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## Trading Pain for Gain: Addressing Misaligned Interests in Prescription Drug Benefit Administration

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## TRADING PAIN FOR GAIN: ADDRESSING MISALIGNED INTERESTS IN PRESCRIPTION DRUG BENEFIT ADMINISTRATION

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Sheva J. Sanders\*

Jessica C. Wheeler\*\*

### ABSTRACT

*Over the last two decades, Pharmacy Benefit Managers (PBMs), organizations that act as middlemen between health plans and drug manufacturers, have become increasingly powerful players in the healthcare industry. PBMs promise to leverage their expertise and ability to aggregate buying power to negotiate lower drug prices and administer prescription drug benefit plans. In practice, however, PBMs are widely criticized for benefitting from, and contributing to, inefficiencies in the prescription drug market, particularly by imposing restrictions on beneficiary access to drugs in exchange for rebates paid to PBMs by manufacturers. To the extent that the rebates are retained by PBMs, or otherwise do not result in a benefit to the beneficiaries, this practice amounts to trading the pain of plan beneficiaries for the PBM's own gain. Despite this criticism, regulatory and enforcement efforts directed against PBMs have been anemic.*

*Existing structural and legal protections for beneficiaries are largely ineffectual. While this problem is widely acknowledged, regulators have failed to pass new laws that successfully address the challenges posed by the insertion of PBMs as middlemen into the web of prescription drug benefits and reimbursement. Regulators express frustration with the complexity of balancing the interests of beneficiaries with PBMs' aspirational goal of cost-control, as well as with addressing the inherent conflict of interest in PBMs' competing goals of profitability for themselves and cost containment for their clients. Lawsuits alleging PBM mistreatment of beneficiaries are sparse, and a consistent vision of what is and is not permissible to PBMs has not emerged from the case law.*

*But the Federal Anti-Kickback Statute can—and there are indications that it increasingly will—be used to regulate manufacturer-PBM rebate arrangements. The U.S. Department of Justice recently settled a case predicated on an allegation that a pharmaceutical manufacturer, Roche, violated the Federal Anti-Kickback Statute when it paid a health insurance company, Humana, a kickback of lump sum debt forgiveness for formulary placement, conditioned on the exclusion of a competitor. Also, the federal government recently adopted a rule applicable to Medicare Part D plans that radically reconfigures the existing incentives by prohibiting manufacturers from extending rebates other than at the point of sale, and from making the rebates contingent on the plans or PBMs taking various steps with respect to encouragement of use of the drugs. These developments likely presage increased use of the Anti-Kickback Statute to attack rebating arrangements and underscore the need for PBMs to reevaluate their current*

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practices with respect to their relationships with manufacturers to ensure that they are complying with the law.

*In this Article, we argue that the Federal Anti-Kickback Statute and its state law analogs, state anti-kickback statutes, can be used to effectively protect beneficiary interests against manufacturer-purchased, PBM-imposed restrictions on access to drugs. We also identify key issues that may be hampering effective enforcement, and suggest an analysis that effectively addresses these issues. We demonstrate that current law is best understood to allow manufacturers to extend discounts and rebates to plans (either directly or through PBMs) but not to PBMs, and that those rebates cannot make those payments contingent on PBMs or plans adopting specific preferences for drugs. By embracing these principles, PBMs can protect beneficiary interests, achieve enforcement certainty, and perhaps ward off the ultimate adoption of more radical restrictions.*

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## INTRODUCTION

Over the last two decades, Pharmacy Benefit Managers (PBMs) have become increasingly prominent and powerful players in the healthcare industry.<sup>1</sup> PBMs contract with health benefit plans to administer pharmacy benefits,<sup>2</sup> interposing themselves as middlemen between their client plans and drug manufacturers. PBMs promise to leverage their expertise and ability to aggregate buying power on behalf of health plans to negotiate lower drug prices, and administer prescription drug benefit plans.<sup>3</sup> In practice, however, PBMs are widely criticized for benefitting from, and contributing to, inefficiencies in the prescription drug market by using that purchasing power to obtain payments from manufacturers that they retain for their own account, rather than pass through to plans and the individuals who receive benefits under the plans (beneficiaries). Despite this criticism, regulatory and enforcement efforts directed against PBMs have been anemic. Confounded regulators have attempted and failed to pass new laws that successfully address the challenges posed by the insertion of PBMs into the web of prescription drug benefits and reimbursement, expressing frustration with the complexity of balancing the interests of beneficiaries with PBMs' aspirational goal of cost-control. Lawsuits alleging PBM mistreatment of beneficiaries are rare, and a consistent vision of what is and is not permissible to PBMs has not emerged from the case law.

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1. PBMs first began to appear in the 1970s but became substantially more prominent after the passage of the 2003 Medicare Modernization Act, which created the Medicare Part D drug benefit. *See generally* Mike Magee, *The Origin Story of PBM's*, HEALTHCOMMENTARY (Aug. 13, 2020), <http://www.healthcommentary.org/2020/08/13/the-origin-story-of-pbms/> [<https://perma.cc/YBQ4-99AN>].

2. PBMs typically offer the following core services in the administration of pharmacy benefits: (1) Contracting with a network of retail pharmacies to dispense drugs to beneficiaries in exchange for a patient copayment established by the plan and a set, discounted payment from the plan; (2) Processing, approving, denying, and otherwise adjudicating claims for drugs submitted by pharmacies; and (3) Obtaining rebates from manufacturers.

3. *See, e.g.*, John Arnold, *Are Pharmacy Benefit Managers the Good Guys or Bad Guys of Drug Pricing?*, STAT (Aug. 27, 2018), <https://www.statnews.com/2018/08/27/pharmacy-benefit-managers-good-or-bad/> [<https://perma.cc/6JBA-YHQ4>] ("PBMs started with the idea that their buying power would reduce health care costs and pass the savings on to consumers. They act like giant buying networks for drugs, representing consumers from multiple employers and insurers. In economic terms, they aggregate demand, which gives them leverage in the market. PBMs use their buying power, combined with utilization management strategies, to lower the total cost of pharmaceuticals.").

There are indications that the enforcement landscape is changing. The U.S. Department of Justice recently settled a case which alleged that pharmaceutical manufacturer Roche violated the Federal Anti-Kickback Statute (AKS) when it paid a health insurance company, Humana, a kickback of lump sum debt forgiveness for formulary placement, conditioned on the exclusion of competitors.<sup>4</sup> Also, the Department of Health and Human Services (HHS) recently adopted a rule amending the discount safe harbor to the AKS with respect to the safe harbor's application to drugs covered under Medicare Part D plans (the New Rule). The New Rule radically reconfigures existing incentives by (via the denial of safe-harbor treatment<sup>5</sup>) prohibiting manufacturers from extending rebates except at the point-of-service (to ensure that the rebate results in a discount in the drug price that plans and beneficiaries pay) and from making those rebates contingent on either PBMs or plans taking certain actions to promote the drugs.<sup>6</sup> These developments suggest the AKS is useful for addressing the harms wrought on beneficiaries by runaway PBM self-interest, and underscore the necessity for PBMs to reevaluate their current practices to ensure that they are in accord with the law.

Since 2014, prescription drug prices in the United States have increased by thirty-three percent, compared to an increase of seventeen percent across prices for all medical items and services.<sup>7</sup> The meteoric rise of prescription drug costs<sup>8</sup> has prompted increasingly creative

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4. See Adam Lidgett, *Whistleblower Gets \$3.6M in FCA Deal with Roche, Humana*, LAW360 (Feb. 8, 2021, 5:56 PM), <https://www.law360.com/illinois/articles/1353175/whistleblower-gets-3-6m-in-fca-deal-with-roche-humana> [<https://perma.cc/RB2J-78TF>]. There have been other False Claims Act cases involving similar allegations but alleging different predicate violations. See, e.g., *United States ex rel. Hunt v. Merck-Medco Managed Care, L.L.C.*, 336 F. Supp. 2d 430 (E.D. Pa. 2004). In that case, which ultimately settled for over \$137 million, the FCA claim was based on a violation of the Anti-Kickback Act of 1986 ("AKA") and the common law, predicated on the fact that among other things, Medco, a PBM affiliated with Merck, favored Merck drugs over other manufacturers' drugs even though Merck drugs were more expensive. See *id.*; Anti-Kickback Act of 1986, 41 U.S.C. § 51 (current version at 41 U.S.C. ch. 87); Settlement Agreement & Mutual Releases, *United States v. Medco Health Solutions, Inc.*, No. 99-cv-2332 (E.D. Pa. Oct. 23, 2006), <https://www.sec.gov/Archives/edgar/data/1170650/000119312506217137/dex101.htm> [<https://perma.cc/MA33-FHSY>].

5. Without the protection of the safe harbor, almost all rebates at least technically implicate the AKS, as they are "remuneration" given to induce a purchase of a covered item. See *infra* Section III.D.

6. See *Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*, 85 Fed. Reg. 76666, 76731 (Nov. 30, 2020) [hereinafter *PBM Final Rule*].

7. Tori Marsh, *Prices for Prescription Drugs Rise Faster than Prices for Any Other Medical Good or Service*, GOODRX HEALTH (Sept. 17, 2020, 3:00 AM), <https://www.goodrx.com/blog/prescription-drugs-rise-faster-than-medical-goods-or-services/> [<https://perma.cc/ZPD7-SN34>].

8. Alison Kodjac, *Prescription Drug Costs Driven by Manufacturer Price Hikes, Not Innovation*, NPR (Jan. 7, 2019, 5:04 PM), <https://www.npr.org/sections/health-shots/2019/01/07/682986630/prescription-drug-costs-driven-by-manufacturer-price-hikes-not-innovation> [<https://perma.cc/2VFG-ABS5>]. Explanations range from innovation in hyper-specialty drugs for the treatment of rare diseases to a complex web of incentives created by the interplay of the U.S.

efforts by many, including managed care plans,<sup>9</sup> to control drug spending.<sup>10</sup> One method managed care plans have used to lower the cost of covered pharmaceuticals is to hire PBMs to negotiate rebate arrangements with manufacturers.<sup>11</sup> The manufacturer offers to return a portion of the drug's purchase price if certain conditions, such as "if the total number of prescriptions dispensed, relative to other medicines in the therapeutic class, exceeds a predetermined threshold"<sup>12</sup> or conferring preferential access to the manufacturer's drugs, are fulfilled.<sup>13</sup>

The main tool that PBMs use to negotiate and earn rebates is the prescription drug formulary, which is a list of drugs that the plan covers along with the conditions under which coverage is available.<sup>14</sup> By erecting and removing barriers to access to particular drugs—such as copayments, prior authorization, and step-therapy—formularies can be used to prefer or disadvantage particular drugs. Making rebates contingent on the achievement of sales volume targets incentivizes PBMs not only to include the drug on formulary, but also to design the formulary to steer patients toward drugs that are subject to the biggest volume rebate.<sup>15</sup> In some cases, the arrangements are more pointed:

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patent laws, drug pricing regulation (or lack thereof), and convoluted commercial pricing schemes. *Id.*

9. Managed care plans are third-party payors that attempt to manage their costs through various utilization management techniques, including differential copayments (set with reference to the formulary tier in which the drug is placed), step therapy, and prior authorization requirements. For further discussion of these techniques, see *infra* Part I.

10. David H. Kreling, *Cost Control for Prescription Drug Programs: Pharmacy Benefit Manager (PBM) Efforts, Effects, and Implications*, OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, U.S. DEP'T OF HEALTH & HUM. SERVS. (Aug. 8, 2009), <https://aspe.hhs.gov/cost-control-prescription-drug-programs-pharmacy-benefit-manager-pbm-efforts-effects-implications> [https://perma.cc/F9CU-DFBG].

11. See Rachel Bluth, *Can Someone Tell Me What a PBM Does?*, KAISER HEALTH NEWS (Apr. 9, 2019), <https://khn.org/news/senate-hearing-drug-pricing-lesson-on-pharmacy-benefit-managers/> [https://perma.cc/R9HS-KA2B].

12. PHRMA, FOLLOW THE DOLLAR: UNDERSTANDING HOW THE PHARMACEUTICAL DISTRIBUTION AND PAYMENT SYSTEM SHAPES THE PRICES OF BRAND MEDICINES 8 (2017), <http://phrma-docs.phrma.org/files/dmfile/Follow-the-Dollar-Report.pdf> [https://perma.cc/4VZ4-2YET].

13. *Id.*

14. PBMs collect revenue in three primary ways: from administrative fees paid to them by plans, through the spread between what they charge plans for drugs and what they pay pharmacies for drugs, and from retaining a portion of the rebates they are paid by manufacturers. See, e.g., *Rutledge v. Pharm. Care Mgmt. Ass'n*, 141 S. Ct. 474, 477–78 (2020); *In re Express Scripts, Inc., PBM Litig.*, No. 05-MD-01672, 2008 WL 2952787, at \*5–6 (E.D. Mo. July 30, 2008); *United States ex rel. Behnke v. CVS Caremark Corp.*, No. 14-cv-824, 2020 WL 1953626, at \*2 (E.D. Pa. Apr. 23, 2020).

15. See *Pharmacy Benefit Managers and Their Role in Drug Spending*, COMMONWEALTH FUND (Apr. 22, 2019), <https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending#3> [https://perma.cc/W7MU-ZEX2] ("But PBMs may also have an incentive to favor high-priced drugs over drugs that are more cost-effective. Because they often receive rebates that are calculated as a percentage of the manufacturer's list price, PBMs receive a larger rebate for expensive drugs than they do for ones that may provide

instead of conditioning rebates merely on attaining volume targets, pharmaceutical manufacturers may also condition discounts and rebates specifically on PBMs giving their drugs *preferential* formulary status vis-à-vis non-drug alternatives, or on imposing access restrictions on competitor drugs.<sup>16</sup> Accordingly, whether implicitly incentivized or explicitly required, rebates often come at the cost of utilization controls that restrict beneficiary access to competitor drugs. PBMs justify such restrictions on access as necessary to give them the negotiating leverage that makes them valuable to plans and beneficiaries, maintaining that PBMs make trades and strike agreements with pharmaceutical manufacturers in order to design a formulary that reduces prescription drug costs on the whole.<sup>17</sup>

The use of a formulary imposes costs on beneficiaries which might include barriers to access to competitive drugs, inconvenience, limited coverage, poorer clinical outcomes, and higher out-of-pocket prices for drugs, copayments, and premiums. To the extent that these costs are offset by a corresponding reduction in price in the preferred drug that is realized by the beneficiary either as a point-of-sale discount or through a reduction in premium cost, the costs may be seen as a fair trade. But when manufacturers adjust drug prices by offering rebates, rather than simply discounting the list price of the drugs, they create an opportunity for PBMs to siphon off, and retain for their own account, a portion of the negotiated “savings.”<sup>18</sup> More fundamentally, rebates incentivize the PBM to prefer the drug with the highest rebate rather than the lowest price.<sup>19</sup> In many instances, the PBM may not even

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better value at lower cost. As a result, people who have a high-deductible plan or have copays based on a drug's list price may incur higher out-of-pocket costs.”).

16. See, e.g., DEP'T OF HEALTH & HUM. 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> [<https://perma.cc/M8TG-RDHY>] [hereinafter BACKDOOR REBATES]. HHS advanced a proposal to “update the discount safe harbor at 42 CFR 1001.952(h) to explicitly exclude reductions in price offered by drug manufacturers to PBMs, Part D, and Medicaid managed care plans from the safe harbor's definition of a ‘discount’” and to “create a new safe harbor designed specifically for price reductions on pharmaceutical products, but only those that are reflected in the price charged to the patient at the pharmacy counter,” because “to the extent that these rebate payments are made to secure preferential formulary treatment, they are not functioning like a reduction in price.” *Id.*

17. See *generally* *Formulary Design*, PHARM. CARE MGMT. ASS'N, <https://www.pcmanet.org/policy-issues/formulary-design/> [<https://perma.cc/9LSG-BVTC>] (“The effective use of formularies can minimize overall medical costs” when “[a] number of cost-saving elements are . . . factored in, such as formulary tiers and step therapy.”).

18. See Jake Frenz, *Industry Voices—Why It's Time for PBM Rebates to Come to an End*, FIERCE HEALTHCARE (Apr. 8, 2019, 10:42 AM), <https://www.fiercehealthcare.com/payer/industry-voices-why-it-s-time-for-pbm-rebates-to-come-to-end> [<https://perma.cc/2YJX-FSKN>] (“But rather than passing negotiated cost savings through to health plans or self-insured companies, who are the customers of the PBM and ultimate payers of the pharmacy benefit, PBMs have largely kept these disbursements for themselves.”).

19. See *Pharmacy Benefit Managers and Their Role in Drug Spending*, *supra* note 15.

disclose the rebates to its client-plans, let alone the plans' beneficiaries.<sup>20</sup> For beneficiaries, the net result of this scheme can be restricted access to therapies that they may prefer (either because of convenience, cost, or clinical efficacy), with no offsetting decrease in overall out-of-pocket costs.<sup>21</sup> Because of this dynamic, it is widely acknowledged that rebate arrangements with PBMs have the potential to harm beneficiaries in a manner that standard, up-front discount arrangements do not.<sup>22</sup>

When the financial benefits from trading access restrictions for price concessions accrue only to the PBMs, beneficiary interests are harmed, and more broadly, the primary goal of managed care—providing appropriate medical care in an economically efficient manner<sup>23</sup>—is undermined. Accordingly, PBMs' practice of retaining the financial benefits of their buying power for themselves has spawned many efforts at reform.<sup>24</sup> In the main, however, these efforts have been either piecemeal or unsuccessful.<sup>25</sup> In this Article, we outline how well-established norms and laws, if better understood and observed, are

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20. See Frenz, *supra* note 18 (“PBMs have kept their arrangements with drug manufacturers opaque and secretive, allowing them to charge higher drug prices to their customers than what they admit to paying themselves, pocketing the difference.”).

21. 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, 2341–42 (proposed Feb. 6, 2019) (to be codified at 42 C.F.R. pt. 1001), <https://www.govinfo.gov/content/pkg/FR-2019-02-06/pdf/2019-01026.pdf> [<https://perma.cc/FN5Q-BA25>] [hereinafter Safe Harbors Proposed Rule]. The Safe Harbors Proposed Rule notes that “[m]any rebates do not flow through to consumers at the pharmacy counter as reductions in price,” nor do they result in robust premium reductions. *Id.* The rebate system creates, moreover, “a financial incentive to [favor higher priced drugs and to] make formulary decisions based on rebate potential, not the quality or effectiveness of a drug.” *Id.*

22. See, e.g., NEERAJ SOOD, ROCIO RIBERO, MARTHA RYAN & KAREN VAN NUYS, UNIV. S. CAL. LEONARD D. SCHAEFFER CTR. FOR HEALTH POL'Y & ECON., THE ASSOCIATION BETWEEN DRUG REBATES AND LIST PRICES 3 (2020), [https://healthpolicy.usc.edu/wp-content/uploads/2020/02/SchaefferCenter\\_RebatesListPrices\\_WhitePaper.pdf](https://healthpolicy.usc.edu/wp-content/uploads/2020/02/SchaefferCenter_RebatesListPrices_WhitePaper.pdf) [<https://perma.cc/4SZM-RVZQ>] (finding that “[r]ebates play a role in increasing drug prices,” including increasing out-of-pocket expenditure by beneficiaries); see also PHRMA, *supra* note 12, at 2 (“But in recent years, plan sponsors have raised doubts about this process and whether incentives are appropriately aligned across all stakeholders. Although PBMs say they prefer lower list prices, as this paper shows, in many cases, the system creates incentives for PBMs to prefer medicines with higher list prices and higher rebates. As a result, some industry observers and government agencies have questioned whether insurers and PBMs are more focused on the size of rebates than on achieving the lowest possible costs and best outcomes for patients.”).

