

Pharmaceutical Care Management Association Statement for the Record

Prepared for the

UNITED STATES SENATE

COMMITTEE ON HEALTH, EDUCATION, LABOR, and PENSIONS

"The Cost of Prescription Drugs: How the Drug Delivery System Affects What Patients Pay"

June 13, 2017



Introduction

The Pharmaceutical Care Management Association (PCMA) is the national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans for more than 266 million Americans who have health insurance from a variety of payers, including: commercial health plans, self-insured employer plans, union plans, Medicare Part D plans, the Federal Employees Health Benefits Program (FEHBP), state government employee plans, managed Medicaid plans, and other payers.

PBMs reduce drug costs for patients and clients by:

- Negotiating rebates from drug manufacturers;
- Negotiating discounts from drugstores;
- Offering more affordable pharmacy channels:
- Encouraging use of generics and more affordable brand medications;
- · Managing high-cost specialty medications; and
- Reducing waste and improving adherence.

From 2016 to 2025, the use of PBM tools will save payers and patients \$654 billion—or up to 30 percent—compared with programs that make little use of proven PBM tools. PBMs are the key industry in America addressing the challenge of reducing costs, expanding access, and improving the quality of pharmacy benefits.

This statement will outline how PBMs offer policy solutions to increase competition among drug manufacturers to bring down drug costs. It will also show how PBMs have created a competitive marketplace among drug manufacturers and drug stores that reduces costs for payers, including employers, plans, unions, government programs and, of course, patients. It will also discuss how PBMs work with pharmacies to generate savings, and will also discuss PBMs' role in combatting fraud and abuse.

Market-Based Solutions for High Drug Costs

While PBMs can negotiate significant discounts and rebates when drugs are subject to competition, the options to achieve lower costs are limited when there is an absence of it. When a sole-source brand drug with no close substitutes enters the market, often similar competing brand drugs will subsequently enter the market, and eventually the original drug's patent will expire and generic versions of it will be produced. However, for various reasons, generic versions of brand drugs do not always come to market after the original drug's market exclusivity has expired. A number of policy changes to enhance competition could lower the cost of drugs generally. The Committee's adoption of the Collins-Franken amendment to promote generic drug approvals is an important step.

PCMA has worked to develop the following list of market-based solutions to address high drug prices. Implementation of these solutions would help lower costs for patients by getting drugs to market faster to increase competition and through allowing more flexible benefit design.



- Reduce innovator biologic exclusivity to seven years. Seven years of data
 exclusivity would still provide a sufficient return to manufacturers, while also speeding
 more affordable biosimilars to market.
- Eliminate "pay-for-delay" agreements. Patent settlements, or "pay-for delay" agreements allow drug patent holders to pay off potential competitors who would otherwise produce a competing generic drug. These anti-competitive agreements should be eliminated.
- Allow for FDA accelerated approval of me-too brands. Accelerated review is granted
 to new drug applications that address "unmet need." The economic need for competition
 to lower prices should be a criterion of unmet need.
- Eliminate the generic review backlog. The Food and Drug Administration (FDA) should have the means to approve generic drugs faster. According to FDA reports, the median review time for a generic drug application is more than three years.
- Improve biosimilar labeling and naming. Substitutable biosimilars should bear identical names and labels to their innovator analogs. Use of different names will only sow confusion among patients and providers and inhibit prescribing of biosimilars.
- Create a safe harbor for value-based drug price negotiations from Medicaid Best Price. Today any drug manufacturer must offer state Medicaid programs the lowest price it offers any other payer. This provision is seen as a price floor and is inhibiting creative value-based pricing arrangements.
- Eliminate the tax deduction for direct-to-consumer (DTC) drug ads. While DTC drug
 ads may encourage some people to see a doctor, they drive up unnecessary utilization
 and the cost of drug benefits. Tax deductions should end for ads mentioning a specific
 product.
- Solve the problem of off-patent drugs not subject to competition. As a first step, the FDA or other qualified entity should compile a list of all drugs and concomitant indications for which market exclusivity has expired, but do not currently have generic or other brand substitutes. Policies to encourage the approval and marketing of a generic drug to compete with such a drug may encourage competition, bring down costs, and discourage the kind of profiteering we have seen with such drugs in recent years.
- Ensuring access to brand drug and biologic samples for development of generics and biosimilars. Some drug manufacturers have made it extremely difficult for potential generic competitors to obtain samples needed for bioequivalence testing, sometimes by invoking FDA Risk Evaluation and Mitigation Strategies (REMS) and/or using extremely limited distribution schemes.ⁱⁱ In the House, there is legislation (The FAST Act, "Fair Access for Safe and Timely Generics," introduced by Rep. McKinley (R-WV) that would make it easier for generic manufacturers to obtain samples.



