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Employee Benefit Plan Review

Cautionary Tale Reveals New Scrutiny of Pharmacy Benefit Manager, Employer and Insurer Liability for Coverage of Innovative Therapies

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A recent district court case, *Henkel of America, Inc. v. ReliaStar Life Ins. Co.*,[1] serves as a cautionary tale for sponsors of self-insured health plans who, while relying on pharmacy benefit managers (PBMs) to set formularies and process certain claims and appeals, and on stop-loss insurers to cover claims above a certain level, may be left addressing significant coverage costs for innovative therapies.

In this case, the employer, Henkel of America, Inc. (Henkel), sued both the PBM that administered the plan's prescription drug benefits and its stop-loss insurer to try to recover about $50 million that the plan paid to cover the cost of innovative therapies for two employees.[2]

Henkel highlights the growing importance to all health care stakeholders (e.g., employers, PBMs, manufacturers and patients) of monitoring and shaping policymaking around patient access to, and payment for, the most innovative therapies.

Background On Self-Insured Plans

Many employers choose to self-insure their group health plans, paying the costs of their employees' medical care rather than paying premiums to a health insurance company to take on the liability for these claims. Self-insuring its health plan gives an employer the benefit of preemption from state insurance law under the Employee Retirement Income Security Act of 1974 (ERISA). Employers that sponsor self-insured health plans will typically hire an administrator (often a health insurance company) to administer claims for medical benefits and a separate administrator (usually a PBM) to administer claims for prescription drug benefits. In addition, employers that self-insure typically buy a stop-loss insurance policy to pay for employees' medical and prescription drug claims that exceed a certain threshold so as to limit the maximum amount for which the employer can be liable under the health plan.

The facts of this case demonstrate how this structure can create risk to the employer. A PBM administering a self-insured pharmacy benefit merely transfers the employer's funds to pharmacies to pay for prescription drugs under the plan. Aside from any performance guarantees or similar provisions for which the employer may negotiate in its contract with a PBM, a PBM generally has no financial incentive to keep prescription drug costs down. When prescription drug costs for a few employees go into the hundreds of thousands or even millions of dollars, there can be potentially severe consequences if the plan's stop-loss insurer denies coverage for prescription drug costs the PBM approved.

The *Henkel* Case

In the *Henkel* case, Henkel's self-insured plan covered certain prescription drugs for a rare blood disease that were thousands of dollars per dose, subject to certain pre-authorization requirements.[3] Two of Henkel's employees were prescribed high doses of these innovative therapies.[4] As the claims to cover the cost of these drugs went into the millions of dollars, Express Scripts, the PBM that administered the prescription drug benefit for Henkel's plan, continued to approve the claims.[5]

In trying to recover the amounts paid for the drugs, Henkel argued that Express Scripts was a fiduciary of the plan under ERISA.[6] The court denied summary judgment on this issue, holding that, except for one narrow exception, this question should be decided by a jury or other factfinder.[7]

Henkel's contract with Express Scripts specified that Express Scripts was a named fiduciary "in accordance with [29 C.F.R. §] 2560.503-1(h)."[8] The court held that, because that section of the Department of Labor's regulations refers only to appeals of claims for plan benefits, Express Scripts was a named fiduciary only with respect to appeals.[9] Separate language in the contract stated that Express Scripts had "authority and discretion" to decide claims and appeals, but the court found that language to be unclear because it could be interpreted to mean that Express Scripts had only authority to decide claims and discretion to decide appeals.[10] The court therefore held that it was not clear whether Express Scripts was a fiduciary under the plan with respect to the first-level claims for specialty drug benefits that Express Scripts had approved.[11] The court also did not decide as a matter of law whether Express Scripts acted as a *functional* fiduciary aside from any contractual provision designating it as a fiduciary.[12]

During the same period that Express Scripts was covering these specialty drugs, ReliaStar Life Insurance Co. (ReliaStar), the plan's stop-loss insurer, imposed a premium rate hike of 40% on Henkel under the plan's stop-loss insurance policy but then denied Henkel's claim for coverage of the total drug costs.[13] Henkel had purchased an endorsement to its stop-loss policy with ReliaStar that provided that ReliaStar would cover payments made according to the terms of Henkel's plan.[14] The endorsement also provided that, in any conflict between the policy and the endorsement, the endorsement would control.[15] ReliaStar argued that the drugs at issue were not covered under the terms of Henkel's plan.[16] The court did not decide this question but did hold that a plan provision giving Henkel discretion to award benefits meant that a deferential standard of review applied to the coverage decision, so ReliaStar could prevail only if approving the drugs was an abuse of discretion.[17]

