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Exposing the Middlemen in Rising
Drug Costs: Modifying Safe Harbor
Protections for Pharmacy Benefit
Manager Rebates Under Federal
Anti-Kickback Statutes

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INTRODUCTION

Pharmacy Benefit Managers (PBMs) have, until very recently, largely escaped public scrutiny or possibly even public consciousness. Although relatively unknown to the average American healthcare consumer, specialized healthcare companies known as PBMs play a direct role in negotiating pharmaceutical drug prices for more than 266 million Americans.¹

Rising pharmaceutical costs, on the other hand, invaded the public consciousness in 2016 when a dramatic increase in the price of pharmaceutical company Mylan's EpiPen sparked outrage across the country.² In 2007, Mylan bought the rights to produce the EpiPen, an autoinjector that delivers epinephrine to those experiencing an anaphylactic reaction.³ When Mylan acquired the rights to the EpiPen, a pack of two EpiPens cost consumers around \$100. By 2016, a pack of two EpiPens had risen by an inexplicable 450%, totaling more than \$600 per pack.⁴

Those consumers battling allergies and rising drug costs were not alone. Diabetes patients have experienced a doubling in the price of insulin since 2011, with some consumers' out-of-pocket costs increasing from \$40 to \$600 for a six-week supply.⁵ Parents of children suffering from a catastrophic form of epilepsy known as infantile spasms also recently saw the price of Acthar, which stops infantile spasms, catapult from \$1,600 per vial in the year 2000 to more than

¹ Cole Werble, *Prescription Drug Pricing: Pharmacy Benefit Managers*, HEALTH AFFAIRS (Sept. 14, 2017), https://www.healthaffairs.org/doi/10.1377/hpb20171409.000178/full/healthpolicybrief_178.pdf [<https://perma.cc/8LDC-QBYJ>].

² Tara Parker-Pope & Rachel Rabkin Peachman, *EpiPen Price Rise Sparks Concern for Allergy Sufferers*, N.Y. TIMES (Aug. 22, 2016, 6:05 PM), <https://well.blogs.nytimes.com/2016/08/22/epipen-price-rise-sparks-concern-for-allergy-sufferers/> [<https://perma.cc/WG97-G2M9>].

³ *Id.*

⁴ *Id.*

⁵ Denise Roland & Peter Loftus, *Insulin Prices Soar While Drugmakers' Share Stays Flat*, WALL ST. J. (Oct. 7, 2016, 5:46 PM), <https://www.wsj.com/articles/insulin-prices-soar-while-drugmakers-share-stays-flat-1475876764> [<https://perma.cc/R52C-TXQE>].

\$39,000 per vial by 2018.⁶ These crippling price increases were met with suspicion by journalists who raised the question of whether the increasing costs were not organic but driven in part by the role that PBMs play in the healthcare industry.⁷

Slowly, the PBM industry is being forced out of its comfortable, relative obscurity. The attention on PBMs has led to congressional hearings, legislation at both the federal and state levels, and a reignited debate regarding the ways in which the government should intervene in the pharmaceutical drug pricing crisis.⁸

Most recently, the Department of Health and Human Services (HHS) has further increased public awareness of PBMs' important role in drug pricing by proposing rule changes that will decimate the most important aspect of PBMs' business model: the rebates they negotiate with drug manufacturers.⁹ However, these rebates have also been championed as one of the only ways the healthcare marketplace can force down drug prices that are otherwise almost exclusively controlled by drug manufacturers themselves.¹⁰

This Comment will first describe PBMs, drug rebate pricing, and the federal statutory scheme that governs PBMs' current practices. In Part II, this Comment will outline recent federal rules proposed to eliminate PBMs' current rebate practices. In Part III, this Comment will argue that although the rebate structure that PBMs operate under is ripe for reform, the scorched-earth regulatory approach recently proposed by the Department of Health and Human Services goes too far and may

⁶ Wayne Drash, *Anatomy of a 97,000% Drug Price Hike: One Family's Fight to Save Their Son*, CNN (June 29, 2018, 3:15 PM), <https://www.cnn.com/2018/06/29/health/acthar-mallinckrodt-questcor-price-hike-trevor-foltz/index.html> [<https://perma.cc/TY2M-DKK5>].

⁷ Roland & Loftus, *supra* note 5.

⁸ Shradha Singh & Yasmeen Abutaleb, *U.S. Congress Invites Pharmacy Benefit Managers to Third Drug Pricing Hearing*, REUTERS (Mar. 12, 2019, 6:12 PM), <https://www.reuters.com/article/us-usa-healthcare-drugpricing/u-s-congress-invites-pharmacy-benefit-managers-to-third-drug-pricing-hearing-idUSKBN1QU04O> [<https://perma.cc/FKR6-QN9L>]; Colleen Becker, *PBM Legislation: States Regulating Pharmaceutical Benefit Managers*, NAT'L CONF. OF ST. LEGISLATURES, (May 16, 2019), <http://www.ncsl.org/research/health/pbm-state-legislation.aspx> [<https://perma.cc/U7QF-EJRQ>].

⁹ Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals, 84 Fed. Reg. 2340 (proposed Feb. 6, 2019) [hereinafter Removal of Safe Harbor Protection] (to be codified at 42 C.F.R. pt. 1001).

¹⁰ VISANTE, PHARMACY BENEFIT MANAGERS (PBMS): GENERATING SAVINGS FOR PLAN SPONSORS AND CONSUMERS 3 (2011), <https://www.pcmnet.org/wp-content/uploads/2016/08/pr-dated-09-19-11-pbms-savings-study-2011-final-2.pdf> [<https://perma.cc/AX6C-K3DH>].

instead end up hurting those at the heart of this debate: American patients. Instead, supporters of increased PBM regulation in the current administration, and on both sides of the aisle in Congress, should channel their energy for drug pricing reform into moderate oversight regulations that do not place the entire PBM industry, and the discounts they are currently responsible for, at risk.

I

HOW PHARMACEUTICAL MIDDLEMEN PROFIT

A. Pharmacy Benefit Managers

When legislators began the process of reforming pharmaceutical costs, targeting a single aspect of the drug industry for reform proved difficult.¹¹ No sector of the complex web of healthcare companies involved in drug distribution has stepped up to claim responsibility for the rising costs. Health plans, drug manufacturers, wholesalers, and pharmacies all seem content with the strategy of shifting blame to each other.¹² Although the most obvious target for reform may be the drug companies who control drugs' patents, recent proposals for reform at the state and federal levels have focused on a lesser-known player in the drug delivery system: Pharmacy Benefit Managers (PBMs).¹³

Although little known to most consumers, PBMs administer drugs for health plans, including commercial and government employee plans, which cumulatively cover more than 266 million Americans.¹⁴ Within the field, three publicly traded PBMs—Express Scripts, OptumRx (a subsidiary of UnitedHealth Group), and CVS Caremark (a subsidiary of the CVS drugstore chain) represent almost 70% of the 266 million Americans and collect more than \$200 billion per year to manage these plans.¹⁵

¹¹ Avik Roy, *Drug Companies, Not 'Middlemen', Are Responsible for High Drug Prices*, FORBES (Oct. 22, 2018, 11:02 PM), <https://www.forbes.com/sites/theapothecary/2018/10/22/drug-companies-are-responsible-for-high-drug-prices-not-middlemen/#5f4b8ce04947> [https://perma.cc/M48Q-M6EF].

