A Playbook for Employers

Addressing Pharmacy Benefit Management Misalignment

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

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Letter from the President & CEO

Pharmacy Benefits Management – Time for a New Direction

For the past three decades, the professional management of pharmacy benefits has become increasingly opaque, convoluted and misaligned. Rather than improving drug value and creating an efficient marketplace, the industry has fueled a flawed contracting model and unprecedented market consolidation, both horizontally and vertically. That market consolidation (three PBMs control more than 80% of the market) has emerged despite a lack of apparent barriers, as evidenced by the more than 100 PBMs in the US today. It has also led to buying power concentration—inhibiting competition, reinforcing practices of self-dealing, rewarding conflicts of interest, and allowing "middlemen" to confiscate the economic benefits that would otherwise go to purchasers and patients.

Increasingly, with health plans and PBMs owning one another and the growing prevalence of side-deal payment arrangements to consultants and brokers, we see classic concerns about the "fox guarding the henhouse." The incentives and monies made in these arrangements increasingly outweigh the more apparent compensation and invariably come with a price. The ambition to nurture business models that would not exist or sustain themselves in the light of day has led to ever-increasing complexity in contracting, organizational structures, and perverse incentives across the board, confounding the interests of the organizations and people paying the bills.

Yet the winds are blowing in a new direction in 2023. With the onset of the Federal Trade Commission investigations, multiple congressional hearings on potential PBM reforms, and innovative new competitors in the PBM ecosystem, we have a unique opportunity to step back, reexamine our motives and the consequences of our actions, and correct our course. Invariably, pushback from the industry to reform efforts has repeatedly been: "We are simply doing what plan sponsors have asked us to do." And, at some level, that is true. While most employers agree there is a problem with the industry, they are equally convinced that they, as purchasers, are not affected by these issues!

As we move forward, we must rethink a basic question (one that has been posed to me on numerous occasions): "*Why do employers buy this way?*" This playbook challenges the status quo, not because these issues are universal, but because they occur with much greater frequency and magnitude than any of us appreciate. If there is prevalent misalignment and self-dealing in the industry, why are we so confident that we are immune to the impact?

In an era of growing transparency, the opportunities to improve value and alignment are so much greater—and so are the risks of not doing so. As fiduciaries, employer plan sponsors have not just a right to expect greater alignment but also a responsibility to deliver it. Business as usual is no longer safe and certainly not responsible. Disruption is essential if we are to do right by our organizations, our health plans, and our employees and their families.

This playbook was developed as a catalyst for change and, equally important, a blueprint to help foster positive, constructive steps to create better PBM alignment. This year can be a turning point to build a more credible and aligned industry—one that is more trustworthy, responsive and sustainable in the eyes of purchasers and the employees and families they serve.

Michael Thompson
President & CEO
National Alliance of Healthcare Purchaser Coalitions

Role of Fiduciary in Pharmacy Benefit Management

The Consolidated Appropriations Act of 2021 (CAA), enacted in 2020, raises the bar for employer-sponsored health plans, requiring these sponsors to pay fair prices for services provided. Employers and other plan sponsors that do not know whether they're paying reasonable prices could face a heightened risk of lawsuits and considerable fines.

Understand the basics:

- Health plan sponsors have a fiduciary obligation to disperse plan assets in a prudent manner for the exclusive benefit of plan participants and beneficiaries.
- Fiduciaries are required to be experts in the subject matter entrusted to them or to become educated by subject-matter experts. The prudent standard for fiduciaries is a prudent expert standard, not a prudent layperson standard. A good faith effort is not enough.

Special Considerations for Pharmacy Benefit Management

- No regulatory oversight of PBMs exists. (This is unique in the healthcare supply chain.)
- Some PBMs refuse to consider themselves regulated by CAA disclosure requirements, which does not mitigate plan fiduciary responsibility.
- Vertical integration (of health plans, PBMs, pharmacies, and providers) opens the opportunity for self-dealing, the "fox guarding the henhouse."
- Inter-party payments, including those to advisors, can compromise disclosure and independence.
- The prevalence of obscure, misaligned practices in the PBM industry and advisor community is both well accepted and not fully appreciated by even the most sophisticated purchasers.

"The prudent standard for fiduciaries is a prudent expert standard."

Overview of General Landscape

Key Areas of Concern

- **Vertical Integration** – PBMs and their business affiliates control the drug supply chain from the initial sale by the manufacturer through the final sale to a consumer.
- **Market Consolidation** – Three PBMs ("Big 3") control more than three-quarters of all the prescription drug business in the US.
- **Biased & Conflicted Requests for Proposal** – The largest PBMs pay significant referral fees to pharmacy benefit consultant firms (including those operating their own coalitions) to steer and influence the PBM selection process in their favor.
- **Perverse Incentives** – PBMs may make more money by promoting higher-priced drugs, covering low-value drugs, and applying lax clinical protocols. In so doing, they garner larger dispensing profits and collect larger rebates (or other third-party payments), some of which they pocket instead of passing them through to plan sponsors.
- **Lack of Transparency & Misleading Contracts** – PBMs have systematically sought to obscure their business practices, which include self-serving contract definitions that favor high-cost/high-rebate drugs on their formularies and recharacterizing rebates as services fees to avoid sharing them.
- **Pharmacy Control** – PBMs control pharmacy reimbursement to the extent that they dictate Favored Nation Pricing, limit in-network access, and restrict the use of non-proprietary mail-order and specialty pharmacies. These practices have at times led to the continued favorable formulary placement of higher-cost drugs and inhibited competition from lower-cost/higher-value drugs (e.g., biosimilars).
- **Pharma-Driven Incentives to Confound Market Pressures** – At the center of pharma manufacturers' market access strategy are the large incentives they give PBMs for favorable formulary placement. This strategy creates perverse conflicts through rebates, credits and other incentives that restrict competition on formularies and soften prior-authorization criteria.

Drivers of Pharmacy Benefit Cost and Value

Drug Price
Unit cost of a specific drug. Gross drug prices are defined as prices before rebates, and net prices are drug prices after accounting for rebates. Also critical in the current environment is "drug price for whom" (e.g., pharmacy, payer, or healthcare provider).

Drug Mix
Mix of drugs within a therapeutic class. Often the impact of the mix is greater than the drug price itself, particularly when formulary management is biased toward high-cost/high-rebate drugs.

Utilization
Number of drugs dispensed. To the extent that drug dispensing is rewarded or administered without regard to patient need/usage, the potential for waste arises.

Appropriateness
Awareness is increasing that not all drugs are suited for all patients and that the cost of paying for inappropriate usage has grown exponentially. Appropriateness is particularly important with high-cost therapies.

Sites of Care
The cost of a drug is affected substantially by where it is administered. In particular, hospital-administered drugs are sometimes marked up at extraordinary levels, and simply shifting to outpatient or alternative low-cost administrators (e.g., home healthcare, doctors' office, infusion center) can generate significant savings.

Affordability
When considering drug value, remember that affordability to patients can alter their willingness to take recommended medications and adhere to treatment plans, affecting outcomes.

Value
Qualitative Output (clinical, wellbeing and functional outcomes and patient experience)/Quantitative Input (cost = price x utilization)

"PBM contracts contain unnecessarily complex definitions of commonly used terms, including 'generic' and 'specialty' drugs, that are often different from how those terms are used in regulation."

