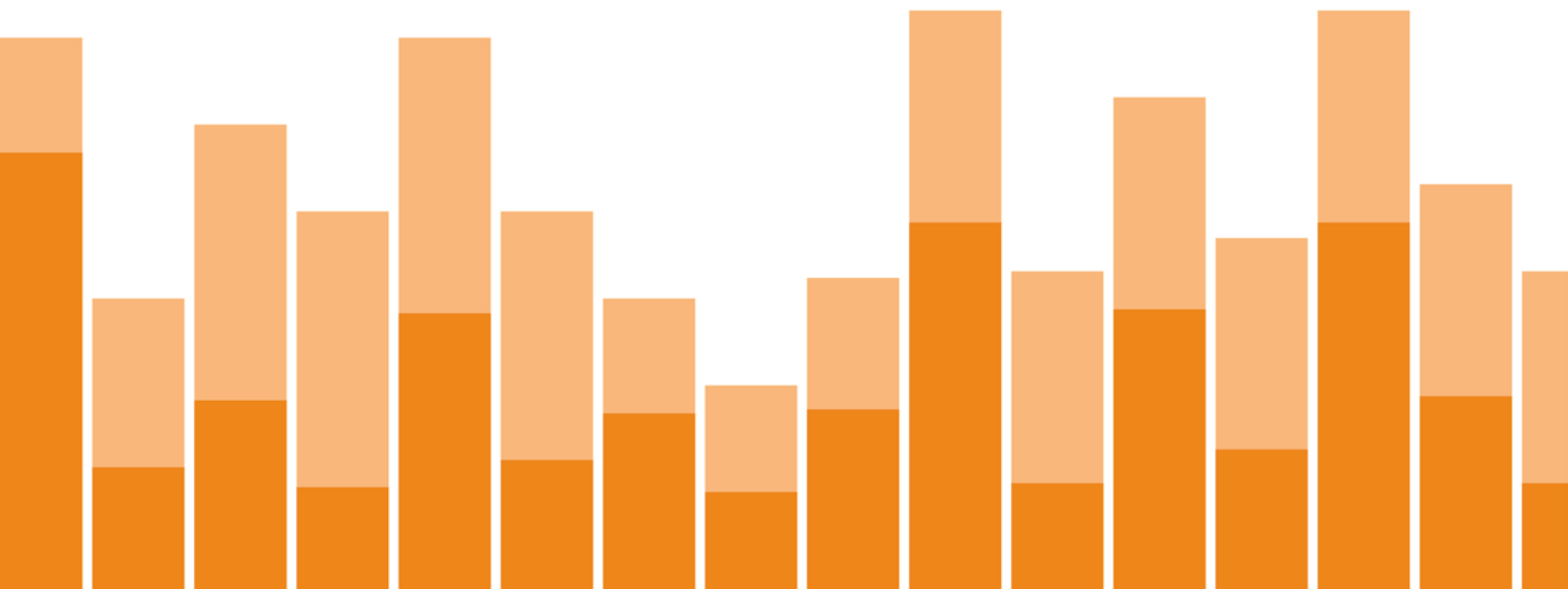


The Prescription Drug Supply Chain “Black Box”

How it Works and Why You Should Care

For the American Health Policy Institute
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About the Author

Henry C. Eickelberg previously served for 18 years as a corporate executive with a Fortune 100 company where he oversaw a number of HR functions, including its benefit strategy and delivery. As such, he was integral to the strategic direction of the company's health & wellness initiatives, which gave him an in depth understanding of the pharmaceutical supply chain. Mr. Eickelberg has dedicated his career to delivering cutting-edge benefit solutions to corporations, saving companies tens of millions in overhead costs, including successfully applying the techniques described in this article. He is currently a Managing Director with The Terry Group, a licensed attorney, CPA, and faculty advisor for the graduate tax program at Georgetown University Law School ERISA program. He received the 2015 Fahy Award for outstanding adjunct faculty member.

Executive Summary

Over the last five years, the rate of health care cost growth (including prescription drugs) has significantly outpaced general inflation and wage growth.¹ In addition, the recent explosive cost growth of certain generic drugs² combined with the impending release of new high-cost drugs (a number of which will be dispensed through specialty pharmacies) makes the near-term outlook for controlling health care costs even more troubling.³ Therefore, self-insured employers who want to hold their pharmacy benefit cost trend flat will need to either (1) shift more of their prescription drug costs to their employees, or (2) take a different approach to contracting with their prescription drug supply chain. This paper is intended to shed light on one of the fastest growing cost areas in an organization's human capital cost structure: the Prescription Drug Supply Chain. This paper also suggests a new prescription drug supply chain model designed to better align pharmacy industry stakeholder interests with those of the plan sponsor and its employees. Senior corporate executives operating in today's high-cost environment need to understand the Prescription Drug Supply Chain in order to address these impending financial challenges.

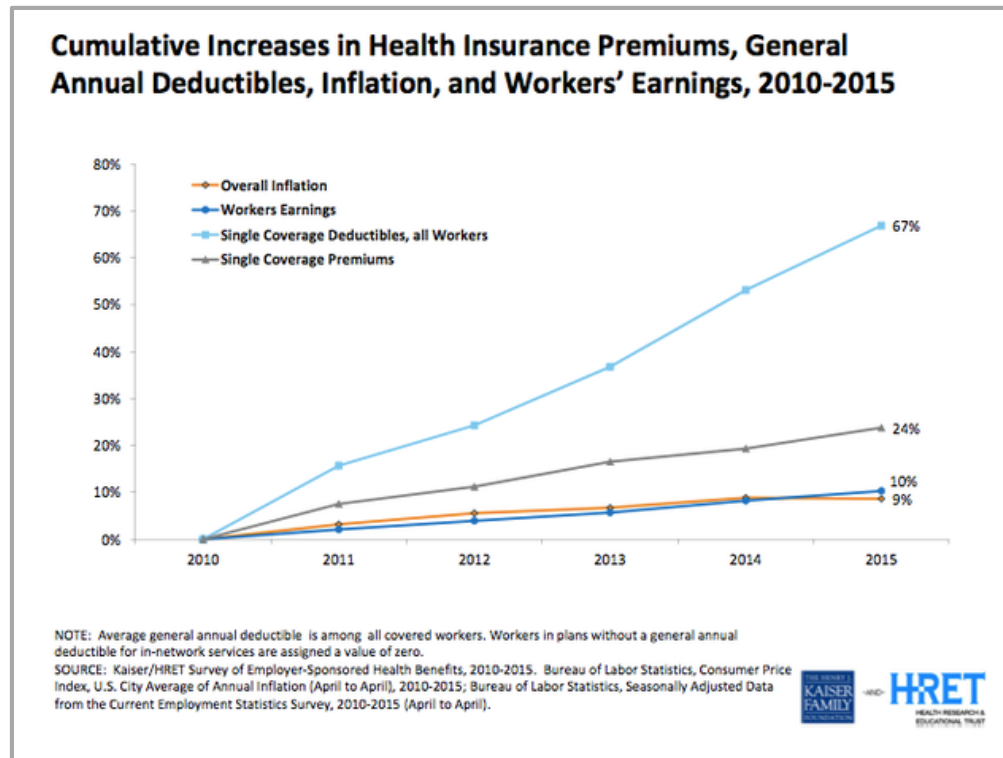
¹ Walker, Joseph. "For Prescription Drug Makers, Price Increases Drive Revenue." *Wall Street Journal*, 5 Oct. 2015. Web. 02 Dec. 2015.

² Jaret, Peter. "Prices Spike for Some Generic Drugs." <http://www.aarp.org>. AARP, July-Aug. 2015. Web. 02 Dec. 2015. Pollack, Andrew. "Drug Goes From \$13.50 a Tablet to \$750, Overnight." *The New York Times*. The New York Times, 20 Sept. 2015. Web. 02 Dec. 2015.

³ "WHO Chief Raises 'serious Concerns' over TPP Impact on Vital Drug Prices." *RT English*. RT Network, 13 Nov. 2015. Web. 02 Dec. 2015.

Challenges Facing Health Care Sponsors

It is no secret that plan sponsors, namely employers, assume the financial risk for the health and welfare programs they offer their employees and eligible dependents. And while this financial risk can be mitigated in the very short-term through the use of insurance, ultimately the plan sponsor bears the risk of cost growth over time.



