely the reason why the Rule was withdrawn in the first instance.

135. Given this context, the Executive Order's directive to the Secretary was clear: The Secretary should reject the settled views of multiple agencies and commercial and actuarial studies, and support adoption of the Rebate Rule with an express finding—contrary to the evidence—that the Rule would not increase federal spending or Part D premiums.

136. Given the material developments since the Proposed Rule's comment period closed nearly 16 months before, PCMA and other commenters reached out to HHS-OIG to address the possibility of a renewed rulemaking process. PCMA emailed a letter to HHS-OIG on this subject on August 3, 2020. *See* PCMA Suppl. Comment Letter, *supra*.

137. PCMA expressed its understanding that the rulemaking's administrative record was closed based on the Proposed Rule's withdrawal in July 2019, and urged HHS-OIG to re-initiate the rulemaking process if it wished to take any additional action. *See* PCMA Suppl. Comment Letter, *supra*, at 2. PCMA's view was informed not only by the APA's notice-and-comment requirement, but also by common sense. More than a year had passed since the public had weighed in on the Proposed Rule, and the evidence was no longer fresh. The country was in the middle of a pandemic whose effects on the health care system were unaccounted for, and a new government study on the Proposed Rule had been published.

138. The August 3, 2020 letter also provided PCMA's views on the CBO analysis, which had not been published when the comment period closed. PCMA explained that the CBO analysis undermined both the foundations of the Proposed Rule and its chances of satisfying the Executive Order's conditions that any rule not increase Federal spending or premiums, because the CBO analysis concluded that the Proposed Rule would increase Medicare Part D spending by $170 billion over ten years and increase overall Federal spending by $177 billion. PCMA Suppl. Comment Letter, *supra*, at 4-5. PCMA reminded HHS-OIG that the CBO remains the "gold standard" for economic projections given its independence, impartial work, and expertise in conducting economic analyses that Congress relies upon when enacting legislation. *Id.* at 5.

139. PCMA emphasized that the CBO's analysis buttressed the CMS OACT analysis, which similarly concluded that Federal spending would increase by nearly $200 billion because

any out-of-pocket savings were overcome by premium increases. PCMA Suppl. Comment Letter, *supra*, at 3. Moreover, PCMA reminded HHS-OIG that a rule limiting rebates would be inconsistent with ongoing innovations in the Part D regulatory system. In the same week that the Executive Order was released, CMS announced that "Part D premiums continue to stay at their lowest levels in years even as beneficiaries enjoy a more robust set of options from which to choose a plan that meets their needs." *Id.* at 10 (quoting CMS, *Trump Administration Continues to Keep Out-of-Pocket Drug Costs Low for Seniors* (July 29, 2020), https://go.cms.gov/2LmkDYB).

140. Finally, PCMA pointed out that two other government reports issued after the close of the comment period focused on how rebates lower Part D program costs. HHS-OIG itself had published a report in September 2019 concluding that rebates save money in the Part D program and that drug prices increase independent of the presence of rebates. PCMA Suppl. Comment Letter, *supra*, at 5-6 (citing HHS-OIG, *Rebates for Brand-Name Drugs in Part D Substantially Reduced the Growth in Spending from 2011 to 2015* (Sept. 2019), https://oig.hhs.gov/oei/reports/oei-03-19-00010.pdf). In addition, the U.S. Government Accountability Office had issued a report in July 2019 on the role of PBMs in the Part D program, finding that competition within therapeutic classes drives down net costs and that rebates were not a major source of PBM revenue because 99.6% of rebates were passed through to plan sponsors. *Id.* at 6 (citing GAO Study, *supra*).

141. PCMA urged HHS-OIG that, in light of this new evidence further casting doubt on the Proposed Rule's underpinnings, it should at minimum open up the Proposed Rule to further notice-and-comment and conduct a new actuarial analysis that followed professional standards. PCMA Suppl. Comment Letter, *supra*, at 6-8.

142. In response to the Executive Order, HHS-OIG restarted the rulemaking process, but did not provide a new or additional notice-and-comment period regarding the Proposed Rule. Indeed, PCMA's supplemental comment letter was not entered on the public rulemaking docket.

F. HHS-OIG Proceeds With The Rebate Rule Over Serious Criticism From Multiple Stakeholders And Federal Agencies

143. In the final months of the Trump administration, HHS-OIG hurried the Rebate rule through OMB review and into the Federal Register. Under Executive Order 12866, OMB ordinarily has 90 days to review a rule, and the OMB Director may extend the review period on a one-time basis for 30 days. Upon information and belief, HHS-OIG threatened that absent quick approval, HHS-OIG would skip OMB review of the final Rebate Rule entirely. Ultimately, HHS-OIG sent the Rule to OMB on November 13, 2020 and received approval five days later, on November 18, 2020.

144. HHS-OIG announced on November 20, 2020 that it would be issuing a regulation "to eliminate the current system of drug rebates in Medicare Part D." HHS Press Office, *HHS Finalizes Rule to Bring Drug Discounts Directly to Seniors at the Pharmacy Counter*, https://www.hhs.gov/about/news/2020/11/20/hhs-finalizes-rule-bring-drug-discounts-directly-seniors-pharmacy-counter.html. HHS-OIG published the final Rebate Rule on November 30, 2020.

145. The final Rebate Rule largely adopts the changes in the Proposed Rule, except that HHS limited the principal provision of the final Rule to Medicare and declined to apply it to Medicaid. *See Rebate Rule*, 85 Fed. Reg. at 76717 (noting that the final Rule otherwise "incorporates, in large part, the amendments to the discount safe harbor and the new safe harbors we proposed in the Proposed Rule").

146. Like the Proposed Rule, the Rebate Rule eliminates the regulatory safe harbor for discounts in the Medicare Part D context by adding a new exception to the regulatory provision defining "discounts." That provision states that "[t]he term discount"—the subject of the safe harbor—"does not include" a list of certain defined categories of transactions. 42 C.F.R. § 1001.952(h)(5). The Rebate Rule adds a new category to the list, as § 1001.952(h)(5)(viii): "[a] reduction in price or other remuneration in connection with the sale or purchase of a prescription pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D either directly to the plan sponsor under Medicare Part D, or indirectly through a pharmacy benefit manager acting under contract with a plan sponsor under Medicare Part D, unless it is a price reduction or rebate that is required by law." *Rebate Rule*, 85 Fed. Reg. at 76731.

147. The Rebate Rule also follows the Proposed Rule by replacing the safe harbor for discounts with the new point-of-sale safe harbor, at 42 C.F.R. § 1001.952(cc), and adopted the new safe harbor for PBM service fees, at § 1001.952(dd). As codified, the new point-of-sale safe harbor specifies that a "reduction in price from a manufacturer to a plan sponsor under Medicare Part D . . . for a prescription pharmaceutical product" is not considered "remuneration"—and is therefore protected from federal anti-kickback liability—if each of three conditions are all met: (1) the amount of the discount is "set . . . in advance, in writing" by the manufacturer and the plan sponsor or PBM; (2) if the discount "involve[s] a rebate" that is not "required by law," its "full value" must be provided through a "chargeback"—meaning the manufacturer pays it "directly or indirectly" to the pharmacy; and (3) the discount is passed on to the enrollee at the point of sale ("completely reflected in the price . . . at the time the pharmacy dispenses" the drug). *Rebate Rule*, 85 Fed. Reg. at 76731.

148. Finally, like the Proposed Rule, the Rebate Rule asserted that "the way many types of rebates have been used" does not qualify for the statutory exception for discounts. *Rebate Rule*, 85 Fed. Reg. at 76690; *accord Proposed Rule*, 84 Fed. Reg. at 2343 ("In the Secretary's view, moreover, the statutory exemption for discounts (42 U.S.C. 1320a-7b(b)(3)(A)) does not apply to most rebates paid by drug manufacturers to part D plans . . . ."). The Rule makes clear that any rebate arrangement that "implicates the anti-kickback statute and does not satisfy an exception or safe harbor would be subject to scrutiny" and face potential "criminal penalties." *Rebate Rule*, 85 Fed. Reg. at 76679.

149. To support these changes, Secretary Azar reached the precise conclusion demanded by the Executive Order. Just before the Rule was published, he issued a public statement on HHS's website "confirm[ing] that in [his] view the [Rebate] Rule . . . is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs." HHS Press Office, *Secretary Azar Confirmation In Response to Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen* (Nov. 20, 2020), https://www.hhs.gov/about/news/2020/11/20/secretary-azar-confirmation-in-response-to-executive-order-on-lowering-prices-for-patients.html ("Azar Statement"). In support of this conclusion, Secretary Azar cited no evidence and did not engage with the numerous actuarial studies—by OACT, Milliman, Wakely, and the CBO—that had rejected this conclusion and unanimously found (including under all seven scenarios that HHS-OIG instructed Milliman to analyze) that the Rebate Rule would at a minimum increase premiums, if not federal spending and even aggregate spending on drug prices. *See supra* ¶¶ 98-108. Instead, Secretary Azar mainly invoked his "experience . . . at a Fortune 500 pharmaceutical company" and his belief

that PBMs are "sophisticated" negotiators and plans would never settle for increased premiums irrespective of the underlying market dynamics. Azar Statement, *supra*.

150. The Secretary's conclusion that "there will not be an increase in federal spending, patient out-of-pocket costs, or premiums for Part D beneficiaries" was a central and essential premise of the Rebate Rule. *Rebate Rule*, 85 Fed. Reg. at 76721. To support this conclusion, HHS-OIG cited the studies by OACT, Milliman, and Wakely, *e.g.*, *Rebate Rule*, 85 Fed. Reg. at 76724-29 & nn.83-84, even though *each* of these analyses found that the Rebate Rule would increase premiums, and OACT—consistent with Milliman—found that the Rule would increase federal spending, *see supra* ¶¶ 98-108. The Rule gave little consideration to the CBO's separate analysis concluding that the Rule would increase premiums and federal spending, *see supra* ¶¶ 105-07. Instead, it blithely dismissed the CBO's estimates as "within the range of estimates presented in the Proposed Rule." *Rebate Rule*, 85 Fed. Reg. at 76720-21.

151. HHS-OIG took the position that the economic effects of rule—including its effect of premiums and federal spending—turned largely on whether manufacturers increased price concessions in response to the Rule, leading to lower net prices, or decreased price concessions, leading to higher net prices. HHS-OIG stated, for example, that "additional price concessions" would mean "lower premiums" for "all beneficiaries," whereas "fewer price concessions" would mean "higher premiums" for "all beneficiaries." *Rebate Rule*, 85 Fed. Reg. at 76720. Similarly, the Rule could lead to "reduced federal spending if more than 100 percent of rebates are converted into list price concessions," while the Rule could lead to "increased Federal spending, if manufacturers reduce price concessions." *Id*. at 76721; *see also*, *e.g.*, *id.* at 76724 ("If list price reductions and increased price concessions led to lower net prices and gross drug costs in Part D plans, beneficiary and Federal spending on premiums and cost-sharing could decrease. If

Part D plans were unable to achieve additional price concessions, and net prices increased, beneficiary and Federal spending on premiums and cost-sharing could increase.").

152. To support the conclusion that the Rebate Rule would "lea[d] to additional price concessions," *Rebate Rule*, 85 Fed. Reg. at 76720, HHS-OIG cherry picked assumptions in one of the Milliman report's seven scenarios that HHS-OIG had contrived for Milliman to analyze in order to manufacture support for the Rule. In that scenario, Milliman had predicted that federal spending could decrease *if* PBMs tightened "formulary controls"—*i.e.*, restricted access to the most expensive drugs—and manufacturers responded by agreeing to increased price concessions (Scenario 3). *See* Milliman Report, *supra*, at 12-13. Milliman offered no evidence that this would happen—it merely predicted the economic consequences of that scenario. Armed with Milliman's predictions, HHS-OIG reverse-engineered a set of assumptions that would achieve its desired conclusions: It simply asserted, without any evidentiary support or reasoning, that the assumptions behind Milliman's Scenario 3 were correct, and PBMs would use the threat of tightening formulary controls to force additional price concessions from manufacturers. *Rebate Rule*, 85 Fed. Reg. at 76724.

