Pharmacy Benefit Management Misalignment

VENDOR ENGAGEMENT TEMPLATE

National Alliance of Healthcare Purchaser Coalitions
Driving Health, Equity and Value

Introduction

Employers are facing increasing challenges in managing rising prescription drug spending, particularly in their relationships with pharmacy benefit managers (PBMs). These intermediaries have come under intense scrutiny due to concerns about their business practices, which are contributing to high costs and access barriers for patients. Legislative efforts, investigations, and ongoing litigation are pushing for reforms that could reshape how PBMs operate, with the aim of improving patient experiences and reducing out-of-pocket costs.

As the pharmacy benefit industry undergoes its most significant transformation in decades, ***employers are at the forefront of driving change.*** The actions they take now—whether through renegotiating PBM contracts, complying with evolving regulations like the Consolidated Appropriations Act (CAA), or implementing advanced data analysis to track costs and employee impact—will play a pivotal role in shaping the future of prescription drug management and determining financial and clinical outcomes.

Employers are also dealing with newer challenges posed by high-cost specialty drugs, biosimilars, and innovative therapies like cell and gene therapies. Balancing these cutting-edge medical advancements with the practical realities of affordability and patient access is a growing concern. Many employers are exploring strategies such as reimagining formulary design, evaluating PBM proposals, considering alternative funding models, and analyzing claims to address rising drug costs and high-cost claims.

To navigate these complexities, some employers are turning to real-world examples and best practices shared by their peers. Through participation in structured workshops and discussions, employers are being provided with valuable insights into how plan sponsors are addressing these challenges.

This PBM Vendor Engagement Template (VET) offers a roadmap for employers as they engage with potential PBM vendors. It includes a summary of high-priority topics raised by employers and provides actionable recommendations to guide employers as they select a PBM partner. The VET includes sample questions for PBM vendors on key topics, along with optimal answers.

National Alliance Companion Resources:

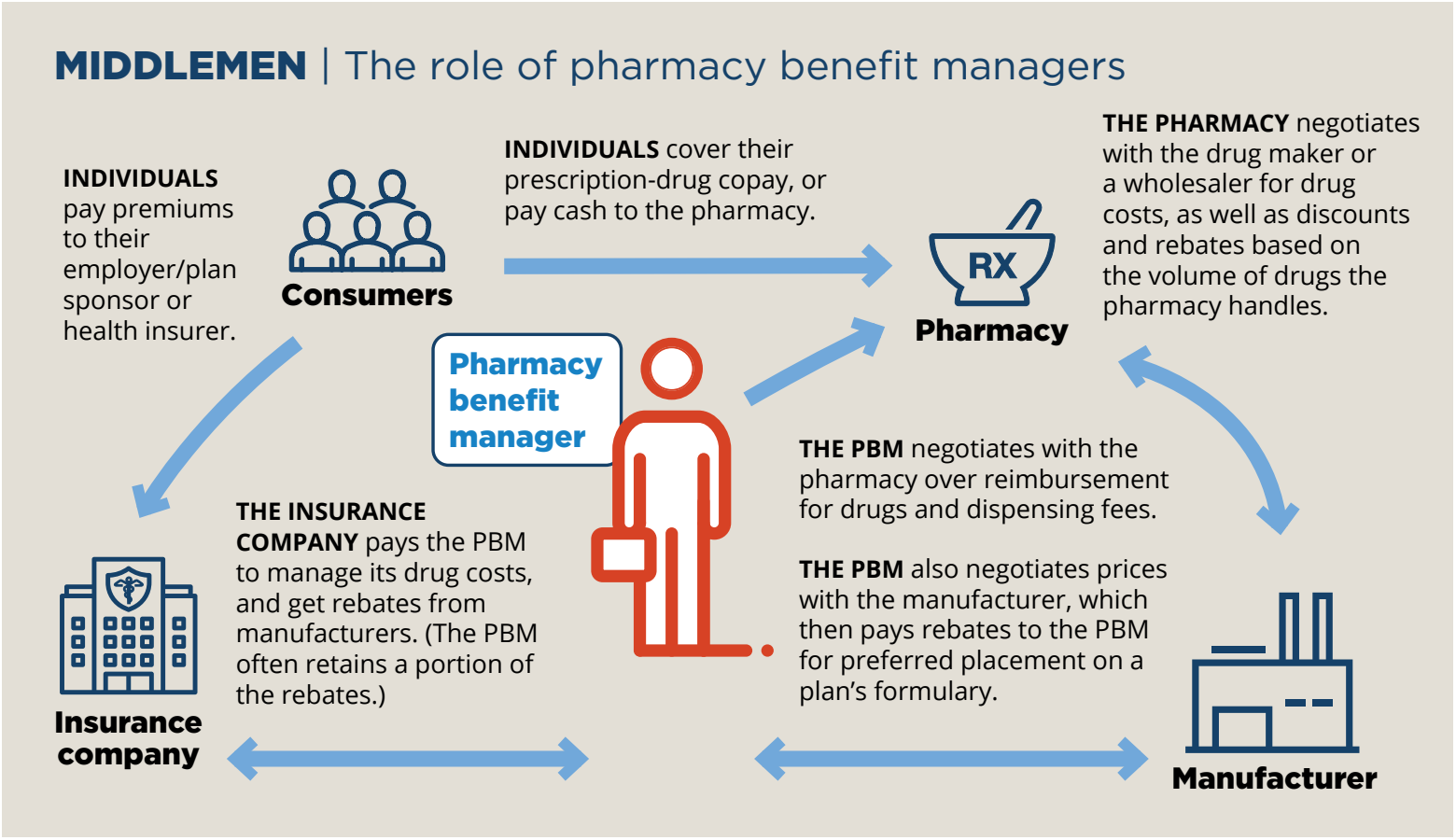
A Playbook for Employers: Addressing Pharmacy Benefit Management Misalignment