In trying to control health care cost growth (including prescription drugs), plan sponsors face two significant challenges:

1. **The “Health Care Blank Check”:** Plan sponsors often incorrectly view purchasing health care as contracting with a vendor or vendors for a finite set of goods and services (including prescription drugs)⁴ for a specified cost. But, what in fact a plan sponsor contracts for is simply the right to have another organization administer and manage the plan sponsor’s health care supply chain. The plan sponsor’s total health care spend will be determined by the cumulative actions of a number of stakeholders unrelated to the plan sponsor (in particular, its employees and eligible dependents). These other stakeholders have far different incentives that may not be aligned with the plan sponsor’s concerns about cost and quantity. Essentially, plan sponsors are not providing their employees with a “Health Care Benefit”, but rather with what tends to become a ‘Health Care Blank Check.’ The plan sponsor’s only recourse to manage this “blank check” is by modifying the plan’s design components (*i.e.*, payroll costs, deductibles and out-of-pocket maximums), and given the passage of the Affordable Care Act (ACA), these control points have been increasingly muted.

⁴ The plan sponsor’s purchase of fully-insured coverage is a short-term financing mechanism.

2. **Inherent Information Disparity:** Plan sponsors and members of the health care supply chain enter into written contracts that define their respective rights and obligations. During this contracting process, plan sponsors face a distinct information disadvantage because health care vendors have far superior market knowledge. They know the inner workings of the supply chain (especially the various income streams), and the health care vendor community has the ability to adjust much more quickly to changes than a contracting plan sponsor. Health care vendors devote significant resources to analyzing and managing the various aspects of the health care supply chain that affect them. Without question, the vast majority of health care supply chain vendors aim to provide a valuable service to health care consumers, while increasing the financial returns to the other stakeholders. This is particularly true in the prescription drug area. Given the complexity of the Pharma supply chain system, plan sponsors need to have significant knowledge about health care contracting schemes and set up contracting relationships that lead to price and utilization transparency in order to stay on par with the health care vendor community.

Given these two challenges, plan sponsors need to be vigilant in understanding the motivations and incentives they create for stakeholders through their plan design, as well as monitoring external health care vendor contracting.

Prescription Drug Costs Continue to Increase

In 2014, large employers spent an average \$920 per coverage life on pharmacy costs, which accounted for almost 20 percent of their total health care spending.⁵ Moreover, pharmacy costs are expected to increase 10 percent in 2015 up from 6.3 percent in 2014, according to a survey of 60 health care vendors, and specialty drugs are projected to jump by almost 23 percent in 2015, up from about an 18 percent increase in 2014.⁶ According to a recent survey, the cost and utilization issues regarding specialty pharmacy are a top pain point for large employers.⁷ Moreover, generic drugs, which have provided employers some respite to the relentless drug price trend, are now also raising concerns. In 222 generic drug groups, prices increased by 100 percent or more between 2013 and 2014, according to Forbes.⁸ Yet, 80 percent of employers agree or somewhat agree that their Pharmacy Benefit Manager does a good job managing specialty drug costs,⁹ and just 31 percent plan to, or are considering an evaluation of their pharmacy benefit contract terms over the next three years.¹⁰

⁵ American Health Policy Institute, survey of large employers who are members of the HR Policy Association, June 2015.

⁶ Rita Pyrellis, Double-Digit Drug Costs Vex Employers, Workforce, October 19, 2015

⁷ Towers Watson and National Business Group on Health, High-Performance Insights: Best Practices in Health Care, November 2015.

⁸ Ifrad Islam, Rising Cost Of Drugs: Where Do We Go From Here?, Health Affairs Blog, August 31, 2015.

⁹ Midwest Business Group on Health, Annual Survey of Employers on Specialty Drug Management, June 9, 2015.

¹⁰ Towers Watson and National Business Group on Health, High-Performance Insights: Best Practices in Health Care, November 2015.

Rethinking the Prescription Drug Supply Chain

The purpose of this paper is to outline a different approach – an approach specifically tailored to addressing the challenges inherent in managing the prescription drug supply chain; *i.e.*, stakeholders with interests not aligned with those of the plan sponsor. In essence, this new model disaggregates the traditional “Pharmacy Benefit Manager” (PBM) supply chain. This allows for better alignment of incentives among the various stakeholders involved in the process.

The traditional PBM model is generally a fully bundled approach. The plan sponsor, often working with a benefit consultant, evaluates prospective Pharmacy Benefit Managers and then hires one to oversee the plan sponsor’s prescription drug benefit program. In the traditional PBM model, the PBM that is “hired” presents the plan sponsor with a pharmacy benefit solution that includes: (1) a retail network, (2) mail order capabilities, (3) drug quantity purchasing discounts, (4) clinical analysis, (5) eligibility determination and tracking, and (6) claims adjudication. The plan sponsor reimburses the PBM for the cost of drugs actually dispensed, plus in some cases, an administrative fee for managing the program. The PBM, in turn, pays each of the other contracting parties (based on the PBM’s contract with that party – not the plan sponsor’s contract with the PBM) and retains any excess revenue as a profit.

As previously stated, plan sponsors do not contract with the PBM to deliver a defined set of products and services at a specified unit cost. The plan sponsor hires a PBM to manage the plan sponsor’s pharmacy benefit program. The plan sponsor has retained the financial risk both in terms of cost increases and excessive or unanticipated utilization. The party on the other side of this contract, the PBM, possesses far superior knowledge as to the inner workings of the pharmacy supply chain it has established such that the plan sponsor cannot directly ensure that the PBM is always acting in the plan sponsor’s best interest.

The only effective mechanism for addressing both the significant information disparity and the financial risk associated with stakeholders with divergent interests is for the plan sponsor to structure a more ‘accountable’ prescription drug supply chain. To do this, the plan sponsor needs to have direct insight into the true financial costs and utilization options available. This is only achievable if the plan sponsor assumes ownership of the supply chain. By using this new structure, the plan sponsor will have greater insight into the various complicated, and often competing, financial incentives that run below the surface of a traditional PBM model.

This new PBM model places the role of the PBM as purely a pharmacy administrator and benefit claims adjudicator. The plan sponsor then structures tailored relationships with each of the other members of the prescription drug supply chain to achieve quality and financial accountability that runs directly to the plan sponsor – not the bundled PBM. Disaggregating the various PBM relationships in this manner will significantly reduce, but not eliminate, the conflicting financial relationships inherent in traditional PBM arrangements. Plan sponsors will see greater cost savings and control over each component of pharmacy supply chain¹¹ – financial benefits that would otherwise run directly to the PBM in a traditional PBM relationship. In short, the plan sponsor will save money while placing itself in a much better position to react quickly to marketplace changes as opposed to having to wait three or four years to renegotiate the PBM contract. From a change management standpoint, this new model also allows the plan sponsor to further strengthen a ‘consumer’ mindset with its employees and eligible dependents.

¹¹ While a disaggregated model is likely to have higher administrative costs, experience shows that the added administrative costs will pale in comparison to the savings yielded.

Prescription Drug Supply Chain – What Is It and Who Really Controls the Spend?

The aggregate spend over a period of time for any good or service is the quantity of the goods and services consumed times the unit price. As we examine the Prescription Drug “Black Box,” it is very important to keep in mind that while a plan sponsor may assume the overall financial risk for their prescription drug program, what determines the actual aggregate spend is the collective actions of others – primarily the plan sponsor’s employees and their eligible dependents, based on their health status and demands for health care good and services.¹² As a result, the plan sponsor’s projected spend at the beginning of the period is not likely to equal the actual aggregate spend at the end of the period. The actual aggregate spend will depend on the accumulative actions of other stakeholders. This reality highlights the importance of understanding each stakeholder’s incentives and motivations.¹³

In influencing the aggregate annual prescription drug spend, a plan sponsor really has only two levers available: (1) the plan’s design (*i.e.*, when and for what the plan pays and, of growing importance, when and for what it won’t pay – much of which is now heavily regulated by the ACA¹⁴) and (2) the negotiated reimbursement¹⁵ that the plan sponsor has agreed to pay. Making this situation even more challenging is the fact that the plan sponsor’s own internal benefits function which is charged with designing and monitoring these programs tends to see these programs through a very different prism – one that places a much higher premium on administrative and communications simplicity than on controlling spending. This order of priorities is clearly understandable coming from a group that conducts its work on the ‘front lines’ with insufficient resources to handle massive institutional change.

