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May 5, 2022

Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue, NW
Washington, D.C. 20580

Re: Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers

To Whom It May Concern:

We are writing on behalf of the Biotechnology Innovation Organization (BIO) to provide comments on the Federal Trade Commission's (FTC's or the Commission's) Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers. BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology companies, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but have also reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

BIO applauds the Commission's attention to market distortions in the prescription drug ecosystem. Increasing complexity in both the number of supply chain intermediaries and relationships between those entities have created a shadow market that ultimately harms the end consumer of medicines: patients. Shedding light on how these markets function (or function inefficiently) will help inform the national discussion on how best to address prescription drug affordability. Without this insight, we are concerned about the proliferation of short-sighted policy proposals that would needlessly harm the development of innovative medicines without addressing the root factors of access to medicines.

Specifically, **we strongly recommend the FTC use its 6(b) authority to conduct a formal study of the business practices of pharmacy benefit managers (PBMs)**. This type of study would be appropriate for several reasons. The market structure for PBM services has evolved haphazardly, with inadequate consideration of the full consequences of its framework and marketplace consolidation. With the historic horizontal integration of PBM services into just a few entities and more recent vertical integration of these services into payor-parent companies, there is legitimate ambiguity about the role PBMs play in the market for medicines and whose interests they serve. This level of market concentration has been attained through the aggressive acquisition throughout the entire ecosystem – from insurers and PBMs to specialty pharmacies and provider services – such that most of a patient's interaction with the

pharmacy benefit is dictated, and therefore, priced by these firms. Policy and enforcement solutions to address these issues may have been ineffective because the FTC and others appear not to have sufficient information regarding how these markets operate.

For example, a traditional conceptualization of PBMs holds that they simply act as intermediaries negotiating prescription medicine rebates on behalf of their plan sponsor clients. However, given the market power consolidated PBMs wield in structuring the prescription benefits of most Americans, we posit a somewhat different view of their role. In today's market, PBMs are gatekeepers to patient access and affordability in a market controlled by only a handful of firms and selected by health plans, not patients. Drug manufacturers must negotiate with PBMs for formulary status so that patients prescribed their medication will be able to access them. At a minimum, this view of "PBMs" reflects the multiple roles these firms can occupy in the prescription medicine ecosystem – reimbursors to pharmacies for services they provide and determiners of patient access to – and cost for – medications through formularies and benefit designs they create.

An in-depth study by the Commission could help illuminate these roles and demonstrate how PBMs have leveraged a lack of transparency to maximize profits, but in ways that often prevent access to beneficial and sometimes life-saving medicines and increase out-of-pocket costs for patients.

The PBM industry shares important characteristics with other sectors in which large, vertically integrated, or conglomerate intermediaries operate in ways that stifle competition and innovation. As Chair Khan recognized with respect to the tech sector:

"Current law underappreciates the risk of...how integration across distinct business lines may prove anticompetitive...because online platforms serve as critical intermediaries, integrating across business lines positions these platforms to control the essential infrastructure on which their rivals depend. This dual role also enables a platform to exploit information collected on companies using its services to undermine them as competitors."¹

Major PBMs have all become vertically integrated and collect information from a multitude of sources while serving numerous roles in the U.S. health care system. These vertically integrated firms have a presence in multiple markets and business areas that are tightly connected in the same vertical value chain, and which impact the same set of manufacturers and patients. A robust antitrust analysis of PBMs should focus not only on "PBM services" but on how different roles played by PBMs affect their market power. An especially important analysis would involve understanding the relationship between insurers and PBM units within these conglomerates as both are considered payors within the healthcare system, both have formularies, and both decide how much patients are charged, and therefore, how much patients will have to pay to pharmacies (some of which are also owned by PBM conglomerates).

