PBM P&T Practices

The HEAT Initiative Is Gaining Momentum

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Introduction

The origins of the modern P&T committee lie in hospital-based drug management practices. As managed care evolved and pharmacy benefit management (PBM) emerged through Medicaid and commercial insurance growth, many former hospital pharmacists moved into the growing variety of managed care pharmacy positions.[1]

The PBM industry has come a long way from its start in the 1960s handling computerized prescription claim adjudication using plastic benefit cards. Its current role focuses on the reduction of pharmacy expenditures among plan sponsors with concurrent improvement in health outcomes. Since 1998, when the Department of Justice (DOJ) first investigated their effectiveness in doing that, PBMs have faced increased scrutiny for a lack of transparency, with some suggesting they are partly to blame for skyrocketing prescription drug prices. As the discourse on prescription drug prices in the United States intensifies, PBMs find themselves in the midst of a major shake-up of the industry regarding antitrust and antikickback laws, standards imposed by the Employee Retirement Income Security Act of 1974 (ERISA), and consumer fraud. Over the past two years, PBMs have fallen into the crosshairs of government investigations about the high cost of pharmaceuticals, with an emphasis on potential health care fraud involving contractual relationships between drug manufacturers and PBMs.

In 2016, PBMs managed pharmacy benefits for 266 million Americans.[2] While there are approximately 60 PBMs in the U.S., the three largest—Express Scripts (formerly Medco Health Solutions), CVS Caremark, and OptumRx—comprise 62% of the market,[3] accounting for approximately four billion retail prescriptions,[4,5] and have enjoyed great profitability. PBMs serve as third-party administrators of prescription programs for commercial health plans, self-insured employer plans, Medicare Part D plans, the Federal Employees Health Benefits Program, and state government employee plans. They play a critical role in the prescription drug supply chain by performing a number of P&T-related activities, such as developing, maintaining, and enforcing the formulary (Table 1). This article specifically focuses on PBM-based P&T and formulary practices.

PBM P&T Processes Under Scrutiny

The formulary decision process involves three key prongs: therapeutic assessment, P&T committee assessment, and value assessment. Formulary design is one of many levers for plan management. Because of the large percentage of Americans covered by PBMs, the commercial success of a drug in the U.S. depends largely on its inclusion on as many formularies as possible. Table 2 lists examples of PBM P&T processes that have drawn enforcement scrutiny.

Exclusions

PBM formulary-restriction strategies have shifted from higher cost-sharing tiers, step therapy, and prior authorization to excluding certain drugs entirely. Last year, Express Scripts projected savings of $1.05 billion tied to formulary exclusions. This occurs frequently with new-to-market drugs, thereby creating patient access issues for innovative therapies,

Table 1 Pharmacy Benefit Managers' P&T Activities

- Creation and maintenance of formularies
- Formulary compliance (academic detailing)
- Formulary-related plan design—exclusions, tiers, copays
- Manufacturer discounts
- Rebate contracting and administration
- Clinical management, such as drug utilization review and disease management
- Patient compliance programs
- Generic substitution programs

Table 2 Pharmacy Benefit Manager P&T Practices Under Scrutiny

- "Inducements" (potentially kickbacks) for preferred formulary status (e.g., rebates and market share incentives)—both soliciting and receiving
- Prohibited drug-switching practices; role of the P&T committee in such switches
- Negotiation misrepresentations (e.g., misrepresenting discounts)
- Failing to require generic substitution on mail and retail prescriptions
- Manipulating generic drug reimbursement rates (maximum allowable cost pricing)
- Switching without medical justification (steering to higher-cost and/or brand drugs)
- Switching patients without their knowledge
- Failing to meet performance standards
- Preauthorization requirements making it impossible for plans to recoup money
- Restrictions due to high costs of drugs rather than prevailing medical guidelines
- Failure to keep clinical criteria for medical necessity or prior authorization updated given new drug introductions to the market

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the clinical consequences of which are unknown. PBM contracts may provide only 120 days' notice of a formulary change, which frequently is insufficient for a patient and his or her physician to evaluate the new formulary and to either adjust treatment or file an appeal. In some cases, "ping-ponging" occurs when drugs excluded from the formulary in one year are included in the next year. This further complicates appropriate formulary use and inconveniences patients.[6]

Indication Restrictions

An additional formulary management tool that is becoming popular among PBMs is off-label and on-label indication restrictions. For example, Express Scripts recently announced a formulary management program entitled "Inflammatory Conditions Care Value Program" to corral pricing and market share of a variety of anti-inflammatories. Niche, single-indication products will be able to compete head-to-head with the two products with the largest market share, etanercept (Enbrel, Amgen) and adalimumab (Humira, AbbVie). The program involves close patient monitoring through Express Scripts' Accredo Specialty Pharmacy to make this therapy class more affordable. Patients currently on the two market-leading drugs will be able to stay on them, and patients put on one of these other niche drugs will generate a rebate to health plans.[7]