PBM Contracting – Helping Offset the Information Disparity

The relationship between a PBM and plan sponsor is based on a contract. This contract spells out each party’s performance obligations. What needs to be part of the contracting process, but is often wholly inadequate, is transparency into the PBM’s contractual relationships with each of its underlying suppliers.

¹² For brevity’s sake references to ‘employee’ or ‘employees’ should be assumed to include their eligible dependents, unless the context or specific reference indicates otherwise.

¹³ CHROs face a unique challenge: how does one manage a program’s ultimate aggregate spend when the personal and financial interests of unaffiliated stakeholders who will ultimately determine the level of that spend (*i.e.*, its employees and its health care supply chain vendors) are not aligned and, in fact, are often adverse? Many line managers will scoff at this financial challenge claiming that they routinely face the same (or even more difficult) challenges on a daily basis, but that is simply not true. With only rare exception, there is no other area of responsibility within the plan sponsor’s entire organization that even comes close to routinely handing out an unfettered financial ‘put option’ on the company’s bank account to a continuously changing horde of financially-adverse “customers” who possess little to no financial accountability for their actions. A line manager who even suggested that the plan sponsor engage in such a business approach would be summarily terminated. But for CHROs, this experience encapsulates their daily existence.

¹⁴ Insert full legal name of ACA (referred to hereafter as the ACA)

¹⁵ The term ‘reimbursement’ will be used verses the term ‘cost’ to avoid any confusion between how much the plan sponsor is paying a vendor verses what the item or service reimbursed actually ‘cost’ the vendor to make or secure.

When the plan sponsor purchases a defined product or service (*i.e.*, when the quantity and type of product or service is spelled out and understood by the parties at the time of contracting), the parties bargain for delivery of a product or service at a specific time and price. To be sure, many complex commercial relationships often involve ‘cost-sharing’ at some level for things that may not be definitely determinable at the time of contracting, but as was stated, in the health care area, the plan sponsor is not purchasing a definitive set of products and services. What the plan sponsor is contracting for is the right to access another party’s supply chain (in this case, prescription drug supply chain) for whatever prescription requirements (as determined by others) may arise over the contracting period.

When a plan sponsor puts its PBM contracting services out to bid, the price quotes the plan sponsor receives back are only estimates of what the plan sponsor would have spent had the plan sponsor’s estimated utilization pattern actually occurred. Since the actual cost will be based on future (unknown) activity, the plan sponsor’s PBM contract is a critical tool that the plan sponsor has to address the actual level of spend. In such a situation, contractual transparency is imperative. In a theoretical world, a plan sponsor pays the PBM for its expertise in assembling and managing the plan sponsor’s financial risk inherent in offering prescription drug benefit to its employees and eligible dependents. In the real world, where the PBM possesses superior market knowledge, the plan sponsor’s rights (as embodied in the contract) have to be significant to help overcome the PBM’s superior information advantage associated with running and managing the underlying prescription drug supply chain.

Given this backdrop, for those plan sponsors who want to control their aggregate prescription drug spend, it is imperative that they fully understand the ‘in’s’ and ‘out’s’ of the prescription drug supply chain (*i.e.*, who are the “players;” what are the various financial incentives in place; how does the supply chain operate; how has it evolved over time; what actions can market players take in response to changes in the marketplace; etc.) and engage in a transparent contracting relationships that facilitate managing a complex supply chain.

Overview – The Prescription Drug Supply Chain

For very legitimate reasons, the prescription drug supply chain involves a number of different parties, each of which is involved in delivering a product or service directed ultimately at servicing the end customer – the patient. In some cases, an organization can fill more than one role (*i.e.*, it may offer PBM services, as well as general retail pharmacy services).

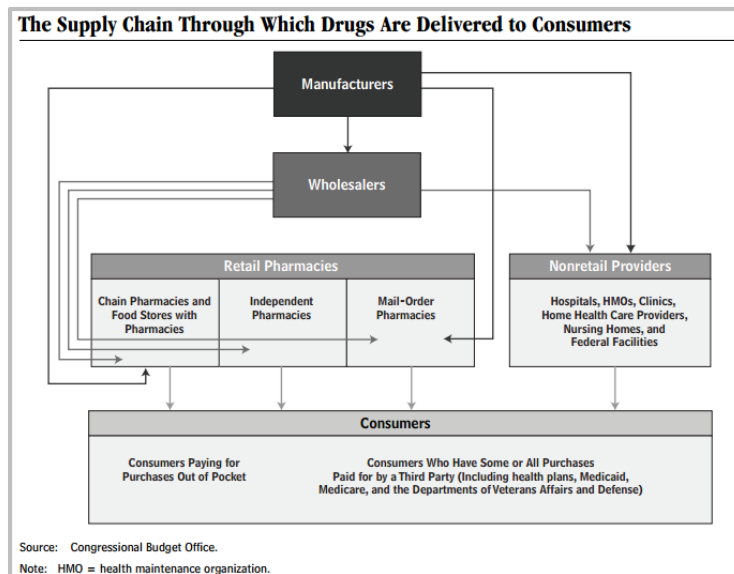
The prescription drug supply chain involves a number of different parties who play various roles (and in some cases, multiple roles):

1. **Drug Manufacturers:**

- a. **Brand Drug:** Organizations that risk an incredible amount of capital to research and secure approval to manufacture and sell a medication with a designated therapeutic use (*i.e.*, ‘on-label’ use).
 - b. **Generic Drug:** Organizations that receive FDA approval to produce an equivalent therapeutic medication to a medication that no longer has patent protection.
- ### 2. **Wholesalers:** Organizations that purchase, warehouse and distribute approved medications. The principal purpose of these organizations is to act as an inventory control point for other players in the prescription drug supply chain.

3. **Pharmacy Benefits Managers (PBM):** An organization that interfaces with plan sponsors, contracts with other parties in the prescription drug supply chain, maintains eligibility, monitors the plan sponsor's plan design, reviews and pays claims, reviews and decides which medications are most effective for each therapeutic use. Often, a PBM will operate a mail-order pharmacy and hold numerous contracts with retail pharmacy chains.
4. **Pharmacies:** An organization authorized to dispense medications to patients. The pharmacy can be found in a variety of settings: retail, mail-order, hospital, long-term care facility and physician's offices to name a few. These facilities dispense the medication to the patient for usage. One pharmacy setting to highlight (because it is the faster growing cost area in the prescription drug supply chain) is specialty pharmacy. Medications are dispensed through a "specialty pharmacy" when the medication is considered to need special handling. For example, the medication may be considered too expensive to waste, or potentially harmful if not administered timely and accurately, or too difficult for patients to administer themselves, or the medication may require special shipping (*i.e.*, refrigerated).
5. **Consumer / Patient:** The person who consumes the medication.
6. **Plan Sponsors:** An employer organization that takes on the program's financial risk and responsibility.
7. **Doctors / Medical Providers:** Authorize the dispensing of medications based on observed clinical condition. May even dispense the medication directly to the patient.
8. **TPA / Insurance Company:** An organization that operates the health care supply chain, including the prescription drug supply chain. Some health care insurance companies operate their own internal PBM, while others outsource that function to another a stand-alone PBM. The most important role insurance companies' play is determining the reimbursement amount for drug claims.

The PBM Industry – Supply Chain Overview



As mentioned, PBMs provide an extremely valuable service to their clients. Properly administered drug therapies purchased through PBMs have saved plan sponsors significant health care dollars and have enabled employees to maintain their health and avoid more costly medical care. In providing these services, PBMs are entitled to earn a profit.