- Revise Part D's protected classes and category minimums. Designating "classes of clinical concern" where all or substantially all drugs in a class must be covered removes the PBM's ability to exclude a drug from its formulary and allows drug manufacturers to name their price. CMS already applies careful plan formulary coverage checks to assure proper coverage. Additionally, CMS should allow appropriate targeted exceptions to its two-drugs-per-class formulary policy, such as when there are only two drugs in a class that are clinically comparable.
- Make biosimilars subject to the 50 percent Part D coverage gap discount. The ACA neglected to apply to biosimilars the 50 percent Part D coverage gap discount. This could have the unintended consequence of encouraging prescribing of more expensive innovator biologics when lower cost biosimilars are available.
- Encourage greater use of generics for Part D LIS enrollees. MedPAC recommended allowing the Secretary of HHS to lower cost sharing on generics and raise it for brands that have generic competition. Allowing plans to lower generic cost sharing would save money for enrollees and Medicare.
- Further facilitate midyear changes in Part D formularies. In the course of a year, new drugs become available and medical knowledge evolves. Not allowing plans to delist drugs that are less effective allows manufacturers to exploit a de facto coverage mandate and unnecessarily raise and/or maintain high prices.

PBMs' Role in the Drug Delivery System

PBMs play a crucial role in keeping drug costs down for payers. PBMs sit outside of the traditional "pharmacy supply chain" that physically moves prescription drugs from manufacturers to drug wholesalers to the pharmacy, where they are ultimately dispensed to patients. In their capacity as pharmacy benefit managers, PBMs do not take possession of pharmaceuticals, but work on behalf of health care payers to reduce costs. PBMs negotiate brand drug rebates with drug manufacturers and discounts on generic drugs and dispensing fees with pharmacies.

On behalf of payers, PBMs pay pharmacies for prescriptions dispensed, and, per contractual agreements, pass through rebates to the payers for whom they work. The payer compensates the PBM for its services through fees or retained rebates, as agreed to in the contract between the PBM and the payer. In addition, PBMs provide clients with audit rights in their contracts as well as programs to protect against drug manufacturer price inflation.

The chart below illustrates how PBMs sit on the payment side of the drug distribution system and interact with payers, drug manufacturers, and pharmacies.



Formulary Agreement Services Agreement **Third-Party** ._____ Manufacturer Formulary Rebates Payer Wholesaler Payment for Product Pass Through of Rebate Service and **Product Shipment Data Fees** Services Contrac Wholesaler (specialty) Product Shipment **Payer Reimbursement** to PBM **Pharmacy Payment for Product Prescription Reimbursement Pharmacy Prime Vendor Agreement** Network Participation Dispense Copayment or **Product Movement** Prescription Coinsurance Financial Flow Contract Relationship

The U.S. Pharmacy Distribution and Reimbursement System for Patient-Administered, Outpatient Prescription Drugs

Chart illustrates flows for patient-administered, outpatient drugs. Please note that this chart is illustrative. It is not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace.

Source: Fein, Adam. J., The 2016 Economic Report on Retail, Mail and Specialty Pharmacies, Drug Channels Institute, January 2016.

