

PBM Industry Could Face Major Challenges From ERISA Suits



February 22, 2024

A lawsuit filed by an employee against Johnson & Johnson could signal that significant changes in the legal obligations of commercial plan sponsors and PBMs around drug pricing are coming, experts say. The suit alleges that J&J violated its fiduciary obligations as a health plan sponsor under the Employee Retirement Income Security Act (ERISA) of 1974 by overpaying the plan's PBM for employees' medications.

If it's successful, the suit could expose plans, plan sponsors and PBMs to significant, ongoing legal risk, experts say. However, they add that the opacity and complexity of drug pricing dynamics mean that the suit's success is far from certain.

Similar suits have begun to proliferate in the medical benefits space, with some legal experts predicting that commercial health plan fiduciary suits over medical benefit reimbursement rates may become a cottage industry. The legal playbook for ERISA medical benefit fiduciary suits is currently under development by ERISA-focused plaintiffs' attorneys, who are digging into health benefits fresh off a wave of victories in similar suits against retirement plan fiduciaries. Experts say that developing similar protocols for PBM-related fiduciary suits will be even more complicated than medical benefit suits.

"The J&J lawsuit is fascinating, and I think it is the beginning of what I expect to be a series of lawsuits," Elizabeth Mitchell, CEO of the Purchaser Business Group on Health (PBGH), tells AIS Health, a division of MMIT. "I think it is interesting that it's focusing on drug prices, because I think that the PBMs have been especially challenging for jumbo employers to get access to needed information [on drug pricing]. They have been particularly opaque and resistant to meaningful transparency."

"Historically, employers just haven't had insight into, for example, how much is a PBM reimbursing the pharmacy for a drug, or what amount are the GPOs [group purchasing organizations] getting for rebates? How much of that

is getting passed through to the PBM? How much is the PBM passing back through to the plan? Even the most sophisticated employer doesn't have visibility into those amounts," says Kendra Roberson, an attorney and partner at Faegre Drinker.

Price Transparency Kicks Off Suits

A key cause of mushrooming health plan fiduciary litigation is the growing availability of federally mandated price transparency data disclosures. That data can be analyzed to determine whether plans have gotten the most bang for their members' buck as ERISA requires. However, similar requirements do not exist for PBMs. Proposals to mandate PBM price transparency are under consideration by Congress and have a good chance of passing. But they're years from yielding any information, even if they pass.

With no PBM transparency data available, PBM-focused plaintiffs like the J&J litigant are likely to have a harder time than medical benefit plaintiffs proving a plan sponsor has failed its fiduciary duty, Roberson says. That is compounded by the complicated drug pricing dynamics already at play.

The suit argues that the "Defendants' mismanagement is most evident in (but not limited to) the prices it agreed to pay...its pharmacy benefits manager...for many generic drugs that are widely available at drastically lower prices" — essentially holding J&J responsible for the price structure of its PBM's formulary.

Roberson couldn't comment on the specifics of the J&J case. However, she says PBM-related fiduciary responsibility suits will likely deal with allegations "implying that there's a fiduciary duty for fiduciaries to steer their participants to the lowest-cost drugs or only offer the lowest-cost drugs."

"I don't think that's an accurate depiction of the law," Roberson says of that legal theory. "I think there's a fiduciary duty for fiduciaries to look at their overall drug [spend] and make reasonable choices about what's in their [plan] participants' best interest in terms of how to administer a plan and a prescription drug benefit. But I wouldn't say there's a duty under the law that employers have to offer the lowest-price prescription drug for every drug [category]."

PBM Transparency Could Trigger Suits

Roberson says that the shifting policy picture adds important hints about the nature of future litigation.

"The FTC [Federal Trade Commission] is now of the view that...extensive vertical integration by PBMs into the drug supply have put employers and other payers in the marketplace at a severe information disadvantage," Roberson explains. Before July, when the FTC rescinded its previous guidance on PBMs, the opposite was true: "In the past, FTC was concerned that mandated disclosure requirements between PBMs and their customers could encourage price coordination and collusion."

In short, Roberson says, "the FTC itself has suggested that it's appropriate for policymakers to require PBMs to provide accurate and timely information to their buyers."

Mitchell raised the issue of shifting transparency disclosure requirements.

"The new...obligations that our members face, which require them to have visibility into the contracts they are signing, into the value of the services they are buying, really it's just in direct conflict with the PBM business model of complete opacity," Mitchell says. "It's going to be a very interesting dynamic as the pressure grows on self-insured employers to be able to demonstrate that they have evaluated not only pricing, but the quality and value and the downstream [cost] implications, for their [PBM] vendors, who have not traditionally provided that."

In addition, Mitchell says, "some of our members have shared that even the good contracts they put in place aren't always adhered to [by PBMs]. And a lot of the PBMs have contract provisions that prevent audits or require use of one of their [in-house] auditors. Then, we know of employers, even when they have audits done and found pretty significant overcharging, they can't get [excess funds] back."

Plan sponsors dealing with that sort of PBM intransigence are unlikely to have breached the fiduciary responsibility standards set out by current ERISA jurisprudence. If plan sponsors make and document a good faith effort to audit

plan expenditures, they will generally be safe from legal liability.

In the J&J case, in addition to the alleged price gouging, the plaintiff's attorneys argue that the company "failed to exercise prudence" required by ERISA "at multiple steps in the process of administering prescription-drug benefits," such as the process of selecting a PBM, agreeing to contract terms, allowing the PBM "to enrich itself," and failing to "actively manage and oversee key aspects" of the pharmacy benefit.

The suit also takes J&J to task for not using its bargaining power to obtain better rates from its own PBM or another "traditional PBM," not moving all or parts of its prescription-drug plan to a "pass-through PBM," and not directing members to "a well-known online pharmacy that charges only a 15% markup," likely Mark Cuban Cost Plus Drug Co.

But, based on current legal trends, if J&J can prove that it exercised due diligence in its PBM bidding process and was stymied by PBMs when it requested information on drug prices paid by its health plans, it may be off the hook.

Broker, Startups Could Feel Effects

Regardless of the merits of the J&J suit, Mitchells predicts that "you will see some movement toward the full pass-through, transparent PBMs as they are more aligned with employer fiduciary strategy."

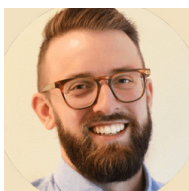
Mitchell also predicts far-reaching shifts in the PBM business if more ERISA fiduciary suits are coming. Brokers, benefits consultants and startup PBMs could all feel the effects.

"A lot of the brokers and consultants have been paid on the back end to promote the traditional PBMs," Mitchell says. Reporting by STAT in 2023 alleged that Aon, WTW, Mercer and Gallagher all take fees from PBMs in exchange for client referrals. "There's a whole learning curve [for] the purchasers, who are now personally liable and are being held to an expert standard," according to Mitchell.

Purchasers "can't just defer to these advisers anymore," Mitchell adds. Instead, she suggests they should "really learn about the implications" of pass-through, transparent PBM models.

"What has happened in the last several years is, when they've been evaluating them sort of head-to-head, it actually looks somewhat more expensive to go with the pass-through PBM, when in fact, in the long term, it isn't," Mitchell says. "There's going to be a new lens, I think, on evaluating...these two options. And because they [purchasers] are going to be required to know how much they're spending, the transparent PBMs will be much better positioned in the market."

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