153. HHS-OIG never explained why it believed these changes in behavior would result from the Rebate Rule. Nor did it explain why—if these changes were desirable to PBMs, plan sponsors, and enrollees—PBMs were not already making them under the current regulations. Indeed, HHS-OIG ignored the reality that the threat of excluding a drug from plan formularies is *already* one of the PBMs' principal sources of leverage in negotiating drug prices, but depending on a number of factors—including the Part D program's requirement that plans cover certain drugs in "protected classes," as well as market conditions and clinical considerations—exclusion is not always an option. And even when exclusion is an option, formulary development also

takes into account enrollees' demand for the drug at issue and the potential disruption that those enrollees would experience if a drug were excluded. Reducing drug access makes drug plans less valuable to enrollees and hurts plans in competing for enrollees. Accordingly, while HHS-OIG speculated that PBMs would simply engage in "tougher negotiation," *Rebate Rule*, 85 Fed. Reg. at 76695, it did not identify any way in which the Rebate Rule would improve PBMs leverage or otherwise enable them to achieve better results than under the current regulations. HHS-OIG also ignored that even under the scenario in which PBMs tighten formulary control and achieve additional price concessions, Milliman predicted that the Rebate Rule would increase federal premiums, contrary to Secretary Azar's conclusions. Milliman Report, *supra*, at 4, Table 4.

154. HHS-OIG likewise failed to adequately address concerns that the Rebate Rule would undermine the confidentiality of PBMs' rebate agreements with manufacturers, giving *manufacturers*—rather than PBMs—greater leverage and allowing manufacturers to *reduce* price concessions. *See supra* ¶¶ 99, 111-18. In rejecting these concerns, HHS-OIG failed to meaningfully engage with the conclusions of multiple other agencies with expertise on these issues—including the FTC and the CBO—that revealing information about pricing would drive up prescription drug prices. *See supra* ¶¶ 41-43. Nor did HHS-OIG acknowledge that in reaching the opposite conclusion, Secretary Azar was parting with the views of his own subagency, CMS—the agency within HHS with the most direct expertise on these issues in the Medicare context. *See supra* ¶ 52. HHS-OIG simply asserted that "PBMs have been extremely effective negotiators in the Medicare Part D program," and "the Department expects that PBMs will continue to be effective negotiators." *Rebate Rule*, 85 Fed. Reg. at 76702-03.

155. Finally, HHS-OIG failed to engage with concerns that the January 1, 2022 effective date for the Rebate Rule's elimination of the regulatory safe harbor for discounts would undermine the process of negotiating rebates, designing plans, finalizing bids, and coming into compliance with all new program rules for the 2022 Medicare Part D contract year. *See supra* ¶¶ 113-16. Rather than coordinate with CMS and time the effective date of the rule to ensure that CMS had time to adopt new regulations adjusting program rules in light of the Rebate Rule—and that PBMs and plan sponsors were able to complete formulary negotiations, design plans, and finalize bids for the upcoming contract year under those new rules—HHS simply stated, 37 separate times, that "[c]omments related to CMS's administration of the Part D program are outside the scope of this rulemaking," or a similar deflection. *Rebate Rule*, 85 Fed. Reg. at 76692; *see also, e.g.*, *id.* at 76673 (same), 76674 (same), 76684 (similar).

III. THE REBATE RULE IS CONTRARY TO LAW AND VIOLATES THE ADMINISTRATIVE PROCEDURE ACT

A. The Rebate Rule Is Ultra Vires And Contravenes Multiple Statutory Limitations

156. The Rebate Rule should be set aside because it is ultra vires and contravenes multiple statutory limitations on the Department's authority. HHS-OIG has no authority to remove from the protections of the regulatory safe harbor conduct that is plainly protected by the statutory exception. Nor is HHS-OIG permitted to set a price structure or interfere with the negotiations between drug manufacturers and plan sponsors (or their PBMs).

1. The Rebate Rule Exceeds The Department's Statutory Authority Under The Anti-Kickback Statute

157. Subjecting retrospective manufacturer rebates under Medicare Part D to liability under the anti-kickback statute exceeds HHS-OIG's authority because—irrespective of the

regulatory safe harbor for discounts—retrospective rebates are exempt from such liability under the *statutory* exception for discounts.

158. The statutory exception provides that the Act's criminal penalties "shall not apply to" a "discount or other reduction in price" that is "properly disclosed and appropriately reflected" in the costs for which reimbursement could be claimed under a federal healthcare program. 42 U.S.C. § 1320a-7b(b)(3)(A). The rebates that PBMs negotiate with drug manufacturers plainly qualify for this exception. *See supra* ¶¶ 77-79.

a. *First*, rebates operate as "discount[s] or other reduction[s] in price," 42 U.S.C. § 1320a-7b(b)(3)(A), from the price ordinarily paid by plans and PBMs for covered drugs. *See Black's Law Dictionary* (6th ed. 1990) (defining a "rebate" as a "[d]iscount" or a "deduction . . . from a stipulated payment . . . after [the payer] has paid the full stipulated sum").

b. *Second*, the amount of these discounts is "properly disclosed and appropriately reflected," 42 U.S.C. § 1320a-7b(b)(3)(A)—first, from PBMs to plan sponsors, and second, from sponsors to the Secretary. Plan sponsors must account for estimated rebates as DIR in making bids, and CMS factors the full rebate amount into its final Medicare payments to Part D plan sponsors. *See supra* ¶ 78.

159. Any other interpretation would be incompatible with the Medicare Act. At the time Medicare Part D was enacted, the regulatory safe harbor already reflected HHS-OIG's understanding that properly disclosed manufacturer rebates were *not* remuneration within the meaning of the anti-kickback statute. As HHS-OIG has long recognized, the regulatory safe harbors, in part, present the agency's "interpretation of the meaning of certain important statutory terms," including the term "remuneration" and the terms in the statutory "discount

exception." *Medicare and State Health Care Programs*, 56 Fed. Reg. at 35957; *accord Medicare and State Health Care Programs*, 64 Fed. Reg. at 63529. And the regulatory safe harbors make clear that, "[a]s used in section 1128B of the Act"—the anti-kickback statute—"'remuneration' does *not* include a discount," including a rebate, that is properly disclosed. 42 C.F.R. § 1001.952(h) (emphasis added); *see supra* ¶¶ 5, 81-82.

160. Multiple provisions of the Medicare Act accordingly reflect Congress's understanding that retrospective manufacturer rebates paid to PBMs were not illegal kickbacks. The Act, for example, requires plan sponsors to make available to their enrollees the "negotiated prices" of covered drugs. 42 U.S.C. § 1395w-102(d)(1)(A). "[N]egotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations," *id.* § 1395w-102(d)(1)(B)—a requirement that necessarily presupposes the existence of retrospective manufacturer rebates.

161. Indeed, at the time Medicare Part D was enacted, the dominant form of price concessions in the private market at the time, as today, was retrospective manufacturer rebates. And the entire point of Medicare Part D was to create a federally subsidized program that would simulate those market practices.

162. HHS-OIG's repeal of the regulatory safe harbor for discounts thus undermines the premises of the Medicare Act.

163. To the extent there is any doubt, moreover, the federal anti-kickback statute must be interpreted narrowly in light of the severe criminal penalties for violations of the statute. *See* 42 U.S.C. § 1320a-7b(b)(1)-(2). Because the anti-kickback statute "has criminal applications," the Court, in interpreting the statute, must "apply the rule of lenity" and resolve any lingering ambiguity in favor of regulated parties—even in the civil context of this case. *United States v.*

Thompson/Ctr. Arms Co., 504 U.S. 505, 518 (1992) (plurality op.). Consistent with the rule of lenity, the Court cannot read the statutory discount exception so narrowly that it entirely misses common industry practices, such as retrospective manufacturer rebates, nor that it permits HHS-OIG to shrink such an important exception via a simple change in regulation.

164. It is no answer, as HHS-OIG repeatedly claims, that the changes to the regulatory safe harbor have "no impact on the statutory exception." *Rebate Rule*, 85 Fed. Reg. at 76691; *see also id.* at 76690 (asserting that it was "not our intent" to "narrow the reach of the statutory discount exception"). The statutory exception sets a minimum level of protection that the regulatory safe harbors cannot dip below. The "practices specified in [those] regulations," Congress explained, "shall be *in addition to*"—not a lesser subset of—"the practices described" in the statutory exceptions. Pub. L. No. 100-93, § 14(a), 101 Stat. at 697 (emphasis added). The "regulatory safe harbor," in other words, "both *incorporates and enlarges upon* the statutory exception," as HHS-OIG has previously understood. *Medicare and State Health Care Programs*, 64 Fed. Reg. at 63528 (emphasis added).

165. HHS-OIG's new theory—that it is free to cut any conduct that it wants from the regulatory safe harbors—is incorrect. "[L]ike other federal agencies," HHS-OIG "'literally has no power to act . . . unless and until Congress confers power upon it.'" *Am. Library Ass'n v. FCC*, 406 F.3d 689, 698 (D.C. Cir. 2005) (omission in original) (quoting *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986)). Here, Congress authorized HHS-OIG to add regulatory safe harbors and to implement the statutory exceptions. *See Medicare and State Health Care Programs*, 56 Fed. Reg. at 35957 (the Act "requires us to add to the exceptions," but also permits "us [to] interpre[t] statutory terms"). Congress never authorized HHS-OIG to *shrink* the statutory exceptions, yet that is exactly what the agency's elimination of the regulatory discount

safe harbor seeks to do. By eliminating the regulatory discount safe harbor, HHS-OIG has created so much uncertainty as to the lawfulness of retrospective rebates as to effectively prohibit the practice absent clarification that it is protected by the statutory exception.

166. HHS-OIG's elimination of a regulatory safe harbor protecting lawful conduct, moreover, cannot be squared with the reason Congress instructed HHS-OIG to issue regulations in the first place. Congress "direct[ed] the Secretary . . . to promulgate regulations" in order to resolve "uncertainty among health care providers as to which commercial arrangements are legitimate, and which are proscribed." S. Rep. No. 100-109, at 27, *reprinted in* 1987 U.S.C.C.A.N. at 707. HHS-OIG cannot provide such clarity in cases like this one, where it amends the regulatory safe harbors to protect *less* conduct than the "statutory language" compels. *Id.*

167. At minimum, eliminating the regulatory safe harbor for discounts is arbitrary and capricious in light of the separate statutory exception. The removal of the regulatory discount safe harbor against the backdrop of the statutory exception creates the immediate effect of generating substantial uncertainty and confusion about the lawfulness of retrospective rebates and thereby chills that conduct. Agency action seeking to regulate lawful conduct by using uncertainty to chill the conduct is not a legitimate or rational reason to amend a safe harbor.

2. The Rebate Rule Violates The Medicare Act's Non-Interference Clause

168. The Rebate Rule also violates the Medicare Act's non-interference clause, which prohibits the Secretary from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and [Part D plan] sponsors." 42 U.S.C. § 1395w-111(i)(1). The Rebate Rule does exactly that. PBMs have long used "rebates as negotiating tools," PCMA Comment Letter, *supra*, at 91, with manufacturers to help bring down drug prices for plan sponsors and, in turn,

premiums and out-of-pocket costs for enrollees. The stated purpose of the Rebate Rule is to diminish the bargaining power of PBMs by taking those tools away and thereby impact ultimate drug prices, and thus impermissibly interferes with the negotiations between PBMs and manufacturers.