Further investigation into the dynamics of PBM business practices can also help patients, plan sponsors, and the public understand the role that these firms play in determining the price of prescription medicines. There has been increased interest on behalf of policymakers at the federal and state level in PBMs' reliance on rebates from drug manufacturers and how these rebates interact with the formulary and benefit designs they offer.

¹ Kahn, L.M. (2017). Amazon's Antitrust Paradox. *Yale Law Journal*, 126, 564-907.

BIO has long been supportive of a more rational and transparent system of rebates – and specifically ensuring that patient cost sharing is based on the net cost of the drug to the payor. We are concerned, however, that the increasingly complex and opaque rebate dynamics, paired with the market power these firms now yield, have created an environment in which patients are harmed and competition is stifled. Simply put, patients who take medicines are not benefiting from the significant discounts manufacturers provide to PBMs.

The rising concentration of pricing power by PBMs underpins this disconnect and is a fundamental factor in the increasing out-of-pocket prices paid by patients. The fixation on discounts in the form of rebates due to PBM-payor contract terms has also led to PBM practices that may hamper competition in certain therapeutic categories by preferring products that generate the highest rebate for payors, not necessarily those products that are more clinically appropriate or less expensive for the patient. We believe a deeper investigation into these dynamics by the Commission would shed light on these inefficiencies and point the way to potential solutions.

BIO supports the FTC investigating PBMs to better understand their market power, identify the conflicts of interest they face, and develop rules to eliminate the harms PBMs cause. Such an investigation is consistent with Chair Khan's priorities.² Current PBM practices are an impediment to competition, innovation, patient access, and an efficient transition to a more value-based health care system. They cannot be changed until they are fully understood.

We appreciate the FTC's continued attention to the issue of transparency and consolidation in the prescription drug supply chain. Below we offer some additional context on harmful PBM practices we believe could be helpful as the Commission considers next steps.

I. Disconnect between gross and net prices in the prescription drug market

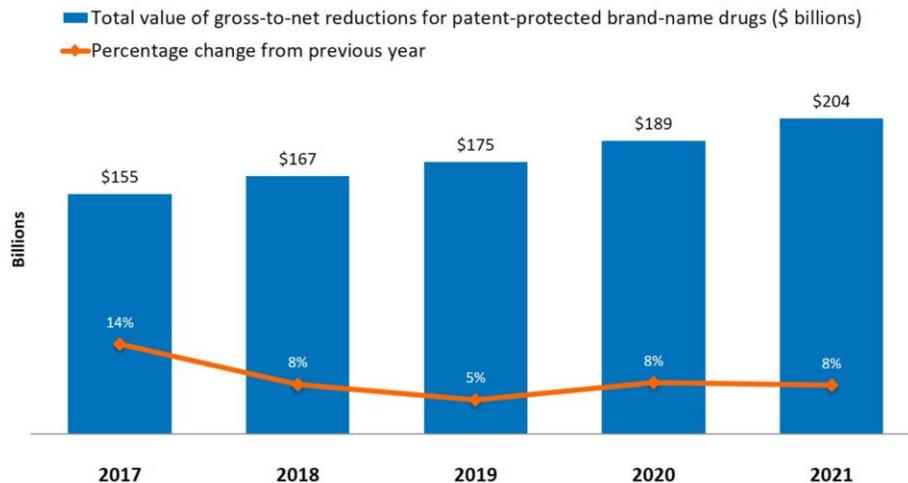
Perhaps the defining feature of PBMs market power is their ability to extract rebate dollars from manufacturers, creating a "gross-to-net bubble" that has distorted conversations about the cost of prescription medicines and harmfully intersects with payors' benefit designs. This gross-to-net bubble represents the difference between the gross price of medicines and the net price manufacturers realize after rebates and discounts have been calculated. These discounts include distribution fees paid to supply chain intermediaries, discounts to hospitals, and other discounts, but are dominated by negotiated and statutory rebates.

