



RE: FTC-2022-0015-0001

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The Alliance for Transparent and Affordable Prescriptions (ATAP) is a coalition of patient and provider groups who are committed to reforming the role pharmacy benefit managers (PBMs) play in drug pricing and patient access. We thank the Federal Trade Commission (FTC) for the opportunity to provide comments on the topics raised in its Request for Information (RFI).

We are aware of the serious issues the independent pharmacy community faces as a result of PBM industry practices and support reforms that will provide patients with continued access to the pharmacies of their choice. However, the issues with the PBM industry extend far beyond its impact on pharmacies. **We hope that our comments will encourage the FTC to undertake a comprehensive study of all aspects and dealings of the PBM industry, including its formulary design and utilization management practices. Furthermore, if the FTC conducts such a study, we urge the Commission to center the *patient* as the PBM's customer, rather than the payer.** We have organized our comments according to the questions posed by the Commission.

FTC question: The impact of PBM rebates and fees on net drug prices to patients, employers, and other payers.

Research on the topic of net prices has found that PBM's current framework of gross-versus-net (i.e., list-versus-discounted) pricing exerts *upward* pressure on list prices: on average, "a \$1 increase in rebates is associated with a \$1.17 increase in list price."¹ This is not a surprising outcome, given the dynamics at play. For drug manufacturers, preferred placement on a formulary is a coveted position, as it virtually guarantees market share. When a drug is "preferred" on formulary, the PBM will leverage patient cost-sharing and aggressive utilization management to steer patients to that drug, as outlined in detail below. The manufacturer can win this coveted position by offering higher price concessions than its competitors on a specific product and/or by contractually bundling its drugs to secure formulary position for a group of its products. List prices must allow for a margin to reflect these concessions:

¹ Neeraj Sood, Ph.D, et al., Leonard D. Schaeffer Ctr. for Health Policy & Economics, *The Association Between Drug Rebates and List Prices* (Feb. 11 2020). Available: <https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/>.

Our finding that increased rebates are positively associated with increased list prices supports the notion that PBMs' demand for rebates is at least partly responsible for increasing list prices. Because the PBM market is highly concentrated, with three companies serving approximately 80 percent of the market, manufacturers face high stakes when negotiating for formulary placement. If one of the three dominant PBMs excludes their drug, they lose access to a large share of the market, making it all the more important to avoid exclusion from the other two PBMs' formularies. Offering higher rebates is an important lever that manufacturers can use to reduce the chance of being excluded. This dynamic can drive the perverse result in which PBM formularies favor drugs that offer higher rebates over similar drugs with lower net costs and lower rebates.²

In our dysfunctional pharmaceutical market, drug companies compete with one another not on clinical value or cost to the patient, but on price concessions to the PBM. And since these price concessions raise list prices, they also increase out-of-pocket costs for the patient, whose cost-sharing is often based on pre-discounted list prices. Any market in which competition *increases* costs for the end consumer is broken.

In recent years, pressure on PBMs has increased to show that they pass price concessions through to patients. For example, the Office of the Inspector General attempted to eliminate the antikickback safe harbor for rebates from drug companies to PBMs, finding that "many rebates do not flow through to consumers at the pharmacy counters."³ In response to the mounting criticism on this issue, PBMs often argue that they use price concessions to reduce premiums. As explained in detail below, this is an unverifiable claim due to the lack of industry transparency. However, even assuming *arguendo* that every price concession dollar is put towards premium reduction, that dynamic turns on its head the very concept of insurance, which is to spread the costs of a small number of sick (i.e., high-cost) individuals across a larger pool of healthy (i.e., low-cost) individuals. If price concessions on high-cost medications are put towards plan-wide premium reduction for all covered lives rather than reductions in out-of-pocket costs for the patients in need of these medications, PBMs are effectively subsidizing the healthy with the sick. That is the antithesis of the basic function of health insurance.

FTC questions: (1) The impact of PBM rebates and fees on formulary design and patients' ability to access prescribed medications without endangering their health, creating unnecessary delay, or imposing administrative burdens for patients or prescribers.
(2) Whether patients are being forced to substitute different prescription drugs to maximize PBM rebates and fees.