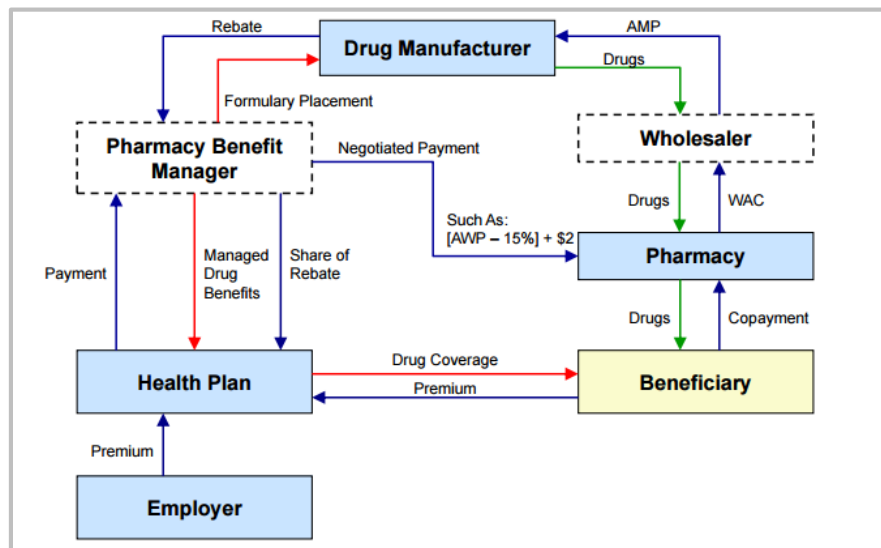
Having said that, the PBM industry is characterized by a general lack of transparency. While plan sponsors of all sizes are willing to pay a reasonable fee for PBM services, the efforts of employers typically have centered on understanding the various financial arrangements between the PBM, the pharmacies, the manufacturers and/or the drug wholesalers. The frustrated plan sponsors have experienced centers on believing they understand how much they are paying to provide a drug benefit to their employees only to find out that the PBM is receiving additional revenue from multiple sources that may or may not have their interests aligned with the plan sponsor.

One party important to the PBM supply chain is drug wholesalers. Drug wholesalers take delivery of product from manufacturers and then distribute them throughout the delivery channel including to the PBM's mail order and specialty drug facilities. Essentially, drug wholesalers act as an inventory buffer for the PBM's mail order facilities. To run efficiently, the PBMs do not stock all drugs that could possibly be dispensed. PBMs will use a drug wholesaler to fill-in inventory on an as-needed basis. As a result of their arrangements with wholesalers, PBM-owned mail order and specialty pharmacies are often entitled to certain contractual benefits with the wholesaler and/or manufacturers such as volume purchase discounts or early payment discounts just like other retail establishments, all of which ultimately lower the cost of a drug product, but may or may not be shared with the plan sponsor.

Retailers are another important player in the PBM's supply chain. PBMs create multiple contractual relationships with a wide variety of retail providers. Some retailers have created PBM services (mail-order services) in order to enhance their business offering and compete with traditional PBMs. Retailers also have an additional incentive not available to traditional PBMs – increasing foot traffic through their retail establishments. There is significant complexity in the PBMs contractual relationships with retailers and payment terms vary widely across the spectrum of payers.

The PBM Industry – An Overview of Pharmaceutical Pricing

Flow of Funds for Single-Source Brand-Name Drugs Purchased at a Retail Pharmacy and Managed by a Pharmacy Benefit Manager for an Employer's Health Plan¹⁶



Drug manufacturers that develop new medications (verses generic drug manufacturers) make significant financial investments to secure Federal Drug Administration (FDA) approval. In undertaking these efforts, it is not uncommon for them to spend significant dollars that are never recovered. However, if they are successful, the drug's manufacturer receives patent protection for the medication, which drives a strong financial incentive to see the drug utilized. The actual cost to manufacture an FDA-approved medication is often miniscule to the drug's sales price. As such, brand-name drug manufacturers have the ability to use a portion of their sales revenue to financially incentivize stakeholders (wholesalers, PBMs, and retail pharmacies) to stimulate demand. The primary financial tools used to drive these incentives are discounts and rebates, and these can take a number of different forms.

The methodology of passing along discounts and rebates starts when the manufacturer establishes its list price otherwise known as the Wholesale Acquisition Cost (WAC). The WAC price (a term defined by federal law) is intended to capture the price a manufacturer would charge a drug wholesaler or other direct purchaser *before* any discounts, rebates or other price reductions. Think of the WAC as the drug's sticker price. From the sticker price, the manufacturer will offer various financial incentives to the supply chain participants in order to stimulate demand. But, just as with an automobile, virtually no one pays the sticker price.

The price wholesalers and pharmacies that are direct purchasers actually pay is known as the "Average Manufacturer's Price" (AMP). This is another federally defined term that is intended to reflect the net sales prices the manufacturers receives *after* subtracting various discounts and rebates.

Once the drug is in the hands of a wholesaler, the next party to receive the drug in the supply chain is the pharmacy. In general, drug wholesalers will charge receiving pharmacies some percentage off of a reference price called the "Average Wholesale Price" (AWP). It is important to understand that AWP is not a real "price" but is simply a number that the manufacturer reports

¹⁶ Prescription Drug Pricing, Cook, Summers, Christian, CBO, January 30, 2009, http://www.nhpf.org/library/handouts/Cook.slides_01-30-09.pdf Last accessed October 16, 2015.

to companies such as Medi-Span, Redbook and others who then publish that number. Thus, AWP does not represent a ‘real price’ that one party pays another in a real transaction – it is simply a reference (or list) price that the drug’s manufacturer reports. In a way, AWP could be thought of as the manufacturer’s “list price” for a drug understanding that no party actually pays that price. AWP does, however, become the basis upon which discounts are referenced. In this case, drug wholesalers price drugs sold to pharmacies as a percentage off of AWP, even though the wholesaler may be paying the manufacturer a price totally unrelated to AWP.

The final step in the sales process is getting the medication from the pharmacy to the consumer. A consumer with no insurance or prescription drug benefit will be charged the ‘cash price.’ A consumer who has insurance of some type will pay an amount determined by the insurance coverage (*i.e.*, the plan design). In most cases, the insurance company or the PBM will have contracts in place with various pharmacy chains to give it and the consumer a price break relative to the cash price. The pharmacy is likely to receive a ‘dispensing fee,’ as well as a reimbursement for the dispensed medication. The amount of the reimbursement may or may not relate to what the pharmacy actually spent to secure the medication. Typically, pharmacies are reimbursed by insurance companies and PBM’s based on a percentage off of the AWP, which again is not related to what the pharmacy may have actually paid for the drug.

When the consumer has insurance coverage or an employer-sponsored benefit program, a PBM will adjudicate the claim, reimburse the pharmacy and bill the plan sponsor for the transaction. In some cases, the PBM will bill the plan sponsor more than it agreed to reimburse the pharmacy. This is known as spread pricing and enables the PBM to draw additional revenue from the transaction.

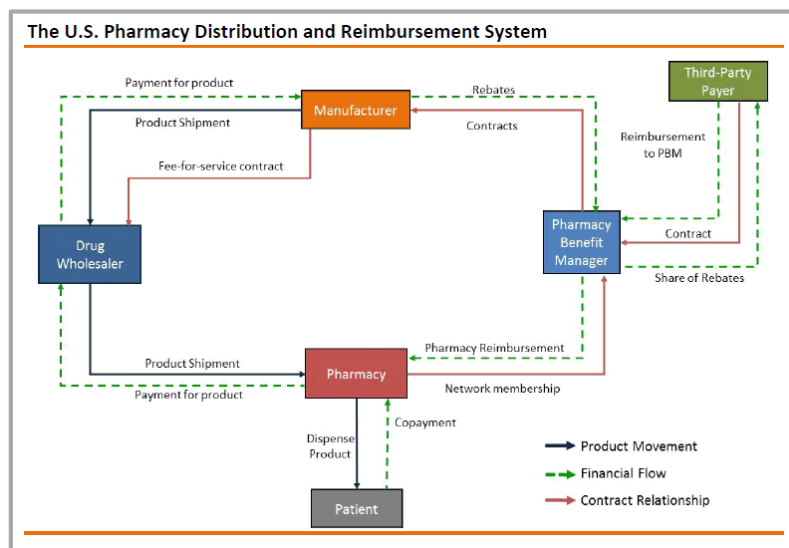
The PBM Industry – Various Financial Incentives

Drug manufacturers will pay rebates to a PBM provided the PBM meets certain tightly managed requirements:

- First, the PBM must submit a listing of all *paid claims* to the drug manufacturer showing the total quantity of the drug actually sold;
- Second, the PBM must provide the drug’s manufacturer with the PBM’s formulary¹⁷ showing that the specific drug is on the formulary for the intended therapeutic class; and
- Third, the PBM will be required to submit other documentation demonstrating that the PBM does not have any protocols in place that would act to ‘disadvantage’ the drug’s sale to patients (*e.g.*, application of a step-therapy¹⁸).