23. See *APC Overcomes the Pitfalls of Managed Care*, VERA WHOLE HEALTH (Aug. 4, 2021), <https://www.verawholehealth.com/blog/managed-care-101-goals-history-and-pitfalls> [<https://perma.cc/XDQ9-BUPT>].

24. See, e.g., Colleen Becker, *States Regulating Pharmaceutical Benefit Managers*, NAT'L CONF. OF STATE LEGISLATURES (Mar. 22, 2019), <https://www.ncsl.org/research/health/pbm-state-legislation> [<https://perma.cc/YEV5-M2RE>]; see also *infra* Part III and accompanying notes.

25. We have not identified a single successful case against a PBM or plan predicated on the misuse of rebates.



already adequate to restrain, if not foreclose, the practice of trading access restrictions for rebates that are not passed through to beneficiaries.

In Part I, we examine the harm to beneficiaries caused by a system that allows PBMs to profit from formulary placement decisions that are clinically, financially, or otherwise detrimental to beneficiaries. We observe that PBMs often do not pass through to beneficiaries (either in the form of reduced premiums or reduced cost-sharing payments) the rebates manufacturers pay PBMs in exchange for formulary placement and restrictions on competitor products. The result of this arrangement, we argue, is that the PBM and the pharmaceutical manufacturer benefit at the expense of the beneficiaries whom PBMs are intended to serve.

In Part II, we take a closer look at the formulary design process, arguing that without regulation, would-be protections that are built into the PBM structure have been rendered ineffective by the extreme misalignment of interests between PBMs and beneficiaries. Focusing on the role of Pharmacy and Therapeutic (P&T) committees in protecting the interests of patients, we argue that the current system—in which P&T committee input is largely restricted to an assessment of therapeutic utility without due regard to beneficiary costs, and often motivated by regard for PBM profits—does not permit P&T committees to fully realize their role and obligations. We observe that, so long as formulary placement is ultimately determined by PBMs, and PBMs are motivated to maximize their own profit, the presence of a P&T committee alone will not be sufficient to protect beneficiary interests.

In Part III, we examine the AKS and by analogy, state anti-kickback laws<sup>26</sup> to demonstrate that, properly understood, those laws protect against the precise harm posed by pay-for-placement arrangements between pharmaceutical manufacturers and PBMs. We explain that, in the context of government health programs, payments made directly to PBMs for inclusion of a drug on a formulary violate the AKS's prohibition against paying for preferential treatment of a covered item. In the case of commercial or other non-governmental plans, such arrangements may implicate similar prohibitions contained in state anti-kickback laws. By limiting the ability of pharmaceutical manufacturers to pay for formulary access or to otherwise influence

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26. Many states have anti-kickback laws that parallel the AKS. See Scott B. McBride, Anthony J. Cocuzza, Rachel Moseson & Jarrett R. Schindler, *A Survey of Health Care Anti-Kickback Law at the State Level*, LOWENSTEIN SANDLER (Feb. 25, 2020) (explaining that all but one state has an AKS analog, and thirty-five of those apply to goods and services reimbursed by private health insurance, rather than a public payor); see, e.g., CAL. BUS. & PROF. CODE § 650 (West 2021); MASS. GEN. LAWS ANN. ch. 175H, § 3 (West 2021); MINN. STAT. § 62J.23 (2021); UTAH CODE ANN. § 26-20-4 (West 2021).

formulary design, the AKS and similar state laws can make it more likely that P&T committee recommendations will be observed and more likely that the price reductions will either be reflected at the point-of-service or result in premium reductions.

In Part IV, we argue that by embracing what we understand to be extant law—that manufacturers may extend discounts and rebates only to plans, and even then, cannot make those payments contingent on according specific preferences to drugs—PBMs can honor these important public policy goals, achieve enforcement certainty, and perhaps ward off the ultimate adoption of more radical restrictions.

#### I. THE PROBLEM: FORMULARY ACCESS RESTRICTIONS MAY NOT SAVE PLANS OR BENEFICIARIES MONEY

Drug formularies—lists of covered drugs, from which some drugs are excluded entirely, and which impose conditions restricting access to some drugs—have long been viewed as a tool plans use to reduce drug costs. In theory, the lower costs associated with the formulary reduce beneficiary premiums and copayments. Beneficiaries are asked to tolerate utilization controls imposed by formularies because they will benefit from the reduced cost of healthcare. This bargain can be fulfilled only if the restrictions are traded for price concessions that are passed through to plans and ultimately to beneficiaries. Where the restrictions are instead traded for payments to PBMs, it is a false bargain.

##### A. *Managed Care Plans Use Access Restrictions to Constrain Utilization and Reduce Costs*

Health insurers have long struggled with balancing the competing imperatives of ensuring access to care and controlling the cost of providing that care to beneficiaries. As the cost of care has grown, the concept of managed care—a mechanism through which insurance and other managed care plans, such as health maintenance organizations (HMOs),<sup>27</sup> control utilization by imposing restrictions on what providers and therapies can be used and under what circumstances—has emerged as a key tool for controlling the cost of healthcare. A central premise of managed care is that access restrictions, such as prior authorization requirements, step-therapy, and beneficiary cost-

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27. For a description of the features of various types of managed care, see *Paying for Health Care in the U.S.*, B.U. SCH. OF PUB. HEALTH, [https://sphweb.bumc.bu.edu/otlt/mph-modules/hpm/americanhealthcare\\_paying/americanhealthcare\\_paying\\_print.html](https://sphweb.bumc.bu.edu/otlt/mph-modules/hpm/americanhealthcare_paying/americanhealthcare_paying_print.html) [<https://perma.cc/NBJ5-49VV>].

sharing, can eliminate unnecessary costs.<sup>28</sup> Managed care plans apply these utilization controls to drugs using a list of drugs that the plan covers, known as a “formulary.”<sup>29</sup> The development of the formulary is typically contracted out to a PBM as part of the administrative services the PBM provides to the plan.<sup>30</sup> Drugs that are excluded from the formulary are not covered by insurance,<sup>31</sup> meaning that a beneficiary may be responsible for paying the full costs of such drugs.<sup>32</sup> Coverage for drugs included on the formulary is variable.<sup>33</sup> Drugs that are included on the formulary are grouped into tiers.<sup>34</sup> Each tier is associated with certain access restrictions.<sup>35</sup> The restrictions become

28. See ROBERT P. NAVARRO & JUDITH A. CAHILL, *ROLE OF MANAGED CARE IN THE U.S. HEALTHCARE SYSTEM* 8, 9, [https://samples.jblearning.com/0763732400/32400\\_CH01\\_Pass2.pdf](https://samples.jblearning.com/0763732400/32400_CH01_Pass2.pdf) [<https://perma.cc/CC5V-XJMW>] (explaining that a core tenet of managed care cost controls is managing demand through controls such as copayment, coinsurance, prior authorization, and step therapy, among others). See generally JESSICA VAN PARYS, *HOW DO MANAGED CARE PLANS REDUCE HEALTHCARE COSTS?* (2014), <http://www.columbia.edu/~jnv2106/jvanparys.jmp.pdf> [<https://perma.cc/P8SS-JBMK>] (evaluating many ways in which managed care plans reduce cost, including access restrictions).

29. See Ana Gascon Ivey, *A Guide to Medication Formularies*, GOODRX (May 19, 2020), <https://www.goodrx.com/insurance/medication-formulary> [<https://perma.cc/2UJQ-MDYA>].

30. See *Pharmacy Benefit Managers and Their Role in Drug Spending*, COMMONWEALTH FUND (Apr. 22, 2019), <https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending> [<https://perma.cc/WN82-L2QD>].

31. Except to the extent that the plan is subject to regulations that require a particular scope of coverage, see, e.g., *A Consumer Guide to Drug Formularies: Understanding the Fundamentals of Behavioral Health Medication*, PARITYTRACK, <https://www.paritytrack.org/issue-briefs/a-consumer-guide-to-drug-formularies-understanding-the-fundamentals-of-behavioral-health-medications/#part-ii-state-and-federal-laws-impacting-drug-formularies> [<https://perma.cc/HM6K-6ZMQ>], and the discussion of the requirements imposed on Part D plans *infra* at Part II, subject to the need to build a formulary that is acceptable to the plan, PBMs are free to exclude or include drugs in the formulary as they desire, with complete discretion. This can result in the exclusion of or imposition of access barriers on particular drugs, or even on classes of drugs. See *infra* Subsection I.B.3 for further discussion of the consequences of exclusion of therapeutic alternatives.

32. See Erica Block, *What Is a Drug Formulary?*, HEALTHCAREINSIDER (Feb. 18, 2021), <https://healthcareinsider.com/what-is-drug-formulary-60486> [<https://perma.cc/H7J9-J3FQ>].

33. See, e.g., *In re Express Scripts, Inc.*, PBM Litig., No. 05-MD-01672, 2008 WL 2952787, at \*6 (E.D. Mo. July 30, 2008) (“[W]here a plan participates in a formulary program, the plan’s involvement in developing and/or controlling the formulary bears a direct relation to its savings. For example, a formulary may be ‘closed,’ i.e. drug product selection that will be reimbursed is limited to ‘Covered’ and/or ‘Generic’ drugs; or ‘open,’ i.e. there are no limitations on the drug products that may be reimbursed under the plan. Moreover, a formulary program may encourage the selection of *particular* ‘preferred’ drugs. Under a ‘preferred’ formulary program, plans relinquish options and control in pursuit of greater rebates.”); see also *White Paper: Formulary Development at Express Scripts*, EXPRESS SCRIPTS (Dec. 2020), <https://www.express-scripts.com/aboutus/formularyinformation/development/formularyDevelopment.pdf> [<https://perma.cc/QW9T-SG3S>] (explaining the difference between open and closed formularies, and also explaining how benefit design may be “tiered,” with generics at the lowest copay level, “preferred” prescriptions at the next copay level, and “non-preferred” products at the highest co-pay level).

34. Block, *supra* note 32.

35. See *id.* (“Some drugs on your plan’s formulary may be covered automatically with a doctor’s prescription. Other medications may require a prior authorization from your doctor, or may be covered only after you’ve tried a different, preferred drug first (also known as step therapy).”).

less stringent as one progresses toward the most preferred tier, thereby incentivizing the use of drugs in the preferred tier.<sup>36</sup> For example, a drug on a higher (preferred) tier may be fully covered, with only a minimal co-pay and no access restrictions. A drug on a lower tier may be subject to a larger co-pay, prior-authorization requirements, or step-therapy requirements (i.e., the requirement that other therapies be tried before the beneficiary's desired therapy is covered). For example, excerpts from United Healthcare's 2021 Drug List illustrate the tiers it utilizes (Figure 1) and the access restrictions it imposes on various drugs (Figure 2).<sup>37</sup>

FIGURE 1. TIER INFORMATION

Drug Tier	Includes	Helpful Tips
<b>Tier 1</b>	<b>\$ Lower-cost</b> Medications that provide the highest overall value. Mostly generic drugs. Some brand-name drugs may also be included.	Use Tier 1 drugs for the lowest out-of-pocket costs.
<b>Tier 2</b>	<b>\$\$ Mid-range cost</b> Medications that provide good overall value. Mainly preferred brand-name drugs.	Use Tier 2 drugs, instead of Tier 3, to help reduce your out-of-pocket costs.
<b>Tier 3</b>	<b>\$\$\$ Highest-cost</b> Medications that provide the lowest overall value.	Ask your doctor if a Tier 1 or Tier 2 option could work for you.

Using lower-tier medications can help you pay your lowest out-of-pocket cost. Your plan may have multiple or no tiers. Please note: If you have a high deductible plan, the tier cost levels may apply once you hit your deductible.

36. In the context of managed care,

[d]rug formularies attempt to encourage appropriate and high-value prescribing through the use of a tiered structure, in which lower-cost medications are placed in tiers with minimal cost sharing for patients. The purpose of a tiered structure is to incent prescribers and health plan members to avoid higher cost medications. Higher tiered (more costly) medications are a particular concern for health plans.

PARITYTRACK, *supra* note 31.

37. UNITED HEALTHCARE, YOUR 2021 PRESCRIPTION DRUG LIST 6 (2021), <https://www.uhcsr.com/common/pdfs/PDL-All.pdf> [<https://perma.cc/P2QG-9CBH>]. Note that this is only part of the drug list, and some portions of the list have been shortened.

In Figure 2, overall value indicates medications' effectiveness and safety, cost, and the availability of alternative medications to treat the same or similar medical condition(s).

FIGURE 2. PARTIAL DRUG LIST & KEY TO CONDITIONS

<b>E</b>	<b>May be excluded from coverage or subject to Prior Authorization in Connecticut, New Jersey and New York. (Referred to as First Start in New Jersey.)</b> – Lower-cost options are available and covered.
<b>H</b>	<b>Health Care Reform Preventative</b> – This medication is part of a health care reform preventative benefit and may be available at no additional cost to you.
<b>H-PA</b>	<b>Health Care Reform Preventative with Prior Authorization</b> – May be part of health care reform preventative and available at no additional cost to you if prior authorization criteria met.
<b>PA</b>	<b>Prior Authorization (sometimes referred to as precertification)</b> – Requires your doctor to provide information about why you are taking a medication to determine how it may be covered by your plan.
<b>QL</b>	<b>Quantity Limits</b> – Specifies the largest quantity of medication covered per copayment or in a defined period of time.
<b>RS</b>	<b>Refill and Save Program</b> – Save money on your copayment when you refill your prescription on time as prescribed. Program eligibility may vary.
<b>SP</b>	<b>Special Medication</b> – Specialty medications treat complex or rare conditions and may require special storage and handling. You may be required to obtain these medications from a specialty pharmacy.
<b>ST</b>	<b>Step Therapy (referred to as First Start in New Jersey)</b> – Requires prior authorization and may require you to try one or more other medications before the medication you are requesting may be covered.

Drug Name	Drug Tier	Requirements & Limits
Analgesics – Drugs for Pain		
acetaminophen-codeine	1	
apap-caff-dihydrocodeine	1	QL
BELBUCA	3	PA, QL
DILAUDID ORAL	3	
DURAGESIC-100	E	PA, ST, QL
fentanyl transdermal patch 72 hour 100 mcg/hr, 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr	1	PA, QL
fentanyl transdermal patch 72 hour 37.5 mcg/hr, 62.5 mcg/hr, 87.5 mcg/hr	E	PA, ST, QL
hydrocodone-acetaminophen oral tablet 10-300 mg, 5-300 mg, 7.5-300 mg	E	
hydrocodone-acetaminophen oral tablet 10-325 mg, 5-325 mg, 7.5-325 mg	1	
hydromorphone hcl er	1	PA, ST, QL
hydromorphone hcl oral	1	
hydromorphone hcl rectal	1	
HYSINGLA ER	E	PA, ST, QL

The use of a formulary tiering system gives certain drugs preferential treatment, thereby incentivizing patients to choose cost-saving alternatives. Formularies also create another cost-savings opportunity: the opportunity for price negotiation with pharmaceutical manufacturers.<sup>38</sup> Formulary design is PBMs' primary source of leverage

38. These rebates are substantial and often cover about fifty percent of the drug's cost. For example, one publication states that in 2019, manufacturers offered discounts of \$315 billion out of a total wholesale acquisition cost of \$671 billion. IQVIA, MEDICINE SPENDING AND AFFORDABILITY IN THE UNITED STATES 6 (2020), [https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-spending-and-affordability-in-the-united-states.pdf?\\_=1608764033660](https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-spending-and-affordability-in-the-united-states.pdf?_=1608764033660) [<https://perma.cc/JZR7-CMWJ>]. Of that \$315 billion, \$160 billion was attributable to supply chain invoice discounts, \$143 billion was attributable to rebates to payers, and \$12 billion was attributable to coupons. *Id.*

to secure discounts and rebates. The threat of access restrictions on even a single blockbuster product creates significant leverage for a PBM to negotiate price concessions, which may relate to that drug or may span any portion of a pharmaceutical manufacturer's portfolio of drugs.<sup>39</sup> PBMs can use several formulary-related tools to negotiate price concessions. These tools have different impacts on formulary design and different implications for beneficiaries.

For example, in exchange for price concessions, PBMs may simply offer the manufacturer access to the formulary, which will result in coverage of the drug once the formulary is adopted by the PBM's client-plan. The PBM may go further and agree to specific formulary placement—that is, to place a given drug on a higher tier than competitor products, such that competitor drugs will be subject to more onerous access restrictions. In either case, price concessions are often made dependent on the achievement of purchase-volume targets for specific drugs.

#### B. By Creating Coverage Barriers, Formularies Place Burdens on Beneficiaries

The primary goals of medicine are to alleviate morbidity and mortality by providing patients with medically necessary care. Managed care introduces another goal—cost containment, which it pursues primarily through the use of utilization controls, such as copayments, prior authorization requirements, and drug formularies that make some drugs less accessible than others.<sup>40</sup> As with other utilization

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39. See Adam J. Fein, *The Big Three PBMs Ramp up Specialty Drug Exclusions for 2021*, DRUG CHANNELS (Jan. 12, 2021), <https://www.drugchannels.net/2021/01/the-big-three-pbms-ramp-up-specialty.html> [<https://perma.cc/HVX5-RRSH>] (“Formulary exclusions have emerged as a powerful tool for PBMs to gain additional negotiating leverage against manufacturers. The prospect of exclusion leads manufacturers to offer deeper rebates to avoid being cut from the formulary. Exclusions are a key factor behind the growing gap between list and net prices for brand-name drugs.”).

40. Daniel Callahan, *Managed Care and the Goals of Medicine*, 46 J. AM. GERIATRICS SOC'Y 385, 385 (1998).

The goals of medicine encompass the relief of pain and suffering, the promotion of health and the prevention of disease, the forestalling of death and the promoting of a peaceful death, and the cure of disease when possible and the care of those who cannot be cured. Managed care, as a system of integrated healthcare delivery designed to control costs, is not, in principle, incompatible with the goals of medicine, but in practice it may well be, depending on whether profit is sought, whether the integrity of physicians' medical judgment is protected, and whether government regulations control managed care practices to prevent abuse and to enhance the quality of care.

*Id.* There is also a tension between the plan's obligation to minimize costs to its beneficiaries and its desire to maximize profitability. *Compare* *Negron v. Cigna Health & Life Ins.*, 300 F. Supp. 3d 341 (D. Conn. 2018) (involving allegations that plans artificially inflated prescription drug costs),

control measures, formulary-imposed access restrictions on prescription drugs are undeniably in tension with the provision of good care because they inject financial considerations into what would otherwise be a decision informed only by the best approach to treatment.<sup>41</sup>

To contain costs, most, if not all, formularies exclude some drugs, such as “lifestyle drugs” (e.g., those for weight loss or sexual enhancement) entirely,<sup>42</sup> making the excluded drugs available only if the beneficiary pays for them out-of-pocket or has supplemental coverage. Aside from simple coverage or non-coverage of drugs, formularies also establish tiers, as described above, of preferred and non-preferred covered drugs, each with a different set of access restrictions.<sup>43</sup> The less preferred the tier, the more intense the access restrictions and, hence, the potential for the greatest beneficiary burden. These burdens can range from inconvenience (e.g., having to wait for a drug to be mailed from a specialty pharmacy rather than picking it up at the local drug store or having to wait a few days for prior-authorization to clear) to significant detriment (e.g., raising out-of-pocket costs to the point that a medically necessary drug is effectively out of reach).

