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Recent State and Federal Scrutiny Presents Unique Opportunity for Plan Sponsor PBM Agreement Negotiation

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INTRODUCTION: THE PBM LEGISLATIVE AND REGULATORY FIRESTORM

Pharmacy benefit managers (PBMs) and their fee generation methods have been controversial for some time. More recently, however, PBMs have begun receiving considerable scrutiny from all sides. Both the Federal Trade Commission and the U.S. Senate have opened parallel probes of "alleged anticompetitive practices by PBMs."[1]

In the U.S. House of Representatives, the House Oversight Committee started an investigation into the tactics used by PBMs and the impacts to customers.[2] As of May 1, 2023, there are at least seven bills winding through Congress to address various aspects of the effect of PBMs on the healthcare marketplace,[3] including The Pharmacy Benefit Manager Transparency Act of 2023 (the "PBMTA"), which advanced out of committee in the Senate on March 23, 2023.[4]

Importantly, Congress passed the Consolidated Appropriations Act, 2021 ("CAA"), which includes certain transparency requirements obligating employer-sponsored group health plans ("Plans") to submit detailed information regarding the Plan's most utilized and costliest prescription drugs. The information that must be disclosed includes details regarding the drug rebates and fees and the impact such rebates have on the Plan's premiums and out-of-pocket costs. Additionally, CAA requires machine-readable files that publicly post the Plan's negotiated rates and historic net prices for prescription drugs to be put in place soon (rule is delayed pending further rulemaking).[5]

All is not quiet in the states either, for PBMs. In recent legislative sessions, 11 states have signed bills into law that regulate different aspects of PBMs and their business model.[6] The Attorneys General of several states have also opened investigations into PBMs,

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[1] Joshua Cohen, *Pharmacy Benefit Managers Are Again In The Crosshairs Of Congress And The FTC: Action To Reform Drug Pricing Increasingly Likely*, Forbes (Apr. 2, 2023).

[2] *Id.*

[3] Paige Twenter, *Seven PBM Bills Wading Through Congress*, Becker's Hospital Review (May 1, 2023).

[4] Angus Liu, *As Pharma Fights IRA, Senate Committee Advances Basket of Bills Aimed at Lowering Drug Prices*, Fierce Pharma (May 12, 2023).

[5] Centers for Medicare & Medicaid Services, Prescription Drug Data Collection (RxDC), CMS.gov.

[6] National Academy for State Health Policy, *2023 State Legislative Action to Lower Pharmaceutical Costs*, (updated May 19,

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and Ohio's AG recently filed suit against Express Scripts, and other related entities based on theories of price fixing, unfair and deceptive trade practices, and civil conspiracy.[7] Express Scripts, OptumRx, and Caremark are known colloquially as the ''Big Three'' PBMs, given that together these three companies control approximately 89% of the PBM market.[8]

Perhaps most notably for those in the employee benefits space, on May 1, 2023, the ERISA Industry Committee (ERIC) — a trade group for large employers in their role as Plan sponsors — joined with more than 30 other employer groups to support the PBMTA.[9] ERIC's letter pointed to four key reforms to how PBMs do business: (1) require complete and unrestricted transparency into the PBM ''black box'' (2) ban so-called ''spread pricing''; (3) require 100% pass-through of rebates, discounts, fees, and other payments from drug manufacturers; and (4) apply fiduciary standards to PBMs.[10]

There is a great deal of support for PBM reform in the air right now, and while these efforts may eventually bear fruit for Plan sponsors seeking transparency in their PBM arrangements, it is not enough to wait to see what happens. The PBM industry is at a critical juncture based, most recently, on ERIC's support for reform. The time to negotiate PBM Agreements and to press the Plan sponsor advantage is now.

THE PBM MARKETPLACE

The pharmacy benefit management market size in the United States stood at $482.4 billion in 2022.[11] By 2021, three PBMs controlled more than 80% of the market.[12] Meanwhile, as of 2022, nearly 159 million non-elderly people obtain health coverage though employer-sponsored plans.[13] Because PBMs control so much of the marketplace, virtually every Plan obtains prescription drug services from or through a PBM. Truly, PBMs have made themselves indispensable parts of the health care system in this country.

