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Pharmacy Benefit Managers: Can They Return to Their Client-Centered Origins?

Pharmacy benefit managers (PBMs) are key players in the complex prescription drug supply chain. They act as middlemen, responsible for developing and maintaining formularies and other clinical management programs, negotiating contracts with pharmacies and pharmaceutical manufacturers and processing prescription drug claims for insurance companies and corporations.

PBMs use their sizable patient networks to negotiate lower reimbursement rates with pharmacies and discounts with drug makers.¹ Today, average discounts for brand drugs range from 15-21 percent off of market price and average discounts for generics range from 72-82 percent.^{2,3} The original idea was that the PBM would pass those savings back to their health plan sponsors who would, in turn, pass savings on to patients.⁴

SUMMARY

Pharmacy benefit managers (PBMs) are key players in the provision of prescription drugs. They act as middlemen, responsible for developing and maintaining formularies and other clinical management programs, negotiating contracts with pharmacies and pharmaceutical manufacturers, and processing prescription drug claims for insurance companies and corporations. Given the client-centered origins of the PBM role, it is somewhat surprising that pharmacy benefit managers are under fire for not acting in their clients' best interest. PBM's have come under scrutiny for anti-competitive behavior, such as drug discrimination, pricing spreads, and other practices that result in higher costs to payers and consumers and may limit access to certain drugs.

PBMs first stirred controversy in the 1990s, when pharmaceutical companies began to acquire them. The Federal Trade Commission (FTC) denied mergers between several pharmaceutical companies and PBMs because of potential conflicts of interest. The FTC believed that these mergers would enable drug manufacturers to coordinate pricing policies, understand their competitors' pricing information and favor their own drugs over competitors.⁵ Due to FTC concerns, manufacturers later sold these joint entities, which led to PBMs adopting a strategy of becoming large stand-alone PBMs or PBM-pharmacy chains.⁶ Today, about 80 percent of the prescription drug benefits market is controlled by just three PBMs—Express Scripts, CVS-Caremark, and OptumRx.⁷

Given the client-centered origins of the PBM role, it is somewhat surprising that pharmacy benefit managers are under fire for not acting in their clients' best interest. PBM's have come under scrutiny for anti-competitive behavior that results in higher costs to payers and consumers, and may limit access to certain drugs. In fact, the way in which PBMs make money has the potential for a conflict of interest vis-a-vis the payers who hire them.

Some PBM Practices Not in the Clients' Best Interests

PBMs often use contracts that obscure pricing and reimbursement mechanisms. These contracts are often designed to maximize the overall profit margin for the PBM, and obscure the pricing of certain drugs.⁸ As a result, payers and consumers may be overpaying for drugs and/or finding it difficult to access certain medications.

PBMs generate revenue through four different methods:⁹

- Administration and service fees charged to health plans for processing claims and prescriptions;
- rebates from pharmaceutical manufacturers for brand drug utilization and market share;
- pricing spreads (markups that financially benefit PBMs); and
- dispensing fees and pricing markups from PBM-owned mail order and specialty drugs sold to health plans.

The latter three have the potential to generate conflicts between the PBM's corporate interests and the plan sponsor and consumers' interests.

Formulary Design Serves PBMs, not the Patient

As noted above, PBMs create formularies, or lists of drugs that will be covered by health plans.¹⁰ PBMs receive payment from drug makers for favoring certain drugs on these formularies. PBMs receive market-share payments from manufacturers, known as rebates, in exchange for favorable positioning on the PBM's drug formulary or based on utilization rates.¹¹ While some of these rebate dollars are passed through to payers, some research has found that major PBMs can retain around 38-40 percent of rebate dollars collected from drug manufacturers.¹² As an example, a single 12-week prescription for Harvoni, a medication that cures Hepatitis C, costs around \$90,000. The PBM can take around \$2,000 to \$20,000 of that \$90,000 in the form of a rebate.¹³

Most rebates are connected to brand drugs, which account for 73 percent of retail drug spending, but only 11 percent of prescriptions. In contrast, generic drugs account for 89 percent of all retail prescriptions and average about \$18 per prescription.¹⁴ Unlike brand rebates, the rebates from generic manufacturers bypass both PBMs and health plans, flowing instead to pharmacies.¹⁵