By way of example, we will consider three major burdens commonly imposed as part of formulary design: (1) increased cost-sharing obligations; (2) step therapy requirements; and (3) restrictions on access to alternative therapies. All of these burdens must be recognized as carrying the potential for real harm to beneficiaries in any analysis that seeks to ensure that beneficiaries’ interests are protected.

In connection with this discussion, we make several public policy-based distinctions that are essential to understanding the extant law. We call price concessions that are offered merely to incentivize coverage, “payments for access.” On the other hand, “payments for placement” are price concessions contingent on (a) the placement of the drug in a particular tier, (b) the exclusion or restriction of competitor drugs, or (c) other elements of formulary design. Payments for access create an impetus for formulary inclusion and perhaps even preferential treatment over competitors, but still allow discretion in formulary design. Payments for placement, on the other hand, *require* that a given drug be given preferential treatment vis-à-vis competitor products. As such, payments for placement usurp discretion by

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with *In re UnitedHealth Grp. PBM Litig.*, No. 16-cv-3352, 2017 WL 6512222 (D. Minn. Dec. 19, 2017) (involving similar allegations that plans caused beneficiaries to overpay for prescription drugs).

41. See *id.*

42. *What Drugs Are Excluded from Part D Plans?*, MEDICARE.ORG, <https://www.medicare.org/articles/what-drugs-are-excluded-from-part-d-plans/> [<https://perma.cc/X2NE-A5NW>].

43. See, e.g., *supra* Figure 2.



dictating formulary design and, as we discuss, have the potential to result in higher costs for beneficiaries by making competitor products harder to access.

We also distinguish between pre-sale discounts and post-sale rebates. Because pre-sale discounts, by their very nature, reduce the list price of the drug, the financial benefits of discounts are capable of being, and often are, passed through to beneficiaries in the form of reduced out-of-pocket costs (via reduced copayments or, if the beneficiary is in the deductible phase of their policy, via reduced costs) at the point of sale and, potentially, through reduced premiums from plans who spend less money on drugs.<sup>44</sup> By contrast, post-sale rebates do not reduce the list price of the drug, so financial benefits may not be realized by the PBM until months after the point of sale, and may never be realized at all by plans. As a result, it is not necessarily true that the value of rebates will be passed through to beneficiaries. Our analysis focuses, therefore, on these rebate arrangements.

### 1. Increased Cost-Sharing Obligations

Lower-tier drugs may be subject to substantially higher cost-sharing obligations than preferred drugs. It is not uncommon for cost-sharing obligations to be so high that the drugs are effectively non-covered, especially with respect to expensive specialty medications<sup>45</sup> of

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44. There is evidence that the system of negotiated discounts has had the overall effect of raising drug prices, creating higher ticket prices so as to allow pharmaceutical manufacturers to discount prices for plans and PBMs without losing revenue. See Michael Mandel, *The 'Prescription Escalator' May Be to Blame for Rising Out-of-Pocket Drug Spending*, STAT NEWS (Nov. 13, 2020), <https://www.statnews.com/2020/11/13/drug-spending-increase-for-many-americans-prescription-escalator/> [<https://perma.cc/G2GA-PQGF>] (arguing that both discounts and rebates contribute to overall increases in prescription drug prices). The relationship between discounts and average list prices is, however, a topic for a different article.

45. The term “specialty drug” generally refers to a “generic or brand name drug which may be identified by an issuer of a health benefit policy as a high cost drug used to treat complex or rare medical conditions.” H.B. 875, 2016 Leg., Reg. Sess. (Ga. 2016), <https://www.legis.ga.gov/legislation/47922> [<https://perma.cc/2EDV-EG93>]. Advocates for Responsible Care notes that

Studies have proven that shifting the [exorbitant] . . . cost of specialty medications onto the beneficiary through the use of Specialty Tiers increases abandonment of prescriptions, which can lead to serious adverse health outcomes. These adverse health events also lead to higher health care and social service expenses due to lack of access to treatment (i.e. emergency room visits, long term home care, permanent disability, etc.). . . . According to a recent study by Avalere Health: . . . In seven classes, more than 20 percent of the plans require coinsurance of 40 percent or more for all medicines in the class. Over 60 percent of the plans place all covered medicines in the class for treating multiple sclerosis on the formulary tier with the highest cost sharing. Similarly, over 60 percent of the plans place all covered medicines in certain classes for

which plans want to discourage use. As a result, the high cost of the drugs puts them out of reach of some beneficiaries.<sup>46</sup> Indeed, if the intended effect of higher cost-sharing obligations is to create an economic incentive that steers patients away from formulary-non-preferred therapies, to be successful such obligations would have to be substantial enough to materially affect patient decision-making. High cost-sharing obligations may, therefore, result not only in a choice to use a formulary-non-preferred drug, but also in a decision to forgo therapy.<sup>47</sup>

## 2. Step Therapy Requirements

Step therapy requires that beneficiaries try formulary-preferred medications before a non-preferred medication will be covered.<sup>48</sup> Step therapy regimes may require a prolonged period (e.g., two years) of

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treating cancer on the formulary tier with the highest cost sharing. Almost all plans (86%) place all medicines in at least one class on the highest cost-sharing tier.

*Specialty Tiers Legislation*, ADVOC. FOR RESP. CARE, <http://www.advocatesforresponsiblecare.org/what-we-are-about/specialty-tiers-legislation> [https://perma.cc/D7J7-8K9M] (citations omitted).

46. For example, a large PBM, Express Scripts,

found that in 2004, among patients taking specialty drugs [which are normally placed in a higher tier] for multiple sclerosis, rheumatoid arthritis, and hepatitis C, specialty pharmacy accounted for 17 percent of their total prescription consumption, but 80 percent of their total annual drug cost. Looked at another way, the average cost of a specialty drug for those ailments was \$12,563, but just \$3,329 for conventional medications.

Ed Silverman, *Copayments: Too Much, Yet Not Enough?*, 2006 BIOTECH. HEALTHCARE 21, 25, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3571026/> [https://perma.cc/5KDK-UWV4].

47. See *id.* at 22 (explaining that research indicates that even relatively low copayments can act as a deterrence to use a drug); see also Rahul Shenolikar, Amanda Schofield Bruno, Michael Eaddy & Christopher Cantrell, *Sensitivity of Medication Use to Formulary Controls in Medicare Beneficiaries: A Review of the Literature*, 4 AM. HEALTH & DRUG BENEFITS 465, 466 (2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4106498/> [https://perma.cc/RA5K-UHZU] (“[T]he evidence shows that more restrictive drug coverage is associated with reduced medication use among Medicare beneficiaries, and fewer restrictions encourage enhanced medication use.”). This failure can have substantial impacts on health. See Sendhil Mullainathan, *When a Co-Pay Gets in the Way of Health*, N.Y. TIMES (Aug. 10, 2013), <https://www.nytimes.com/2013/08/11/business/when-a-co-pay-gets-in-the-way-of-health.html> [https://perma.cc/7B9X-LZ98] (describing a study in which people with copays were less likely to utilize medication for the same conditions as those whose copays were waived, and as a result suffered more adverse health consequences).

48. See *Step Therapy*, PRESCRIPTION PROCESS, <http://prescriptionprocess.com/barriers-to-access/step-therapy/> [https://perma.cc/4L6L-FCCV] (“Step therapy, also known as ‘fail first,’ is a process used by health insurers to control costs. It requires patients to try one or more medications specified by the insurance company, typically a generic or lower cost medicine, to treat a health condition. Patients must then fail on the medication(s) before allowing a ‘step up’ to another medicine that may be more expensive for the insurer.”).

alternative therapy before a non-preferred therapy is covered.<sup>49</sup> The cost of step therapy for beneficiaries is more than nuisance or delay. In addition to the costs associated with more doctor's appointments,<sup>50</sup> step therapy may increase out-of-pocket costs for beneficiaries by requiring that beneficiaries pay for months (or even years) of additional, less effective therapies before they can access a therapy that works. Moreover, step therapy may delay access to effective therapy until it is too late, allowing health conditions to worsen, sometimes irreversibly, during the course of the less effective alternative therapies.<sup>51</sup> Because many people switch insurance plans from year to year, step therapy may also effectively keep patients from ever accessing effective therapies. A patient who is subject to two years of step therapy may, for example, switch insurance plans one-and-a-half years into step therapy. The patient may have to start step therapy from scratch with the new insurer, or face the substantial administrative burden of collecting paperwork and proving to the new plan that step therapy has been underway.<sup>52</sup> Even where beneficiaries stay on the same insurance plan, the requirement that the beneficiary fail treatment on a preferred drug to gain coverage for a nonpreferred drug may be triggered not only at the onset of therapy, but every year, as drugs cycle on and off the formulary. For example, a patient may be successfully using one asthma inhalant, but if that inhalant is moved to a non-preferred tier, the patient may be required to fail a trial of the

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49. See, e.g., *Limiting Step Therapy Policies to Protect Patients*, CAL. RHEUMATOLOGY ALL., <https://cqrcengage.com/cra/steptherapy> [<https://perma.cc/MJN7-CPPG>].

50. See, e.g., *Step Therapy: The Patient Impact*, PRESCRIPTION PROCESS, <http://prescriptionprocess.com/wp-content/uploads/2016/12/Step-Therapy-The-Patient-Impact.pdf> [<https://perma.cc/PL8G-SQH4>] (describing a Georgia Medicaid study in which step-therapy "saved" the state \$19.62 per member per month on schizophrenia medications, but the savings were accompanied by \$31.59 per member per month increase for outpatient services, thereby implying that restrictions on access resulted in poorer health).

51. See, e.g., Adrienne Chung, Joanna MacEwan & Dana P. Goldman, *Does a 'One-Size-Fits-All' Formulary Policy Make Sense?*, HEALTH AFFS. BLOG: HEALTH EQUITY (June 2, 2016), <https://www.healthaffairs.org/doi/10.1377/hblog20160602.055116/full/> [<https://perma.cc/ZTG9-N35Z>] ("‘Fail-first’ policies, as their name suggests, increase the risk of dangerous side effects[.] For certain patients—like those who need immunologic and biologic agents—these concerns are particularly salient. Researchers found that 18 insurance plans—representing approximately 97 million insured lives—required 45 percent of beneficiaries to ‘step through’ one or two drugs bearing an FDA ‘black box warning’ of serious adverse events before progressing to a drug without such warning. As a result, patients may needlessly face severe health risks in disease areas that have benefited from recent advances in immunologic and biologic therapy, such as cancer and inflammatory diseases.").

52. See, e.g., *Step Therapy*, ARTHRITIS FOUND., <https://www.arthritis.org/advocate/issue-briefs/step-therapy> [<https://perma.cc/Z85P-WJJE>] ("A survey of more than 1,400 patients conducted in 2016 by the Arthritis Foundation revealed that over half of all patients reported having to try two or more different drugs prior to getting the one their doctor had originally ordered. Step therapy was stopped in 39 percent of cases because the drugs were ineffective, and 20 percent of the time due to worsening conditions. Incredibly, nearly a quarter of patients who switched insurance providers were required to repeat step therapy with their new carrier.").

preferred drug before again becoming eligible for coverage of the original inhalant.

### 3. Restrictions on Access to Therapeutic Alternatives

Where two or more drugs are therapeutically equivalent, it is not uncommon for one drug to be on-formulary or preferred, while alternatives are not covered<sup>53</sup> or are placed on lower tiers. In its most straightforward form, this occurs when a generic drug is cheaper than a branded drug. The PBM may include the generic drug on-formulary, while excluding or placing at a lower tier the branded drug, therefore incentivizing patients to choose the generic drug. This dynamic gets distorted, however, when the PBM can profit from preferring the higher-cost brand drug. For example, manufacturers may offer the PBM a lucrative rebate or other payment for placement to induce inclusion of the more expensive drug in a higher tier; or, the PBM may also profit when negotiations between the PBM and manufacturer occur across a manufacturer's entire portfolio of products.<sup>54</sup> In such a scenario, the PBM may agree to place access restrictions on (or not even cover) lower cost alternatives to a competitor drug in order to secure discounts, rebates, or other concessions on the expensive drug or on other drugs in the manufacturer's portfolio.

Unequal treatment of therapeutically-equivalent drugs on formularies has several implications for beneficiaries. Where a pharmacy only stocks one alternative, for example, a beneficiary may find that her local pharmacy does not stock the drug covered. Normally, a pharmacy would simply work with the beneficiary's healthcare provider to substitute the equivalent medication that is in stock. But if the stocked medication is off-formulary or subject to access restrictions, the formulary may prevent the pharmacy from doing so without significant cost to the beneficiary. Such a scenario may cause the patient inconvenience and delay in obtaining therapy at a time when the patient is under considerable illness-induced stress.

The exclusion of drugs from a formulary when there is no therapeutically-equivalent drug is more clearly problematic as it has the potential to stop patients from receiving a therapeutically beneficial drug. For example, formularies may exclude an expensive drug such as

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53. See, e.g., 2021 National Preferred Formulary Exclusions, EXPRESS SCRIPTS (2021), [https://www.express-scripts.com/art/pdf/NPF\\_Prefered\\_Formulary\\_Exclusions2021.pdf](https://www.express-scripts.com/art/pdf/NPF_Prefered_Formulary_Exclusions2021.pdf) [<https://perma.cc/4XA6-YQLU>]; Ipsita Smolinski, *Special Formulary Exclusions Gaining Traction*, MORNING CONSULT (Jan. 6, 2015, 5:00 AM), <https://morningconsult.com/opinions/specialty-formulary-exclusions-gaining-traction/> [<https://perma.cc/SP3H-ZA3X>].

54. See *infra* Part III for further discussion of this dynamic.

sofosbuvir for hepatitis C because it sells for about \$1,000 per tablet.<sup>55</sup> Patients will be harmed by this exclusion if there is no drug with similar efficacy included in the formulary; or if, as compared to excluded drugs, included drugs have more profound side effects; or if the regime is longer or the drug more difficult to administer.<sup>56</sup>

Tiering can be designed to encourage utilization of lower-priced alternatives (e.g., generics vs. brands), as well as to discourage the use of higher priced drugs even where there is no alternative available.<sup>57</sup> Where tiering is deployed, access restrictions such as onerous prior-authorization requirements, step-therapy, and high copayments may put the most effective therapy out of reach for many beneficiaries, leaving beneficiaries with only second-best therapeutic options.

Access restrictions often result in the exclusion of competitors who could offer a cheaper price to patients, and these restrictions may also lead to increased beneficiary costs.<sup>58</sup> A common example of this phenomenon occurs when preferential treatment is given to brand-name drugs. In such cases, patients may not have access to a cheaper generic or biosimilar drug because only the brand drug is covered. Where patients have cost-sharing obligations such as copayments and deductibles, restricted access to generic and biosimilar drugs may substantially increase beneficiary out-of-pocket costs—for preferential treatment of a drug that is therapeutically indistinguishable from its generic competitors. As one commentator notes, discussing insulin:

Studies have revealed that pharmaceutical companies give pharmacy benefits managers (PBMs) volume-based rebases [sic] in exchange for keeping competing generic/biosimilar competitors off the formulary. A study found that only 17 percent of Medicare plans for seniors covered Basaglar, a

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55. See F. Randy Vogenberg & Judith Gomes, *The Changing Roles of P&T Committees: A Look Back at the Last Decade and a Look Forward to 2020*, 39 PHARMACY & THERAPEUTICS 760 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4218672/> [<https://perma.cc/4WPC-8MAE>].

56. This could happen with hepatitis C drugs, for example, as “[t]here is a range of different medications for hepatitis C because there is no single drug that works for everyone” and these drugs have different therapeutic implications, including length of treatment and side effects of a number of drugs used to treat hepatitis C.” Jon Johnson, *What Are the Best Hepatitis C Drugs?*, MEDICAL NEWS TODAY (Jan. 17, 2019), <https://www.medicalnewstoday.com/articles/324209> [<https://perma.cc/SE9C-DQ2N>].

57. See *Improving Value: Drug Formulary Design*, ALTARUM HEALTHCARE VALUE HUB, <https://www.healthcarevaluehub.org/improving-value/browse-strategy/drug-formulary-design> [<https://perma.cc/KX93-4SVB>] (“Tiered formularies divide covered medications into groups, usually based on cost. Insurers use these categories to encourage enrollees to opt for cheaper generic or brand-name drugs instead of higher cost alternatives.”).

58. See, e.g., Jay Hancock & Sydney Lupkin, *Secretive ‘Rebate Trap’ Keeps Generic Drugs for Diabetes and Other Ills out of Reach*, KAISER HEALTH NEWS (Jan. 18, 2019), <https://khn.org/news/secretive-rebate-trap-keeps-generic-drugs-for-diabetes-and-other-ills-out-of-reach/> [<https://perma.cc/A94X-RCCX>].

biosimilar drug, although nearly all plans covered Sanofi's more expensive biologic drug Lantus (Basaglar's originator).<sup>59</sup>

Another study found that only nineteen percent of generic drugs covered by Medicare Part D were in formulary tiers that imposed the lowest out-of-pocket costs on beneficiaries.<sup>60</sup>

Formulary restrictions on access to lower priced drugs is costly in another way: it may push Medicare Part D beneficiaries into a coverage "doughnut hole" between the maximum amount of standard drug coverage that a plan offers and the point at which catastrophic coverage kicks in. For Medicare Part D beneficiaries, drug benefits change once the plan has spent approximately \$4,000 on a beneficiary in a given year.<sup>61</sup> At that point, a new scheme begins, and the beneficiary is responsible for a higher proportion of the beneficiary's prescription drug costs.<sup>62</sup> This new coverage scheme, which is substantially more costly to the beneficiary, continues until the beneficiary has spent approximately \$6,000 of their own money out-of-pocket.<sup>63</sup> At that point, catastrophic coverage kicks in.<sup>64</sup> Centers for Medicare and Medicaid Services (CMS) explained the impact of higher cost drugs on beneficiary out-of-pocket costs vis-à-vis the doughnut hole:

[T]he list prices also play an important role in a beneficiary's progression through the different phases of the Part D benefit; higher list prices mean quicker progression through the benefit and higher overall costs in the catastrophic phase once the beneficiary reaches it. Rebates and other price concessions received after the point-of-sale do not mitigate these impacts.<sup>65</sup>

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59. *Improving Value: Drug Formulary Design*, *supra* note 57.

60. Chris Sloan & Elizabeth Carpenter, *Seniors Pay More for Medicare Part D Generics Despite Stable Prices*, AVALERE (May 22, 2018), <https://avalere.com/press-releases/seniors-pay-more-for-generics-in-medicare-prescription-drug-plans-despite-stable-prices> [<https://perma.cc/E6zX-9MNA>] (assessing a period between 2011 and 2015). Along the same lines: "Brand-drug sellers 'pay for position' on the formulary, said Michael Rea, CEO of Rx Savings Solutions, which helps health plans and employers manage pharma costs. 'In this country, the most cost-effective drugs don't necessarily mean anyone will have access to them . . . [Companies with] the deepest pockets win.'" Hancock & Lupkin, *supra* note 58.