Time to Act: Understanding PBM Practices Enables Employers to Ignite Change

Employers Beware: Alternative Funding Programs Require Careful Review to Avoid Negative Consequences

Employer Playbook on Biosimilars

Understanding the Role of PBMs in the Pharmaceutical Supply Chain



Source: Avalere Health LLC

Vendor Options

Evaluating and comparing proposals from the "Big 3" vs. other PBMS

Selecting the appropriate PBM vendor can lead to better cost management, compliance, and improved employee health outcomes. Prior to conducting interviews with prospective vendors, employers can engage in multiple activities to achieve more constructive, fit-for-purpose interactions with potential PBM partners.

Rather than optimizing drug value and creating an efficient marketplace, the PBM industry has fueled a flawed contracting model and unprecedented market consolidation. Three PBMs (CVS Caremark, Express Scripts, OptumRx) now control over 80% of the market. Consolidation has led to power concentration that undercuts economic benefits for employers/purchasers and consumers.

Prior to conducting PBM vendor interviews, lay the groundwork:

1. **Create a decision-making committee.** Create an independent healthcare committee (include member representation and non-benefits members) for decision-making.

2. **Develop a scorecard**. Create a scorecard for decision-making and use it to document all metrics and scoring before final decisions.
   - 2.1. Develop scores that are qualitative and weight those more heavily than financial metrics. Do not prioritize "false savings estimates" over true value. Value is measured on outcomes, not promises.
   - 2.2. Separate financial metrics into unit costs, projected costs, and projected savings. Weight unit costs (true prices and charges) more heavily than "projected" values as many of these never materialize at the end of the plan year.
   - 2.3 Assess current performance against these standards.

3. **Develop your "ask" of potential vendors.** Rebates are not savings — treat them as projected values, not real numbers. Ask for...
   - ▶ Rebates to be presented by drug name, not therapy class.
   - ▶ Unit prices, not discounts.
   - ▶ Benchmarking values from existing customer-paid prices.
   - ▶ Cash prices from public sources.
   - ▶ Evidence that savings were achieved for other customers and get names/phone numbers to check references.
   - ▶ Trend guarantees, not savings guarantees, which can be manipulated.

Essential Requirements for a PBM

Describe the importance of vendor interviews in selecting an appropriate PBM. Asking vendors about how they meet standard requirements, allow for claims auditing, and structure their formularies can guide more constructive interviews and advance improved alignment between employer health benefit goals and their PBM.

Due to the heightened fiduciary responsibilities of self-insured employers, it's essential for them to understand and ensure that a fair price is being paid for the benefit of plan participants and beneficiaries. For example, they must know what is paid to pharmacies/providers and what revenue is collected by their PBM; whether there is appropriate utilization relative to industry benchmarks and best practices; if drug prices are reasonable within each channel; and whether compensation to all plan vendors is appropriate.