Many PBMs are reluctant to disclose rebate agreements with pharmaceutical manufacturers and the portion of rebates they retain, leading to concern that PBMs might design the drug benefit to maximize rebates and

A **drug formulary** is a list of prescription drugs covered by the health plan, typically grouped into cost-sharing tiers. Drugs from higher tiers will cost the patient more out of pocket than drugs from lower tiers. **Formulary design** refers to the process of selecting which drugs will go into which tiers, with the objective of incentivizing patients to use more cost-effective options or sometimes to maximize rebates received by the PBM.

discourage patients from taking drugs that may be cheaper and just as effective but produce less profit.¹⁶ A report from the Tufts Center for the Study of Drug Development highlighted how more cost-effective brand name drugs are not always recommended over other less cost-effective brand name drugs in the same therapeutic class.¹⁷ For example, in 2016, Express Scripts accepted rebates from Novartis Pharmaceuticals to recommend the iron chelation drug Exjade to Medicaid patients, instead of a less expensive alternative.¹⁸

Pricing Spreads

PBMs negotiate two types of contracts: one with pharmacies and one with plan sponsors. PBMs reimburse pharmacies one rate for dispensing a medication but charge a higher rate to the plan sponsor for the same medication—pocketing the “spread” between the two prices. Plan sponsors need to be aware that PBMs use various state price reference databases, like the Virginia drug pricing database, to obtain average wholesale prices (AWPs), which can vary significantly. PBMs can pay pharmacies the price from one reference database (one with the lowest AWP) while charging its plan sponsors using another (the one with the highest AWP listing), to maximize the spread on every claim.¹⁹

Audits and industry analyses have found some PBMs pocketing 50 percent or more of the price difference between what the PBM actually pays a pharmacy for prescriptions and what they charge their clients—the employer/consumer.²⁰ For example, according to a 2013 article in *BenefitsPRO*, Meridian Health System was billed \$92.53 for generic amoxicillin by Express Scripts,

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but the PBM paid the pharmacy \$26.91—a spread of \$65.62. In another example, Meridian was billed \$26.87 for a prescription of the antibiotic azithromycin and Express Scripts paid the pharmacy \$5.19 to dispense the prescription, creating a spread of \$21.68.²¹

Another example of pricing spread is when drug costs are lower than patient copays. PBMs often force pharmacies into contracts where they have to sell drugs at the contracted rates, and then claw back the excess copay for themselves. PBMs prohibit pharmacies from notifying patients about cheaper options, which has led to legislation targeting this action (described below).²²

Mail Order Services

As the PBM industry has grown, PBMs have expanded their service offerings to include in-house mail-order prescription drug delivery service.²³ Plan sponsors and patients can clearly benefit from certain aspects of mail-order, such as enhanced convenience, dispensing accuracy and efficiency, formulary adherence monitoring and patient drug compliance.²⁴ However, the claim by PBMs that these mail-order programs offer significant cost savings to health plans may be overstated.

PBMs often limit competition by (a) refusing to allow other mail order pharmacies to fill prescriptions for their client plans, (b) refusing to allow community pharmacies to dispense the same 90-day supplies dispensed by PBM-owned mail order facilities, (c) making retail pharmacies appear more expensive to consumers by charging higher patient co-pays that are incommensurate to any alleged difference in the true costs of mail and retail and (d) making retail pharmacies appear more expensive to plans by charging a large spread for drugs dispensed by retail pharmacies and using that spread to subsidize lower prices for the PBM-owned mail order pharmacy.²⁵

Another concern is that by having their own mail order services, it provides an opportunity for PBMs to increase the price of a drug using different reference pricing or Maximum Allowable Cost (MAC) lists than what the PBM uses for retail pharmacies.²⁶ Many PBMs use their MAC lists to generate significant revenue.²⁷ Typically, they use a low MAC price list to reimburse their contracted pharmacies and a different, higher list of prices when they sell to their clients or plan sponsors.²⁸ Most plan sponsors are unaware that multiple MAC lists are being used and how much revenue the PBM retains.