¹⁷ A formulary is a listing of preferred drugs (brand and generic) available to patients for each therapeutic class. For example, if a patient needs a drug to control his or her level of cholesterol, the dispensed brand-name drug used will be pre-designated as Crestor. The PBM could have picked any one of a number of statins (which is what Crestor is), but since the PBM picked Crestor, Crestor’s drug manufacturer will give the PBM a financial incentive (*i.e.*, rebate) for actually selling Crestor as the PBM’s formulary statin.

¹⁸ A step-therapy is a utilization management protocol. Some step-therapies are clinically-based for patient safety (*i.e.*, requiring a patient to use a less potent or less dangerous drug before trying a higher dosage or more inherently dangerous drug). Other step-therapies are financially-based (*i.e.*, limits patient access to certain more expensive medications before they have tried equally effective lower cost alternatives).



Drug manufacturers only pay rebates dollars to the party responsible for adjudicating the pharmacy claim. The assumption is that the party that adjudicates the claim (for example, a PBM) is the party that has the ability to ‘steer’ utilization of the drug. For this reason, drug manufacturers normally do not pay rebates to retail pharmacies because the drug manufacturers do not perceive that retail chains can effectively steer patients to the particular drug in question. The same is true for drug wholesalers. As a result, rebates tend only to be available to PBMs because only PBMs can demonstrate to the manufacturer an adequate ability to steer patient utilization. To participate in rebates, some retail pharmacies have set-up, or acquired, PBM services in order to capture rebate dollars such as preferred formularies and clinical programs that drive specific brands.

Challenges Managing the Prescription Drug Supply Chain

When it comes to managing the prescription drug supply chain, even the most sophisticated plan sponsors find themselves at a disadvantage to PBMs because only the PBM understands the whole range of the financial opportunities available in the supply chain. The frequent answer for most plan sponsors is to simply re-compete their PBM services, but even with the smoothest of implementations, there is a significant risk of employee disruption when a plan sponsor moves from one PBM to another. This fact gives plan sponsors great pause when considering their options.

As a general rule, PBMs tend to be very tough negotiators and with good reason. PBMs possess superior knowledge of the prescription drug supply chain. PBMs understand and can better anticipate future changes in the marketplace. In the end, PBM contracts tend to be very one-sided and often include:

- Sharp limitations on client access to data (even claims data that documents what the PBM is asking the plan sponsor to reimburse);
- Unclear or heavily ambiguous definitions (or even silence) for important terms;

¹⁹ Adam J. Fein, Ph.D, (January, 2015). 2014-2015 Economic Report on Retail, Mail & Specialty Pharmacy. Drug Chains Institute, page vi. Retrieved from http://www.drugchainsinstitute.com/products/industry_report/pharmacy

- Sharp limits on audit rights and stringent approval process for audit firms (including excluding some audit firms from the ability to act on behalf of a client);
- A lack of clarity in the PBM's drug pricing algorithm;
- A lack of transparency in the PBM's retail network contracts (most plan sponsors do not realize that a PBM may have multiple contracts with the exact same retail network);
- A lack of disclosure as to the financial incentives the PBM may receive from manufacturers and/or wholesalers;
- Pricing disparities between retail dispensed drugs and the cost of the same drug dispensed by the PBM's mail order facility;
- Definitional issues between generic versus brand drugs; and
- A habit of directing patients to higher cost therapies just prior to the therapy losing patent protection.

While there are additional areas that a plan sponsor needs to concern itself with in PBM contracting, the above list gives a flavor for the sophistication needed when contracting with and effectively monitoring a PBM. Further exacerbating this situation is the fact that benefit consulting firms hired to assist plan sponsors have worked out less than transparent 'deals' with specific PBMs. These deals between the consultant and the PBM significantly call into question the consultant's independence.

Below are some examples of challenges that plan sponsors face when contracting with a PBM:

- *Package Size Pricing:* Typically, a PBM promises a plan sponsor a certain percentage discount to the Average Wholesale Price (AWP); *e.g.*, 16 percent off AWP for brand-named drugs. What is not readily apparent is that the AWP price is based heavily on the package size. For example, the plan sponsor's price guarantee may be measured as some percentage discount off of AWP for a package size of 100 pills (or in some cases, less), whereas the PBM is likely purchasing the drug in lots of 50,000 or greater at a substantially lower price point. Structuring the PBM contract in this manner (which is often silent) allows the PBM to say it saved the plan sponsor some percentage off of AWP, when in fact the actual drug acquisition cost as to the PBM was significantly less.
- *Retail Network Management:* In addition to mail-order pharmacy services, PBMs contract with broad retail networks. What is not apparent to most plan sponsors (or their consultants) is that the PBM will often have multiple contracts (with varying financial arrangements) with the exact same retail pharmacy networks. So plan sponsors believing that they have secured a fully-transparent PBM contract may well be subsidizing a separate contract as previously stated. The question then arises as to what would drive a PBM to act in this manner? Again, the reason is that the PBM is trying to manage its aggregate contractual relationship with the retailer to make sure that PBM is delivering on its financial commitments to the retail chain. In doing this, some plan sponsors win, while others lose. Who wins and who loses is typically based on the bargaining power with small and medium size companies (and multiemployer health & welfare funds) paying substantially more. All PBM clients do not get the same economic advantage with bigger clients getting bigger (better) deals and smaller clients get smaller (less lucrative) deals – said differently, the size of the relationship does matter.

- *PBM Formulary Management:* PBMs have an incentive to tightly manage their formularies. As such, it would not be unusual for a PBM to reshuffle their formulary within a year of an important drug losing its patent protection. The PBM would do this to continue to secure rebate dollars from the manufacturers. For example, within a year of Lipitor losing patent protection, it would not be unheard of for a PBM to change its formulary to remove Lipitor as the designated brand-name drug for that therapeutic class and replace it with Crestor, which was not losing patent protection for some time. By doing so, the PBM can maintain its rebate dollars from Crestor's manufacturer.
- *Inability to Access Claims Data:* Plan sponsors who want to bid their PBM contracts have frequently found out that their current PBM will not give the plan sponsor their own data necessary to bid out the PBM contract. PBMs frequently refuse to turnover this information citing various privacy and contractual constraints.
- *Auditor Selection and Approval:* Understandably, PBMs jealously guard their propriety information. PBM contracts often give the PBM the right to veto the plan sponsor's choice of auditor assigned to validate the financial guarantees embedded in a PBM contract. In addition, PBM contracts often limit the length of time the plan sponsor has the right to audit (the audit can only look back over the last two years).
- *PBM Pricing Algorithms:* PBMs use complex pricing algorithms to derive the plan sponsor's 'cost' or to show that the PBM met an agreed-to price guarantees. For example, the PBM may guarantee that the plan sponsor will not pay any more than AWP minus 16 percent. The percentage savings (16 percent) is determined by dividing the total ingredient costs for all drugs purchased by the total AWP for all drugs purchased. Achievement of this savings target is determined on an aggregate basis. If the savings the PBM promised are not achieved, the PBM will pay the plan sponsor the difference. However, in determining whether the percentage off of AWP was actually achieved, some PBMs will exclude certain claim types from the calculation that would hurt the PBMs performance and include others that alter the performance calculation. In addition, some PBMs may use an artificially low ingredient cost that allows them to achieve the aggregate savings guarantee. For example, in cases where the plan sponsor pays the entire cost of the drug (because the cost of the drug is less than the employee's copay), the PBM may stick in a minimal cost figure (e.g., \$0.05) for the ingredient cost to allow the PBM to book a large discount to the AWP.
- *Contractual Over-Charging:* There have been some instances of PBMs deliberately failing to meet contractually-required price guarantees by over-charging the employer more money throughout the year. When the guarantee calculation is processed after the close of the year, it turns out that the PBM owes the plan sponsor a sizable refund. By over-charging the plan sponsor throughout the year and settling up some time after the year has closed, the PBM is essentially using the plan sponsor's capital at no cost. If in response, a frustrated plan sponsor decides to bid out the work, the plan sponsor may put any pending refunds at-risk. During the PBM bidding process, the current PBM may suspend processing further refunds pending the bidding process outcome, and pocket the guarantee money if the incumbent PBM loses the work.
- *Rebates versus Purchase Order Discounts:* PBMs are paid rebates because the PBMs run clinical programs that steer employees to certain medications. Given the fact that many plan sponsors understand that the PBM is securing rebates, plan sponsors have asked the PBM for 'transparent' pricing. If in response, the industry has moved to

‘reclassifying’ the rebate dollars as “purchase order discounts’ or ‘administrative fees’. Since the plan sponsor is often only contractually entitled to those things specifically defined in the contract as a “rebate,” the PBM will pocket the purchase order discounts. Thus, while a plan sponsor may believe that it has negotiated a fully ‘transparent’ PBM deal (receiving 100 percent of the revenue coming from the manufacturer), what the plan sponsor doesn’t realize is that some portion of the rebates have been carved-off and paid to the PBM as a purchase order discounts or admin fee etc.