As noted above, PBMs construct formularies to give preferential treatment to manufacturers who provide the highest price concessions; manufacturers who attempt disruptive pricing may find themselves frozen

² *Id.*

³ "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 Fees" Proposed Rule by the Health and Human Services Department, Office of Inspector General (Feb. 6, 2019).

out of formularies. Price concessions are primarily absorbed by the PBM or, in the best-case scenario, applied to premium reduction. However, in addition to the financial implications, patients' quality of their care suffers when year-over-year formulary changes primarily reflect the outcomes of contract negotiations instead of products' safety and efficacy profiles and when utilization management serves the PBM's bottom line instead of care quality.

Utilization management takes various forms, but the most commonly used are:

- Step therapy – often referred to as “fail first” – requires patients to first try and fail the PBMs' contractually preferred medication before being covered for the medication prescribed by the treating provider.
- Prior authorization requires the insurer or PBM to first approve a prescription before allowing coverage of it. This can delay the filling of a prescription by weeks or even months.
- Non-medical switching involves changing a stable patient's medication for a reason that is not clinical. For example, a patient may be forced by the insurer or its PBM to switch because the current medication has lost preferred formulary placement (or lost formulary access altogether) in the most recent negotiations with the drug company.

All of these tactics serve a formulary that brings in the highest revenues, regardless of the disruption to patient care. That is why a recent survey conducted by Mississippi's State Auditor found that 60 out of 65 independent pharmacy owners surveyed – a full 92% – characterized PBMs as “an obstacle between the patient and healthcare provider.”⁴ Utilization management has become so aggressive that many physicians and other stakeholders believe it amounts to the practice of medicine. Unfortunately, publicly traded PBMs owe a duty only to shareholders to maximize revenues; unlike the medically trained professional prescribing the medication, a PBM owes no duty of care to the patient and holds no legal liability related to patient outcomes, even when its tactics result in serious harm.

Anecdotal evidence as to the harm of these policies abounds, as found in a recent article examining the topic:

In one example, a woman with lupus said her vision was severely affected after an insurer forced her to try multiple medications before paying for one that her doctor initially wanted to prescribe. In another, a patient with lung cancer took a break from a successful chemotherapy regimen, then was blocked by her insurer from resuming it until she had tried other drugs.⁵

The discussion forums on patient group websites are filled with similar stories, with some patient groups dedicating entire separate websites to the topic. For example, Global Healthy Living Foundation – one of ATAP's members – collects patient stories related to step therapy on a website called *Fail First Hurts*:

⁴ “Pharmacies vs. Big Corporations: Survey Illustrates the Challenges of PBMs for Independent Pharmacies”, Office of the State Auditor, Mississippi (March 2022). Available:

https://www.osa.ms.gov/documents/Special_Reports/PBM%20Report.pdf.

⁵ “Are insurance policies saving patients money, or keeping them from the treatment they need?” by Bob Tedeschi, STAT (Aug. 22, 2016). Available: <https://www.statnews.com/2016/08/22/step-therapy-patients-insurance-treatments/>.

<https://failfirsthurts.org/stories/>. Stories on these kinds of forums and sites are anecdotal, but they provide a powerful glimpse into the Kafkaesque nature of contemporary utilization management for patients with serious chronic conditions. Even in the case of progressive diseases such as rheumatoid arthritis or cancer, where a delay can mean irreversible damage or death, utilization management barriers are rampant.

Researchers have quantified the prevalence and impact of these policies in more formalized ways, via large-scale surveys or research on clinical outcomes:

- The American Medical Association conducts an annual survey of its members on prior authorization. In 2021, 93% of responding physicians reported care delays due to prior authorization, while 34% reported that it has led to a serious adverse event for a patient in their care. Almost a quarter of physicians (24%) responded that prior authorization has led to a patient's hospitalization.⁶
- A 2020 retrospective study found that, for rheumatoid arthritis and psoriatic arthritis patients in plans that required step therapy, the odds of treatment effectiveness were 19% and 27% lower, respectively, compared with patients whose plans did not require step therapy.⁷
- A 2019 nationwide survey of cancer patients by the American Cancer Society Cancer Action Network found that 1 in 3 (34%) cancer patients and more than half (56%) of doctors reported having to wait for an insurance plan to approve a cancer treatment, test, or prescription drug.⁸
- A 2016 survey conducted by the Arthritis Foundation found that step therapy was stopped in 39% of cases because the drugs required by the PBM or insurer were ineffective and in 20% of cases because the patient's condition worsened. Yet almost a quarter of patients who switched insurance providers were required to repeat step therapy for the new insurer.⁹
- A 2015 review of prescription policies related to psychiatric conditions found that "patients with a reported medication access or continuity problem had 3.6 times greater likelihood of a reported significant adverse event, including an emergency visit, psychiatric hospitalization, increase in suicidal or violent ideation or behavior, homelessness, or incarceration in prison or detention in jail. Overall, 72.2% of patients with medication access problems were reported to have experienced an adverse event, compared with 49.4% for patients with no reported access problems."¹⁰

