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Benefits Alert

October 13, 2023

Fiduciary governance: Fiduciary oversight of pharmacy benefit managers

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Discover the many facets of PBM contracts that should
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What's the impact?

- Health plan fiduciaries should retain a qualified independent pharmacy consultant, specialized auditor, and ERISA legal counsel to assist with PBM monitoring.
- Various audits are recommended to assess compliance, market changes, claims data, pricing, and performance, among other factors.
- Consider conducting RFPs every few years to adjust to market changes and business needs.

As we reach the midway point in our Health & Welfare Fiduciary Governance Series, we have already described the need for health plan fiduciaries to exercise their fiduciary duty of care by monitoring the activities of third-party administrators (TPAs). In our prior installment related to pharmacy benefit managers (PBMs), we highlighted various best practices when evaluating, selecting, and contracting with PBMs. As with medical benefit TPAs, once a PBM is selected and

the service engagement implemented, health plan fiduciaries have an obligation to monitor the PBM's activities. Here, we discuss key aspects of health plan fiduciary oversight of PBMs.

Understanding PBMs

It is no secret that the primary driver of increasing health plan costs are prescription drugs, especially new and expensive specialty medications. Employers and health plan fiduciaries, with the help of specialized pharmacy consultants and ERISA counsel, must monitor these growing costs. In addition to monitoring costs, quality, and effectiveness of the pharmacy program, health plan fiduciaries must monitor PBM contract compliance. Set forth below are key methods that employers and health plan fiduciaries can employ to achieve these objectives.

Ongoing PBM monitoring

To assist with PBM monitoring, health plan fiduciaries should retain a qualified independent pharmacy consultant (preferably with pharmacists on staff) with experience advising on plans of comparable size and complexity. Independence from the PBM is key to ensure that the consultant is acting in the best interests of the plan without potential conflicts of interest. With a pharmacy benefit consultant in place, health plan fiduciaries have the following tools at their disposal to assist with ongoing monitoring.

PERIODIC CLAIMS REPORTS

Health plan fiduciaries should get from the PBM periodic claims reports showing overall spend, spend across primary therapeutic classes, trends, and application of utilization management programs. Usually, these reports are provided on an aggregate basis and on a monthly or quarterly timeline. The pharmacy consultant, however, should have access to much more detailed claims data (individual claims that are deidentified) and should receive the data feed on a weekly or bi-weekly basis. The pharmacy consultant can then conduct a more detailed analysis of spend and utilization patterns, and can make recommendations based on what they are seeing.

For instance, over the past 12–18 months, many employers have shown a significant increase in costs related to weight loss and/or diabetic medications being prescribed off-label for weight loss. High off-label prescribing may warrant application of utilization management (e.g., prior authorization), and the pharmacy consultant with access to frequent data feeds would be in the best position to make that recommendation. These reports may also provide an early warning about any fraud in prescribing and dispensing certain drugs (e.g., compound medications).

FORMULARY MANAGEMENT OVERSIGHT

PBMs establish a preferred drug list (or formulary) that identifies those drugs that are covered or excluded, and drugs that are within various cost sharing tiers (i.e., generic, brand preferred, brand non-preferred, and specialty). There are thousands of FDA-approved drugs and products, and there are thousands more in the development pipeline. Each PBM has a pharmacy and therapeutics (P&T) committee that evaluates these drugs and determines which should be covered and in which coverage tier they should be placed. Although the P&T committees purportedly do not take cost into consideration when making formulary decisions, which drugs are covered in each coverage tier can greatly impact cost.

Health plan fiduciaries should instruct their pharmacy consultants to actively monitor a PBM's formulary management and make recommendations in the event an alternative formulary design would be appropriate. This is particularly important as new generic or biosimilar drugs often become available, and adding those drugs to the formulary can greatly reduce pharmacy benefit costs.

MARKET CHECKS

Assuming the health plan fiduciaries have this right under the PBM agreement, the fiduciaries should work with their pharmacy consultants to conduct an annual market check. As part of the contracting process, the PBM and fiduciaries agree to various financial terms (such as ingredient cost, dispensing fee, and rebate guarantees) that could become unfavorable to the market over time. Under typical market check provisions, if a pharmacy consultant can show that a benchmark plan of comparable size and complexity has pricing that results in a cost disparity of 1% or more, the financial terms of the contract will be adjusted to reflect the current market provisions.