169. PhRMA, the trade association representing pharmaceutical manufacturers, supported the Rebate Rule on the basis that it would weaken PBMs' bargaining power. PhRMA Comment Letter, *supra*, at 21. According to PhRMA, PBMs "leverage th[eir] market power in their negotiations with manufacturers," and have taken steps to "further enhanc[e] their negotiating leverage through a series of consolidations" and other actions. *Id.* PhRMA thus supported the Proposed, and now Final, Rebate Rule as a way to "more appropriately align" PBMs' incentives during the "negotiations with manufacturers." *Id.* Or as Novartis, another manufacturer, put it, the Rule will counter the "ability of PBMs and plans to extract significant rebates from manufacturers." Novartis Comment Letter, *supra*, at 5. In light of this record, HHS-OIG cannot credibly claim that the "rule does not interfere in any negotiations between Part D sponsors" and "manufacturers." *Rebate Rule*, 85 Fed. Reg. at 76671. It plainly does.

170. HHS-OIG's response is unavailing. It argues that amendments to the "parameters of the safe harbor do not . . . interfere with negotiations between plans and pharmacies," and presumably manufacturers (*see* 42 U.S.C. § 1395w-111(i)(1)), "because they do not have any bearing on the ultimate prices negotiated among the parties." *Rebate Rule*, 85 Fed. Reg. at 76671. As an initial matter, a direct impact on the outcome of the negotiations between the parties (*i.e.*, an impact on the ultimate agreed-upon prices) is not necessary to show "interfer[ence] with the negotiations," 42 U.S.C. § 1395w-111(i)(1), themselves. Weakening the negotiating posture of one of the parties is itself "interference"—it "acts as an obstacle to" a

PBM negotiating price concession, regardless of whether the obstacle is ultimately overcome. *Stevenson v. FedEx Ground Package Sys., Inc.*, 69 F. Supp. 3d 792, 796 (N.D. Ill. 2014) (an employer's "minor, or even de minimis," notification requirement nevertheless "interferes" with an employee's ability to take a protected action). In any event, HHS-OIG repeatedly makes clear that the purpose of removing the regulatory discount safe harbor is to change the PBMs' negotiating strategy in a way that *will* affect ultimate prices: The "Department believes," for example, "that rebates are a major driver of high list prices, and that, by removing the incentives of the rebate system, PBMs and payors will have a strong incentive to negotiate lower net prices." *Rebate Rule*, 85 Fed. Reg. at 76686; *see also, e.g.*, *id.* ("The Department believes rebates are an important driver of increased list prices."). HHS-OIG has thus made clear that the Rebate Rule is specifically designed to have "a bearing on the ultimate prices negotiated by the parties" by changing the dynamic of the negotiations between PBMs and manufacturers.

171. At minimum, the Medicare Act's non-interference clause is further evidence that Congress expected negotiations between PBMs and manufacturers to follow the market—including industry practices like retroactive rebates that were common when Part D was enacted and have added value to the Medicare Part D program—and that Congress intended such practices to continue.

3. The Rebate Rule Impermissibly Institutes A Price Structure

172. The Rebate Rule also impermissibly institutes a price structure, violating the statutory command that the Secretary may not require "a particular formulary or institute a price structure for the reimbursement of covered [P]art D drugs." 42 U.S.C. § 1395w-111(i)(2). HHS-OIG again claims that amending the "parameters of the safe harbor" does not "institute a price structure" "because [it] do[es] not have any bearing on the ultimate prices negotiated among the parties." *Rebate Rule*, 85 Fed. Reg. at 76671. That is incorrect and belied by the Rebate Rule

itself. As explained above, *supra* ¶¶ 152-54, removing rebates from PBMs' toolbox of negotiating tools is how HHS-OIG seeks to "driv[e]" "list prices" where it wants them—which is exactly what HHS-OIG is not permitted to do.

B. The Rebate Rule Is Arbitrary And Capricious

173. Even if this Court were to conclude that HHS-OIG had statutory authority to regulate in this manner, the Rebate Rule must be vacated as arbitrary and capricious and contrary to the APA in multiple respects.

1. The Effective Date Of The Rebate Rule Disrupts The Bidding Process For Contract Year 2022 And Makes It Impossible For CMS To Timely Issue Necessary Determinations That PBMs And Plan Sponsors Must Account For Before The Bidding Deadline

174. At the threshold, irrespective of the merits of the Rebate Rule itself, this Court should promptly set aside the Rule's effective date in order to prevent a significant disruption of the planning process for the 2022 Medicare Part D contract year.

175. The revisions to the discount safe harbor will take effect on January 1, 2022, *see Rebate Rule*, 85 Fed. Reg. at 76666, meaning they will apply to drug plans sold and marketed in 2021 for the 2022 contract year.

176. As detailed *supra* in ¶¶ 62-64, PBMs and plan sponsors began the planning process for 2022 more than a year in advance, in June and July 2020, and PBMs began their negotiations with manufacturers in October 2020. By the time HHS-OIG published the Rebate Rule on November 30, 2020, therefore, the months-long process of negotiating rebates, finalizing plan formularies and plan design, preparing bids for submission to CMS, and coming into compliance with the new program rules was already well underway.

177. By purporting in November 2020 to prohibit—starting in 2022—the longstanding retrospective rebate model that PBMs, plan sponsors, and manufacturers have followed since the

start of Medicare Part D, HHS-OIG has changed the rules of the game in the middle of the planning cycle. These changes upset the reliance interests of PBMs and plan sponsors who have invested resources in negotiations with manufacturers under the prior rules. Further, imposing these changes so late in the process risks setting back the time-sensitive process of preparing bids and completing other preparations for the 2022 contract year.

178. As of this filing, PBMs and plan sponsors have less than five months remaining to complete negotiations with manufacturers, finalize their plans, and submit their bids by the June 7, 2021 bid deadline. But PBMs and plan sponsors still lack critical information that they will need to complete those steps. And the Rebate Rule leaves unresolved a host of issues regarding the bidding process, formulary designs, enrollee-facing materials, and other considerations that CMS will need to determine well in advance of the June 2021 deadline so plan sponsors can account for it in their plan designs and bids. As PCMA and others outlined in comment letters, those issues include the following:

a. Bidding process and review. CMS will need to determine how negotiated price concessions need to be allocated in the bid; how to update its Bid Pricing Tool, which sponsors need in order to input bid data for submissions; and whether CMS will revise its definition of "negotiated price," 42 C.F.R. § 423.100, to align with the Rebate Rule and price reductions processed via chargebacks at the point of sale. *Rebate Rule*, 85 Fed. Reg. at 76673-74; *see* PCMA Comment Letter, *supra*, at 66-68.

b. Formularies. Commenters questioned whether CMS's formulary review process would change, what "potential effects" the change to point-of-sale discounts would create, how formulary plans should treat manufacturers' drugs that used

alternate National Drug Codes to allow for price concessions, and whether discounted drugs could be placed on a separate formulary tier. *See Rebate Rule*, 85 Fed. Reg. at 76673; PCMA Comment Letter, *supra*, at 70.

c. Enrollee materials. Plan sponsors provide potential Plan D enrollees with information so that individuals can make informed choices about which plan to enroll in. Similarly, the Medicare Plan Finder is a tool that allows individuals to compare and contrast multiple plans and identify the lowest-cost option for them personally—factoring in premiums, deductibles, copayments, and coinsurance—before they select which plan to enroll in. The Rebate Rule injects uncertainty into these enrollee-facing communications. For example, PCMA asked what changes to "model marketing materials" may be required because of the Rebate Rule, what current and prospective enrollees would be told about price concessions at the point of sale, and whether plans should report the list price or the discounted price in the plan's Explanation of Benefits, a monthly summary of prescription drug claims and costs that drug plans must provide to enrollees who fill a prescription. PCMA Comment Letter, *supra*, at 69-70. Moreover, commenters expressed concerns about how and when the Medicare Plan Finder would be updated to reflect the new enrollee experience under the Rebate Rule—changes that typically require multiple years to make—including changed cost-sharing obligations at the point of sale, changed premiums, and changed deductibles. *See Rebate Rule*, 85 Fed. Reg. at 76692, 76695.

d. Administrative and Operational Concerns. Commenters raised the need for CMS clarifications about how the Rebate Rule would impact "data reporting"

requirements under Part D, which in general are designed to avoid duplicate discounts, disputed discounts, or erroneous discounts. *Rebate Rule*, 85 Fed. Reg. at 76673; PCMA Comment Letter, *supra*, at 68-69. In addition, the National Council for Prescription Drug Programs, a non-profit standards development organization for information exchanges related to healthcare, outlined a few potential methods that it could implement to administer point-of-sale transactions and chargeback amounts. NCPDP Comment Letter, *supra*, at 3-4. It estimated that the process would take about 10-12 months from publication of any final rule, plus additional time for the industry to modify its operations accordingly. *Id*. at 6, 10.

e. Benefit Structure. Plan sponsors can design plans that use copays (in which the enrollee pays a flat amount of the drug's costs), coinsurance (in which an enrollee pays a percentage of the drug's price), or a combination of both. Eight of the top ten Part D plans by enrollment require copays for preferred drugs, rather than coinsurance. PCMA Comment Letter, *supra*, at 57 (citing Kaiser Family Foundation study). When plan sponsors create benefit designs, plan sponsors' calculations incorporate whether rebates are provided for drugs with either copays or coinsurance. The Rebate Rule, by changing where the rebate money flows, necessarily impacts the benefit design and will change the way that copays and coinsurance designs are implemented. But HHS-OIG gave plan sponsors no guidance on how a Part D plan should process rebates for drugs subject to fixed copays, and CMS has not provided any guidance, either.

179. CMS will have to make many of these determinations through notice-and-comment rulemaking. Even prior to the Supreme Court's 2019 decision in *Allina*, much of this information is the type of information, that in previous years, CMS would have included in its Policy and Technical Changes rule promulgated through notice-and-comment rulemaking, rather than in subregulatory guidance such as the annual Call Letter that CMS historically included in Part II of its annual Advanced Notice. And following *Allina*, CMS has now determined that even the information historically included in its Call Letter must be shifted to its Policy and Technical Changes rule and promulgated through notice-and-comment rulemaking to comply with *Allina*. *See supra* ¶ 71.

180. It will be impossible for CMS to make these determinations in time for plan sponsors to account for them in their June 7, 2021 bids. As discussed, plan sponsors depend on reliable checkpoints to meet the bidding deadline: They need CMS decisions on formularies, enrollee materials, and benefit structure with sufficient lead time to complete negotiations by March, design plans and finalize actuarial assumptions by the first week of May, and finalize and submit bids by the first Monday in June. *See supra* ¶¶ 62-64.

181. But CMS will not be able to provide this information through its Policy and Technical Changes rule for months. CMS will need to work internally to resolve the myriad issues that HHS-OIG left open, make decisions about how to address each issue, and draft a Notice of Proposed Rulemaking. After that, CMS must solicit public comments for 60 days. *See* 42 U.S.C. § 1395hh(b)(1) ("before issuing in final form any regulation" that establishes or changes a substantive legal standard, the agency must provide "not less than 60 days for public comment"). Then it will take CMS time to review, analyze, discuss, and answer comments as part of any final rule. Even after CMS's job is done, CMS must send the final rule to OMB for

review, and OMB has at least 90 days to review the rule (a review period that the OMB Director may extend to 120 days). *See* Exec. Order 12866 § 6(b)(2), 58 Fed. Reg. 51735, 51742 (Oct. 4, 1993).

