

Is PBM Transparency an Answer to Controlling Rising Drug Costs?

James Jorgenson, MS, RPh, FASHP; and Anthony Zappa, PharmD, MBA

edications represent one of the fastest growing elements of healthcare expenses. This is due in part to increases in overall drug spend given to a combination of the introduction of a number of new drugs, greater use of specialty drugs for complex diseases, a lower than usual rate of patent expirations, and an overall increase in marketplace demand as a result of expanded coverage for a population that had previously been underemployed or chronically uninsured. Methods employed in the past to control the cost of medication therapy may no longer be adequate. A fresh look into how pharmacy benefit managers (PBMs) make money from their clients can help to negotiate more equitable oversight and distribution of the drug benefit.

Prescription Cost Trends and Drivers

According to the IMS Institute's April 2015 report on US use and spending shifts for medicines, total costs for prescription drugs reached \$373.9 billion in 2014.1 This represents a 13.1% change over 2013—the highest increase in medicines spend since 2001 when the rate of growth was 17% over the previous year.

Much of this increase can be attributed to a growth in the number of new medicines, which contributed an additional \$20.3 billion to the 2014 spending. A large portion of the new medicines' spend was attributed to specialty drugs (high-cost drugs used to treat complex conditions) which increased by 26.5%. This category of drugs now accounts for about a third of all medication spending, up from 23% just 5 years ago. Innovative new drugs for the treatment of hepatitis C, cancer, and multiple sclerosis were the largest cost drivers in the specialty drug category in 2014. For hepatitis C alone, over 161,000 patients started treatment in 2014—nearly 10 times more than in 2013; the use of new oral hepatitis C treatments accounted for \$12.3 billion (60%) of the spending increase for new drugs. Other new medicines, including treatments for multiple sclerosis and cancer as well as non-specialty conditions such as diabetes, added \$8.9 billion in new spending that year.1

ABSTRACT

Objectives: To familiarize readers of The American Journal of Pharmacy Benefits with the trends in drug expenditures in the United States and to examine how pharmacy benefit managers (PBMs) structure compensation as an incentive to investigate with a more transparent approach to how health plans contract with their PBMs.

Study Design: The authors drew on their personal experience and expertise as well as a review of current literature to determine different approaches used by PBMs to generate revenue. This was contrasted with a growing interest in PBM transparency in their contracting with clients.

Methods: The authors reviewed the most current reports of the nature and cause of increases in drug spend and the means by which PBMs generate revenue.

Results: Neither model is recommended over the other, however, a list of elements to examine when comparing traditional PBM payment structures to a more transparent model is provided.

Conclusions: Medications represent one of the fastest growing elements of healthcare expenses. This is due in part to increases in overall drug spend given the number of new drugs, greater use of specialty drugs for complex diseases, a lower than usual rate of patent expirations, and an overall increase in marketplace demand as a result of expanded coverage for a population that had previously been underemployed or chronically uninsured. Methods employed in the past to control the cost of medication therapy may no longer be adequate. A fresh look into how PBMs make money from their clients can help to negotiate more equitable oversight and distribution of the drug benefit.

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In addition to the impact of new medicines, patent expirations for brand name medicines occurred at the lowest level in 5 years. Cost reductions associated with generic drug introductions, which had been a consistent offset to rising brand name costs, contributed only \$11.9 billion in savings. At the same time, overall price increases for medicines in 2014 hit double digits, 1 as prices for brand, generic, and specialty drugs combined increased by 10.9%. By category, prices for brand name drugs rose 14.8%, specialty drug prices increased 9.7%, and generic medicines rose 4.9%.2

All of these pricing trends happened on top of increased prescription utilization, largely as a result of new patients entering the insurance market. The uninsured rate in the United States also declined significantly in 2014, driven largely by the Affordable Care Act and an improving US economy. New state and federal health exchanges, as well as expanded Medicaid programs, caused increased beneficiary enrollments in October 2013 for coverage effective in January 2014, and by the close of 2014, the uninsured rate was reduced by 5.1%, adding 15.7 million people to the insured population. Concurrently, the US unemployment rate dropped 1.5%, and many of the 2.3 million newly employed were offered healthcare coverage by their employers. Medicare enrollment also increased as more baby boomers reached the age of eligibility; some of whom had been previously uninsured.1

Pharmacy Benefit Management: Controlling the Cost Trend

Together, these factors have served to create a "perfect storm" affecting the trajectory of cost for prescription medicines. Patients, payers, and employers alike are feeling the impact of these rising costs and are looking for new strategies to help them to better manage their medicines spend. The collective concern is that methods employed in the past to control the cost of medicines may no longer be enough.