61. *See Costs in the Coverage Gap*, MEDICARE.GOV, <https://www.medicare.gov/drug-coverage-part-d/costs-for-medicare-drug-coverage/costs-in-the-coverage-gap> [<https://perma.cc/PKU7-UQ58>].

62. *Id.*

63. *Id.*

64. *See, e.g., Catastrophic Coverage*, MEDICARE.GOV, <https://www.medicare.gov/drug-coverage-part-d/costs-for-medicare-drug-coverage/catastrophic-coverage> [<https://perma.cc/89MT-WC68>].

65. *Medicare Part D – Direct and Indirect Remuneration (DIR)*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Jan. 19, 2017), <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir> [<https://perma.cc/WJ96-5BT5>].

Access restrictions that drive beneficiaries toward higher-priced drugs may increase costs for beneficiaries in a number of ways. Beneficiary copayments may increase, especially where copayment obligations are calculated as a percentage of a drug's list price. Beneficiaries who have not yet met their deductible, moreover, may be responsible for the entire list price of the drug. A higher list price may also push beneficiaries into coverage doughnut holes where they have hit their standard coverage cap, but have not yet met the out-of-pocket amount necessary for catastrophic coverage to kick in.

In sum, as a part of negotiations with manufacturers, PBMs may agree to restrict access to more or equally effective therapies to secure price concessions that benefit the PBM and sometimes the plans they work for, but often not the beneficiaries who purchase the drugs. Access restrictions may operate to the clinical and financial detriment of patients who have been prescribed restricted drugs. There are, of course, at least some circumstances in which restricting access to competitive drugs may result in price reductions that are passed through to beneficiaries. As the next Section discusses, however, under certain circumstances, and especially in the context of rebates, payment-for-placement arrangements may operate exclusively to the detriment of beneficiaries.

### C. Access Restrictions May Not Benefit Plan Members

Even though beneficiaries clearly bear the cost of access restrictions, they do not always benefit from them.<sup>66</sup> By aggregating the buying power of their client plans and using formulary design to concentrate purchasing volume, PBMs can extract deeper price concessions than can their clients acting independently.<sup>67</sup> As a district court recently explained:

[M]anufacturers contract with PBMs to pay “rebates” . . . directly attributable to the plan’s use of “preferred”

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66. See, e.g., *The PBM Problem: Consumers Face an Unfair Disadvantage at the Pharmacy Counter*, NAT'L CONSUMERS LEAGUE, <https://nclnet.org/pbms> [<https://perma.cc/7R8-FY8C>] (“PBMs impede the savings that should be going to consumers in many ways. PBMs often demand that drug companies provide them ‘rebates’ or discounts to offer medicines as part of a drug benefit plan. These discounts are meant to lower the out-of-pocket costs consumers pay at the pharmacy counter, but we aren’t seeing the savings. PBMs also steer consumers to the higher-cost drugs that will make them the most money, regardless of patient and treatment considerations.”).

67. See John Arnold, *Are Pharmacy Benefit Managers the Good Guys or Bad Guys of Drug Pricing?*, STAT (Aug. 27, 2018), <https://www.statnews.com/2018/08/27/pharmacy-benefit-managers-good-or-bad/> [<https://perma.cc/5U2U-JA3H>].

formulary pharmaceuticals. . . . [R]ebates are owed, and directly paid, to the PBMs.

Oftentimes, PBMs develop proprietary formularies, irrespective of the plans with which they deal; in other cases, plans participate in selecting certain criteria or identifying specific drugs for inclusion (and/or exclusion). . . . Where the plan participates in a formulary program, PBMs are often paid an additional amount, e.g., a portion of market share rebates, for their performance of services related to encouraging pharmacies, physicians, and members to participate in and/or facilitate the same.<sup>68</sup>

Because PBMs often retain a portion of rebates as payment for their services, PBMs have an incentive to maximize rebates.

A rebate is a partial refund of a purchase price, made after the sale of the subject item. As such, the rebates secured by PBMs are not reflected in a drug's list price, but rather are paid retrospectively after the time of sale.<sup>69</sup> Therefore, rebates may not flow through to beneficiaries in the form of lower cost-sharing obligations. Indeed, CMS has observed that, while manufacturer payments to PBMs as a proportion of drug cost trended dramatically upwards during a recent five-year period, these payments have not resulted in a proportionate reduction in the price assessed at the point-of-service.<sup>70</sup> As beneficiary cost-sharing obligations are often assessed as a percentage of the point-of-service price, any reduction in drug cost that is not reflected at the point-of-service will not result in a reduction of the beneficiary's cost-sharing obligation.<sup>71</sup> *Everson v. Blue Cross and Blue Shield of Ohio* includes a discussion of how a discount or rebate may benefit a payor but not result in a reduction in copayments.<sup>72</sup> The *Everson* plaintiff-beneficiaries alleged the defendant-group health plan had caused them

to make copayments in excess of the fixed percentage set forth in the group plan. Plaintiffs claim that the excess payments are

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68. *In re Express Scripts, Inc., PBM Litig.*, No. 05-MD-01672, 2008 WL 2952787, at \*5–6 (E.D. Mo. July 30, 2008). For a good explanation of how PBMs retain a portion of the discounts that they receive from pharmacies (i.e., the “spread”), see *Qui Tam Complaint, United States ex rel. Behnke v. CVS Caremark Corp.*, No. 14-cv-824, 2020 WL 1953626 (E.D. Pa. Apr. 23, 2020).

69. Deana K. Bell & Karen L. Nixon, *Rebates at the Point of Sale*, ACTUARY (May 2020), <https://theactuarmagazine.org/rebates-at-the-point-of-sale/> [https://perma.cc/A6S2-5VH6].

70. See, e.g., U.S. GOV'T ACCOUNTABILITY OFF., GAO 19-498, MEDICARE PART D: USE OF PHARMACY BENEFIT MANAGERS AND EFFORTS TO MANAGE DRUG EXPENDITURES AND UTILIZATION (2019), <https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/Medicare%20Part%20D%20GAO%20Report.pdf> [https://perma.cc/BW5X-LN2U].

71. See *id.*

72. *Everson v. Blue Cross & Blue Shield of Ohio*, 898 F. Supp. 532, 536 (N.D. Ohio 1994).



the result of the allegedly undisclosed practice of defendant negotiating discounts with health care providers and failing to pass a proportionate share of such discounts on to its insureds. As a result, plaintiffs allege that defendant actually pays a percentage of the health care providers' charges which is less than that specified by the terms of the plan. *The insureds' portion, on the other hand, is not discounted, but is still based on the total charges. Thus, the copayment paid by the insured is greater than that specified by the terms of the plan.*<sup>73</sup>

Even if rebates do not reduce drug prices at the point-of-service, one might expect that rebates would benefit plans and, ultimately, beneficiaries, in the form of lower premium costs. However, this is not always the case. PBMs do not usually pass rebates through in their entirety—or even at all—to plans, and plans do not always pass through any cost savings they do realize to beneficiaries.<sup>74</sup> All of this means that the PBM's opportunity to profit from formulary design decisions, including attendant access restrictions, often does not correlate with benefits to beneficiaries in the form of reduced costs or improved access to care.

The incentives that rebate arrangements create for PBMs can be at odds with the incentives plans have to minimize plan costs, particularly when the rebate is a payment for placement. Rebate arrangements can result in higher costs, which in turn result in higher premiums and, even when they do not, can result in higher copayments<sup>75</sup> or other cost-sharing obligations for beneficiaries.<sup>76</sup> Rebates may also cause clinical

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73. *Id.* (emphasis added).

74. See, e.g., Dae Y. Lee & Jonathon E. Levitt, *Understanding the Truth About PBMs and Manufacturer Rebate Revenue*, FRIER LEVITT (June 22, 2020), <https://www.frierlevitt.com/articles/understand-the-truth-about-pbms-and-manufacturer-rebate-revenue/> [https://perma.cc/3RS9-7GFA].

75. Notably, to the extent that discounts are extended via rebates and not via point-of-service price reductions, beneficiaries whose copayment obligations are calculated as a percentage of price will not benefit from the rebates through copayment reduction. On the other hand, to the extent that copayments are flat amounts determined by the tier in which the drug is placed, preferential treatment can reduce drug costs. In either case, “tier placement remains a key determinant of consumer cost.” See Charles Roehrig, *Rebates, Coupons, PBMs, and the Cost of the Prescription Drug Benefit*, HEALTH AFFS.: HEALTH AFFS. BLOG (Apr. 26, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20180424.17957/full/> [https://perma.cc/6L7R-R9QP].

76. See U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 70, at 13. Consider the following:

Rebates and other price concessions reduce the cost of the Part D program to beneficiaries and the federal government. In developing their bids, Part D plan sponsors may subtract rebates and other price concessions that are passed along to them from their estimated drug costs. When they do, rebates and other price concessions reduce a plan sponsor's estimate of liability that is reflected in bid amounts, which, in turn, reduce beneficiary premiums because they are partially based on the bid amount. This downward pressure on premiums is one reason that premiums remained

or other benefits of competing drugs to be eclipsed in the formulary design process.<sup>77</sup> As a result, the PBM's guiding light is not a careful consideration of healthcare and cost outcomes for beneficiaries, but rather the ultimate profitability to the PBM of the placement decision, which may be entirely divorced from (if not adverse to) beneficiary interests. The opportunity of a PBM to profit from limiting drug access is fundamentally at odds with patient clinical and economic wellbeing. When PBMs accept and retain rebates in lieu of pre-sale discounts or other price concessions that are passed through to beneficiaries, and when PBMs agree to lift utilization controls from one drug but then apply them to others in exchange for a payment for placement, the interests of PBMs, patients, and plans diverge. In this system, rather than acting in the interest of cost-containment through benefit administration, PBMs become rent-seeking, third-party intermediaries whose involvement is primarily one of economic friction—driving up costs for beneficiaries (in terms of dollars, time, or clinical outcome) so as to collect a reward merely for their presence in the pharmaceutical distribution and payment system.

## II. PHARMACY & THERAPEUTIC COMMITTEES PLAY A LIMITED ROLE IN PROTECTING BENEFICIARY INTERESTS

In theory, where the interests of PBMs and beneficiaries diverge, the interests of beneficiaries should be accounted for in the formulary design process through the use of P&T committees.<sup>78</sup> P&T committees are comprised of clinical professionals (such as physicians and pharmacists) and other persons with expertise in healthcare, public

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relatively unchanged between 2010 and 2015, according to CMS, even though total gross Part D drug costs grew about twelve percent per year in that period. Rebates have additional implications for Part D beneficiaries and the Part D program more generally. Since beneficiary cost sharing is calculated based on the price of the drug at the time of purchase (i.e., before rebates are paid), beneficiaries pay higher cost sharing than they would if rebates were paid at the point of sale. In addition, higher pre-rebate drug prices may result in beneficiaries more quickly reaching the catastrophic coverage phase, where the federal government's share of drug costs increases and the plan sponsors' share decreases.

*Id.*

77. See, e.g., Rachel Cohrs, *Without Rebates, Evidence Could Be Key for Formulary Placement*, INSIDE HEALTH POL'Y (Apr. 18, 2019), <https://insidehealthpolicy.com/inside-drug-pricing-daily-news/without-rebates-evidence-could-be-key-formulary-placement> [<https://perma.cc/HS3L-CTPX>]. Eliminating rebates “could force drug companies to compete more directly on value” and “require a shift in strategy toward more robust evidence generation, the development of support services, and greater competition in value-based contracts.” *Id.* (citing and quoting Deloitte executive Greg Reh). See also U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 70, at 13.

78. The use of P&T committees to protect beneficiary interests is broadly acknowledged and is often required by law. See, e.g., 42 C.F.R. § 423.120(b)(1) (2020).

health, and benefits design.<sup>79</sup> These committees are tasked with assessing available therapeutic options and advising on formulary design.<sup>80</sup> Because P&T committees are intended to serve as a check on self-interested decision-making by PBMs, they function with some amount of independence from the PBMs they advise.<sup>81</sup> Indeed, in many contexts, P&T committees are required to have a certain number of members that are free of any conflict of interest that may cause them to prioritize PBM or plan preference over the interests of beneficiaries in receiving safe and effective therapy.<sup>82</sup> P&T committee members who are clinical professionals, moreover, must act in a manner that is

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79. See *id.* (requiring that a majority of members of any Part D P&T committee be practicing physicians or pharmacists); see also *Formulary Management*, ACAD. OF MANAGED CARE PHARMACY (Nov. 2009), <https://amcp.org/sites/default/files/2019-03/Formulary%20Management.pdf> [<https://perma.cc/Y2TU-VQHJ>] (“The P&T committee is responsible for developing, managing, updating and administering the formulary. The P&T committee also designs and implements formulary system policies on utilization and access to medications. Utilization management strategies such as quantity limits, step therapy and prior authorization criteria may be reviewed and approved by P&T committees. Access policies include medical exception process protocols to allow patients coverage for non-formulary drugs under defined circumstances.”).

80. The role of P&T committees in assessing the safety, efficacy, and public health implications of drugs is taken very seriously, with potentially severe penalties for fraudulent actions that damage the integrity of the P&T committee’s review. For example, in 2020, Shaun Thaxter, a former executive at a pharmaceutical company, Indivior, was criminally convicted for providing false information to Massachusetts Medicaid (“MassHealth”) regarding Indivior’s drug for the treatment of opioid dependence, Suboxone Film. Press Release, U.S. Dept’t of Justice, U.S. Att’y’s Off., W. Dist. Va., Suboxone Manufacturer Indivior’s Former Chief Executive Officer Sentenced to Jail Time in Connection with Drug Safety Claims (Oct. 22, 2020), <https://www.justice.gov/usao-wdva/pr/suboxone-manufacturer-indiviors-former-chief-executive-officer-sentenced-jail-time> [<https://perma.cc/P9SQ-L3LJ>]. The Department of Justice’s press release noted that:

Thaxter oversaw and encouraged Indivior’s efforts to secure formulary coverage for Suboxone Film from . . . MassHealth. Thaxter asked Indivior employees . . . to devise a strategy to win preferred drug status for Suboxone Film and counteract a non-opioid competitor MassHealth was considering for opioid-addiction treatment. Certain Indivior employees subsequently shared false and misleading safety information with MassHealth officials about Suboxone Film’s risk of accidental pediatric exposure. Two months after receiving that false and misleading information, MassHealth announced it would provide access to Suboxone Film for Medicaid patients with children under the age of six.

*Id.*

81. See, e.g., Stephen Barlas, *P&T Committees Face New Medicare Rules: Proof Needed of “Independent” Members’ Independence*, PHARMACY & THERAPEUTICS (May 2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4422628/> [<https://perma.cc/L4H4-SKPY>].

82. Under the Affordable Care Act, plans offered on Affordable Care Act marketplaces must employ the services of a P&T committee, at least twenty percent of members of which must have no conflicts of interest with the issuer of the plan or any pharmaceutical manufacturer. 45 C.F.R. § 156.122(a)(3)(i)(D) (2020). Those members who do have a conflict of interest are prohibited from voting on any matters for which the conflict exists. 45 C.F.R. § 156.122(a)(3)(i). Likewise, regulations governing the administration of Medicare Part D plans require that P&T committee members be free from conflicts of interest. 45 C.F.R. § 156.122(a)(3)(i)(C) (“The P&T committee must: . . . Prohibit any member with a conflict of interest with respect to the issuer or a pharmaceutical manufacturer from voting on any matters for which the conflict exists.”).

consistent with their status as licensed medical professionals, under rules that are dictated by state laws, state professional licensing boards, and non-government professional associations. These rules—which apply not only when such professionals are treating individual patients, but also any time such professionals act in their capacity as licensed clinical professionals<sup>83</sup>—include standards that broadly require that physicians and pharmacists act only in the best interests of patients, making decisions free from conflict of interest or undue influence.<sup>84</sup>

Despite the generally-accepted role of P&T committees, there is no standard approach to assuring that P&T committees engage in a robust cost-benefit analysis from a beneficiary's perspective, meaning that the role of P&T committees has been mostly limited to advising on the comparative safety and therapeutic value of available drugs without consideration for the broader, pharmacoeconomic implications of formulary design.<sup>85</sup> In many cases, P&T committees are explicitly

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83. Several state medical boards have taken disciplinary action against physicians for actions taken as agents of insurance providers (as opposed to the role of direct care provider). In *Murphy v. Board of Medical Examiners of State of Arizona*, the Court of Appeals of Arizona concluded that the Arizona State Medical Board did have jurisdiction to discipline a physician for actions taken in his role as a plan Medical Director. *Murphy v. Bd. of Med. Exam'rs of the State of Ariz.*, 949 P.2d 530, 532 (Ariz. Ct. App. 1997). The court explained that the duty of the Board, by statute, is broadly “to protect the public from unlawful, incompetent, unqualified, impaired or unprofessional practitioners.” *Id.* at 535–36. The Missouri Supreme Court has likewise found insurance plan Medical Directors to be acting in their professional capacity when making decisions that are determinative of insurance coverage. *State Bd. of Registration for Healing Arts v. Fallon*, 41 S.W.3d 474, 477 (Mo. 2001). The court explained that although “the choice to cover a patient's expenses is an administrative choice, a physician's finding of ‘medical necessity’ is a purely medical decision.” *Id.* at 477; *see also* AM. MED. ASS'N, HOUSE OF DELEGATES, PROCEEDINGS: 148TH ANNUAL MEETING 267, 268–69 (1999). The proceedings explain that physicians are obligated to place the interests of patients above the financial interests of their employers and that “[p]hysicians must uphold their professional, ethical duties regardless of whether they are engaged in direct patient care or in clinical decision-making that affects patient care provided by another physician or licensed health care professional.” AM. MED. ASS'N, *supra*, at 268.

84. *See, e.g.*, MINN. STAT. § 147.091 (2021) (allowing the state medical board to take disciplinary action against physicians who fail to uphold certain standards of conduct); *Code of Ethics for Pharmacists*, AM. PHARMACISTS ASS'N (Oct. 27, 1994), <https://www.ashp.org/-/media/assets/policy-guidelines/docs/endorsed-documents/code-of-ethics-for-pharmacists.ashx> [<https://perma.cc/9AMN-SYDH>] (“[A] pharmacist promises to help individuals achieve optimum benefit from their medications, to be committed to their welfare, and to maintain their trust. . . . A pharmacist avoids discriminatory practices, behavior or work conditions that impair professional judgment, and actions that compromise dedication to the best interests of patients.”); *AMA Principles of Medical Ethics*, AM. MED. ASS'N, <https://www.ama-assn.org/about/publications-newsletters/ama-principles-medical-ethics> [<https://perma.cc/4SH7-EDAP>] (“As a member of this profession, a physician must recognize responsibility to patients first and foremost, as well as to society, to other health professionals, and to self. . . . A physician shall, while caring for a patient, regard responsibility to the patient as paramount. . . . A physician shall support access to medical care for all people.”).