⁶ 2021 AMA Prior Authorization (PA) Physician Survey. Available: <https://www.ama-assn.org/system/files/prior-authorization-survey.pdf>.

⁷ "Impact of Plan-Level Access Restrictions on Effectiveness of Biologics Among Patients with Rheumatoid or Psoriatic Arthritis" by Natalie Boytsov, Xiang Zhang, Kristin A. Evans, and Barbara H. Johnson, *Pharmacoecoon Open* (March 2020). Available: <https://pubmed.ncbi.nlm.nih.gov/31177506/>.

⁸ "New Survey: Utilization Management Delays Cancer Care; Leads to More Stress and Contributes to Worse Outcomes" American Cancer Society Cancer Action Network (March 2019). Available: <https://www.fightcancer.org/releases/new-survey-utilization-management-delays-cancer-care-leads-more-stress-and-contributes>.

⁹ Issue Brief: Step Therapy, Arthritis Foundation. Available: <https://www.arthritis.org/advocate/issue-briefs/step-therapy>.

¹⁰ "Medicaid Prescription Drug Policies and Medication Access and Continuity: Findings From Ten States" by Joyce C. West Ph.D., M.P.P., Joshua E. Wilk Ph.D., Donald S. Rae M.A., Irvin S. Muszynski J.D., Maritza Rubio Stipeck Sc.D., Carol L. Alter M.D., Karen E. Sanders M.S., Stephen Crystal Ph.D., Darrel A. Regier M.D., M.P.H., *Psychiatric Services*, (Published online 13 Jan 2015). Available: <https://ps.psychiatryonline.org/doi/full/10.1176/ps.2009.60.5.601>.

The above list is but a sample of the extensive documentation of the harm resulting from utilization management protocols, which exist in large part to drive the formulary most profitable to the PBM. These protocols are pervasive, negatively impact patient care and clinical outcomes, and create significant administrative burdens on patients, caregivers, and medical providers.

FTC question: PBMs' use of methods to steer patients away from unaffiliated pharmacies and methods of distribution and toward PBM-affiliated specialty, mail-order, and retail pharmacies.

Many medical practices that administer medical benefit drugs in-office use the “buy and bill” model, whereby the practice handles all of the logistics related to getting the drug to the patient: purchasing, storing, preparing, and ultimately administering. Once administered, the practice bills the insurer for the drug and its administration. In recent years, PBMs and payers have begun pushing a model referred to as “white bagging” to steer the purchase and delivery of medical benefit drugs into the PBM’s preferred pharmacy – which, of course, it often owns.

Ironically, white bagging increases wastage of what are often incredibly expensive medications. Under the current buy-and-bill model, a practice estimates and orders its medication needs for the month or for the quarter, but drugs are not “earmarked” for a specific patient until the time of administration. Although this model places the practice at financial risk since it will not be reimbursed until after administration has occurred, it also enables the clinician to make adjustments up until the moment the medication is administered. By contrast, the white bagging model assigns specific orders to specific patients ahead of administration and does not allow for clinician flexibility or for reassigning inventory among patients.

For example, a practice may have a month’s supply of a certain medication on hand, estimated based on its current patient volume needs. However, patient circumstances change: a patient may wish to try a different medication due to an unexpected loss of efficacy of the current medication, another patient may wish to temporarily discontinue treatment due to pregnancy, a third may have experienced a weight fluctuation requiring a dosage change, and so on. Under the current model, these “over-ordered” amounts of that medication can be used on other patients, perhaps new patients that same month or existing patients the following month. Under the white bagging model, if a medication cannot be administered to a patient as ordered, it must be discarded, even though the patient has usually already paid the coinsurance for it. This is terribly frustrating at a time when high drug prices are a constant concern for patients.