One of the staples for effective medication cost management has been the use of PBMs. From their inception in the early 1970s—when they were largely just claims processing entities—PBMs have evolved into very large and sophisticated operations, focusing on multiple elements of medication use. PBMs are now the de facto standard for administering prescription drug insurance benefits in the United States, as they have demonstrated the ability to reduce medication costs, provide pharmacy access on a national basis, and administer customized benefits that can meet the needs of a wide variety of clients in a very highly automated environment. Their core strategies for reducing prescription drug expenses include minimizing

administrative overhead, obtaining discounts on drug cost, leveraging volume for reduced dispensing fees, and managing drug selection and utilization.

Now a multi-billion dollar industry, PBMs are also one of the most influential groups in the entire medicines supply chain. They have been successful in reducing medication cost by negotiating lower drug prices from pharmacies and rebates and other discounts from manufacturers, and they have been likewise successful in improving utilization of medicines by working with prescribers on drug selection and helping patients adhere to prescribed medication regimens to better manage their disease(s). Combined, this is a complex process that often is not fully understood by many self-funded employers using PBM services.

PBM services are structured around the drug benefits designed by their clients. The benefit design determines which drugs are covered and the extent to which generics and preferred brand name (ie, formulary) drugs are mandated. Also, the benefit plan defines the co-payment structure that determines cost-sharing levels between the client and their employees or members. In addition to the benefit plan, PBMs work with clients to establish and maintain large retail pharmacy-based networks within certain geographic and access standards. They may also operate or contract with mail order pharmacies, Internet pharmacies, and specialty pharmacies to expand access. All of the participating pharmacies agree to discount their pricing in exchange for access to the PBM's members.

PBMs provide their clients with a highly automated claims processing environment. Nearly all pharmacy claims are electronically adjudicated at the point of dispensing based on data entered in the pharmacy's dispensing and billing system. The claims system receives the claim, checks the member's eligibility and benefit design to determine coverage and cost sharing, calculates the pharmacy reimbursement, and performs a series of drug interaction checks across the member's claims history (which may include multiple pharmacies). The pharmacist receives real-time messaging for all of these steps, typically within 1 to 2 seconds. PBMs receive a processing fee per claim for this service.

PBMs contract with pharmaceutical manufacturers of branded drugs to receive rebates and administrative fees, which are paid for with increases in market share and/or utilization of their products. It is common for PBMs to share the rebates with their clients, but retain 100% of the administrative fees. Those PBMs that operate mail order pharmacies may receive extra rebates or better pricing for specific drugs purchased through those pharmacies because they more directly control utilization of those products.³



PBMs also provide significant clinical programs, which include:

Formulary management. PBMs combine clinical evidence and product cost to define which drugs in each therapeutic class should be used as primary and secondary options within the benefit plan. Formulary programs are overseen by Pharmacy and Therapeutics Committees, either at a national level or a client/plan-specific level. These programs may also include prior authorization and step therapy protocols to ensure that drugs are used in a rational, proven progression and only for indications supported by evidence-based clinical literature.

Therapeutic substitution programs. Within each formulary program, certain therapeutic classes include substitution recommendations or mandates to optimize the cost-effectiveness of drug therapy. Members and prescribers have options to request exceptions or overrides to the substitution program, including medical necessity protocols.

Disease management programs. PBM clinical pharmacists, nurses and case managers work with clients to identify and manage members at risk for suboptimal therapeutic outcomes based on poor adherence, adverse event rates, or lifestyle factors. These members are assigned to personalized care plans that engage them in their care and promote proper use of their medications.

PBMs may bundle these programs into their standard administrative fees or charge separate per member or per service fees.