The gross-to-net bubble has grown substantially in recent years. In 2017, the total value of pharmaceutical manufacturers' reductions to list price totaled \$155 billion. By 2021, that amount had grown to just over \$200 billion, growing by mid-single digits each year (see below).³

² See FTC, Statement from Chair Lina M. Kahn (September 22, 2021), available at: https://www.ftc.gov/system/files/documents/public_statements/1596664/agency_priorities_memo_from_chair_lina_m_khan_9-22-21.pdf ("The second area I'd like us to prioritize addressing is dominant intermediaries and extractive business models. Research documents how gatekeepers and dominant middlemen across the economy have been able to use their critical market position to hike fees, dictate terms, and protect and extend their market power. Business models that centralize control and profits while outsourcing risk, liability, and costs also warrant particular scrutiny, given that deeply asymmetric relationships between the controlling firms and dependent entities can be ripe for abuse.")

³ Drug Channels, *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Exhibit 168. Gross-to-net reductions include the total value of rebates, off-invoice discounts, copay assistance, price concessions,

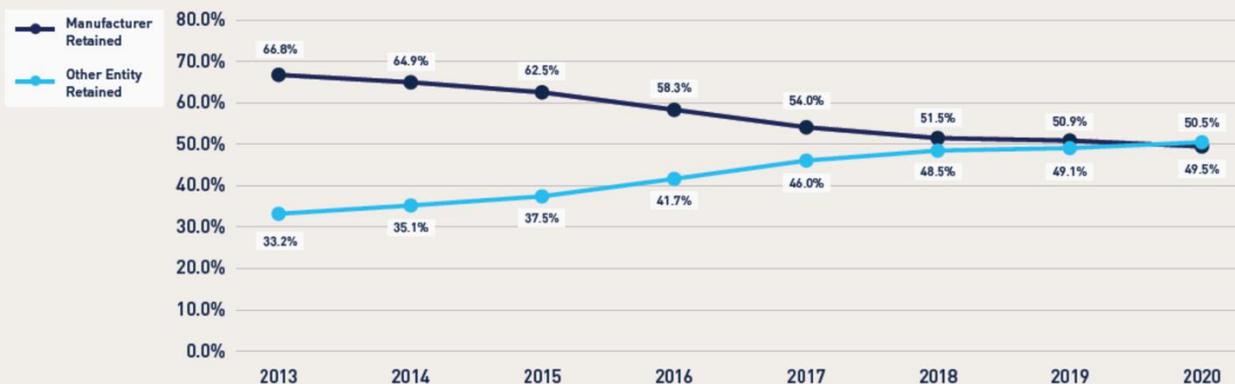
Total Value of Pharmaceutical Manufacturers' Gross-to-Net Reductions for Patent-Protected, Brand-Name Drugs, 2017 to 2021



At the same time, net prices for all branded medicines have grown in the low single digits – at or below the consumer price index – for the last four years.⁴ In 2020, net prices for these products fell by 2.9%.⁵ Many manufacturers have similarly reported negative price growth for their own portfolios in recent years.

As supply chain intermediaries have consolidated, they have been successful in capturing a growing share of prescription drug expenditures. In 2013, manufacturers retained about two-thirds of medicine spending, with the remainder retained by other entities in the supply chain.⁶ In the following years, the amount of spending retained by manufacturers fell significantly. And for the first time in 2020, the amount of gross spending retained by entities that develop the medicines fell below 50% (see below).

FIGURE 3. Total Gross Expenditures for Brand Medicines Received by Manufacturers and Other Stakeholders (2013-2020)



and such other reductions as distribution fees, product returns, the 340B Drug Pricing Program, and more. Includes value for patent-protected brand-name drugs that do not face generic competition. Figures have been updated and restated to reflect new disclosures and updates to underlying data sources. Published on [DrugChannels](#) on March 22, 2022.