- *Definitions – Brand versus Generic:* The way a drug is defined (*i.e.*, whether generic vs. brand) drives which aggregate discount the drug contributes to (*i.e.*, the generic discount or the brand discount). PBMs use the contract language to exercise great discretion in determining when a drug has actually moved from ‘brand’ to ‘generic.’ The timing may have a great impact on the pricing guarantees the PBM has contractually obligated itself to supply. For example, even after a drug has a generic equivalent available, PBMs may not consider the drug as a generic (and include in the drug in the generic pricing guarantees) until the PBM has determined (in its sole discretion) that there is a sufficient supply in the marketplace, which could be months or years after the drug has gone generic.
- *Reimbursements Differences Between Retail and Mail-Order:* It is not unusual to find a PBM reimbursing a retail pharmacy network less than the cost the plan sponsor is being charged for the same drug through the PBM’s mail order service (*i.e.*, spread pricing). This fact was the primary motivation for the creation of the HR Policy Association’s PharmaDirect program.
- *Manufacturer Administrative Fees:* In the PBM/Manufacturer contract, the PBM will require that the manufacturer pay the PBM an ‘administrative’ fee. The PBM will not classify these funds as a ‘rebate.’ The payment is to offset the PBM’s costs in reporting drug usage data back to the manufacturer so that the manufacturer can calculate any rebate due the PBM, as well as better understand the market data for its drugs.
- *Mail-Order Purchase Discount:* Finally, a fairly recent scheme now being deployed is the use of a “mail-order purchase discount.’ The drug manufacturer pays these funds to the PBM for drugs dispensed through the PBM’s mail order facility (as well as any PBM-owned retailed pharmacies). In the vast majority of plan sponsor/PBM contracts, the PBM is retaining 100 percent of these funds claiming that they are not a manufacturer’s rebate as defined by the plan sponsor’s contract with the PBM.

A New Model – Unbundled PBM Services

Borrowing from the efforts and experiences of Caterpillar, Inc. an innovative approach to address many of the issues identified above is to remove the PBM as the controlling organization in the prescription drug supply chain. This is not to say that the plan sponsor needs to stand-up a PBM with all of its required infrastructure, but rather the plan sponsor needs to limit by contract the PBM’s role in managing the prescription drug supply chain.

- *PBM Services:* A PBM is still needed to handle a number of required administrative responsibilities (eligibility determination, claims adjudication, formulary determination, implementation of step-therapies, management of pre-authorizations, etc.). For these services, the PBM is compensated solely through an administrative fee. For most plan sponsors, this administrative fee will be substantially *higher* than what they are paying

their PBM currently. The reason is very simple: the administrative fee will be the PBM's only source of revenue.

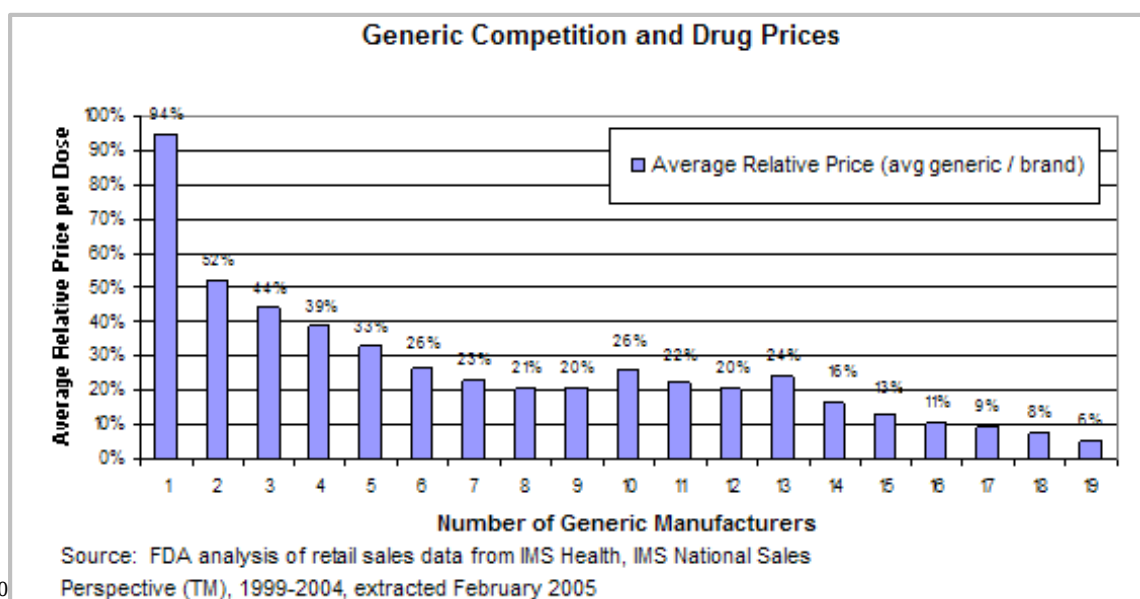
- *Mail Order Services:* The PBM may or may not be retained to provide mail order services. The plan sponsor will want to have mail order capabilities available to its employees and eligible dependents. The plan sponsor would unbundle the mail order services from the PBM and bid those services separately. The plan sponsor will need to be aware of the various contracting issues that underlie the PBM/Wholesaler/Manufacturer relationship, but given the fact that the plan sponsor is taking a more active role in managing the prescription drug supply chain, the plan sponsor can exert more leverage.
- *Retail Pharmacy Services:* This is the area where the plan sponsor can see the greatest financial impact: managing the retail pharmacy network without the PBM stepping into the middle of the financial arrangement. To be sure, the PBM is still responsible for transferring eligibility to the retail pharmacies and for properly adjudicating claims, but by working directly with select retail pharmacy chains, the plan sponsor has far greater visibility into the various financial arrangements. The PBM should be responsible for managing a website that allows the plan sponsor's employees and eligible dependents to easily shop between selected retail pharmacies. Experience shows that the retail pharmacies are very price competitive and look at a relationship with a plan sponsor with an eye towards increasing 'foot traffic' into their stores. Plan sponsors can use a PBM's retail network (versus putting their own retail network in place), but doing so runs the risk of losing transparency on each of the relationships.
- *Direct Contracting:* The plan sponsor will have more parties to contract with, but having separate contracts with the PBM and the preferred retail networks makes those parties responsible to the plan sponsor – not a PBM or consulting firm. Direct contracting allows for great accountability with each of the parties in the prescription drug supply chain.
- *Monitoring the Use of Consultants:* As part of this process, the plan sponsor needs to review the relationships that its consultants has with select PBMs and ask if the consultant is providing advice or advocating a specific solution. Most major consulting firms are aligned with a PBM and have multiple relationships with them. Naturally, this places the consultant in a position of potential conflict with the plan sponsor's interests.

Conclusions

PBMs clearly provide an important role in helping keep employees healthy and productive. Despite these efforts, the industry is beset with a lack of transparency that is difficult to deal with even for the largest plan sponsors. Unfortunately, benefit consultants, who are often relied upon to help plan sponsors with complex situations, are often aligned with specific PBMs thereby limiting their independence. As discussed above, experience shows that the PBM supply chain is a constantly evolving environment. Plan sponsors have a common objective: to remain vigilant to make sure that they are getting the most for the dollars being spent on pharmaceuticals by themselves, their employees and dependents, and their retirees. More transparency – in both process and pricing – would help plan sponsors meet that important objective.

