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ALERT

PBM Contracting and Administration: What Are the Rules of the Road for Self-Insured Employees?

December 2, 2024

In February 2024, a group representing (among others) the Johnson & Johnson Group Health Plan and its component plans (Plaintiffs) sued Johnson & Johnson and The Pension & Benefits Committee of Johnson and Johnson (J&J) over the administration of its self-funded group health plan (the J&J case). Specifically, the Plaintiffs alleged that J&J violated its fiduciary duties under the Employee Retirement Income Security Act (ERISA) by failing to properly manage its specialty-drug prescription benefit program. ERISA requires that fiduciaries act "solely in the interest of the participants and beneficiaries" and "with the care, skill, prudence, and diligence under the circumstances..." The amended complaint states that J&J knew or should have known that their pharmacy benefit management (PBM) contracts were unreasonable and failed to protect the group health plan.

The J&J case is currently progressing and, as with any litigation, the outcome is uncertain. However, the mere filing of the lawsuit and the potency of the allegations compel consideration of potential warning signals sent to plan sponsors and plan administrators. This lawsuit comes at an opportune time, as the world of PBM contracting is under scrutiny at many levels. In 2023 alone, there were several federal and state legislative efforts aiming to reform the PBM regulatory scheme (see our prior alert). Additionally, Congress increased its activity and oversight of PBMs over the last few years to review their practices and improve drug costs. Most recently, the Federal Trade Commission (FTC) signaled forthcoming litigation against the largest PBMs after publishing an interim report in July 2024 assessing the PBM industry, which one of the PBMs (Express

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Health Care

Health Care Contracting

Pharmacy Benefit Manager (PBM) Contracting

Scripts, Inc.) is currently suing the agency over (see our prior alert).

As a result of the growing scrutiny of PBMs by regulators, litigation involving PBMs has only increased. The J&J case has received particular attention as it further highlights the already volatile issue of how PBMs are operating, and the proper level of oversight that must be given. The J&J case indicates rising frustration with the slow progress of these regulatory efforts and a heightened willingness to target plan sponsors and plan administrators to drive change. Specifically, the J&J case advances the proposition that the scope of fiduciary responsibility under ERISA for plan sponsors or plan administrators of self-funded group health plans (plans) might be broader than many plans have appreciated. As a result, it appears the J&J case could mark the beginning of a new wave of lawsuits against plan sponsors and plan administrators with respect to their health plans.

Thus, no matter the outcome of the case, it is important for plans to be aware of their fiduciary obligations under ERISA as it relates to their pharmacy programs. Below we provide concrete steps plan sponsors and plan administrators can take now that can curtail any resulting liability arising from this litigation or any subsequent actions that follow.

What Actions Should Plan Sponsors and Plan Administrators Consider Now?

The Plaintiffs specifically alleged that J&J mishandled its prescription drug benefit program by: (i) failing to adequately negotiate with its PBM, consider alternative PBMs, and exercise contract rights to ensure that the plan paid only reasonable amounts for prescription drugs; (ii) neglecting to oversee and monitor third parties with conflicts of interest who were managing the plan; and (iii) failing to properly monitor the drugs included in the plan's formulary. According to the complaint, these failures led to millions of dollars in damages, including excessive payments for drugs and higher out-of-pocket costs for plan members. Although the legitimacy of these allegations as they relate to J&J's conduct remains undetermined, each of these claims offers directional insights for plans to consider in the administration of their benefit plans, as summarized below.

1. Establish a PBM Procurement Process That Ensures Competition

Contracting with a PBM is a time- and resource-intensive and substantively complex process. Understanding the multi-layer drug distribution system, the drivers of significant differences among guarantees (e.g., the impact of formulary/clinical management on rebate guarantees), and the universe of potential administrative fees, requires a keen understanding of the overall PBM marketplace, as well as common differences among the competing PBMs/pharmacy service providers. It is impossible to understand the scope of the differences – and the speed at which they can change – without comparing the PBMs in an active competition. As a fiduciary, a plan must act prudently in its selection of a PBM to obtain the best terms for its members, and this goal rarely can be attained outside a competitive process that allows you to evaluate the PBM competitors against uniform standards.

Put more directly, setting forth an unambiguous procurement process for selecting (or re-selecting) a PBM is the essence of demonstrating a plan's commitment to fulfill its fiduciary duties of loyalty and prudence to its plan members. Indeed, a vigorous procurement process compels PBMs to compete among other PBMs/pharmacy service providers against plan-specific standards and goals. Whether a plan elects either a traditional procurement and contracting process (i.e., procurement, announcement of award, then contracting with the awardee), or a competitive contracting process (i.e., the Wiley-developed approach of negotiating the contract as an element of the procurement), competition allows a plan to engage meaningfully in selecting a PBM that will best serve its members.

2. Continuous Oversight of the Selected PBM and the PBM Marketplace

Plan sponsors and plan administrators should ensure their PBM contracts allow for the requisite oversight and monitoring capabilities needed to fulfill their fiduciary responsibilities under ERISA. The PBM marketplace is in flux, currently facing attempts at increased regulation from both the federal and state level, as well as rising litigation against key players.

In addition to the changing marketplace, overall prescription drug spending is expected to rise from 10% to 12%.[1] Due to the complexity of the health care system, and specifically the delivery of drug benefits to members, profound regulatory changes can happen quickly, and potentially render a prescription drug benefit program (or its contract) outdated or obsolete over a matter of a few years. Thus, it is important for plan sponsors and plan administrators to retain visibility into their prescription drug benefit program.

To the extent regulatory scrutiny or escalating drug costs result in large changes to the PBM industry (e.g., increased transparency requirements, heavier reporting obligations to regulators, etc.), plan sponsors and plan administrators need to be able to adapt their contracts quickly and efficiently to recognize necessary changes to their oversight processes and contract requirements.

3. Routine Review of Your PBM Contract(s)

Plans should routinely review their existing PBM contracts to understand their contractual rights, and, importantly, how the PBM's performance reconciles to its contractual commitments. The J&J case includes an allegation that J&J also failed to understand and exercise the full extent of their rights under the PBM contract and to effectively advocate in the best interest of its plan members. As counsel for plans and health plans, we strongly encourage our clients (and work with them as necessary) to evaluate their PBM contract terms for compliance with regulatory and statutory requirements, financial accuracy, and performance metrics against the changing PBM landscape, and to assess whether their PBM contracts align with their fiduciary responsibilities.

Areas of the PBM contract that may need special attention for this purpose include: (i) reporting and disclosure requirements; (ii) final approval rights over the content, form, format, and/or frequency of their formularies and formulary changes; (iii) limiting/narrowing of PBM channels for profit (i.e., rebates, discount programs, etc.); and (iv) review of pricing models (i.e., traditional vs. spread). In our prior alert, Wiley has outlined some critical high-value issues for health plans to consider. Nevertheless, plan sponsors and plan

administrators are encouraged to consult counsel on specific contractual provisions that will help the health plan maintain oversight and monitoring of their PBM contracts and the overall drug benefit program.

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While the exact outcome of the J&J case is undetermined, this case nonetheless underscores the importance of plans' fiduciary responsibility concerning the management and oversight of the pharmacy benefit programs and the PBM selected to administer the programs. The allegations in the J&J case (along with current industry trends to regulate PBMs) emphasize the potential for fiduciary accountability to extend directly to a plan's pharmacy program.

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Wiley's PBM Contracting team of experienced attorneys and advisors is available to assist with any questions.

Contact Us

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