[Available at http://drugchannelsinstitute.com/products/industry_report/oharmacv/)

Payers determine how the rebates are deployed; PBMs do not determine how payers use the reimbursements that are passed back to them. Most choose to apply them to overall program costs or reduce premiums for all plan enrollees. For payers who receive rebates as a part of their contractual arrangement with PBMs, 100 percent rebate pass-through is the most common rebate arrangement.ⁱⁱⁱ Experts estimate that PBMs pass back to payers more than 90 percent of total rebate dollars received from brand-name pharmaceutical manufacturers.^{iv}

Managing Benefits

It is important to note that PBMs do not make coverage decisions; rather, they provide their payer clients with various options for savings on prescription drug costs. PBMs advise their clients on ways to structure drug benefits to encourage the use of lower cost drug alternatives — such as generics — when appropriate. The PBMs' role is advisory only; the client retains responsibility for establishing the plan design. Payers themselves guide how actively pharmacy benefits are managed. For example, they determine formulary coverage, copayment tiers, utilization management, and pharmacy channel options. In addition, PBMs use a variety of tools such as drug utilization review and medication management to encourage the best clinical outcomes for patients. In making these choices, the payers weigh a multitude of factors, including cost, quality, and their employee/enrollee needs, and patient satisfaction.



How PBMs Create Market Competition among Brand Manufacturers

The first link in the drug supply chain is the drug manufacturer, which sets the price for the drug. The PBMs competing in the marketplace, across all lines of business, represent total patient populations of tens of millions of individuals, bringing significant negotiating leverage to the table with brand manufacturers.

PBMs drive competition among drug manufacturers by negotiating with them for rebates. The rebate amount is generally based on the market share a PBM can demonstrate it moved, through formulary and drug benefit design, to that drug. In these cases, the end or "net" cost of a product to the client cannot be determined until after the end of the time period for the agreement and the resulting total sales volume is known.

A drug formulary is a continually updated list of drugs that represents the current clinical judgment of providers who are experts in the diagnosis and treatment of disease. The primary purpose of the formulary is to encourage patients and prescribers to choose safe, effective, and affordable drugs.

For most payers, formularies are developed by an independent pharmacy and therapeutics (P&T) committee comprising primary care and specialty physicians, pharmacists, and other health care professionals. P&T committees evaluate all available evidence in clinical and medical literature to recommend the best medications for different patients' diseases and conditions, along with relevant information on the use of medications by patients, FDA-approved prescribing information and safety data, current therapeutic use guidelines, and health care provider recommendations. Where at least two comparable drugs exist, PBMs can encourage competition among manufacturers for better coverage of their drugs.

A formulary usually features at least two tiers, and in some cases, as many as six. Tiers may simply distinguish between brand and generic drugs, or may separate out preferred generics, preferred brands, and preferred specialty drugs from non-preferred. Because PBMs work to get the lowest net cost of drugs for their clients, PBMs typically recommend generics, where available, be tiered on formularies in such a way to incent patients to use them instead of the brand version of the same drug. Well over 80 percent of prescriptions now dispensed are for generic drugs.

With respect to brand drugs, manufacturers negotiate with PBMs for favorable placement on the PBM's formulary. The more favorable a drug's placement on the formulary, the more market share a drug will realize, and the greater a rebate the drug's manufacturer may agree to. PBMs use the prospect of moving market share to a given drug and the threat of excluding drugs from formularies to simultaneously drive competition among the manufacturers and offer a value-based prescription drug formulary to the clients they serve.

Recent events demonstrate how competition in the marketplace can drive significant savings on expensive drugs. In 2013, the first highly effective drug to cure hepatitis C was priced at \$84,000 for a cycle of treatment. However, by 2015, after that drug faced competition from additional market entrants, PBMs were able to negotiate a 46 percent rebate —saving billions. Market competition and the threat of formulary exclusion compelled the manufacturer to agree to this steep rebate. Indeed, after some PBMs excluded the first drug and opted to prefer a



competing manufacturer's drug when the competing drug's manufacturer was willing to drop the cost, other PBMs were able to prefer the first drug in their formulary, when the first manufacturer matched the competition. Still other PBMs were then able to keep both on their formulary as the market evolved.

