

December, 2022

Pharmacy Benefit Tactics Drive Up Drug Prices, Limit Access, Contribute to Health Risks





Executive Summary

Shrouded in complexity and lacking transparency, pharmacy benefit managers (PBMs) have devised multiple strategies that contribute to spiraling drug costs, which jeopardize patient health and threaten the sustainability of employer-and-public-purchaser sponsored health insurance. Regaining control of drug expenditures to meet new fiduciary obligations and to help ensure good health for employees will require that employers and public purchasers work collectively to understand, expose and terminate abusive PBM activities.

Originally established to process claims and perform other administrative functions on behalf of payers, pharmacy benefit managers (PBMs) today have morphed into powerful gatekeepers that exert enormous and often-harmful influence over drug cost and access for <u>266 million</u> Americans.

Over the past 40 years, drug costs have climbed more than <u>ten-fold</u>, from \$30 billion in 1980 to <u>\$348 billion</u> in 2020. It is true that multiple factors contribute to ever-higher drug costs, including often-exorbitant manufacturer drug prices. While much has been written about the role of drug manufacturers in driving up prices, far less publicized is the undeniable link between price increases and the ever-expanding supply-chain dominance of pharmacy benefit managers.

PBMs act as middlemen between drug manufacturers upstream and insurance companies, employers, public purchasers, pharmacies and patients downstream. Over time, they've methodically used this intermediary role to distort supply chain processes in pursuit of outsized profits. Because these activities take place behind a curtain of nearly impenetrable ambiguity, most stakeholders remain largely uninformed or uncertain about challenging the status quo.

Fortunately, growing awareness of the many ways in which PBMs use their leverage in the system has created an unprecedented opportunity to compel fundamental and lasting reform. Altering PBM behavior is not a given, however, and ultimately will depend on sustained, collective action by the employers and public purchasers who provide health benefits for more than half of all Americans.

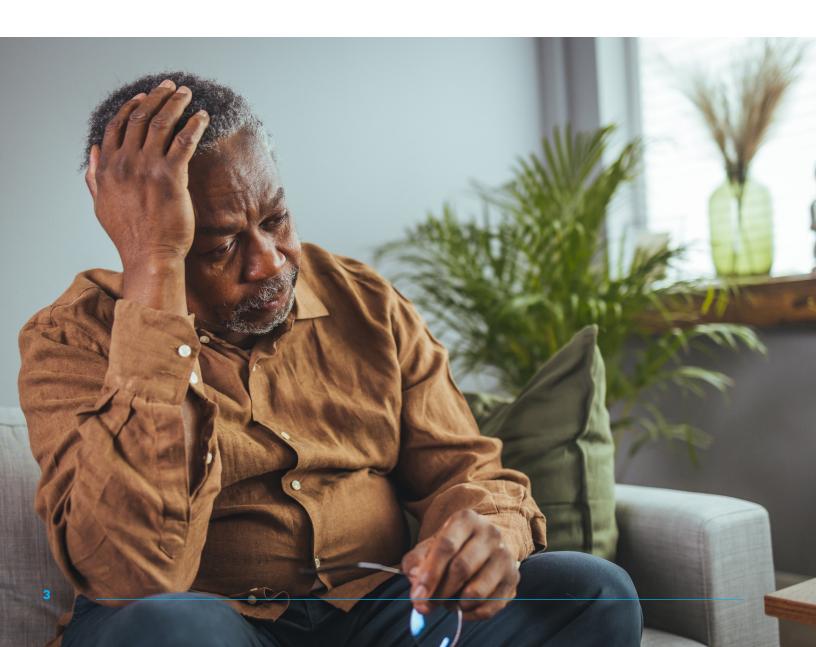
Only by digging deep into the intricacies of pharmaceutical sourcing to unpack, understand and confront PBM practices will employers and public purchasers be able to put an end to exploitation by the industry. Even then, significant federal and state action will be essential to level the playing field.

