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Pharmacy Benefit Managers (PBMs) – Excessive Drug Pricing and Potential Fiduciary Issues

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Introduction

Over the past year, the ERISA plaintiffs' bar has set its sights on health plans, and more specifically on the question of the high costs of prescription drugs in employer-sponsored health plans. The focus of these lawsuits is the allegation that plan sponsors are paying "excessive fees" to the powerful middlemen — pharmacy benefit managers (PBMs).

Employers are acutely aware of similar "excessive fee" cases that have been brought against them as fiduciaries of 401(k) and 403(b) retirement plans. In those cases, plaintiffs assert breaches of ERISA fiduciary duties based on the plan fiduciaries' alleged overpayment of fees for investment management and recordkeeping services. Most of these cases allege that the investment options selected by plan sponsors are overly expensive and/or underperforming compared to other investment vehicles.

In these new health plan cases, the plaintiffs' excessive fee claims are based on information obtained under the transparency rules issued under the Affordable Care Act (ACA) and the Consolidated Appropriations Act, 2021 (CAA). Plaintiffs now have access to tools that show the amount that they — and their health plans — pay for the cost of prescription drugs. Using this information, plaintiffs are comparing the health plan negotiated rates for prescription drugs against the costs of these same drugs when obtained outside of their health plan — and alleging that the plan sponsor has failed to act prudently when negotiating with the PBM for drug prices.

Most of these cases filed against health plan sponsors are in their early stages. But, in one case the claim for fiduciary breach based on alleged injuries in the form of higher premiums was dismissed with leave to amend for lack of Article III standing as the claims were speculative. However, we assume the plaintiffs' bar will continue to file these cases, trying to find a way to move beyond motions to dismiss. Given the uncertainty about what new causes of actions may be filed, it is helpful for plan sponsors to understand how PBMs make money from group health plans, the allegations in current lawsuits, potential defenses and ways to help protect against being the next target of the plaintiffs' bar.

The Ecosystem of Prescription Drug Benefits in Health Plans

PBMs are the entities that administer the prescription drug portion of a health plan. PBMs are the middlemen between employers that sponsor health plans, plan participants, pharmacies and drug manufacturers.

- For an employer-sponsored plan, the employer contracts with the PBM to manage and administer the prescription drug portion of a health plan, including negotiating drug prices, creating drug formularies (i.e. a list of drugs covered by the plan), creating pharmacy networks and administering claims and appeals. This contract is used to determine the ultimate cost to the plan and participants for prescription drug benefits under the plan.
- Separately, the PBM enters into contracts with the pharmacies that dispense the drugs to participants, and those contracts address the amount that the pharmacies will be paid for the drugs dispensed. (The pharmacy gets the drugs it dispenses from a wholesaler who in turn gets the drugs from the drug manufacturer.)
- The PBMs also have a separate contract with the drug manufacturers about amounts that will be paid to the PBM for placing their drugs on health plan formularies. This is referred to as a "rebate." Rebates aim to incentivize PBMs to include the pharmaceutical company's drugs on the PBM's formularies and to obtain preferred "tier" placement.

How PBMs Make Money

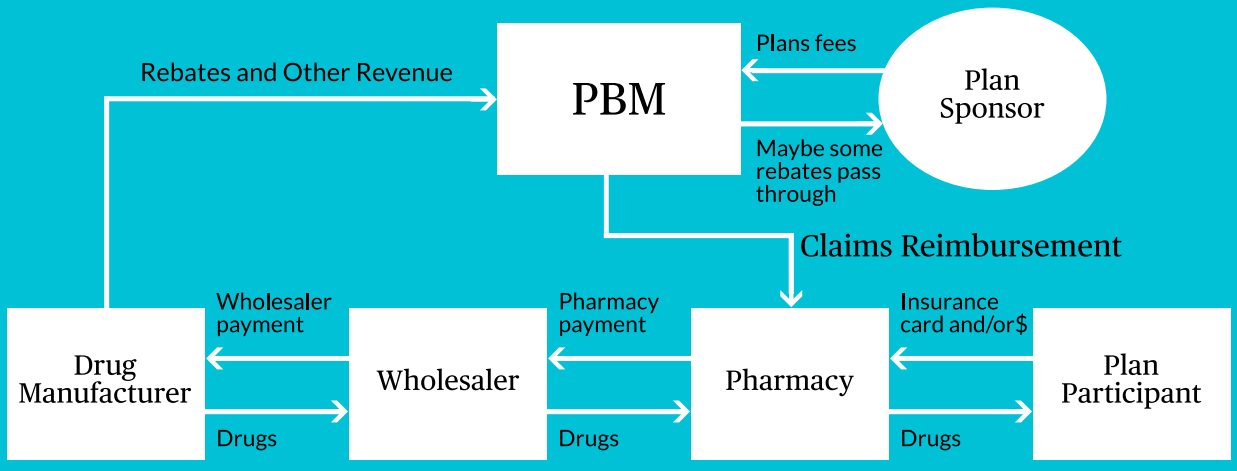
There are numerous ways that PBMs make money, but the recent lawsuits filed by plaintiffs focus on spread compensation. Spread compensation occurs when a PBM enters into a contract with a health plan sponsor stating that the plan sponsor will pay a certain amount to the PBM for a drug when it is dispensed by the pharmacy to a participant. The PBM has a separate contract with the pharmacy that sets the amount the PBM will pay the pharmacy when the drug is dispensed to a participant.

For example, the PBM has a contract with the pharmacy to reimburse the pharmacy for a drug that it dispenses at the price of $300. However, the PBM separately charges the health plan $2,000 when that drug is dispensed. The $1,700 differential is referred to as the "spread compensation," which the PBM retains as profits from the transaction. The amount of the spread compensation is not disclosed to the plan sponsor.