— EMPLOYERSRX

Economics and Conflicts of Pharmacy Benefit Management

Failures in the PBM Value Chain

Retail Pharmacy

- Gag clauses
- Lack of utilization management

Specialty Pharmacy

- Gag clauses
- Highest cost and highest margins
- Lack of utilization management
- Blended pricing (brand/generic)

Manufacturer

- Captive to Big 3 PBM demands for revenue, rebates, and administrative fees
- No external control of price markups
- Non-competitive practices (e.g., blocking biosimilars)
- Physician detailing and "off-label" usage promotion
- Limiting copay assistance programs

PBM

- Spread pricing
- Inflated Maximum allowable cost (MAC) and average wholesale price (AWP)
- Hidden clauses and definitions
- "Admin fees"
- Rebate- and revenue-centric contracting and formulary management
- Lack of appropriateness screening

PBM-Affiliated Pharmacy

- Captive mail, specialty, retail
- Margins, self-dealing
- Conflicted dispensing (e.g., biases toward brand, 90-day retail)
- Lack of utilization management
- Competition limiting
- PBM-affiliated

Rebate Aggregator

- "Sheltered rebates"
- Ambiguous rebate definitions

Physician Prescriber

- Influence of physician and patient detailing
- Economic interests in some treatments (e.g., cancer)

Member/Patient

- Inflated costs and cost share
- Affordability and adherence
- Stockpiling

Plan Sponsor/Employer

- Lack of transparency
- Reliance on conflicted advisors
- Price- and rebate-centric value assessment
- Lack of end-to-end audit
- Variable copay (copay accumulator and maximizer)

"These rebates and fees may shift costs and misalign incentives in a way that ultimately increases patients' costs ..."

—UNITED STATES FEDERAL TRADE COMMISSION

Potential Misuse of Pharmacy & Therapeutics Committee

A pharmacy and therapeutics (P&T) committee formulates policies regarding the evaluation, selection, diagnostic and therapeutic use, and monitoring of medication and medication-associated products and devices. It's important for employers and other plan sponsors to understand the P&T committee's role—and where concerns may lie.

The P&T Committee's Role in Pharmacy Benefit Management

- Every PBM and pharmacy management organization has a P&T committee composed of pharmacists, physicians, and other business professionals who, collectively, should be qualified to assess the relative efficacy, coverage and management of individual treatments on a formulary.
- A clinical pharmacist will typically bring research and evidence from clinical trials, FDA rulings, and ideally (but rarely) real-world evidence to support potential recommendations for the decision-making process of the P&T.
- Independent value assessments (e.g., ICER) may also influence coverage policies and, ideally (but rarely), assessment of comparative effectiveness.
- Outputs from the P&T should (but often do not) influence contracting strategies, formulary placements, utilization management (e.g., step therapy), and coverage policies (including appropriateness guidelines).
- The results of the P&T evaluation should drive, but may at best be an input or afterthought to, the PBM's formulary and oversight management.

Potential Concerns

- When PBMs are motivated by self-interested and conflicted business terms, they can potentially compromise the clinical and economic evaluation of the treatment. This can result in inappropriate coverage of high-cost/low-value drugs, biases toward high-cost/high-rebate drugs, the limiting of drug classes with a high heterogeneity of efficacy, and fail-first policies without appropriate considerations of the impact on outcomes.
- PBMs may not make formulary decisions until they have a signed rebate agreement with one or more high-rebate manufacturers. P&T considerations may be an afterthought.
- Evidence can be clear-cut, limited, or gray. Purchasers are rarely brought into the decision-making process for final determination.
- Real-world evidence is rarely reviewed to assess or reassess the effectiveness of policies that have been implemented.
- Drug costs are often viewed with a limited scope of value, unless such value accrues directly to the PBM or health plan. (Value uniquely accrued to purchasers or patients may be highly discounted.)
- Due to a lack of independence, business objectives override clinical evidence, and members of the P&T committee are not required to be independent of the PBM, creating an inherent conflict of interest.

Given the misuse and misalignment of PBM P&T Committees, plan sponsors should:
1) Retain control of their formulary.
2) Use clinical advisors to examine appropriateness of drug management strategy.

Flaws in the Current PBM Selection Process

By negotiating with drug manufacturers and pharmacies to control drug spending, PBMs have a significant behind-the-scenes impact in determining total drug costs for insurers, shaping patients' access to medications, and determining how much pharmacies are paid, according to *HealthAffairs*. While PBMs are facing growing scrutiny of their role in rising prescription drug costs and spending, plan sponsors also play an important role in tightening the management of PBM partner selection.

Typical RFP Approach

- 3–5 year deal
- Focused on "discounts" and "rebates" based on current utilization
- Prices indexed off "gross price"
  - For brand – % AWP
  - For generics – MAC pricing
  - Variations for mail, specialty
- Aggregate rebate guarantee
- Limit to "Big 3" plus 1–2 others that meet pre-defined parameters
- Exclusive specialty, mail

Flaws

- Lack of alignment with fiduciary obligation of plan sponsors
- No focus on drug mix or utilization, except to the extent those impact rebates and rebate guarantees
- Bias toward high-price/high-rebate drugs
- Impossibility of assessing and comparing the net cost of any drug or drug class
- Lack of standardization in terms
- Lack of focus on per member per month (PMPM) drug costs
- Lack of focus on the total cost of care
- Ignores or rewards lack of utilization management
- Has yielded incomprehensible and indefensible margins (the most abusive margins in the healthcare supply chain)
- Lack of accountability or alignment to plan sponsor interests
- No interim market checks
- Each PBM has its own specialty drug list, MAC list, and list of claim exclusions from the guaranteed pricing discounts and guaranteed minimum rebate amounts.
- Big PBMs exclude various categories of brand drugs from their contract calculations, which the consultant may or may not have fully captured in projecting rebates and discounts.

Standard Industry Pricing: A Fundamental Flaw in the Market

Current approach is "weak attempt" to evaluate net cost of drugs purchased

- Drug prices are defined as a percentage discount off AWP, but brand AWPs increase semiannually, and generic AWPs are wholly unrestricted.
- Rebates are not guaranteed, or even knowable, at the drug level over the course of the contracting period.
- MAC pricing (for generics) is uniquely defined and independently controlled by each PBM.
- Only the largest PBMs have market control/influence on drug prices and rebates over a contracting period.

Unintended impact

- PBMs have a strong incentive/bias toward higher prices and higher rebates.
- AWP grows disproportionately to net prices. PBMs have no incentive to fight drug price increases, resulting in exponential growth in patient cost-sharing, concerns about equity and affordability, and added pressure for copay subsidy programs.
- Incentives for PBM rebate generation with formulary placements promote the use of high-cost/low-value drugs, discourage the use of generics or biosimilars, minimize utilization management, trigger abnormally high prior-authorization approval rates, and reward wasteful spending.
- This approach increases opportunities to obscure other PBM revenue sources.
- Guarantees related to average rebate dollars per script can also be manipulated by redefining which drugs are included in those averages.

Potential future directions

- There is growing discussion of alternative benchmarks indices to AWP. Two such indices are average sales price (ASP) and average manufacturer price (AMP), both of which are geared toward the manufacturer's selling price, rather than an artificial "retail price" no one pays.
- Transparency laws currently being considered should improve the access to reporting for specific rebates at the drug level.

A Vicious Cycle – How Rebates Drive Price Inflation

"Health care spending rarely follows an ordinary, rational model. Yet even in that context, prescription drug prices are rising at a puzzling rate. What is causing the phenomenon? Quite simply, incentives percolating throughout the prescription drug market push players toward higher prices. At the center lies the highly secretive and concentrated pharmacy benefit manager (PBM) industry."