To achieve better alignment with a PBM, employers should ask questions to gauge if the vendor meets essential requirements related to transparency, data sharing, pharmacy networks, and fees.

Vendor Questions	Sample Responses
1. What specific rights do we have regarding access to data and conducting audits on our pharmacy benefit plan?	Your organization will have ownership rights to all data elements created during administration. You may obtain any data at any time with no cost assessment. You also have the right to conduct an audit at any time with any service provider without restrictions on scope of audited data or information.
2. What is your approach to conducting price benchmarking for our pharmacy benefit plan to ensure competitive pricing?	We conduct periodic (e.g., monthly) price benchmarking of net prices against multiple benchmarks (AWP/NADAC/cash price).
3. How do you conduct fee benchmarking for our pharmacy benefit plan to ensure fees are reasonable and competitive?	We disclose fee ranges for service providers to be supplied by your consultant/broker. Fee ranges for services are provided at the discrete service level, not aggregate PMPM/PMPY. Fee benchmarking is conducted annually.
4. What are your practices regarding the management and distribution of credits, incentives, and rebates within the pharmacy benefit plan?	We disclose all credits, incentives, and rebates provided to the PBM from pharma for any and all drug purchases conducted on behalf of your health plan. We also disclose all values at the drug level, not in aggregate or by drug class/therapy class.

5. Do your contracts include any exit penalties or provisions? If so, outline the conditions under which they would apply and how they are structured.	We do not assess a financial penalty for early termination and require only 1–2-year contracts, not "evergreen renewable" or 3+ year term agreements. We work closely with clients to ensure that the terms are fully transparent upfront. If a client needs to exit the agreement, we ensure there are no unexpected penalties, and we provide a clear process to facilitate the transition to a new PBM or plan structure, minimizing any disruption to employees.
6. How do you ensure the level of integrity and long-term sustainability of your pharmacy network?	We include independent pharmacies in the network and follow the CMS "Any Willing Provider" rule. We also require dispensing fees for all pharmacies to be at parity with what the PBM pays itself and we disclose those fees.

Audits

Top 10 Audit Questions

In seeking ways to keep expenses under control, employers/purchasers may overlook the value of claims auditing. To ensure that PBMs are complying with contract terms, managing trends, and delivering the expected claims processing and quality of service, plan sponsors must conduct routine pharmacy benefit claims audits.

Generally, employers/purchasers should not rely on their service providers to create attestation documentation. As fiduciaries, ***employers are accountable for ALL requirements of the CAA***. One of the most overlooked requirements is the calculation of how much non-transparent financial payments have or will impact employee premiums. Employers must conduct a financial impact analysis after all gag clauses are removed from contracts, all audits are complete, and all financial payments to PBMs are disclosed.

Vendor Questions	Sample Responses
1. What are all the credits, incentives, and fees collected from third parties for the purchase of products, drugs, devices, and any other supplies required to administer the pharmacy benefit?	We disclose those at the drug level. No-cost audits are available upon request.
2. What services or supports involve contracted third parties (e.g., drug manufacturers, providers, wholesalers, distributors, pharmacies)?	We can provide you with a list of partners that will be providing support to administer your plan. **Please note:** Employers may encounter some resistance when requesting details of third-party agreements, which may be considered proprietary.
3. Who are the members of your pharmacy and therapeutics (P&T) committee? What are their education and clinical training backgrounds? How are they compensated? How long do they serve? How do you ensure there are no conflicts of interest?	We provide a copy of all resumes and biographies, including how members are credentialed. We select our members through _____ process and each serves a term of _____. They are not compensated for their service on the committee. Due diligence processes ensure independence of advice and disclosure of any conflicts of interest (e.g., employment by business partners; payments from manufacturers…). **Note:** Some vendors may apply an additional fee.