PBM AUDITS

Similar to medical benefit TPA oversight, a primary method for PBM oversight is conducting audits pursuant to the audit rights provisions under the PBM agreement. Best practice is to retain a specialized auditor that is independent from the PBM and brokers/consultants that assist on PBM selection and monitoring. There are four primary audit categories that could be targeted in the PBM context: claims, pricing, performance guarantees, and overall contract compliance. Claims, pricing, and performance guarantee audits should be conducted at the same time and on an annual basis. Overall contract compliance audits, which can be more complex, can be completed every few years. Each of the audits is briefly described below.

CLAIMS AUDITS

On an annual basis, fiduciaries should direct its auditor to review claims to ensure that the PBM is adjudicating claims and appeals in accordance with the coverage terms of the plan. Typically, the

auditor will have access to a limited number of claims (depending on the size of the plan, it could be between 300–500 claims). If the auditor identifies claims discrepancies that appear to be systemic, a more comprehensive claims review may be warranted.

PRICING AUDITS

As noted above, PBM agreements typically have ingredient cost, dispensing fee, and rebate guarantees. These guarantees are generally based on the calendar or plan year, so health plan fiduciaries should ensure that the guarantees have been satisfied. The plan's auditor can work with the plan's pharmacy consultant to review all necessary claims data and manufacturer agreements to ensure that the guarantees have been met. The auditor and pharmacy consultant should carefully review the PBM's exclusion of any claims from the guarantee calculation to ensure that the claims have been properly excluded under the terms of the PBM agreement. If a guarantee fails, the PBM should be required to make the plan whole for the underperformance.

PERFORMANCE GUARANTEE AUDITS

Many PBM agreements contain various performance standards that PBMs must satisfy. If any of those standards are not met, the PBM would be penalized based on the terms of the agreement. These standards may include the following: dispensing accuracy and timing, timely reporting, customer service metrics (e.g., answering speed, abandoned calls, etc.), and claims adjudication accuracy.

CONTRACT COMPLIANCE AUDITS

In addition to the annual claims, pricing, and performance guarantee audits, health plan fiduciaries should consider a more comprehensive contract compliance audit every 3–5 years. These audits would go beyond the standard annual audits and could evaluate compliance with the following common contractual terms:

- **Eligibility**—ensure that the PBM is only covering claims for eligible employees and their eligible dependents.
- **Plan Exclusions**—confirm that the PBM is not approving claims for drugs that should be excluded from coverage based on the terms of the plan.
- **Utilization Management**—review of the utilization management program to ensure that the PBM is properly applying prior authorization, step therapy, and dose/quantity limitations.
- **DAW Copayment Differentials**—confirm that the PBM is properly collecting copayment differentials when a brand name drug with a generic alternative is dispensed without a "dispense as written" indicator from the prescriber.
- **House Generic/Drug Interchange Programs**—assess any house generic or drug interchange program (i.e., programs that allow the PBM or prescriber to dispense a brand name drug as if

it were a generic) to ensure that it results in a lower overall cost to the plan.

- **Fraud, Waste, and Abuse Programs**—evaluate any fraud, waste, and abuse programs adopted by the plan to confirm that it is operating as intended.

The scope of a contractual compliance audit would vary depending on the size and complexity of the plan. Health plan fiduciaries should work with the auditor, pharmacy consultant, and ERISA legal counsel to develop the appropriate audit scope.

Requests for Proposals

Perhaps the most important method that health plan fiduciaries have to ensure that it is paying reasonable fees for PBM services is by conducting periodic requests for proposals (RFPs). The RFP process has been discussed in prior installments of this benefits alert series, so we will not describe the process here. RFPs remain important even when the PBM agreement permits periodic market checks because the competitive nature of an RFP with several bidding PBMs allows a fiduciary to not only evaluate pricing, but also to assess other important contractual terms, such as formulary management, utilization management, and programs and services. Given the dynamic nature of the pharmacy benefit environment, fiduciaries should conduct PBM RFPs every 3–5 years.

Takeaways

As described above, health plan fiduciaries have tools at their disposal to monitor PBM activities with respect to their plans. Not all of them must be deployed to ensure compliance with ERISA's fiduciary obligations. For smaller and less complex plans, perhaps only a few would be necessary. For larger and more complex plans, most if not all should be considered. In any event, fiduciaries should ensure that all of these activities are adequately documented and records are retained for several years.

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