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## YALE LAW & POLICY REVIEW

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### Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs

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Pharmacy benefit managers (PBMs) manage the drug benefits for over ninety percent of Americans with prescription drug coverage. However, conflicts of interest inherent in the PBM business model create perverse incentives for drug price increases. The most significant conflict of interest arises from manufacturer rebates paid to PBMs. PBMs negotiate rebates from drug manufacturers in exchange for giving the manufacturers' drugs preferred status on a health plan's formulary. Because the rebates paid to PBMs are typically a percentage of a drug's list price, drug makers are pressured to increase list prices in order to satisfy PBMs' demands for higher rebates. Although a portion of the increasing rebate dollars may eventually find its way to patients in the form of lower co-pays, many patients still suffer from the list prices increases. This Article analyzes various proposals to rein in PBM rebates and asserts that, compared to the other proposals, a partial point-of-sale rebate system maintains many of the benefits of selective contracting while minimizing incentives to increase drug list prices.

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## INTRODUCTION

In the debate over drug prices, policymakers are only beginning to understand the critical role of pharmacy benefit managers (PBMs). PBMs currently manage the drug benefits for over ninety percent of Americans with prescription drug coverage.<sup>2</sup> They employ various tools meant to lower drug costs for their health plan or employer clients. However, their role as the middlemen between drug manufacturers, pharmacies, and drug plans also creates significant conflicts of interest. Under their current business model, PBMs' profit incentive often conflicts with efforts to minimize drug costs for drug plans and beneficiaries and, instead, can lead to higher drug prices for all patients.

The most significant conflict of interest arises from manufacturer rebates paid to PBMs. PBMs negotiate rebates from drug manufacturers in exchange for giving the manufacturers' drugs preferred status on a health plan's formulary. A formulary is a list of preferred drugs for different medical conditions for which the plan will provide coverage. Because formulary status can significantly increase the sales of a drug, manufacturers compete intensely for formulary status and offer to pay significant rebates and fees to PBMs to have their drugs listed on the formulary.<sup>3</sup>

The current formulary-for-rebate arrangement between PBMs and manufacturers is a form of selective contracting that has been employed in the provision of health care since the 1980s. Selective contracting involves exclusive arrangements between insurers and medical providers under which the insurer channels patients to the provider in exchange for the provider offering significantly discounted prices. These

<sup>2</sup> .See U.S. CENSUS BUREAU, HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2018, at 3 (Nov. 2019), <https://www.census.gov/content/dam/Census/library/publications/2019/demo/p60-267.pdf> [<https://perma.cc/TN5J-CU8K>] (showing approximately 297 million Americans to have health insurance); *Our Industry*, PHRM. CARE MGMT. ASS'N, <https://www.pcmnet.org/our-industry/> [<https://perma.cc/JK9W-XCY9>] (reporting that PBMs administer drug prescription plans for more 270 million Americans).

<sup>3</sup> .See discussion *infra* Part II.

arrangements between health insurers and doctors and hospitals have been found to reduce the cost of health care for both insurers and patients. Similarly, selective contracting between PBMs and drug manufacturers has generated significant rebates that could be used to lower the cost of drugs.<sup>4</sup> Because the rebates are paid retrospectively, however, the savings from selective contracting often do not make it to the patients who need them most. Moreover, the current rebate system has created a perverse incentive for manufacturers to increase drug list prices.

Because the rebates paid to PBMs are typically a percentage of a drug's list price, PBMs have an incentive to select more expensive drugs for formulary status. They also have the incentive to encourage drug list-price increases (or at least to discourage decreases) in order to increase their profits. In fact, evidence suggests that drug manufacturers are increasing drug list prices in order to satisfy PBMs' demands for higher rebates.<sup>5</sup> Over half of the increase in drug list prices from 2012 to 2016 was paid to PBMs as higher rebates, and the value of rebates paid to PBMs doubled over this period.<sup>6</sup> Drug makers assert that they are pressured to increase drug list prices out of fear that, if they do not, PBMs will retaliate by dropping their drugs from the formularies.

Although a portion of the increasing rebate dollars may eventually find its way to patients in the form of lower co-pays, many patients still suffer from the list-price increases. The 29 million Americans without drug plan coverage pay more for their medications when list prices increase. Even patients with insurance typically have cost-sharing obligations that require them to pay between thirty and forty percent of list prices.<sup>7</sup> Moreover, insured patients within the deductible phase of their drug plan pay the entire higher list price until they meet their deductible. Higher list prices jeopardize patients' health as well as their finances; as out-of-pocket costs for drugs increase, patients are less likely to adhere to their medication routine and more likely to abandon their drug regimen altogether.<sup>8</sup>

<sup>4</sup> .See discussion *infra* Part I.

<sup>5</sup> .Adam Fein, *New Data Show the Gross-to-Net Rebate Bubble Growing Even Bigger*, DRUG CHANNELS, (June 14, 2017), <https://www.drugchannels.net/2017/06/new-data-show-gross-to-net-rebate.html> [<https://perma.cc/6MFF-M625>].

<sup>6</sup> .*Id.*

<sup>7</sup> .KAISER FAMILY FOUND., 2017 EMPLOYER HEALTH BENEFITS SURVEY (Sept. 2017), <https://www.kff.org/report-section/ehbs-2017-section-9-prescription-drug-benefits/> [<https://perma.cc/4P2K-CYCS>].

This Article analyzes various proposals to rein in PBM rebates including efforts to completely eliminate rebates, proposals to decouple rebates from list prices, efforts to impose a fiduciary duty on PBMs, and proposals to replace the current after-purchase rebate system with point-of-sale rebates. It asserts that, compared to the other proposals, a point-of-sale rebate system maintains many of the benefits of selective contracting while minimizing incentives to increase drug list prices. Under this system, rebates would be passed through to the patient at the pharmacy counter, or “point-of-sale,” to reduce out-of-pocket spending. Thus, this would maintain the current rebate-for-formulary arrangements between drug manufacturers and drug plans, which generate significant rebate payments that lower the net price of drugs, but it would ensure that these rebates actually save patients money rather than end up in the hands of PBMs. Moreover, because PBMs would not retain rebates, they would have no incentive to promote higher list prices. Slower growth in list prices would benefit all patients—both insured and uninsured—by reducing out-of-pocket drug spending.

Specifically, this Article argues that the best approach is a partial point-of-sale rebate system in which some sizable portion, but not all, of the total rebate is applied at the point of sale to reduce patient out-of-pocket spending. Drug manufacturers would then pay the remaining balance to drug plans at the end of the period. This system would maximize the benefits of selective contracting because the end-of-period rebates could be based on whether the drug plan’s members generated significant revenue for the manufacturers. In addition, a partial point-of-sale system would protect competitively sensitive information about the total rebates negotiated between drug makers and PBMs because the end-of-period rebates would not be visible to market competitors.

In February 2019, the Department of Health and Human Services (HHS) issued a proposed rule that would have established a point-of-sale rebate system in Medicare Part D and Medicaid.<sup>9</sup> Although the proposal was eventually withdrawn for political reasons, the growing popularity of point-of-sale rebates makes it critical for policymakers to understand both the rationale and the potential pitfalls of the system.

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<sup>8</sup> .See discussion *infra* Part II.

<sup>9</sup> .See Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 84 Fed. Reg. 2340 (Feb. 6, 2019).

I. BACKGROUND ON PBMS

Many private sector entities, such as employers, HMOs, and unions, that provide medical insurance also offer prescription drug coverage to their members. These entities typically hire pharmacy benefit managers (PBMs) to manage the prescription drug benefits for their members and to act as the middlemen among the drug plan, pharmacies, and drug manufacturers. Over ninety percent of Americans with prescription drug coverage receive their benefits through a PBM.<sup>10</sup>

PBMs provide various services to their drug plan clients. PBMs originated in the 1970s and 1980s as intermediaries that simply processed the prescription drug claims of their clients. This process involves verifying drug coverage when a consumer presents a prescription at a pharmacy, determining which drug within the therapeutic class is covered by the consumer's plan, establishing the consumer's co-pay, seeking payment from the drug plan after the prescription is filled, and reimbursing the pharmacy for dispensing the drug.<sup>11</sup> Over the years, the role of PBMs has evolved to include many activities beyond simple claims processing. For example, PBMs often require that pharmacies substitute generic drugs for brand-name drugs when clinically appropriate, a tool that has successfully reduced drug spending.<sup>12</sup> Some PBMs employ prior authorization programs that require the PBM or drug plan to approve the dispensing of certain drugs.<sup>13</sup> Others use step-therapies that limit members' access to certain

<sup>10</sup> .See Letter from Fed. Trade Comm'n to Senator Richard L. Brown, North Dakota Senate, 4 (Mar. 8, 2005), [https://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-comment-honorable-richard-l.brown-concerning-north-dakota-h.b.1332-regulate-contractual-relationship-between-pharmacy-benefit-managers-and-covered-entities/050311northdakotacomnts.pdf](https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-richard-l.brown-concerning-north-dakota-h.b.1332-regulate-contractual-relationship-between-pharmacy-benefit-managers-and-covered-entities/050311northdakotacomnts.pdf) [https://perma.cc/M9VB-D6UB].

<sup>11</sup> .Allison Dabbs Garrett & Robert Garis, *Leveling the Playing Field in the Pharmacy Benefit Management Industry*, 42 VAL. U.L. REV. 33, 34 (2007).

<sup>12</sup> .U.S. GEN. ACCOUNTING OFFICE, EFFECTS OF USING PHARMACY BENEFIT MANAGERS ON HEALTH PLANS, ENROLLEES, AND PHARMACIES 14 (Jan. 2003), <http://www.gao.gov/cgi-bin/getrpt?GAO-03-196>.

<sup>13</sup> .See, e.g. FED. TRADE COMM'N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES 12-14 (Aug. 2005), [https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitprt\\_0.pdf](https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitprt_0.pdf) [https://perma.cc/Z57N-3MPS].

drugs until they have tried lower cost alternatives.<sup>14</sup> Many PBMs employ mail-order pharmacies (their own or independent) and encourage members to fill prescriptions for ongoing, chronic conditions at a discounted price through the mail-order pharmacies.<sup>15</sup> Similarly, many PBMs own specialty pharmacies and direct plan members to the pharmacies with deeper discounts than are offered at non-PBM-owned pharmacies.<sup>16</sup>

In addition, PBMs use selective contracting to negotiate lower drug prices with both pharmacies and drug manufacturers. Selective contracting has been a common practice in the provision of health care since the 1980s.<sup>17</sup> In medical services, selective contracting involves contractual arrangements among insurers and health care providers that give covered individuals a financial incentive to obtain health care from a limited panel of providers. For example, insurers create plans such as health maintenance organizations (HMOs) that form exclusive arrangements with physicians, hospitals, and other health care providers to whom the HMO will steer patients. Health care providers compete for the exclusive agreements, and the increased revenues they bring, by offering health services at discounted prices. A substantial body of empirical research has shown that selective contracting by managed care plans such as HMOs has lowered the prices that both insurers and patients pay for health care.<sup>18</sup>

Selective contracting has now extended from medical services to prescription drug coverage. Just as physicians, hospitals, and other health care providers have competed to be part of exclusive networks of covered providers for over thirty years, pharmacies now compete to be included in exclusive networks of pharmacies.<sup>19</sup> PBMs enter these exclusive arrangements with a limited number of retail pharmacies, creating a “pharmacy network,” and then steer drug plan members to

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<sup>14</sup> .*Id.*

<sup>15</sup> .*Id.* at 23-40.