—PROFESSOR ROBIN FELDMAN, *HARVARD JOURNAL ON LEGISLATION*

(View Professor Feldman's March 30, 2023, Senate Finance Committee written testimony)

Managing Conflicts in the Advisor Selection Process

Common Concerns

- Established, "preferred" providers with direct and potentially conflicted compensation from PBM (GPA business model)
- Standard, flawed selection methodology that favors "preferred providers"
- Gag clauses, formulary restrictions, and audit limitations with "preferred" providers
- Required "compensation terms" that disqualify potential RFP respondents
- Firm profitability drives advisor priorities and assessment approaches (lack of independence)
- "Seller's agent" not "buyer's agent" (advisor business models as dependent, or more dependent, on PBM compensation than client fees)
- Trusted "non-specialized" advisors not fully appreciating misalignment of RFP process

Advisor Selection Considerations

- A "buyer's agent" – no direct or indirect compensation from PBMs.
- Competency – a demonstrated knowledge of "games being played."
- Commitment to transparency – contractual obligation to disclose and explain all PBM practices that lead to self-dealing or misalignment.
- Alignment in what constitutes value-based outcomes.
- RFP process designed to assess and achieve value-based outcomes, including assessments of formulary, utilization management, and contract provisions protecting the plan sponsor (not the PBM).
- Specialized talent, including expertise on plan design, clinical, contract, and financial considerations.
- Advisor does not evaluate its own collaborative, which would pose a conflict of interest.
- Value-based formularies, lower prior-authorization approval rates, more favorable contracting terms, and willingness to help the plan sponsor control spending are often ignored in the standard consultant RFP spreadsheet. These areas should be both evaluated and recognized in RFP scoring.
- Contractual obligation to notify plan sponsor of industry developments, including PBM attempts to increase its profits rather than serve the plan sponsor.
- Auditors independent of the PBM and its subsidiaries or parent companies.
- Auditors not restricted contractually or otherwise to only comment on compliance with contract. Auditors should be contractually required to offer commentary wherever the existing PBM contractual arrangement is misleading, leading to misaligned behaviors or potential self-dealing.

"Large employers, health plans, and government payers have shown limited appetite for change and continue to rely on the largest companies for PBM services."

—ADAM J. FEIN, CEO, DRUG CHANNELS INSTITUTE

The Impact of Biosimilars

Biosimilars have the potential to reduce the cost of specialty drugs by a dramatic 20%–40%

- Until recently, most biologics (branded specialty drugs) that lost patent protection faced no competitive product (in contrast to the challenge generics pose to small molecule drugs).
- The biosimilar market has grown in the last several years, establishing a firm place in leading value-focused health plans (e.g., Kaiser) and European health systems.
- Adoption in the US has lagged in Medicare Part D and commercial plans, primarily due to biases toward high-cost, high-rebate drugs in these plans.
- Low utilization rates threaten continued biosimilar development in any markets that do not justify biosimilar manufacturer investment. This has a major long-term impact on the potential for a competitive market for some of the most expensive treatments.

In the United States, biologics only make up 2% of prescriptions but account for 37% of net drug spending.

—AJMC | THE CENTER FOR BIOSIMILARS

Potential Concerns

PBM bias toward high list prices (with higher rebates) must be overcome by strong plan sponsor adoption of biosimilars and reduced access to reference biologic drugs. Purchasers cannot rely on PBM or pharmacy benefit consultants to drive biosimilar adoption. Here are some top concerns:

- There is a need for any other consistent pricing benchmark whenever there are multiple makers for the same biologic drug.
- Plan design implications include confusion about how biosimilars are defined (they should be treated like generics) and a lack of biosimilar availability due to PBMs restricting access or claiming low inventory. Biosimilars can be preferred on the formulary, while the reference biologic is limited to special circumstances.
- Confusing information on the clinical appropriateness of a biosimilar substitution for the reference biologic. Some are interchangeable and may be substituted by the pharmacist (e.g., Semglee insulin). Biosimilars are FDA-approved, regardless of interchangeability status.
- Manufacturers of biologic reference drugs have raised their rebates to discourage biosimilar utilization or uptake ("pay to delay" strategy).
- Tier placement can generate biosimilar savings availability. Placing generics and biosimilars on a lower tier with a low co-pay (or low deductible) promotes their use.
- Biosimilar utilization rates in the US lag far behind those in other countries, due in part to PBM actions to prevent formulary coverage, as well as pharma companies protecting their existing market share of products threatened by a biosimilar launch. There are no PBMs or financially conflicted consultants in Europe, so biosimilar uptake is significant and growing.

PBM Principles for Contracting and Governance

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 ensure the fulfillment of fiduciary duty, self-insured employers are within their rights to require full transparency from all parties, considering this best-practices checklist:

- Confirm PBM and consultant/broker compensation, commissions and rebates.
- Understand and validate all negotiated prices, claims data, financial transactions, and fees.
- Understand the agreement terms of these transactions (formulary concessions, gag clauses, audit restrictions).
- Identify and evaluate potential and actual vendor conflicts of interest (ERISA may require replacement of conflicted vendor).
- Identify and determine all service fees and operational fees (access to claims files, claim appeals, prior authorization reviews, clinical programs, etc.).
- Remove provisions that hinder cost recovery.
- Restrict PBMs from including weak inflation-protection programs in lieu of a price-protection rebate.

Further, because of a lack of consistency among PBMs, it's important to validate contract terms by taking these actions:

- Negotiate the "definitions" section on all contractual terms to confirm alignment with how each PBM defines terms.
- Avoid revenue and guarantee loopholes (ill-defined terms, related entities).
- Oversee contract management during contract periods.
- Evaluate market options in a formalized manner at the end of every contract benefit year.
- Avoid provisions that present a conflict of interest for the broker/consultant and provisions that favor the claims administrator or carrier/PBM.
- Verify that all promises made by the PBM during the RFP process are included in the final PBM contract.

For governing PBM contracts:

- Have an independent auditor conduct a comprehensive review of the contract (e.g., plan design conformance, pricing and rebate guarantees).
- Review PBM and vendor contracts against clearly defined and measurable performance and pricing guarantees and savings.
- Maintain contractual flexibility to access lower-cost options from other pharmacies if the PBM prices become unreasonable/uncompetitive (e.g., through mail-order or specialty pharmacies).
- Obtain plan utilization reports and prices for specialty drugs to identify PBM annual compliance with lower, clinically equivalent alternatives.
- Request new-drug pipeline reports and market launches to determine potential impact on covered drugs/prices.
- Conduct market price checks, including pricing of generics vs. cash-pay options for best price.
- Evaluate and assess whether cost-control strategies are effectively reducing prescription drug spending.