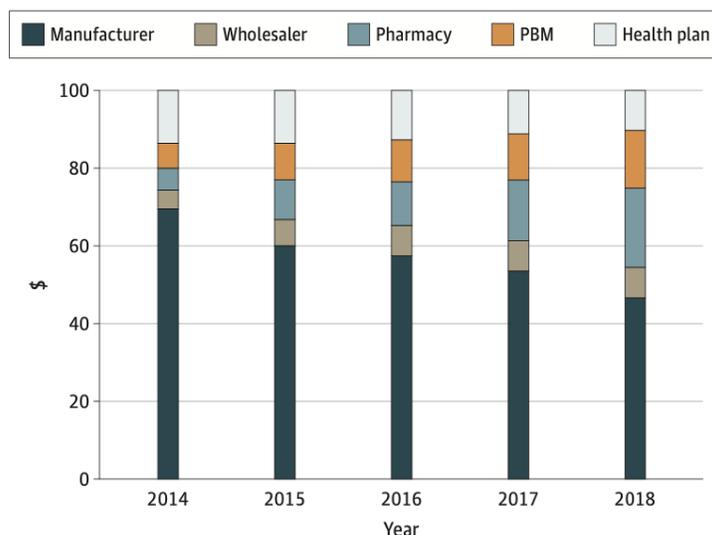
⁴ IQVIA, *The Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025*. (2021). Exhibit 29.

⁵ Ibid.

⁶ BRG, *The Pharmaceutical Supply Chain, 2013-2020*. January 2022. Figure 3.

This dynamic has been observed specifically in the market for insulin products – a therapeutic class where the disconnect between list and net pricing has been a focus for patients and policymakers. A recent study analyzed the hypothetical distribution of \$100 of spending on 32 insulin products across manufacturers, insurers, and other supply chain entities from 2014-2018. The authors found that while expenditures per 100 units of insulin changed little over this time, the distribution of spending changed significantly (see below).⁷

Figure 3. Average Distribution of \$100 in Insulin Expenditures for 32 Insulin Products Across Distribution System Participants, 2014-2018



Over this period, the share of spending retained by insulin manufacturers and health plans fell (by 33% and 24.7%, respectively), while the amounts retained by supply chain intermediaries increased substantially: wholesalers (74.7%), pharmacies (228.8%), and PBMs (154.6%). We believe the market power of these horizontally and vertically integrated health plan systems is allowing the capture of more value than would be observed in a competitive market and warrants increased scrutiny.

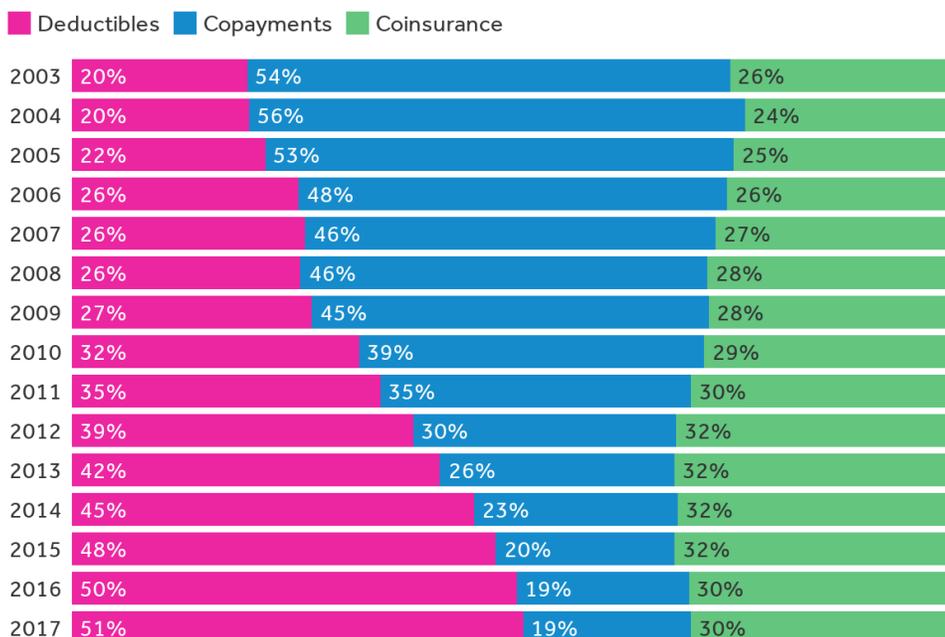
Trends in health insurance benefit design over the same time have exacerbated the distortions caused by the growing gross-to-net bubble. In the early 2000s, policymakers, health plans, and employers began experimenting with so-called “consumer driven health plans.”⁸ Among the key features of these plans is that they purposefully expose their enrollees to greater financial risk (in the form of deductibles and coinsurance) than more traditional plans, which generally feature first-dollar coverage of health care services. Underlying this benefit design is the theory that, when exposed to more of the cost of health care, patients will allocate their dollars to more efficient, lower-cost services, thereby lowering overall spending.