¹² *Id.*

¹³ Nathaniel Weixel, *Top Republicans Concerned Over Impact of Potential Trump Drug Rule*, THE HILL (Aug. 9, 2018, 1:08 PM), <https://thehill.com/policy/healthcare/401102-lawmakers-concerned-over-economic-cost-of-potential-drug-rebate-rule> [https://perma.cc/B6ZJ-FJZ8].

¹⁴ Thomas A. Hemphill, *The "Troubles" with Pharmacy Benefit Managers*, 40 REGULATION (Spring 2017), at 14, 14.

¹⁵ Michael Hiltzik, *How 'Price-Cutting' Middlemen Are Making Crucial Drugs Vastly More Expensive*, L.A. TIMES (June 9, 2017, 12:00 PM), <http://www.latimes.com/business/hiltzik/la-fi-hiltzik-pbm-drugs-20170611-story.html> [https://perma.cc/HJ7Q-TVJ4].

A patient's actual interaction with a PBM begins when they go to a pharmacy to pick up a prescription drug covered by their health plan. When a patient enters a pharmacy with a prescription, the pharmacist looks up whether the patient has prescription drug coverage. If the pharmacist confirms that the patient has prescription drug coverage, the pharmacist fills the prescription, and the patient then pays the requisite co-pay, depending on the patient's own healthcare plan. The rest of the cost of the drug is then covered by the patient's health plan. Although this process is well known to American consumers of prescription drugs, many are unaware that the price they pay has been directly negotiated by the PBM their pharmacy contracts with.¹⁶

PBMs act as middlemen between manufacturers and those who pay for the medications, such as insurers.¹⁷ Each PBM usually acts on behalf of multiple private insurer clients. PBMs market their role as cost-savers, building up a large enough client base and leveraging their market share of consumers to negotiate a better market price with the drugs' manufacturers.¹⁸

PBMs also hold leverage when negotiating with drug manufacturers because of the "formularies" of drugs they offer to their clients.¹⁹ A PBM's formulary is essentially a hierarchical list of approved drugs their client pharmacies can then prescribe,²⁰ meaning PBMs put together lists of drugs, based on pricing and treatment options, that a health plan may cover. Then, when patients arrive at a pharmacy to fulfill a prescription, pharmacists use this list to make sure the patient's health plan covers the drug.²¹ This list includes not only the names of drugs approved and purchased by the PBMs but also the methodology a doctor or insurer must use to prescribe medicine to their patients.²² Therefore, a PBM has significant control over which drugs a consumer has access to. This list is continually updated based on the deals a PBM

¹⁶ Joanna Shepherd, *The Fox Guarding the Henhouse: The Regulation of Pharmacy Benefit Managers by a Market Adversary*, 9 NW. J.L. & SOC. POL'Y 1, 5 (2013).

¹⁷ STAN FINKELSTEIN & PETER TEMIN, REASONABLE RX: SOLVING THE DRUG PRICE CRISIS 24 (2008).

¹⁸ Shepherd, *supra* note 16, at 5.

¹⁹ Hemphill, *supra* note 14, at 14.

²⁰ CVS CAREMARK, FORMULARY DEVELOPMENT AND MANAGEMENT AT CVS CAREMARK (2018), <https://www.caremark.com/portal/asset/FormDevMgmt.pdf> [<https://perma.cc/CT8N-EYW4>].

²¹ Joseph C. Bourne & Ellen M. Ahrens, *Healthcare's Invisible Giants: Pharmacy Benefit Managers*, FED. LAW 50 (2013).

²² *Id.*

makes, and drug companies fight to be on approved formulary lists so their medications can be prescribed to large swaths of consumers.²³ PBMs, such as CVS Caremark, say they use formularies to create affordable and clinically sound plans and to help manage drug spending by guiding the appropriate selection and use of drug therapy.²⁴

Regardless of the arguable merits of the formulary system, the inherent competitive nature of formularies makes them susceptible to manipulation by drug manufacturer pricing practices and thus an area future regulations may focus on.

B. Rebates

PBMs typically receive a majority of their profit from both administrative fees and the rebates they collect from drug manufacturers.²⁵ When negotiating formulary placement and drug pricing, manufacturers typically pay rebates to PBMs for increases in market share and use of their products.²⁶ The higher the manufacturer sets the net gross cost of the drug, the higher the rebate the PBM receives.²⁷ Hypothetically, these rebates are designed to lower the overall cost of drugs with the discounted price from the rebate being passed onto the consumer; this is hypothetical because PBMs do not have to reveal the amount of rebates they negotiate with drug manufacturers to the insurers on the other side of PBM contracts.²⁸ The opaqueness of rebate rates has prompted widespread concern that PBMs may be keeping a portion of the rebates for their own financial benefit rather than passing on the incentive to the patient or retail pharmacy.²⁹

²³ *See id.*

²⁴ CVS CAREMARK, *supra* note 20.

²⁵ Greg Radinsky, *The Spotlight on PBMs: Federal Enforcement of the Anti-Kickback Statute on the Pharmaceutical Benefit Management Industry*, 36 J. HEALTH L. 213, 218 (2003).

²⁶ PRICEWATERHOUSECOOPERS LLP, STUDY OF PHARMACEUTICAL BENEFIT MANAGEMENT 9 (2001), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/cms_2001_4.pdf [<https://perma.cc/Z4GZ-4ZFG>].

²⁷ Jonathan D. Rockoff, *Behind the Push to Keep Higher-Priced EpiPen in Consumers' Hands*, WALL ST. J. (Aug. 6, 2017, 5:01 PM), <https://www.wsj.com/articles/behind-the-push-to-keep-higher-priced-epipen-in-consumers-hands-1502036741> [<https://perma.cc/D3D9-PZVR>].

²⁸ *Id.*

²⁹ Hemphill, *supra* note 14, at 16.

As an example of a suspicious rebate, from 2011 to 2016 the manufacturer's list price for the insulin known as Humalog more than doubled to \$254.80 per vial.³⁰ However, after paying out rebates to the PBMs that listed the drug, the manufacturer collected less revenue at the higher list price than at the previous lower price.³¹ The manufacturer's explanation for the phenomenon of higher list prices with no corresponding increase in net profit is that PBMs demanded higher rebates.³² The PBMs also keep their administrative fee, paid by manufacturers for administrative tasks PBMs perform, which is based on a percentage of the list price.³³

Although the Humalog insulin example demonstrates the correlating rise in PBM revenue from rebates and the increase in drug costs, PBMs maintain that the drug manufacturers are the entities that actually raise the cost of the drugs.³⁴ However, although PBMs may not explicitly demand that drug manufacturers raise the net price of their drugs, the manufacturers know that an increased price, which allows for an increased rebate and administrative fee, will lead to better placement on the PBM's formulary. Because manufacturers want PBMs to assign them better formulary placements than their direct competitors in order to have manufacturers' drugs prescribed to more patients, manufacturers will raise the list price of the drugs in order to increase the possible rebate amount. After purchase by a consumer, the rebate is then mailed to the patient's plan sponsor, such as an employer or the government, and the drug price is thereby reduced for the insurer. However, this means that any rebate applied to a drug does not directly benefit consumers at the pharmacy, but ideally provides benefits to consumers by lowering their overall premiums.

Regardless of the way rebates are characterized by other healthcare stakeholders, PBMs claim, in comments made on pending regulations, that rebates are an unavoidable result of antitrust lawsuits against drug manufacturers in the 1990s.³⁵ Prior to the lawsuits, drug manufacturers

³⁰ Roland & Loftus, *supra* note 5.