85. An analysis of P&T committees in England described a similar lack of defined analytical process for P&T committees, despite the crucial role played by P&T committees in the continuum of care:

[L]ocal formulary committees are key players in the management of scarce resources. However, little is known about the information and processes used when making

limited by their mandates to consider only the relative safety and efficacy of drugs.<sup>86</sup> Where P&T committee mandates instruct the P&T committee to conduct a more holistic, pharmacoeconomic analysis that accounts for costs to beneficiaries, the resulting analysis may be limited to simple comparisons of list price between therapeutic equivalents or may explicitly be made subordinate to considerations of cost to the plan.<sup>87</sup> More fundamentally, even if P&T committees function entirely

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decisions on the inclusion of new treatments. This paper reports research on the use of economic evaluations in technology coverage decisions in England, although the findings have a relevance to other health care systems with devolved responsibility for resource allocation. . . . Our main research finding is that it is an exception for cost-effectiveness analysis to inform technology coverage decisions. Barriers to use include access and expertise levels, concerns relating to the independence of analyses and problems with implementation of study recommendations. Further barriers derive from the constraints on decision makers, a lack of clarity over functions and aims of local committees, and the challenge of disinvestment in medical technologies. The relative weakness of the research-practice dynamics in this context suggests the need for a rethinking of the role of both analysts and decision makers. Our research supports the view that in order to be useful, analysis needs to better reflect the constraints of the local decision-making environment. We also recommend that . . . the National Health Service more clearly identify the 'problems' which they are charged with solving and how their outputs contribute to broader finance and commissioning functions. This would help to establish the ways in which the routine use of cost-effectiveness analysis might become a reality.

Iestyn P. Williams & Stirling Bryan, *Cost-Effectiveness Analysis and Formulary Decision Making in England: Findings from Research*, 65 SOC. SCI. & MED. 2117, 2117 (2007), <https://www.sciencedirect.com/science/article/pii/S0277953607003450?via%3Dihub>; see also Zhixiao Wang, J. Warren Salmon & Surrey M. Walton, *Cost-Effectiveness Analysis and the Formulary Decision-Making Process*, 10 J. MANAGED CARE PHARMACY 48 (2003) (explaining that use of cost-effectiveness analysis for formulary decision-making is limited by current methodological concerns).

86. For example, Washington State's Medical Assistance P&T Committee is limited to evaluating "available evidence regarding the relative safety, efficacy, and effectiveness of prescription drugs within a class or classes of prescription drugs and to making recommendations . . . for . . . the development of the state's preferred drug list." *P&T Committee Plan of Operations*, WASH. STATE HEALTH CARE AUTH., <https://www.hca.wa.gov/assets/program/pt-plan-of-operations.pdf> [<https://perma.cc/JD8L-UZC2>]. Such review may include "outcome studies of the long-term effects of drugs" and drug utilization review. *Id.*

87. For example, HealthPartners, a managed care plan, states that the mission of the plan's P&T committee is "to promote the appropriate use of high quality and cost-effective pharmaceuticals for [plan] members." HEALTHPARTNERS, PHARMACY AND THERAPEUTICS COMMITTEE POLICIES AND PROCEDURES 2 (2021), [https://www.healthpartners.com/ucm/groups/public/@hp/@public/documents/documents/cntrb\\_043361.pdf](https://www.healthpartners.com/ucm/groups/public/@hp/@public/documents/documents/cntrb_043361.pdf) [<https://perma.cc/283L-9VCB>] (emphasis added). This policy explicitly acknowledges beneficiary interests, stating that the committee is to be guided by these competing principles: effectiveness, safety, pharmacoeconomics, emphasis on products essential to health, patient adherence, convenience, patient satisfaction relative to such issues as storage and dosing convenience, and supporting standard treatment protocols. *Id.* at 3. The HealthPartners policy says that it will consider: "Significant improvements in patient convenience, adherence, and satisfaction. We will review more favorably products that have significant improvements in patient convenience, adherence, and satisfaction. Examples include variables such as dosing convenience, variety of dosage forms, taste, ability to crush or divide doses, and storage requirements (refrigeration)." *Id.* However, the policy instructs that "[t]hese principles are prioritized in descending order," such that considerations of cost to the plan will always supersede considerations of patient convenience. *Id.*

independently of plan and PBM interests, fully accounting for beneficiary interests in their analysis, PBMs and plans are not bound by the recommendations of P&T committees; this means that PBMs and plans can and do simply disregard P&T committee recommendations that may increase PBM costs or decrease PBM revenues.<sup>88</sup>

As an illustration of both how beneficiary costs may be overlooked and how PBM consideration of profitability infects formulary design, we take a brief look at the formulary design of Express Scripts, a PBM that services about a quarter of the market.<sup>89</sup> Express Scripts explains

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TRICARE, the Department of Defense managed care healthcare program, mandates the use of a P&T committee, which is explicitly charged with considering costs when making formulary design recommendations. 10 U.S.C. § 1074g(a)(2)(A); 32 C.F.R. § 199.21(e)(1)–(2) (2020). The only costs that it is mandated to consider are the Government's. *Id.* We note that this effect is offset by the broad coverage mandate—all drugs with clinical efficacy are to be included, unless one is materially superior—and by the use of a Beneficiary Advisory Panel. *See id.*

Under Affordable Care Act regulations, P&T committees that serve plans offered on Affordable Care Act marketplaces must consider the impact of any formulary placement decisions on beneficiary access. Specifically, the P&T committee must ensure the formulary drug list: “[p]rovides appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time.” 45 C.F.R. § 156.122(a)(3)(iii)(H)(2) (2020). While this regulatory requirement would appear to protect beneficiary interest, it is weakened by lack of clarity regarding what considerations are encompassed by the concept of “appropriate access to drugs.” Furthermore, formulary decision-making under the Affordable Care Act is open to challenge by beneficiaries only on grounds of comparative therapeutic effectiveness. Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, 80 Fed. Reg. 10750, 10818 (Feb. 27, 2015); 45 C.F.R. § 156.122(c).

88. Perhaps the clearest and most robust requirements for P&T committees to protect the interest of beneficiaries are those contained within regulations that apply to Medicare Part D plans. These requirements include that P&T committee clinical decisions be based “on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate,” and on a consideration of “whether the inclusion of a particular Part D drug in a formulary or formulary tier has any therapeutic advantages in terms of safety and efficacy.” 42 C.F.R. § 423.120(b)(1)(v)–(vi) (2020). P&T committees must endeavor to ensure “that beneficiaries receive clinically appropriate medications at the lowest possible cost,” and that utilization controls do not harm beneficiaries. CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE MODERNIZATION ACT FINAL GUIDELINES—FORMULARIES 1, <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/formularyguidance.pdf> [https://perma.cc/832C-EBPT]. With respect to the burdens imposed on beneficiaries through utilization controls, CMS requires Part D plan sponsors to “perform adequate oversight of their PBMs and other delegated entities to verify that “utilization management requirements applied at point of sale (POS), such as prior authorization (PA), step therapy (ST), and quantity limits (QL) not based upon the FDA's maximum daily dose limits” not cause “beneficiary harm due to impermissible delayed or denied access to Part D drugs.” CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL, CHAPTER 6—PART D DRUGS AND FORMULARY REQUIREMENTS 23 (2016), <https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf> [https://perma.cc/E75U-KYLL].

89. The PBM market is dominated by just a few big players, with the distribution in 2019 being: (1) Caremark (CVS Health)/Aetna: thirty percent; (2) Express Scripts: twenty-three percent; (3) OptumRx (UnitedHealth): twenty-three percent; (4) Humana Pharmacy Solutions: seven percent; (5) MedImpact Healthcare Systems: six percent; (6) Prime Therapeutics: six percent; and (7) All other PBMs and cash pay: four percent. Alia Paavola, *Top PBMs by Market Share*, BECKER'S

that it uses “a four-step process involving the work of three distinct committees.”<sup>90</sup>

The first step is taken by the Therapeutic Assessment Committee, which is made up of PBM-employed clinical pharmacists and physicians, whose task is to evaluate new drugs and make a formulary placement recommendation to the P&T committee.<sup>91</sup> It is unclear whether this committee considers the profitability of the drug for the PBM in making its recommendations, but it seems likely that it does, given the specific disclaimer of such considerations with respect to the National Pharmacy & Therapeutics Committee.

The second step is taken by the National Pharmacy & Therapeutics Committee (referred to by Express Scripts as the P&T Committee), which is made up of independent physicians and pharmacists.<sup>92</sup> According to Express Scripts, at this stage:

The P&T Committee is tasked to review medications from a purely clinical perspective. The Committee does not have access to, nor does it consider, any information regarding Express Scripts’ rebates/negotiated discounts, or the net cost of the drug after application of all discounts. The Committee does not use price, in any way, to make formulary placement decisions. . . . The P&T Committee can establish one of the following four placement designations: *include*, *access*, *optional*, or *exclude* from a formulary.<sup>93</sup>

The third step is taken by the Value Assessment Committee (VAC), which is made up of PBM-employees who consider the

net cost, market share, and drug utilization trends of clinically similar medications [to make formulary recommendations]. . . . [E]conomic considerations are superseded by the clinical requirements of the P&T Committee. Once complete, formulary and tier placement recommendations are then forwarded to the P&T Committee for final approval.<sup>94</sup>

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HOSP. REV. (May 30, 2019), <https://www.beckershospitalreview.com/pharmacy/top-pbms-by-market-share.html> [<https://perma.cc/NT7G-3EH5>].

90. EXPRESS SCRIPTS, WHITE PAPER: FORMULARY DEVELOPMENT AT EXPRESS SCRIPTS (2019), [https://corporate-site-labs-prod.s3.us-east-2.amazonaws.com/2019-11/Formulary%20Development\\_November%202019%5B2%5D.pdf](https://corporate-site-labs-prod.s3.us-east-2.amazonaws.com/2019-11/Formulary%20Development_November%202019%5B2%5D.pdf) [<https://perma.cc/86FY-2BZJ>].

91. *Id.*

92. *Id.*

93. *Id.*

94. *Id.*

The VAC committee clearly injects economic considerations of the plan and PBM into the mix, with the caveat that they are to be “superseded by clinical requirements.”<sup>95</sup>

The fourth and final step is taken by the National Pharmacy & Therapeutics Committee. At this juncture, this committee seems to perform a broad oversight function rather than engage in any significant independent analysis. The National Pharmacy & Therapeutics Committee’s mandate with respect to this last step is to annually “review the final formulary recommendations, by drug class, for the upcoming plan year. The Committee uses this opportunity to ensure adherence to previously established formulary placement recommendations, and to validate continued alignment with best medical practices.”<sup>96</sup>

Notably, despite what would appear to be a robust, multi-layer review structure, none of the considerations mentioned at any stage are beneficiary costs or benefits, other than clinical safety and efficacy. To the extent that beneficiary interests supersede the PBM’s own financial considerations, it is only with respect to the P&T committee’s assessment of the clinical safety and efficacy of a drug. It would appear, therefore, that in practice the two-step consideration of clinical, then economic, effects, means that so long as the drug is clinically appropriate, the determining factor as to where it will be placed is economic and largely informed by the benefit (measured in terms of short-term profit) of the placement to the PBM, (and, perhaps to the plan), with little, if any, regard to the cost to patients or to the public.

When the Express Scripts formulary development process is taken as a whole, the minor effort to manage conflicts—segregation of cost considerations from clinical considerations—perversely renders the P&T committee unable to ensure that PBM cost data and recommendations are not infected by a conflict of interest or to ensure that beneficiary interests are appropriately taken into account. The result is a formulary design system in which the only limit on the PBM’s ability to trade beneficiary interests for profit is a requirement that the PBM not go so far as to wholly ignore the clinical assessments of the P&T committee. This limitation does little to protect against the strong incentives for PBMs to act in contravention of beneficiary interests in order to obtain payments for placement from pharmaceutical manufacturers.<sup>97</sup>

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95. *Id.*

96. *Id.*

97. Rumore and Vogenberg note that “[b]etween 2004 and 2008, PBMs were the subject of six major federal or multidistrict cases involving P&T fraudulent practices, resulting in more than \$371.9 million in damages to states, plans, and patients.” Martha M. Rumore & F. Randy Vogenberg, *PBM P&T Practices: The HEAT Initiative Is Gaining Momentum*, 42 P&T 330, 332 (2017),



Adding to this problem is that incentives that may have biased PBM decision-making are not transparent. As noted above, the P&T committee itself may be entirely unaware of how profit-related considerations have biased the data which it is provided. Beneficiaries and plans are also in the dark, because rebate contracts are secret.<sup>98</sup> Accordingly, nobody knows the full extent of the practice nor how much it costs the health system in unrealized savings. In this regard, Professor Robin Feldman, of the University of California, Hastings College of the Law explained:

The deals between the drug companies and the PBM middle players are guarded as fiercely as Fort Knox. . . . No one gets to see them. But new research is turning up plenty of evidence of rebates distorting the market, such as numerous instances of effective, less expensive generics missing from formularies or

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<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5398626/> [<https://perma.cc/7D7K-YWVN>]; see, e.g., *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 298 (1st Cir. 2005). *Rowe* explained that PBMs acting as intermediaries

have the opportunity to engage in activities that may benefit the drug manufacturers and PBMs financially to the detriment of the health benefit providers. For example, in cases of “therapeutic interchange,” a PBM may substitute a more expensive brand name drug for an equally effective and cheaper generic drug. This is done so that the PBM can collect a fee from the manufacturer for helping to increase the manufacturer’s market share within a certain drug category. Similarly, a PBM might receive a discount from a manufacturer on a particular drug but not pass any of it on to the health benefit provider, keeping the difference for itself. The health benefit provider, however, often has no idea that a PBM may not be working in its interest. This lack of awareness is the result of the fact that there is little transparency in a PBM’s dealings with manufacturers and pharmacies. As the district court noted, “[w]hether and how a PBM actually saves an individual benefits provider customer money with respect to the purchase of a particular prescription drug is largely a mystery to the benefits provider.”

*Rowe*, 429 F.3d at 298 ; see also Jason Laday, *PBMs Blamed for Step Therapy, Nonmedical Switching, Other Restrictions on Patients*, HEALIO (Aug. 21, 2019), <https://www.healio.com/news/rheumatology/20190821/pbms-blamed-for-step-therapy-nonmedical-switching-other-restrictions-on-patients> [<https://perma.cc/6KYH-YFNL>] (“The PBMs are in the center: they are the controllers, and they interact with the manufacturers and decide placement on formulary, deciding which drugs we can prescribe first, leading to step therapy and nonmedical switching, and all the other horrible utilization management things for our patients,” Levin, who practices at Bay Area Rheumatology, in Clearwater, Florida, told attendees at the 2019 Rheumatology Nurses Society Annual Conference. ‘The PBMs are the cause of it. They create formularies, and the manufacturers have to pay to get that formulary placement.’ ‘Formulary placement is not rational,’ he added. ‘It is not rational based on what works for our patients, or what is efficacious or safe, or well-tolerated. None of that really counts. The only thing that counts is how much money — how big of a truck they can pull up, filled with cash — they can give to the PBMs. That is really what all of this is about.’”).

98. See Hancock & Lupkin, *supra* note 58; see also *Qui Tam Complaint*, *supra* note 68, at 6 (recounting the statement by a Caremark official that Caremark was not required to disclose the actual prices that it was paying pharmacies to its plan-client, Aetna).

patients burdened with higher out-of-pocket costs for generic drugs.<sup>99</sup>

P&T committees are perhaps the only structural aspect of the formulary design process that, at least theoretically, may protect beneficiary interests. However, because P&T committees are so closely affiliated with and largely dependent on PBMs, they are unable to robustly protect beneficiary interests. Under a system that allows manufacturers to pay PBMs for formulary placement, PBMs have every incentive to, and do, limit P&T committees to a therapeutic advisory role. This dynamic renders P&T committees ineffective at, if not entirely unconcerned with, preventing the imposition of barriers to access to care. Simply put, there is no one assuring that beneficiaries are fairly rewarded for the restrictions imposed upon them, as cost-savings that result from the formulary structure are often diverted to PBMs and plans, rather than reflected in lower costs to beneficiaries.

### III. ANTI-KICKBACK STATUTES COULD MITIGATE MANUFACTURER INFLUENCE ON PBMS

While the risk of harm posed to beneficiaries by payment to PBMs for placement seems clear, whether and how to address this risk has been a source of great consternation for legislators and regulators.<sup>100</sup> In this Part, we demonstrate that the federal,<sup>101</sup> and by analogy, the state anti kickback laws,<sup>102</sup> can be used to stop manufacturers from paying PBMs to influence purchasing decisions through formulary placement.<sup>103</sup> The anti-kickback laws create a comprehensive framework of powerful beneficiary protections that has proven effective with respect to other arrangements for the delivery of healthcare items and services. Making it clear that PBMs must follow the path established by this framework should go a long way toward protecting beneficiary interests. Despite much handwringing by lawmakers and regulators as to whether and how to refine these laws so as to better address PBM incentives, these laws can be employed, *in their current*

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99. See Hancock & Lupkin, *supra* note 58.

100. See generally Charles Roehrig, *Rebates, Coupons, PBMs, and the Cost of the Prescription Drug Benefit*, HEALTH AFFS. (Apr. 26, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20180424.17957/full/> [<https://perma.cc/H5DQ-SJJ8>] (explaining how payments for placement can result in overall higher health care costs).

101. 42 U.S.C. § 1320a-7b(b).

102. See *supra* note 26 and sources cited.

103. The federal AKS pertains to federal health care programs (e.g., Medicare Part D, Medicaid MCOs, and TRICARE), while the state analogs may pertain to state governmental programs, all payors, commercial or governmental, or only commercial plans.

form, to address misalignment in economic incentives that causes PBMs to enter into arrangements that harm beneficiaries. In other words, the problem is not that the law permits the abuse of beneficiaries, but that understanding and enforcement of the law has been sub-par, rendering it essentially meaningless in this context.

In this Part, we argue for a clearly expressed, coherent, and predictable approach to anti-kickback enforcement. This enforcement must focus on manufacturer payments to PBMs for placement, which we argue are legally impermissible, as distinct from payments to plans for access or inclusion, which we argue are legally permissible. Whether payments for placement are styled as rebates or otherwise, they are designed to induce the PBM-recipient to *improperly drive* purchase volume toward the manufacturer's product. Clearly, these payments are not permissible price concessions offered to *plans* (or to PBMs as agents for the plans), but are, rather, payments offered to PBMs for their own account.<sup>104</sup> This is problematic because there is at least the prospect that payments made to plans may be passed through to beneficiaries in the form of lower drug prices or lower premiums, whereas payments to PBMs will not benefit plans, let alone beneficiaries. Also, these payments for placement differ from permissible price concessions, and would be problematic regardless of the intended recipient. Permissible price concessions come without any strings attached (i.e., with only the hope or expectation that favorable treatment may result), while payments for placement are contingent on placement; that is, they are made in exchange for taking specific action to prefer a drug over its competitors.<sup>105</sup> Price concessions offered without conditions serve the interests of price competition without requiring the imposition of burdens on beneficiaries. On the other hand, price concessions with conditions require that burdens be imposed on beneficiaries, and essentially supplant the P&T committee's role in the formulary design process. The distinction between payments for placement and payments for inclusion is well-supported by existing law, with the former being permitted if structured properly (and made to a plan), and the latter being prohibited. However, this distinction is often ignored in

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104. To the extent that rebates are retained only as an offset to administrative fees, we think they should be seen as essentially paid to the plans. In that instance, the arrangement should qualify for GPO safe harbor protection. *See supra* Section III.B.