⁷ Van Nuys, Ribero, Ryan, and Sood, “*Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans from 2014 to 2018*.” JAMA Health Forum. November 2021. Available at: <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2785932>

⁸ See The Wall Street Journal, “Consumer Health Plans May Be Inevitable, but Will They Work?” August 2002. Available at: <https://www.wsj.com/articles/SB1029532124158556915>

Setting aside the somewhat contentious debate about whether this theory has borne out in practice, the practical implication for patients is that they have been exposed to greater cost sharing for their medicines (and all health care services). Data from large employer health plans show the growing popularity of this type of benefit design. In 2003, only one-fifth of all cost sharing occurred in the deductible phase of the benefit.⁹ By 2017, deductible spending amounted to 51% of all spending, while flat dollar copays comprised just 19% (see below).

Distribution of out-of-pocket spending for people with large employer coverage, 2003-2017



Source: KFF analysis of IBM MarketScan Commercial Claims and Encounters Database

Peterson-KFF
Health System Tracker

Important to understanding how this change in benefit design interacts with the gross-to-net bubble is that when patients are in the deductible phase of the benefit (or are paying coinsurance), their cost sharing is often based on the *gross price* of the medicine (i.e., the price prior to any discounts or rebates received from the manufacturer). Since many discounts and rebates are effectuated after a prescription is filled, patient cost sharing at the pharmacy counter is based on the undiscounted price. There are ways for these rebates to be passed through to patients at the point of sale. However, many PBMs and payors have become so dependent on rebate revenue *and* the disproportionate cost sharing paid for these medicines that to do so works against their business model.

In short, PBMs' ability to extract greater rebates from drug manufacturers, while simultaneously leveraging their health plan function to implement benefit designs that require

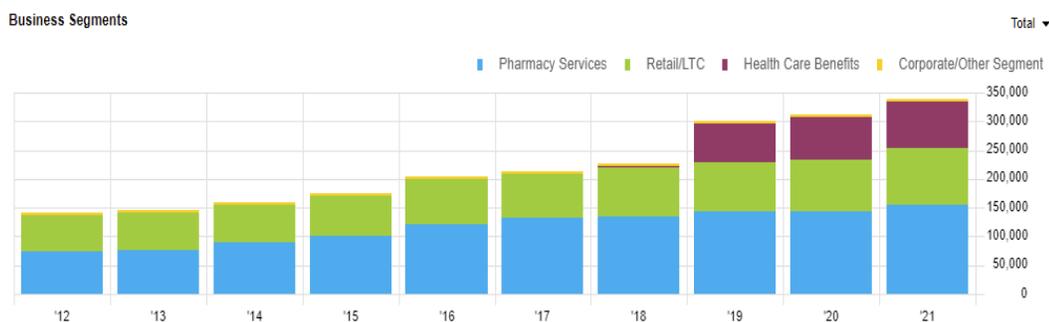
⁹ Peterson-Kaiser Health System Tracker, "Tracking the rise in premium contributions and cost-sharing for families with large employer coverage." August 2019. Available at: <https://www.healthsystemtracker.org/brief/tracking-the-rise-in-premium-contributions-and-cost-sharing-for-families-with-large-employer-coverage/>

patients to pay cost sharing based on gross prices has created numerous market distortions, which we discuss below.