Why Is This Happening?

Some of the reasons why employer-sponsored health plans are having to pay such high fees for prescription drugs are: (1) despite new laws, PBM fees are still opaque, making it difficult for employers to understand and evaluate those fees, (2) employers lack bargaining power as three PBMs own 80% of the market and (3) PBMs are subject to minimal rules under ERISA. It is unclear if Congress will take any action in the near future to address these issues or if the battle regarding the high costs of drugs will occur in the federal courts in the form of class action lawsuits against plan sponsors.

PBMs as the Middlemen of the Prescription Drug Benefit Ecosystem



Main Allegations by Plaintiffs in These New Cases

The class action lawsuits that have been filed against health plan sponsors (in their fiduciary capacity) focus on an alleged violation of the fiduciary duty of prudence.

These complaints allege the following breaches of fiduciary duties:

- Failure to adequately negotiate the PBM agreement;
- Failure to monitor the PBM (such as conducting a market check on drug prices); and
- Failure to consider alternative PBM pricing models (such as a pass-through model that does not include spread pricing).

One of the complaints (Navarro et al. v. Wells Fargo & Company et al.) also includes an allegation that the plan fiduciaries engaged in prohibited transactions under ERISA by causing the plan to pay excessive and unreasonable administrative fees to its PBM. (In general, ERISA prohibits transactions between a health plan and its service providers unless only reasonable compensation is paid for the services.)

Possible Defenses

The biggest challenge for plaintiffs in these lawsuits is "standing" — the plaintiffs must establish that they have: (1) sustained a concrete injury, (2) the injury was caused by the defendant, and (3) the injury could be redressed by a court order. The defendants contend that the plaintiffs did not suffer any injury, let alone one that can be redressed by a court. Instead, they contend that plaintiffs received all the benefits they were contractually entitled to receive — the prescription drug benefits offered under the health plan at the cost established under the plan documents. Thus, the defendants maintain that the plaintiffs have no standing to bring a lawsuit.

At the time this article was authored, these suits were in their infancy. To date, only one motion to dismiss has been decided (the *Lewandowski v. Johnson and Johnson* case, which was partially dismissed with leave to amend), but that decision was in part fact-specific, focusing on the fact that the named plaintiff had prescription drug costs that far exceeded the plan's particular out-of-pocket maximum. We presume that the plaintiffs' bar will continue to re-tool their theories attacking prescription drug fees as they file additional lawsuits in pursuit of a large payday.

Actions That Plan Sponsors Might Consider

ERISA is a process-driven statute. The focus is not if the fiduciary came to the "right" answer or obtained the "best" deal, but if the fiduciary engaged in a prudent process. We have seen this defense — the use of a prudent process — in the 401(k) excessive fee cases.

For PBM contracts, some employers have taken some of the following steps as possible way to evidence the prudent process undertaken when entering into a contract with a PBM:

- √ Conduct a request for proposal (RFP) for a consultant that then will conduct an RFP for the PBM — this is encouraged so that the employer knows if the consultant has any conflicts of interest (such as various revenue streams from the PBMs);
- √ At a regular cadence (every 3-5 years), conduct an RFP for PBM services;
- √ As part of the RFP for PBM services, include specific questions about all direct and indirect compensation received by the PBM;
- √ Train the HR/Benefits department on the basics of pricing issues and contract terms for PBM contracts so that they can more meaningfully engage in the RFP process;
- √ Create a health and welfare fiduciary committee that engages in the RFP process and takes regular actions to monitor the PBM;
- √ Educate applicable employees (such as the HR/Benefits department or the members of a health and welfare committee) on fiduciary obligations for health plans; and
- √ Document the procedures listed above.

[1] *Lewandowski v. Johnson and Johnson et al*, D.N.J., No 3:24-cv-00671.

The Future

We expect that the plaintiffs' bar will continue to bring excessive fee cases against the fiduciaries of employer-sponsored health plans. If they are able to establish standing and survive a motion to dismiss, the flood gates will open. Even if plaintiffs are not successful with the specific claims described above, we believe they will continue to bring lawsuits against the employer-sponsored plans and PBMs under different theories. Now is a good time for employers to reevaluate their procedures for reviewing PBM contracts and monitoring PBMs, and to ensure that they have adequate Fiduciary Liability Insurance in place with an experienced, reputable insurer.

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Mary Powell has over twenty-five years of experience in all aspects of employee benefits. She is a Chambers rated lawyer and a Northern California Super Lawyer. In addition, she is a Fellow in the American College of Employee Benefits Counsel, the highest level of recognition for an ERISA attorney. Today, her main focus is the Consolidated Appropriations Act, 2021 (CAA), the Affordable Care Act (ACA), executive compensation and nonqualified deferred compensation. Mary is an expert in negotiating and reviewing pharmacy benefit manager (PBM) contracts. She has lectured frequently on various employee benefits topics, such as drug pricing under health plans and fiduciary duties for health and welfare plans, for many clients and organizations including The Commonwealth Club of California, a National Public Radio (NPR) affiliate and the Western Pension and Benefits Conference.

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Alison L. Martin is a Senior Vice President and the Fiduciary Product Manager for Chubb Insurance's North American Financial Lines, where she is responsible for crafting Fiduciary Liability Insurance for all varieties of organizations, including publicly traded and privately held companies, not for profit companies and multiemployer plans. She has over 25 years of experience in underwriting Fiduciary Liability Insurance and handling ERISA class actions. Prior to joining Chubb, Alison was a trial lawyer and a Member of the Board of Governors for the Western Pennsylvania Trial Lawyers Association. As Chubb's Fiduciary Product Manager, she speaks extensively at events, educating people on fiduciary obligations and exposures and transferring risk for these exposures through the use of fiduciary liability insurance.