<sup>16</sup> .U.S. SENATE COMM. ON FIN. MINORITY STAFF, A TANGLED WEB: AN EXAMINATION OF THE DRUG SUPPLY AND PAYMENT CHAINS 1, 31 (June, 2018), <https://www.finance.senate.gov/imo/media/doc/A%20Tangled%20Web.pdf> [<https://perma.cc/M27T-2ES2>].

<sup>17</sup> .See Michael A. Morrissey, *Competition in Hospital and Health Insurance Markets: A Review and Research Agenda*, 36 HEALTH SERVICES RES. 191, 192, 195 (2001).

<sup>18</sup> .See *id.* at 192; G. A. Melnick et al., *The Effects of Market Structure and Bargaining Position on Hospital Prices*, 11 J. HEALTH ECON. 217 (1992).

<sup>19</sup> .See Joanna Shepherd, *Selective Contracting in Prescription Drugs: The Benefits of Pharmacy Networks*, 15 MINN. J.L. SCI. & TECH. 1027 (2014).

these in-network pharmacies with the promise of lower prices. The pharmacies, eager to be part of an exclusive network that will provide access to significant sales, compete aggressively to be included in the network by offering price discounts for filling prescriptions. Evidence confirms that PBMs' use of selective contracting in pharmacy networks has lowered the cost of prescription drugs.<sup>20</sup>

Similarly, PBMs use selective contracting to negotiate favorable rebates from drug manufacturers. They work with their drug plan clients to create a list of preferred drugs for different medical conditions, called a "formulary," for which the plan will provide coverage. Much like the PBM directs members to in-network pharmacies, it steers members to formulary drugs by offering incentives such as lower copayments. Because formulary status can significantly increase the sales of a drug, manufacturers compete intensely for formulary status and offer to pay significant rebates and fees to PBMs to have their drugs listed on the formulary.<sup>21</sup> The rebate calculation for a specific drug, which is typically some percentage of the drug's list price plus an additional amount if certain market-share thresholds are met, is specified well in advance of a patient's purchase of the drug.<sup>22</sup> However, the drug maker pays the rebate to the PBM long after the drug is purchased and paid for. On average, manufacturers pay rebates of between ten and twenty percent

<sup>20</sup> .VISANTE, HOW PHARMACY NETWORKS COULD SAVE MEDICARE, MEDICAID, AND COMMERCIAL PAYERS \$115 BILLION 4 (Jan. 2013), <https://www.pcmanet.org/wp-content/uploads/2016/08/pr-dated-01-25-13-visante-pcma-pharmacy-networks-study-1-24-13-final.pdf> [<https://perma.cc/8LMB-GJA8>] (finding that preferred networks lower prescription costs by an estimated five percent compared to open networks); CENTERS FOR MEDICARE AND MEDICAID SERVICES, PART D CLAIMS ANALYSIS: NEGOTIATED PRICING BETWEEN PREFERRED AND NON-PREFERRED PHARMACY NETWORKS (2013), <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/PharmacyNetwork.pdf> [<https://perma.cc/ZV94-KA54>] (finding that prescription drug costs are between two and twelve percent cheaper at preferred pharmacies compared to non-preferred pharmacies).

<sup>21</sup> .See Letter from Fed. Trade Comm'n to Assembly Member Greg Aghazarian, California General Assembly, 6-7 (September 7, 2004), <http://www.ftc.gov/be/V040027.pdf> [<https://perma.cc/8EKR-5WWM>].

<sup>22</sup> .PHRMA FOLLOW THE DOLLAR: UNDERSTANDING HOW THE PHARMACEUTICAL DISTRIBUTION AND PAYMENT SYSTEM SHAPES THE PRICES OF BRAND MEDICINES 8 (Nov. 2017) <http://phrma-docs.phrma.org/files/dmfile/Follow-the-Dollar-Report.pdf> [<https://perma.cc/85MX-XVS2>].

of total drug revenues.<sup>23</sup> However, some manufacturers pay rebates as high as fifty percent while other manufacturers pay nothing.<sup>24</sup>

Figure 1 illustrates the selective contracting agreements that take place between PBMs, on the one hand, and pharmacies and manufacturers on the other. It also depicts the arrangements between PBMs and their drug plan clients. Beyond claims processing and other services, PBMs may provide to drug plans discounted drug prices that they negotiate from pharmacies and a share of the rebates that they negotiate from manufacturers. In exchange, PBMs receive various forms of payment that may include fees from drug plans, a share of rebates they retain, and the difference between the price charged to the drug plan every time a drug is dispensed and the price paid to the dispensing pharmacy (called the “spread”).

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<sup>23</sup> .VISANTE PHARMACY BENEFIT MANAGERS (PBMs): GENERATING SAVINGS FOR PLAN SPONSORS AND CONSUMERS 13 (Feb. 2016), <https://www.pcmagnet.org/wp-content/uploads/2016/08/visante-pbm-savings-feb-2016.pdf> [<https://perma.cc/8D4Z-2GPS>].

<sup>24</sup> .*Id.*

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Figure 1: PBM Arrangements with Pharmacies, Manufactures, and Drug Plans

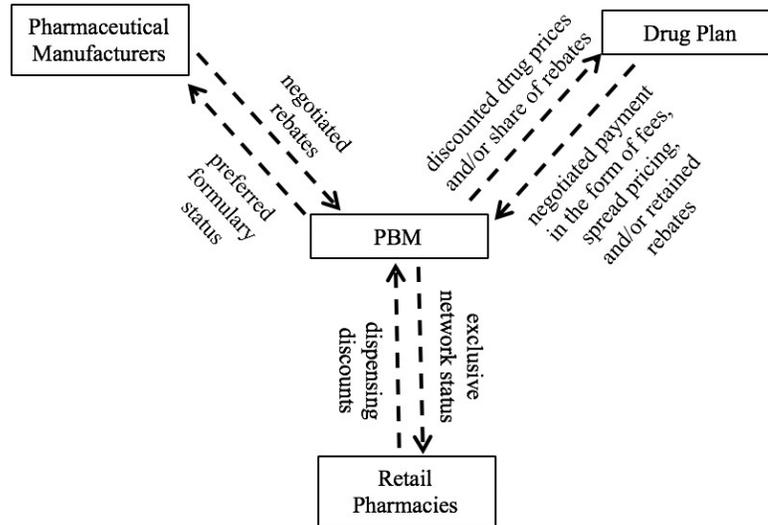
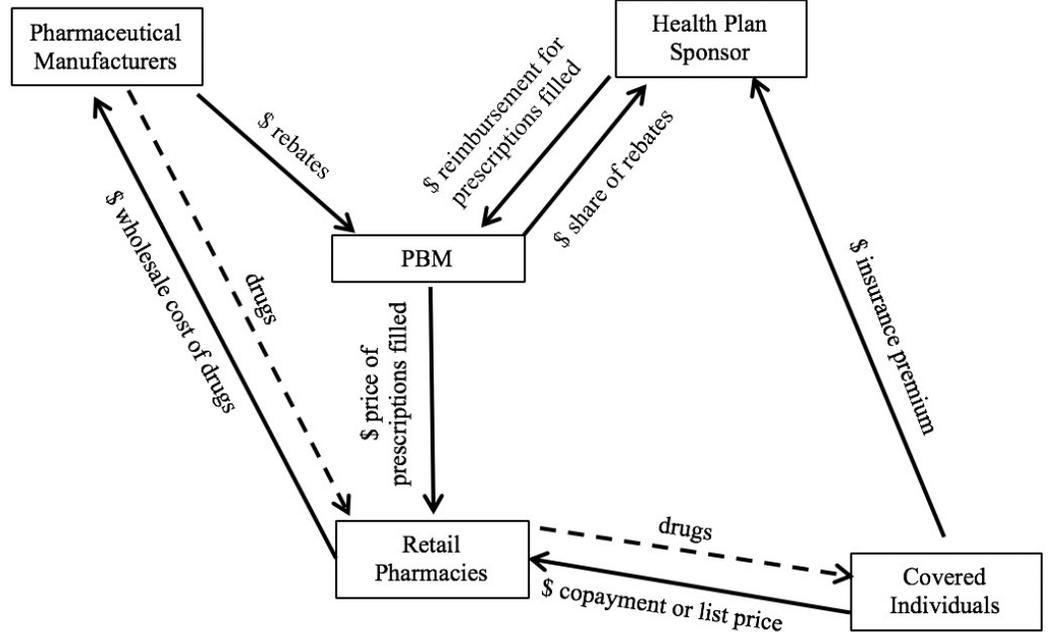


Figure 2 illustrates the basic flow of money and prescription drugs among PBMs, drug plans, retail pharmacies, manufacturers, and the individuals covered by the drug plan.<sup>25</sup> The dollar flows are represented by the solid arrows, and the flows of prescription drugs are represented by the dashed arrows. Note that prescription drugs flow only from manufacturer to pharmacy to individuals—PBMs never take possession.

<sup>25</sup> .Figure 1 presents the basic set of arrangements. Often there are drug wholesalers involved.

Figure 2: Flow of Payments and Prescription Drugs



The rebates generated from PBMs' selective contracting with drug manufacturers could be used to reduce overall drug spending. For example, in 2018, average drug list prices increased by an average of 5.7%. However, after considering rebates and discounts, net drug prices increased by only 1.5%.<sup>26</sup> Moreover, many manufacturers reported no increase, or even a decrease, in net prices despite the fact that the list prices for their drugs increased.<sup>27</sup> As shown in Figure 3, the differential between the growth in list prices and net prices has persisted for years. As a result, whereas drug spending calculated at invoice prices has increased by sixty percent since 2007, net drug spending

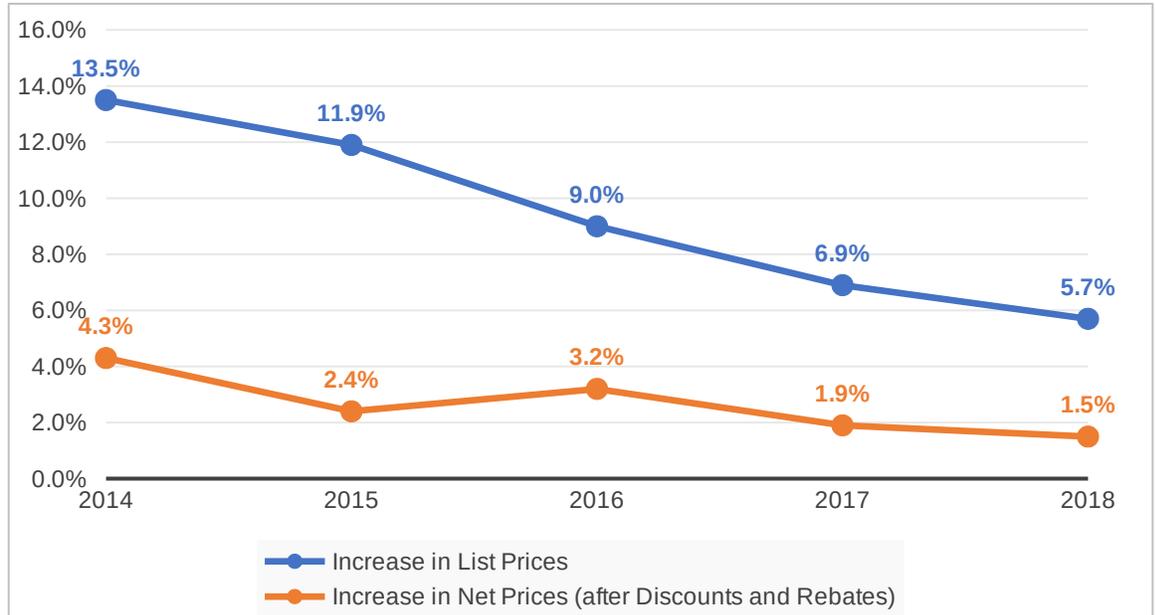
<sup>26</sup> .Murray Aitken et al., *The Global Use of Medicine in 2019 and Outlook to 2023*, IQVIA INST. FOR HUMAN DATA SCIENCE 10-11 (Jan. 2019), <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023.pdf> [<https://perma.cc/NMB6-JBGZ>].