The Risks Associated with Rising Drug Costs

At stake in this struggle are lives, livelihoods and the financial sustainability of employer-sponsored health care coverage. One-in-four Americans have been forced to put their health at risk by skipping prescribed medications due to costs, and researchers predict that if current drug price trends continue, more than 100,000 people will die each year over the next decade due to cost-related, non-adherence to drug therapy.

Financially, rising drug costs and the increasing health insurance premiums they help drive represent a hidden tax on employees and their families: Growing premiums eat up a greater percentage of total compensation to <u>reduce</u> take-home pay and also constrain <u>wage increases</u>.

For employers and public purchasers, the costs of providing health benefits are fast becoming untenable: A recent survey of leaders at 300 of the country's largest employers found that nearly 90% believe the costs of providing health insurance will become unsustainable within five-to-10 years. In the near term, rising health care costs make it more difficult to sustain the kind of employee benefits that can help companies recruit and retain top talent in a volatile and unforgiving labor market.

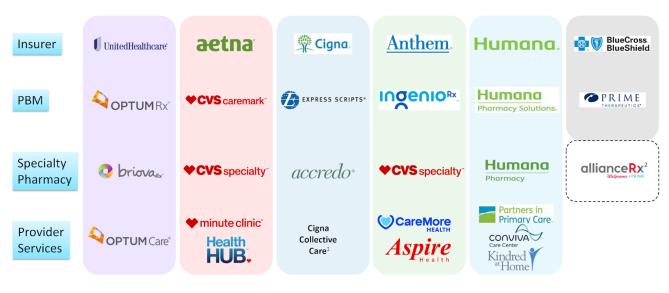


Shrouded in Secrecy and Complexity — and Now Insurer Owned

PBMs' market power has been sustained by their position in the care ecosystem and by the layers of secrecy and complexity they've imposed to mask strategies that pull revenue from each point in the supply chain. As drug prices continue to rise, those practices have become more visible, sparking mounting stakeholder resistance and new political momentum behind legislative and regulatory reforms at both the state and federal levels.

But even as PBMs confront growing scrutiny, their business models continue to evolve to preserve unimpeded revenue extraction from drug manufacturers, pharmacies, employers, public purchasers and patients. At the same time, large-scale vertical integration and other business arrangements make already-insufficient regulation and oversight even more ineffective while expanding the avenues available for financial gain.

Today, the three largest PBMs — CVS Caremark, Express Scripts and OptumRx — account for nearly 80% of U.S. market share. All three are integrated with the country's largest health insurers (Aetna, Cigna and UnitedHealthcare, respectively), as well as affiliated pharmacies and provider organizations. The growing marketshare of PBMs and their insurer parents raises fundamental questions about conflicts-of-interest, given that it increases their collective influence in determining where patients receive care, which drugs they can access, how much they pay and where their prescriptions are filled. Consolidation and lack of transparency also makes it even more difficult for employers and public purchasers to fulfill their fiduciary obligations of monitoring health care purchases, performance and reasonableness of fees.



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AllianceRx Walgreens Prime is jointly owned by Prime Therapeutics and Walgreens Boots Alliance.
Source: Drug Channels Institute research; <u>The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers</u>, Chapter 5.



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Absence of Transparency

At the core of the largest PBMs' ability to continue exerting enormous influence over the drug supply chain — and therefore billions of dollars from employers, public purchasers and other entities that pay for health care — is the industry's major defining feature: An absence of transparency.

Contracts with large purchasers typically do not provide details about fee or rebate schedules or amounts, prices, fees generated from manufacturers and other parties, drug definition criteria, or amounts charged to pharmacies. This dearth of information can make it impossible to determine if the PBM is acting in the purchasers' and employees' best interest and likewise makes comparing PBMs virtually impossible. PBMs' control over information extends to employer efforts to clarify or enforce contract compliance: Some contracts prohibit employers and public purchasers from auditing the PBM they're contracting with or alternatively, require that a PBM-designated auditor be used. It is difficult, if not impossible, to identify other vendors of purchased services in any supply chain that prohibit auditing and accountability.