While PBM profits are enormous, the precise way in which PBMs generate income often intentionally is left opaque, making it difficult for Plan sponsors to determine how much value they are receiving for the fees paid to PBMs. This creates a conundrum. The Employee Retirement Income Security Act of 1974, as amended (''ERISA'') imposes a fiduciary duty upon Plan sponsors.[14] In turn, Plan sponsors have a fiduciary obligation to ensure that their Plan's assets are being spent prudently and in the best interests of the participants, which applies to health care prices, including pharmacy costs.[15]

The purpose of this article, therefore, is to discuss:

- What a PBM is and how it works;
- How a PBM's revenue generation affects Plan sponsors; and
- How a Plan sponsor may be able to reduce PBM fees to obtain greater value from its PBM.

The ultimate intent of this article is to help Plan sponsors better understand the various PBM fees so that they can determine, as required of a fiduciary, that such fees are reasonable. To the extent not reasonable, fiduciaries must negotiate those fees with the goal of reducing the overall costs for prescription drug benefits.

WHAT IS A PBM AND HOW DOES IT WORK?

A PBM is an administrator of prescription drug programs. More specifically, PBMs are involved in ''contracting with a network of pharmacies; establishing payment levels for network pharmacies; negotiating rebate arrangements; developing and managing formularies, preferred drug lists, and prior authorization programs; performing drug utilization review; and operating disease management programs.''[16] Some PBMs may also operate mail-order services.[17]

While there are several variations on the theme, a drug formulary is an evolving list of prescription medications created by the PBMs for plans. The formulary establishes which prescription drugs are covered and to what extent. The formulary generally con-

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2023).

[7] Ohio Attorney General, Press Release, *Yost Sues Express Scripts, Prime Therapeutics and 5 Others, Blaming Exorbitant Drug Prices on Their Collusion* (Mar. 27, 2023).

[8] Maia Anderson, *How 3 Companies Came to Dominate the PBM Market*, HealthCare Brew (Feb. 15, 2023).

[9] ERISA Industry Committee, Press Release, *ERIC and 30+ Employer Groups Support Pharmacy Benefit Manager Reform Act* (May 1, 2023)

[10] *See id.*

[11] Grandview Research, U.S. Pharmacy Benefit Management Market Size, Share & Trends Report by Business Model (Standalone, Health Insurance Providers, Retail Pharmacy), By End Use (Commercial, Federal), and Segment Forecasts, 2023-2030.

[12] Denise Myshko and Peter Wehrwein, *Beyond the Big Three PBMs*, 32 Managed Healthcare Exec. 12 (Dec. 14, 2022).

[13] Kaiser Family Foundation, 2022 Employer Health Benefits Survey.

[14] *See* 29 U.S.C. §1104.

[15] *See* Jeffrey M. Harris, *Using ERISA to Ensure Transparent Health Care Prices*, 36 ABA J. of Labor & Emp. Law 2 (2022) at 363.

[16] *A Tangled Web an Examination of the Drug Supply and Payment Chains*, U.S. Senate Committee on Finance, Minority Staff (June 2018), at 25.

[17] *Id.*

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sists of prescription drugs recommended by a multidisciplinary team of medical professionals, referred to as a Pharmacy and Therapeutic (P&T) committee. The P&T committee's chief role is to ensure that the prescription drugs contained in the formulary are based upon the most current data. Of course, once the formulary is in place, it impacts the specific prescription drugs a Plan's participants will use most, based on whether the prescribed drug is contained in the PBM's formulary and the cost. The formulary may use a tiering process, such that some drugs require a smaller out-of-pocket payment than others. The formulary may also be based, in part, on the ability of a PBM to negotiate favorable terms and costs for the inclusion of a specific drug from manufacturers and pharmacies.

A timely and real-life example of how a PBM can work with a manufacturer and leverage a formulary to its advantage relates to the drug Humira. Humira was the world's best-selling drug. When Humira finally went off-brand, Amgen created two generic versions of the drug. Both versions were exactly the same except one version cost $1,700 more than the other version. OptumRx (one of the largest PBMs) placed the more expensive version high on the formulary list. Amgen and OptumRx justified this by claiming the rebates for the costlier version were higher (and thus more beneficial to the Plan), even if ultimately participants were forced to pay more.