³¹ *Id.*

³² *Id.*

³³ *Id.*

³⁴ Jacklyn Wille, *CVS, Express Scripts Sued Over EpiPen Pricing*, BLOOMBERG LAW (June 5, 2017, 8:30 AM), <https://news.bloomberglaw.com/employee-benefits/cvs-express-scripts-sued-over-epipen-pricing> [<https://perma.cc/7YCZ-VP9C>].

³⁵ PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, ANTITRUST CONSIDERATIONS OF PROPOSALS TO LIMIT REBATES (2018), <https://www.pcmnet.org/wp->

offered discounts on drugs to preferred classes of customers such as hospitals, health maintenance plans, mail-order companies, and other companies with large customer bases.³⁶ This is in contrast to the current system, where manufacturers do not directly give discounts to these parties, but pass along cost savings by negotiating rebates with PBMs. Pharmacies alleged that while they were stuck paying full price for drugs, manufacturers would make contracts with favored customers who enjoyed large market shares. Those contracts allowed such customers to purchase drugs at a discounted rate from wholesalers, and the manufacturers would then reimburse the wholesalers.³⁷

Judge Posner and the Seventh Circuit found that this type of price discrimination, made possible by the manufacturers' power to raise drug prices above the cost charged for some customers without losing customers, was evidence of the manufacturers' monopoly power.³⁸ Manufacturers feared drawn-out litigation, as the court found merit in the early stages of the pharmacies' claims and characterized manufacturers' up-front discount practices as collusion among drug manufacturers to keep prices artificially high for some customers. Rather than continuing to fight through litigation, the drug manufacturers settled without admitting wrongdoing.³⁹ As a part of the settlement with affected pharmacies, drug manufacturers were required to offer pharmacies the same discounts offered to customers with larger market shares and commit to ending two-tiered pricing driven by up-front discounting.⁴⁰

The result of this case left a gap in the healthcare industry where manufacturers' past methods of providing up-front discounts once stood. To fill the gap, manufacturers needed to find a way to still offer discounts to only those providers that had a large enough patient base to make the discounts profitable.⁴¹ In place of up-front discounts,

content/uploads/2018/07/Legal-Analysis_-Antitrust-Considerations-of-Proposals-to-Limit-Rebates.pdf [https://perma.cc/G66W-S6WR] [hereinafter PCMA].

³⁶ *In re* Brand Name Prescription Drugs Antitrust Litigation, 123 F.3d 599, 603 (7th Cir. 1997).

³⁷ *Id.*

³⁸ *Id.*

³⁹ Edwin McDowell, *Judge Agrees to Settlement in Drug Case*, N.Y. TIMES (June 22, 1996), <https://www.nytimes.com/1996/06/22/business/judge-agrees-to-settlement-in-drug-case.html> [https://perma.cc/QB5M-75YF].

⁴⁰ *Id.*

⁴¹ Katie Gudiksen, *A Drug Rebate's Tale: How a Class Action Lawsuit in the 90s Shaped Drug Pricing*, SOURCE ON HEALTHCARE PRICE & COMPETITION: THE SOURCE BLOG (Feb. 24, 2018), <http://sourceonhealthcare.org/a-drug-rebates-tale-how-a-class-action-lawsuit-in-the-1990s-shaped-drug-pricing> [https://perma.cc/F938-VZF9].

manufacturers moved to offering back-end rebates through PBMs. Manufacturers give these rebates after dispensing pharmacies verify that government and commercial insurance plans have met certain volume of sales requirements.⁴² Thus, manufacturers avoid antitrust concerns by hypothetically offering uniform rebates to any payer regardless of size, but can continue actually granting rebates only to preferred, large payers by awarding rebates to insurance companies only after they demonstrate a threshold amount of drug sales for a particular drug of the manufacturer.⁴³

Thus, although the rebate system has evolved into the modern-day system of opaque and intricate back-end discounts on drugs, PBMs continue to argue that rebates are the only way to discount drugs following the antitrust litigation.⁴⁴ With up-front discounts banned by the terms of the PBMs' settlement, PBMs argue that rebates are the only substitution that ensures some way of negotiating lower drug prices with manufacturers.⁴⁵

C. Federal Enforcement Mechanisms

Following the Seventh Circuit's decision, which drew attention to the enduring secretive nature of PBMs even after the move away from up-front discounts, the federal government has undertaken several initiatives to further reform the rebate system.

1. Prior Legislative Initiatives

In recent years, there has been increased federal attention on mechanisms available to hold healthcare companies accountable for opaque rebate arrangements. For instance, in 2009 the Department of Health and Human Services (HHS) created the Health Care Fraud Prevention and Action Team initiative to reduce fraud or hidden arrangements in the Medicare and Medicaid systems.⁴⁶

Through this initiative, allegations by the Department of Justice of PBMs violating the Anti-Kickback Statute (AKS) have led to multiple

⁴² PCMA, *supra* note 35.

⁴³ Gudiksen, *supra* note 41.

⁴⁴ PCMA, *supra* note 35.

⁴⁵ *Id.*

⁴⁶ Martha M. Rumore & F. Randy Vogenberg, *PBM P&T Practices: The HEAT Initiative Is Gaining Momentum*, 42 HEALTH CARE & L. 330, 330 (2017).

settlements with PBMs.⁴⁷ Via the False Claim Act,⁴⁸ these suits generally alleged that while providing drugs for Medicaid and Medicare, PBMs negotiated rebate agreements with manufacturers in exchange for primary formulary status and did not disclose these rebates to the government. These private financial agreements were considered a kickback.⁴⁹

More recent legislative initiatives have gone beyond these efforts focused on individual PBM transactions as violations of the AKS and have criticized all PBM-induced manufacturer rebates as a potential form of kickback prohibited by the federal AKS as a class.⁵⁰

2. *The Anti-Kickback Statute*

The federal AKS makes it illegal for any company to “knowingly and willfully” solicit, receive, offer, or pay “any remuneration (including any kickback, bribe, or rebate) directly or indirectly” in return for the referral of patients or purchasing, leasing, or arranging or recommending the purchase or lease of items or services reimbursable by Medicare or any other federal healthcare program.⁵¹ Any company found guilty of these AKS offenses can be fined up to \$100,000 per violation.⁵²

According to the current Department of Health and Human Services, Congress’s intent behind using the term “remuneration” was to encompass the transfer of anything of value whatsoever.⁵³ This includes payments made discretely or in the open and all types of payments, including both cash and in-kind.⁵⁴ However, because of the broad reach of the statute and concern that the wording would capture innocent commercial transactions, Congress later mandated the formulation of safe harbor provisions to specify certain business transactions that would not be subject to sanctions under the act.⁵⁵ The safe harbors describe payments and business practices that may potentially be implicated by Anti-Kickback rules, but that Congress has

⁴⁷ DEP’T OF JUSTICE, OFFICE OF PUB. AFFAIRS, *ASTRAZENECA TO PAY \$7.9 MILLION TO RESOLVE KICKBACK ALLEGATIONS* (2015), <https://www.justice.gov/opa/pr/astrazeneca-pay-79-million-resolve-kickback-allegations> [<https://perma.cc/P8GV-NVVJ>].

⁴⁸ *Id.*

⁴⁹ Rumore & Vogenberg, *supra* note 46.

⁵⁰ Radinsky, *supra* note 25, at 219.

⁵¹ 42 U.S.C. § 1320(b)(1)–(2) (2018).

⁵² *Id.* § 1320(b)(2).

⁵³ Removal of Safe Harbor Protection, 84 Fed. Reg. at 2345.