<sup>27</sup> .Denise Roland, *Despite Raising Prices, Big Pharma Is Selling Drugs for Less*, WALL ST. J. (Jan. 30, 2019), <https://www.wsj.com/articles/novartis-seeks-growth-in-newer-drugs-amid-pricing-challenges-11548838137> [<https://perma.cc/Y9JX-W58N>].

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after discounts and rebates has only increased by thirty-six percent.<sup>28</sup> However, whether the slower growth in net drug spending ultimately benefits patients depends on whether PBMs pass along rebates to drug plans and whether the drug plans use the rebates to lower premiums or co-pays for covered members.

Figure 3: Increases in Drug List Prices versus Net Prices after Rebates and Discounts



The more drug plan members a PBM represents, the more effectively it can harness the buying clout of members to negotiate rebates from drug manufacturers and discounts from pharmacies. This reliance on member numbers has incentivized significant consolidation in the PBM industry. In 2012, the Federal Trade Commission indicated that there were “at least ten significant competitors” in the PBM industry when approving the merger of two large PBMs.<sup>29</sup> However, by 2017, the

<sup>28</sup> .Murray Aitken & Michael Kleinrock, *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022*, IQVIA INST. FOR HUMAN DATA SCIENCE 4 (Apr. 2018), <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf> [<https://perma.cc/JN6J-PVDT>].

<sup>29</sup> .Statement of the Federal Trade Commission Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc., FTC File No. 111-0210, at 2 (Apr. 2, 2012),

top three PBMs—Cigna’s Express Scripts, CVS Health’s Caremark, and UnitedHealth’s OptumRx—managed sixty-six percent of all prescription claims,<sup>30</sup> and accounted for about seventy percent<sup>31</sup> of the \$370 billion in revenues generated by the PBM market.<sup>32</sup>

The consolidation among PBMs and the resulting increases in PBMs’ market power have dramatically changed the landscape of the pharmaceutical market. In the 1970s, most prescription drugs were prescribed by physicians that were largely insensitive to price, perfunctorily filled by pharmacists, and paid for by consumers or third-party payors that had little influence over the drug chosen or the price paid.<sup>33</sup> As a consequence, physicians primarily decided which drugs patients took, drug manufacturers decided on the drugs’ prices, and patients decided which pharmacies to visit. In contrast, the market for prescription drugs today is one in which the PBMs and drug plans now have enormous control over which drugs consumers take, what they pay for the drugs, and which pharmacies they use.<sup>34</sup> Patients primarily take only the drugs that are on the PBM-created formulary; drug prices are determined by intense negotiations between PBMs, drug manufacturers, and pharmacies; and patients primarily visit only the pharmacies in the PBM-established pharmacy network.

PBMs’ significant influence in the pharmaceutical market is exhibited by the share of total drug spending captured by these entities.

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[https://www.ftc.gov/sites/default/files/documents/public\\_statements/statement-federal-trade-commission-concerning-proposed-acquisition-medco-health-solutions-express/120402expressscripts.pdf](https://www.ftc.gov/sites/default/files/documents/public_statements/statement-federal-trade-commission-concerning-proposed-acquisition-medco-health-solutions-express/120402expressscripts.pdf)  
[<https://perma.cc/4BUT-MKEZ>].

<sup>30</sup> .Neeraj Sood et al., *The Flow of Money Through the Pharmaceutical Distribution System*, UNIV. OF S. CAL. LEONARD D. SCHAEFFER CTR. FOR HEALTH POL’Y & ECON. (June 2017), [https://healthpolicy.usc.edu/wp-content/uploads/2017/06/USC\\_Flow-of-MoneyWhitePaper\\_Final\\_Spreads.pdf](https://healthpolicy.usc.edu/wp-content/uploads/2017/06/USC_Flow-of-MoneyWhitePaper_Final_Spreads.pdf) [<https://perma.cc/E7BM-PD55>].

<sup>31</sup> .See Letter from U.S. House Comm. on Energy and Commerce, to Joseph Simons, Chairman, Fed. Trade Comm’n (July 27, 2018), <https://republicans-energycommerce.house.gov/wp-content/uploads/2018/07/20180727FTC.pdf> [<https://perma.cc/H44V-LUW5>].

<sup>32</sup> .Nicole Fisher, *John Sculley Weighs In on Amazon, Health M&A and the Future of PBMs*, FORTUNE (June 30, 2018), <https://www.forbes.com/sites/nicolefisher/2018/06/30/john-sculley-weighs-in-on-amazon-health-ma-and-the-future-of-pbms/#5d344b6c7897> [<https://perma.cc/7HNB-TQK6>].

<sup>33</sup> .Henry Grabowski, *The Evolution of the Pharmaceutical Industry Over the Past 50 Years: A Personal Reflection*, 18 INT’L J. ECON. BUS. 161, 167 (2011).

<sup>34</sup> .*Id.*

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In 2015, brand manufacturers that actually develop new drugs, go through the arduous and expensive FDA approval process, bear the risk of drug failures, and produce and market approved drugs received only thirty-nine percent of the gross national spending on drugs.<sup>35</sup> In contrast, forty-two percent of gross spending was captured by PBMs, health plans, and supply-chain entities, such as pharmacies and wholesalers.<sup>36</sup> Moreover, with their increasing market power, PBMs have been able to claim an increasing share of total drug spending while drug manufacturers' share of spending has steadily declined.<sup>37</sup> As a result, PBMs now realize larger revenues than most drug manufacturers even though they engage in almost no innovation, bear little risk, and, unless they own a mail-order or specialty pharmacy, do not even take possession of drugs.<sup>38</sup> Indeed, in 2018, the companies owning the three largest PBMs—Express Scripts, CVS Health's Caremark, and UnitedHealth's OptumRx—ranked in the top twenty-five companies on the Fortune 500 list with annual revenues over \$100 billion.<sup>39,40</sup> In contrast, most of the largest drug manufacturers earn less than \$50 billion.<sup>41</sup>

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<sup>35</sup> .Eleanor Blalock & Aaron Vandervelde, *The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized by Stakeholders*, BERKELEY RSCH. GRP. 4 (Jan. 2017), <https://ecommunications.thinkbrg.com/44/1664/uploads/vandervelde-phrma-january-2020.3.3-addendum-clean.pdf> [<https://perma.cc/A7QF-NHRC>].

<sup>36</sup> .*Id.*

<sup>37</sup> .*Id.* at 6.

<sup>38</sup> .Geoffrey Joyce, *An Economist's Change of Heart: It's Time to Regulate the Prescription-Drug Middlemen*, MARKETWATCH (Aug. 20, 2018), <https://www.marketwatch.com/story/an-economists-change-of-heart-its-time-to-regulate-the-prescription-drug-middlemen-2018-08-13> [<https://perma.cc/QK9B-UF9S>].

<sup>39</sup> .*Fortune 500*, FORTUNE (2018), <https://fortune.com/fortune500/2018/> [<https://perma.cc/R2M5-GFNS>].

<sup>40</sup> .Note that in 2018, Express Scripts Holding Company merged with Cigna. See Press Release, Cigna, Cigna Completes Combination with Express Scripts, Establishing a Blueprint to Transform the Health Care System (Dec. 20, 2018), <https://www.cigna.com/about-us/newsroom/innovation/cigna-completes-combination-with-express-scripts> [<https://perma.cc/BR6D-W3AN>].

<sup>41</sup> .*Id.*

## II. CONFLICTS OF INTEREST IN THE PBM BUSINESS MODEL

Although each contractual arrangement between a PBM and its drug plan client is unique, PBMs generally earn money in four different ways. First, the drug plans typically pay various administrative fees to the PBMs for processing the prescription drug claims of their members.<sup>42</sup> Second, PBMs that operate their own mail order or specialty pharmacies are reimbursed for dispensing drugs in the same way that retail pharmacies are reimbursed.<sup>43</sup> Third, PBMs earn money by charging the drug plan a higher price for dispensed drugs than they reimburse the pharmacy<sup>44</sup>—the difference is called the “spread.”<sup>45</sup> Fourth, PBMs receive rebates or fees from drug manufacturers in exchange for inclusion in the drug formulary.<sup>46</sup> PBMs often pass along a portion of the rebates to their health plan clients, but research shows that PBMs also keep a sizable share for themselves.<sup>47</sup>

Unlike anyone else in the prescription drug supply chain, PBMs engage in pricing negotiations with almost every other entity—manufacturers, drug plans, and pharmacies. This central role, and the fact that the details of the pricing negotiations are typically kept secret, create significant conflicts of interest as PBMs attempt to maximize their profits in every negotiation. Although there is evidence that PBMs’ ability to harness the buying clout of millions of plan members initially constrained drug spending, new research shows that PBMs’ growing role in the distribution chain may actually be inflating drug costs.<sup>48</sup> Instead, PBM consolidation and their resulting increase in market power have enabled these entities to profit from the conflicts of interest in the

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<sup>42</sup> .Garrett & Garis, *supra* note 11, at 37.

<sup>43</sup> .*Id.*

<sup>44</sup> .*Id.*

<sup>45</sup> .U.S. SENATE COMM. ON FIN. MINORITY STAFF, *supra* note 16, at 29.

<sup>46</sup> .Garret & Garis, *supra* note 11, at 37.

<sup>47</sup> .Adam Fein, *Solving the Mystery of Employer-PBM Rebate Pass-Throughs*, DRUG CHANNELS (Jan. 14, 2016), <https://www.drugchannels.net/2016/01/solving-mystery-of-employer-pbm-rebate.html> [<https://perma.cc/2VAN-56ZC>]; Cole Werber, *Health Policy Brief: Pharmacy Benefit Managers*, HEALTH AFFAIRS (Sept. 14, 2017), <https://www.healthaffairs.org/doi/10.1377/hpb20171409.000178/full> [<https://perma.cc/LMS8-3SB8>].

<sup>48</sup> .Michael Carrier, *A Six-Step Solution to the PBM Problem*, HEALTH AFFAIRS (Aug. 30, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20180823.383881/full> [<https://perma.cc/5RUL-T4WM>].

current business model, potentially harming both drug plans and patients.