As it relates to pharmaceutical manufacturers, PBMs generate revenue through two main types of payments. In the first scenario, the manufacturers pay the PBMs to obtain preferential treatment in the PBM's drug formulary, and in the second the manufacturers make market-share payments to incentivize PBMs to increase the utilization of their drugs over those of their competitors. These payments are typically referred to somewhat nebulously as ''rebates,'' ''discounts,'' or, more recently, ''fees'' (e.g., financial incentive fees and manufacturing administrative fees).

In effect, PBMs negotiate rebates directly with pharmaceutical manufacturers, based on preferred placement on a formulary tier (e.g., placement on a ''preferred brand'' tier with more favorable cost-sharing amounts relative to products on a higher tier of the formulary) or based on utilization (e.g., if the manufacturer is able to achieve a certain percentage of the PBM's utilization for a particular therapeutic class of drugs).

PBMs also make money on the margin between the amount charged to Plan sponsors and the amount paid out to pharmacies for a prescription (also referred to as ''spread pricing''). In effect, PBMs negotiate a lower reimbursement rate with pharmacies.

Finally, PBMs generate revenue from Plan sponsors through administration and service fees charged to Plan sponsors for processing prescriptions, and through operation of their own mail-order and specialty pharmacies.

HOW DOES A PBM'S REVENUE GENERATION AFFECT PLAN SPONSORS?

For Plan sponsors, the relationship with a PBM is typically contractual, through a PBM Agreement, where the PBM agrees to provide prescription drug services for the Plan, including setting the formulary and administering the benefit. The contractual relationship between Plan sponsor and PBM includes various provisions that increase the costs of operating the Plan, which, in turn, increases the profits of the PBM. Two of the most prevalent methods PBMs use to increase profits are:

- *Spread pricing*: Spread pricing occurs when the cost to the Plan sponsor or policyholder is more than what the PBM pays the pharmacy for the medications. For example, assume that Drug X is a common prescription drug. The PBM has contracts in place with pharmacies to purchase Drug X at a discounted price of $10. When a PBM is using spread pricing, it may charge the Plan sponsor $25 for Drug X, which adds $15 (the ''spread'') in costs from the Plan to the PBM. By contrast, if a PBM does not use spread pricing, the cost to the Plan sponsor would be $10 charged by the PBM, subject to the base fees of the PBM Agreement. It is not difficult to see, in the aggregate, how the cost to the Plan increases exponentially in a spread pricing arrangement. The amount of the spread is almost never disclosed to the Plan sponsor.
- *Rebates*: In this context, a rebate is no different conceptually than ones offered to consumers for items such as cars and electronics: it is simply the return of part of the purchase price from the seller to the buyer. Here, pharmaceutical manufacturers pay prescription drug rebates to the PBMs. This incentivizes the PBM to create more spread revenue by driving up the costs of prescription drugs through formulary product selection. In turn, PBMs promote products that have higher rebates, creating an incentive for manufacturers to price products higher and deeply rebate the products back to the PBMs. In many cases, even where the PBM agrees to pass rebates on to the Plan, the PBM retains all or most of the rebate. As a result, Plan sponsors and members pay more because, in addition to not benefitting from the rebate, the rebates encourage PBMs to move less expensive (but equally effective) generic drugs into more ex-

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pensive tiers or out of the Plan's formulary altogether, which artificially increases the cost of drugs subject to the rebate.

By building these (and other) revenue streams into a PBM Agreement, PBMs are able to charge Plan sponsors an attractive administrative fee, which appears to be a savings to the Plan. Despite what appears to be a competitive administrative fee, the PBM Agreement allows the PBM to generate substantial revenue in other ways at the expense of the Plan and its participants. The PBM Agreement typically does not describe these revenue streams clearly or does not disclose them at all. The PBM Agreement often is drafted in a manner that restricts a Plan sponsor's ability to get the data needed to determine what the fees are and whether they are reasonable. This frustrates the Plan sponsor's ability to fulfill the fiduciary obligation to determine that the fees the Plan pays for PBM services are reasonable.