Critics charge that PBM ownership of mail order pharmacies creates several other conflicts of interest. A PBM may be incentivized to:

- Perform fewer generic substitutions;
- switch patients to higher-cost therapeutic alternatives (therapeutic substitution); or
- purchasing drugs in bulk (e.g., 50,000 tablets) at a much lower price, then charging the customer based on the AWP of the smaller-package size while not passing on the savings associated with large-volume purchasing.²⁹

Other Concerning PBM Practices

Formulary Design Discrimination: Researchers at the University of Texas and Harvard found that certain plans offered on ACA marketplaces utilized formulary benefit design to screen out unprofitable patients by offering poor coverage for certain medications.³⁰ While the ACA requires plans to cover at least one drug in each therapeutic category and class, there is no requirement as to how the drugs should be tiered within a formulary. The study found that drugs with higher reimbursements are about 70 percent more likely to be placed on a specialty tier relative to other drugs in the same plan and relative to the same drugs in employer plans.³¹

Similarly, an analysis by Avalere Health found that some marketplace plans placed all drugs—including generics—used to treat complex diseases, such as HIV, cancer and multiple sclerosis, on the highest drug formulary cost-sharing tier.

Federal rules prohibit marketplace plans from adopting benefit designs that discriminate based on age, illness, race, gender or sexual orientation, among other things.

States are starting to fight back against formulary discrimination. For example, a 2015 California law prohibits insurers from placing most or all of the drugs for a specific condition in the highest cost tier.³² In addition, the federal Department of Health and Human Services has signaled to insurers that placing all or most drugs in a high-cost tier is discriminatory.³³

Drug Switching: Drug switching is a practice where the doctor prescribes one drug for a patient, but the PBM uses therapeutic substitution and changes the prescription to a different drug it believes to be of similar therapeutic value.³⁴ Drug switching can be motivated by pure financial incentive on the PBM's part—either through manufacture rebates, pricing spreads or targeted discounts. For example, in 2006, Medco paid \$163 million to settle federal charges that it defrauded customers by shorting, changing and canceling their prescriptions. In a three-month period, Medco had persuaded doctors through financial incentives to switch more than 71,000 prescriptions from Lipitor to Zocor, a more-costly drug.³⁵

Lack of Fiduciary Obligation

These potential conflicts of interest loom large because, perhaps surprising to some given their origins, PBMs typically do NOT have a fiduciary responsibility to prioritize the plan sponsors' best interests. A fiduciary duty is the legal obligation of one party to act in the best interest of another, for example, the best interest of the consumer.

Health plans and PBMS are regulated either by state insurance regulators or the U.S. Department of Labor (DOL). Efforts to impose fiduciary obligation have been tried in both areas.

Efforts to Impose ERISA Fiduciary Responsibility

The Employee Retirement Income Security Act (ERISA) is a federal law that sets minimum standards for most voluntarily established pension and health plans in private industry to provide protection for

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individuals in these plans. ERISA is overseen by the DOL.³⁶ ERISA authorizes a participant to sue an entity for breach of its fiduciary duties and to make good on any monetary losses resulting from such fiduciary breach. Legal action to date has turned on whether the PBM satisfies the definition of “fiduciary” under the ERISA statute. Courts have uniformly answered “no,” the PBM is not an ERISA fiduciary and hence does not face a fiduciary responsibility to pass the savings they negotiate along to the payers (employers, patients, and health plans).³⁷

In September 2014, the ERISA Advisory Council made two recommendations that attempted to increase accountability of PBMs to plan sponsors:

- The Department of Labor could require PBMs to disclose all direct and indirect compensation to ERISA plans in order for ERISA plans to evaluate whether the compensation to PBMs, pharmacies—including PBM-owned mail-order pharmacies—and other subcontractors is reasonable.³⁸
- Alternatively, the DOL could issue guidance to assist plan sponsors to determine whether and how to conduct a PBM audit of direct and indirect compensation.

The Department of Labor has not acted on these recommendations.

State Efforts

While states cannot regulate self-insured employer plans (due to ERISA), they can regulate fully insured products. Various states, including Maine and the District of Columbia, have attempted to enact legislation that imposes fiduciary responsibilities, financial terms and certain disclosure requirements on pharmacy benefit managers. If the states designate PBMs as fiduciaries, the savings related to the deals they cut must be passed on to

the companies that hired them. Only the efforts in Maine and Washington, D.C., have so far been successful.