Employers, public purchasers and patients confront a similar information vacuum when it comes to clinical information. Clinical efficacy is a top consideration for purchasers seeking to improve and maintain employee health. Yet PBMs are not required to disclose the clinical evidence used to support their decisions about which drugs they make available through a benefit plan or why some drugs are excluded or dropped. For patients, the result can be uncertainty, anxiety and growing difficulty maintaining their treatments.

And until the practice was banned by Congress in 2018, PBMs could impose gag clauses that prohibited pharmacies from informing patients if a drug costs less when paid for out-of-pocket versus processing through insurance.

If there's any good news, it's that federal and state transparency laws and regulations are finally forcing health care organizations, including PBMs, to provide access to price data – critical, long-withheld information that employers need to shop for, and monitor, health care services. For employers and public purchasers, access to this information is more important than ever, given their recently expanded legal responsibilities as employee health plan fiduciaries.

Understanding the Complex Matrix of Profit Centers and Access Restrictions

In light of these new fiduciary obligations, it is vital that employers and public purchasers work together to mitigate PBM abuses and ensure their beneficiaries have access to affordable medications. Central to this task is developing a clear understanding of the innumerable ways in which PBMs act against the interests of employers, public purchasers and employees.

Admittedly, PBM operations can seem impenetrable. They are profoundly opaque by design. But deconstructing the interrelated stratagems PBMs use to exert influence over the supply chain and maximize revenue is essential to understanding how distorted and inflated the pharmaceutical benefits market has become. The following list highlights some of the most frequent behaviors and practices PBMs use to limit drug access and drive up costs.

1. Drug Rebates

Rebates, or fees paid by the drug manufacturer to the PBM, have long formed an important pillar of PBM profitability. With control over large insured populations, PBMs can leverage their size and influence over the drugs made available through employer health benefits plans to win significant price concessions from drug manufacturers. In short, if drug companies won't play ball with the PBMs, they can be shut out of billions of dollars of business. Manufacturer discounts take the form of price rebates, which can make up to $\frac{40\%}{100}$ or more of a drug's manufacturer price.

At least one <u>study</u> has shown a direct link between rising rebates and increasing drug prices. Using data on 1,300 U.S. branded prescription drugs that accounted for 84% of branded drug sales between 2015 and 2018, researchers calculated that, on average, a \$1 increase in rebates was associated with a \$1.17 increase in drug prices.

PBMs claim to work on behalf of purchasers and their employees in keeping drug costs down. But the reality is they're entirely incentivized to include the highest-priced drugs in their formularies, since both manufacturer rebates, as well as the administrative fees they charge large employers and public purchasers, are calculated as a percentage of the drug's price.

Patient deductibles and co-insurance likewise are tied to drug manufacturers' prices, so one might assume higher rebates translate into lower prices for patients. But the opposite has historically been true. That means higher rebates have resulted in ever-greater out-of-pocket costs for patients — and additional revenue for the PBM. Between 1987 and 2018, patient's real out-of-pocket costs increased 222% and today, it's estimated that more than a quarter of consumer's prescription costs are due to rebates alone.

So dependent are PBMs on high prices and the rebates they generate that at least one company requires significant advanced notice (up to two years) if a drug manufacturer plans to reduce a product's price. Failure to provide the notice can result in the PBM requiring the manufacturer to continue paying the PBM rebates based on the higher price.

In the face of growing pressure to pass through rebate monies, PBMs' business models are evolving to boost revenue from other sources. Chief among these are new and higher fees paid by drug manufacturers (over and above rebates), pharmacies and other supply chain entities.

2. Growing Service Fees

Manufacturer rebate revenue, coupled with fees charged to employers and public purchasers for administrative services, remains important to the PBM business model. But as awareness has grown about the extent to which PBMs have manipulated and exploited rebates, so too have demands that employers and public purchasers receive all, and not just a percentage, of negotiated rebates. Before 2018, less than 50% of Express Scripts' commercial clients received all negotiated rebates; by 2021, the portion of commercial clients receiving a full rebate pass-through had increased to 75%.