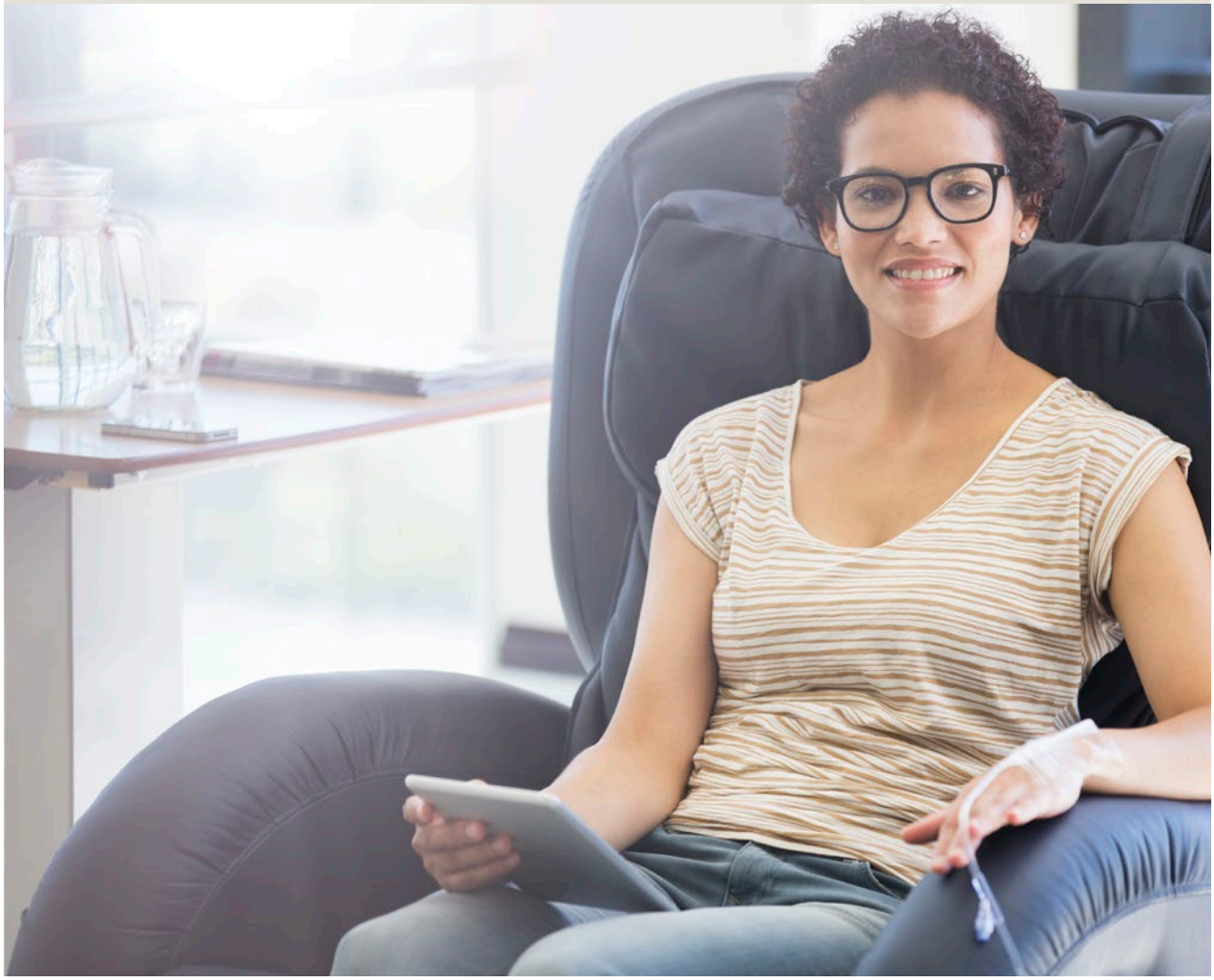
Medical Drugs: Cost-Savings Opportunities

Drugs administered in the hospital can be especially abusive due to the lack of cost management.

- Drug markups within hospitals can reach 100%–600%. Since many of the drugs administered through the hospital are specialty drugs, the underlying cost is already high, and these margins are clearly unjustified.
- These costs may be compounded by exorbitant administration and facility fees, charged in addition to the ingredients cost for the drugs.
- The same drugs administered in the home, at the doctor's office, or in an infusion center typically cost a fraction of what most hospitals charge.

Approaches to control

- Shift the site of service to the lowest-cost setting.
- Cover and promote "brown bagging" and "white bagging" approaches:
  - **Brown bagging** – The medical drug is purchased through a specialty pharmacy and shipped directly to the patient, who takes it to the provider's office for administration.
  - **White bagging** – The medical drug is purchased through a specialty pharmacy and shipped to the provider's office for administration.



The Unintended Impact of 340B

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.

- Rather than channel savings to enhance services for the targeted population, 340B has become a major profit center for intermediaries, who mark up the drugs and pocket the difference.
- The problem has been compounded as qualifying entities contract with other related entities to take advantage of the 340B pricing. Instead of passing along savings to patients or purchasers, these entities usually pocket the difference between standard, inflated list prices and 340B prices as another source of profits.
- The issue is further exacerbated by PBM contracts, since PBMs continue to establish the pricing at inflated list prices, but there are no rebates on 340B drugs (which are discounted heavily up front, leaving no room for rebates). This means that while intermediary profits on 340B drugs soar, purchaser costs increase substantially when 340B drugs are used (if the purchaser pays the same inflated list price without counter-balancing rebates).
- Because 340B claims are not eligible for rebates, they may be omitted from rebate-per-script guarantees.
- This issue is a broad area of concern for policymakers and is drawing attention for potential reforms.

What should be done

- Plan sponsors should expect that drugs purchased through 340B pricing are identified and treated separately.
- Plan sponsors should request separate contract terms (with deeper discounts) on all 340B claims or insist that such drugs be passed through on a cost-plus basis.
- Policymakers should ban markups of 340B prices by all intermediaries, other than the costs associated with dispensing these drugs.

"...A well-intended program designed to help poor people obtain prescription drugs is riddled with abuse and creates a perverse incentive for healthcare providers to game the system for profit."

—PACIFIC RESEARCH INSTITUTE REPORT

Purchaser Strategic Recommendations

Work with partners who work for you

- Independent and qualified advisor(s) with pharmacy benefit management experience*
- Fiduciary alignment required**
- Total transparency of pass-through prices and all manufacturer payments to PBMs, along with a commitment to value (to plan and plan members)
- Elimination of indirect revenue streams that convert a buyer's agent to seller's agent and protect the PBM over the plan sponsor and its members

Evaluate and manage with a balanced scorecard

- Net cost by drug class (includes unit price net of any offsets and drug mix)
- Waste and appropriateness management
- Focus on value, outcomes, and total cost of care
- Member affordability, adherence, equity and experience prioritized
- Elimination of indirect revenue streams that convert buyer's agent to seller's agent and protect the PBM over the plan sponsor and its members

Own the relationship

- Claims data ownership
- Broad audit rights of PBM
- Contract development – definition of terms (e.g., generic drugs, AWP, specialty drugs) and requirements
- Formulary and utilization management, including customization that may be necessary or appropriate

*reference Sample Questionnaire

**reference Fiduciary-Like Standards & Contract Language

About

Sponsors

The National Alliance gratefully acknowledges support, including clinical expertise and funding from:

Biosimilars Forum: A nonprofit organization to advance biosimilars and improve health care in the US by providing evidence-based information to inform and support public policies that encourage awareness, access and adoption of biosimilars.

Drexi: An AMPS Company: A pharmacy benefit manager offering pass-through pricing on prescriptions through a premier nationwide network of over 65,000 pharmacies. Following the development of a customized pharmacy spend plan, Drexi's enterprise platform allows users to proactively see extensive claims data and address issues to improve care and reduce costs.

AffirmedRx: AffirmedRx brings a patient-centric approach founded on integrity and trust to pharmacy benefit management, supporting self-funded employer groups and their health plan members in responding to the complex and ever-changing world of healthcare and pharmacy needs.

US-Rx Care: A clinical pharmacy organization providing fiduciary pharmacy risk management services to self-insured employers, union trust funds, and health plans of all sizes. Clients have access to proven pharmacy risk management programs and solutions that have consistently delivered reductions in pharmacy benefit spend by 30%–50% or more for at-risk health plan sponsors.