Switching

Over time, PBMs have been accused of a lack of financial transparency, engaging in inappropriate conduct (pressure toward pharmacists; misrepresentation to patients, pharmacists, or physicians; or failing to disclose ownership interest when advocating a switch) in order to shift a patient from one drug to another and profit from the change.[4,8,9] Switching patients to other medications has both financial and disruptive effects. Switching patients to higher-cost drugs that may be less efficacious to maximize rebates is seen as an egregious consumer protection violation. Patients do not directly benefit from plan rebates, and the value of switching is unclear from the patient's perspective. Patients may feel the cost increases as copays and often do not fill the prescriptions, leading to decreased adherence, disease-state worsening, and higher health care costs for the plan and society.[9,10]

Formulary Preference—Bundled Rebates

Brand manufacturers want evidence of shifted market share to improve market terms and will typically achieve that via rebates, not discounts, as rebates pose a lower risk for them. This is especially true for drug classes in which brand use may be more prevalent. In some cases, PBMs have chosen drugs for formularies based on rebates and discounts rather than cost-effectiveness and efficacy—although the lack of transparency in their dealings can make that allegation difficult to prove. Examples of such activity can occur when a brand drug goes generic under the Hatch-Waxman Amendments, with the first generic version being granted six months of market exclusivity. In exchange for substantial rebates, manufacturers have approached PBMs for an exclusive extension of their brand drug, which circumvents Hatch-Waxman and blocks generic competition. Similarly, when brand Drug Y goes off patent, a PBM would be incentivized to change its formulary to remove Drug Y and replace it with Drug Z, which is not losing patent protection for some time, thereby receiving rebate dollars from Drug Z's manufacturer.[8]

Generic Drug Substitution And MAC Pricing Spreads

A large portion of PBM profits come from maximizing spreads on generic drugs (i.e., the difference between the price they pay pharmaceutical manufacturers and the price they charge plan sponsors). Maximum allowable cost (MAC) lists are PBM-generated lists of generic drugs that include the highest amount a PBM will pay for generics and brand drugs with generic versions. Pharmacies and plans are not informed of MAC prices, how they are determined, or how products are included or excluded from MAC lists. In some cases, the patient's copay is greater than the cost agreed to by the PBM and pharmacy. For example, the copay on a particular generic might be $15, but the medication actually costs $2. The pharmacist receives $7, a profit of $5. The PBM "claws back" the remaining $8 from the pharmacy. Numerous lawsuits have been filed regarding claw-backs.[11,12]

Another PBM pricing practice under scrutiny involves direct and indirect remuneration (DIR) fees assessed to dispensing pharmacies in the form of service fees, network access fees, administrative fees, and reconciliation. Pharmacies don't know if or when these fees are in place or how much they are. The fees, in essence, are a way to work around state transparency laws. Legislation is pending regarding Medicare Part D and DIR fee transparency.[13] However, because claw-backs and DIRs are not specifically a P&T issue, we will not discuss them further in this article.

Public Sector—HEAT On PBM P&T Practices

Early PBM litigation involved formularies and the favoring of certain drugs when the PBM was owned by the pharmaceutical manufacturer, i.e., vertical integration. Following the Merck-Medco merger, Merck's volume for its own drugs increased 10% to 15%.[14,15] A 1995 lawsuit between Pfizer and PCS, a PBM then owned by Eli Lilly, was based upon failure to include certain Pfizer drugs (e.g., an antidepressant in direct competition with Eli Lilly's Prozac [fluoxetine]) on the PCS formulary, in violation of a contractual agreement. Pfizer prevailed on its anticompetitive claims. In 1996, PCS again came under scrutiny via petition from the National Association of Chain Drug Stores and consumer groups for a closed formulary that indicated the P&T committee's independence could not be verified.[16] Between 2004 and 2008, PBMs were the subject of six major federal or multidistrict cases involving P&T fraudulent practices, resulting in more than $371.9 million in damages to states, plans, and patients. Examples of litigation involving PBM P&T practices appear in Table 3.