In the face of growing pressure to pass through rebate monies, PBMs' business models are evolving to boost revenue from other sources. Chief among these are new and higher fees paid by drug manufacturers (over and above rebates), pharmacies and other supply chain entities. For instance, PBMs charge manufacturers for administering, invoicing, allocating and collecting rebates. Other examples of charges include fees for "maintenance and operations of the systems," "access to drug utilization data" and "medication education, medication monitoring, data management."

PBMs' shift toward a fee-based business model is reflected in a recent <u>analysis</u> of PBMs' sources of profit. In 2017, retained rebates contributed \$4.04 billion to gross profit, while manufacturer administrative fees accounted for \$3.7 billion. By 2019, the numbers had flipped: rebates' contributions to gross profit had fallen 61%, to \$1.56 billion, but manufacturer administrative fees had climbed 51% to \$5.71 billion. Total profits, which included affiliated mail order and specialty pharmacies as well other sources, totaled \$28.05 billion in 2019, up from \$25.15 billion in 2017.

Employers and public purchasers likewise have been subjected to a growing array of service fees, including per-prescription and/or per-member transaction fees, as well as formula compliance, price protection, data warehousing and other fees.

3. Adding Layers of Middlemen

Tellingly, PBMs' falling rebate revenue has been accompanied by an apparently related development: The creation of group purchasing organizations (GPOs), or rebate contracting or aggregator entities, by the big-three PBMs. Although little public information currently is available about these businesses, they're ostensibly charged with negotiating manufacturer drug prices and rebates, collecting rebates and disbursing them to clients on behalf of PBMs and their insurer parents.

But with control of more than 265 million lives, the GPOs are ideally positioned to squeeze additional fees from drug manufacturers to support PBMs' growing reliance on non-rebate revenue. Those manufacturers that balk can lose access to tens of millions of potential customers. The net result is yet another set of middlemen and continually higher drug costs.

Creating quasi-independent, parallel entities also increases the opacity surrounding rebates and fee structures and makes it more difficult for employers, public purchasers and even manufacturers to track and monitor performance. Significantly, two of the big-three GPOs were established outside the U.S. (Express Script's Ascent Health Services in Switzerland in 2019 and OptumRx's Emisar Pharma Services in Ireland in 2021), a fact which will likely make regulatory and employer oversight more difficult.

4. Excluding Access to Needed Medications

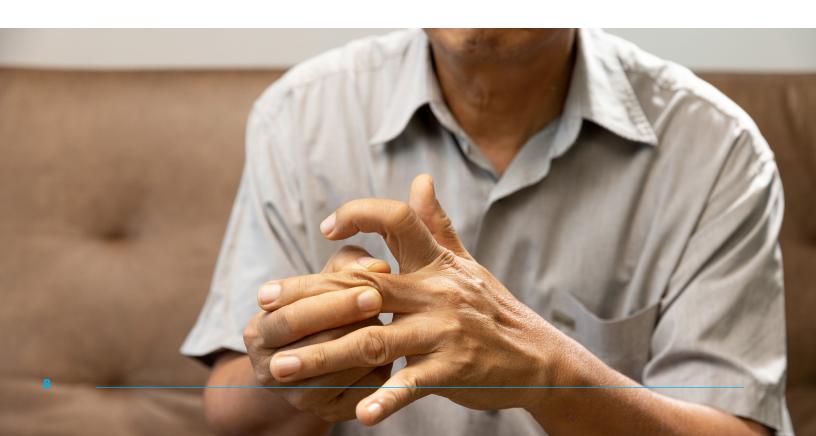
Given PBMs' need to keep drug prices high, manufacturers of lower-cost medications run the risk of being excluded from employer, public purchaser and insurer formularies and effectively locked out of the market. This phenomenon has negative implications for patient access, care quality and cost, and it continues to accelerate: The three largest PBMs placed a total of 1,156 unique medicines on their formulary exclusion lists in 2022, up from 850 drugs in 2020 and just 109 in 2014.