⁵⁴ *Id.*

⁵⁵ *Id.*

decided not to treat as offenses under the statute.⁵⁶ Transactions that do not fall under a specific safe harbor are not automatically illegal, but are more likely to be considered an impermissible kickback.⁵⁷

Currently, the AKS contains five limited exceptions to activities potentially classified as kickbacks: (1) a properly disclosed discount; (2) certain payments from an employer to employee; (3) amounts paid to certain purchasing agents; (4) waivers of coinsurance under Part B; and (5) remunerations in a risk-sharing arrangement.⁵⁸ The statute also provides an exception for any payment practice specified by the Secretary of Health and Human Services in regulations.⁵⁹

Since the AKS was established prior to Congress involving the federal government in the purchase of prescription drugs via the Medicare Part D program, the AKS does not directly address the purchase of prescription drugs or the use of rebates.⁶⁰ Although PBMs and the rebates they use do not directly fall under existing safe harbor exceptions, rebates between insurance plans, including government-run Medicare plans, have been impliedly permitted by federal law because the rebates are not expressly barred under the AKS.⁶¹

3. The Discount Safe Harbor

Up until the current administration,⁶² PBM rebates have been presumed by the healthcare industry to be analogous to the “discount” safe harbor and thereby allowable under federal law.⁶³ The discount safe harbor allows for discounts on an item or service for which payment may be made on behalf of a federal healthcare program.⁶⁴ A “discount” is defined as a “reduction in the amount a buyer . . . is

⁵⁶ Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88,368, 88,368 (Dec. 7, 2016) (to be codified at 42 C.F.R. pt. 1001).

⁵⁷ Radinsky, *supra* note 25, at 222.

⁵⁸ 42 U.S.C. § 1320(b)(3) (2018).

⁵⁹ *Id.* § 1320(b)(3)(E).

⁶⁰ Removal of Safe Harbor Protection, 84 Fed. Reg. at 2346.

⁶¹ Stephanie Armour & Joseph Walker, *Trump Administration Moves to Curb Drug Rebates in Medicare, Medicaid*, WALL ST. J. (Jan. 31, 2019, 7:34 PM), <https://www.wsj.com/articles/u-s-proposes-curbing-drug-rebates-in-some-medicare-medicaid-plans-11548971322?mod=searchresults&page=1&pos=4> [<https://perma.cc/X2GU-4VMS>].

⁶² Removal of Safe Harbor Protection, 84 Fed. Reg. at 2343.

⁶³ Radinsky, *supra* note 25, at 223.

⁶⁴ 42 C.F.R. § 1001.952(h) (2018).

charged for an item or service”⁶⁵ Discounts cannot include cash payments, but include “rebates,” defined as a discount whose terms 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.”⁶⁶ In order for a discount to be protected under the safe harbor, it must be earned based on purchases of the same good, claimed in the same fiscal year in which the discount was earned, and the buyer must fully and accurately report the discount in the fiscal year in which the discount is earned.⁶⁷

The Office of the Inspector General (OIG) has released guidance that a tiered, percentage-based rebate program—similar to the structure of PBM rebates—would be covered by the discount safe harbor.⁶⁸ The OIG reasoned that where the discount on one product was not contingent on the purchase of another product, the discount would be dependent on items purchased.⁶⁹ This rebate structure would then permissibly constitute a rebate because the terms are set out at the time of purchase, even though the rebate is redeemed at a later date.⁷⁰

The structure of PBM rebates does not directly qualify under the discount safe harbor because PBMs do not directly buy drugs from the manufacturers. Instead, health insurance providers purchase the drugs directly from the manufacturers. Indeed, Alex Azar, the current Secretary of HHS, has expressly declared that he does not believe the discount safe harbor covers rebates.⁷¹

If PBM rebates are not covered by the discount safe harbor, such rebates will be subject to sanctions under the AKS. To combat this new interpretation, going forward, PBMs could highlight previous administrations’ acceptance of their practices under the AKS and argue their structure of rebates is very similar to the percentage-based rebates approved by the OIG. Additionally, PBMs could adhere closely to the reporting requirements imposed on discounts and proactively report the specific rebates they receive from manufacturers. As the current Federal Drug Administration (FDA) Commissioner, Scott Gottlieb, has

⁶⁵ *Id.* § 1001.952(h)(5).

⁶⁶ *Id.* § 1001.952(h)(4).

⁶⁷ *Id.* § 1001.952(h)(1)(ii).

⁶⁸ Dep’t of Health & Human Servs., Office of Inspector Gen., Opinion Letter on No. 13-07, 2 (July 1, 2013), <https://oig.hhs.gov/fraud/docs/advisoryopinions/2013/advopn13-07.pdf> [<https://perma.cc/ZP7F-GEJX>] [hereinafter Opinion Letter].

⁶⁹ *Id.*

⁷⁰ *Id.* at 6.

⁷¹ Removal of Safe Harbor Protection, 84 Fed. Reg. at 2340.

repeatedly stressed in speeches, one of the healthcare community's largest issues with PBMs is the lack of transparency regarding whether or not the entire rebate is being passed on to consumers.⁷² By proactively adhering as closely as possible to the existing transparency requirements, PBMs may effectively argue their rebate structure should similarly be protected.

II

RECENT FEDERAL ATTEMPTS TO REMOVE SAFE HARBOR APPLICABILITY

Following up on his campaign promise to bring down drug prices,⁷³ President Trump has focused aspects of his strategy on undoing the rebate system that PBMs rely on. Following the President's Council of Economic Advisors' criticism of the significant market power and opaqueness of the PBM industry, in February 2018 the Health and Human Services Agency released regulations aimed at breaking up the PBM industry.⁷⁴

The administration signaled its intent to drastically alter the rebate system in May 2016 when the HHS released a request for information (RFI) entitled, "HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs."⁷⁵ Within the RFI, HHS relied on the premise that "[i]ncreasingly higher rebates in Federal health care programs may be causing higher list prices in public programs, and increasing the prices paid by consumers."⁷⁶ HHS sought comments directly on the impact of rebates on drug pricing, asking, "What incentives or regulatory changes (e.g., removing the discount safe harbor) could restrict the use of rebates and reduce the effect of rebates on list prices?"⁷⁷

⁷² Angelica LaVito, *FDA Commissioner to Drug Middlemen: You're Part of the Problem*, CNBC (Apr. 19, 2018, 4:25 PM), <https://www.cnbc.com/2018/04/19/fda-commissioner-to-drug-middlemen-youre-part-of-the-problem.html> [<https://perma.cc/EGP3-TMUY>].

⁷³ Kerry Close, *Donald Trump's New Promise: I Will 'Bring Down Drug Prices,'* MONEY (Dec. 7, 2016, 12:36 PM), <http://time.com/money/4593536/donald-trump-person-of-the-year-drug-prices> [<https://perma.cc/3K3B-N5YW>].

⁷⁴ David Dayen, *Trump Eliminates the Middleman*, AM. PROSPECT (July 27, 2018), <http://prospect.org/article/trump-eliminates-middleman> [<https://perma.cc/26C6-W2KQ>].

⁷⁵ HHS Blueprint to Lower Drug Prices, 83 Fed. Reg. 22,692 (published May 16, 2018).

⁷⁶ *Id.* at 22,698.