105. This distinction has been a long-standing feature of AKS jurisprudence. *See, e.g.*, *United States v. McClatchey*, 217 F.3d 823, 834 (10th Cir. 2000) ("[A] hospital or individual may lawfully enter into a business relationship with a doctor and even hope for or expect referrals from that doctor, so long as the hospital is motivated to enter into the relationship for legal reasons entirely distinct from its collateral hope for referrals."); *United States v. Rogan*, No. 02 C 3310, 2006 WL 8427270, at \*16 (N.D. Ill. Oct. 2, 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008) ("[A] hope, expectation or belief that referrals may ensue from remuneration for legitimate services is not a violation of the AKS.").

analyzing when a payment from a manufacturer to, or through, a PBM is proper.

#### A. Other Bodies of Law Fail to Sufficiently Protect Beneficiaries

To the extent that targeted attempts have been made to address misaligned incentives between PBMs and beneficiaries, they have, at best, been piecemeal and insufficient to meaningfully protect beneficiary interests—and, at worst, entirely failed. For example, plaintiffs in lawsuits against PBMs have asserted that PBMs and plans have violated their ERISA<sup>106</sup>-based fiduciary duties by entering into payment-for-placement arrangements with pharmaceutical manufacturers that disadvantage the plan beneficiaries.<sup>107</sup> On the whole, these plaintiffs have not succeeded in their arguments because courts have held that the PBM is not a fiduciary to the plan beneficiaries.<sup>108</sup> States have also passed legislation imposing various duties on PBMs,<sup>109</sup> seeking to protect beneficiaries from being charged

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106. ERISA is the primary law that governs employee benefit plans. See *Fact Sheet: What Is ERISA*, U.S. DEP'T OF LAB., <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/fact-sheets/what-is-erisa> [<https://perma.cc/WRY9-FGJ8>].

107. See, e.g., *In re Express Scripts, Inc.*, PBM Litig., No. 05-MD-01672, 2008 WL 2952787 (E.D. Mo. July 30, 2008); *In re Medco Health Solutions, Inc.*, Pharmacy Benefits Mgmt. Litig., No. 03-MDL-01508 (S.D.N.Y. June 26, 2009).

Additionally, some cases focus on the behavior that the PBM is incentivized to engage in, rather than on the payments that are made to the PBM patients and physicians to encourage use of drugs that result in higher rebates to PBMs. See, e.g., *States Attorneys General v. Caremark, Inc.*, et al. (filed Feb. 14, 2008).

108. See, e.g., *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 301 (1st Cir. 2005) (holding that the duty to disclose conflicts of interests and payments from drug manufacturers is “purely ministerial” and “simply not sufficient” to find that the PBMs act as fiduciaries under ERISA); *In re Express Scripts, Inc.*, PBM Litig., No. 05-MD-01672, 2008 WL 2952787, at \*10 (E.D. Mo. July 30, 2008) (“Plaintiffs state that ESI exercised discretion in negotiating with the pharmaceutical manufacturers over rebates, and in controlling plan assets, i.e. the rebates due to the plans. Plaintiffs’ position is an ineffective attempt at placing the cart before the horse. Rebates are not *per se* plan assets. . . . Once these amounts became payable, they became ‘plan assets.’ Prior to this point, i.e. when ESI was negotiating with pharmaceutical manufacturers for its entire book of business, without regard to any particular plan; the rebates were *not* plan assets. . . . The fact that ESI conducted negotiations *in the absence of plans*, does not trigger some duty to represent the best interests of the plans. . . . Next, once the rebates became payable, ESI was contractually required to pay the plan a fixed portion of the same. Thus, ESI did not exercise discretion in the disposition of plan assets. . . . Accordingly, ESI is not a fiduciary for the purpose of negotiating rebates with pharmaceutical manufacturers.” (citations omitted)); see also *Negron v. Cigna Health & Life Ins.*, 300 F. Supp. 3d 341 (D. Conn. 2018); *In re UnitedHealth Grp. PBM Litig.*, No. 16-cv-3352, 2017 WL 6512222 (D. Minn. Dec. 19, 2017) (involving allegation of claw backs, not specifically linked to formulary design).

109. See, e.g., *Rowe*, 429 F.3d at 298–99 (“With the aim of placing Maine health benefit providers in a better position to determine whether PBMs are acting against their interests, and correspondingly, to help control prescription drug costs and increase access to prescription drugs, the Maine Legislature enacted the UPDPA in the spring of 2003. The UPDPA imposes a number of requirements on those PBMs that choose to enter into contracts in Maine with ‘covered entities’—

more in cost-sharing than would be the case if they were to buy a comparable drug (e.g., a generic) outside of the plan, as well as “anti-claw-back”<sup>110</sup> and “anti-gag rule”<sup>111</sup> legislation. However, the effects of these state laws are sometimes undermined by ERISA preemption.<sup>112</sup> In any event, these types of state laws are directed at fixing very limited problems deriving from the current state of PBM-manufacturer relationships, but they do not address the fundamental problem of distorted, hidden incentives, and they have not stopped PBMs from entering into problematic payment-for-placement arrangements with manufacturers.

Some state<sup>113</sup> and federal<sup>114</sup> laws attempt to mitigate the risks posed by PBM conflicts of interest by mandating transparency. These laws require disclosure of financial information that could shed some light on the extent to which PBMs may be profiting from arrangements that are costly to beneficiaries.<sup>115</sup> These laws depend on “sunshine” having its intended effect, which, in such a complex area, seems unlikely.

meaning health benefit providers and including, in part, insurance companies, the state Medicaid program, and employer health plans. Such PBMs are required to act as fiduciaries for their clients and adhere to certain specific duties. For example, they must disclose conflicts of interest, disgorge profits from self-dealing, and disclose to the covered entities certain of their financial arrangements with third parties. ME. REV. STAT. ANN. tit. 22, §§ 2699(2) (A–G) (West 2005). The disclosures made by the PBMs to the covered entities are protected by confidentiality. None of the disclosures are available to the public.”). UPDPA has since been repealed. Unfair Prescription Drug Practices Act, 22 ME. REV. STAT. ANN. tit. 22, § 2699 (West 2003) (repealed 2011).

110. See, e.g., N.J. STAT. ANN. § 17B:27F-6 (West 2021) (prohibiting PBMs from requiring covered persons to make a payment at the point of sale that exceeds the amount the person would pay if purchasing the drug without using a health plan).

111. See, e.g., 42 U.S.C. § 300gg-19b (“A group health plan or a health insurance issuer offering group or individual health insurance coverage shall—(1) not restrict, directly or indirectly, any pharmacy that dispenses a prescription drug to an enrollee in the plan or coverage from informing (or penalize such pharmacy for informing) an enrollee of any differential between the enrollee’s out-of-pocket cost under the plan or coverage with respect to acquisition of the drug and the amount an individual would pay for acquisition of the drug without using any health plan or health insurance coverage; and (2) ensure that any entity that provides pharmacy benefits management services under a contract with any such health plan or health insurance coverage does not, with respect to such plan or coverage, restrict, directly or indirectly, a pharmacy that dispenses a prescription drug from informing (or penalize such pharmacy for informing) an enrollee of any differential between the enrollee’s out-of-pocket cost under the plan or coverage with respect to acquisition of the drug and the amount an individual would pay for acquisition of the drug without using any health plan or health insurance coverage.”).

112. See, e.g., *Rutledge v. Pharm. Care Mgmt. Ass’n*, 141 S. Ct. 474 (2020) (illustrating an unsuccessful ERISA preemption challenge to a state law regulating PBMs).

113. See, e.g., Unfair Prescription Drug Practices Act, 22 ME. REV. STAT. ANN. tit. 22, § 2699 (repealed 2011). The law imposed the duty to disclose, among other things, any “conflict of interest” and “all financial terms and arrangements for remuneration of any kind that apply between the [PBM] and any prescription drug manufacturer or labeler.” *Id.*

114. There are two recent attempts by the Federal government at mandating transparency. See 86 Fed. Reg. 66662 (Nov. 23, 2021); 84 Fed. Reg. 65464 (Nov. 27, 2019).

115. For example, “[s]tatutes enacted as part of the Affordable Care Act require PBMs to disclose competitively sensitive information to certain health plan sponsor clients and to the federal government. Specifically, the Act requires PBMs that manage drug coverage under a

Most recently, an attempt to essentially outlaw rebates to PBMs or plans for drugs reimbursed by Medicare Part D plans (via amendment of the AKS's regulatory discount safe harbor) seems doomed to flounder for both political and procedural reasons.<sup>116</sup> As discussed further below, even if this regulation is adopted, it applies only to Part D plans and leaves some important questions unanswered.

Though well intended, these piecemeal efforts at regulating PBMs have proven ineffective. They are largely side-stepped or ignored by PBMs and have been enforced only sporadically. Significantly, rather than provide clarity, the regulatory focus on transparency, when combined with limited enforcement (and the fact that much enforcement ends in settlements rather than opinions providing authoritative guidance) opens the door to confusion and defensiveness, especially in the face of widespread acknowledgment of manufacturer payments to PBMs. For example, a PBM may think or argue that manufacturer rebates to PBMs are permissible so long as they are disclosed (under the rationale that the disclosure requirement connotes the permissibility of the underlying arrangements). Likewise, a PBM may think or argue that there is ambiguity as to what is prohibited by the AKS, or as to the wrongfulness of the conduct (i.e., that the practice is so widespread and well known that if it were impermissible, there would be more enforcement).<sup>117</sup> Even though there are clearly counterarguments to these assertions,<sup>118</sup> the government should more clearly signal that it supports, and then in fact engage in, enforcement of, a bright-line prohibition on the problematic behavior—that is, payments for placement by manufacturers to PBMs. This will provide clear guidance to PBMs and manufacturers, change the way business is done, and protect beneficiary interests.

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contract with a Medicare Part D drug plan or qualified health benefits plans offered through a state exchange to disclose certain financial and prescription drug dispensing information relating to their client contracts. The required information includes: (1) 'the aggregate amount, and the type of rebates, discounts, or price concessions . . . that the PBM negotiates that are attributable to patient utilization under the plan,' (2) 'the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor,' (3) 'the total number of prescriptions that were dispensed,' and (4) '[t]he aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies. . . .' From this information, PBM clients can calculate amounts relevant to the contractual arrangement between the PBM and sponsor clients." Joanna Shepherd, *Is More Information Always Better? Mandatory Disclosure Regulations in the Prescription Drug Market*, 99 CORNELL L. REV. 1, 14 (2013), [https://www.ftc.gov/system/files/documents/public\\_comments/2014/02/00006-88685.pdf](https://www.ftc.gov/system/files/documents/public_comments/2014/02/00006-88685.pdf) [<https://perma.cc/Y9WH-QPPM>] (quoting 42 U.S.C. § 1320b-23) (citations omitted).

116. See *infra* Section III.C.

117. The retort to this is that an absence of widespread enforcement does not necessarily signal an endorsement.

118. See *supra* notes 105–06.

*B. The AKS's Potential Remains Untapped*

To our knowledge, despite the widespread practice of making payments to PBMs for inclusion and/or placement, and the various governmental statements indicating that the practice implicates the AKS, there has been little AKS enforcement activity in this area. For example, we are not aware of any cases squarely holding that manufacturer rebates to PBMs conditioned on formulary inclusion or placement violate the AKS. The government has acknowledged that the “current system” is problematic, essentially for all the reasons that we have discussed, but seems to assume that some radical regulatory change is required in order to address these problems.<sup>119</sup>

We speculate that a number of factors contribute to this lack of AKS enforcement against manufacturer payments to PBMs for inclusion or placement. First, the fact that the practice is so widespread creates both practical and political problems. The PBM industry is powerful and large, and its profitability is dependent on the receipt of manufacturer rebates.<sup>120</sup> There is a strong lobby advocating that PBMs serve important policy goals.<sup>121</sup> Second, volume rebates to plans are clearly permissible and desirable, and it is difficult to identify when a payment is being made for the account of the PBM and when it is being made to the PBM as an agent for the plan. Indeed, the two settlements we have located that deal with the legality of manufacturer payments for placement under the AKS both seem to assume that rebates to PBMs are legally permissible, presumably under the discount safe harbor, so long as the payment is made in the form of a rebate on the drug being accorded the preference, rather than in some other fashion.<sup>122</sup> Third, it

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119. See, e.g., Safe Harbors Proposed Rule, *supra* note 21.

120. See *supra* Section I.C.

121. See, e.g., Lev Facher, *PBMs, Under Fire from the Trump Administration, Spend a Record Sum on Lobbying*, STAT (Apr. 23, 2019), <https://www.statnews.com/2019/04/23/pbms-phrma-lobbying-q1-2019/> [<https://perma.cc/HA7D-VUTQ>].

122. The first settlement involved rebates paid by the pharmaceutical manufacturer, Roche, to the insurance company, Humana. See Sanford Heisler Sharp, LLP, *Humana and Roche Settle False Claims Act Lawsuit for \$12.5 Million*, GLOBENEWSWIRE (Feb. 8, 2021), <https://www.globenewswire.com/news-release/2021/02/08/2171502/0/en/Humana-and-Roche-Settle-False-Claims-Act-Lawsuit-for-12-5-Million.html> [<https://perma.cc/JF7Z-WWMU>]; Second Amended Complaint, *United States ex rel. Derrick v. Roche Diagnostics Corp.*, 14-cv-04601 (N.D. Ill. 2017), ECF No. 29, [<https://perma.cc/4PF7-XB6F>]. The case, in which the U.S. Department of Justice chose not to intervene, settled for \$12.5 million. *Id.* That case was predicated on an allegation that Roche paid Humana a kickback for formulary placement in the form of lump sum debt forgiveness conditioned on the exclusion of competitors. *Id.* The debt resulted from an overpayment of rebates by Roche to Humana, which in turn resulted from Humana's failure to follow through on its promise to Roche—a condition to earning the rebates—to accord Roche's products favorable copayment status. *Id.* While the relator in that case alleged that trading debt forgiveness for placement implicated the statute, she apparently did not question the legitimacy of the underlying rebate arrangement. *Id.* She alleged simply that “Roche's reduction of Humana's obligation to repay Roche in exchange for new and continued access to Humana's formularies violates the AKS's

is not easy to articulate a clear analytical distinction between rebates that are protected by the discount safe harbor and those that are not. Making this distinction requires that one identify not only when rebates are extended to PBMs and when they are extended to plans (as the discount safe harbor categorically excludes the former but not the latter), but also when they are extended to plans, when they are made in exchange for actions that implicate the AKS, and when they are extended solely in the service of price competition. Depending on the facts, these distinctions can be fairly subtle and may not be widely appreciated.

These complexities are underscored by the New Rule,<sup>123</sup> under which the Office of the Inspector General (OIG) has indicated that payments to plans predicated on the performance of some contingencies (denominated as “services”) are impermissible, but that other contingencies are not considered services and may be permitted.<sup>124</sup> In this regard, the government explains that developing

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prohibition against providing and accepting remuneration for referral of medical items paid for by federal health care programs.” *Id.* at 15–16. In other words, she seems to be assuming that a rebate given in exchange for imposing burdensome copayment restrictions on competitive products does not implicate the statute, but that debt relief given for formulary inclusion would implicate the statute—perhaps reasoning, we think incorrectly, that the initial payment was protected by the discount safe harbor, whereas the latter was not. The second case resulted in a \$7.9 million settlement between the Government and AstraZeneca. Press Release, U.S. Dept’t of Justice, AstraZeneca to Pay \$7.9 Million to Resolve Kickback Allegations (Feb. 11, 2015), <https://www.justice.gov/opa/pr/astrazeneca-pay-79-million-resolve-kickback-allegations> [https://perma.cc/VZ9S-7333]. In that case, the relator seems to have similarly assumed that payments for placement are permissible, so long as they are made for the same drugs as are accorded the placement preference. *Id.* The settlement resolved

allegations that AstraZeneca agreed to provide remuneration to Medco Health Solutions, a pharmacy benefit manager, in exchange for Medco maintaining Nexium’s “sole and exclusive” status on certain Medco formularies and through other marketing activities related to those Medco formularies. The United States alleged that AstraZeneca provided some or all of the remuneration to Medco through price concessions on drugs other than Nexium, namely on Prilosec, Toprol XL and Plendil. The United States contended that this kickback arrangement between AstraZeneca and Medco violated the Federal Anti-Kickback [S]tatute, and thereby caused the submission of false or fraudulent claims for Nexium to the Retiree Drug Subsidy Program.

*Id.* While this enforcement action could be seen as supporting the proposition that payment to PBMs for placement is illegal, it is probably better understood to suggest that the problem is not with the payment of rebates but with according rebates for preferences on another.

123. It is unclear whether this rule will ultimately be implemented. While its original effective date was not until 2022, as of this writing, its adoption has been delayed until at least 2023 by a court order issued in a case brought by the pharmaceutical industry based largely on principles of administrative law. Order, Pharm. Care Mgmt. Ass’n v. U.S. Dept’t of Health and Hum. Servs., No. 21-cv-00095 (D.D.C. Jan. 30, 2021), ECF No. 19, <https://s3-prod.modernhealthcare.com/2021-02/Drug%20Rebate%20Decision%20Date%20Order.pdf> [https://perma.cc/C6G3-W42B].

124. The new rule articulates a fairly comprehensive approach to the issue of rebates. First, it reprises the principle that manufacturer rebates to PBMs are not protected. See PBM Final Rule, *supra* note 6, at 76731. It goes further, however, and also prohibits rebates to plans. *Id.* In fact, under this rule, rebates are protected only if they are passed through to beneficiaries at the point-



and managing a formulary is a service that a PBM provides to a plan, and thus, presumably is not something for which a manufacturer could ever pay a plan.<sup>125</sup> Additionally, developing and managing preferred drug lists and prior authorization programs, performing drug utilization review, and operating disease management programs all qualify as “services” for which payment is not protected, and, thus, essentially prohibited under the Final Rule.<sup>126</sup> However, “[w]hether other arrangements would be considered a ‘service’ that would not be protected, such as . . . conditioning a reduction in price on a formulary not covering a competing drug . . . , would be subject to a case-by-case analysis.”<sup>127</sup> Conditioning payment on exclusion of a competitive drug would seem to implicate the statute in the same manner as the services for which that government has indicated it is impermissible to pay (i.e., developing and managing a preferred drug list and paying for competitive placement seem to be the same thing). It is unclear why OIG sees this as an open question, or why it has not seen fit to articulate the rationale on which it might predicate such a distinction. Also unarticulated are the factors that will be used to determine what constitutes a service in any particular case. Accordingly, even in the context of what appears to be an attempt at comprehensive reform, the government has not grappled with exactly what contingences are improper, and has left the door open to imposing significant contingences as a quid pro quo for a rebate (albeit one that is passed to beneficiaries).<sup>128</sup>

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of-service, and then, only if the rebates are not made contingent on the performance of certain acts, called “services.” *Id.* The rule specifically excludes from the definition of protected “discounts,” any rebate or other reductions in price “in connection with the sale or purchase of a prescription pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D either directly to the plan sponsor under Medicare Part D, or indirectly through a pharmacy benefit manager acting under contract with a plan sponsor under Medicare Part D, unless it is a price reduction or rebate that is required by law.” *See id.* Notably, the new rule does not exclude from the ambit of safe harbor protection payments made to PBMs, as those would not (as we have argued) be covered by the safe harbor in the first instance.