Furthermore, providers and patients report significant delays with white bagging, causing canceled appointments and disease progression. The rigidity and administrative hurdles of the white bagging model cause a logistical nightmare for practices’ inventory and overhead management. It also drops patients into an administrative morass, since they become responsible for coordinating with the specialty pharmacy, authorizing dispensing to a third party/location (i.e., their site of care), navigating utilization management requirements, and so on. Most egregiously, patients usually must meet their entire cost-sharing up front, before the specialty pharmacy will ship the medication. This is in stark contrast to

providers using the buy-and-bill model, who will often work with patients to spread out payments over time, handle utilization management requirements, help access charitable foundation help, and generally work with patients however they can to help ensure affordability.

There is no clinical benefit or administrative streamlining for patients in this model; in fact, white bagging creates delays in care and administrative burdens for patients and providers alike. The only benefit from this model accrues to the PBM, who can take in additional revenue when it pushes patients through its own pharmacy.

FTC question: PBMs' policies and practices related to specialty drugs and pharmacies, including criteria for designating specialty drugs, reimbursements to specialty pharmacies, practices for encouraging the use of PBM-affiliated specialty pharmacies, and practices relating to dispensing high-cost specialty drugs over alternatives.

With regard to the criteria for designating specialty drugs, these are unclear and vary across PBMs, and sometimes even within a single PBM's different formularies. This leads to absurd scenarios such as a PBM treating brand-name drugs as generics or vice versa, despite the fact that those terms are defined in federal law and used by the Food and Drug Administration, drug companies, and other stakeholders according to their statutory, commonly understood definitions. Remarkably, PBMs have treated the same drug differently in the same contract.¹¹ **Another reform for policymakers to consider is to ensure that key terms in PBM contracts are used in accordance with their definition in federal law or widely accepted industry standard (e.g., generic, biosimilar, reference product, etc.).**

FTC question: Potential conflicts of interest and anticompetitive effects arising from horizontal and vertical consolidation of PBMs with insurance companies, specialty pharmacies, and providers.

Three PBMs control between 75% and 80% of the prescription drug market, estimated to amount to more than 260 million patients.¹² Additionally, several PBMs have merged with pharmacies and insurance companies and are now even acquiring physician practices, creating almost full vertical consolidation. The resulting market power of "the big three" is enormous, and far greater than that of any other stakeholder in our prescription drug market, including pharmacies and even drug manufacturers.

Immense market pressure is not nefarious *per se*, but the remarkable level of vertical consolidation in this industry has upended the traditional view of the insurer/payer as the customer of the PBM. Now, the payer and PBM are no longer distinct entities contracting with one another at arms' length and providing some oversight to one another as potentially adverse parties. Instead, they have become related corporate entities, which means the primary purpose of each entity is no longer to maximize its own revenues and market power. Instead, their main purpose as entities under common ownership is to

¹¹ "When is a brand a generic? In a contract with a PBM" by Linda Cahn, *Managed Care* (Sept. 1, 2010). Available: <https://www.managedcaremag.com/archives/2010/9/when-brand-generic-contract-pbm>.

¹² Health Affairs, Health Policy Brief, *Pharmacy Benefit Managers 1-2* (Sept. 14, 2017).

minimize external oversight and maximize revenues, market share, and tax advantages across the family of entities. **Any regulatory approach to these entities must account for the now prevalent scenario in which the traditional “customer” of a PBM has become its owner, its subsidiary, or otherwise related under common ownership.**

Furthermore, over-consolidation has virtually eliminated any hope of transparency. Since meaningful reform rests in large part on policymakers’ ability to track revenues from price concessions, the opacity and ability to funnel money through various related entities create a roadblock to reform. As noted above, PBMs claim they pass through price concessions to patients in the form of premium reductions, but this cannot be verified with certainty due to the black box in which these revenues are held. Researchers who have looked into the question of pass-through have found that PBMs retain much of the price concessions they extract.