182. This timeline simply does not work. Even if CMS issued the proposed rule the day of this filing, solicited public comments for 60 days, took 30 days to respond to comments, and received approval from OMB in 90 days, the final rule would not be published until July 9, 2021—more than a month after the bid deadline.

183. Comparing this bidding cycle to previous years shows the impossibility of CMS making the necessary determinations in time for the June 7, 2021 bid deadline. Before *Allina*, CMS provided much of the information that plan sponsors needed through a Call Letter, which involved only a 30-day comment period. *See* CY 2019 Advance Notice Part II, *supra*, at 1. And CMS released the Call Letter by the beginning of February to make the timing work. *See id.* (Feb. 1, 2018 issuance date); *see also supra* ¶¶ 67-68.

184. CMS's Policy and Technical Changes rulemakings similarly took months. For contract year 2019, it took CMS five months to finalize its proposed Policy and Technical Changes rule. *See* 82 Fed. Reg. 56336 (Nov. 28, 2017) (proposed rule); 83 Fed. Reg. 16440 (Apr. 16, 2018) (final rule). For contract year 2021—the only post-*Allina* bidding cycle—CMS took four months to propose its Policy and Technical Changes rule, receive comments, consider comments, and finalize the rule. *See supra* ¶ 71; 85 Fed. Reg. 9002 (Feb. 18, 2020) (proposed rule); 85 Fed. Reg. 33796 (June 2, 2020) (final rule). Even then, CMS was able to address only a "subset of the provisions that were proposed in the February 2020 proposed [Policy and Technical Changes] rule" because of the time crunch. 85 Fed. Reg. at 33875; *see id.* at 33800 (explaining that CMS was "not finalizing" several "provisions of the February 2020 proposed

rule"). And CMS cut the process as close as it possibly could, publishing the final rule days before the bidding deadline. *Contract Year 2021 Medicare Advantage and Part D Final Rule (CMS-4190-F1) Fact Sheet*, *supra* (noting that CMS "issued" the final rule on "May 22, 2020").

185. This year's process is different in both magnitude and kind, and promises to require even more time. Unlike in previous years, CMS's Policy and Technical Changes rule will need to account for the top-to-bottom changes to the Part D program resulting from the Rebate Rule. *See supra* ¶ 71. Addressing these additional, complex issues will only extend the period necessary to complete notice-and-comment rulemaking. With less than five months remaining before the bidding deadline, there is no realistic way that CMS can provide the necessary answers to plan sponsors through its Policy and Technical changes rulemaking in time. CMS is already behind schedule, with even more work to do because of the Rebate Rule's impact on every dimension of Part D bids and plan operations, and will need to undertake a rigorous notice-and-comment process to address the Rebate Rule.

186. These problems were not unknown to HHS-OIG. Commenters rang alarm bells about the timing implications of the Rebate Rule during the comment period.

187. First, commenters warned that if HHS-OIG issued a final rule in the middle of a bidding cycle, after plan sponsors and PBMs had spent months and invested significant resources to negotiate contracts with manufacturers for the contract year in which the rule took effect, "plan sponsors would need to essentially begin the process again, . . . renegotiat[ing] . . . contracts" covering thousands of medicines. BlueCross BlueShield Association Comment Letter, *supra*, at 16. A rule released any later in the bidding process would be even more disruptive, forcing plan sponsors to scrap ongoing bid development and "re-pric[e] . . . bids," *id.*, or wastefully develop two sets of alternative bids, one reflecting the

proposed rule and one reflecting the current regulatory regime, American Academy of Actuaries Comment Letter, *supra*, at 1-2.

188. Second, commenters warned HHS-OIG that if it finalized the Rebate Rule, CMS would need to initiate "additional rulemaking and guidance on a host of Medicare . . . issues" to resolve ambiguities arising from the Rebate Rule about the bidding process, formulary designs, benefit structure, and beneficiary-facing materials. Magellan Health Comment Letter, *supra*, at 5; *see also* CVS Health Comment Letter, *supra*, at 13 ("A final rule released without sufficient lead time to provide definitive direction for plan bids before they are due cannot impact the [upcoming] plan year."); BlueCross BlueShield Association Comment Letter, *supra*, at 16-17 (identifying the need for CMS guidance on numerous issues, such as calculating "patients' true out-of-pocket costs," "plan sponsor reporting," "beneficiary-facing communications," and "risk adjustment model[s]"); Prime Therapeutics Comment Letter at 12 (Apr. 8, 2019) ("Additional CMS guidance will be necessary for plan actuaries to properly incorporate changes into prescription coverage benefits."), https://www.regulations.gov/document?D=HHSIG-2019-0001-19964. PCMA provided HHS-OIG with six pages of Part D details that would require CMS rulemaking. PCMA Comment Letter, *supra*, at 66-71. "Importantly," PCMA cautioned HHS-OIG, "these CMS programmatic issues must be addressed and resolved prior to the effective date of any safe harbor changes in order to provide the Part D program some level of certainty as to how the program will operate." *Id.* at 65. Accordingly, commenters encouraged HHS-OIG to coordinate with CMS for a smooth transition to the Rebate Rule. *See id.* at 9 ("[T]he issuance of this Proposed Rule solely by OIG and without coordination with CMS is inappropriate . . . .").

189. Even CMS recognized, in an April 2019 guidance document, that changes to the regulatory safe harbors could create substantial uncertainty. That is why the agency noted that,

"[i]f there is a change in the safe harbor rules effective in 2020," it would "conduct a [two-year] demonstration that would test an efficient transition for beneficiaries and plans to such a change in the Part D program." Memorandum from Seema Verma, Administrator, CMS, to Part D Plan Sponsors (Apr. 5, 2019), https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/Downloads/HPMS-Memos/Weekly/SysHPMS-Memo-2019-Apr-5th.pdf.

190. Third, commenters warned HHS-OIG about the extensive administrative hurdles to implementation and compliance that HHS-OIG ignored or overlooked, given the numerous "program and legal requirements that Part D sponsors . . . must comply with." National Council for Prescription Drug Programs Comment Letter at 2 (Apr. 8, 2019), https://www.regulations.gov/document?D=HHSIG-2019-0001-19807; *see* AHIP Comment Letter, *supra*, at 2 (detailing "concerns about the likelihood of significant operational challenges associated with moving to a new system with little time to rigorously test the system"). For example, it would take about 10 to 12 months from the final rule's publication for organizations to implement methods to administer point-of-sale transactions. *See supra* ¶¶ 116, 178.

191. In light of these concerns, commenters told HHS-OIG during the 2019 comment period to "provide stakeholders sufficient time to comply" with a final rule by "delay[ing] the [rule's] effective date to at least" the contract year *after* the one for which plan sponsors and PBMs were preparing for when HHS-OIG issued the rule. CVS Health Comment Letter, *supra*, at 13. ***At the time***, therefore, commenters proposed an effective date of ***2022***, as plan sponsors were working anticipating a final rule issued in mid- to late 2019, at the start of the planning process for the 2021 contract year. *See id.* The commenters were not simply pushing off compliance to another day. As a group of actuaries summarized, "[m]ajor changes such as those

in the proposed rule typically require the full multi-year bid development period to properly incorporate the changes," so any regulatory changes needed to "provide enough lead time for any new requirements to be incorporated into plan bids." American Academy of Actuaries Comment Letter, *supra*, at 1-2; *see id.* at 2 ("Bids are the culmination of more than a year's work, including actuarial analysis of prior claims and trend projections, provider and vendor negotiations, product changes, and planning for / implementation of new regulatory requirements.").

192. HHS-OIG entirely missed the point of these comments. Rather than set the Rebate Rule's effective date for the year after the contract year at issue in whatever bid cycle was underway when the Rebate Rule was published—here, that would have been contract year ***2023***—HHS-OIG set a January 1, 2022 effective date, the earliest date that commenters suggested would have been appropriate *had the rule been promulgated in 2019*. HHS-OIG claimed that in doing so it was honoring commenters' request for a 2022 effective date. *See Rebate Rule*, 85 Fed. Reg. at 76691 (noting that a commenter "urged OIG to delay the effective date of the final rule until 2022," and responding that "[b]ased on the comments received and further consideration . . . we are finalizing our proposal for the changes to . . . the discount safe harbor to be effective January 1, 2022"). But HHS-OIG never accounted for the fact that it was issuing the Rebate Rule in November 2020—more than a year after the 2019 issuance date contemplated in the Proposed Rule—so the agency would need to further adjust the effective date to address both commenters' concerns and the passage of time.

193. Further, HHS-OIG simply punted on the need to coordinate with CMS, concluding instead that avoiding disruptions to the current, in-progress bidding cycle was simply not its problem. HHS-OIG largely slammed the door on the topic by declaring (more than 37 separate times) that all "[c]omments related to CMS's administration of the Part D program are

outside of this rulemaking," *Rebate Rule*, 85 Fed. Reg. at 76692; *see also id.* at 76673 (same), 76674 (same), 76684 (similar). Although HHS-OIG also said that it "consulted with CMS in the promulgation of this final rule and anticipat[ed] that by finalizing this rule with a January 1, 2022 implementation date . . . we have addressed concerns related to the 2020 bid submission," *id.* at 76692-93, HHS-OIG provided no details regarding how it consulted with CMS, what CMS's views were, or what CMS may anticipate doing to alleviate the commenters' concerns.

194. CMS's actions indicate a lack of coordination with HHS-OIG. Although President Trump issued his Executive Order directing HHS-OIG to restart the rulemaking process in July 2020, CMS proceeded with its Advance Notice process without accounting for the forthcoming Rebate Rule in any way. CMS released Advance Notices "earlier than in past practice," issuing the first in September 2020 and the second in October 2020. CMS, *Advance Notice of Methodological Changes for Calendar Year (CY) 2022 – Part I* at 3 (Sept. 14, 2020), https://www.cms.gov/files/document/2022-advance-notice-part-i.pdf ("2022 Advance Notice Part I"); CMS, *Advance Notice of Methodological Changes for Calendar Year (CY) 2022 – Part II* at 5 (Oct. 30, 2020), https://www.cms.gov/files/document/2022-advance-notice-part-ii.pdf ("2022 Advance Notice Part II"). The comment period on the CY2022 Advance Notices ended on November 30, 2020. *See* 2022 Advance Notice Part II, *supra*, at 1. That was the *same* day the Rebate Rule was published in the Federal Register. *See Rebate Rule*, 85 Fed. Reg. at 76666. As a result, neither the CMS notices issued as part of the 2022 Advance Notice process nor any of the comments submitted in that process had an opportunity to address the Rebate Rule—even though that rule will have profound impacts on bidding, benefits, and payments for plans and beneficiaries. *See* PCMA Comment on Advance Notice of Methodological Changes for Calendar Year (CY) 2022, at 1 (Nov. 30, 2020) ("The [CMS] Notice does not address in any way

the final [Rebate Rule] . . . ."), https://www.regulations.gov/document?D=CMS-2020-0093-0068.

195. In addition, CMS released on December 23, 2020 its instructions for completing the Bid Pricing Tool—the CMS-approved format for plan sponsors to provide information to CMS in its bid submissions—and glaringly provided instructions that could make sense only in the pre-Rebate Rule world. In informing plan sponsors how to enter "the total amount of rebates received" by plan sponsors, CMS noted that "[t]otal rebates include all direct and indirect remuneration received after the point-of-sale transaction." CMS, *Attachment E-2: Instructions for Completing the Prescription Drug Plan Bid Pricing Tool for Contract Year 2022* at 36, https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10142; *see also id.* at 37 (same, for supplemental drugs), 46 (same). That is, CMS's instructions contemplate bids accounting for the kind of rebates from which HHS-OIG has now removed protections—underscoring the lack of appropriate coordination between HHS-OIG and CMS when HHS-OIG issued the Rebate Rule.