In May 2009, the DOJ and the Department of Health and Human Services (HHS) announced the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative to prevent or reduce Medicare and Medicaid fraud. The HEAT initiative has recovered more than $15.3 billion in cases involving fraud through violations of the Anti-Kickback Statute involving False Claims Act cases.[17–19] Allegations of violations

Table 3 PBM Litigation Involving P&T-Related Issues

Case	Basis, Route of Complaint, and Allegations
Eli Lilly/PCS merger (1985)[28]	Federal Trade Commission. Vertical merger resulted in formulary preferences. Settled via consent order.
Mulder v PCS Health Systems, Inc. (1998)[29]	ERISA. Resolved against plaintiff. Self-dealing, including formulary practices and drug-switching practices.
Merck & Co. Inc./Medco merger (1999)[28]	Federal Trade Commission. Vertical merger resulted in formulary preferences. Settled via consent order.
United States v Merck-Medco Managed Care, LLC, et al. (1999 and 2000)[29]	False Claims Act. Settled for $184.1 million, cumulatively. Allegations of switching patients' prescriptions to different drugs without their knowledge/consent; false reporting of physician contacts for switching; secret rebates for increasing market share.
United States ex rel Ramadoss v Caremark, Inc. (1999)[29]	False Claims Act. Settled in 2013. Alleged preauthorization requirements made reimbursement impossible.
Bickley v Caremark, Inc., et al. (2002)[29]	ERISA. Resolved against plaintiff. Alleged that PBM negotiated with manufacturers to favor more expensive (but equivalent) drugs in drug-switching program in exchange for compensation (i.e., kickbacks).
Medco Health Solutions, Inc., litigation (2003)[29]	ERISA. Settled for $42.5 million. Allegations of promoting more expensive Merck drugs over less costly alternatives. Breach of fiduciary duty in management of formulary and drug-switching programs.
Board of State Teachers Retirement System of Ohio v Medco Health Solutions, Inc. (2003)[29]	Breach of contract. Settled for $7.8 million. Allegations of steering of physicians, pharmacists, and patients to choose brand-name and higher-cost medications manufactured by Merck rather than generic equivalents; switching patients to different drugs without patient knowledge/consent; soliciting and receiving kickbacks.
Group Hospitalization and Medical Services v Merck-Medco Managed Care, LLP, et al. (2003)[29]	State law. Negligent misrepresentation, unjust enrichment. Settled July 31, 2008. Alleged failure to require generic substitution; choosing drugs for formulary based on rebates rather that cost-effectiveness/efficacy; engaging in drug switching to higher-cost drugs without medical justification.
Moeckel v Caremark, Inc., et al. (2004)[29]	ERISA. Resolved against plaintiff. Self-dealing, including formulary practices and drug-switching practices.
State of New York v Express Scripts, Inc., et al. (2004)[29]	Breach of contract. Settled for $27 million. Allegations of inducing physicians to switch patients, often to higher-cost drugs, based on PBM rebates.
State Attorneys General v Express Scripts, Inc. (2008)[29]	Consumer protection acts. Settled for $9.3 million, with up to $200,000 to affected patients. Numerous states alleged PBM illegally encouraged doctors to switch patients to different brand-name medications while profiting from same without passing savings on to plans.
State Attorneys General v Caremark, Inc. (2008)[29]	Consumer protection acts. Settled for $41 million. Twenty-nine attorneys general alleged deceptive trade practices and failure to inform of profits from drug switches. Patients were switched from originally prescribed brand drugs to different brand drugs.
United States v AstraZeneca (2015)[20]	Anti-Kickback Statute. Settled for $7.9 million. Allegations that PBM received kickbacks to maintain "sole and exclusive" formulary status for certain drugs.
United States ex rel Kester et al. v Novartis et al. (2015)[30]	Anti-Kickback Statute. Settled for $390 million; specialty pharmacy settled for $60 million. Allegations of inducement of specialty pharmacies to increase prescriptions for Novartis drugs by paying kickbacks in the form of rebates.

ERISA = Employee Retirement Income Security Act of 1974; PBM = pharmacy benefit manager.

of the Anti-Kickback Statute have led to large settlements by PBMs. The lawsuits, many of which are *qui tam*, or whistleblower suits, typically allege that the PBM negotiated rebates from pharmaceutical companies that it did not disclose to the government. Such hidden financial agreements are considered kickbacks, which can increase drug prices, influence formularies, and inappropriately guide pharmaceutical prescription decisions.

In 2015, under the HEAT initiative, DOJ allegations of potential kickback arrangements in which pharmaceutical companies provided price concessions on other products in exchange for sole and exclusive formulary status in violation of the False Claims Act resulted in very large settlements and judgments. In two cases, the price concessions or discounts were not disclosed to Medicaid as required under the Medicaid Drug Rebate Statute's "best price" reporting requirements. The companies settled for

$7.9 million each.[17,20] In 2016, again under the HEAT initiative, the U.S. attorney served civil investigative demands (CIDs) for information from Johnson & Johnson, Merck, and Endo concerning their PBM contracts, services, and payments going back to 2006. While the CIDs pertain to the False Claims Act, the actual allegations are unknown.