CAN A PLAN SPONSOR REDUCE PBM FEES AND OBTAIN GREATER VALUE FROM ITS PBM?

The strongest argument for PBMs' full disclosure of how they discharge their services to a Plan arises from the Plan sponsor's fiduciary duty under ERISA to:

(a) Ensure that the fees the Plan is paying any service provider are reasonable and appropriate; and

(b) Comply with the CAA transparency in coverage rules.

While a Plan sponsor is best served by addressing a PBM's financial structure prior to engaging the PBM, there is no reason for a Plan sponsor to withhold inquiries about a PBM's compensation structure while the PBM Agreement is in effect and before a renegotiation.

Plan sponsors should take the following steps to address the concerns mentioned in this article:

- Review the current PBM Agreement to identify all fees being paid directly or indirectly to the PBM related to the services being provided.
- Work to understand those fees and where appropriate, request all fee data (including rebates obtained and passed on to the Plan, discounted rates with pharmacies and/or pharmaceutical companies, etc.) as required under the CAA.
- Review the obtained fee data to ensure that any and all promised rebates and discounts are being passed on to the Plan in accordance with the PBM Agreement.
- Re-negotiate any fees that appear excessive and get certainty around unclear fees.
- Consider engaging in an RFP process to work with a different PBM to the extent current PBM is uncooperative.
- Document each of the above steps to show fiduciary due diligence in the event the Plan is challenged for excessive fees.
- Request the PBM to acknowledge its fiduciary status.

Often the PBM Agreement will establish that the Plan sponsor will pay some percentage of the average wholesale price (''AWP''). This raises several issues:

- There are multiple ways a PBM can determine the AWP, as there is not one set source for the data.
- AWP represents the ''list price'' or the ''sticker price'' of a drug. Thus, the AWP has a premium built into the price.
- While the Plan sponsor may be required to pay a certain percentage of the AWP for a drug, the PBM may have a contract in place with the pharmacy to reimburse the pharmacy for a drug at a lesser rate. This is a good example of spread pricing.

Plan sponsors can address these issues through careful and strategic negotiations.

As discussed above, PBMs receive rebates from the manufacturer tied to preferential treatment of a particular drug. There are several points to review and consider in negotiation, including ensuring that the PBM's formularies include a good mix of generic drugs.

For purposes of negotiation or as part of the Plan's auditing process, access to the data underlying the Plan sponsor's payments is critical for transparent pricing. In either case, the Plan sponsor should push for access to a myriad of information points, including a list of all financial benefits that the PBMs receive, and all payments made by the PBMs on behalf of the Plan's participants (separate and apart from what the Plan sponsor pays the PBM).

CONCLUDING THOUGHTS

By focusing on the details of PBM Agreements, the current spotlight on PBMs, and the various legislative initiatives for transparency, Plan sponsors — and Plan participants — can and should make every effort to achieve short- and long-term savings.

Because there are so many eyes trained on PBMs at this moment, Plan sponsors should ride the momentum, using the scrutiny as leverage to ask for terms that, in the past, might have been non-starters. For ex-

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ample, while it is unclear how effective ERIC's push for reform will be, Plan sponsors can argue in good faith that the PBM has a fiduciary obligation to provide data and transparency to all of its group health plan clients.

A Plan sponsor cannot expect that pushing back on its PBM will be easy, or that every point above will be conceded in whole or in part. PBMs are an entrenched business model, dominated by three large and influential players who are reluctant to cut their fees. Additionally, PBM Agreements are drafted by the PBM to restrict the amount of data the PBM is required to share with the Plan.

All those things being true, a Plan sponsor's fiduciary duty and its obligation to comply with the CAA are a strong counterweight. By articulating to the PBM the requirements incumbent upon a fiduciary, a Plan sponsor can address some of the more onerous provisions in its PBM Agreement, and with proper memorialization of the process will adhere to fiduciary standards, all while accruing savings to the Plan.

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