II. Market distortions caused by rebates not being shared with patients at the point of sale

Consider the following (highly simplified) example of a patient filling a prescription for a heavily rebated product: A patient, enrolled in a health plan with a deductible of \$8,000, goes to the pharmacy to fill a prescription for a chronic medication. It's January, so the patient has not met any of their deductible spending for the year. The medication is a rheumatoid arthritis drug in a highly competitive class, and so the health plan's PBM has negotiated a significant rebate of 50% off the medicine's list price of \$2,000. When the patient fills the prescription, they will pay cost sharing totaling \$2,000, while the net cost of acquiring the medicine to the PBM is only \$1,000. Or in other words, the filling of the prescription to treat a debilitating condition costs the patient \$2,000 while generating \$1,000 for the PBM. This is not how insurance is supposed to work. In the aggregate, the market distortions caused by this perverse system of reverse insurance are myriad.

While the \$1,000 generated for the PBM/payor may be used to hold down overall pharmacy costs for the plan, the burden of such a large cost sharing obligation until the patient reaches their deductible could be catastrophic. And beyond the immediate implications for patients who might be struggling to afford their plan-imposed cost sharing, the dual system of growing rebates while proliferating benefit designs that do not share them at the point of sale has harmed consumers while growing revenues for these conglomerates across their three profit centers: insurance companies receive premiums and provide little coverage (first business line), which forces patients to pay significant sums out of pocket to their pharmacies (second business line) while PBMs extract significant rebates from drug manufacturers, may not pass those savings on to patients but instead charge patients "cost-sharing" based on undiscounted prices (third business line). This dynamic is illustrated in CVS Health's financial statements over time, which show that their "pharmacy services" segment (PBM business) has doubled revenues and the retail pharmacy segment has almost doubled its revenues over the last decade. Meanwhile, its insurance segment has grown revenues by 1300% since its acquisition.¹⁰



The opaque system of rebates further complicates an already labyrinthian system of how we pay for prescription medicines. In a situation where rebates to PBMs are increasing,

¹⁰ Data and chart from FactSet

resulting in net prices decreasing, benefit designs that push more of the cost burden onto patients can cause patients to believe that the price of their medicine is increasing when the net price to the PBM is actually falling. This dynamic can complicate the public's understanding of how medicines are priced.

Perhaps more problematic is the impact that this system has on critical patient protections. As part of the Affordable Care Act, insurers and group health plans were generally prohibited from "risk rating" – or charging differential premiums based on health conditions – in addition to guaranteed renewal and prohibitions against pre-existing condition exclusions and annual and lifetime limits.¹¹ These reforms significantly improved the financial protection that health insurance should offer. However, the confluence of rebates calculated as a percentage of list price and benefit designs that charge patients based on list price when that is not the price actually paid by the insurer has created a revenue stream that allows plans to collect additional funds from patients, even when medicines are deeply discounted. This system of "reverse insurance" – where patients with serious conditions fund lower premiums for the healthy – is an extreme distortion of the market for prescription drugs that is enabled by consolidation of the payor side of health care.