In February 2017, a class action lawsuit was filed against three large insulin manufacturers claiming violations of the Racketeer Influenced and Corrupt Organizations (RICO) Act, accusing them of intentionally raising list prices to gain favorable treatment from PBMs based on an increased "spread."[21] While PBMs are not defendants in the lawsuit, they were identified as complicit in favoring insulin products with increased list prices. The 171-page complaint attacks PBM rebates, stating: "Consumers in high-deductible plans or Medicare must pay the inflated list prices until they reach their deductible or, in the case of Medicare, the 'donut hole.'"

The HHS Office of Inspector General (OIG) has also focused on arrangements between pharmaceutical manufacturers, pharmacies, and PBMs. The OIG Work Plan 2017 includes determining what steps the Centers for Medicare and Medicaid Services and Medicare Part D sponsors have taken to improve oversight of P&T committee conflicts of interest. Prior OIG work found lack of adequate supervision to ensure compliance with federal conflict-of-interest requirements for P&T committees.[22]

There have also been claims that potential kickback arrangements that remain secret (the last PBM to publicly disclose rebates was Medco in 2012) have caused health plans to operate against the interest of their members. While PBMs have repeatedly argued that they do not have a fiduciary duty to place their clients' financial interests above their own, about 20 states (including Maine, Maryland, Mississippi, North Dakota, South Dakota, Vermont, and the District of Columbia) have enacted so-called PBM "transparency laws." In addition, both the Patient Protection and Affordable Care Act[23] and Medicare Part D require PBM transparency. These transparency laws requiring mandatory disclosure of rebates and discounts, as well as formulary and switching practices in some cases, have been challenged under ERISA, state unfair trade practices acts, and as violations of the "taking and due process" clause of the U.S. Constitution.[24] PBMs have argued that terms of rebate contracts are variable and secret and that PBM leverage depends on the number of lives covered. In addition, PBMs argue that if pharmaceutical manufacturers knew the terms of their competitors' rebates, they could use that information either to demand similar rebates or to foster tacit collusion with competitors.

State legislative oversight of PBMs also includes fair pharmacy audit legislation, "any willing provider" statutes, and MAC laws. An organization called "PBM Watch" provides online summaries of state laws pertaining to PBMs.[25] Some states, such as Kentucky and New Mexico, have enacted PBM licensing requirements. The PBM trade group, the Pharmaceutical Care Management Association, is responding to all the finger pointing, and it is fighting a many-front battle over its position in the drug-pricing conflicts.

While claims against pharmaceutical manufacturers traditionally have come from plaintiffs physically injured by side effects, there has been substantial private litigation against PBMs, and new and expanding third-party payer claims are emerging. Third-party payers have been increasingly successful in convincing courts that improper marketing or promotion efforts resulted in a drug being improperly placed on PBM formularies, which, in turn, resulted in payments for covered prescriptions that these third-party payers should not otherwise have had to incur. For example, in *International Union of Operating Engineers Local #68 Welfare Fund v Merck & Co., Inc.,*[26] the plaintiff's causation theory was that fraud by Merck induced PBM P&T committees to place rofecoxib (Vioxx) on plan formularies and that Vioxx then harmed patients.

Implications for Commercial And Employer Plans

Options other than government pricing mandates or continuing to use PBMs are emerging, such as use of transparent pass-through models that require PBMs to disclose their negotiations and financial interactions with drug manufacturers. Other plans are eliminating their PBMs and managing their own pharmacy benefits directly. TRICARE anticipated savings of $1.67 billion by negotiating its own pharmacy benefits, including rebates.

Another emerging option is outcomes-based contracting, in which the pharmaceutical manufacturer will refund some of the money to plans if a drug does not perform as expected. At least six pharmaceutical manufacturers have entered into such agreements within the past year (e.g., Novo Nordisk with liraglutide [Victoza] and Novartis with sacubitril/valsartan [Entresto]). PBMs criticize value-based pricing paradigms as too complicated and unrealistic for various disease states, citing instances where patients would need additional tests solely for reimbursement determinations. Also, specified biometric achievement is not a guarantee of achieving desired clinical outcomes from a plan sponsor perspective.

Looking to the Future

A recent Tufts University study predicts more aggressive formulary management by PBMs and plans via exclusion lists and indication restrictions.[27] This would suggest that the controversy surrounding PBMs is unlikely to dissipate and that they will remain DOJ targets under HEAT. To help prevent fraud, legislation could require that PBMs disclose to plans both the cost of drugs and any benefit or payment directly or indirectly accruing to the PBMs if they make a substitution in which the substitute drug costs more than the prescribed drug.

Care outside the hospital, like P&T committee responsibilities outside the hospital, is necessarily different. New processes and solutions, such as cloud computing, can help improve performance and transparency of benefit management for purchasers or users of health care services. The current role of PBMs includes concurrent improvement in health outcomes, so the take-home message is that in making formulary decisions, clinical care (outcomes) should come first.

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