These conflicts of interest arise from several different sources. One of the most obvious conflicts arises from PBMs' ownership of mail-order and specialty pharmacies. Ownership of substitutes for retail pharmacies gives PBMs the incentive to aggressively channel plan members to their own pharmacies, potentially to the detriment of plan members. An early 2003 study by the U.S. General Accounting Office found that drug prices at PBM-owned mail order pharmacies were lower than at retail pharmacies.<sup>49</sup> However, critics have more recently argued that, when patients use PBMs' own pharmacies, the PBMs have the incentive to switch plan members to higher-cost drugs or away from generic drugs so the PBMs can earn higher manufacturer rebates.<sup>50</sup> Some PBMs have been criticized for not passing along to drug plans or plan members the volume discounts they receive by ordering drugs in bulk at the mail-order pharmacies.<sup>51</sup> Critics also argue that PBMs are harming competition by narrowing plan members' retail pharmacy options as they redirect customers to the PBM-owned pharmacies.<sup>52</sup> Indeed, several retail pharmacies have filed suits against PBMs for these allegedly anticompetitive practices.<sup>53</sup>

Another conflict of interest arises from the common practice of spread pricing. PBMs typically negotiate with their drug plan clients to keep the spread between the price charged to the drug plan every time a drug is dispensed and the price paid to the dispensing pharmacy. Drug plans agree to a price they are willing to pay for a drug, and if the PBM can negotiate a lower dispensing price with a pharmacy, the drug plans generally allow the PBM to pocket the difference, even though the plans are kept in the dark about the size of the difference.<sup>54</sup> Drug plans assume that allowing PBMs to keep the spread is a way to facilitate

<sup>49</sup> .U.S. GEN. ACCOUNTING OFFICE, EFFECTS OF USING PHARMACY BENEFIT MANAGERS ON HEALTH PLANS, ENROLLEES, AND PHARMACIES 1, 9 (Jan. 2003), <http://www.gao.gov/cgi-bin/getrpt?GAO-03-196> [<https://perma.cc/3L2K-V5W60>].

<sup>50</sup> .APPLIED POLICY, CONCERNS REGARDING THE PHARMACY BENEFIT INDUSTRY 1, 8-9 (2015), <http://www.ncpa.co/pdf/applied-policy-issue-brief.pdf> [<https://perma.cc/6GH4-C2C6>].

<sup>51</sup> .U.S. SENATE COMM. ON FIN. MINORITY STAFF, *supra* note 16, at 43.

<sup>52</sup> .Katie Thomas, *Specialty Pharmacies Say Benefit Managers Are Squeezing Them Out*, N.Y. TIMES (Jan. 9, 2017), <https://www.nytimes.com/2017/01/09/business/specialty-pharmacies-say-benefit-managers-are-squeezing-them-out.html> [<https://perma.cc/9SG2-2J6F>].

<sup>53</sup> .*Id.*

payment to a PBM without having to make the payment themselves. However, spread pricing agreements restrict savings that could be passed on to drug plans and their members to reduce overall drug spending. The spreads, and thus the potential savings, can be considerable. For example, one of Express Scripts' clients discovered that the PBM was paying a pharmacy \$26.91 to fill a prescription for a generic antibiotic for which it charged the client \$92.53.<sup>55</sup> In another recent example, CVS Caremark billed a client \$198.22 for a drug for which it reimbursed the pharmacy only \$5.73.<sup>56</sup> Moreover, a recent study found that spreads are growing, meaning that patients and plans are missing out on an increasing share of negotiated savings.<sup>57</sup>

"Gag" clauses have, until recently, constituted another conflict of interest arising from contracts between PBMs and pharmacies. In some instances, a patient's standard co-pay is higher than the out-of-pocket cost of a drug at a pharmacy. Gag clauses are contract provisions that prevent pharmacists from telling patients when they could pay less for a drug by not billing it to their insurance. When patients pay the higher co-pay, PBMs pocket the difference between the co-pay and the drug cost, called the "clawed back" amount.<sup>58</sup> A 2018 study found that, for twenty-three percent of filled prescriptions, patients pay a co-pay that is higher than the out-of-pocket cost of a drug.<sup>59</sup> Moreover, for nine of the twenty most commonly prescribed drugs, patients overpay the higher co-pay amount for over forty percent of the filled prescriptions. As a result of gag clauses, patients often spend more on drugs than they would if they were informed of lower drug prices.

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<sup>54</sup> .David M. Katz, *Drug Discount Peddlers*, CFO MAG. (Oct. 28, 2005), <https://www.cfo.com/human-capital-careers/2005/10/drug-discount-peddlers> [<https://perma.cc/EPS5-3UEC>].

<sup>55</sup> .Katherine Eban, *Painful Prescription*, FORTUNE (Oct. 10, 2013), <https://fortune.com/2013/10/10/painful-prescription> [<https://perma.cc/5FFY-H6BL>].

<sup>56</sup> .Robert Langreth et al., *The Secret Drug Pricing System Middlemen use to Rake in Millions*, BLOOMBERG (Sept. 11, 2018), <https://www.bloomberg.com/graphics/2018-drug-spread-pricing/> [<https://perma.cc/5RHR-NCKP>].

<sup>57</sup> .*Id.*

<sup>58</sup> .U.S. SENATE COMM. ON FIN. MINORITY STAFF, *supra* note 16, at 33.

<sup>59</sup> .Karen Van Nuys, et al., *Overpaying for Prescription Drugs: The Copay Clawback Phenomenon*, UNIV. OF S. CAL. LEONARD D. SCHAEFFER CTR. FOR HEALTH POL'Y & ECON. 2 (2018), [https://healthpolicy.usc.edu/wp-content/uploads/2018/03/2018.03\\_Overpaying20for20Prescription20Drug\\_s\\_White20Paper\\_v.1-2.pdf](https://healthpolicy.usc.edu/wp-content/uploads/2018/03/2018.03_Overpaying20for20Prescription20Drug_s_White20Paper_v.1-2.pdf) [<https://perma.cc/6GH4-C2C6>].

The most significant conflict of interest arises from manufacturer rebates paid to PBMs. PBMs negotiate rebates from drug manufacturers in exchange for giving the manufacturers' drugs preferred formulary status. Favorable placement on the formulary, in turn, channels more customers to the drugs and increases manufacturers' overall profits because of higher volume sales. Rebates are thus the product of selective contracting negotiations with drug manufacturers. However, whereas selective contracting in the provision of medical services produces savings that flow directly to insurers and patients, rebates are paid directly to PBMs. The difference is that there is generally no middle-man equivalent to PBMs in the provision of medical services. Thus, only in selective contracting between drug manufacturers and PBMs are the gains of selective contracting not directly realized by health plans and patients.

PBMs may pass along some of the higher rebates to their drug plan clients that can then use the money to reduce plan costs or lower co-pays for all members. However, the share of rebates retained by PBMs is rarely negotiated or disclosed, even to their drug plan clients, so it is difficult to measure the share that PBMs are retaining.<sup>60</sup> Evidence suggests that rebate-sharing agreements vary dramatically among PBMs and their drug plan clients, with some clients receiving one-hundred percent of rebates and others receiving nothing.<sup>61</sup> Moreover, even in situations where PBMs have agreed to pass on a specific share, they may re-categorize rebates as fees to circumvent rebate-sharing agreements.<sup>62</sup> In fact, critics assert that PBMs designate as much as twenty-five or thirty percent of the negotiated rebates as fees to avoid sharing the rebates.<sup>63</sup>

Critics argue that PBMs design formularies based on which manufacturers offer the PBMs the highest rebates, rather than on which

<sup>60</sup> .See, e.g., GABRIELA DIEGUEZ, ET AL., A PRIMER ON PRESCRIPTION DRUG REBATES: INSIGHTS INTO WHY REBATES ARE A TARGET FOR REDUCING PRICES (May 2018), <http://www.milliman.com/uploadedFiles/insight/2018/Prescription-drug-rebates.pdf> [<https://perma.cc/JNT9-JYLY>]; U.S. SENATE COMM. ON FIN. MINORITY STAFF, *supra* note 16, at 33.

<sup>61</sup> .Fein, *supra* note 47.

<sup>62</sup> .Henry C. Eickelberg, et al., *The Prescription Drug Supply Chain "Black Box": How It Works and Why You Should Care*, AM. HEALTH POL'Y INST. 1, 13-14 (2015), [http://www.americanhealthpolicy.org/Content/documents/resources/December%202015\\_AHPI%20Study\\_Understanding\\_the\\_Pharma\\_Black\\_Box.pdf](http://www.americanhealthpolicy.org/Content/documents/resources/December%202015_AHPI%20Study_Understanding_the_Pharma_Black_Box.pdf) [<https://perma.cc/UQX9-NLFQ>].

<sup>63</sup> .U.S. SENATE COMM. ON FIN. MINORITY STAFF, *supra* note 16, at 29.

drugs are the least expensive for drug plans and their members. In fact, because the rebates paid to PBMs are typically a percentage of a drug's list price, PBMs have an incentive to select more expensive drugs for formulary status.<sup>64</sup> Moreover, they have the ability to switch out an originally prescribed drug in favor of another drug within the same therapeutic class that has more favorable rebate terms. Indeed, PBMs have paid settlements—Express Scripts paid \$36.3 million in 2008<sup>65</sup> and Medco paid \$29.3 million in 2004<sup>66</sup>—to resolve allegations that they switched patients to higher-cost drugs on the formulary in order to realize higher rebates.

Moreover, because rebates are generally calculated as a percentage of list prices, PBMs have the incentive to encourage list price increases (or at least to discourage decreases) in order to increase their profits. In fact, raising list prices is a way drug manufacturers can compete for formulary placement without reducing their profit.<sup>67</sup> For example, consider a drug with a list price of \$100 and a PBM-negotiated rebate percentage of forty percent. If the manufacturer needed to compete for formulary status by increasing the rebate paid to the PBM, it could raise the list price to \$120 and increase the rebate percentage to fifty percent. Doing so would increase the rebate from \$40 to \$60, but the drug manufacturer wouldn't be any worse off; it would retain the same \$60.

Critics claim that drug manufacturers are increasing drug list prices to satisfy PBMs' demands for higher rebates.<sup>68</sup> Indeed, a current class

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<sup>64</sup> .*Id.* at 27.

<sup>65</sup> .Press Release, New York State Office of the Attorney General, Attorney General Cuomo Secures \$27 Million Dollar Agreement to Crack Down on Pharmacy Benefit Managers Secretly Switching New Yorkers Prescription Drugs (July 29, 2008), <https://ag.ny.gov/press-release/attorney-general-cuomo-secures-27-million-dollar-agreement-crack-down-pharmacy-benefit> [<https://perma.cc/MQK4-A2A3>].

<sup>66</sup> .Milt Freudenheim, *Medco to Pay \$29.3 Million to Settle Complaints of Drug Switching*, N.Y. TIMES (Apr. 27, 2004), <https://www.nytimes.com/2004/04/27/business/medco-to-pay-29.3-million-to-settle-complaints-of-drug-switching.html> [<https://perma.cc/2DPD-FGWL>].