196. HHS-OIG's rush to issue the Rebate Rule, coupled with its ostrich-like approach to the timing considerations identified above, will create—and indeed is already creating—major disruptions in the Plan D bidding process for contract year 2022. Plan sponsors have been forced to renegotiate contracts, and have been left adrift in a sea of regulatory uncertainty about how they need to structure their bids as they hurtle toward a June 7, 2021 bidding deadline. Making matters worse, plan sponsors have no meaningful prospect of receiving the necessary determinations from CMS with sufficient time before the bidding deadline. At minimum, the Rebate Rule will cause plan sponsors to significantly raise premiums for contract year 2022 to account for the uncertainty they face, in addition to the Rule's significant long-term effects on

premiums. HHS-OIG's failure to address these concerns is arbitrary and capricious. Therefore, the Rebate Rule's January 1, 2022 effective date should be vacated.

2. The Rebate Rule's Central Premise—That The Rule Will Not Increase Premiums Or Federal Spending—Is Arbitrary And Capricious

197. The Rebate Rule is also arbitrary and capricious because it rests on the faulty premise that the Rule will not increase Part D premiums or federal spending.

198. HHS-OIG's statement that "there will not be an increase in federal spending, patient out-of-pocket costs, or premiums for Part D beneficiaries," *Rebate Rule*, 85 Fed. Reg. at 76721, is a central premise of the Rebate Rule. President Trump's Executive Order expressly conditioned its directive that HHS-OIG "complete the rulemaking" on a finding by the Secretary that the "action is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs." *Exec. Order 13939*, 85 Fed. Reg. at 45759. Secretary Azar complied with this requirement by "confirm[ing] that in [his] view the [Rebate] Rule . . . is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs." Azar Statement, *supra*. And HHS-OIG cited that statement in the final Rebate Rule to show compliance with the Executive Order. *Rebate Rule*, 85 Fed. Reg. at 76666.

199. Indeed, concerns about increased premiums and federal spending are the very reason the Proposed Rule was withdrawn the first time around: Executive officials were concerned that the Rule's "cost was exorbitant," Abutaleb, et al., *supra*, and the President did "not want any risk that [HHS-OIG's] actions could cause seniors' premiums to increase," Sullivan, *supra*. Assurances that the Proposed Rule would *not* have these effects are thus critical to the agency's decision to again proceed with the Rule.

200. HHS-OIG's reliance on the central premise that premiums and federal spending will not increase is fatal to the Rebate Rule because that premise cannot be sustained as the

product of reasoned decisionmaking and is not supported by record evidence. HHS-OIG has never publicly acknowledged the concerns about increased premiums and federal spending that drove it to withdraw the Rule, and it has never explained why it changed its position in proceeding with the Rule. Either way, HHS-OIG's position is incorrect and contrary to common sense and the views of multiple agencies, including HHS's own actuaries. And HHS-OIG's defense of that position is contrary to the evidence and to common sense. The Rebate Rule is therefore arbitrary and capricious.

a. The Rebate Rule Will Increase Net Prices Because Public Disclosure Of Sensitive Price Information Will Undermine Pharmacy Benefit Managers' Bargaining Power

201. As HHS-OIG readily acknowledges in the Rebate Rule, the central premise that premiums and federal spending will not increase simply assumes that manufacturers will continue to offer the same price concessions under the Rebate Rule that they do now—either by lowering their list prices or by shifting discounts to the point of sale—so that the net prices for prescription drugs will not increase. *See supra* ¶¶ 151-52. The Milliman scenarios that found no increase in federal spending similarly assumed that net prices would not increase, and as HHS-OIG recognized, every study that found increased net prices concluded that premiums and federal spending would rise. *See supra* ¶¶ 100-02, 108, 150; *Rebate Rule*, 85 Fed. Reg. at 76724, 76726-28. As HHS-OIG concedes, "[i]f . . . net prices increased, beneficiary and Federal spending on premiums and cost-sharing could increase." *Rebate Rule*, 85 Fed. Reg. at 76724.

202. HHS-OIG's conclusion that net prices will not increase is contrary to the evidence that was before the agency. PBMs' bargaining power and ability to achieve the deepest price concessions from manufacturers depends on their ability to negotiate confidentially, maintaining the details of their rebate contracts as trade secrets that are not openly available to all manufacturers. *See supra* ¶¶ 37-43. But the point-of-sale chargeback system imposed by the

Rebate Rule will eliminate that confidentiality and allow manufacturers to reverse engineer the level of other manufacturers' price concessions from information disclosed to pharmacies and patients at the point of sale. PCMA Comment Letter, *supra*, at 34. Disclosure of this sensitive information will allow manufacturers to tacitly collude in their negotiations and avoid the deepest discounts, driving up the net price paid for prescription drugs after all discounts and rebates, and thus increase premiums and federal spending (not to mention manufacturers' profits). *See supra* ¶¶ 39-40.

203. Such public disclosures gut PBMs' bargaining power by reducing PBMs' leverage and ability to negotiate. Lacking that leverage, PBMs will lose an important negotiating tool for extracting price concessions from drug manufacturers.

204. Congress and state governments have each recognized the need for confidentiality in this area. The negative effects of disclosure on PBM bargaining power is the reason why federal law treats information that reveals the "prices charged for drugs" as confidential, 42 U.S.C. § 1396r-8(b)(3)(D), and therefore a trade secret, 18 U.S.C. § 1905; *see also supra* ¶¶ 37, 51. State law reflects similar concerns about disclosures of this kind of business information: The Uniform Trade Secrets Act—which 47 states have adopted, *see* Uniform Law Comm'n, *Trade Secrets Act*, https://www.uniformlaws.org/committees/community-home?CommunityKey=3a2538fb-e030-4e2d-a9e2-90373dc05792—prohibits the disclosure of "information . . . that derives independent economic value, actual or potential, from not being generally known to" other persons, Uniform Trade Secrets Act § 1(4) (Nat'l Conference of Commissioners on Uniform State Laws 1985). Manufacturer rebate contracts are among the most closely guarded pieces of information in the pharmaceutical industry—so much so that manufacturers themselves keep this information even from trusted consultants.

205. Other agencies both within and outside HHS have likewise acknowledged that disclosure of this sensitive information could lead to increased net prices. CMS found in a 2008 rulemaking that "releas[ing] commercially or financially sensitive data" about confidential negotiations would undermine Part D's "competitive business model" and Part D "sponsors' ability," through PBMs, "to negotiate for better prices, and ultimately affect the ability of sponsors to hold down prices for beneficiaries and taxpayers." *Medicare Program; Medicare Part D Claims Data*, 73 Fed. Reg. at 30668; *see supra* ¶ 52. The CBO and the FTC have reached the same conclusion. *See supra* ¶¶ 42-43, 53; CBO Transparency Study, *supra*, at 4; FTC Letter, *supra*, at 3, 9.

206. HHS-OIG now stands alone against these agencies' views, despite lacking CMS's expertise in Medicare administration, the CBO's expertise in budgetary projection, or the FTC's expertise in market dynamics and competition. HHS-OIG's failure to account for legislative policy at both the federal and state levels, and the views of other agencies with relevant expertise—despite multiple comments raising these issues—is arbitrary and capricious. Indeed, the Secretary—whose predecessor signed CMS's 2008 statement, *Medicare Program; Medicare Part D Claims Data*, 73 Fed. Reg. at 30683 (reflecting then-Secretary Leavitt's approval)—failed even to acknowledge that his statement justifying the Rebate Rule in response to the Executive Order, that premiums and federal spending will not increase, represents a reversal of HHS's position on this issue. The failure to engage with these authorities further renders the Rebate Rule arbitrary and capricious.

207. HHS-OIG's support for its conclusion about net prices is also woefully inadequate. In response to comments by PCMA and other commenters that the Rebate Rule will weaken PBMs' bargaining power and undermine manufacturers' incentives to agree to the

deepest price concessions currently offered, HHS-OIG offers only speculation—without any empirical evidence—that PBMs "will continue to be effective negotiators" because they "have been extremely effective negotiators" in the past. *Rebate Rule*, 85 Fed. Reg. at 76702-03. That is the height of arbitrariness. Simply labeling PBMs "effective negotiators" is cold comfort when the Rebate Rule undercuts the very bargaining power that has made them effective. PBMs are participants in a market who lack unilateral authority to dictate prices—the drug manufacturers set the prices of the drugs they manufacture. If PBMs had limitless power to set their preferred price levels irrespective of manufacturers' business motivations, net prices would not be on the rise year after year. Even the Rule's proponents in the pharmaceutical industry acknowledge that the Rebate Rule will alter the relative bargaining power of the parties and that doing so will change the outcome of negotiations. PhRMA, for example, touts the Rule as a solution to what it perceives as PBMs' excessive "negotiating leverage," PhRMA Comment Letter, *supra*, at 21, and Novartis claims that public disclosure will counter the "ability of PBMs and plans to extract significant rebates from manufacturers." Novartis Comment Letter, *supra*, at 5. HHS's contrary assertion—and unexplained departure from Congressional policy and the expert views of CMS, the CBO, and the FTC—is arbitrary and capricious.

b. Even If Net Prices Remain Constant, The Rebate Rule Will Increase Premiums And Federal Spending

208. Even setting aside the effect of publicly disclosing the results of PBMs' confidential negotiations on future drug prices, HHS-OIG's central premise that the Rebate Rule will not increase premiums or federal spending cannot be sustained.

209. To begin with, HHS-OIG's conclusion about premiums fails basic arithmetic. Enrollees share the price of prescription drugs with plans through deductibles, copayments, and coinsurance at the point of sale. If enrollees' share decreases—as the Rebate Rule is intended to

ensure, then the plan's share must necessarily increase. By design, Medicare Part D ensures that plans' costs are reflected in their bids and premiums level, *see supra* ¶ 60, so the increase in plans' share of the price of prescription drugs necessarily means higher bids, higher premiums, and higher government spending.

210. The Rule also increases the plan's share of drug prices by reducing manufacturers' payments in the coverage gap phase of Part D coverage—*i.e.*, after the enrollee and the plan sponsor have spent $4,130 combined on covered drugs—during which drug manufacturers are required to provide a "coverage gap discount" of 70% of most drug prices. *See supra* ¶ 56. Reducing enrollees' deductible and coinsurance at the point of sale would cause fewer enrollees to enter the coverage gap phase. PCMA Comment Letter, *supra*, at 58. For those that enter the coverage gap phase, the Rule would also reduce the coverage gap discount because the discount would now be calculated based on the price paid *after* any point-of-sale discount. *Id.* Drug manufacturers would thus reap a windfall from paying fewer and smaller coverage gap discounts. *See id.*; Prime Therapeutics Comment Letter, *supra*, at 9-10. CMS's own actuaries determined that manufacturers would save $40 billion. OACT Analysis, *supra*, at 5. If net prices remain constant, these savings to manufacturers necessarily mean greater spending by plans, and thus (once again) higher bids, premiums, and federal spending.

211. The Rebate Rule's intended goal of reducing enrollees' cost-sharing payments at the point of sale also means that the Rule will increase utilization of less cost-effective drugs as enrollees become less sensitive to their true costs, further driving up premiums and federal spending. *See* CBO Analysis, *supra*, at 4; *Rebate Rule*, 85 Fed. Reg. at 76724. Indeed, one of the reasons cost-sharing exists—and is set by CMS regulations (for standard plans) and plan sponsors (for alternative plans) at the specific levels that apply to each coverage phase, *see supra*

¶¶ 56-57—is to incent appropriate utilization and drive enrollees to use more cost-effective alternatives. Forcing PBMs and plan sponsors to reduce cost sharing by passing discounts through to enrollees at the point of sale undermines both the Medicare Act's design and plan sponsors' decisions with respect to benefit design. Increased utilization in turn means greater spending by plans, which will be reflected in higher bids, higher premiums, and higher federal spending. As HHS-OIG thus acknowledged, "the rule will increase prescription drug utilization, resulting in increased Part D spending." *Rebate Rule*, 85 Fed. Reg. at 76721.