Aligning PBM and Plan Objectives: The Transparent PBM Model

In the past several years, the question of how PBMs make their money has been consistently raised as organizations struggle to better address the rising costs of medicines. PBMs generate revenue in several ways; the most common and understandable method is by charging health plans adjudication and service fees for processing claims. They also gain revenue by selling prescription drugs through their own mail order pharmacies. Less visible and the primary source of client confusion, however, is revenue associated with pharmaceutical manufacturers and network pharmacies. As noted earlier, PBMs negotiate formulary and market share discounts with pharmaceutical manufacturers as incentives to use their drugs (in mail order pharmacies) or promote products on formularies. These can be paid as direct, on-invoice discounts (as with purchases) or off-invoice retrospective rebates. In both cases, discounts are generally calculated as a percentage of the drug's wholesale price and can be 40% to 50% or higher.

Table. Elements of a Base Financial Comparison

Traditional PBM		Transparent PBM	
Service fees	\$XX	Flat fee/prescription	\$XX
Spread pricing	\$XX		
Rebates	\$XX		
PhRMA fees	\$XX		
Other misc fees	\$XX		
TOTAL	\$XX	TOTAL	\$XX

Misc indicates miscellaneous; PBM, pharmacy benefit manager; PhRMA, Pharmaceutical Research and Manufacturers of America.

Another major source of PBM revenue is derived from the difference between what the PBM reimburses the pharmacy for a drug and what it charges the health plan. The difference, commonly called "spread pricing," can lead to substantial revenues for PBMs. Brand name drugs, including high-cost specialty products, can have a spread of 1% to 3%. Generics, which are reimbursed using fixed price schedules (known as Maximum Allowable Cost [MAC] lists), can have spreads of over 10%. Because spreads can be different across pharmacy networks, with each chain having different reimbursement rates and MAC lists, PBMs can create situations where clients have no idea if they are receiving the correct discounts and how significant the spread actually is. Given this lack of information, negotiating a PBM contract and trying to ensure that all parties have achieved an equitable deal that contributes to optimal control of medication costs can be very challenging.

Recently, the PBM industry has been responding to requests for greater openness and access to information with a new model: the fully transparent PBM. In this model, the client is charged only a negotiated service or administrative fee—usually per claim or per member. The PBM discloses and provides the client with the full extent of all negotiated pharmacy and manufacturer discounts. According to the Pharmaceutical Strategies Group, this new PBM model is designed to: simplify the PBM procurement process; leverage more value from the PBM/supplier relationship; reduce or eliminate the potential for perverse incentives to increase costs (eg, pushing higher cost brand drugs to obtain rebates); obtain better information to facilitate better plan coverage and management decisions; and reduce the overall cost of the PBM relationship.⁴

While the fully transparent PBM model has the potential to significantly reduce pharmacy benefit costs, comparing the new model to a traditional model can be confusing in itself. Using a traditional PBM Request for Proposal when considering a PBM change rarely provides for an effective evaluation or comparison of the new model. In essence, when making the base financial comparison, organizations need

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to understand and compare the elements mentioned in the **Table** to ensure that their overall PBM costs will be reduced.

The pricing analysis should also be accompanied by an evaluation of how drug mix could change under each management model based on each vendor's formulary, pharmacy network accessibility, clinical program strategy, and medication therapy management initiatives. As noted by Snook and Filipek in their white paper, the ultimate question that a plan sponsor needs to answer is: How much does the pharmacy benefit cost and can that be effectively reduced? This answer is more complicated than just considering PBM fees, prescription prices, spreads, and rebates; it also has to do with the long-term benefits and costs associated with improving patient health, increasing medication adherence, and other factors.⁵

At the end of the day, it is apparent that alternative strategies must be deployed to address the rising cost of medicines. While traditional PBM models have been successful in the past, we should definitely not consider a "one size fits all" approach for the future. With the emergence of new PBM models using pass-through pricing versus traditional lock-in pricing, there are now alternatives that could help with further cost reductions for the pharmacy benefit. The key to better management of the pharmacy benefit is a complete understanding of what a plan is actually buying from a PBM. Whether incorporating a traditional lockin approach or a pass-through arrangement, both can be transparent as long as the revenue sources are disclosed and understood and a high degree of communication exists between the PBM and its client. In either case, the key to reducing drug costs for a plan sponsor is transparency, and organizations evaluating their PBM programs should work to fully understand their options and to ensure an equitable "apples to apples" comparison in any PBM analysis.

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Send correspondence to: James A. Jorgenson, MS, RPh, FASHP, Visante Inc, 101 E 5th St, #2220, St Paul, MN 55101. E-mail: jjorgenson@visanteinc.com.

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