125. *Id.* at 76683. This point is made in the context of talking about what services are eligible for protection under the provisions of the safe harbor that protect fixed fees to PBMs from manufacturers, stressing that a manufacturer cannot pay a PBM for a service that a PBM provides to a plan.

126. *Id.* at 76688.

127. *Id.* at 76683.

128. Even if adopted, the Final Rule’s impact will not negate the need for the analysis we outline. In addition to leaving open the key question of what is a “service,” the impact of the Final Rule is limited to formularies utilized in connection with certain federal health care programs. *See id.* (“HHS/OIG did not implement its proposal to extend this provision to rebates related to Medicaid Managed Care Organizations (MCO). The stated basis for this decision is that rebates in the Medicaid MCO context have minimal impact on beneficiaries because of the way in which Medicaid cost-sharing obligations are structured. The Preamble also makes clear that sales covered by Medicare Part B are not covered by the new definition.”). The Rule will not have a direct impact on other health care programs. If the Rule is ultimately implemented, it may have a broader impact to the extent that these other programs are governed by state mini-AKSs, and those

While current law can be fairly read to prohibit PBMs and plans from accepting payments for formulary placement, applying that law is a painstaking process that requires an understanding of many factual and legal subtleties. Given this, the PBM industry might do well to consider following the example of other industry actors faced with similar problems by adopting a code of ethics that clarifies what is and is not permissible in terms of day-to-day patterns of operation.<sup>129</sup>

### C. A Brief Overview of the Anti-Kickback Statute

The AKS, 42 U.S.C. § 1320a-7b, is a federal anti-corruption law which seeks to prohibit financial incentives from distorting selection decisions of persons in a position to mediate access to healthcare items and services that are paid for by Medicare, Medicaid, or other federal government healthcare programs.<sup>130</sup> To ensure that the selection of covered products is made on the basis of appropriate considerations, such as price, quality, and service, rather than on the basis of personal benefits to gate-keepers, the AKS prohibits a pharmaceutical manufacturer from paying anything of value to a person who can

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statutes incorporate by reference the federal safe-harbors, or are amended to incorporate the substance of the Final Rule. *See, e.g.*, CONN. GEN. STAT. ANN. § 53a-161c (West 2021); FLA. STAT. ANN. § 400.474 (West 2021); TEX. HUM. RES. CODE ANN. § 32.039 (West 2021). All three state statutes expressly incorporate the federal safe harbors.

The OIG's reluctance to establish a bright line on this topic is clear in the following exchange in the preamble to the New Rule:

The commenter also asked OIG to state that it will subject PBMs to heightened scrutiny for any arrangements conditioned on formulary placement that do not fit within the new safe harbors.

*Response:* . . . OIG agrees with the commenter that the proper question is whether entities are in compliance with the anti-kickback statute; we reiterate, however, that compliance with a safe harbor is voluntary. Any arrangement that implicates the anti-kickback statute and does not satisfy an exception or safe harbor would be subject to scrutiny; as discussed in more detail below, we reiterate our concern about any kind of payment to buy or provide remuneration tied to formulary placement that is not a safe harbored reduction in price.

PBM Final Rule, *supra* note 6, at 76679.

129. *See, e.g.*, ADVAMED, ADVAMED CODE OF ETHICS (2021), <https://www.advamed.org/wp-content/uploads/2021/05/AdvaMed-Code-of-Ethics-2021.pdf> [<https://perma.cc/8JCV-XAGY>]; *Code on Interactions with Health Care Professionals*, PHRMA (Aug. 6, 2021), <https://www.phrma.org/resource-center/Topics/STEM/Code-on-Interactions-with-Health-Care-Professionals> [<https://perma.cc/3Q4M-3WRV>].

130. For a summary history of the AKS, see Thomas S. Crane, Samantha Kingsbury, Karen Lovitch & Carrie Roll, *What Is the Anti-Kickback Statute*, AM. BAR ASS'N, [https://www.americanbar.org/groups/young\\_lawyers/publications/tyl/topics/health-law/what-is-anti-kickback-statute/](https://www.americanbar.org/groups/young_lawyers/publications/tyl/topics/health-law/what-is-anti-kickback-statute/) [<https://perma.cc/G467-Q7BG>].

influence product selection (such as a PBM) to induce that person to purchase a covered product.<sup>131</sup> Specifically, the statute provides that:

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind . . .

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.<sup>132</sup>

Subsection (2) of the statute contains identical provisions applicable to the offeror of the remuneration.<sup>133</sup>

A violation of the AKS occurs only when remuneration is given with the improper purpose of inducing the recipient to deliver business.<sup>134</sup>

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131. See, e.g., Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003), <https://oig.hhs.gov/documents/compliance-guidance/799/050503FRCPGPharmac.pdf> [<https://perma.cc/T6BQ-W5PG>] [hereinafter Compliance Program Guidance].

132. 42 U.S.C. § 1320a-7b(b). While there are no definitive definitions of the terms “refer” or “arrange,” the preamble to the regulations indicates that conduct designed to encourage use would contemplate a recommendation or arranging for the use of a product:

The statute . . . prohibits the offering or acceptance of remuneration . . . for the purposes of “arranging for or recommending purchasing, leasing, or ordering any . . . service or item” payable under Medicare or Medicaid. Thus, we believe that many marketing and advertising activities may involve at least technical violations of the statute. We, of course, recognize that many of these advertising and marketing activities do not warrant prosecution in part because (1) they are passive in nature, i.e., the activities do not involve direct contact with program beneficiaries, or (2) the individual or entity involved in these promotions is not involved in the delivery of health care. Such individuals or entities are not in a position of public trust in the same manner as physicians or other health care professionals who recommend or order products and services for their patients. Thus, we agree that many advertising and marketing activities warrant safe harbor protection under the personal services and management contracts safe harbor.

However, we have experienced many instances where promoters and consultants have become involved in marketing activities that encourage health care providers and others to violate the statute, such as to develop impermissible joint venture arrangements or to routinely waive coinsurance and deductible amounts owed under Medicare Part B. It would be inappropriate to allow such activities to receive safe harbor protection.

Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952 (July 29, 1991).

133. 42 U.S.C. § 1320a-7b(b)(2).

The AKS does not contain a definition of “inducement” and the term has not been conclusively defined. However, courts have indicated that in order to be considered inducement, the intention must be to actually exert influence through the provision of the remuneration, rather than simply understanding that the situation might normally lead to business. For example, the 2000 Tenth Circuit case *United States v. McClatchey*<sup>135</sup> holds that the mere hope or expectation that referrals may result from remuneration designed for entirely different purposes is not a violation of the AKS, and that there must be an actual offer or payment of remuneration with the goal of inducing referrals.<sup>136</sup>

The AKS has been interpreted to cover any arrangement where *one purpose* of remuneration is to induce or reward such actions, even if the arrangement serves other, legitimate purposes.<sup>137</sup> Thus, even if there is a proper justification for the payment at issue, that proper purpose is irrelevant if there is evidence of an additional, improper purpose.

A discount clearly is something of value, normally offered with the intent of inducing purchases, and, without more, would consequently implicate the AKS. But the AKS allows certain discounts as long as they are properly disclosed and appropriately reflected in the provider’s claim.<sup>138</sup> The statute does not specify when a reduction in price is “properly disclosed and appropriately reflected.” The OIG’s regulatory guidance clarifies that what must be reported is the reduced price, net of discount, not a comparison to a list or contract price.<sup>139</sup> In other words, a discount is properly reported if the applicable report shows the price actually paid by the buyer.

Many states have enacted “mini-AKSs” that mirror the language and purpose of the AKS, but often they are not limited to government-reimbursed healthcare items or services; they also apply to items or services paid for by commercial insurers.<sup>140</sup> Taken together, state mini-AKSs and the federal AKS create a comprehensive (and overlapping) legal framework that is explicitly designed to prevent financial incentives from improperly influencing the decision-making of those who are in a position to drive healthcare purchases.<sup>141</sup>

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134. *United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000).

135. *Id.*

136. *Id.*

137. *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985).

138. 42 U.S.C. § 1320a-7b(b)(3)(A).

139. Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63518, 63527 (Nov. 19, 1999).

140. See *supra* note 26.

141. For a discussion of whether the federal AKS preempts state AKSs that apply to federal health care program business, see Franklin T. Pyle III, *The Federal Anti-Kickback Statute Has No*

Regulations that implement the federal AKS contain a number of safe harbors protecting common remuneration arrangements that regulators have deemed non-problematic.<sup>142</sup> Arrangements that meet the requirements of a safe harbor are protected from the inference that any remuneration that flows between parties to the arrangement may be grounds for liability under the AKS. For example, an arrangement with a physician in which the physician is paid for bona fide consulting services will be deemed non-problematic if it meets the requirements of the safe harbor for personal services, including the requirement that all payments be fair market value for the consulting services rendered, without additional inquiry into the subjective purpose of the arrangement.<sup>143</sup>

Recognizing the necessity of price competition in a commercial health care market, both the AKS and state mini-AKSs (either implicitly or explicitly) permit purchase incentives that take the form of discounts.<sup>144</sup> The federal AKS accomplishes this through a regulatory discount safe harbor.<sup>145</sup> It provides that “the term discount means a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms-length transaction.”<sup>146</sup> Accordingly, to qualify for safe harbor protection, the discounts must be offered *to a buyer*, either directly, or through an intermediary, such as a PBM.<sup>147</sup> This means that the discount safe harbor does not protect inducements to middlemen who are not buyers. Thus, as further developed below, *the discount safe harbor does not protect payments to PBMs that are not passed through to plans as price reductions.*

Also, under the discount safe harbor, the discount must be limited to incentivizing selection based on price.<sup>148</sup> The discount safe harbor does not protect discounts that are given to induce plans or PBMs to take some action that benefits the pharmaceutical manufacturer in a

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*Preemptive Power, Or Does It? Florida's Supreme Court Holds Florida's Medicaid Anti-Kickback Statute Unconstitutional*, 112 PENN. STATE L. REV. 631 (2007).

142. 42 C.F.R. § 1001.952 (2020).

143. 42 C.F.R. § 1001.952(d).

144. See, e.g., CONN. GEN. STAT. ANN. § 53a-161c (West 2021); FLA. STAT. ANN. § 400.474 (West 2021); TEX. HUM. RES. CODE ANN. § 32.039 (West 2021).

145. 42 C.F.R. § 1001.952(h). There is also a statutory exclusion for discounts. 42 U.S.C. § 1320a-7b(b)(3)(A). However, the government has opined that any discount that falls outside of the safe harbor is at least a technical violation of the statute, and subject to prosecution in the event that it is deemed abusive. For example, the OIG has taken the position “that the regulatory safe harbor includes *all* discounts Congress intended to protect under the statutory exception.” Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63518, 63527 (Nov. 19, 1999).

146. *Id.*

147. See 42 C.F.R. § 1001.952(h).

148. See *id.* § 1001.952(h)(5).

manner otherwise precluded by the AKS beyond simply “purchasing” the drug because it is cheaper.<sup>149</sup> In the context of formulary development, a discount is protected by the safe harbor if offered to a plan with the goal of influencing the plan, acting through its PBM, to put the drug on formulary, *because doing so will save the plan money*. Discounts are not protected by the safe harbor (and violate the AKS) if made contingent on plans (or PBMs) engaging in specific behaviors that encourage the use of the drug over another, such as placing the drug in a preferred tier or giving a drug specific utilization-related preferences (e.g., conditioning the discount on exempting the drug from prior authorization requirements). Such a payment is not a discount, but rather a payment for the service of arranging for the purchase of the drug, and therefore does not fall under the discount safe harbor—instead, it squarely implicates the statute. Accordingly, as further developed below, the AKS and its state law analogs<sup>150</sup> should be read to preclude any payments to PBMs for either formulary access or formulary placement, as well as payments to plans for formulary placement.

*D. Payments by Manufacturers to PBMs Implicate the AKS and Are Not Protected by the Discount Safe Harbor*

Payments by manufacturers to health insurers who offer Part D, Medicare Advantage (Part C),<sup>151</sup> or Medicaid managed care plans implicate the AKS because the federal government pays for some or all of the premiums for coverage extended under these plans, and thus can be indirectly seen as a purchaser of the items and services covered by the plan; that is, they are “federal health care programs” (FHPs) within the meaning of the AKS.<sup>152</sup> Depending on the terms of the mini-AKS,

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149. *See id.*

150. While only some of the state statutes precisely mirror the language of the AKS, they are often interpreted to be consistent with the AKS. *See, e.g., State Health Care Anti-Kickback Analogues*, LOWENSTEIN SANDLER, <https://www.lowenstein.com/media/5538/state-health-care-anti-kickback-analogues.pdf> [<https://perma.cc/38PS-WFED>] (surveying differing language in each state).

151. We have not addressed Part C plans in this Article because of the very limited drug coverage extended under them.

152. An FHP is any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States government (other than the Federal Employees Health Benefits Program), or any state health care program (including the Medicaid program, the Maternal and Child Health Services Block Grant program, or the Block Grants to States for Social Services program). 42 U.S.C. §§ 1320a-7b(f), 1320a-7(h); 42 C.F.R. § 1001.2 (2020). By executive fiat, ACA plans are not subject to the AKS. HHS stated that it “does not consider [qualified health plans] QHPs, other programs related to the Federally-facilitated Marketplace, and other programs under Title I of the Affordable Care Act to be federal healthcare programs.” Letter from Kathleen Sebelius, Sec’y of the Dep’t of Health &

state and non-governmental funded plans may be regulated under these statutes either because the states pay for the services, or because the statutes are designed to apply regardless of payor. When a plan that is covered by the AKS or a mini-AKS makes a coverage or utilization review related decision, it is influencing the choice of covered items or services, and thus is arranging for provision of the item or service within the meaning of these laws.<sup>153</sup> Most fundamentally, insurance coverage influences which items or services are ordered (a physician may, for example, choose to write a prescription for a covered drug, rather than a non-covered drug) and whether referrals ultimately result in a purchase (a patient may, for example, choose not to purchase a prescribed drug if it is not covered).<sup>154</sup> When manufacturers make payments for access and payments for placement, they are paying PBMs to permit and encourage access to their product and, more specifically, to drive purchase volume toward their product.<sup>155</sup> As with remuneration flowing between manufacturers and insurance plans, therefore, payments from manufacturers to PBMs likewise implicate the AKS.

Where an arrangement implicates the AKS, the question becomes whether the arrangement falls within a safe harbor. Whereas discounts from list price, whether extended as up-front discounts or after-the-fact rebates to plans and beneficiaries could be protected by the discount safe harbor, rebate payments to PBMs cannot. The discount safe harbor protects discounts and rebates from the AKS only if such discounts and rebates are made to a buyer.<sup>156</sup> The government has long observed that payments from manufacturers to PBMs are not protected under the discount safe harbor because PBMs are not buyers. CMS has explicitly stated: "Rebates paid by drug manufacturers to or through PBMs to buy formulary position are not reductions in price. In the Secretary's view, such a payment would not qualify as 'a discount or

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Hum. Servs., to Jim McDermott, U.S. Rep. (Oct. 30, 2013), <https://www.hlregulation.com/files/2013/10/The-Honorable-Jim-McDermott.pdf> [<https://perma.cc/DU9G-46U5>].

153. See, e.g., Safe Harbors Proposed Rule, *supra* note 21, at 2340. The proposed rule explained the need for a new amendment that would

explicitly exclude from the definition of a discount eligible for safe harbor protection certain reductions in price or other remuneration from a manufacturer of prescription pharmaceutical products to plan sponsors under Medicare Part D, Medicaid managed care organizations as defined under section 1903(m) of the Act (Medicaid MCOs), or pharmacy benefit managers (PBMs) under contract with them.

*Id.*

154. See, e.g., *supra* Section I.C.

155. See *id.*

156. 42 C.F.R. § 1001.952 (h)(5) ("[F]or purposes of this paragraph, the term discount means a reduction in the amount a buyer . . . is charged for an item or service based on an arms-length transaction.").

other reduction in price.”<sup>157</sup> OIG has also explained that payments by drug manufacturers to PBMs “that are based on, or otherwise related to, the PBM’s customers’ purchases potentially implicate the anti-kickback statute”<sup>158</sup> and that they can be protected by structuring them “to fit in the [group purchasing organizations] safe harbor at 42 C.F.R. § 1001.952 (j).”<sup>159</sup> That same guidance provides that “[l]ump sum payments for inclusion in a formulary or for exclusive or restricted formulary status are problematic and should be carefully scrutinized.”<sup>160</sup> In late 2020, the government again affirmed this view, stating that payments to PBMs, because they are not buyers, have never been protected by the discount safe harbor.<sup>161</sup>

*E. Payments by Manufacturers to PBMs Are Generally Not Protected  
by the GPO Safe Harbor*

In the face of both the law and this guidance, the widespread practice of PBMs retaining a portion of the rebates can be justified only if the retention qualifies as a protected administrative fee under the group purchasing organizations (GPOs) safe harbor, or can be characterized as a payment by the manufacturer to the plan, and then from the plan to the PBM for its services.<sup>162</sup> To our knowledge, most rebating arrangements do not fit neatly into either such category.

The GPO safe harbor explicitly allows for the payment of fees by manufacturers to GPOs, in return for their services in acting as broker between manufacturers and purchasers. Since payments for placement are made to PBMs for their services, they would seem much more susceptible to characterization as GPO fees paid to PBMs than discounts paid to plans, and, indeed, the government has specifically

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157. See Safe Harbors Proposed Rule, *supra* note 21, at 2340.

158. See Compliance Program Guidance, *supra* note 131. The use of the term “potentially” creates an opening to argue that such payments could be legally permissible in some, as yet undefined, circumstances. However, our guess is the government intended only to signal that protection under the GPO or managed care safe harbor (in circumstances where the PBM assumes risk) might be available.

159. That safe harbor requires, among other things, that the payments be authorized in advance by the PBM’s customer and that all amounts actually paid to the PBM on account of the customer’s purchases be disclosed in writing at least annually to the customer. 42 C.F.R. § 1001.952(j). In addition, arrangements with PBMs that assume risk may raise different issues; depending on the circumstances, protection for such arrangements may be available under the managed care safe harbors at 42 C.F.R. § 1001.952 (m), (t), and (u).

160. See Compliance Program Guidance, *supra* note 131.

161. PBM Final Rule, *supra* note 6.

162. Because it is unusual and involves fundamentally different considerations, we do not discuss the circumstances under which it would be permissible for a risk-bearing PBM to retain a rebate.



recommended the use of the GPO safe harbor for such payments.<sup>163</sup> In our experience, however, rebate arrangements are not typically structured for conformance with the GPO safe harbor,<sup>164</sup> likely because it requires quite a bit of transparency,<sup>165</sup> and providing that level of transparency would put the PBMs at a negotiating disadvantage.