Research on hepatitis C drug costs has subsequently shown that by 2015, when competition had emerged, hepatitis C drug costs negotiated in the U.S. by PBMs for Medicare Part D were usually lower than those in price-controlled European countries and Japan. The case of hepatitis C drugs illustrates clearly the effectiveness of the threat of formulary exclusion to bring manufacturers to the negotiation table.

<u>There is No Connection between Drug Manufacturer Price Increases and Negotiated</u> Rebates

Research by Visante finds no correlation between the prices drug manufacturers set and the rebates they negotiate with PBMs. The study shows prominent cases of higher-than-average price increases in drug categories where manufacturers negotiate relatively low rebates. At the same time, it shows prominent cases of lower-than-average price increases in drug categories where manufacturers negotiate relatively high rebates. Overall, it finds drug manufacturers are increasing prices regardless of rebate levels. Major findings of the study include:

- There is no correlation between increasing prices set by manufacturers and rebates for brand drugs. Based on an analysis of price growth and estimated rebate levels for the top 200 brand drugs by 2016 U.S. sales, there is no correlation between the increasing prices that manufacturers set on individual drugs and the rebates that they negotiate with PBMs on those products. Top brand drugs that offered little to no commercial-sector rebates during the 2011-2016 time period still increased their prices.
- Drug manufacturers raise prices even when rebates are low in major drug categories. Manufacturers have increased list prices an average 125 percent on multiple sclerosis drugs from 2011 to 2016, despite relatively low rebates on these medications. This has resulted in an average net price increase of \$3,232 per prescription for MS drugs over that time period. Additionally, large list price increases for rheumatoid arthritis drugs and anticonvulsants—two categories with relatively low rebates—have resulted in similarly high net price increases for those drugs after rebates are deducted.
- Rebates are unrelated to the launch prices of new drugs. In addition to price increases on existing products, higher launch prices on new brands have also contributed to rising prescription costs, however, these trends are not correlated with drug rebate levels negotiated by PBMs. Among the top 200 brand drugs by 2016 sales, the launch prices for drugs introduced from 2012 to 2016 were double the launch prices for those introduced prior to 2012. While rebates for the second drug introduced into a competitive class are higher than the first drug's rebate 72 percent of the time, the chance of the second drug having a higher launch price than the first drug is only 50 percent.



While the Visante study referenced above shows that there is <u>no correlation</u> between manufacturer price increases and negotiated rebates, separate evidence shows a <u>strong correlation</u> between lower net prices for, and more competition between, substitutable drugs. Specifically, a recent analysis by Credit Suisse finds "a strong correlation" between the size of drug rebates and the extent that drugs are substitutable. Thus, drug manufacturers with "more unique" products pay lower rebates than companies with more substitutable products. This analysis confirms that PBMs negotiate lower drug costs when they can bring competition to bear.

Further, the same Credit Suisse analysis referenced above finds that in 2016, manufacturers' U.S drug price increases accounted for 100 percent of the growth in earnings per share for drug manufacturer stocks.^{xiii} Thus, manufacturers can—and do—raise their prices to directly benefit themselves and their shareholders at the expense of individuals and governments paying for drugs.

Copay Coupons Encourage Patients to Take Expensive Brands Instead of Generics

Drug manufacturers now offer copay coupons to undermine efforts by payers to reduce costs by assigning higher consumer copays to expensive drugs and lower copays to more affordable drugs. While manufacturers may portray such efforts as charitable, they actually are significant cost drivers that manufacturers use to subvert value-based formularies. The economics of brand copay coupons are simple: to take a hypothetical example, each time a drug company can sell a \$300 product by helping cover a \$50 copay, it gains \$250 in revenue, which is paid by the payer that offers coverage.

By definition, copay promotions target those who already have prescription drug coverage (i.e., those who pay copays). These programs are not means tested or designed to help the poor or uninsured. Instead, they are designed to encourage insured patients to bypass less expensive drugs (which typically have lower copays) when multiple options are on the formulary, raising the cost of drug coverage.