Historically, PBMs have excluded medicines with generic equivalents or from classes of drugs in which multiple products achieve similar clinical outcomes. But increasingly they're excluding a range of important chronic disease medications. These include "medicines for conditions where it is particularly important for patients and physician to have multiple treatment options, such as oncology and autoimmune disorders," according to an industry report by AmerisourceBergen, a pharmaceutical wholesaler. The report goes on to say that rising rates of excluding medications designed to treat complex conditions "raise potentially serious concerns about quality of care."

One prominent example of exclusions involves biosimilars, a relatively new class of drug often used to address chronic and debilitating diseases, such as Crohn's and ulcerative colitis. Biosimilars are essentially generic versions of biologic drugs, or medications made from living organisms. The first biosimilar was approved by the Food and Drug Administration in 2015 and today more than 20 are on the market in the U.S.

Although biosimilars have the same clinical properties as the previously approved biologics they mimic, they're typically from 10%-to-37% cheaper. Despite their value and efficacy, biosimilars are increasingly subjected to formulary exclusion in lieu of the more-costly — and profitable — biologics. OptumRx became the first of the big three PBMs to exclude biosimilars in 2018, followed by CVS Caremark and Express Scripts in 2019. In total, 14 biosimilars have been excluded by at least one or more PBM for at least one year.

A <u>study</u> that analyzed the impact on patients of 563 formulary exclusions imposed by Express Scripts in 2022 determined that close to half (46%) "had questionable clinical or financial benefits to patients, requiring prescribers to choose treatments that may have adverse financial or medical outcomes for their patients."



5. PBM-Controlled Pharmacies

Because the major PBMs own, or are affiliated with, retail, mail order and specialty pharmacies, they're frequently able to determine which drugs are available and how much they'll cost. They're also in a position to steer patients away from independent pharmacies and toward their own outlets. PBMs accomplish this by establishing preferred pharmacy networks that promise patients lower out-of-pocket costs versus out-of-network competitors. Today, about 97% of Part D prescription drug plans and 66% of Medicare Advantage prescription drug plans have adopted preferred pharmacy networks.

PBMs exert additional financial pressure on non-aligned pharmacies by ratcheting down reimbursement rates and by imposing an assortment of fees collectively referred to as direct and indirect renumeration (DIR) fees. Exploiting a loophole in Medicare regulations, PBMs can claw back fees against money already paid to the pharmacy for filling Medicare prescriptions, often months after the transaction is complete. DIR can be described by the PBM as fees for network access, administrative services, reconciliation and quality measure performance.

Not unlike many of the fees PBMs charge manufacturers, employers and public purchasers, pharmacy fees can be arbitrary, ever-changing, opaque and beyond the pharmacy's control. According to the Centers for Medicare and Medicaid Services (CMS) use of DIR fees shot up more than 100,000% between 2010 and 2020. Not coincidently, that period coincides with mounting pressure on PBMs to pass through manufacturer rebate revenue to employers.

One consequence of PBMs' expanding pharmacy market share has been increased closures of independent community pharmacies. According to one <u>study</u>, one in eight pharmacies closed between 2009 and 2015, with independent pharmacies in low income neighborhoods disproportionately affected. Closures were twice as likely to occur in those areas. All told, about a quarter of pharmacies in low-income neighborhoods closed between 2009 and 2015.

Closures have also had a major impact on rural populations. A 2018 <u>study</u> found that 1,231 of the nation's 7,624 independent rural pharmacies, about 16% of the total, closed between 2003 and 2018, leaving 630 communities effectively pharmacy deserts with no independent or retail drug stores.

Patient health can be affected when local community drug stores close. A 2019 <u>study</u>, the first to examine the relationship between health and pharmacy closures, determined that closures "are associated with persistent and clinically significant declines in adherence to cardiovascular medications among older adults in the United States."