<sup>67</sup> .Clinton Leaf, *Two Stories That Help Explain Runaway Drug Prices*, FORTUNE (June 30, 2017), <https://fortune.com/2017/06/30/drug-prices-problem> [<https://perma.cc/8HVS-5CMR>].

<sup>68</sup> .Paul Barrett & Robert Langreth, *The Crazy Math Behind Drug Prices*, BLOOMBERG BUSINESSWEEK (June 29, 2017), <https://www.bloomberg.com/news/articles/2017-06-29/the-crazy-math-behind-drug-prices> [<https://perma.cc/654M-7J73>].

action lawsuit and investigations by at least five states' Attorneys General assert that insulin list prices have increased by at least 270% over the past decade at least in part to allow PBMs to receive larger rebates.<sup>69</sup> In fact, although drug makers have increased list prices, they are paying a larger and larger share of these list prices as rebates. Whereas drug makers paid rebates of 18.5% of drug purchases calculated at the list price in 2012, by 2016, they were paying rebates of 28.2% of list price purchases.<sup>70</sup> Over this time period, rebates more than doubled, and over half of the increase in list price purchases was paid to PBMs as higher rebates. Thus, although drug list prices are increasing, drug makers are keeping a decreasing share of the revenue while PBMs are keeping an increasing share.

Moreover, because of the trend toward increasing rebates, drug makers claim that they feel pressure to keep list prices high despite the public outrage over drug spending. If manufacturers were to lower list prices, the rebates paid to PBMs would decrease. Drug makers assert that PBMs would retaliate for this drop in revenue by eliminating drugs from the formularies. Thus, the only ways drug makers can maintain the trend of increasing rebates are to either increase list prices and/or pay PBMs an even larger share of existing list prices. Indeed, Health and Human Services (HHS) Secretary Alex Azar has identified drug makers' fear of retaliation from PBMs as a major impediment to reducing drug list prices.<sup>71</sup>

Although a portion of the increasing rebate dollars may trickle down from PBMs to drug plans to insured members, many patients will still suffer from the list-price increases. First, for the almost 29 million Americans without drug plan coverage, the higher drug list prices directly increase their cost of purchasing medicines.<sup>72</sup> However, even insured patients will suffer from higher drug list prices. Most drug plan members have cost-sharing obligations that require them to pay a

<sup>69</sup> .*Id.*

<sup>70</sup> .Fein, *supra* note Error: Reference source not found (\$59 billion/\$318 billion in 2012 is 18.5% and \$127 billion/\$450 billion in 2016 is 28.2%).

<sup>71</sup> .*Hearing on The Cost of Prescription Drugs: Examining the President's Blueprint 'American Patients First' to Lower Drug Prices Before the Sen. Comm. on Health, Education, Labor and Pensions, 115th Cong. (2018)* (statement of Alex Azar, Secretary, Dep't of Health and Hum. Servs.) [hereinafter Statement of Azar].

<sup>72</sup> .*Early Release of Selected Estimates Based on Data From the January–September 2017 National Health Interview Survey*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Sept. 2017), [https://www.cdc.gov/nchs/data/nhis/earlyrelease/EarlyRelease201803\\_01.pdf](https://www.cdc.gov/nchs/data/nhis/earlyrelease/EarlyRelease201803_01.pdf).

percentage, often between thirty and forty percent, of list prices.<sup>73</sup> These patients will pay more when the list price increases. Other insured patients within the deductible phase of their drug plan will pay the entire higher list price until they meet their deductible, which could equate to thousands of out-of-pocket dollars. In the last decade, more and more patients have enrolled in high-deductible plans or plans with significant cost-sharing obligations. As a result, patients are increasingly responsible for all of or a share of the higher drug list prices. In fact, patients' out-of-pocket spending for drugs under their cost-sharing obligations now accounts for twice the share of total drug spending that it did ten years ago.<sup>74</sup> Similarly, patients' spending in the deductible phase now accounts for three times the share of total drug spending that it did ten years ago.<sup>75</sup>

Moreover, even if rebates are passed from PBMs to drug plans, and then drug plans pass along some of the savings to members, the rebate dollars are generally not benefiting the patients that need them most. When drug plans do pass along the rebate savings, they generally use them to lower premiums instead of reducing cost-sharing obligations.<sup>76</sup> As a result, the rebate dollars generated from the drug purchases of the members that spend the most on drugs are used to lower premiums for all drug plan members. Hence, the out-of-pocket spending by the sickest patients subsidizes coverage for the other members.

Higher out-of-pocket spending as a result of increasing drug list prices is more than just a financial challenge for patients. It also puts their health at risk. A significant body of evidence establishes that, as out-of-pocket costs for drugs increase, patients are less likely to adhere to their medication routines.<sup>77</sup> For example, evidence suggests that as

<sup>73</sup> .KAISER FAMILY FOUND., *supra* note Error: Reference source not found.

<sup>74</sup> . GARY CLAXTON, LARRY LEVITT, & MICHELE LONG, PAYMENTS FOR COST SHARING INCREASING RAPIDLY OVER TIME, PETERSON-KAISER HEALTH SYST. TRACKER (Apr. 12, 2016), <https://www.healthsystemtracker.org/brief/payments-for-cost-sharing-increasing-rapidly-over-time> [<https://perma.cc/R2YS-4W9D>].

<sup>75</sup> .*Id.*

<sup>76</sup> .PHRMA, COMMENTS OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA CONCERNING HHS BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS 1, 19 (2018), <https://www.phrma.org/public-communication/rfi-comments-on-hhs-blueprint-to-lower-drug-prices-and-reduce-out-of-pocket-costs> [<https://perma.cc/8ZEN-V57V>].

<sup>77</sup> .IMS INSTITUTE FOR HEALTHCARE INFORMATICS, EMERGENCY AND IMPACT OF PHARMACY DEDUCTIBLES: IMPLICATIONS FOR PATIENTS IN COMMERCIAL HEALTH PLAN 1 (2015); Zarek Brot-Goldberg, et al., *What Does A Deductible Do? The Impact of Cost-Sharing on Health Care Prices*,

patients' out-of-pocket spending for drugs increases by \$50, they are four times more likely to abandon their regimens altogether.<sup>78</sup>

Moreover, increasing concentration in the PBM market has exacerbated the risk that conflicts of interest in the PBM business model harm drug plans and their members. In a more competitive market in which PBMs competed for drug plan clients based on drug pricing and availability, PBMs would have the incentive to share with drug plans the savings they negotiate with drug makers or pharmacies. Failure to do so would reduce a PBM's competitive position and could result in them losing a client to another PBM that did pass along these savings. However, as competition in the PBM market declines, so too does the incentive to share savings with drug plans and their members in order to compete on the basis of drug price. Instead, PBMs' role as the middlemen between drug makers, pharmacies, and drug plans creates significant conflicts of interest. As the Administrator for the Centers for Medicare and Medicaid Services recently said, PBMs' role "makes it unclear who they're actually aligned with."<sup>79</sup> Ultimately, the profit incentive for PBMs is in direct conflict with efforts to minimize drug costs for drug plans and beneficiaries and, instead, leads to higher drug prices for all patients.

### III. POSSIBLE AREAS OF REFORM

A number of reforms have been proposed over the years to mitigate the conflicts of interest inherent in the PBM business model. Recently, the *Patients Right to Know Drug Prices Act* prohibits gag clauses and mandates that pharmacies cannot be penalized for informing patients

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*Quantities, and Spending Dynamics*, 132 Q. J. ECON. 1261 (2017); Jalpa Doshi, et al., *High Cost Sharing and Specialty Drug Initiation Under Medicare Part D: A Case Study in Patients with Newly Diagnosed Chronic Myeloid Leukemia*, 22 AM. J. MANAGED CARE S78 (2016); Michael Eaddy, et al., *How Patient Cost-Sharing Trends Affect Adherence and Outcomes*, 37 PHARMACY & THERAPEUTICS 45 (2012).

<sup>78</sup> .William Shrank et al., *The Epidemiology of Prescriptions Abandoned at the Pharmacy*, 153 ANNALS OF INTERNAL MED. 633 (2010).

<sup>79</sup> .Seema Verma, Adm'r, Cents. for Medicare and Medicaid Servs., Remarks at the American Hospital Association Annual Membership Meeting (May 7, 2018), <https://www.cms.gov/newsroom/fact-sheets/speech-remarks-cms-administrator-seema-verma-american-hospital-association-annual-membership-meeting> [<https://perma.cc/CTK6-EJLD>].

when cash prices are less than insurance co-pays.<sup>80</sup> Enactment of this federal bill prohibiting gag clauses nationwide ensures that patients no longer pay higher prices at the pharmacy because PBMs hope to pocket the difference between lower cash prices and higher co-pays.

Future reforms should target PBM compensation schemes in order to better align incentives between PBMs, drug plans, and patients. PBMs can and do provide a valuable service to their drug plan clients by selectively contracting with drug makers and pharmacies. However, some of the current ways in which PBMs are compensated create significant conflicts of interest. Reforms should preserve as many benefits of the PBM business model as they can, while minimizing the perverse incentives that can harm drug plans and patients.

#### A. *Increased Transparency and Disclosure Requirements*

One of the most frequent criticisms levied at PBMs involves the lack of transparency about their business practices. Critics argue that, because PBMs do not reveal the nature of their negotiations with other entities in the pharmaceutical market, their drug plan clients do not know how much they are benefitting from their arrangements with PBMs.<sup>81</sup> PBMs rarely disclose the rebates they receive from manufacturers, and in situations in which they've agreed to share rebate information, the PBMs may recategorize rebates as fees to circumvent disclosure obligations.<sup>82</sup>

Proponents of increasing PBMs' disclosure obligations contend that more transparency about the amount and nature of manufacturer rebates would ensure that the middlemen are acting in the best interest of their drug plan clients.<sup>83</sup> They argue that requiring public disclosure of rebates and other price concessions will both inform drug plan clients

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<sup>80</sup> .Patient Right to Know Drug Prices Act, Pub. L. No. 115-263, 132 Stat. 3672 (2018).

<sup>81</sup> .OFFICE OF THE INSPECTOR GEN., U.S. DEP'T. OF HEALTH AND HUM. SERVS., CONCERNS WITH REBATES IN THE MEDICARE PART D PROGRAM, ii (2011), <https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf> [<https://perma.cc/KV3T-GA2C>] ("The lack of transparency raises concerns that sponsors may not always have enough information to oversee the services and information provided by PBMs.").

<sup>82</sup> .EICKELBERG, et al., *supra* note 62, at 13-14.

<sup>83</sup> .NAT'L ACADS. OF SCI., ENG'G, AND MED., MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE 1, 65 (Norman R. Augustine, Guru Madhavan, & Sharyl J. Nass eds., 2017).

about PBMs' sources of profits and allow drug plans to negotiate for a larger share of those profits.<sup>84</sup>

Bills requiring more transparency of PBM rebates have stalled at the federal level. For example, the *Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act* of 2017, would have required the disclosure of both PBM-negotiated rebates and discounts and the extent to which these rebates and discounts are passed on to drug plan clients.<sup>85</sup> The bill would have also required PBMs to disclose the amount of the spread, or difference between the price of drugs charged to the drug plan and the price paid to dispensing pharmacies. However, the bill did not make it out of the Senate Finance Committee.