212. HHS-OIG nonetheless concludes—based on the CBO's analysis of the economic effects of the Rebate Rule—that federal spending will not increase because the "increase in Part D spending is estimated to be offset by savings in Medicare Parts A and B" resulting from decreased spending in Part A and Part B. *Rebate Rule*, 85 Fed. Reg. at 76721. But even if true, that is no answer to concerns that increased utilization will increase *Part D premiums*, which is contrary to HHS-OIG's central premise. Further, it is arbitrary and capricious for HHS-OIG to cherry-pick supportive points from the CBO's analysis while ignoring the CBO's bottom-line conclusion that both premiums and federal spending *will* increase. And in any event, the CBO did not detail its methodology sufficiently to support a conclusion that Part A and B savings will completely offset any increase in utilization, particularly given the difficulty of squaring that conclusion with the high cost of many of the brand name drugs for which the Rebate Rule will increase utilization.

213. Finally, HHS-OIG's premise that premiums and federal spending will not increase fails to account for the significant costs of implementing the Rebate Rule. The industry will have to invest a substantial amount of financial and administrative resources to conform to the Rule's drastically reshaped system. PBMs will have to update and renegotiate network and

payment contracts with thousands of pharmacies to account for the new point-of-sale system, re-contract with Part D plan sponsors, negotiate rebate agreements with pharmaceutical manufacturers that align with the point-of-sale safe harbor, change their business practices, and update information technology and claims processing systems, among other implementation costs. *See* PCMA Comment Letter, *supra*, at 47-53. PBMs must do all of these things in an environment of regulatory uncertainty, a compliance risk which has its own significant costs. Those implementation costs, which affect all stakeholders, "will be passed along to consumers and taxpayers in the form of higher drug prices," *id.* at 53, and higher premiums.

214. In nonetheless concluding that premiums and federal spending will stay the same, HHS-OIG ignores that its own actuaries concluded otherwise, finding that premiums would increase by 25% and that Federal spending would increase by $196 billion over ten years. *Rebate Rule*, 85 Fed. Reg. at 76726, 76728. HHS-OIG's failure to adequately acknowledge or explain its departure from its own actuaries and expert agencies is arbitrary and capricious.

215. HHS-OIG also ignores that *every* actuarial study it considered—including in all seven scenarios considered by Milliman—found that premiums would rise if HHS-OIG followed through and finalized the Proposed Rule. *See Rebate Rule*, 85 Fed. Reg. at 76726 & Table 2. Indeed, each of these studies found that premiums would increase by at least 13%, except in the two Milliman scenarios (Scenarios 2 and 3) that assumed increased formulary control—*i.e.*, reducing access to expensive drugs. *Id.*

216. HHS-OIG's reliance on Milliman Scenarios 2 and 3 only further undermines the Rule. HHS-OIG was able to reduce—but not eliminate—its prediction of the Rule's impact on premiums only by instructing Milliman to adopt assumptions about stakeholder behavior that neither HHS-OIG nor Milliman ever showed through evidence to be likely or even plausible.

Even in those scenarios, Milliman found that premiums would increase by 2% to 4%. *Rebate Rule*, 85 Fed. Reg. at 76726 & Table 2. And if HHS-OIG's answer is that, as in these two scenarios, PBMs will protect current premium levels by slashing access to higher-priced drugs—a completely unrealistic assumption anyway, given CMS requirements such as providing coverage of certain drugs in protected classes, and offering two drugs per category and class, *see Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses*, 84 Fed. Reg. 23832, 23834-35 (May 23, 2019)—it was arbitrary and capricious not to consider the health and economic consequences of those cuts in benefit levels.

3. The Rebate Rule Reflects Flawed And Unsupported Assumptions About The Growth Of List Prices

217. Even setting aside the acknowledged costs of the Rebate Rule, the Rule is arbitrary and capricious because HHS-OIG fundamentally misunderstood the problem that it was trying to address. According to HHS-OIG, the Rule addresses concerns that PBMs are driving up list prices in order to increase rebates and thereby increase PBM compensation. *Proposed Rule*, 84 Fed. Reg. at 2340-41, 2353. That assertion fails at every step.

218. *First*, HHS-OIG is simply wrong that PBMs have an incentive to drive up list prices in order to generate greater rebates. PBM compensation is not "derived from … the gap between the list price and 'net price,'" as HHS-OIG suggests, *Proposed Rule*, 84 Fed. Reg. at 2341, nor could it be under existing Medicare Part D regulations. HHS-OIG does not dispute the finding of its fellow agency, the GAO, that PBMs pass ***99.6%*** of all rebates through to Part D plan sponsors. *See* GAO Study, *supra*. Further, the plan sponsors are required to report the ***full*** rebate to CMS as DIR, inclusive of any portion that may be retained as compensation for the PBM's services, as negotiated by contract with the plan sponsor. *See* 42 C.F.R. §§ 423.308,

.322(a), .343(c). HHS-OIG offered no evidence that retained rebates constitute a significant source of PBM revenue.

219. *Second*, even if PBMs had an incentive to prefer increased list prices, they have no practical ability to increase them. Instead, manufacturers unilaterally set the prices of the drugs they manufacture. *See Proposed Rule*, 84 Fed. Reg. at 2340 ("Prescription drug manufacturers prospectively set the list price . . . of the drugs they sell . . . ."); AHIP Comment Letter, *supra*, at 14 ("Drug makers have sole control over setting and increasing (or decreasing) list prices.").

220. *Third*, the administrative record is devoid of any evidence that rebates are in any way responsible for the recent growth of list prices or the gross to net bubble. Indeed, in response to comments that HHS-OIG's "conclusion that rebates are the primary cause of high list prices" lacked "support," HHS-OIG offered only a single citation. *Rebate Rule*, 85 Fed. Reg. at 76686 & n.34 (citing *A perspective from our CEO: Gilead Subsidiary to Launch Authorized Generics to Treat HCV. Gilead Pharmaceuticals* (Sept. 24, 2018), https://www.gilead.com/news-and-press/company-statements/authorized-generics-for-hcv ("Gilead Statement")). That citation—a press release by a drug company executive, stating anecdotally that the company could not "quickly" lower list prices for a specific drug once already locked into a rebate agreement, *see* Gilead Statement—says nothing about drug companies' ability to lower their list prices before negotiating rebates with PBMs and plan sponsors. The statement offers no proof whatsoever of *anything*, let alone evidence that rebates drive the growth of list prices or that PBMs are complicit in that outcome.

221. Ultimately, therefore, the theory behind the Rebate Rule amounts to nothing more than the same debunked claims that Secretary Azar has been asserting without evidence for years

on behalf of the pharmaceutical industry, as part of a strategic effort to "'get Americans mad'" at PBMs and thereby "shift the blame" for manufacturers' decisions to increase drug prices. Letter from Senators Elizabeth Warren and Tina Smith to HHS Secretary Alex Azar, at 6 (Aug. 17, 2018), https://s3.amazonaws.com/assets.fiercemarkets.net/public/004-Healthcare/external_Q32018/2018.08.16+Letter+to+Azar+re+drug+prices.pdf (challenging and demanding factual support—which Secretary Azar never provided—for Secretary Azar's June 2018 Senate testimony, which blamed PBMs for rising prescription drug prices).

222. Because the Rebate Rule wrongly attributes the growth of list prices to PBMs, it fails to address the real root cause of the problem or to offer a cogent justification for eliminating the regulatory safe harbor for discounts. The Rule is therefore arbitrary and capricious.

4. The Rebate Rule Will Not Achieve Its Intended Purpose And Will Only Harm The Vast Majority Of Enrollees

223. The Rebate Rule is arbitrary and capricious for another reason: For most Medicare Part D enrollees, the Rule will not achieve its objective of lowering out-of-pocket spending and will only harm them with higher premiums.

224. Contrary to the Rebate Rule's intended purpose, HHS's own actuaries and the Wakely analysis—in studies cited in the Proposed Rule and the final Rebate Rule—each recognize that the Rebate Rule will *increase* total drug spending for the majority of enrollees. According to OACT, although "average beneficiary costs would decrease, the majority of beneficiaries would see an increase in their total [out-of-pocket] and premium costs." OACT Analysis, *supra*, at 5, 8. Even assuming that manufacturers would continue to provide the same discount at the point of sale under the Rebate Rule that they currently provide through retrospective rebates, Wakely concluded that 70% of non-low-income enrollees would

"experience a net increase in out of pocket expenses," as increases in their premiums would outpace savings at the point of sale. Wakely Report, *supra*, at 1.

225. Moreover, the Medicare coverage phases—in which enrollees and plan sponsors share costs at certain prescribed limits, *see supra* ¶¶ 56-57—necessarily limit the value that rebates at the point of sale can provide. An enrollee's cost-sharing in each phase is capped at certain percentages and amounts of drug costs, and those percentages and amounts do not change depending on when in the supply chain a discount occurs. And the majority of Part D plans require copays for preferred drugs under alternative benefit plans, rather than coinsurance under standard benefit plans. PCMA Comment Letter, *supra*, at 57. With copays, enrollees pay a flat amount toward the drug's price; with coinsurance, enrollees pay a percentage. *Id.* As indicated *supra* ¶ 178, CMS has yet to determine whether and how point-of-sale discounts under the Rebate Rule must be reflected in these fixed copayments. But the answer to this question has profound implications for whether the Rebate Rule will have its intended effect. Indeed, the most preferred drugs are priced high enough after rebates that enrollees paying copayments under the replaced Rebate Rule likely will not see *any* reduction in out-of-pocket costs. *Id.* at 57-58.

226. All of this assumes, moreover, that the Rebate Rule actually succeeds in channeling manufacturer discounts through the point-of-sale safe harbor. But trade secrets and antitrust laws cast serious doubt on whether manufacturers will be willing and able to access that new safe harbor. And if parties cannot use the point-of-sale safe harbor, the Rebate Rule's goals are undercut entirely.

227. **Trade Secrets.** As noted above, manufacturer rebate contracts are among the most closely guarded pieces of information in the pharmaceutical industry, and are considered

protected under state trade secrets laws. *See supra* ¶¶ 37, 51. But the Rebate Rule calls for the public disclosure of sensitive information, including point-of-sale discounts, that are protected by state trade secrets laws. *See supra* ¶ 202.

228. Although commenters informed HHS-OIG that the Rebate Rule would lead to violations of state trade secrets laws, *see, e.g.*, PCMA Comment Letter, *supra*, at 92-93, HHS-OIG refused to engage the problem. HHS-OIG responded only that it was "not in a position to respond to comments on state laws" because these issues are "independent of the" Anti-Kickback Statute and "state laws governing trade secrets . . . are outside the scope of this rulemaking." *Rebate Rule*, 85 Fed. Reg. at 76680. But state trade secret laws are part of the legal context in which the Rebate Rule will be applied. If those laws make it impossible to use the point-of-sale safe harbor—as HHS-OIG does not deny—then the Rebate Rule will not achieve its goals and will have unpredicted effects. HHS-OIG's refusal to even address these concerns was arbitrary and capricious.