Vendor Questions	Sample Responses
4. Will you disclose all data elements in claim records, including all financial transaction data, for analysis?	Yes, we routinely disclose upon request.
5. How often do you conduct a fraud, waste, and abuse audit to investigate improper, duplicate, fraudulent, or otherwise suspicious payments to any recipient?	We conduct audits and perform assessments of our provider network annually and take action on any findings of fraud or misappropriation of funds. **Please note:** Some vendors may apply an additional fee when conducting a custom audit on a plan's network and experience.
6. Do you also conduct a spot audit of prior authorization processes and review blinded samples of clinical documentation to assure compliance with plan guidance and appropriate clinical protocols?	We engage an independent third party to conduct audits of our prior authorizations to ensure adherence to clinical guidelines and the prevention of adverse patient outcomes.
7. Do you compare financial data and pricing to publicly available pricing data (e.g., cash prices) to determine reasonableness of payments?	Part of our routine practice is to compare financial data to determine reasonable payments. For example...
8. Do you compare drug pricing and payments between the medical and pharmacy benefit to determine whether facilities are overcharging for similar products?	Yes, this is baked into our audit processes, and we use ingredient costs whenever possible.
9. Will you conduct a deep dive on high-cost claims involving the most expensive drugs?	We use the top 50 highest unit price or the top spend drugs to determine which ones are high cost and provide that in our monthly reports.
10. Will you provide a copy of the formulary and how decisions are made for drug placement in tiers?	Yes, and decisions for formulary placement are made based on clinical criteria or financial criteria. We will also provide our related policies and procedures.

Special Coverage

Biosimilars

The broader acceptance and use of biosimilars—lower-cost versions of patented and branded drugs—by employers and other healthcare purchasers are key to preserving economic competition in the marketplace. PBMs can help support plan sponsors in adopting biosimilars into their health and pharmacy benefit plans.

Vendor Questions	Sample Responses
1. How will you help us improve biosimilar adoption?	We understand that biosimilars are an important component to lowering brand-name drug costs. We offer biosimilars "preferred" on the formulary with the originator product.

The rapidly evolving biosimilars market can be confusing. Check out the "National Alliance Employer Playbook on Biosimilars" to learn more. This helpful "Where do I Start?" graphic is found on page 13.

340B Drug Pricing

The 340B Drug Pricing Program is a US federal government program that requires drug manufacturers to provide deeply discounted outpatient drugs to qualifying hospitals and clinics that treat low-income and uninsured patients. The program designed to serve these patients instead enriches intermediaries across the supply chain, adding costs for purchasers and patients. In fact, hospitals charged commercial insurers and uninsured patients nearly five times what they paid to acquire oncology medicines through 340B.

Source: Community Oncology Alliance

Vendor Questions	Sample Responses
1. Should we be asking for 340B pricing?	Employers, in general, should not be receiving blanket 340B pricing on their claims. This program is intended for underserved people and those with incomes below the federal poverty threshold. Some hospitals and their contract pharmacies and PBMs are exploiting 340B regulations to offer these prices to employers to entice them for business. Because the federal government is investigating these entities and they are considering tightening the legislation, we steer clients away from this to avoid unnecessary litigation risk.


Flawed 340B Program Raises Costs for Employers and Working Families

From a small program intended to support safety-net providers, the 340B drug pricing program has grown exponentially into a massive arbitrage opportunity for corporate healthcare systems to drive up costs systemwide without meaningfully benefiting the vulnerable communities it was intended to serve.

Corporate healthcare systems have increasingly taken advantage of this to the point that today, 340B is the second-largest federal drug program behind Medicare Part D.[1]

Total Discounted 340B Purchases (2005–2023)[2,3]

$66.3B
$5.3B
$2.4B
2005
2010
2023

5.4× the average markup found by a state treasury to oncology drugs billed to the state health plan—averaging profits of $6,026 per claim.[4]

$5.2B cost of 340B to employers in lost rebates alone.[4]

STRUCTURAL FACTORS IN 340B COST EMPLOYERS BILLIONS

The 340B program allows participating hospitals to "buy low and sell high," purchasing medicines at a steep discount while charging patients with insurance full price—resulting in profits at the expense of employers and working families and creating significant distortive effects across the market.

Health System Consolidation: Corporate healthcare systems can increase their 340B spread by acquiring smaller, non-340B hospitals or independent physician practices. It is well-documented that consolidation does not improve health outcomes, reduces access, and leads to higher costs of care.[5]

Explosion of Pharmacy Networks: 340B hospitals can contract with networks of external retail and mail-order pharmacies. Today, hospitals average dozens of pharmacy locations, often located in wealthy areas to maximize 340B spreads. These pharmacy arrangements are not only lining the pockets of corporate hospitals, but of large PBMs.[5]

Incentives to Prescribe Higher-Cost Drugs: 340B's structure encourages the prescribing of higher-priced medicines to maximize the spread, rather than lower-cost biosimilars that might be equally effective.[6]

COMPREHENSIVE 340B REFORM IS NEEDED

Given the tremendous burden that the 340B program places on working families' paychecks and employers' bottom lines, the federal government must rein in the program's unchecked expansion. Real reform would include provisions that improve transparency to ensure that bad actors are not abusing the program and refocus benefits on low-income patients while ensuring that working families and employers don't see increased health care costs.