States have had more success in enacting laws requiring disclosure of PBM-negotiated rebates. For example, in 2018, Connecticut and Louisiana enacted bills requiring PBMs to disclose both the amount of rebates received from manufacturers and the portion paid to drug plan clients.<sup>86</sup> In 2017, Nevada enacted a law requiring similar disclosure of the amount of rebates and portion passed on to drug plan clients, but required disclosure only to rebates paid for diabetes drugs.<sup>87</sup>

PBMs have opposed these reform efforts with arguments that they already disclose information about rebates to the extent that their contracts with individual drug plan clients require it.<sup>88</sup> Indeed, many contracts between PBMs and their drug plan clients require disclosure and grant audit rights to client drug plans, even without mandatory disclosure regulations.<sup>89</sup>

<sup>84</sup> .Carrier, *supra* note 48.

<sup>85</sup> .Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act of 2017, S. 637, 115th Cong. (2017).

<sup>86</sup> .S.B. 283, 2018 Leg., Reg. Sess. (La. 2018); H.B. 5384, 2018 Gen. Assemb. (Conn. 2018).

<sup>87</sup> .S.B. 539, 2017 Leg., 79th Sess. (Nev. 2017).

<sup>88</sup> .MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM, 426 n. 18 (2017).

<sup>89</sup> .See, e.g., FED. TRADE COMM'N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES 58 (Aug. 2005), [https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitrpt\\_0.pdf](https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitrpt_0.pdf) [<https://perma.cc/A2CL-8KB9>]; Milt Freudenheim, *Employers Unite in Effort to Curb Prescription Drug Costs*, N.Y. TIMES (Feb. 3, 2005), <https://www.nytimes.com/2005/02/03/business/employers-unite-in-effort-to-curb-prescription-costs.html> [<https://perma.cc/H9HX-5MCV>]; Milt Freudenheim, *Big Employers Join Forces in Effort to Negotiate Lower Drug Prices*, N.Y. TIMES (June 12, 2004),

Moreover, increased transparency could have the unintended consequence of harming competition and raising drug prices.<sup>90</sup> Increased disclosure requirements will increase costs for PBMs as they collect, prepare, and present the new information and hire additional consultants and/or lawyers to help them with the process. PBMs will initially pay these additional costs out of pocket. However, the costs will likely be passed on to drug plans and beneficiaries in the form of increased fees or reduced savings, both of which will increase drug spending. The FTC has acknowledged that additional disclosure “will increase health care costs, and such costs may be reflected in the price of drug plans that health plans are able to offer . . . , the scope of coverage consumers receive under such plans, or the number of consumers who have access to such coverage.”<sup>91</sup>

More importantly, mandatory disclosure will release competitively sensitive information about rebate terms, reducing PBMs’ ability to negotiate significant rebates in the future. When rebate terms are kept private, manufacturers have the incentive to bid aggressively for formulary status by offering significant rebates. Not only are they trying to outbid “unknown” offers, but the manufacturers know that any offers they make to a specific PBM and drug plan will be kept secret.<sup>92</sup> However, when rebate terms are disclosed, this incentive disappears. Any rebate arrangement the manufacturers make will be known by their competitors who can then try to match or outbid them. Moreover, other PBMs and drug plans will know the rebate arrangements the manufacturer has made, and demand similar terms. Indeed, federal antitrust agencies maintain that information sharing among rivals can increase prices because it “can blunt a firm’s incentive to offer customers better deals by undercutting the extent to which such a move

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<https://www.nytimes.com/2004/06/12/business/big-employers-join-forces-in-effort-to-negotiate-lower-drug-prices.html> [<https://perma.cc/N4D3-UYB5>].

<sup>90</sup> .For a discussion, see Joanna Shepherd, *Is More Information Always Better? Mandatory Disclosure Regulations in the Prescription Drug Market*, 99 CORNELL L. REV. ONLINE 1 (2013).

<sup>91</sup> .Letter from Fed. Trade Comm’n to Senator James L. Seward, N.Y. Senate 4 (Mar. 31, 2009), [https://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf](https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf) [<https://perma.cc/BE5Q-QWYG>].

<sup>92</sup> .Letter from Fed. Trade Comm’n to Assembly Member Greg Aghazarian, Cal. Gen. Assembly 9 (Sept. 7, 2004), <http://www.ftc.gov/be/V040027.pdf> [<https://perma.cc/M7AJ-URV5>].

would win business away from rivals” and “also can enhance a firm’s incentive to raise prices, by assuaging the fear that such a move would lose customers to rivals.”<sup>93</sup> This will likely have the result of reducing the rebates manufacturers are willing to pay and, in turn, increasing the cost of drugs for drug plans and their members.

Such transparency may even foster tacit collusion among drug makers.<sup>94</sup> The Federal Trade Commission and Department of Justice have concluded that the disclosure of sensitive business information, such as price, can lead to tacit collusion among drug makers: “the sharing of information related to a market in which the collaboration operates or in which the participants are actual or potential competitors may increase the likelihood of collusion on matters such as price . . . .”<sup>95</sup>

### *B. Imposing a Fiduciary Duty on PBMs*

Other proposals have suggested imposing a fiduciary mandate on PBMs.<sup>96</sup> PBMs do not currently have a fiduciary duty to their clients, despite efforts to impose one. The Employee Retirement Income Security Act of 1974 (ERISA),<sup>97</sup> overseen by the Department of Labor (DOL), is a federal law that establishes minimum standards for health plans and pension plans in private industry.<sup>98</sup> PBMs do not meet the well-established fiduciary definition under ERISA because they “have no power to make any decisions as to plan policy, interpretations, practices or procedures” and “[do] not have discretionary authority or discretionary control respecting management of the plan, [do] not exercise any authority or control respecting management or disposition of the assets of the plan, and [do] not render investment advice with

<sup>93</sup> .U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, HORIZONTAL MERGER GUIDELINES §7 (Aug. 19, 2010), <http://ftc.gov/os/2010/08/100819hmg.pdf> [<https://perma.cc/7Y25-V6L4>] (describing anticompetitive effects of coordination among rivals).

<sup>94</sup> .See, e.g., Svend Albaek et al., *Government-Assisted Oligopoly Coordination? A Concrete Case*, 45 J. INDUS. ECON. 429 (1997).

<sup>95</sup> .FED. TRADE COMM’N & U.S. DEP’T OF JUSTICE, ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS § 3.31(b) (Apr. 2000), <http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf> [<https://perma.cc/ZC5F-YHDA>].

<sup>96</sup> .Joyce, *supra* note 38.

<sup>97</sup> .See Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406, 88 Stat. 829 (codified in part at 29 U.S.C. § 18 (2018)).

<sup>98</sup> .See ERISA, U.S. DEP’T LAB., <https://www.dol.gov/general/topic/health-plans/erisa> [<https://perma.cc/AC9B-YKWY>].

respect to any money or other property of the plan . . . .”<sup>99</sup> Indeed, courts have repeatedly concluded that PBMs are not ERISA fiduciaries and that state laws imposing a fiduciary duty are preempted by ERISA.<sup>100</sup>

However, Congress could reconsider this ERISA preemption and allow states to impose a fiduciary duty on PBMs. Proponents of this proposal contend that a fiduciary duty would ensure that PBMs do not take actions, such as promoting higher list prices, that would have a harmful impact on their clients. Fiduciary status also might prevent PBMs from collecting manufacturer rebates, distributing drugs through their own specialty pharmacies,<sup>101</sup> employing spread pricing that charges a drug plan client a higher price than the reimbursement to the pharmacy, or incorporating gag clauses into pharmacy contracts.<sup>102</sup> In fact, Congress could declare any decision made by a PBM for the primary purpose of increasing its own profits as a breach of fiduciary duty. Doing so could provide broader protection for consumers because it would deter PBMs from finding loopholes to circumvent reforms aimed at specific practices.

However, a fiduciary mandate would have to be implemented in a way that did not create conflicting obligations for PBMs. HHS has indicated that it is considering imposing a fiduciary duty on PBMs to either or both of “the entity for whom they are managing pharmaceutical benefits” (i.e. the drug plan client) and “the ultimate payer” (i.e., consumers).<sup>103</sup> However, in many situations, a heightened duty to PBMs’ drug plan clients would conflict with a heightened duty to the ultimate beneficiaries. For example, certain PBM tools, such as a

<sup>99</sup> .29 C.F.R. § 2509.75-8 (2020).

<sup>100</sup> .See, e.g., *Pharm. Care Mgmt. Ass’n v. Dist. of Columbia*, 613 F.3d 179 (D.C. Cir. 2010); *Bickley v. Caremark Rx*, 361 F. Supp. 2d 1317 (N.D. Ala. 2004), *aff’d* 461 F.3d 1325 (11th Cir. 2006); *Seaway Food Town, Inc. v. Med. Mut. of Ohio*, 347 F.3d 610, 619 (6th Cir. 2003); *In Re Express Scripts/Anthem ERISA Litigation*, 285 F. Supp. 3d 655 (S.D.N.Y. 2018); *Moeckel v. Caremark, Inc.*, 622 F. Supp. 2d 663, 678 (M.D. Tenn. 2007).

<sup>101</sup> .Charley Grant, *Reckoning for Drug Middlemen Is Postponed, Not Canceled*, WALL ST. J. (May 11, 2018), <https://www.wsj.com/articles/reckoning-for-drug-middlemen-is-postponed-not-canceled-1526072704> [<https://perma.cc/KL9S-4KFL>].

<sup>102</sup> .Joyce, *supra* note 38.

<sup>103</sup> .U.S. DEP’T OF HEALTH & HUM. SERVS., AMERICAN PATIENTS FIRST: THE TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS 33 (May 2018), <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf> [<https://perma.cc/CV45-XDLG>].

preferred formulary or exclusive pharmacy network, are designed to reduce the total costs paid by the drug plan and all covered members. However, these tools may increase the costs or limit the access for specific members that purchase non-formulary drugs or fill prescriptions at non-network pharmacies.

Moreover, a fiduciary duty could backfire and result in increased drug costs for plans' consumers. Because fiduciary status would subject PBMs to broader legal liabilities, they likely would take certain defensive measures that would increase prescription drug benefit costs for both drug plans and beneficiaries. For example, the uncertainty and complexity of a new fiduciary status would compel PBMs to increase spending on litigation departments and outside counsel in an effort to understand the implications of their new status.<sup>104</sup> Similarly, PBMs would likely purchase additional liability insurance to offset the increased legal risk.<sup>105</sup> A fiduciary mandate would also increase administrative costs as PBMs revise existing contracts to conform with the new requirements.<sup>106</sup> PBMs would likely pass along these higher litigation, insurance, and administrative costs to drug plans in the form of higher fees or reduced savings. PBMs would also likely decrease the use of certain cost-saving tools to mitigate the risk of lawsuits. For example, they may decrease the use of preferred formularies and exclusive pharmacy networks to reduce the litigation risk that arises from reduced patient access. Similarly, PBMs may be unwilling to use incentives to channel patients to a PBM-owned mail order pharmacy with lower drug costs because those actions could be interpreted as profiting at the expense of their clients.<sup>107</sup> Curtailing these cost-saving tools would also raise drug benefit costs for both drug plans and their members.