229. **Antitrust.** Antitrust law also impedes parties' ability to use the new point-of-sale safe harbor. The Rebate Rule scraps a rebate system that grew out of antitrust litigation against pharmaceutical drug pricing. By making this choice, HHS-OIG reintroduced the threat of antitrust liability, which will discourage manufacturers from shifting to a point-of-sale rebate system or, if they make such a shift, will push them toward reducing discounts. Either way, antitrust law prevents the Rebate Rule from achieving its intended effect of not increasing federal spending or premiums, and HHS-OIG did not adequately respond to the many comments raising concerns about how the Rebate Rule would work given the constraints of antitrust law.

230. Before the mid-1990s, most manufacturers offered upfront discounts on their products in exchange for greater volume, much like the type of upfront pricing now set forth in

the Rebate Rule. In 1994, retail drugstore pharmacies brought a lawsuit to challenge that system under the Robinson-Patman Act, which requires that sellers give each drug purchaser an equal opportunity to receive the benefit of higher or lower prices. *See* 15 U.S.C. § 13(a) (making it unlawful "to discriminate in price between different purchasers of commodities of like grade and quality"). The pharmacies argued that drug manufacturers violated the Robinson-Patman Act by refusing to offer pharmacies the same discounts on drug purchases that were offered to other purchasers, such as health plans. The case eventually settled, and in approving the settlement, the district court identified "two commitments which it felt to be appropriate on the part of the settling defendants: 1. That a manufacturer shall not refuse to discount its goods based solely on the status of the buying entity; and 2. To the extent that retail pharmacies and retail buying groups can demonstrate an ability to affect market share in the same or similar manner in which managed care entities are able, retailers will be entitled to the same types of discounts given to managed care entities for this reason." *In re Brand Name Prescription Drugs Antitrust Litig.*, 1996 WL 351180, at *3 (N.D. Ill. June 24, 1996).

231. In the wake of the settlement, manufacturers moved away from upfront, volume-based price concessions (discounts that, under antitrust law and the settlement, generally needed to be extended to all purchasers on the same terms). In its place, manufacturers shifted toward the current retrospective rebate practice, which allows manufacturers to tailor their price concessions to each purchaser's ability to move market share. *See* Scott Gottlieb, *How Congress Can Make Drug Pricing More Rational*, Forbes (Sept. 12, 2016) ("[The rebate system is] the outcome of a two-decade old legal dispute that forced drug makers to try and conceal just how much they discounted off the medicines that they were selling to health plans. ... To work around the litigation, and the settlement they struck with the pharmacies, drug makers came up with a

rebate scheme rather than offering discounts up front."), https://www.forbes.com/sites/scottgottlieb/2016/09/12/how-congress-can-make-drug-pricing-morerational/2/#26155e936532/.

232. Under a retrospective rebate system, manufacturers may differentially price their products without violating applicable antitrust laws. Competing purchasers of all sizes can compete for rebates. Accordingly, retail pharmacies can access beneficial discounts previously not offered to them to the extent they are capable of affecting market share, and thus can compete on equal footing with health plans and PBMs. *See* Testimony of Sarah F. Jaggar, Director of Health Services Quality and Public Health, Before the House Subcomm. on Oversight & Investigations of the House Comm. on Commerce at 6 (Sept. 19, 1996) (manufacturers agreed that "retail pharmacies and buying groups that are able to demonstrate an ability to affect market share will be entitled to discounts based on that ability, to the same extent that managed care organizations would get such discounts"), https://www.gao.gov/assets/110/106654.pdf.

233. The Rebate Rule seeks to replace this retrospective rebate system with upfront discounts similar to what existed before the mid-1990s settlement. By making this replacement, HHS-OIG has reinjected antitrust problems into the system. Manufacturers will be operating in the shadow of antitrust law that subjects them to liability if their upfront discounts are offered to some purchasers but not others. These risks will make manufacturers unwilling or unable to offer the same level of price concessions that they can offer through market share-based rebates. Under the rebate system, manufacturers could increase rebate amounts to reflect a buyer's market share, but under the Rebate Rule, manufacturers will have an incentive to choose the lowest discount they are willing to give to any particular customer and then offer that same discount to *all* customers, even those who would otherwise receive larger discounts. And if

manufacturers do *not* offer the same level of price concessions under the Rebate Rule that they currently do, then federal spending and premiums would increase as HHS concedes. *See supra* ¶¶ 104, 108, 201.

234. Numerous commenters alerted HHS-OIG to the antitrust implications of the Rebate Rule. HHS-OIG failed to adequately respond, or even consult the FTC, the federal agency with antitrust expertise.

235. PCMA warned about the "very real impact of antitrust law on future manufacturer discounting behavior"—namely, that "manufacturers will be forced to move to a system of lower and unvaried discounts offered to all competing purchasers." PCMA Comment Letter, *supra*, at 94. PCMA carefully discussed how the practice of retrospective rebates emerged largely out of the *In re Brand Name Prescription Drug Antitrust Litigation* settlement and "the very real risk under the Robinson-Patman Act." *Id.* at 94-95. And PCMA explained that eliminating the use of retrospective rebates that are uniquely capable of accounting for market share would create the "very real legal and practical reality of an upfront discounting system" in which manufacturers move to "lower and unvaried discounts" because of potential "liability under the Robinson-Patman Act." *Id.* at 95-96.

236. BlueCross BlueShield Association similarly warned HHS-OIG that "antitrust laws present a meaningful barrier to successfully achieving the goal of the Proposed Rule—negotiating lower drug costs." BlueCross BlueShield Association Comment Letter, *supra*, at 10. In particular, BlueCross identified the "reasonable expectation that some entities in the pharmaceutical industry will use th[e] history of antitrust litigation as a defense to avoid taking appropriate and necessary steps to negotiate up-front discounts that are at least equal in size to current rebate levels. The result would be higher net prices." *Id.*

237. Anthem echoed these concerns, explaining that it "met with several drug manufacturers" following the Proposed Rule's publication, "and not a single one ha[d] committed to convert rebates into discounts . . . due to concern for litigation resulting from th[e antitrust] legal settlement." Anthem Comment Letter, *supra*, at 4. Anthem described that it is not *actual* liability, but rather the *threat* of liability, that causes lower price concessions. Litigation under the Robinson-Patman Act "carries the potential for treble damages (and fees and costs)." *Id.* at 9. To mitigate this risk, "manufacturers may determine the lowest rebate that they are willing to give to a customer, and apply that same low rebate to all customers. In other words, in light of the potential for litigation, the manufacturers may be unwilling to offer some customers better discounts, and will use the threat of litigation as a shield to offer a lower discount to all." *Id.*

238. The AARP, National Business Group on Health, America's Health Insurance Plans, and Magellan Health all raised similar concerns, arguing that the Proposed Rule implicated antitrust law in a way that would prevent HHS-OIG from achieving its stated goals. *See* Nat'l Bus. Grp. on Health Comment Letter at 3 (Apr. 8, 2019) (explaining the Proposed Rule would "increase list prices by failing to address antitrust law," which "may prohibit manufacturers from offering the same level of price concessions through an upfront discounting system that they do currently by way of market share-based rebates"), https://bit.ly/3p9yNL4; AARP Comment Letter at 5 (Apr. 8, 2019) (similar), https://bit.ly/34rjiqi; Magellan Health Comment Letter, *supra*, at 30 (similar); AHIP Comment Letter, *supra*, at 18 (noting that "if HHS were to move forward with a proposal that shifts away from the existing rebate structure," "there would be significant uncertainty about the degree to which discounts would be available under the new structure").

239. HHS-OIG responded that it was "not persuaded that the threat of Robinson-Patman Act litigation will dissuade manufacturers from offering pro-competitive price concessions in the form of upfront discounts" because the 1996 settlement did not "ma[k]e any distinction between retrospective rebates and upfront discounts and did not result in any decision suggesting that the former are less problematic than the latter. Both retrospective rebates and upfront discounts, to the extent they are true price concessions, could theoretically be applied in a discriminatory fashion." *Rebate Rule*, 85 Fed. Reg. at 76669-70. HHS-OIG also relied on comments from pharmaceutical manufacturers who "pointed out that rebates do not occupy a unique position insulated from antitrust scrutiny." *Id.* at 76669.

240. HHS-OIG's answer was nonresponsive to the full problem before it. Some manufacturers may well decline to shift to a point-of-sale model because of potential antitrust liability. But more importantly, commenters did not simply raise concerns that upfront discounts violated antitrust law while rebates would not, such that manufacturers could not offer *any* price concessions in the form of upfront discounts. Instead, commenters raised concerns that manufacturers would not offer the same level of price concessions through upfront discounts that they offered through rebates because of antitrust laws—and if rebates are not converted into increased price concessions, then the Rebate Rule's goals will not be accomplished. *See* PCMA Comment Letter, *supra*, at 94-96; *see also supra* ¶¶ 104, 108, 201. HHS-OIG failed to explain why it believed that antitrust laws would not prevent increased price concessions.

241. HHS-OIG's inadequate response is underscored by its refusal to consult with the FTC, the federal agency with expertise in the antitrust field. HHS-OIG stated that it "does not administer antitrust law." *Rebate Rule*, 85 Fed. Reg. at 76670. But HHS-OIG rejected requests that it solicit an advisory opinion from the FTC "upon which stakeholders could rely" regarding

the applicability of antitrust law under the Rebate Rule to mitigate the risk created by the Rule. *Id.* HHS-OIG gave no indication that it had consulted with the FTC to solicit and incorporate the FTC's expertise on the significant antitrust issues raised by numerous commenters. Instead, immediately after conceding it lacked expertise in the field, HHS-OIG rested on its self-formed view that "whether the price discrimination is achieved by something labeled a 'rebate' versus something labeled a 'discount' would not be relevant for purposes of Robinson-Patman Act liability." *Id.*

5. The Rebate Rule Will Undermine Value-Based Arrangements

242. The Rebate Rule also threatens the continued use of value-based arrangements, which reward healthcare providers with incentive payments based on the quality of care provided. *See* CMS, *Value-Based Programs* (last updated Jan. 6, 2020), https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Value-Based-Programs. HHS has previously embraced the promotion of these arrangements as an important goal, but it now adopts a rule that will likely gut their effectiveness, without any satisfactory explanation for this abrupt change in position.

243. The Secretary has previously declared that "[v]alue-based transformation of our entire healthcare system is a top HHS priority." *HHS Blueprint*, 83 Fed. Reg. at 22696. The industry is making great strides in this regard under the existing safe harbor system. As of the middle of 2018, there were at least 40 value-based contracts underway between commercial or public payers and drug manufacturers. *See* PhRMA, *Value-Based Contracts: 2009 – Q2 2018* (June 21, 2018), http://phrma-docs.phrma.org/files/dmfile/PhRMA_ValueBasedContracts_Q2.pdf. Commercially insured patients in health plans with value-based contracts for diabetes, high cholesterol and HIV medicines had copays that were, on average, 28% lower for those medicines compared to patients in other plans. See PhRMA, *Value-Based Contracts May Lower Patients'*

Out-of-Pocket Costs by 28 Percent (Feb. 26, 2018), https://www.phrma.org/press-release/value-based-contracts-may-lower-patients-out-of-pocket-costs-by-28-percent. Many organizations participating in a recent CMMI demonstration chose prescription drug-based interventions, showing there is great appetite for value-based arrangements when all parties are adequately protected from risk. *See* CMS, *Medicare Advantage Value-Based Insurance Design Model* (last updated Dec. 14, 2020), https://innovation.cms.gov/initiatives/VBID.