National Alliance of Healthcare Purchaser Coalitions

The National Alliance is dedicated to tackling the high costs of healthcare that employers and working families face, in part due to the exploitation of the 340B program. Click here to learn how the National Alliance is engaging with policymakers to provide insights on the 340B program, its impact on escalating healthcare expenses for working families and employers, and potential areas for reform.

Formularies and Dispensing

Tiering formulary drugs

In many cases, generic medications offer a much cheaper cash price. In these cases, employers may consider carving them out our their benefit plans and letting employees shop for the lowest out-of-pocket expense.

Vendor Questions	Sample Responses
1. Which drugs should be in tier one?	Tier one drugs are typically generics, but it is also where we place biosimilars as a preferred first line option to the originator drug (formerly patented/branded).
2. Which drugs are in tier two?	Tier 2 drugs are typically branded (patented products) but some PBMs prioritize based on rebate contracts. This can artificially increase the unit price of the product to fund the rebate (which is paid back later). We can provide a list of the branded drugs on our formulary as well as what our rebate expectations are and what projected rebate payments would be back to you as a plan sponsor. **Please note:** Rebates are not savings — treat them as projected values, not real numbers. (See details on number 3, Page 4.)
3. Which drugs land in tier three or four?	Specialty drugs are typically placed on tier 3 or 4 depending on whether the employer has a preferred list or is using a standard formulary. We will help develop a custom formulary.
4. How do you evaluate the appropriateness of your medication management approach (e.g., formulary, step edits...)?	Regular assessment of the medication management approach should align with evidence-based practices (this includes regular review of formulary, step therapy edits, and other medication management strategies to ensure they align with the latest clinical guidelines for particular conditions). Patient experience and outcomes should be continuously evaluated through feedback and outcome assessments, helping optimize strategies for effective and appropriate care.

Excess Supply and Early Dispensing

To maximize revenue, PBMs often take advantage of the early refill threshold, typically set in the 70%–75% range. Dispensing an excess supply (more days than necessary) for mail-order prescriptions allows them to bill for 90 days when it's not needed. This excess supply is wasteful and leads to unnecessary cost.

Vendor Questions	Sample Responses
1. What is your practice around excess supply and early dispensing?	We restrict such practices in our contract to mitigate wasteful practices.

Site of Care Management

Many new drugs are either injectable or infusible but having them administered in a hospital setting can cost more than double what clinics, home health care, and infusion centers charge.

Vendor Questions	Sample Responses
1. How do you ensure clinically appropriate, lowest cost site of care?	While use of hospital infusion sites is sometimes necessary, we steer patients to lower-cost, safe, and effective alternatives whenever possible.

Addendum

CAA Brief

The Consolidated Appropriations Act of 2021 (CAA), which amended ERISA, is the most significant regulatory challenge for employers since the 2009 enactment of the Affordable Care Act.

One new requirement is of particular importance: Employers and other purchasers must now focus more on the quality of care employees and their families receive. Several prominent compliance lawsuits have been filed, and the Department of Labor issued key long-awaited new guidance that sets the stage for new enforcement on February 23, 2023.

The statute provides that data shall be reported not later than one year after the date the CAA was enacted, and not later than June 1 of each year thereafter.

The data submission required under section 9825(a) of the Code, section 725(a) of ERISA, and section 2799A-10(a) of the PHS Act (section 204 data submissions) includes:

- **General information on the plan or coverage**, such as the beginning and end dates of the plan year, the number of participants, beneficiaries, or enrollees, as applicable, and each state in which the plan or coverage is offered.
- Plans and issuers must also report the **50 most frequently dispensed brand prescription drugs**, and the total number of paid claims for each such drug; the 50 most costly prescription drugs by total annual spending, and the annual amount spent by the plan or coverage for each such drug; and the 50 prescription drugs with the greatest increase in plan or coverage expenditures from the plan year preceding the plan year that is the subject of the report, and, for each such drug, the change in amounts expended by the plan or coverage in each such plan year (top 50 lists).