⁷⁷ *Id.*

The RFI then signaled the myriad of routes future regulations may take with a series of questions designed to elicit responses from across the healthcare industry:

- (1) Do PBM rebates and fees based on the percentage of the list price create an incentive to favor higher list prices (and the potential for higher rebates) rather than lower prices?;
- (2) Do higher rebates encourage benefits consultants who represent payers to focus on high rebates instead of low net cost?; . . .
- (3) What effect would imposing [a] fiduciary duty on PBMs on behalf of the ultimate payer (*i.e.*, consumers) have on PBMs' ability to negotiate drug prices?; . . .
- (4) Should Medicare Part D prohibit the use of rebates in contracts . . . to be based only on a fixed price for a drug over the contract term?⁷⁸

The Administration accompanied the RFI with the release of “American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.”⁷⁹ Of the four main sections and goals, the “Incentives for Lower List Prices” section included both short- and long-term proposed regulations.⁸⁰ The AKS was specifically targeted under the “further opportunit[y]” of enacting “[m]easures to restrict the use of rebates, including revisiting the safe harbor under the Anti-Kickback statute for drug rebates.”⁸¹ When placing blame on portions of the healthcare industry for higher drug costs, HHS depicted a “sophisticated PBM industry demanding higher rebates and restricting access to markets” with the effect of “boost[ing] the prices paid by payers and, especially, consumers.”⁸²

The formal proposed rule was released in February 2019.⁸³ Following a statement that the current Secretary does not believe the current discount safe harbor applies to PBM rebates, the rule proposes to cement that view and overturn years of industry understanding by explicitly excluding from the definition of eligible discounts the rebates

⁷⁸ *Id.*

⁷⁹ U.S. DEP'T OF HEALTH & HUMAN SERVS., AMERICAN PATIENTS FIRST: THE TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS (2018), <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf> [<https://perma.cc/ZS8U-QY3K>].

⁸⁰ *Id.* at 11.

⁸¹ *Id.*

⁸² *Id.* at 15.

⁸³ Removal of Safe Harbor Protection, 84 Fed. Reg. at 2340.

paid by manufacturers to plan sponsors as negotiated by PBMs.⁸⁴ To replace the status quo of the PBM rebate process, the proposed rule also adds two additional safe harbors related directly to pharmaceutical drug pricing.⁸⁵

The first proposed safe harbor, to be known as “Point-of-Sale Reductions in Price for Prescription Pharmaceutical Products,” seeks to protect price reductions offered by drug manufacturers. These price reductions are embedded into the drug’s price at the point of sale to the consumer, rather than offered as a rebate that is processed through the health plan or PBM.⁸⁶ In order to be eligible for the new Point-of-Sale safe harbor, the reduction in price must be set in advance and fixed and disclosed in writing to the health insurance company.⁸⁷ Once again, the safe harbor explicitly requires that the reduction in price cannot take the form of a rebate, and it must be completely reflected in the price charged to the patient at the point of sale.⁸⁸

The second proposed safe harbor protects PBM service fees from liability under the AKS.⁸⁹ This “service fee” safe harbor would explicitly allow payment of flat fees to PBMs for administrative services that PBMs currently provide for manufacturers, such as preventing duplicate discounts, or tasks that depend on or use data gathered by PBMs from their health plan customers.⁹⁰ The service fee safe harbor also explicitly covers flat fees for contracting with pharmacies, establishing payment levels for pharmacies, negotiating rebate arrangements, and developing and managing preferred drug lists and formularies.⁹¹ To ensure that the service fee proposal remains distinct from any hidden rebates, the service agreements must be in writing, be consistent with fair market value, be a fixed payment rather

⁸⁴ *Id.* at 2343 (noting that while the proposed rule is limited to plan sponsors under Medicare and Medicaid due to limits on agency power, federal legislation has been proposed in Congress to extend the proposed rule to private healthcare plans and their contracted PBMs. S. 657, 116th Cong. (2019). This Comment proceeds under the assumption that these restrictions will also eventually apply to private health plans via the accompanying federal legislation).

⁸⁵ Removal of Safe Harbor Protection, 84 Fed. Reg. at 2344.

⁸⁶ *Id.* at 2348.

⁸⁷ *Id.* at 2349.

⁸⁸ *Id.*

⁸⁹ *Id.* at 2340.

⁹⁰ *Id.*

⁹¹ *Id.* at 2350.

than a percentage of sales, and not be determined in a manner that takes into account the volume or value of any referrals.⁹²

As a whole, this proposed scheme would transform the current system for reducing drug prices from a rebate-dependent system to one that encourages negotiation of up-front discounts. Rather than spread savings out to everyone via lower health plan premiums, up-front discounts would apply directly to the consumer at the time of purchase. Practically, a system based on negotiated discounts rather than rebates would transform the PBM industry to one that functions more like a group purchasing organization combined with a benefits administrator.⁹³

This function change attempts to accomplish the government's goal of detaching payments and contracts within the healthcare industry from the list prices of drugs, with the ultimate goal of disincentivizing raising list prices of drugs to increase rebate and profit levels.⁹⁴ Therefore, although the physical drug distribution system would remain unchanged, compensation of intermediaries, such as payments to manufacturers and pharmacies, would be based on per-prescription fees instead of drug prices later reduced by rebates based on the total volume of sales.⁹⁵

Under the proposed regulations, formulary placement would also no longer incentivize raising list prices to enable higher rebates. Instead, when PBMs consider formulary placement of drugs, the only differentiator would be the net prices of drugs. Therefore, any discounts to drugs to influence formulary placement would have to be made up front, which also contributes to the new goal of passing discounts along to patients at the time of purchase.

However, on July 11, 2019, President Trump announced his decision to rescind the proposed PBM rebate reform.⁹⁶ Following an aggressive lobbying campaign from PBMs and a disagreement between HHS Secretary Azar and Trump cabinet officials on the merits of the rule,

⁹² *Id.*

⁹³ ADAM J. FEIN, A SYSTEM WITHOUT REBATES: THE *DRUG CHANNELS* NEGOTIATED DISCOUNTS MODEL 4 (2018), http://www.drugchannelsinstitute.com/files/Drug_Channels_NDM-Fein-02August2018.pdf [<https://perma.cc/FU84-ST2U>].

⁹⁴ Removal of Safe Harbor Protection, 84 Fed. Reg. at 2341.

⁹⁵ FEIN, *supra* note 93, at 4.

⁹⁶ Stephanie Armour, *Trump Administration Drops Plan to Curb Drug Rebates*, WALL ST. J. (July 11, 2019, 4:34 PM), https://www.wsj.com/articles/trump-administration-drops-plan-to-curb-drug-rebates-11562845155?mod=hp_lead_pos7 <https://perma.cc/FU84-ST2U>].

the President rescinded the rebate rule with little explanation.⁹⁷ However, White House officials listed pending bipartisan legislation on PBM rebate reform as a reason the President rescinded the rule.⁹⁸ Senator Mike Braun also subsequently promised to introduce legislation ending rebates in the commercial market.⁹⁹ The recently proposed HHS regulations amending the AKS are the most likely blueprint for these changes and any future efforts for reform of the PBM industry.

III

THE CASE FOR (SOMEWHAT) PRESERVING REBATES

Although PBMs have been granted a reprieve from impending HHS regulations, the industry is under increasing scrutiny.¹⁰⁰ At the beginning of 2019, three dozen drug manufacturers increased the cost of hundreds of drugs by an average of 6.3%.¹⁰¹ Following the increase in drug prices, Senator Susan Collins, as chair of the Senate Special Committee on Aging, blamed PBMs for the increase in list prices by requiring greater rebates.¹⁰² In a letter to HHS, Senator Collins urged HHS to quickly implement new regulations limiting the use of rebates as a way to “incentivize lower list prices.”¹⁰³

Regardless of where responsibility for increasing drug prices is allocated, PBMs have become a high-profile target for reform throughout both the executive and congressional branches and will most likely not escape this round of scrutiny by maintaining the status quo when it comes to how they administer rebates.