<sup>104</sup> .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, 20-21 (2013)

<sup>105</sup> .VISANTE, INCREASED COSTS ASSOCIATED WITH PROPOSED STATE LEGISLATION IMPACTING PBM TOOLS 7 (Feb. 2018), <https://www.pcmanet.org/wp-content/uploads/2018/03/Visante-Study-on-the-Increased-Costs-Associated-With-State-Legislation-Impacting-PBM-Tools-FINAL-1.pdf> [<https://perma.cc/S6AE-AP2K>].

<sup>106</sup> .*Id.*

<sup>107</sup> .Fed. Trade Comm'n to Assembly Member Nellie Pou, NJ. Gen. Assembly 6 (Apr. 17, 2007), <http://www.ftc.gov/be/V060019.pdf> [<https://perma.cc/6DQM-MZUA>].

### C. Reining in Rebates

One of the most promising avenues for reform involves reducing the rebates paid to PBMs. The current retrospective rebate structure creates perverse incentives for manufacturers to increase drug list prices. Because rebates are typically a percentage of drug list prices, higher list prices produce larger rebates for PBMs. PBMs have the incentive to put drugs that produce larger rebates on the drug formulary. Thus, higher list prices may earn manufacturers placement on drug formularies, channeling more customers to the drugs and increasing manufacturers' profits.

Efforts to rein in rebates take two general forms. Some proposals aim to eliminate the practice of manufacturers paying rebates to PBMs. Others allow the practice to continue but suggest reforms to ensure that rebates do not increase list prices or impose other harms on drug plans and consumers.

Certain proposals that advocate significant changes to the rebate structure could potentially run afoul of the Medicare Part D "non-interference clause." The statute establishing the Medicare Part D program provides that the Secretary of HHS "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs."<sup>108</sup> Critics of regulatory reform efforts argue that reforms mandating certain types of pricing or prohibiting specific discounting practices might violate the non-interference clause.<sup>109</sup> For example, as discussed below, regulations replacing the current rebate system with pre-negotiated, fixed price discounts may be deemed an unlawful interference in negotiations. However, reform advocates argue that the rebate system can be modified without violating the non-interference clause.<sup>110</sup> Specifically, administrative reforms that would require a portion of

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<sup>108</sup> .42 U.S.C. § 1395w-111(h)(i).

<sup>109</sup> .Letter from Pharm. Care Mgmt. Ass'n to Secretary Alex Azar, U.S. Dep't of Health and Hum. Servs., HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs Request for Information 90-91 (July 16, 2018), <https://www.pcmnet.org/wp-content/uploads/2018/07/PCMA-comments-on-Blueprint-RFI-July-16-2018.pdf> [<https://perma.cc/Q6PE-DRQE>].

<sup>110</sup> .Jim C. Stansel, *Pass-Through Rebates Do Not Violate Non-Interference Clause but They Do Increase Savings for Seniors*, PHRMA: CATALYST (July 2, 2018), <https://catalyst.phrma.org/pass-through-rebates-do-not-violate-non-interference-clause-but-they-do-increase-savings-for-seniors> [<https://perma.cc/9KEG-2HMT>].

rebates be shared with drug plans and/or beneficiaries would not dictate a specific drug price or formulary nor interfere in negotiations between PBMs and drug makers.

### 1. Eliminating Rebates

Some rebate critics have proposed doing away with rebates altogether. HHS Secretary Alex Azar has argued that “we may need to move toward a system without rebates, where PBMs and drug makers just negotiate fixed-price contracts. Such a system’s incentives, detached from artificial list prices, would likely serve patients far better.”<sup>111</sup> Similarly, Food and Drug Administration Commissioner Scott Gottlieb has asserted that “one of the dynamics I’ve talked about before that’s driving higher and higher list prices, is the system of rebates between payers and manufacturers . . . . so what if we took on this system directly?”<sup>112</sup>

HHS has explained that it can effectively eliminate rebates in federal health programs by reducing the protections for rebates under federal anti-kickback laws. Anti-kickback laws prohibit remuneration paid in order to induce the referral of business under Federal health programs like Medicare, Medicaid, and others.<sup>113</sup> Although this prohibited behavior sounds exactly like a rebate paid for formulary placement in order to channel customers to a drug, PBM rebates are generally exempt from the anti-kickback statute.<sup>114</sup> In 1999, the Department of Health and Human Services created an exemption from anti-kickback enforcement

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<sup>111</sup> .Statement of Azar, *supra* note 71.

<sup>112</sup> .Food and Drug Administrator Scott Gottlieb, Keynote Address to the 2018 FDLI Annual Conference (May 3, 2018), <https://www.fda.gov/NewsEvents/Speeches/ucm606541.htm>.

<sup>113</sup> .42 U.S.C. § 1320a-7b (2018).

<sup>114</sup> .On occasion, PBM rebates have been treated as unlawful kickbacks. For example, both drug maker AstraZeneca and PBM Medco, which has since been acquired by Express Scripts, each paid \$7.9 million to settle claims that they were involved in an illegal kickback scheme. *Medco to Pay \$7.9 Million to Resolve Kickback Allegations*, DEP’T OF JUST. (May 20, 2015), [www.justice.gov/opa/pr/medco-pay-79-million-resolve-kickback-allegations](http://www.justice.gov/opa/pr/medco-pay-79-million-resolve-kickback-allegations). The government’s complaint alleged that Medco solicited various financial inducements from AstraZeneca in exchange for keeping the drug Nexium on the Medco formulary, even though competing drugs would have been cheaper for drug plans and their clients, but then concealed the nature of the financial inducements to prevent the client from realizing any of the savings. Compl., *United States ex rel. DiMattia v. Medco Health Solutions, Inc.*, 2015 WL 4384492 (D. Del. 2015)

for PBM rebates that are “a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or other entity under a Federal health care program.”<sup>115</sup>

In January 2019, the HHS Office of Inspector General released a Proposed Rule that would eliminate this “safe harbor” exemption from anti-kickback laws that currently protects manufacturers’ practice of paying retrospective rebates to PBMs.<sup>116</sup> The proposal would amend the existing safe harbor so that it explicitly excludes rebates from manufacturers paid to PBMs, Medicare Part D plans or Medicaid managed care plans.

Unlike federal health care programs, HHS has no authority over commercial plans. Thus, the elimination of the exemption wouldn’t directly affect rebates in private drug plans. However, disrupting a critical piece of the PBM business model for a large segment of the U.S. insurance market—federal health care programs account for over forty percent of drug spending<sup>117</sup>—would no doubt have a rippling effect across other segments. Moreover, HHS has suggested that current OIG rules may prevent manufacturers from offering rebates to private plans without offering them to Medicare or Medicaid plans.<sup>118</sup> Although questions remain about HHS’s authority to eliminate the rebate safe harbor exemption,<sup>119</sup> if the proposal is successful, it would make rebates

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<sup>115</sup> .42 U.S.C. § 1320a-7b. See Dept. of Health and Human Servs., *Federal Health Care Programs: Fraud and Abuse; Statutory Exception to the AntiKickback Statute for Shared Risk Arrangements*, 64 FED. REG., 63,504 (Nov. 19, 1999), at 42 C.F.R. § 1001 (2020).

<sup>116</sup> .*Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*, 84 Fed. Reg. 2340 (Feb. 6, 2019).

<sup>117</sup> .U.S. CTRS FOR MEDICARE & MEDICAID SERVICES, OFFICE OF THE ACTUARY, NATIONAL HEALTH STATISTICS GROUP, NATIONAL HEALTH EXPENDITURES DATA, TBL.4 (2015), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html>.

<sup>118</sup> .DEP’T OF HEALTH & HUMAN SERVS., FACT SHEET: TRUMP ADMINISTRATION PROPOSES TO LOWER DRUG COSTS BY TARGETING BACKDOOR REBATES AND ENCOURAGING DIRECT DISCOUNTS TO PATIENTS (2019), <https://www.hhs.gov/sites/default/files/20190131-fact-sheet.pdf>.

<sup>119</sup> .Joshua Cohen, *Improving Drug Price Transparency: From Removing Pharmacy Gag Clauses to Reforming The Rebate System*, FORBES (Oct.

paid under federal health care programs illegal and may also restrict rebates paid to private plans.

Eliminating rebates would transform the way that PBMs are reimbursed and the way that manufacturers compete for formulary status. Presumably, the rebates would be replaced with some other sort of compensation for PBMs and manufacturer concessions for formulary status. HHS would need to ensure that, in whatever new system emerged, PBM compensation was no longer tied to the prices of drugs chosen for the formulary. Otherwise, the perverse incentives to keep list prices high would remain. For example, if manufacturers paid PBMs fees based on the total revenue generated from the PBMs' drug plan clients, then PBM compensation would continue to be based on list prices (total revenue is price multiplied by quantity sold). PBMs would continue to favor more expensive drugs because they would generate higher revenues and, in turn, higher PBM fees. Alternatively, if drug plans compensated PBMs based on the discounts from the list prices the PBMs could negotiate with manufacturers, then PBM compensation would also be tied to list prices. PBMs would still have the incentive to grant formulary status to drugs with high list prices because there would be more room for PBMs to negotiate larger discounts, increasing the compensation they were paid from drug plans.

## 2. Decoupling Rebates from List Prices

Other proposals are aimed at altering PBM rebates so that they don't lead to higher list prices for drug plans and consumers. Several reforms have been proposed. First, some proposals have called for a decoupling of rebates from drug list prices.<sup>120</sup> Because rebates are typically calculated as a percentage of list prices, drug makers have the incentive to increase list prices to meet PBMs' demand for higher rebates. Regulatory reforms could prohibit rebates based on a percentage of list prices, and instead require that rebates be based on some other measure of market share. For example, PBMs and drug

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17, 2018),  
<https://www.forbes.com/sites/joshuacohen/2018/10/17/improving-drug-price-transparency-from-removing-pharmacy-gag-clauses-to-reforming-the-rebate-system/#153e7305303b> [https://perma.cc/87MG-CNEM]; Ike Swetlitz & Nicholas Florko, *In Bold New Proposal, Trump Administration Pitches an End to Certain Drug Rebates*, STAT (Jan. 31, 2019), <https://www.statnews.com/2019/01/31/in-bold-new-proposal-trump-administration-pitches-an-end-to-certain-drug-rebates/> [https://perma.cc/58B8-CE8C].

<sup>120</sup> .PHRMA, *supra* note 76, at 22.

makers could agree in advance to a schedule of rebates based on certain market share goal posts. In this scenario, the rebates paid by drug makers would still give PBMs the incentive to channel customers to the formulary drugs, maintaining the traditional formulary status-for-rebate system but decoupling the rebate amount from the list price.

However, a potential problem with this approach is that, even if rebate amounts are disassociated from list prices, drug makers would still be willing to pay higher rebates for drugs that earn them greater revenue. For example, a drug maker might be willing to pay \$100 million in rebates for a drug that generates several billion in revenue, but not for a drug that generates \$150 million in revenue. Because revenue is simply quantity sold multiplied by the list price, revenue is directly tied to list prices. Thus, the schedule of rebates proposed by drug makers for different drugs would still depend, in part, on list prices, maintaining the incentive for PBMs to prefer drugs with higher list prices for formulary status.