244. In the Proposed Rule, HHS-OIG stated that it "d[id] not intend for this proposal to have *any effect* on existing protections for value-based arrangements between manufacturers and plan sponsors under Medicare Part D." *Proposed Rule*, 84 Fed. Reg. at 2348 (emphasis added). As PCMA warned in comments, however, the Rebate Rule will make the implementation of any value-based arrangements in Part D nearly impossible, outside of certain narrow exceptions. PCMA proposed several alternative rule changes that could preserve the ability to offer these arrangements on a prospective basis. *See supra* ¶ 118.

245. In an about-face, the Rebate Rule expressly recognized that "not all value-based pharmaceutical arrangements for Part D prescription drugs would fit into the revised discount safe harbor or the new safe harbor for point-of-sale reductions in price" (although some conceivably "might"). *Rebate Rule*, 85 Fed. Reg. at 76678. In other words, HHS-OIG *admitted* that the Rebate Rule did not comport with its previously announced "inten[tion]" to avoid "any effect" on "existing protections for value-based arrangements." *Proposed Rule*, 84 Fed. Reg. at 2348. But it refused without reasoned explanation to modify its safe harbors to carry out that professed intention.

246. Moreover, HHS-OIG compounded its error by immediately promulgating another regulation undermining the rationale of the Rebate Rule on this point. Just two days after

promulgating the Rebate Rule, HHS-OIG published another final rule modifying and adding several other safe harbors to the anti-kickback statute "for certain value-based arrangements that would improve quality, outcomes, and efficiency." *Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements*, 85 Fed. Reg. 77684, 77684 (Dec. 2, 2020). HHS-OIG promulgated those new safe harbors because it expressly recognized the "chilling effect" that could otherwise hinder "innovation" in this area, because value-based "arrangements in which providers and others coordinate the care of patients with other providers, share resources among themselves to facilitate better care coordination, share in the benefits of more efficient care delivery, and engage and support patients can implicate [the anti-kickback statute]." *Id.* HHS-OIG specifically *excluded* PBMs and others in the pharmaceutical market from eligibility for these safe harbors, even though the same dynamics apply to value-based arrangements in that context. *See id.* at 77685 ("entities ineligible to use the value-based safe harbors [include]: Pharmaceutical manufacturers, distributors, and wholesalers; pharmacy benefit managers (PBMs)"). The agency acknowledged "the role that PBMs serve in supporting value-based care." *Id.* at 77710. But it deemed their "unique" status to raise "different" issues beyond those "contemplated by this rulemaking" and therefore persisted in making them "ineligible to rely on the value-based safe harbors to protect remuneration." *Id.*

247. As a result of HHS-OIG's refusal to allow PBMs and drug manufacturers to utilize the new pathway of the value-based safe harbors, the discount safe harbor at issue here is the only viable option to protect most value-based arrangements in this context. The net effect of these two nearly simultaneous rulemakings is to remove a critical tool used to effectuate these arrangements, which are a high priority for HHS, and replace that tool with nothing at all.

248. The Rebate Rule's unfaithfulness to the priority of value-based arrangements represents unreasoned decisionmaking, because it departs without explanation from prior positions, contradicts the Department's own professed goals, and ignores an important aspect of the problem of drug costs by actively harming a greatly successful initiative that is already working to lower costs in this area.

C. HHS-OIG Failed To Comply With The Procedural Requirements For Amending The Regulatory Safe Harbors

249. The Rebate Rule is also unlawful because HHS-OIG failed to comply with two procedural requirements for amending the regulatory safe harbor for discounts: (1) the APA's notice-and-comment-rulemaking requirement; and (2) the anti-kickback statute's requirement that HHS-OIG consult with the Attorney General before proposing any amendment to the regulatory safe harbors.

1. The Rebate Rule Was Not Promulgated With The Required Notice-And-Comment

250. The APA requires rules to undergo notice-and-comment procedures, absent certain statutory exceptions that HHS-OIG did not invoke in promulgating the Rebate Rule. 5 U.S.C. § 553(b)-(c). HHS-OIG promulgated the Rebate Rule unlawfully by failing to provide a notice-and-comment period after it withdrew the Proposed Rule.

251. HHS-OIG issued its Proposed Rule to eliminate the discount safe harbor on February 6, 2019. *See Proposed Rule*, 84 Fed. Reg. at 2340. The comment period on the Proposed Rule closed on April 8, 2019. *Id.*

252. HHS-OIG withdrew the Proposed Rule on July 10, 2019.

253. Following the Proposed Rule's withdrawal, regulated entities reasonably viewed HHS as having abandoned its plan to revise the discount safe harbor, and regulated entities had

no reason to anticipate that HHS would issue final, binding regulations eliminating the discount safe harbor without providing any additional opportunities to comment.

254. Because HHS-OIG's withdrawal terminated the first rulemaking process, new notice-and-comment procedures were required before HHS-OIG could adopt or issue any rule revising the discount safe harbor regulation or adding two new safe harbors.

255. The need for a new notice-and-comment period was particularly strong because more than a year had passed since HHS-OIG withdrew the Proposed Rule, and additional evidence—including the CBO Analysis cited in the final Rebate Rule—was published *after* the initial period for public comment had closed. Given that the CBO disagreed with the central premise of the Rebate Rule, HHS-OIG was required to give the public an additional opportunity to weigh in on the agency's plan to push forward with a final rulemaking.

256. HHS-OIG did not undertake new notice and comment procedures before issuing the Rebate Rule. *Rebate Rule*, 85 Fed. Reg. at 76666. Accordingly, the regulation is arbitrary, capricious, was adopted without observance of procedure required by law, and is otherwise not in accordance with law.

2. HHS-OIG Failed To Consult With The Attorney General Before Proposing The Rebate Rule

257. Even if HHS-OIG's February 2019 notice of proposed rulemaking could be considered part of the same rulemaking process through which the final Rebate Rule was promulgated, that rulemaking process would still be unlawful because there is no evidence that HHS-OIG consulted with the Attorney General before publishing the Proposed Rule.

258. The Medicare and Medicaid Patient and Program Protection Act of 1987 instructed the HHS Sectary to promulgate the initial set of regulatory safe harbors "not later than 2 years after the date of the enactment." Pub. L. No. 100-93, § 14(a), 101 Stat. at 697. But the

1987 statute did not authorize the Secretary to *amend* these safe harbors once they were promulgated.

259. Congress gave the Secretary that power in 1996 in the Health Insurance Portability & Accountability Act of 1996, Pub. L. No. 104-191, § 205, 110 Stat. 1936, 2001 (Aug. 21, 1996), which codified the authority at 42 U.S.C. § 1320a-7d(a)(2). *See Rebate Rule*, 85 Fed. Reg. at 76667 (noting that § 1320a-7d provides authority for "modifying" safe harbors).

260. The process for amending regulatory safe harbors is set forth in § 1320a-7d(a)(1)(B). *See also* 42 U.S.C. § 1320a-7d(a)(2) (setting forth criteria for "modifying and establishing safe harbors *under paragraph* (*1*)(*B*)" (emphasis added)). That subsection, in turn, (a)(1)(B), authorizes the Secretary to "issue final rules modifying the existing safe harbors" only after: (1) publishing proposed modifications in the Federal Register "in consultation with the Attorney General"; (2) soliciting public comment during a 60-day comment period; and (3) "considering any public comments received during this period." *Id.* § 1320a-7d(a)(1)(B). HHS-OIG was therefore required to consult with the Attorney General before issuing its notice of proposed rulemaking.

261. HHS-OIG apparently ignored this requirement. The agency issued a notice of proposed rulemaking in February 2019 and a final rule in November 2020, but never stated or suggested that it had "consult[ed] with the Attorney General" or that either document had been issued based on such a consultation. 42 U.S.C. § 1320a-7d(a)(1)(B). Accordingly, the regulation is arbitrary, capricious, was adopted without observance of procedure required by law, and is otherwise not in accordance with law.

COUNT I
(CONTRARY TO LAW)

262. Plaintiff incorporates the preceding paragraphs as if fully set forth herein.

263. The Rebate Rule constitutes final agency action.

264. PCMA and its members are adversely affected and aggrieved by the regulation.

265. The Rebate Rule exceeds the Department's statutory authority because it removes from the protections of the *regulatory* safe harbor for discounts conduct that is unambiguously protected under the plain text of the *statutory* discount exception.

266. The Rebate Rule also violates the Medicare Act. It violates that statute's non-interference clause because it "interfere[s] with the negotiations between drug manufacturers and pharmacies and [Part D plan] sponsors." 42 U.S.C. § 1395w-111(i)(1). And it impermissibly "institute[s] a price structure for the reimbursement of covered [P]art D drugs." *Id*. § 1395w-111(i)(2).

267. Accordingly, the Rebate Rule is not in accordance with law, in violation of 5 U.S.C. § 706(2)(A), and in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, in violation of 5 U.S.C. § 706(2)(C).

COUNT II
(ARBITRARY AND CAPRICIOUS)

268. Plaintiff incorporates the preceding paragraphs as if fully set forth herein.

269. HHS-OIG's decision to promulgate the Rebate Rule was arbitrary and capricious. Among other things, HHS-OIG failed: to engage in reasoned decisionmaking; to acknowledge and provide good reasons for changing policy positions; to meaningfully consult with, respect the views of, and grapple with evidence presented by other agencies that possess subject-matter expertise; to act in accordance with the evidence before it; to consider important aspects of the problem it believed it faced; to provide an adequate explanation for its decision; to address and adequately account for reliance interests on an earlier policy; to adequately assess the implications of other laws on the Rule; to respond adequately to significant arguments raised in

comments; and to promulgate the Rebate Rule in accordance with required notice-and-comment procedures.

270. Accordingly, the Rebate Rule is arbitrary, capricious, and is otherwise not in accordance with law, in violation of 5 U.S.C. § 706(2)(A), and was promulgated without observance of procedures required by law, in violation of 5 U.S.C. § 706(2)(D).

COUNT III
(DECLARATORY JUDGMENT)

271. Plaintiff incorporates the preceding paragraphs as if fully set forth herein.

272. Pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, "any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought."

273. HHS-OIG has emphatically denied that "the way many types of rebates have been used" qualifies for the statutory exception for discounts. *Rebate Rule*, 85 Fed. Reg. at 76690; *accord Proposed Rule*, 84 Fed. Reg. at 2343 ("In the Secretary's view, moreover, the statutory exemption for discounts (42 U.S.C. 1320a-7b(b)(3)(A)) does not apply to most rebates paid by drug manufacturers to part D plans . . . ."). And it has made clear that any rebate arrangement that "implicates the anti-kickback statute and does not satisfy an exception or safe harbor would be subject to scrutiny" and face potential "criminal penalties." *Rebate Rule*, 85 Fed. Reg. at 76679.

274. HHS-OIG's threat to subject the industry's current retrospective rebate practices to federal anti-kickback liability by eliminating the regulatory safe harbor for discounts and simultaneously denying that the statutory exception applies creates substantial uncertainty for PBMs, plans, and manufacturers that will chill the industry from continuing current rebate

practice, even though—contrary to HHS-OIG's assertions—those practices are entirely lawful under the statute.

275. As a result, there exists a substantial controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that rebates negotiated between pharmaceutical manufacturers and PCMA's members do in fact qualify for the statutory exception for discounts.

PRAYER FOR RELIEF

Plaintiff prays that this Court:

1) Declare the Rebate Rule unlawful.

2) Vacate and set aside the Rebate Rule.

3) Issue all process necessary and appropriate to postpone the effective date of the Rebate Rule and to maintain the status quo pending the conclusion of this case.

4) Declare that the statutory discount exception protects retrospective rebates paid to Part D plan sponsors and PBMs.

5) Award Plaintiff its costs and reasonable attorney's fees as appropriate.

6) Grant such further and other relief as this Court deems just and proper.

Respectfully submitted,

Dated: January 11, 2021

/s/ Helgi C. Walker

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