These are the primary reasons why BIO and its members have supported the sharing of rebates with patients at the pharmacy counter. Efforts at the federal and state levels to require PBMs and plan sponsors to pass these discounts through to patients would result in a more transparent and equitable reimbursement system for medicines. As we also noted in our comments to HHS on their past proposal to effectuate this change for Medicare beneficiaries, negotiation between PBMs and manufacturers for point-of-sale discounts would be an efficient and effective way to determine formulary placement – and possibly an improvement over the current system of rebates that are not reflected in patient cost sharing.¹²

III. PBM Practices Impede Access to Needed Medicines and Harm Patients

Ultimately, those harmed most by the consolidation and opaque business practices of PBMs are patients trying to access needed medicines. Control over the prescription drug benefit has become so granular and control of the payor space so consolidated that patients' ability to access their medicines can come with significant financial and/or administrative burdens that, for some patients, may prevent them from obtaining their medicines at all. The rebate dynamics we describe above have led to a situation where PBMs are driven to seek discounts in the form of rebates from drug manufacturers for payors. Unfortunately, this can mean that PBMs may prefer products with higher list prices that, depending on the PBM/payor established benefit design, can have higher cost sharing for patients. This calls into question whether the PBM model really works for patients.

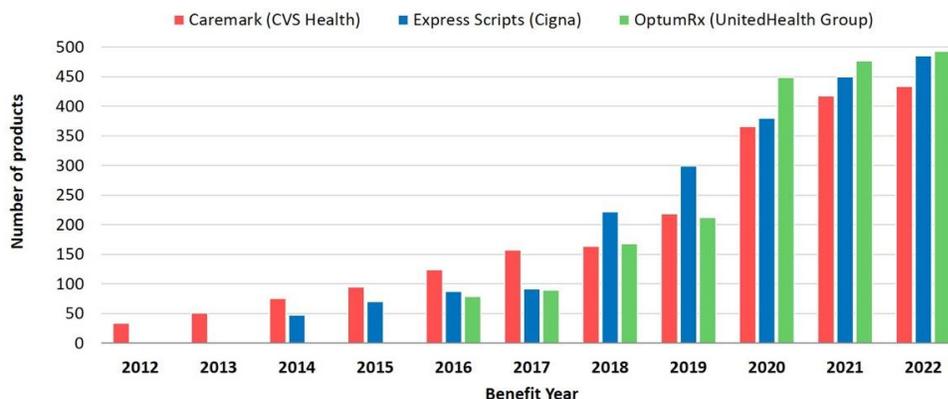
PBMs' increasingly complex management of the prescription drug benefit also means that they have amassed an unprecedented amount of control over which products patients can access, and what hurdles they must overcome to ultimately do so. So called "utilization management" (UM) tools like step therapy, prior authorization, and formulary exclusions create numerous barriers to patients accessing prescribed therapies. One particular area of concern –

¹¹ See Public Health Service Act, Sections 2701 (Fair Health Insurance Premiums), 2704 (Prohibition of Preexisting Condition Exclusions), 2711 (Lifetime and Annual Limits), and 2712 (Prohibition on Recissions)

¹² See BIO Comments Re. 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 Services Fees. OIG-0936-P. April 8, 2019.

formulary exclusions – is magnified by the extreme consolidation of the PBM market at a time when medicines are increasingly targeting more specific forms of disease. A decision by one or all the large PBMs to exclude a therapy effectively closes the door on those patients accessing what might be the only or best therapy to treat a patient’s condition.

Formulary exclusions across the large PBMs have been growing in tandem with firms’ vertical and horizontal integration. Each year, the three large PBMs publish a list of those products that are excluded from their standard formularies. In 2022, each of these PBMs excluded roughly 450 products (see below).¹³



Source: Drug Channels Institute analysis of company reports; Xcenda. Note that some data have been restated due to midyear additions to exclusion lists. Express Scripts did not publish exclusion lists before 2014. OptumRx did not publish exclusion lists before 2016. Note that PBMs may exclude many of the same medications, so certain products may appear on multiple lists.

Published on Drug Channels (www.DrugChannels.net) on January 19, 2022.