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ Sarah Oweremohle, et al., *Trump Leaning on Sanders-Style Ideas to Save His Drug Plan*, POLITICO (July 11, 2019, 11:11 PM), <https://www.politico.com/story/2019/07/11/white-house-drug-rebate-rule-1405884> [<https://perma.cc/UC7K-P3VZ>].

¹⁰⁰ Jared S. Hopkins, *Senator Collins Presses HHS to Reform Drug Rebate System*, WALL ST. J. (Jan. 10, 2019, 2:06 PM), https://www.wsj.com/articles/senator-collins-presses-hhs-to-reform-drug-rebate-system-11547139211?mod=hp_lista_pos4 [<https://perma.cc/S3W3-2F84>] [hereinafter *Senator Collins*].

¹⁰¹ Jared S. Hopkins, *Drugmakers Raise Prices on Hundreds of Medicines*, WALL ST. J. (Jan. 1, 2019, 9:13 PM), https://www.wsj.com/articles/drugmakers-raise-prices-on-hundreds-of-medicines-11546389293?mod=article_inline [<https://perma.cc/PU3U-PLRL>] [hereinafter *Drugmakers Raise Prices*].

¹⁰² *Senator Collins, supra* note 100.

¹⁰³ *Id.*

Therefore, Part III of this Comment argues that PBMs should actively support congressional adjustments to their rebate practices in an effort to both appease federal regulators and protect the lower prices they fight to get for patients. However, I will also argue that both Congress and the executive branch should be temperate when crafting new regulations regarding PBM safe harbors, as completely denying protection of, or applicability to, PBM rebates could leave a market hole in negotiating consumer drug discounts that actually increases patients' out-of-pocket costs. After examining attempts by states to regulate PBM practices, this Comment will argue that expedited and cohesive federal legislation is the appropriate path forward.

A. Unintended Consequences

Completely nixing rebates by modifying the AKS to directly exclude PBM rebates in the newly proposed rule, which HHS Secretary Azar has touted as a cure-all solution to rising drug costs,¹⁰⁴ would send a powerful signal to the healthcare industry. Since rebates and drugs' corresponding placement on formularies form the heart of how prescription drugs are priced and distributed in this country, the entire healthcare industry, following the new irrelevance of PBMs, would have to be restructured.¹⁰⁵ This drastic restructuring would accomplish many policy makers' goal of sending a signal to the drug industry that arbitrary increases in drug prices are no longer an acceptable status quo. However, ending rebates and the negotiating power of PBMs would also leave drug pricing power entirely with drug manufacturers themselves.

Although manufacturers frequently insist they raise list prices only to accommodate PBMs' demands for ever-increasing rebates,¹⁰⁶ the role PBMs play as the point of negotiation with manufacturers over list prices is currently the main mechanism of pushback against manufacturer prices. The unique nature of the prescription drug marketplace, where consumers are forced to buy a product based on health needs rather than shopping around for the best deal, means that without PBMs manufacturers will not face the same pressure as other

¹⁰⁴ Angelica LaVito, *Trump's Health Chief Intensifies Attack on Drug Middlemen, Suggests Getting Rid of Rebates*, CNBC (June 12, 2018, 6:02 PM), <https://www.cnbc.com/2018/06/12/hhs-secretary-azar-outlines-trump-administrations-drug-pricing-plan.html> [<https://perma.cc/NJH6-CLUX>] [hereinafter *Trump's Health*].

¹⁰⁵ *Id.*

¹⁰⁶ Roland & Loftus, *supra* note 5.

businesses in a free market economy to lower prices and entice demand.

PBMs' crucial role in negotiating drug prices was previously confirmed by the most recent comprehensive government study available, which concluded that PBM rebates do significantly lower drug prices for consumers.¹⁰⁷ In a study of PBMs effectiveness at lowering the drug costs of federal employees, the General Accounting Office (GAO) found that PBMs obtained an average price of drugs for retail pharmacies that was 18% below the average price paid by cash-paying customers for fourteen selected brand-name drugs.¹⁰⁸ The GAO also found PBM rebates were responsible for a 47% decrease in the price of a selection of generic drugs.¹⁰⁹ When PBM-operated mail-in pharmacies were used, the cost savings increased to 27% and 53% for brand-name and generic drugs, respectively.¹¹⁰

More recently, the Centers for Medicare and Medicaid Services (CMS) reported that the rebates offered by manufacturers were set to increase significantly in 2018.¹¹¹ However, the CMS also concluded that these increased rebates were also “a major reason for decreases in overall Part D [(the federal prescription drug program)] costs when compared” to the CMS report from 2017.¹¹² Therefore, even according to a government report on increasing rebates, the rebates were found to significantly benefit patients.

The Federal Trade Commission has also found that PBMs did pass along a significant portion of rebates from manufacturers to consumers.¹¹³ Depending on the size of the PBM and whether the PBM

¹⁰⁷ U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-03-196, FEDERAL EMPLOYEES' HEALTH BENEFITS: EFFECTS OF USING PHARMACY BENEFIT MANAGERS ON HEALTH PLANS, ENROLLEES, AND PHARMACIES 9 (2003), <https://www.gao.gov/assets/240/236828.pdf> [<https://perma.cc/9FYC-7HRZ>].

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ CENTERS FOR MEDICARE & MEDICAL SERVICES, 2018 ANNUAL REPORT OF THE BOARD OF TRUSTEES OF THE FEDERAL HOSPITAL INSURANCE AND FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUNDS 143 (2018), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf> [<https://perma.cc/536P-XN7G>].

¹¹² *Id.*

¹¹³ Fed. Trade Comm'n, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES 59 (2005), <https://www.ftc.gov/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report> [<https://perma.cc/VL55-SZRW>].

was insurer-owned, PBMs passed along an average of 25% to 91% of rebates negotiated with manufacturers.¹¹⁴ This shows that although some PBMs do retain a portion of rebates, consumers are indeed paying a lower price when using a PBM-negotiated plan than those consumers using cash payments.

Therefore, although banning rebates entirely is a policy change that would likely resonate with fed-up consumers and be an effective takedown of an opaque and confusing PBM industry, it does not make sense to gut a system that government regulators have found financially benefits consumers in a significant way. Restricting rebates will completely demolish the leveraging and negotiating power that PBMs employ to achieve lower drug costs.

With no negotiating power, a market without PBMs will lead to the more likely possibility of tacit collusion among manufacturers to set high prices and would do nothing to increase price competition.¹¹⁵ These anticompetitive consequences of explicitly excluding PBM rebates from the AKS would leave a vacuum in drug pricing negotiations. Although public and political anger over drug pricing could serve as a limiting factor for manufacturers, there is no natural successor to PBMs to consistently and formally sit down with manufacturers to negotiate lower prices or rebates.

*B. Working Within the Anti-Kickback Statute:
Detangling Administrative Fees from List Prices*

Given the limited free market regulating forces present without PBMs and the proven cost-saving effects of PBM rebates, it may be a more advantageous policy to work within the existing enforcement mechanism of the federal Anti-Kickback statute. By adjusting the existing statutory and regulatory framework, Congress could more closely regulate the opaque aspects of the PBM industry while still encouraging the negotiating function of PBMs that actually saves consumers money at the pharmacy.