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Appendices

A. PBM Terms and Models

- **Spread Pricing** – Under spread pricing, PBMs pay fees/contracted rates to pharmacies for drugs dispensed to members but charge employers a different, much higher rate than the PBMs originally paid. The difference employers pay is retained as profit by the PBMs.
  - ***Limitations*** – *Spread pricing is tied to indices that are not well defined and which no one pays (e.g., AWP). Rather than defining administrative fees directly, PBMs are rewarded for "working the spread," using drug mix, coverage, definitions, etc., to meet contracted guarantees while maximizing spread (their profits). AWP is an irrational price index. MAC pricing is not universally defined, with each PBM defining it uniquely to benefit their contracting. There is no focus on utilization management, drug mix, waste, appropriateness, etc.*
- **Pass-Through Pricing** – With pass-through pricing, PBMs are paid administrative fees as their only source of revenue under the contract. This model can help employers avoid spread pricing and focus the PBM on protecting the interest of the plan sponsors and members paying the bill.
  - ***Limitations*** – *While pass-through of acquisition costs is standard, even this model can be compromised, as PBMs can contract with an affiliated service provider (and therefore have undue influence in defining acquisition cost). "Pass-through" alone also provides no assurances that the costs passed through are competitive or that the clinical utilization management is appropriate. Some traditional PBMs have consistently offered "pass-through pricing" options that are inexplicably non-competitive with "spread pricing" (their clear preference). Pass-through pricing does not eliminate conflicts of interest with PBM-owned mail-order and specialty pharmacies.*
- **Pass-Through Rebates** – PBMs commit to pass through 100% of rebates and discounts.
  - ***Limitations*** – *Definitions of rebates and discounts can be manipulated to exclude "other" indirect payments made to PBMs or their affiliates. These arrangements are inherently not truely "pass-through" if they preserve PBM mark-ups of ingredient costs. Lack of rebate transparency at the drug level continues to permit gaming of contracts and drug management. Vertical integration also makes it difficult to determine what is actually passed through. Pass-through does not control for misalignment related to formulary mismanagement or loose application of clinical protocols. Shifting rebate collection to the PBM-wholly-owned but distant entities further obscures transparency on what is passed through versus retained by PBMs.*
- **Value-Based/Evidence-Based Formulary Management** – Value-based formulary management was developed with the premise that some drug therapies have a greater value due to the greater clinical efficacy of a drug for its cost. Employers can institute an incremental cost-effectiveness ratio to set tiering levels with a nominal but flexible cost-utility threshold. Evidence-based formulary management gives a high degree of focus on appropriateness, with clinical trials and real-world evidence supporting the expected clinical impact of the treatment.
  - ***Limitations*** – *Although this approach is designed to support coverage of the right drug*

under the right circumstances, it may result in suboptimal contracting leverage on price or the competitiveness of overall pricing.

- **PBA Aggregator Model** – A traditional PBM owns the entire process from purchase through dispensing, including rebate negotiations, exercising maximum end-to-end control to optimize contracting and rebates (typically for its own benefit). Under the pharmacy benefit administrator (PBA) model, an employer can contract each piece separately: 1) a PBA, which processes claims and manages mail-order and specialty networks (billed a PMPM flat administrative rate); 2) a contracted pharmacy network employing either a full, open network or a limited network with preset pricing or negotiated ingredient cost and dispensing fees; and 3) a rebate aggregator with preset pricing for services rendered or a flat percentage of rebates, such as a wholesale acquisition cost (WAC) fee. By breaking up the pieces, formulary management and sourcing of drugs may be handled independently.
  - ***Limitations*** – *While this approach maintains the independence of formulary management from contracting, it may take away the leverage of potential formulary management from favorable contracting. Some PBAs insist on, or provide strong incentives for, use of their proprietary pharmacy network or rebate aggregator, eliminating the independence of the functions.*
- **Capitation Guarantee** – Under some PBM contracts, the PBM will guarantee a total PMPM cost to the plan, but the cost escalates over several years. This can be used to "guarantee" the overall effectiveness of pharmacy benefit management and integrates unit costs, drug mix, utilization management, and appropriateness.
  - ***Limitations*** – *This "all in" approach appears to consider multiple factors but can potentially reward the extremes of utilization management and drug costs, regardless of drug appropriateness, value, or member experience. Where those strategies are challenged or rationalized, any guarantees could be considered invalid. New risk or high-cost claims are sometimes excluded from guarantees.*
- **Net Cost** – Under a net-cost arrangement, the focus of contracting is to minimize net costs (after any rebates) within a therapeutic class. This puts less focus on rebates and more on the drug mix and the net amount charged for any drug within a drug class.
  - ***Limitations*** – *Few PBMs will actually provide rebates or net-cost guarantees at the drug level. Those that do may be very conservative in years that have yet to be contracted for.*

B. Top 10 Pharmacy Benefit Management Concerns

The top 10 pharmacy benefit management concerns identified by an industry advisory committee and purchasers working with the National Alliance for this initiative are:

1. Promotion of higher-price drugs when lower-price drugs are available.
2. Coverage and/or preference of a brand when a generic or biosimilar is available.
3. Coverage of specialty drugs for circumstances that clinical evidence does not support (e.g., "off-label use").
4. Automated approval process for prior authorizations causing rates to soar over 90%.
5. Redefining generics as brand drugs or vice-versa to manipulate (i.e., meet/reduce) guaranteed pricing discounts.
6. Systematic approaches to encourage waste (e.g., refill too soon, automatic 90-day refill).
7. Coverage of high-cost, low-value drugs (e.g., drugs that have less expensive over-the-counter alternatives—the "stupid drugs").
8. Replacing drugs eligible for rebates with 340B drugs not eligible for rebates, without passing through the substantially lower price of 340B drugs (continuing to charge plan sponsors and patients the same inflated list price).*
9. Narrow definition of "rebates," which allow the PBM to "pocket" 50% or more of the manufacturer revenue because they have been recharacterized as something else.
10. Plan sponsors being "held hostage" on any and all PBM contract terms, financial guarantees, and provisions, regardless of magnitude or changes desired by the benefit plan (formulary changes, carve out of proprietary services, modifications to utilization management, etc.).

*Although this may be more of a pharmacy-level concern, PBMs control a significant portion of pharmacy supply chain, including mail order and specialty.

C. Sample Questionnaires for Pharmacy Benefit Consultant

Background/Credentials

1. Name, physical location, phone number, and email address:

2. Do you work for an insurance brokerage firm or employee benefit consulting firm?

3. If so, name, address and phone number of your firm:

4. Years of employment at your current firm:

   Years of employment at previous relevant employers:

5. Do you specialize in medical benefits, pharmacy benefits, or both?

6. If you do not specialize in pharmacy benefits, who will help you advise us on pharmacy benefit issues, if we hire you?

7. If you do specialize in pharmacy benefits, please provide (a) the number of years you have spent in this specialty; and (b) a description of your pharmacy benefit expertise.

8. For approximately how many prescription drug benefit plans do you (or your immediate team) serve as the primary pharmacy benefit advisor/consultant?

9. Briefly describe your post-high school education and any professional credentials.

10. Briefly describe the credentials of immediate team members.

Pharmacy Benefit Consulting Services

1. Provide a list of the deliverables included in your standard services agreement for pharmacy benefit plan consulting services. See Section D below.

2. Describe your typical fee arrangement for pharmacy benefit consulting services.

3. Confirm that you and your firm (i.e., senior management/ownership) will sign a full disclaimer statement (drafted by our ERISA counsel), which certifies that neither your firm, its owners, affiliates, etc., receive any "indirect compensation," as that term is defined in Section 202 of the Consolidated Appropriations Act of 2021, from any PBM. In this regard, "indirect compensation" includes compensation or anything of value that is received in connection with our plan, regardless of whether (i) it is received on a book-of-business basis and on a plan-by-plan basis, or (ii) it is not received for services rendered to our plan. (If you have any questions regarding this inquiry, please provide them to us in writing.)