### 3. Adopting Point-of-Sale Rebates

Finally, some proposals recommend maintaining rebates but changing their structure to ensure that they directly benefit patients. These proposals aim to replace the current after-purchase rebate system with point-of-sale rebates that are passed through at the pharmacy counter to reduce out-of-pocket spending. They assume that PBMs and drug plans could create formularies based on which manufacturers offered the most significant point-of-sale rebates. Thus, this reform would preserve the benefits of selective contracting that generate significant rebates to lower the net price of drugs, but it would also ensure that rebates actually save patients money rather than end up in the hands of PBMs or drug plans.

Moving to a point-of-sale rebate system would also ensure that the sickest patients receive the rebate savings. Whereas current rebate dollars, when they are passed along from PBMs to drug plans to members, are generally used to lower premiums for all beneficiaries, a point-of-sale system would primarily benefit the beneficiaries that buy the most drugs. Incorporating rebate savings into the purchase price of a drug reduces the out-of-pocket spending for any drug plan member filling a prescription, but the sickest patients that buy the most drugs would see the greatest reductions in their total drug spending.<sup>121</sup>

<sup>121</sup> .Some commentators have argued that the rebate savings generated by the sickest patients should subsidize all drug plan members because the reverse often occurs with premiums: the premiums of the healthiest members may be used to subsidize the sickest beneficiaries. See, e.g.,

Although a point-of-sale rebate system would not directly benefit the twenty-nine million Americans without drug plan coverage, it would indirectly benefit them by curtailing the rise in drug list prices. Under a point-of-sale system, PBMs would not retain rebates and, thus, would have no incentive to promote higher list prices. If the growth in list prices were to slow, uninsured Americans would benefit because their out-of-pocket drug spending would be significantly reduced.

Because a point-of-sale system would eliminate PBMs' retention of rebates, PBMs would need to be compensated in some other way that continues to incentivize their negotiation of significant point-of-sale rebates from manufacturers. As with the previously discussed proposals to eliminate rebates altogether, the new form of PBM compensation should not be tied to the prices of drugs chosen for the formulary.

Critics of a point-of-sale rebate system argue that passing through all rebates at the point of sale may violate antitrust precedent.<sup>122</sup> In the 1990s, a series of antitrust lawsuits brought by pharmacies against drug makers resulted in the elimination of up-front discounts and the creation of back-end rebates.<sup>123</sup> Prior to this litigation, drug makers often offered discounted prices to HMOs, hospitals, and nursing homes that could influence doctors to channel patients towards specific drugs. In contrast, the drug makers offered no such discounts to pharmacies that could not influence doctors' prescribing practices. The pharmacy plaintiffs claimed these differential discounts stemmed from a price-fixing conspiracy instead of normal market forces. After an unfavorable federal court ruling, several drug makers agreed to settle the case.<sup>124</sup> The eventual settlement approved by a federal court provided that drug makers would generally offer the same up-front discounts to all buyers. However, because the court did not condemn the use of back-end rebates, the

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Susan Morse, *HHS Secretary Alex Azar Backs Point-of-Sale Drug Rebates by UnitedHealthcare, CVS Health*, HEALTHCARE FINANCE (Mar. 9, 2018), <https://www.healthcarefinancenews.com/news/hhs-secretary-alex-azar-backs-point-sale-drug-rebates-unitedhealthcare-cvs-health> [<https://perma.cc/A745-YY49>].

<sup>122</sup> .PHARMACEUTICAL CARE MANAGEMENT ASS'N, ANTITRUST CONSIDERATIONS OF PROPOSALS TO LIMIT REBATES (July 15, 2018), [https://www.pcmnet.org/wp-content/uploads/2018/07/Legal-Analysis\\_-\\_Antitrust-Considerations-of-Proposals-to-Limit-Rebates.pdf](https://www.pcmnet.org/wp-content/uploads/2018/07/Legal-Analysis_-_Antitrust-Considerations-of-Proposals-to-Limit-Rebates.pdf).

<sup>123</sup> .*In Re Brand Name Prescription Drugs Antitrust Litigation*, Civ. No. 94 C 897, MDL 997 (N. D. Ill. 1994).

<sup>124</sup> .Thomas Burton & Elyse Tanouye, *Four Drug Giants Agree to Settle Pricing Lawsuit for \$350 Million*, WALL ST. J. (July 14, 1998), <https://www.wsj.com/articles/SB900435014904441000> [<https://perma.cc/PE5P-GERP>].

settlement preserved the ability of drug makers to offer different net prices to different buyers through the use of rebates.<sup>125</sup> Critics of current proposals to adopt a point-of-sale rebate system argue that doing so may violate the terms of the approved 1990s settlement.<sup>126</sup> However, the 1990s settlement only involved certain manufacturers and only covered conduct for a three-year period.<sup>127</sup> Thus, allowing drug makers to build in rebates at the point-of-sale would not violate the terms of this 20-year-old settlement.

A point-of-sale rebate system would generate a few implementation issues. First, because some portion of rebates is generally based on the market share attained in a given period, the full rebate amount may not be known at the point of sale. In addition, if all rebates were passed through at the point of sale, the results of negotiations between PBMs and drug makers would no longer be private. Much like the previously discussed full disclosure of rebate terms could reduce the rebates that manufacturers offer to PBMs, point-of-sale rebates that are transparent to rivals could have the same effect. That is, manufacturers would likely offer lower rebates if the purchase prices of drugs were to reflect all negotiated rebates. Currently, manufacturers offer different rebates and discounts to different PBMs and drug plans, depending on how many beneficiaries they cover. However, if rebates were visible to anyone because they were fully reflected in the purchase price, manufacturers would be reluctant to offer significant rebates to one PBM or drug plan because other PBMs would demand the same terms. Similarly, the manufacturers' rivals could learn the specifics of their negotiated rebates and then offer the same or better terms.

A partial pass-through of rebates at the point-of-sale would solve both problems. Under this system, some sizable portion of the total rebate would apply at the point-of-sale to reduce patient out-of-pocket spending. Then, at the end of the period, drug makers would pay additional rebates if the revenue generated from the drug plan's members met negotiated market share thresholds. Drug plans could retain this later portion of the rebate to lower costs for all beneficiaries by decreasing co-pays or cost-sharing obligations. Alternatively, drug plans could reimburse the original patient for this additional rebate, just as current health insurers often reimburse patients who pay too much

<sup>125</sup> .Scott Gottlieb, *How Congress Can Make Drug Pricing More Rational*, FORBES (Sept. 12, 2016), <https://www.forbes.com/sites/scottgottlieb/2016/09/12/how-congress-can-make-drug-pricing-more-rational/> [https://perma.cc/GS2C-VAHH].

<sup>126</sup> .*Id.*

<sup>127</sup> .Ken Rankin, *Drug Manufacturers Agree to Abandon Unfair Discounts*, 18 DRUG STORE NEWS p3 (1996).

up front for medical services. A partial point-of-sale rebate system would also protect competitively-sensitive information about the total rebates negotiated between drug makers and PBMs.

In January 2019, the HHS and OIG issued a Proposed Rule that would create a new safe harbor from anti-kickback laws to protect point-of-sale rebates under federal health care programs like Medicare Part D and Medicaid.<sup>128</sup> Moreover, several drug plans have adopted a version of point-of-sale rebates on their own. United Healthcare, which owns PBM OptumRX, began passing along a portion of rebates at the point-of-sale to some patients in 2019.<sup>129</sup> Similarly, PBM Express Scripts has announced that, for one set of its drug plan clients, it will pass through 100% of the rebates it receives from drug makers at the point-of-sale.<sup>130</sup> However, because many drug plans do not have sufficient bargaining power to demand a point-of-sale rebate arrangement from their PBM, only legislation or agency action can achieve this change for all plans and patients.

#### CONCLUSION

PBMs' role as the middlemen between drug manufacturers, pharmacies, and drug plans can lead to significant conflicts of interest that pit PBMs' profit incentives against efforts to minimize drug costs. Manufacturer rebates paid to PBMs give rise to the most significant conflict of interest because they give PBMs the incentive to favor more expensive drugs and encourage drug price increases in order to increase their own profits. Although a portion of the increasing rebate dollars may eventually find its way to patients in the form of lower co-pays, many patients—both insured and uninsured—still suffer from increasing drug prices.

The current manufacturer rebate system is a variation of selective contracting that has been employed in the provision of health care since the 1980s. Selective contracting involves exclusive arrangements between insurers and medical providers under which the insurer channels patients to the provider in exchange for the provider offering

<sup>128</sup> .84 Fed. Reg. 2340, *supra* note 116.

<sup>129</sup> .UnitedHealthcare Implements Point-of-Sale Discounts for Eligible Plan Participants, UNITEDHEALTHCARE (Apr. 16, 2018), <https://www.uhc.com/employer/news/brokers/unitedhealthcare-implements-point-of-sale-discounts-for-eligible>.

<sup>130</sup> .Adam Fein, *PBM Pricing Overhaul: Express Scripts Prepares for a World Without Rebates—But Employers May Not Change*, DRUG CHANNELS (Oct. 25, 2018), <https://www.drugchannels.net/2018/10/pbm-pricing-overhaul-express-scripts.html> [<https://perma.cc/J8TH-3GC9>].

significantly discounted prices. In the case of manufacturer rebates, drug plans and PBMs channel patients to specific drugs on a drug plan's formulary in exchange for the manufacturer paying significant rebates to the PBM. Selective contracting has been found to greatly reduce the cost of doctors' and hospitals' provision of health care services. It has also generated significant manufacturer rebates that could be used to lower the cost of drugs. Unfortunately, savings are often retained by PBMs and do not make it to the patients who need them most. The current system also creates the perverse incentive for drug manufacturers to increase drug prices.

Reforms of the current rebate system should try to preserve the benefits of selective contracting—the negotiated savings generated from current rebate-for-formulary arrangements. However, they should also aim to minimize the costs of the system—the incentives to increase drug prices and the failure of rebates to lower patients' out-of-pocket spending at the pharmacy. Moreover, reforms that do not completely dismantle the current system are the most feasible to implement in the immediate future.

Replacing the current after-purchase rebate system with partial point-of-sale rebates is the best way to achieve these goals in the near future. Under this system, a sizable portion of rebates would pass through to the patient at the pharmacy counter, or "point-of-sale." Thus, these rebates would be guaranteed to save patients money rather than end up in the hands of PBMs. Partial point-of-sale rebates would maintain current selective contracting arrangements between drug manufacturers and drug plans, which generate significant rebate payments that lower the net price of drugs. However, because PBMs would not retain much of the rebates, they would have little incentive to promote higher list prices. Slower growth in list prices would benefit all patients—both insured and uninsured—by reducing out-of-pocket drug spending. Moreover, a partial point-of-sale rebate system would also protect competitively-sensitive information about the total rebates negotiated between drug makers and PBMs.

Policymakers must understand the critical role that PBMs play in drug pricing and the conflicts of interest inherent in the PBM business model. A point-of-sale rebate system would better align incentives between PBMs, drug plans, and patients, ensuring that PBMs benefit, not harm, drug plans and their patients. Fortunately, HHS is headed in the right direction with its January 2019 proposal to replace retrospective rebates with point-of-sale rebates in Medicare Part D and Medicaid. Congress should act to ensure that the benefits of point-of-sale rebates are realized in commercial health plans as well.