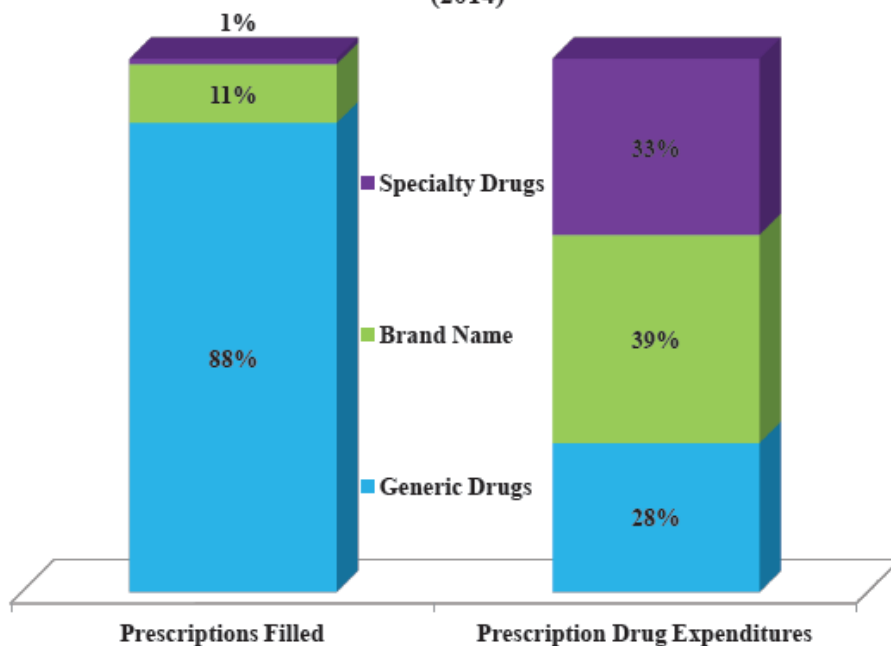
Appendix A – Common Terms

- Wholesale Acquisition Cost:** Wholesale Acquisition Cost (WAC): represents the manufacturers' (for this purpose, the term "manufacturer" includes manufacturers, re-packagers, private labelers and other suppliers) published catalog or list price for a drug product to wholesalers as reported by the manufacturer. WAC does not represent actual transaction prices and does not include prompt pay or other discounts, rebates or reductions in price. Publishers of WAC price schedules typically do not do any independent investigation or analysis of the prices reported to compile the WAC price schedules, but rely solely on what manufacturers to reports. See more at: <http://www.fdbhealth.com/policies/drug-pricing-policy/#sthash.oE9Wbvf4.dpuf>
- Average Acquisition Ingredient Cost (more commonly the Average Acquisition Cost, or AAC):** AAIC rate schedules are based on the premise that chemically equivalent drug products in the same strength and dosage should be reimbursed similarly. The AAIC is the cost at which pharmacies within a state purchase a drug, as defined, calculated and reported by the relevant state's Medicaid program. Since all states do not report an AAIC, AAICs price schedules include only those states where it is available. See more at: <http://www.fdbhealth.com/policies/drug-pricing-policy/#sthash.oE9Wbvf4.dpuf>



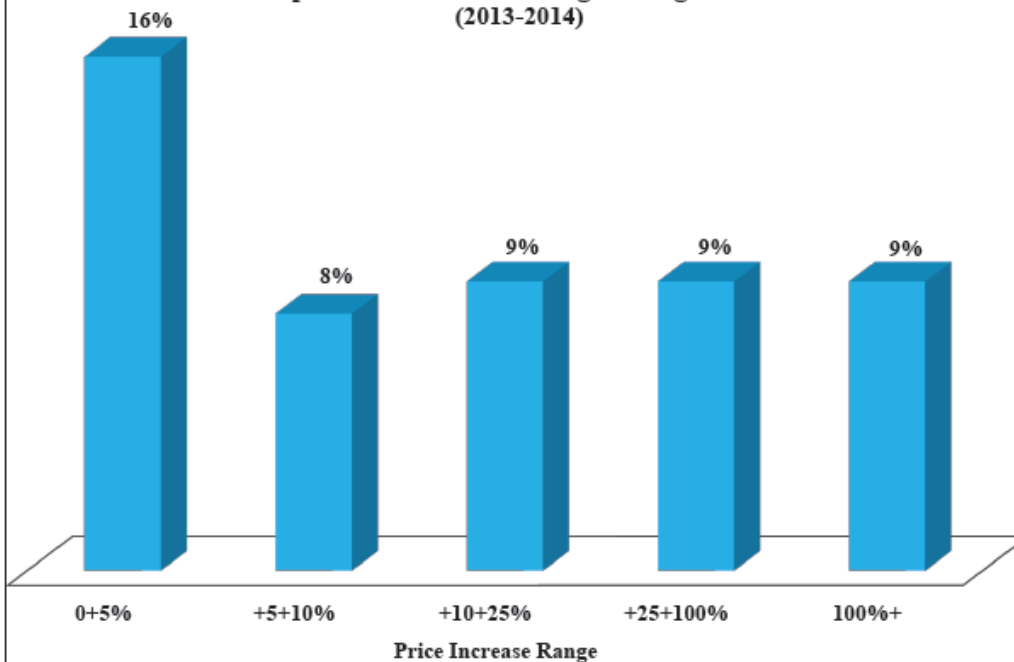
²⁰ FDA Analysis of Retail Sales Data from IMS Health, <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm> Last checked October 16, 2015.

Figure II
Prescription Drug Utilization
(2014)



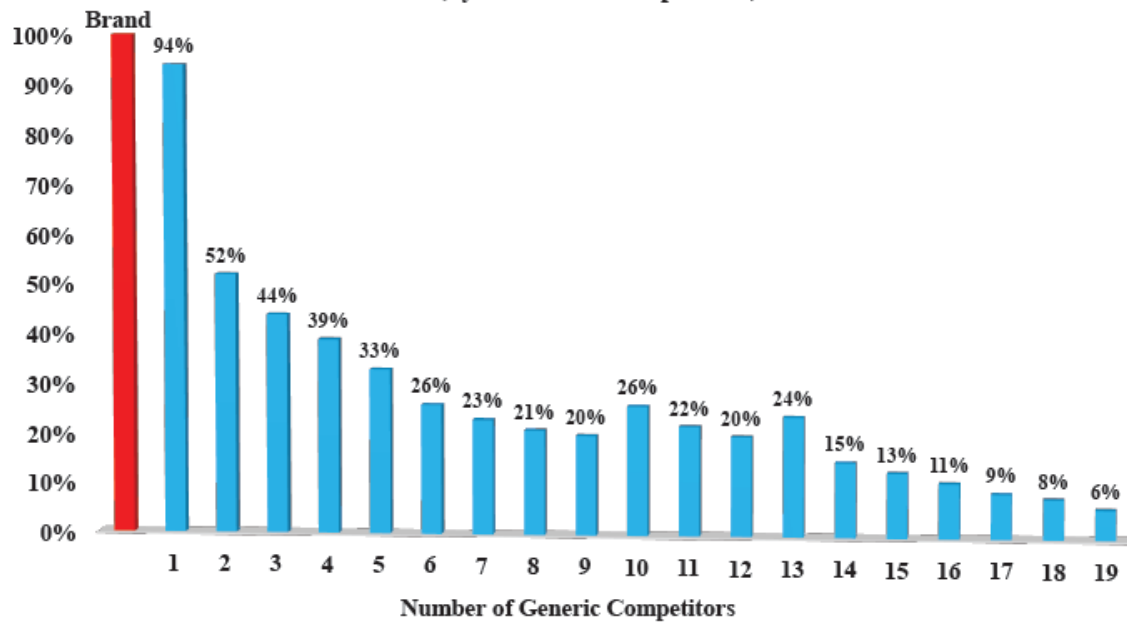
Source: Murray Aitken, Michael Kleinrock, Jennifer Lyle, Deanna Nass and Lauren Caskey, "Medicine Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014," IMS Institute for Healthcare Informatics, April 2015.