Additionally, plans and issuers must report:

- **Total spending on healthcare services by the plan or coverage broken down by the type of costs** (including hospital costs; healthcare provider and clinical service costs, for primary care and specialty care separately; costs for prescription drugs; and other medical costs, including wellness services).
- **Spending on prescription drugs by the plan or coverage as well as by participants**, beneficiaries, and enrollees, as applicable; and the average monthly premiums paid by participants, beneficiaries, and enrollees and paid by employers on behalf of participants, beneficiaries, and enrollees, as applicable.
- Plans and issuers must report any **impact on premiums by rebates, fees, and any other remuneration** paid by drug manufacturers to the plan or coverage or its administrators or service providers, including the amount paid with respect to each therapeutic class of drugs and for each of the 25 drugs that yielded the highest amounts of rebates and other remuneration under the plan or coverage from drug manufacturers during the plan year (top 25 list).
- Finally, plans and issuers must report any **reduction in premiums and out-of-pocket costs** associated with these rebates, fees, or other remuneration.

The departments intend to provide greater technical detail regarding each data element in the section 204 data submission in the instructions for the information collection instrument. The Departments also intend to provide an internet portal where reporting entities can submit the required data. On July 9, 2021, President Biden issued Executive Order 14036, "Promoting Competition in the American Economy." Executive Order 14036 directed the federal government to

"enforce the antitrust laws to combat the excessive concentration of industry, the abuses of market power, and the harmful effects of monopoly and monopsony."

The data collection required by these interim final rules will provide valuable information about competition and market concentration in the pharmaceutical and health care industries. Policymakers can use the prescription drug and healthcare spending data to make informed decisions in support of the goals of Executive Order 14036, including identifying any excessive pricing of prescription drugs driven by industry concentration and monopolistic behaviors, promoting the use of lower-cost generic drugs, and addressing the impact of pharmaceutical manufacturer rebates, fees, and other remuneration on prescription drug prices and on plan, issuer, and consumer costs.

Section 9825(a)(7) of the Code, section 725(a)(7) of ERISA, and section 2799A-10(a)(7) of the PHS Act require plans and issuers to report the total annual spending on health care services, broken down by the types of cost, including: (1) Hospital costs; (2) healthcare provider and clinical service costs, for primary care and specialty care separately; (3) costs for prescription drugs; and (4) other medical costs, including wellness services. For prescription drug spending, plans and issuers must report separately the costs incurred by the plan or coverage and the costs incurred by participants, beneficiaries, and enrollees, as applicable. The provisions related to these requirements are being codified at 26 CFR 54.9825-6T(b)(4) through (5), 29 CFR 2590.725-4(b)(4) through (5), and 45 CFR 149.740(b)(4) through (5).

Health Equity/Mental Health

When employers seek to improve behavioral health access and ensure health equity in PBM strategies, it's important to consider a few key elements. A recent report on ongoing reforms spotlights several issues within PBM practices that align with the National Alliance publication, "Addressing Pharmacy Benefit Management Misalignment." Content includes information about what is contributing to disparities in access to care, particularly in racially, ethnically, and culturally diverse communities.

The market concentration of PBMs, combined with their integration with insurers and pharmacies, often leads to employees facing restricted access and higher out-of-pocket costs. These challenges exacerbate the divide between those who can access mental care and those who cannot, contributing to longstanding disparities.

To ensure health equity is prioritized in behavioral health drug management, employers should evaluate a PBM vendor's commitment to health equity and expect responses that reflect a commitment to transparency and fairness. Based on National Alliance advocacy efforts for PBM reform. Here are some key points to expect:

1. Clear explanations regarding pricing methodologies, the flow of rebates, and affiliations between PBMs and pharmacies. Vendors must be willing to disclose how drug pricing and formulary decisions are made, ensuring these do not disproportionately affect minority populations.
2. Actively preventing self-preferencing and ensure that patients have access to a broad array of pharmacies, including independent ones, to increase affordability and options.
3. Ability to demonstration efforts to address healthcare disparities by ensuring that medications, especially those for behavioral health, are accessible to all employees, regardless of socioeconomic status or geographic location.

Without taking these steps, the PBM system and practices will continue to disadvantage employees, particularly those from underserved communities, by continuing to widen the gap in healthcare access and affordability. Employers have an important role as an advocate for a more equitable and just PBM system that is inclusive and works in the best interest of the patients it serves.

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National Alliance
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Driving Health, Equity and Value

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