6. Spread Pricing

PBMs have routinely reimbursed retail pharmacies an amount lower than what they've charged the health plan or employer for the same medication, then pocketed the difference. This arrangement, known as spread pricing, relies on confidentiality clauses that make it difficult, if not impossible, for the employer to identify what pharmacies pay — and vice versa.

The strategy can be enormously profitable. In Ohio, state auditors determined that two PBMs charged the state's Medicaid program \$2.5 billion for generic and branded drugs but paid pharmacies \$2.3 billion, resulting in a spread margin of \$245 million during a one-year period. Similar schemes have been uncovered in a host of other state Medicaid programs, including Michigan (\$64 million in overcharges), Virginia (\$29 million), Maryland (\$72 million) and Kentucky (\$123 million). For commercially insured companies, no mechanism currently exists to uncover spread pricing. Hence, the margin any given employer may be paying over the amount actually charged to the pharmacy is unknown.

7. Non-Medical Decisions to Change Patient Treatments

An exclusion that unilaterally and without explanation forces a patient to shift from a successful, current medication to a drug that may be less effective but offers the PBM a higher rebate is known as non-medical switching. For patients on established drugs, the result of these sudden shifts can be treatment disruptions, new adverse side effects, severe allergic reactions, worsening symptoms and accelerating disease progression.

In a 2018 <u>survey</u> of patients who'd been subjected to non-medical switching, 70% reported decreased drug effectiveness, 86% had worse side effects and 48% had to try multiple medications before finding an alternative that worked after the switch. A separate physician <u>survey</u> found that most doctors had ethical concerns about non-medical switching, believed it negatively impacted care and increased their practice burden.

8. Dictating Medication Use with Utilization Management

PBMs exert additional access control through <u>utilization management</u> (UM), an array of treatment review strategies designed to influence or dictate drug usage, regardless of physician or patient preference. Chief among these is prior authorization, which requires providers to seek approval for a specific prescription by documenting that the medication is medically ecessary and/or is being prescribed in a manner consistent with the formulary's clinical requirements.

A 2021 <u>study</u> found that UM has increased in the commercial market for drugs used in a range of therapeutic areas, including cancer, mental health, autoimmune disorders and diabetes. As a result, the study noted, "providers treating patients with serious chronic conditions may experience increased administrative burdens associated with UM processes, and patients may experience delays in accessing prescribed medicines."

PBMs also impose step therapy, a form of UM that grants patients access to a specific formulary drug only after other alternatives have been tried and deemed unsuccessful. Also known as "fail first," this tactic can delay <u>patient access</u> to needed medication, potentially leading to uncontrolled symptoms, unchecked disease progression and emergency care. <u>Researchers</u> at Tufts University who studied the use of step therapies across 17 payers found wide variance in how the tactic is used: in more than half the cases (55%), step therapy protocols were more stringent than recommended clinical guidelines.



9. Copay Adjustment Programs

In an effort to defray rising costs, pharmaceutical manufacturers frequently offer copayment cards or coupons directly to patients to reduce or eliminate the patient's portion of the drug expense. The coupons typically are associated with costly specialty drugs.

In response, PBMs and payers have implemented initiatives that penalize coupon users as a means of increasing revenue collected from the patient. Specifically, copay adjuster programs prevent manufacturer coupons from counting toward a patient's annual out-of-pocket maximums. That means once the value of the coupon is exhausted, patients are required to cover the full amount of their annual out-of-pocket maximum before plan benefits can be accessed.

Copay adjuster programs can significantly <u>increase overall drug costs</u> for patients with complex conditions who are unable to switch to lower-cost, alternative drugs, and also boost spending for patients whose cost-sharing is based on a percentage of cost, rather than a fixed amount.





Momentum Building Around Reform Efforts

Growing recognition of the harm PBMs cause has triggered a wave of legislative activity and a growing recognition that a national solution is needed. Unlike health insurers, PBMs are largely unregulated and not subject to federal, industrywide rules.