As explained above, the current safe harbor most applicable to the PBM rebate system is the discount safe harbor. However, this safe harbor does not adequately encompass PBMs because PBMs do not directly purchase the drugs from the manufacturer, and the safe harbor

¹¹⁴ *Id.*

¹¹⁵ Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro- or Anticompetitive?*, 22 INT'L J. ECON. BUS. 245, 263–64 (2015).

provides that the discount must be provided at the time of the sale of the good.¹¹⁶

Overall, when creating this existing discount safe harbor, Congress intended to encourage some level of competitive behavior that ultimately benefitted federal health programs.¹¹⁷ The goal of the adjustment to the safe harbor law to allow for PBM rebates should be similar: as much of the negotiated rebate as possible should be passed through to the consumer. Although maintaining PBMs is necessary to preclude anticompetitive behavior by manufacturers, changes must be made to the rebate system to avoid negotiations over list prices and rebates that do not consider costs to the consumer.¹¹⁸

To encourage honest behavior by PBMs and increase transparency, the government should encourage good faith drug pricing that is not focused on raising the list price of the drug to maximize PBM profits. To accomplish this goal, the new safe harbor regulations should follow the pioneering approaches of the private sector discussed below and detangle allowable rebates or discounts from the fees PBMs receive for the administrative services provided to parties across the pharmaceutical supply chain.

1. Lessons from the Private Sector: A Case Analysis of Caterpillar Inc.

For example, when Caterpillar, a construction and mining equipment manufacturer, experienced a doubling of its prescription drug costs from the 1990s to the early 2000s, the company examined excessive bloat in their pharmaceutical supply chain expenses.¹¹⁹ As a company that spends more than \$160 million per year on pharmaceuticals for more than 150,000 employees and dependents,¹²⁰ the resulting methodology Caterpillar implemented to lower its expenditures can serve as a model for larger-scale implementation.

Caterpillar first focused on clearly separating the administrative fees that PBMs charge from the list price of drugs. One of the ways PBMs make a profit, and therefore one of the major sources of costs to an

¹¹⁶ 42 C.F.R. § 1001.952(h)(1)(iii)(A) (2018).

¹¹⁷ Opinion Letter, *supra* note 68, at 4.

¹¹⁸ Roland & Loftus, *supra* note 5.

¹¹⁹ John Carroll, *Having Mined Gold in Pharmacy Deal, Caterpillar Sets Sights on Gold-Standard Therapies*, 6 BIOTECHNOLOGY HEALTHCARE 49, 49 (2009).

¹²⁰ *Id.*

insurance payer such as Caterpillar, is by charging administrative fees for some of their services.¹²¹ PBMs charge these fees on handling drug transactions as the middleman on both ends of their contracts, to both insurance plan sponsors (such as companies like Caterpillar) and the pharmacies that provide drugs to the plan sponsors.¹²² Adding to the hidden nature of these administrative fees and the inability to challenge these administrative fees as excessive, both insurance payers and pharmacies that contract with each other via a PBM are unable to learn what is the other's respective reimbursement rate on a drug transaction.¹²³

This administrative fee is labeled as a contracted reimbursement and is based on a percentage of the total price of each drug, rather than being directly tied to the administrative services performed by the PBM.¹²⁴ Thus, increasing manufacturer list prices, which PBMs have been shown to drive up using rebates, are contractually tied to PBM administrative fees. Manufacturers pay PBMs for certain services using PBMs' sales data, such as preventing double discounts and monitoring medication usage.¹²⁵ These fees are often calculated as a percentage of the list price of particular drugs or the volume of drugs sold and are often compensated at a rate above fair market price.¹²⁶ As detailed in Part I of this Comment, some stakeholders and commentators are concerned that a direct link between PBM administrative fees and the list price of a drug incentivizes PBMs to drive up the list price of a drug. Driving up the list price subsequently increases the amount PBMs realize, returned as their administrative fee for handling transactions between manufacturers, payers, and pharmacies.¹²⁷

¹²¹ PATRICIA M. DANZON, 2014 ERISA ADVISORY COUNCIL: PBM COMPENSATION AND FEE DISCLOSURE 4 (2014), <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure-danzon-06-19.pdf> [<https://perma.cc/QZ5Q-EPWJ>].

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ Removal of Safe Harbor Protection, 84 Fed. Reg. at 2344.

¹²⁶ *Id.*

¹²⁷ Press Release, PhRMA, Biopharmaceutical Industry Takes Bold New Policy Position on How Payments Should Work in Supply Chain (July 16, 2018), <https://www.phrma.org/Press-Release/Biopharmaceutical-Industry-Takes-Bold-New-Policy-Position-on-How-Payments-Should-Work> [<https://perma.cc/WX4A-4C3R>]. See Katie Thomas, *Meet the Rebate, the New Villain of High Drug Prices*, N.Y. TIMES (July 27, 2018), <https://www.nytimes.com/2018/07/27/health/rebates-high-drug-prices-trump.html> [<https://perma.cc/5LCB-288P>].

After identifying PBM administrative fees based on drug list price as a major source of the waste in the company's drug supply chain, Caterpillar set out to form a unique contract arrangement that bypassed the need for a significant portion of its PBM's administrative fee and established a baseline for the fee that was independent of the manufacturer's wholesale price.¹²⁸

2. Lessons from the Private Sector: Contracting Around PBMs

First, Caterpillar went around its existing PBM and the typical PBM-driven pharmacy selection process and directly contracted with Wal-Mart's pharmacy to provide the generic drug portion of their benefits to employees.¹²⁹ By directly approaching a pharmacy to cover a significant portion of its employee's drug needs, Caterpillar successfully eliminated the need to pay a PBM for finding a pharmacy and the per-drug-transaction cost of the PBM's reimbursement administrative fee. Instead, Caterpillar directly paid Wal-Mart's pharmacy for the drug costs.¹³⁰

Second, Caterpillar lowered the cost it pays to the pharmacy by modifying the cost basis of prescription drugs from the pre-existing standard of the average wholesale price (AWP) to establish that Wal-Mart will reimburse the pharmacy only for the exact cost of the drugs to Wal-Mart.¹³¹ By basing the company's reimbursement costs on the real invoice cost and eliminating the administrative fee associated with the PBM handling the transaction, Caterpillar lowered the overall cost of drugs to its company and employees. To ensure that Wal-Mart did not inflate its reimbursement cost, as PBMs do by basing the reimbursement fee on the AWP, Caterpillar negotiated for an option to use a third-party auditor.¹³² With this option, Caterpillar can request an independent audit to ensure that only the actual cost of drugs is passed along to its company. Finally, with a lower overhead cost, Caterpillar eliminated the need for co-pays by its employees for generic drugs.¹³³

¹²⁸ Peter Pitts, *The Big Cat Finds ROI Where the Sun Don't Shine*, drugwonks.com (May 7, 2018), <http://drugwonks.com/blog/the-big-cat-finds-roi-where-the-sun-don-t-shine> [<https://perma.cc/N9Y2-A7QR>].

¹²⁹ Carroll, *supra* note 119.

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² *Id.*

¹³³ *Id.*

3. *Lessons from the Private Sector: Preserving a Role for PBMs*

Caterpillar's practices also demonstrate that detangling administrative fees from the list price is a solution that could also be beneficial to PBMs. While adding additional transparent PBM practices, basing administrative fees on fair market value does not completely eliminate the need for a PBM, as proposed government regulations may. Caterpillar's PBM will still negotiate drug prices and pharmacy supply chains for nongeneric drugs, such as brand-name drugs without a generic option that Wal-Mart could not supply.¹³⁴ This assures PBMs that uncoupling administrative fees from the list price of drugs will not completely undermine the need for PBMs, while also ultimately leading to lower prices for consumers.