Patients (and physicians) might be unaware of when and why a product is removed from the formulary of a PBM they had no choice in selecting in the first place, leaving them to make hurried decisions about their alternatives (if any) based on the PBM’s negotiating power. The ability to gatekeep the market for medicines in this way is an underappreciated feature of the market in which PBMs operate. While some of these practices may be rooted in clinical practice or legitimate cost containment (e.g., formulary exclusions in a class with multiple products), the misaligned incentives and lack of transparency into how these decisions are made are concerning.

Utilization management tools such as prior authorization and step therapy may negatively impact patients’ ability to access needed treatments in a timely manner and may impact health outcomes in some therapeutic categories. Step therapy, often referred to as “try and fail” or “fail first,” is a policy that many commercial – and some government – health plans have implemented to force beneficiaries to try lower-cost options in a drug class before permitting them to “step up” to the potentially more costly, but in some cases, more clinically appropriate, branded drug originally prescribed. While the drugs patients are forced to “step through” may lead to near-term savings for plans and PBMs, in some therapeutic categories such substitutions can also potentially yield adverse clinical effects and/or suboptimal outcomes for patients. As a result, such policies may lead to increased costs in the long run.

¹³ DrugChannels, “Five Big Takeaways from the Big Three PBMs’ 2022 Formulary Exclusions.” January 2022. Available at: <https://www.drugchannels.net/2022/01/five-takeaways-from-big-three-pbms-2022.html>

Another PBM tactic threatening access to medicines in recent years is the proliferation of copay accumulator and maximizer programs. These programs – which PBMs have been able to implement because of their deep integration into the pharmaceutical supply chain – exclude the value of copay assistance provided by manufacturers directly to patients from accruing towards deductibles and annual limitations on cost sharing. The rise of these programs has caused significant confusion and access issues for patients who rely on this direct manufacturer assistance to meet their cost sharing obligations.

The application of an accumulator or maximizer program to a patient's medicine often comes with little or no warning and disrupts the assistance upon which they depend. By not applying the value of the assistance – intended for patients – to patient cost sharing obligations, accumulator and maximizer programs drive up costs for patients and threaten adherence to their medicines or services recommended by their health care provider. The link between excessive cost sharing and prescription abandonment is well established. Research has shown that more than two-thirds of commercially insured patients (69%) abandoned their prescription at the pharmacy when cost sharing exceeded \$250, while only 11% did so when cost sharing was \$30 or less.¹⁴

By helping patients meet their cost sharing obligations, manufacturer assistance programs can help to improve patient adherence and prevent unnecessary medical spending. One recent analysis found that from 2015 to 2020, manufacturer-provided copay assistance in the commercial market reduced patient out-of-pocket spending by nearly 25%, while increasing medicine utilization between 4.8-16.7%, which also raised health outcomes by 1% to 3.3%.¹⁵ In 2019 alone, this translated to between \$8 billion and \$29 billion in avoided medical costs.¹⁶

That PBMs can implement accumulator programs and other tools to “manage” utilization based on the PBM's own financial objectives, rather than the health objectives of the patients they serve, speaks to the disconnect and ambiguity around the role these firms hold in our health care system.

¹⁴ IQVIA “Patient Affordability Part Two: Implications for Patient Behavior & Therapy Consumption.” May 2018. Available at: <https://www.iqvia.com/locations/united-states/patient-affordability-part-two>

¹⁵ Tomas J. Philipson, Troy Durie, *The Patient Impact of Manufacturing Copay Assistance in an Era of Rising Out-of-Pocket Costs*. December 2021. Available at: https://cpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2021/12/2021_12_15-Copay-Assistance-Final-Draft-Clean.pdf

¹⁶ Ibid.

IV. Conclusion

We appreciate the Commission's interest in the dynamics of the PBM industry and strongly support additional investigation through a 6(b) study. Policymakers and the public would benefit from greater transparency into this largely unregulated market and how its business practices impact the ecosystem for prescription medicines. If we can be of any assistance as the Commission moves forward with these efforts, please do not hesitate to contact us.

Sincerely,

/s/

John A. Murphy III
Chief Policy Officer