4. Include a sample of your standard PBM RFP questionnaire, which we will keep confidential and will share only with our benefits team and ERISA counsel.

5. Provide a brief narrative description of how your RFP process differs from the standard spreadsheet format used by most pharmacy benefit consultants for the past 15–20 years, and if so, why?

6. Describe the top 5–6 contract provisions you pursue for the benefit of your plan sponsor clients in a final PBM contract and why.

7. Describe three recent developments in the prescription drug industry that you have emphasized to your plan sponsor clients and why.

8. Provide a list of the 7–10 PBMs most commonly used by your plan sponsor clients, with a rough breakdown by percentage or number, showing the most used, second most used, etc. We will keep this information confidential and will share it only with our benefits team and ERISA counsel.

9. Provide three reasons you recommend using a traditional PBM (e.g., top 7–8 PBMs by number of lives covered).

10. Provide three reasons you recommend using a smaller or mid-sized PBM, rather than a traditional PBM.

Specific Challenges

1. Describe your recommendations to plan sponsor clients regarding the coverage of Humira vs. the 8–10 biosimilars launched or expected to launch in 2023.

2. Describe how you help plan sponsor clients determine whether the rebates they receive from their PBM include all drug-maker revenue streams, which are based on the plan's drug spending (and formulary placement), even if some of such revenue streams are recharacterized as manufacturer administrative fees, price protection amounts, formulary placement fees, inventory purchase discounts, market share incentives, or bona fide service fees, or have any other non-rebate label.

3. Describe your efforts to monitor and customize a plan's formulary to (i) prefer only generics and biosimilars on tier one of the co-pay schedule, (ii) prefer lower-cost/higher-value drugs over higher-cost/lower value drugs in all major therapeutic categories, and (iii) use comparative effectiveness research to ascertain the relative clinical value of the competing drugs in any therapeutic category.

4. Describe your efforts to monitor and customize a plan's prior-authorization, step-therapy, and quantity-limit protocols and administrative processes to minimize wasteful spending on high-cost drugs that are not the most clinically appropriate for a certain member at a certain time.

5. Describe all the steps you take to ensure a PBM's MAC List (i) is broad enough; (ii) contains only one, highly competitive unit price for each national drug code; (iii) is applied for every MAC drug claim; and (iv) is not manipulated in any fashion throughout a contract year.

Sample Services Agreement

- ☐ Provide a sample services agreement that would serve as a first draft in good faith if you were selected as a finalist to provide the consulting services described herein.

- ☐ Include PBM RFP, PBM contract review, PBM audit, PBM monitoring, drug market monitoring, and any other services you regularly offer in this area.

Other Actual or Potential Conflicts of Interest

1. Describe your ownership structures and confirm your firm has no financial ties to any insurance company, drug manufacturer, PBM, drug wholesaler, pharmacy or chain of pharmacies, or drug-manufacturer coupon processor.

2. Describe any arrangement or relationship your firm has with any GPO or rebate aggregator.

D. "Fiduciary-Like" Standards

Potential standards for a PBM contract to establish a minimum set of duties and obligations:

- **Reasonable and prudent standard** – Perform duties at the standard of a person seeking in good faith to comply with contractual obligations and in so doing in the general conduct of its undertaking.
  - *Reasonable and prudent standard means the standard of a person seeking in good faith to comply with its contractual obligations and, in so doing and in the general conduct of its undertaking, exercising that degree of skill, diligence, prudence and foresight that would reasonably and ordinarily be expected from a skilled and experienced person complying with all applicable laws, directives, industry documents, and required authorizations and engaged in the same type of undertaking under the same or similar circumstances and conditions.*
- **Reasonable cost management** – Managing cost means that the cost for a service or item that is delivered to the client and their beneficiaries is consistent with the market standards for comparable services or items. This includes a periodic and independent benchmarking of prices that are disclosed to the client and its beneficiaries.
- **Independence** – Perform duties on behalf of the client by placing the interests of the client and their beneficiaries above their own. Do not engage in self-dealing or share profits or savings with other stakeholders that provide products or services for use by the client and its beneficiaries.
- **Transparency** – Provide periodic disclosure of final net prices for goods and services provided, as well as all sources of PBM revenue.

NOTE: Plan sponsors do not have a direct contract with any network pharmacies or the rebate aggregator sponsor, so the plan sponsor must require the PBM to assume this access in the PBM contract and ensure such access does not violate any of their contractual terms.

E. Sample "Fiduciary-Like" Contract Standard Language

Formulary Standard

PBM agrees to construct, manage, maintain and administer the plan's formulary in the best interest of the plan and plan members.

In this regard, the PBM agrees to make all formulary coverage and tier placement recommendations giving the highest priority to (i) covering and preferring drugs with the best clinical outcomes based on comparative effectiveness research, (ii) covering and preferring generics and biosimilars over their reference brand drugs in all cases (unless an exception is approved by the plan sponsor in writing), (iii) covering and preferring the low-cost version of a biosimilar and excluding the high-cost version when a drug maker offers a low-cost and high-cost version of the biosimilar, and (iv) avoiding wasteful spend on overpriced or clinically inferior drug products, including brand drugs that have a less expensive generic or biosimilar equivalent and any drug which has a clinically effective OTC alternative. For this purpose, biosimilars shall be deemed equivalent to their reference biologic with or without interchangeability status.

Further, the PBM is prohibited from favoring a higher-cost (WAC) drug over a lower-cost (WAC) drug based on the theory that the higher-cost (WAC) drug will have a lower net cost after rebates, unless the PBM is willing to prove that theory is accurate to the plan sponsor on a drug-by-drug basis via confidential disclosure of per drug rebate documents to the satisfaction of the plan sponsor.

The PBM agrees to provide the plan sponsor with a full copy of the formulary chosen for the plan, which copy shall include all drugs covered, all drugs excluded from coverage, the tier placement of each drug, brand vs. generic status, biologic vs. biosimilar status, specialty vs. non-specialty status, and the MAC vs. non-MAC status of each generic drug. The PBM further agrees to provide the plan sponsor with an updated copy of the complete formulary as described above at least quarterly, with all changes to the previously provided copy of the formulary highlighted or listed in an attachment with the effective date of each change.

Prior Authorization Standard

The PBM agrees to construct, manage, maintain and administer the plan's prior authorization, step therapy, and quantity limit protocols and application procedures in the best interest of the plan and plan members.

In this regard, the PBM agrees to recommend, develop and apply all prior authorization, step therapy, and quantity limit protocols regardless of whether a protocol was designed by the PBM or plan sponsor, giving the highest priority to (i) strict application of all demographic, clinical and other pre-conditions that are necessary or appropriate to assure the drug will be safe and optimally clinically effective for the member, (ii) generating and maintaining full documentation of all aspects of applying the protocol for each claim, to facilitate retrospective reviews of the process, (iii) avoiding off-label usage, and (iv) avoiding wasteful spend. The PBM agrees that it is prohibited from implementing any exception to the protocols without the prior written consent of plan sponsor. The PBM agrees to notify the plan sponsor in writing of any instance in which the PBM would like to apply less than the full protocols and/or applicable review procedures in order to generate additional rebates from a specific drug maker on a specific drug. Such actions are strictly prohibited unless and until the plan sponsor agrees to any such requested modification.