Figure III
Proportion of Generic Drugs Rising in Price
(2013-2014)



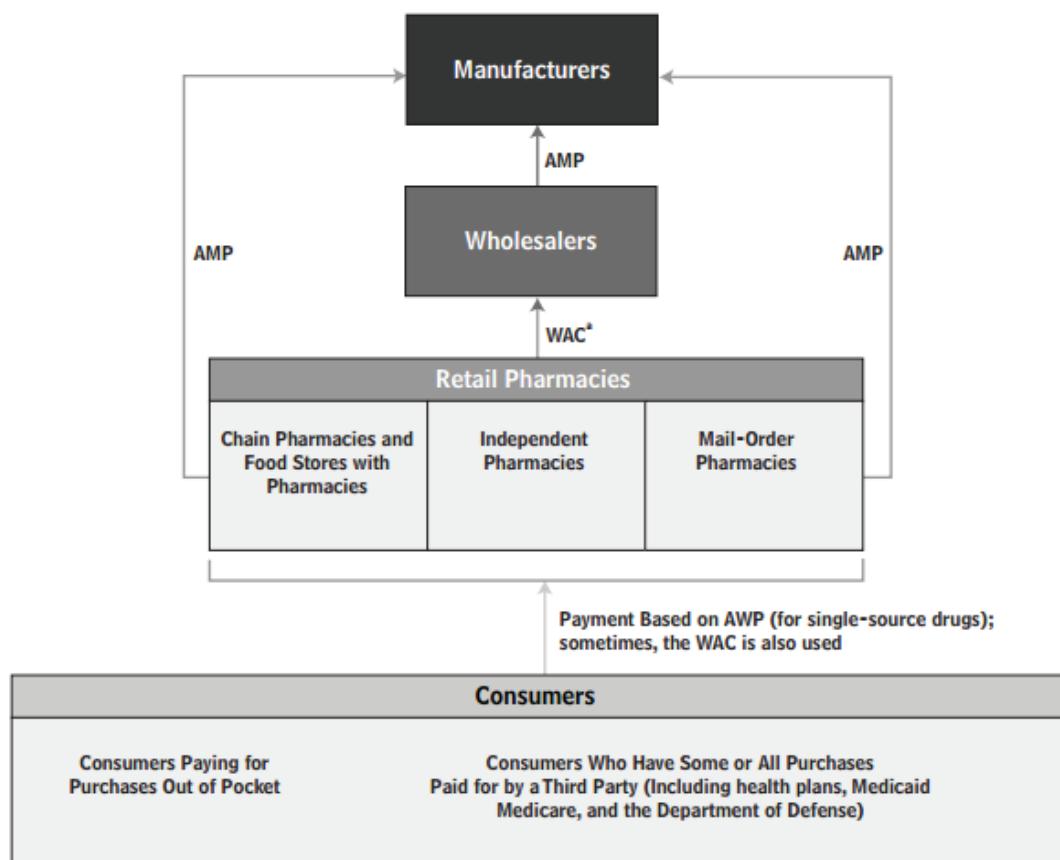
Source: Adam J. Fein, "Retail Generic Drug Inflation Reaches New Heights, Drug Channels Institute, August 12, 2014. Available at <http://www.drugchannels.net/2014/08/retail-generic-drug-inflation-reaches.html>

Figure V
Generic Drugs Prices as a Percentage of Branded Drug Prices
(by number of competitors)



Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective (TM), 1999-2004, extracted February 2005. Cited in Office of the Assistant Secretary for Planning and Evaluation, "Expanding the Use of Generic Drugs," ASPE Issue Brief, Office of Science and Data Policy, U.S. Department of Health and Human Services, December 1, 2010. Available at <http://aspe.hhs.gov/sp/reports/2010/genericdrugs/ib.pdf>.

Measures of Prices in the Retail Pharmacy Market



Source: Congressional Budget Office.

Notes: AMP = average manufacturer price; WAC = wholesale acquisition cost; AWP = average wholesale price.

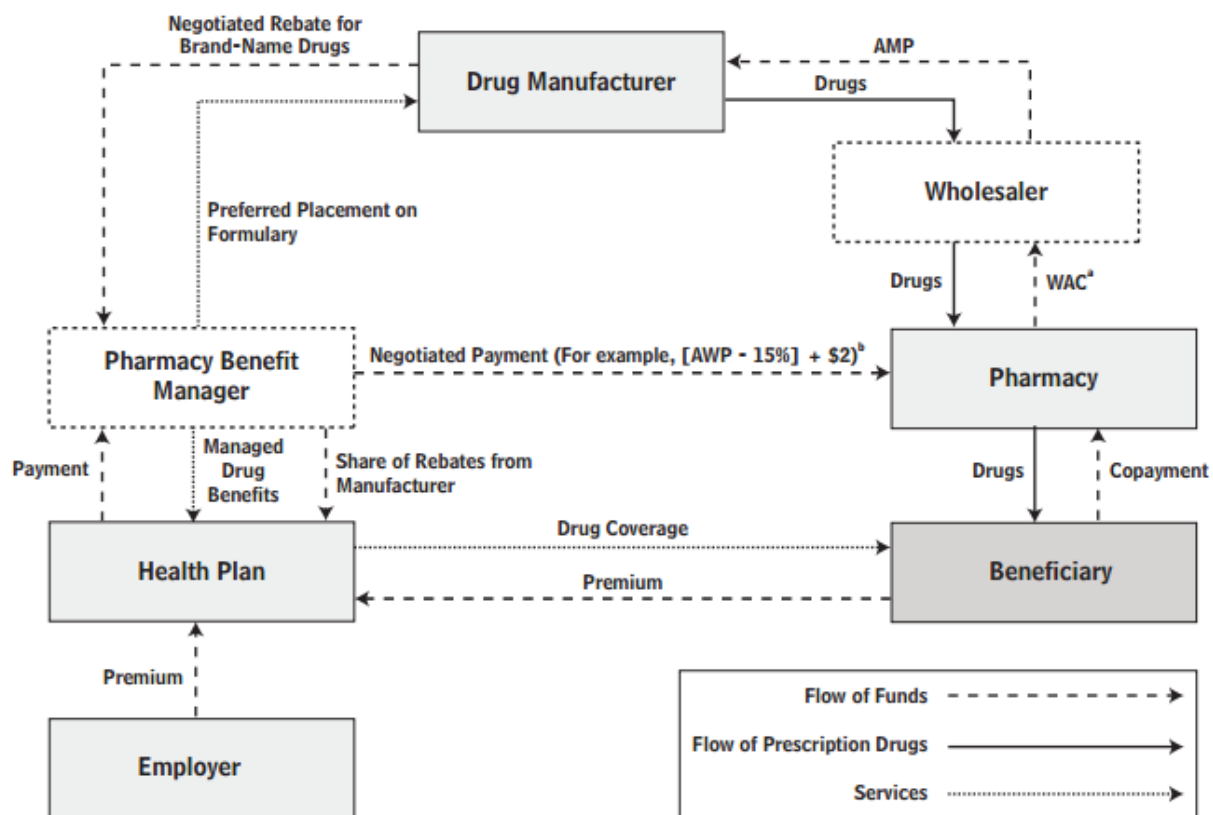
The AMP is an average of actual transaction prices. In contrast, the WAC and the AWP are list prices, like a sticker price in the automobile industry.

The role of the pharmacy benefit managers in the payment process is shown in Figure 4.

- a. The WAC approximates what conventional retail pharmacies pay wholesalers for single-source brand-name drugs. It does not approximate what retail pharmacies pay wholesalers for multiple-source drugs.

²¹ Congressional Budget Office. Prescription Drug Pricing in the Private Sector. (Online). January 2007. Available: <https://www.dol.gov/ebsa/pdf/CBO010711.pdf>. Referenced: December 1, 2015.

Flow of Funds for Single-Source Brand-Name Drugs Purchased at a Retail Pharmacy and Managed by a Pharmacy Benefit Manager for an Employer's Health Plan



Source: Congressional Budget Office.

Note: AMP = average manufacturer price; WAC = wholesale acquisition cost; AWP = average wholesale price.

- The WAC is a list price that approximates what conventional pharmacies pay wholesalers for single-source brand-name drugs.
- Based on Novartis Pharmaceuticals Corporation, *Pharmacy Benefit Report: Facts & Figures* (2004), p. 16.

²² Congressional Budget Office. Prescription Drug Pricing in the Private Sector. (Online). January 2007. Available: <https://www.dol.gov/ebsa/pdf/CBO010711.pdf>. Referenced: December 1, 2015.