Maine's Unfair Prescription Drug Practices Act, signed in 2003, requires PBMs to disclose pricing information negotiated with pharmaceutical companies and pass the savings on to consumers. The legislation was challenged by the PBM Medco Health Solutions but upheld. The law was subsequently not enforced and then repealed in 2011 because the transparency requirements had discouraged PBMs from doing business in the state, which resulted in less competition and higher drug costs.³⁹

The District of Columbia's 2004 AccessRx Act would have required PBMs to perform "in accordance with the standards of conduct applicable to a fiduciary." The act included fully insured and self-funded health plans. However, the U.S. Circuit Court of Appeals for DC ruled in 2010 that ERISA, which bars states from enacting legislation relating to employee benefit plans, pre-empted the District of Columbia law.⁴⁰

Another tactic states have used to increase PBM responsibility is enacting transparency legislation. In 2017, a wide range of state bills were introduced that would regulate pharmacy benefit managers.⁴¹ A focus of many proposals is stricter price transparency from PBMs and drug manufacturers and new standards for PBM pricing—particularly with regard to maximum allowable cost pricing. Other bills would prohibit PBMs from offering incentives for healthcare providers to switch from one prescription drug to the other. Finally, some bills would explicitly define the fiduciary responsibility of PBMs.⁴²

A 2017 Connecticut law forbids any future legislation preventing pharmacists from disclosing specified information to an individual purchasing a drug (i.e., the availability of any alternative, less expensive medications) from passing.⁴³ Georgia passed a law in 2017 that authorizes the state Commissioner of Insurance to enact rules and regulations that prohibit PBMs from requiring the use of mail-order pharmacies, and bans PBMs from prohibiting pharmacists or pharmacies from providing patients with information on the amount of the patient's prescription drug cost share and the clinical efficacy of a lower-priced alternative drug, if one is available.⁴⁴

While advocates say these bills will improve transparency by requiring that PBMs disclose other sources of revenue

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aside from the fees they collect from employers, some benefit consultants say the state laws do not achieve transparency because most PBMs are not yet forthcoming about their true drug acquisition costs, as mentioned above.⁴⁵

Employer Contracting Options

Employers can do more to ensure that PBMs uphold their fiduciary responsibility. Both self-insured and fully-insured employers can assign a PBM fiduciary responsibility in a contract, thus increasing accountability. Employers can also try to include more transparency and guarantees in their contracts, such as disclosing rebates on drugs, retaining 100 percent of these rebates and halting the practice of co-pays exceeding the acquisition cost for the drug.⁴⁶ Employers may wish to establish contracts that prohibit PBMs from retaining co-pays and instead direct the extra money back to the company in order to lower co-pays for their employees.⁴⁷ Additional strategies may include performance-based contracting that penalizes PBMs for not meeting certain goals and exercising full auditing rights within PBM contracts to review financial and outcome performance.⁴⁸

Employers can also mobilize to achieve fair drug prices. The Health Transformation Alliance (HTA) is a nonprofit formed by more than three dozen companies that hopes to more directly manage their employees' healthcare, including the determination of the best drugs and physicians to treat costly diseases and conditions.⁴⁹ The hope is that the leverage of the combined companies, along with the guaranteed rebates and audit rights listed in their contracts with CVS and UnitedHealth Group, will lower spending and provide more consistent prices from these two PBMs.⁵⁰ However, it is necessary to note that this remedy is more feasible for larger employers.

Conclusion

Drug formularies crafted by PBMs can be successful at compelling doctors and consumers to choose effective, less-expensive medicines. However, formulary designs that are used to amplify PBM revenues through rebate concealment and excessive pricing spreads, can increase costs for plan sponsors and consumers.⁵¹ The combined absences of transparency and fiduciary responsibility for PBMS should be of concern to all.

PBMs are currently under intense scrutiny from employers and state and federal policymakers. Remedies include contracts or legislation that impose fiduciary responsibility and increase transparency for PBMs. Similarly, the Department of Labor should act upon the recommendations of the 2014 ERISA Advisory Council. Even though PBMs are seen in a negative light at the moment, we need to remember the benefits they used to provide for consumers. Through legislation and regulation, PBMs can be salvaged to their original purpose of increasing value for consumers and plan sponsors in a transparent and financially responsible way.

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