Pricing Transparency Standard

The PBM agrees to act in the best interest of the plan and plan members in providing (i) claim files, (ii) pricing

information, and (iii) rebate information, to the plan sponsor. In this regard, the PBM agrees to provide bi-weekly or monthly disclosure of all ingredient costs, dispensing fees, taxes, and any other charges incurred by the plan sponsor under this contract for the reporting period. A full claim file shall accompany the PBM's invoices for each covered claim, which claim file shall include the ingredient cost, dispensing fee, member cost share (e.g., co-pay, coinsurance) and any other amount (e.g., deductible, co-pay penalty) paid by the member on each claim. Further, all MAC, specialty, DAW 5, DAW 9, zero balance due, and 340B claims shall be clearly marked as such on the claim file. In addition, all claims impacted by a co-pay coupon or other manufacturer subsidy, all claims impacted by a co-pay penalty (for taking a brand when a generic was available), and all claims excluded from a pricing discount guarantee or guaranteed minimum rebate amount calculation shall be marked as such in the claim file, with unique and explicit identifiers which are explained to plan sponsor in writing.

The PBM also agrees to provide certified copies of all rebate invoices submitted to drug makers by the PBM or its GPO/aggregator for claims incurred by the plan during the prior calendar quarter. The PBM agrees to provide quarterly disclosure of all dollar amounts (including rebates, administrative fees, and any other amounts) received by the GPO/aggregator from a drug maker which relate (directly or indirectly) to the plan's drug spend in any prior calendar quarter with a breakdown of the amounts by the quarter in which the claim was incurred.

F. Additional Guidance for PBM Contracts

Request for Proposals

- Choose an advisor that has fully disclaimed the acceptance of any indirect compensation from PBMs.
- Require the right to early termination of the contract without impact on rebates or any other penalties.
- Require RFP bidders to accept and agree to all contract provisions requested in the RFP if they are going to bid on the contract.
- Define the term "rebate:"
  - Define all revenue streams from pharma and identify which streams are included in "rebates" and which are not.
  - Watch for the recharacterization of rebates as "service fees," rather than rebates.
- Request full disclosure of all affiliated pharmacy-related entities during the RFP.
- Seek to obtain full disclosure of net/ingredient cost (i.e., real cost) instead of average unit cost, variable benchmarks, and AWP percentage.

Pricing and Guarantees

- Be cautious of bundle prices, which limit price transparency.
- Do not allow any offsets of overperformance on one guarantee against underperforming on another guarantee.
- Identify and revise arbitration language to permit fraud, waste and abuse (FWA) recoveries (1) to avoid arbitration altogether, (2) during arbitration, or (3) audits.
- Ensure rights to conduct annual market checks.
- Understand the PBM clinical programs and how they are executed for PMPM guarantee contracts (for example, prior-approval rates increased to bypass PMPM rebate guarantee terms).
  - Must be accompanied with the ability to select an independent arbitrator (if necessary).

Formulary Design

- Maintain a value-based drug formulary (instead of a rebate-driven formulary), which prefers lower-cost brand drugs over higher-cost brand drugs when clinical efficacy is equal or better.
- Use an objective pharmacy consulting and contracting lawyer (neither paid by the PBM) to educate plan fiduciaries on current prescription-drug pricing and rebates and on common PBM profit-making strategies.
- Require flexibility to customize the formulary without financial penalty (e.g., to cover insulin glargine at a 65% discount to Lantus, rather than Semglee at a 5% discount to Lantus).
- Reduce/eliminate 100–200 low- and no-value drugs with low clinical efficacy or much less expensive alternatives.
- Remove any delay/blockage of new generics and/or biosimilars being added to the formulary; this helps prevent higher-cost brand drugs from continuing to be favored and sold.

Data Ownership

- Verify your right to all data generated by the plan, including adjudicated claims.
- Confirm your ability to receive 2–3 years of historical data and not just the current year.
- Retain an independent data analytics firm or hire internal staff to receive a duplicate set of your pharmacy claims monthly for a readily available independent analysis when needed.

Audits

- Ensure that full audit rights of your PBM contract, pharmacy records (for pass-through pricing or pricing guarantees), and rebate agreements are granted to you as the plan sponsor.

- Confirm whether rebate agreements are available for audit review (if a GPO) and scope of audit rights.
- Conduct annual audits and remove any language restricting your ability to hire an independent auditor of your choice (e.g., avoid PBM veto right).
- Obtain a commitment from the PBM to remediate audit shortfalls and other overpaid claims through:
  - Offsets against future payments to the same pharmacy from the same plan.
  - Issuance of a credit or payment to plan sponsor.
- Complete an audit of current PBM contract(s) with a prescription analytics company:
  - Scrub claims for potential savings; identify/ investigate overcharges, payment errors, and adjudication anomalies and pursue recovery.
  - Request a reprice of a year of pharmacy claims data at benchmark market rates.

Sample Contract Language

Do not allow any offsets/overages from one guarantee to be taken off another guarantee.

- *LANGUAGE:* "Over-performance in one contract area will not offset under-performance in other contract areas."
- *EXPLANATION:* This means that as the PBM measures its guaranteed discounts and dispensing fees, guaranteed minimum rebate amounts, and similar financial guarantees at the end of each year, they must pay the plan sponsor back for any underperformance in any category, dollar-for-dollar. Each guarantee must be met on its own. If they performed well in some areas, then that's great for the plan sponsor, but they cannot use overperformance to reduce the amount they owe for any other shortages.

  NOTE: Include this language is each section containing guarantees.

Ensure that full audit rights of the PBM contract, pharmacy records (for pass-through pricing or pricing guarantees), and rebate agreements are granted to you as the plan sponsor.

Determine whether rebate agreements are available for audit review (especially if under a GPO).

- *LANGUAGE:* "The [plan sponsor] has sole authority to determine who to choose for any kind of audit: Contract compliance, pricing, financial, rebates, or other. This audit right extends to any subcontractors of the PBM (e.g., rebate processor)."
- *LANGUAGE:* "If the [plan sponsor] contracts with a private entity to conduct an audit of [PBM], the [plan sponsor] will require the auditing entity to negotiate a reasonable non-disclosure agreement with the [PBM] that will ensure that the auditor is independent, has no conflict of interest with the [PBM], and has acceptable procedures in place to ensure that no information derived from the audit of rebates or network pharmacy contracts is used in, or accessible to, any consulting function the auditor may provide. The PBM shall not attempt to limit the [plan sponsor]'s audit rights in any way or timeframe; the [plan sponsor] in its sole authority and with execution of any confidentiality document shall be allowed to audit the PBM on any contracted service, discount, pass-through transparent pricing provision, claims processing, customer service, or any other provision of this contract by whomever the [plan sponsor] in its sole authority deems it appropriate."

Use an independent auditor to conduct a comprehensive review of the contract (i.e., guarantees).

Conduct annual audits, and seek removal of any language prohibiting plan sponsor's choice of an independent auditor.

- *LANGUAGE:* "In no instance shall the [PBM] advise the [plan sponsor] that one set of auditors is appropriate while another set is not. In addition, the [plan sponsor] may audit or re-audit for any time period and at any time. Previous audits of a set of claims, pharmacies, time periods, or any other sort of audit does not negate the [plan sponsor]'s right to re-audit the same information again later. There shall be no audit blackout periods at any point during a year and no charges or fees in any form for any audits that the [plan sponsor] chooses to exercise."

G. Policy Recommendations

Employers' Prescription for Affordable Drugs

Statement for the Record

United States Senate Committee on Finance

Hearing on

"Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers"

Prepared by *EmployersRx Coalition: Employers' Prescription for Affordable Drugs*

March 30, 2023

Chairman Wyden, Ranking Member Crapo, and Members of the Committee, on behalf of the *Employers' Prescription for Affordable Drugs (EmployersRx)* and our undersigned members, we want to thank you for holding this important and timely hearing on pharmacy benefit managers (PBMs) and the drug supply chain. We offer our appreciation to all of the witnesses and members focused on the impact unaffordable prescription drugs have on Americans and thank you for your actions in support of meaningful PBM reform. *EmployersRx* stands ready to help as you begin this critical work.