When formulating a safe harbor similar to the discount safe harbor to encompass a PBM rate structure, HHS should incorporate a provision that codifies lessons learned from Caterpillar's decoupling of its PBM's fee from the drug list price, similar to the proposed PBM service fee safe harbor. The hypothetical "PBM rebate" safe harbor should include a provision requiring a similar bifurcated structure that separates administrative fees from the list price of drugs. While the new safe harbor should allow PBMs to continue negotiating drug prices and establishing pathways for delivery of drugs to the consumer—the aspects most beneficial for cost savings to the consumer—the safe harbor should explicitly prohibit fees based on the list price of the drug. Instead, administrative fees should be based on the scope of services offered by the PBM to its various clients. A flat administrative fee should be established up front in the PBM's contract. With this structure, PBMs' administrative fees would be statutorily required to be independent of both manufacturer drug list prices and the ultimate volume of drugs consumed by patients, thereby also reducing the relevance of rebates.

Additionally, as included in the current discount safe harbor, the PBM rebate safe harbor could be formulated to include additional transparency requirements focused on rebates. Discounts or rebates under the current discount safe harbor must be "fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service."¹³⁵ Similarly, a new PBM rebate safe harbor could include a requirement that the amount of manufacturer rebates received by a PBM must be disclosed at the beginning of a contract.

¹³⁴ *Id.*

¹³⁵ 42 C.F.R. § 1001.952(h)(1)(iii)(A) (2018).

PBMs may have concerns with this requirement. Wal-Mart expressed concerns that Caterpillar's independent auditor provision revealed too much proprietary pricing information to the other entities Wal-Mart contracted with. To counter this concern, the regulations could take yet another note from Caterpillar's experiment. For instance, the regulations could provide that although the amount of rebates negotiated with manufacturers must be available to other parties necessary for the transaction, such as payers and pharmacies, the merit of the rebate (and any subsequent increases) can be evaluated by an independent and confidential third party. This arrangement would prevent the release of contracted prices and preserve PBMs' negotiating power.

However, the transparency provisions in a hypothetical PBM rebate safe harbor should not extend as far as the proposed PBM service fee safe harbor does.¹³⁶ Within HHS's proposed PBM service fee safe harbor, the agency considers requiring PBMs, among others, to disclose information about valuation and valuation methodology to HHS.¹³⁷ In a competitive industry, where PBMs compete against each other to get rebates or discounts from manufacturers, disclosing valuation information to HHS may put PBMs at a disadvantage with drug manufacturers if the manufacturer discovers, via the information released to HHS, that another PBM requires lesser discounts for better formulary placements. Therefore, even under HHS' proposed framework for up-front discounts, these extensive transparency requirements pertaining to valuation methodology may undermine the ultimate goal of obtaining lower list prices for consumers.

However, there are private sector practices that safe harbor requirements could incorporate to improve transparency in the PBM industry. These include rebate transparency requirements, bifurcation standards for administrative fees, and list prices in an Anti-Kickback statute modification. Implementing these practices could be a viable approach to assuage many legislators' and consumers' concerns regarding the opaque nature of current PBM drug pricing practices.¹³⁸

Further, contrary to HHS Secretary Azar's preferred scorched-earth policy of amending the AKS to completely ban the rebate system,¹³⁹

¹³⁶ See Removal of Safe Harbor Protection, 84 Fed. Reg. at 2350.

¹³⁷ *Id.*

¹³⁸ Senator Collins, *supra* note 100.

¹³⁹ Trump's Health, *supra* note 104.

incorporating these modifications preserves the proven cost-saving aspects of PBM practices, such as acting as a moderating force for drug prices set by manufacturers. Modifying the AKS to accommodate and more closely regulate PBM practices—rather than eliminating the safe harbors—may not be the most politically expedient way for members of Congress to show their constituents they are being tough on the pharmaceutical industry, but this approach keeps the consumer’s best interest in mind and encourages the lowest possible drug prices.

C. State Regulation of PBMs

States’ attempts at regulation of the PBM industry, beginning in the early 2010s, also pose a danger of inconsistent regulation and harm to drug prices and make the case for a federal modification to PBM regulation even more urgent. A combination of states’ limited ability to influence largely federally regulated drug prices and states’ legislatures’ desire to appear as if they are proactively combating prescription drug prices has led to a focus on states’ abilities to license PBMs operating in their states—an aspect of the drug industry they *can* control.¹⁴⁰

Beginning with Mississippi in 2011, and including Oregon in 2013,¹⁴¹ states have begun to shift regulatory authority over PBMs, including licensing and annual submission of balance sheets and income statements, from neutral insurance commissions to possibly more biased state boards of pharmacies.¹⁴² This shift has sparked concern that pharmacies, as entities in direct competition with PBMs (who often operate their own pharmacies), will use this new regulatory power to undercut PBMs as their market adversaries.¹⁴³ For example, the Mississippi Board of Pharmacy has subsequently issued a requirement that PBMs disclose sensitive financial information, which is to be shared with pharmacies in direct competition with PBMs.¹⁴⁴

This expanding practice of allowing regulatory boards composed of market participants to oversee their competitors has also alarmed the Federal Trade Commission, which warned the structure “may create

¹⁴⁰ Shepherd, *supra* note 16, at 12.

¹⁴¹ OR. REV. STAT. § 735.532 (2018).

¹⁴² Shepherd, *supra* note 16, at 13.

¹⁴³ *Id.* at 13–14.

¹⁴⁴ *Id.* at 18.

tensions and conflicts of interest” and ultimately reduce competition and increase prices in the pharmaceutical marketplace.¹⁴⁵

By imposing a structure of government-sanctioned adversarial oversight, states have shown that their ability to regulate PBMs is insufficient to adequately address the opaqueness of PBM practices while also preserving the lower drug prices PBMs create. The federal government and Congress should take these arguably failed experiments as confirmation of a broad and increasing desire to implement some sort of fix to PBM practices and as a warning that policies that too severely limit PBMs’ core practices will also not solve the actual problem at hand: rising drug costs.

CONCLUSION

PBMs are mostly obscure middlemen whose practices touch the lives and healthcare of more than 200 million Americans. Although PBMs’ negotiating power fills an important gap in the healthcare industry and serves as a check on the otherwise monopolistic power of pharmaceutical companies to determine drug pricing, the intricacies of their industry and the dangers resulting from a major lack of transparency have proven ripe for abuse by bad actors. By starting the process to amend the AKS and remove any safe harbor protections for PBM rebates, this administration and Congress have shown they are serious about addressing price gouging spurred by PBMs.

However, while crafting policies to reign in PBMs, policymakers must keep in mind the good that PBMs work toward: actively lowering the cost to consumers for prescription drugs the consumers need to live. If policy decisions and modification of the AKS go too far and eliminate the aspects of PBMs that have been proven to increase access to affordable prescription drugs, American patients will have once again become forgotten pawns in the game of drug prices. By taking a moderate approach and modifying the AKS to increase oversight and regulation of PBMs, rather than entirely destroying the industry, Congress and regulators have a real chance to reform an industry gone

¹⁴⁵ *Id.* at 16; Letter from Susan S. DeSanti et al., Director Office of Policy Planning, Fed. Trade Comm’n, et al., to Mark Formby, Representative, Mississippi House of Representatives 5 (Mar. 22, 2011), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-letter-honorable-mark-formby-mississippi-house-representatives-concerning-mississippi/110322mississippipbm.pdf [https://perma.cc/L7VX-BP6G].

awry and take a large step toward making prescription drugs more affordable.