As a result, many states have passed a patchwork of <u>laws</u> that attempt to impose reasonable regulation and oversight on PBM activities. Common elements or provisions include bans on pharmacy clawbacks, spread pricing, patient steering and pharmacy network restrictions. Many of the laws also require PBMs to pass through rebates to payers or patients, disclose price and cost information, and generally be subjected to more rigorous state compliance monitoring and enforcement.

The PBM industry had long contended that federal Employee Retirement Income Security Act (ERISA) and Medicare preemption laws precluded states from overseeing PBMs. But in 2020 the U.S. Supreme Court <u>ruled</u> otherwise and opened the door for some state action against PBMs. It nonetheless remains to be seen how aggressive and widespread enforcement actions will be, or what PBM workarounds may emerge in response to the array of differing state laws.

In the meantime, legislation has been proposed in the U.S. Senate to impose reforms at the federal level. The Pharmacy Benefit Manager Transparency Act of 2022 would create prohibitions on pharmacy clawbacks and spread pricing, as well as encourage PBMs to pass through rebates to plan sponsors and beneficiaries. Separately, the Federal Trade Commission launched an in-depth <u>investigation</u> into PBMs business practices in June 2022. The inquiry will scrutinize "the impact of vertically integrated pharmacy benefit managers on the access and affordability of prescription drugs," according to the agency.

Employer-Driven Solutions

Employers and public purchasers provide coverage for 155 million workers and their families, or about half of all Americans. As such, they have the market clout to collectively exert pressure and compel changes in PBM behavior. But doing so will require specialized PBM expertise, which many purchasers do not possess individually, as well as a set of consistent purchaser standards adopted and communicated by a critical mass of organizations. The Purchasers Business Group on Health is currently working to develop common standards and contract language that can help employers and public purchasers navigate PBM relationships and strengthen their negotiating capabilities.

Now or Never

The enormous financial resources available to PBMs, coupled with their entrenched position in the health care system, will make efforts to compel changes in their behavior difficult and slow. Yet a reluctance to implement meaningful reforms in the PBM industry today will, in future years, rightly be seen as an enormous missed opportunity and a tragic failure of will. It will cost lives, waste billions, and put organizations at growing risk for breach of their fiduciary responsibilities.

That's why employers and public purchasers must push for Congress and policymakers to act and eliminate the perverse aspects of the PBM business model. At a minimum, that effort should include:

- **1. Transparency and reporting requirements:** PBMs and their parent companies should be required to provide regular reporting to employers on costs, fees and total manufacturer revenue.
- **2. Prohibition or limits on spread pricing:** PBMs should not be allowed to charge employers, health plans or patients more for a drug than the PBM paid the pharmacy for that drug.
- 3. Transparency regarding PBM-owned pharmacies: PBMs should be required to submit information to group health plans sponsors regarding transactions between the PBM and any pharmacy wholly or partially owned, including mail-order, specialty and retail pharmacies, by the PBM.
- 4. Pass-through of rebates: PBMs should be required to pass on 100% of all rebates and volume or access-based administrative fees to employers and plan sponsors. Currently, manufacturer revenue is paid to the Group Purchasing Organization and the GPO contracts with the PBM. Policy language must be sufficiently expansive to impact the new legal entities being created by PBMs with the goal of shielding the PBM legal entity from transparency and regulation.
- **5. Definition and regulation of bona fide service fees:** PBMs should be required to disclose the fees they receive from drug manufacturers for nonspecific services affecting plan design and costs to employers and patients.
- **6. Establishment of clear regulatory oversight for PBMs:** PBMs should be subject to federal and/or state regulation similar to the oversight of health insurance plans and employers. This should include consideration of extending ERISA fiduciary responsibilities to PBMs.

Only by aligning around common goals will it be possible for employers and public purchasers to take back control of drug expenditures and in so doing, help ensure the good health and financial well-being of both their organizations and employees for years to come.