EmployersRx is a nationwide effort led by the Purchaser Business Group on Health that includes The ERISA Industry Committee (ERIC), American Benefits Council, National Alliance of Healthcare Purchaser Coalitions, Silicon Valley Employers Forum, HR Policy Association, and the Small Business Majority. Our members share a common goal — to bring more transparency to healthcare, ensuring employers and their employees are empowered by information. This is especially important with regard to PBM transparency to ensure employees have access to affordable prescription drugs.

Growing awareness about the lack of transparency, layers of complexity, and the many activities PBMs have devised that contribute to our country's spiraling drugs costs has created an unprecedented opportunity to compel change. The US has a health care affordability crisis and employers, workers and clinicians are all struggling in a healthcare system that incentivizes high-cost, low-quality care.

This crisis is greatly exacerbated by healthcare industry consolidation, including the fact that the three largest PBMs, which control 80% of the market, are now integrated with the country's largest health insurers as well as affiliated pharmacies and provider organizations. Their collective market power to determine where patients receive care, which drugs they can access, how much they pay, and where their prescriptions are filled raises real questions about conflict of interest.

Employers' Prescription for Affordable Drugs

PBMs and their insurer parents exert enormous and often-harmful influence over drug cost and access for the 158 million Americans receiving healthcare through employer-sponsored coverage.[1] Employers have a legal responsibility as plan fiduciaries — we are bound by law to act in the best interest of the plan beneficiaries and to be financially responsible of plan assets. For PBMs, the exact parameters of their responsibilities should align with the best interest of plan beneficiaries.

Selecting and monitoring good healthcare services for workers and their families and paying for reasonable plan expenses is not only the obligation under the law, but also good business as it helps companies recruit and retain top talent. However, despite being the primary customers for PBMs and even some of the country's largest companies and purchasers of health care — employers are no match against PBMs' significant market power. Employers continue to encounter barriers to PBM pricing and other data and simply lack the bargaining power to require it.

For all these reasons, employers strongly believe the market is not functioning as intended and Americans are being denied access to affordable health care, including needed medicines. Therefore, federal action is essential to address the anticompetitive aspects of the PBM business model by establishing clear regulatory oversight of the industry. These actions should include:

1. **Strong transparency and reporting requirements.** Transparency for the primary customers of PBMs — employers — is a critical aspect to reform. Contracts between PBMs and employers typically do not provide details about fee or rebate schedules or amounts, prices, and fees generated from manufacturers and other parties, drug definition criteria, or amounts charged to pharmacies. Sometimes PBM control of information extends to an employer's effort to enforce contract compliance, as they may either prohibit an employer from auditing the PBM or require a PBM-designated auditor.
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. Confidentiality clauses make it difficult for employers to identify what pharmacies pay and vice versa. This strategy has been especially profitable for PBMs, as exposed in numerous state Medicaid program audits.
3. **Pass-through of 100% of all rebates and volume or access-based administrative fees by PBMs.** The exploitation and manipulation of manufacturer rebate revenues and fees charged to employers for an ever-growing array of service and administrative fees has historically been a critical aspect of a PBMs' business model. Due to significant pressure to pass rebate funds through to employers, PBMs are creating and/or increasing fees (over and above rebates) on manufacturers, pharmacies, other supply chain entities, and employers.
4. **Prohibition on all "workarounds."** Falling rebate revenues has led to the creation of group purchasing organizations (GPOs), or rebate aggregator entities by the big three PBMs — of which two are established outside of the US. These workarounds must be addressed in any legislation put forward this year to guard against current and future gamesmanship of a PBM's legal requirements.

[1] [1] "Improving and Strengthening Employer-Sponsored Insurance" Bipartisan Policy Center, October 2022. https://bipartisanpolicy.org/download/?file=/wp-content/uploads/2022/10/BPC-Improving-and-Strengthening-Employer-Sponsored-Insurance-Oct-2022.pdf

Employers' Prescription for Affordable Drugs

5. **Transparency regarding PBM-owned pharmacies.** American workers and their families rely on local pharmacies in many communities, especially in rural and low-income neighborhoods. PBMs should be required to submit information regarding transactions between the PBM and any pharmacy wholly or partially owned, including mail-order, specialty and retail pharmacies, by the PBM.

6. **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 their plan beneficiaries.

7. **Establishment of clear regulatory oversight.** Employers are required as plan fiduciaries to ensure they are good stewards of the healthcare benefits they provide for their employees. To fulfill that obligation, employers believe any legislation must require clear oversight and accountability of PBMs and specify the exact parameters of PBM responsibility.

The Senate Finance Committee has a key role in both uncovering the concerning practices of the PBM industry, as well as leadership in addressing this important issue. We support and applaud the Committee's desire to act. We also encourage you to work with your colleagues in the other Senate and House committees of jurisdiction to ensure this important legislation lays the critical foundation and groundwork to reduce spending on prescription drugs and make healthcare more affordable and attainable for America's workers and their families.

EmployersRx looks forward to working with you to design and enact bipartisan, commonsense legislation that can pass Congress and be signed into law by President Biden. Together, we can bring true accountability and reform to the PBM industry. Please contact Alan Gilbert, Vice President for Policy, The Purchaser Business Group on Health at agilbert@pbgh.org for further information on this or any other matter of mutual concern.

Sincerely,

Purchaser Business Group on Health

National Alliance of Healthcare Purchaser Coalitions

The ERISA Industry Committee (ERIC)

American Benefits Council

Silicon Valley Employers Forum

HR Policy Association

The Small Business Majority

RESOURCES

- PBM Best Practices Series: What to Expect from your PBM Account team *(Milliman, August 5, 2022)*
- 2022 Profile: Biopharmaceutical Research Industry *(PhRMA report, December 12, 2022)*
- Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies? *(IQVIA White Paper, October 2022)*
- The Federal 340B Drug Pricing Program: What it is, and why it's Facing Legal Challenges *(The Commonwealth Fund, September 8, 2022)*
- Fact Sheet: The 340B Drug Pricing Program *(American Hospital Association, March 2023)*
- Part D Plan Preference for Higher-Cost Hepatitis C Drugs Led to Higher Medicare and Beneficiary Spending *(U.S. Department of Health and Human Services Office of Inspector General, 2022)*
- Alternative Price Bases Could Replace AWP *(Managed Healthcare Executive, February 1, 2009)*
- PBMs Ranked by Market Share: CVS Caremark is No. 1 *(Becker's Hospital Review, March 8, 2022)*
- Exclusive Drug Dealing: Anticompetitive Practices in the Pharmaceutical Supply Chain *(The Capitol Forum, May 2023)*
- FTC Launches Inquiry into Prescription Drug Middlemen Industry *(Federal Trade Commission, June 7, 2022)*
- CVS-Miller Whistleblower Lawsuit *(STAT News, March 28, 2022)*
- PBM Accountability Project
- 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 Man *(Health and Human Services Department Federal Register, November 20, 2020).*
- Findings on the State of the PBM Industry *(National Alliance of Healthcare Purchaser Coalitions, 2020)*
- Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products *(Federal Trade Commission, June 16, 2022)*
- 'It's Beyond Unethical': Opaque Conflicts of Interest Permeate Prescription Drug Benefits *(STAT News, June 20, 2023)*

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