Lessons For Employers

PBMs

One direct take-away from this case for employers that sponsor self-insured health plans is to carefully review any provision in the agreement with the plan's PBM to ensure that the agreement states that the PBM is an ERISA claims fiduciary that is authorized to decide both claims and appeals for benefits. The court's decision in the *Henkel* case turned on language in the contract between Express Scripts and Henkel. That contract language had the effect of limiting Express Scripts' fiduciary status to appeals of benefit claims and did not clearly grant Express Scripts discretion to decide first-level claims.

However, even if Henkel were able to establish as a matter of law that Express Scripts was a fiduciary, Henkel would still need to prove that Express Scripts breached its fiduciary duties and that this breach resulted in liability to Henkel. Henkel might be able to seek relief under ERISA on the basis that it was also a fiduciary of the plan and that any losses awarded to the plan should be paid to Henkel, assuming the plan has no trust and no plan assets. However, recovery on such a claim would not be automatic.

To ensure the clinically appropriate utilization of high doses of specialty drugs, and to avoid the potential difficulties of recovering damages under a theory that a PBM is a fiduciary, employers can consider drafting their plans to require pre-authorization or utilization review for certain drugs. If the plan includes these types of limitations on coverage, employers should take measures to review their PBM's coverage of specialty prescription drugs to ensure that the PBM is correctly applying these restrictions. Employers should also consider including audit rights, performance guarantees, and similar provisions in their contracts with their PBMs to ensure that the PBM will be properly incentivized to carefully review unusual claims and will be required to bring them to the employer's attention. Employers should also review and evaluate how the PBM determines the formulary of drugs that will be covered under the terms of the plan, including how the PBM determines which drugs – and which doses of any covered drugs – are classified as experimental or investigational.

Stop-Loss Insurance

Another lesson for employers is that purchasing a stop-loss insurance policy that covers any expenses covered by the plan can preclude many arguments an insurer might make in trying to deny a claim for coverage. The court emphasized that Henkel had purchased an endorsement to its stop-loss policy that provided coverage for all payments made according to the terms of the plan. As a result, ReliaStar's only argument for denying coverage was that the drugs were not covered by the plan, and ReliaStar could not prevail on that argument unless Henkel abused its discretion in covering the drugs. In addition, the endorsement's provision that it controlled in the event of conflict with the policy prevented ReliaStar from prevailing on any of its arguments about limitations on coverage contained in its policy. Without this endorsement, ReliaStar could have argued that its policy simply did not cover the cost of the drugs, regardless of whether they were covered under the plan.

Lessons for Life Sciences Companies

As a result of *Henkel*, employers that sponsor self-insured health plans may further scrutinize formularies and seek to limit, remove, or place additional utilization management requirements for the most innovative specialty therapies. Manufacturers may consider engaging in conversations with employers, industry groups and policymakers advocating for the imposition of fiduciary and fiduciary-like obligations on PBMs, such as duties of good faith and fair dealing. In addition, manufacturers should be apprised about the evolving practices of PBMs and employer-provided health coverage and the potential impact on certain patient populations and coverage policies.

Life sciences companies should also engage in policymaking around coverage of stop-loss insurance policies and potential carve-outs from those policies, particularly for innovative therapies. Framing the value conversation remains pivotal because a growing pipeline of innovative and curative therapies will receive approval from the U.S. Food and Drug Administration in the coming years. Stop-loss carriers may have their eye on this pipeline of emerging therapies and might consider defensive actions to limit their costs and patient coverage.

In order to maintain broad patient access to these innovative therapies, manufacturers should raise concerns with employers and policymakers about any proactive patient targeting and exclusionary activity.

Notes

1. Henkel of America, Inc. v. ReliaStar Life Ins. Co., No. 3:18-cv-965 (JAM), 2023 WL 1801923 (D. Conn. Feb. 7, 2023) (slip op.).
2. Id. at *1.
3. Id. at *2.
4. Id. at *1.
5. Id. at *4.
6. Id. at *6.
7. Id. at *6-7.
8. Id. at *8.
9. Id.
10. Id.
11. Id.
12. Id. at *6.
13. Id. at *11.
14. Id. at *8.
15. Id. at *9.
16. Id. at *8.
17. Id. at *9.

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