It might be argued that the rebates are payments by manufacturers to plans, and that the PBMs are merely serving as conduits for the payments. However, rebates are almost never passed through in full,<sup>166</sup> thereby suggesting that the PBMs are not serving as conduits. It might also be possible to argue that the portion of the rebate retained by the PBM is simply an offset for the PBM's fee. However, in a situation where the plan knows neither the amount of the rebates or the "offset," such a characterization seems strained. If this is not enough, in a situation where the rebate payment is negotiated and received by the PBM, in exchange for PBM commitments, it seems clear that the payment is to the PBM and not the plan. In short, under the traditional model, where a secret payment is made by manufacturers to PBMs in exchange for favorable treatment, and only a portion of that payment ever reaches the plans, it strikes us as a stretch to characterize rebates as being made to plans rather than PBMs.<sup>167</sup> Rather, it would seem that any payment for placement not intended as a pass-through can be best characterized as a payment by the manufacturer in exchange for the PBM's agreement to influence formulary placement. In this regard, the terms of the contract between both the manufacturer and the PBM and the PBM and the plan would be relevant to determining the issue of

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163. See Compliance Program Guidance, *supra* note 131, at 23736.

164. It appears that some PBMs may now be setting up offshore GPOs. See, e.g., Rebecca Pifer, *CVS Reportedly Creating Group Purchasing Organization for PBM Business*, HEALTHCARE DIVE (July 1, 2020), <https://www.healthcaredive.com/news/cvs-reportedly-creating-group-purchasing-organization-for-pbm-business/580889/> [<https://perma.cc/3LPC-5MDY>].

165. In pertinent part, the GPO safe harbor requires that the GPO "disclose in writing to the entity at least annually, and to the Secretary upon request, the amount received from each vendor with respect to purchases made by or on behalf of the entity." 42 C.F.R. § 1001.952(j)(2).

166. There are a few PBMs that are beginning to use a more transparent model under which all rebates are passed through to the plans. See, e.g., *Transformative Pass-Through Approach*, NAVITUS, <https://www.navitus.com/pass-through-pbm> [<https://perma.cc/7QXK-J9E2>]. On information and belief, these are by far the exception.

167. In the preamble to the new rule, OIG notes that there is

a lack of transparency in the current system. With respect to rebates, we explained that OIG work showed that some Part D plan sponsors had limited information about rebate contracts and rebate amounts that their PBMs negotiated. A lack of transparency could create a potential program integrity vulnerability because compliance with program rules may be more difficult to verify.

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, 85 Fed. Reg. 76666, 76668 (Nov. 30, 2020).

intent, as well as such considerations as the plan having title to the rebate, knowledge of the amount of the rebate, and the amount charged as PBM fees. However, we are aware of no authorities that give clear guidance as to when a rebate should be considered to be paid to a plan through a PBM and when it should be considered to be paid directly to the plan. This ambiguity perhaps accounts for some of the lack of enforcement activity.

*F. Payments for Placement by Manufacturers to Plans Implicate the AKS and Are Not Protected by the Discount Safe Harbor*

Even when the payment is made to a plan, it cannot be made for services and still be afforded protection under the discount safe harbor.<sup>168</sup> Most fundamentally, the discount safe harbor protects discounts, which are defined as “a reduction in the amount a buyer . . . is charged for an item or service based on an arms-length transaction.”<sup>169</sup> Among other exclusions, the term *discount* does not include either “[s]ervices provided in accordance with a personal or management services contract; or . . . [o]ther remuneration, in cash or in kind, not explicitly described in paragraph (h)(5) of this section.”<sup>170</sup> In other words, a payment that is made in return for a service is not a discount within the meaning of the discount safe harbor.<sup>171</sup>

As the Government explained in its brief in *United States ex rel. Herman v. Coloplast Corp.*:<sup>172</sup>

If [the distributor] CCS and [the manufacturer] Coloplast simply agreed to a pricing structure that offered escalating discounts in return for increased sales . . . then the United

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168. There is some ambiguity about what constitutes a service. According to the government, payments for marketing and for success in switching prescriptions to the payor's drugs clearly do, but payments only for formulary inclusion, do not. See PBM Final Rule, *supra* note 6.

169. 42 C.F.R. § 1001.952(h)(5).

170. *Id.*

171. Formulary inclusion can be seen as analogous to a distributor's decision to carry a drug for resale, because it is the cheapest drug. Viewed in this way, payments for inclusion are indistinguishable from any other purchasing decision driven by price, and, as such, are allowable if they comply with the discount safe harbor. In other words, in order to allow price competition, discounts must be allowed to incentivize, and be made contingent upon, a purchase. A discount that is made contingent on the placement of the drug in a particular tier would be precluded, however, as the latter *requires* specific “services”—that is, the application of utilization controls. In a nutshell, incentivizing plans to prefer the discounted drug over others because it is cheaper, remains permissible under this rule (and the reduced price may be a factor that results in the imposition of utilization controls), but *requiring* plans to impose certain utilization controls (or to do things, such as placing the drug in a particular tier, which amount to the same) remain prohibited.

172. *United States ex rel. Herman v. Coloplast Corp.*, 295 F. Supp. 3d 37 (D. Mass. 2018).

States agrees that such an arrangement would qualify as a “discount” and therefore would not violate the AKS. In contrast, if CCS and Coloplast agreed that CCS would undertake patient conversion and referral activities in return for Coloplast granting price concessions, the United States submits that such an agreement would not be a “discount” at all and would violate the AKS. . . .

Relators’ allegations carry a reasonable inference that Coloplast was paying CCS to use its special influence with its customers to switch them to the Coloplast products. As alleged, CCS’s agreement to undertake conversion campaigns in exchange for the price concessions thus transformed the price concessions into illegal kickbacks. Such an arrangement is different in kind from merely offering escalating discounts in return for increased sales volumes in an arms-length transaction. The collusive quality of the arrangement alleged by the relators fundamentally distorts the transparency of price competition in the healthcare market that Congress sought to promote with the discount exception. . . .

In a 1994 Special Fraud Alert, the HHS OIG made clear its view that the AKS prohibits manufacturers from offering financial incentives to those selling their products to effectuate “product conversion” programs where one purpose is to induce the increase [sic] use of such products covered by Federal health care programs. 59 Fed. Reg. 65,371, 65,372, 65,376 (Dec. 19, 1994). One of the examples provided in the Special Fraud Alert was of a “product conversion” program in which a drug manufacturer provided supplier pharmacies with cash awards for changing from a competitor’s product to the drug manufacturer’s product. *Id.* at 65,376. A price concession is functionally no different than such a cash award, regardless of the label the parties use to describe it.

In sum, a price reduction conditioned on promotional or conversion campaign activities is not a “discount” within the meaning of the discount exception at 42 U.S.C. § 1320a-7b(b)(3). A price reduction that is contingent on the recipient taking affirmative steps to generate additional business for the seller

does not foster price competition that inures to the benefits of the federal health care system.<sup>173</sup>

As discussed at length in Part II, tiering (or placement) decisions are often made for the purpose of promoting one drug over another. When such a payment is made for placement, it is being made not just with the hope or expectation that the PBM (as agent of the plan) might prefer the discounted product, but specifically in exchange for the PBM taking specific action designed to promote a particular drug over its competitors. In other words, the payment is made for the services of the PBM in driving purchasing volume away from competitor products and toward a given manufacturer's products. More fundamentally, the fact that payments for placement are often articulated in terms of a percentage rebate on products sold by the manufacturer to plan beneficiaries does not make them discounts in the true sense of the word. Rather, they are payments made to plans and PBMs that are contingent on formulary design services achieving the desired outcome—driving sales volume toward the manufacturer's product. It seems clear, then, that payments for placement are not *bona fide*

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173. United States' Statement of Interest Regarding Plaintiff's Motion for Reconsideration of the Court's Dismissal of CCS, *United States ex rel. Herman v. Coloplast Corp.*, 295 F. Supp. 3d 37 (D. Mass. 2018), <http://www.fdalawblog.net/wp-content/uploads/archives/docs/Coloplast%20-%20US%20SOI.pdf> [<https://perma.cc/7G4C-JQLH>]; cf. Brief of *Amicus Curiae* Pharm. Rsch. & Mfrs. of Am. in Support of Defendant CCS Med. Supplies, Inc.'s Motion to Reconsider the Court's August 24, 2016 Order or to Certify the Matter for Interlocutory Appeal, *United States ex rel. Herman v. Coloplast Corp.*, 295 F. Supp. 3d 37 (D. Mass. 2018), <http://www.fdalawblog.net/wp-content/uploads/archives/docs/Coloplast%20-%20PhRMA%20Brief.pdf> [<https://perma.cc/FAU5-ZXW5>]. For further information, see Press Release, U.S. Dep't of Justice, Coloplast Corp. and Liberator Medical Agree to Pay over \$3.6 Million to Resolve False Claims Act Allegations (Dec. 23, 2015), <https://www.justice.gov/opa/pr/coloplast-corp-and-liberator-medical-agree-pay-over-36-million-resolve-false-claims-act> [<https://perma.cc/9H9C-366Y>] (announcing that Coloplast settled with the federal government for \$3.16 million); *United States ex rel. Lisitza v. Johnson & Johnson, Ortho-McNeil-Janssen Pharms., Inc.*, No. 07-cv-10288, 2011 WL 1827357 (D. Mass. May 12, 2011). After an unsuccessful petition for reconsideration, Johnson & Johnson settled with the federal and state governments for \$149 million. See *Johnson & Johnson to Pay More than \$2.2 Billion to Resolve Criminal and Civil Investigations*, U.S. DEP'T OF JUST. (Nov. 4, 2013), <https://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations> [<https://perma.cc/JF8T-3MWE>]. In another case, *United States ex rel. Banigan v. Organon USA Inc.*, 883 F. Supp. 2d 277, 284 (D. Mass. 2012), the relators alleged that defendants Omnicare and PharMerica, two institutional pharmacies, received kickbacks from a third defendant, drug manufacturer Organon. *Id.* It appears that Omnicare settled for \$23 million and Organon, the manufacturer, settled for \$31 million. See Rachel Graf, *Omnicare Pays \$23M to End Kickback, Medicaid Fraud Suit*, LAW360 (May 26, 2017), <https://www.law360.com/articles/928510/omnicare-pays-23m-to-end-kickback-medicare-fraud-suit> [<https://perma.cc/2EN8-Y937>]. In *United States ex rel. Kester v. Novartis Pharms. Corp.*, 23 F. Supp. 3d 242, 246 (S.D.N.Y. 2014), Novartis settled for \$370 million plus a \$20 million forfeiture of proceeds. See *Manhattan U.S. Attorney Announces \$370 Million Civil Fraud Settlement Against Novartis Pharmaceuticals for Kickback Scheme Involving High-Priced Prescription Drugs, Along with \$20 Million Forfeiture of Proceeds from the Scheme*, U.S. DEP'T OF JUST. (Nov. 15, 2015), <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-370-million-civil-fraud-settlement-against-novartis> [<https://perma.cc/KS5L-CZWB>].

discounts off list price that are provided in an arms-length transaction. Rather, payments for placement are payments made by manufactures to secure beneficial formulary design and formulary administration services which redirect purchase volume away from competitor products and toward the manufacturer's products.

*G. Effective AKS Enforcement Would Enable P&T Committees to  
Meaningfully Protect Beneficiaries*

Restricting manufacturers from paying PBMs rebates for formulary placement should remove PBMs' incentives to favor drugs that are more profitable for them, and thus, more closely align the interests of PBMs and P&T committees. This makes it more likely that PBMs will give their P&T committees latitude to consider the full range of beneficiary interests, and ultimately more likely that PBMs will adopt P&T committee recommendations. Limiting manufacturers to incentivizing plans for formulary access means that the relative cost of the drug, and not the value of the rebate, is likely to drive purchasing decisions. Thus, beneficiaries would benefit from lower drug prices in the form of either point-of-service reductions (where the manufacturer offers a discount) or premium reductions (where the manufacturer offers a rebate).

Rebates may still encourage plan sponsors to depart from the P&T committee's recommendation and prefer a drug that is most profitable to the plan, but the plan must do so (1) of its own volition (i.e., without the placement being dictated by pharmaceutical companies), which would presumably weaken the effect of any volume-contingent payment; and (2) in the face of a formal finding by the P&T committee that an alternative formulary structure would have benefitted their beneficiaries to a greater extent. This behavior may leave them open to attack through a number of avenues: for ERISA plans, as breach of fiduciary duty; for Part D plans, as being inconsistent with CMS requirements; and for commercial plans, in a court of law (and in the court of public opinion).

Because these laws prohibit PBMs from siphoning off a portion of the payments for placement for their own account, funds should be readily available for pass-through to beneficiaries who are burdened by the attendant access restrictions. If these laws are properly enforced to prohibit PBMs from conditioning formulary design decisions on receipt of wheel-greasing payments from manufacturers, P&T committee recommendations are more likely to carry the day. So, the P&T committee would have both the latitude and the funds to protect beneficiaries. Any impetus on the part of a plan to deviate from the committee's recommendations would be mitigated by the fact that such

deviation would be an overt, documented departure from the best interests of patients, which might be actionable under state laws imposing fiduciary duties on PBMs<sup>174</sup> and principles of fiduciary duty applicable to ERISA plans (which require that plan sponsors act in the best interests of their beneficiaries and ensure that third parties they employ do the same).<sup>175</sup> With respect to Medicare Part D plans,<sup>176</sup> the departure would be obvious to CMS, and would seem inconsistent with CMS's concern that plan sponsors "perform adequate oversight of their PBMs and other delegated entities to verify" that "utilization management requirements applied at point of sale (POS), such as prior

174. See NEV. REV. STAT. ANN. § 683A.178 (West 2021) ("A pharmacy benefit manager has an obligation of good faith and fair dealing toward a third party or pharmacy when performing duties pursuant to a contract to which the pharmacy benefit manager is a party. Any provision of a contract that waives or limits that obligation is against public policy, void and unenforceable.").

175. See *Fiduciary Responsibilities*, U.S. DEP'T OF LAB., <https://www.dol.gov/general/topic/healthplans/fiduciaryresp> [<https://perma.cc/2L8Q-QU28>] ("The primary responsibility of fiduciaries is to run the plan solely in the interest of participants and beneficiaries and for the exclusive purpose of providing benefits and paying plan expenses. Fiduciaries must act prudently and must diversify the plan's investments in order to minimize the risk of large losses. In addition, they must follow the terms of plan documents to the extent that the plan terms are consistent with ERISA. They also must avoid conflicts of interest. In other words, they may not engage in transactions on behalf of the plan that benefit parties related to the plan, such as other fiduciaries, services providers, or the plan sponsor.").

176. Healthcare reimbursement is governed by a complex and overlapping scheme of state and federal law. Very generally, commercial health plans and the entities with which they contract are subject to state law, while Medicare plans (Medicare Advantage plans and Medicare Part D plans) are governed by federal law, and, more specifically, CMS regulation. See HEALTH LAW: CASES, MATERIALS AND PROBLEMS 621–24, 628–35 (Barry R. Furrow, Thomas L. Greaney, Sandra H. Johnson, Timothy Stoltzfus Jost, Robert L. Schwartz, Brietta R. Clark, Erin C. Fuse Brown, Robert Gatter, Jaime S. King & Elizabeth Pendo, eds., 8th ed. 2018). Employer-sponsored employee benefit plans are regulated under the federal law, ERISA, which preempts the application of state laws directed at regulating insurance. See Katherine L. Gudiksen, Samuel M. Chang & Jaime S. King, *Navigating Legal Challenges to State Efforts to Control Drug Prices: Pharmacy Benefit Manager Regulation, Anti-Price Gouging Laws, and Price Transparency*, NAT'L ACAD. FOR STATE HEALTH POL'Y (2019), [https://www.nashp.org/wp-content/uploads/2019/10/Legal-Challenges-to-State-Rx-Laws-final-9\\_12\\_2019.pdf](https://www.nashp.org/wp-content/uploads/2019/10/Legal-Challenges-to-State-Rx-Laws-final-9_12_2019.pdf) [<https://perma.cc/YY3F-6LCP>]. The scope of ERISA's preemption of state law, especially as it relates to entities (such as PBMs) that are contracted to provide services to ERISA plans, is a complex and often-litigated matter. See, e.g., *Pharm. Care Mgmt. Ass'n v. Rutledge*, 891 F.3d 1109, 1112–13 (8th Cir. 2018), *rev'd and remanded*, 141 S. Ct. 474 (2020); *Pharm. Care Mgmt. Ass'n v. Gerhart*, 852 F.3d 722 (8th Cir. 2017); *Pharm. Care Mgmt. Ass'n v. District of Columbia*, 613 F.3d 179 (D.C. Cir. 2010). For the purposes of this Article, it is sufficient to note that it is often unclear whether regulation of particular PBM activities is preempted by ERISA. According to CMS:

The scope of Federal preemption is broad. MA standards set forth in 42 CFR 422 supersede any State laws, regulations, contract requirements, or other standards that would otherwise apply to MA plans, with the exception of licensing laws and regulations and laws and regulations relating to plan solvency. In other words, unless they pertain to licensure and/or solvency, State laws and regulations that regulate health plans do not apply to MA plans offered by MA organizations.

CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE MANAGED CARE MANUAL: CHAPTER 10 - MA ORGANIZATION COMPLIANCE WITH STATE LAW AND PREEMPTION BY FEDERAL LAW 30.1 (2011), <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c10.pdf> [<https://perma.cc/K3KV-HM34>].

authorization (PA), step therapy (ST), and quantity limits (QL) not based upon the FDA's maximum daily dose limits" not cause "beneficiary harm due to impermissible delayed or denied access to Part D drugs."<sup>177</sup> We suggest that the P&T committee's duty may extend to conditioning their services upon their recommendations being respected.

### CONCLUSION

Formularies are a useful tool in managing over-utilization and drug costs. However, they impose burdens on beneficiaries. These burdens are not ethically tolerable if they do not result in a comparable benefit to beneficiaries. At present, the benefits are often siphoned off to PBMs in the form of retained rebates, and there is no real commitment to passing them through to beneficiaries. Ensuring that all rebates are passed through to plans, and that they are not made in exchange for formulary placement, will protect beneficiary interests.

The extant laws, regulations, and guidance detailed in Part III can be used to address this problem and ensure that beneficiary interests are better protected. Enforcing these principles would create an environment where P&T committees are free to engage in a true pharmacoeconomic analysis, and where that analysis—not manufacturers—would dictate formulary placement. Even if the New Rule is not implemented, at least for Part D and Medicaid managed care plans, the AKS can be used to entirely preclude manufacturer-rebates to PBMs and to plans for specific placement conditions. With respect to other plans, state statutes can be used to achieve the same result. By observing existing law and recognizing the distinctions between payments to plans and payments to PBMs, as well as the distinction between payments for coverage and payments for placement, beneficiaries could be protected without further legislation.

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177. CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL: CHAPTER 6 – PART D DRUGS AND FORMULARY REQUIREMENTS 30.2 (2016), <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf> [<https://perma.cc/68Q5-YLSA>]. Notably, CMS approves plan formularies. *See id.* ("CMS encourages Part D sponsors to submit formularies similar to those in widespread use today. CMS will check the formulary to ensure inclusion of a range of drugs in a broad distribution of therapeutic categories and classes, in order to satisfy the Medicare Modernization Act (MMA) requirement that a sponsor's categorization system does not substantially discourage enrollment by any group of beneficiaries. CMS will consider the specific drugs, tiering and utilization management strategies employed in each formulary. CMS will identify outliers from common benefit management practices for further evaluation. Sponsors may be asked to provide written clinical justification for unusual benefit features that are identified as outliers.").