In fact, full pass-through may not occur even when customers contractually require it. This is perhaps the most pernicious side effect of the lack of transparency: unequal access to information between the PBM and its contractual partners. A PBM’s agreements with drug companies and pharmacies are confidential, which leaves the payer (for example, an employer) reliant on the PBM itself to report the amounts and types of price concessions it extracts from these entities. This fox tends to fail in its henhouse guarding duties, as evidenced by the fact that a leading PBM settled litigations with Ohio and Mississippi following allegations of spread pricing and has since set aside over a billion dollars to settle with other states, perhaps indicating that this behavior was not unique to its contracts with Ohio and Mississippi.¹³ States should not have to file litigation to learn – let alone receive – what is contractually due to them and their taxpayers. But lacking any parallel access to information, states and other payers may conclude that litigation and its attendant discovery process are the only option.

With increased attention on formulary rebates, PBMs have begun to rename rebates as administrative fees, price protection fees, and other types of charges to manufacturers. In a 2017 litigation between a PBM and a drug company, documents revealed that the PBM charged an “administrative fee” for a product that soared right after the manufacturer increased the drug’s price, which suggests that this was not a flat fee in exchange for set administrative functions.¹⁴ Furthermore, the amount of administrative fees dwarfed that of the rebates: in a four-month period, the PBM invoiced a total of \$26,812.50 for formulary rebates while charging \$363,160.04 for administrative fees.¹⁵ **Any transparency requirements should apply to all revenues flowing into the PBM, ideally from all sources, but at a minimum from drug companies and pharmacies.**

Finally, the large PBMs have recently created subsidiary entities called “rebate aggregators.” This structure could enable a PBM to claim that it passes through 100% of the rebates *it receives* – without

¹³ “U.S. Drug Prices Distorted to Favor Pharmacy Benefit Managers” by Fred Gebhart, *Drug Topics* (March 22, 2022). Available: <https://www.drugtopics.com/view/us-drug-prices-distorted-to-favor-pharmacy-benefit-managers>.

¹⁴ *Express Scripts, Inc., et al. v. kaléo, Inc.*, No. 17-cv-01520 (E.D. Mo. May 16, 2017).

¹⁵ *Id.* See also: “Express Scripts Lawsuit Should Raise Everyone’s Eyebrows” available: <https://nationalprescriptioncoveragecoalition.com/express-scripts-lawsuit-should-raise-everyones-eyebrows/>.

adding that most of the price concessions accrue to an aggregator. The fact that some of these aggregators are organized offshore may limit the reach of any reforms by the U.S. Congress or regulatory agencies.¹⁶

The lengths to which this industry will go to avoid any transparency as to the ultimate destination of price concession dollars is perhaps most indicative of who benefits from this system. Even if excessive industry consolidation could be addressed, the only way out of this system is a fully transparent fee structure that does not tie a PBM's revenue to the price of a drug. **Increasingly, employers will demand full transparency, and federal health programs should do the same. Drug prices must be delinked from payments to PBMs by drug companies; PBMs should be paid for administrative services via flat fee payments. This will begin to create a system in which drug companies compete based on clinical value and the out-of-pocket cost to the patient filling the prescription.**

Thank you for the opportunity to submit comments. If you require any additional information or have any questions, please don't hesitate to reach out to any of the undersigned organizations.

American Academy of Dermatology Association
American Association of Clinical Urologists
American College of Rheumatology
Association of Woman in Rheumatology
California Rheumatology Alliance
Coalition of State Rheumatology Organizations
Florida Society of Rheumatology
Georgia Society of Rheumatology
Global Healthy Living Foundation
Infusion Access Foundation
International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)
Kentuckiana Rheumatology Alliance
Looms for Lupus
Lupus and Allied Diseases Association, Inc.
MidWest Rheumatology Association
National Infusion Center Association
National Organization of Rheumatology Management
New York State Rheumatology Society
North Carolina Rheumatology Association
Rheumatology Nurses Society
South Carolina Rheumatism Society
Tennessee Rheumatology Society
Virginia Society of Rheumatology

¹⁶ "Cautionary tale: Plan sponsors losing manufacturer rebate dollars to PBMs through rebate aggregators" by Jonathan E. Levitt and Dae Y. Lee, *BenefitsPRO Expert Opinion* (April 15, 2021). Available: <https://www.benefitspro.com/2021/04/15/cautionary-tale-plan-sponsors-losing-manufacturer-rebate-dollars-to-pbms-through-rebate-aggregators/?slreturn=20211015144426>.