Such practices are illegal in federal programs such as Medicare Part D and have long been under scrutiny by the Health and Human Services Office of Inspector General (OIG) because they are viewed as "kickbacks" that encourage wasteful spending for the profit of an outside third-party. Copay offset programs are estimated to increase pharmacy spending by \$32 billion.xiv To help cover the \$4 billion spent annually on copay coupons, manufacturers can simply raise prices. Manufacturers reportedly earn as much as a six-to-one return on investment on copay coupon programs. Because payers foot this bill, these programs increase premiums.

The OIG recently described the problem clearly, that:

"the availability of a coupon may cause physicians and beneficiaries to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available. When consumers are relieved of copayment obligations, manufacturers are relieved of a market constraint on drug prices."

Additionally, drug manufacturers often require consumers to submit confidential, personal information in order to redeem copay coupons. Manufacturers have long sought (but found



difficult to obtain) such sensitive patient data, which enables them to identify and directly target individual patients with brand-loyalty marketing programs.

PBMs Drive Efficiency through Pharmacy Networks and MAC Reimbursement

PBMs have innovated by negotiating with pharmacies to offer lower costs in exchange for higher volume, as well as better value and higher quality, as part of preferred pharmacy networks. These networks comprise all types of pharmacies, including independent pharmacies. First created for improving Part D benefits, pharmacy networks are now also used in the commercial sector. Payers using pharmacies offering preferred cost sharing have proven enormously popular—currently 75 percent of Medicare Part D beneficiaries have chosen these types of plans. While not every pharmacy achieves preferred status in every plan, the vast majority of pharmacies are in at least one plan as a preferred pharmacy, giving beneficiaries the opportunity to stay with a pharmacy with preferred cost sharing by carefully choosing their Part D plan every year.

Evidence shows that patients have embraced the savings that preferred pharmacies bring. A national poll conducted by Hart Research Associates shows that seniors in Part D plans with preferred pharmacy networks are overwhelmingly satisfied, citing lower costs and convenient access to pharmacies, among other benefits. The survey revealed that 80 percent of those in preferred pharmacy plans—which translates to over 7 million seniors—would be very upset if their plan was no longer available.^{xvi} For Part D overall, 89 percent of Americans age 65 and older are satisfied with their coverage and 85 percent say that they consider their Medicare drug plan to be a good value.^{xvii}

PBMs create further efficiencies in the drug supply chain using maximum allowable cost (MAC)—now one of the most common methodologies used in paying pharmacies for dispensing generic drugs. By definition, MAC is the maximum allowable reimbursement by a PBM for a particular generic drug that is available from multiple manufacturers and sold at different prices. Each manufacturer has its own price for a particular generic drug and these prices can differ extensively by manufacturer. The use of MAC encourages competition: the purpose of MAC pricing is to encourage pharmacies to obtain the lowest-cost generic from among identical products from various manufacturers.

PBMs use MAC lists to balance providing fair compensation to pharmacies with being able to provide a cost-effective drug benefit plan to their payer clients. MAC pricing has become the industry standard—it is used by 79 percent of private employer prescription drug plans for retail generic prescriptions. In addition, 45 state Medicaid programs now use MAC lists. States adopted MAC lists after government audits showed that Medicaid reimbursements based on cost-plus reimbursement for generic drugs far exceeded a pharmacy's acquisition costs.

MAC reimbursement is a negotiated term in contracts between pharmacies and PBMs. Far from being at a contract negotiating disadvantage, independent pharmacies typically pool their collective purchasing power to increase leverage. More than 80 percent of independent pharmacies (18,103 of the 21,511 pharmacies identified by National Council for Prescription Drug Programs data) use large third-party organizations known as pharmacy services administrative organizations (PSAOs) or group purchasing organizations to increase their leverage in negotiating their payment terms and conditions with PBMs. *Viii The largest PSAOs



are controlled by three multi-billion dollar suppliers to pharmacies, providing a further negotiating advantage for independent pharmacies due to the size and sophistication of these parent companies.

PBMs Keep Costs Down for Patients through Specialty and Mail Pharmacies

Some PBMs operate specialty pharmacies that enhance the safety, quality, and affordability of care for patients receiving specialty medicines. Pharmacists and clinicians at specialty pharmacies offer support to patients with complex medical conditions such as blood disorders, cancer, Crohn's disease, HIV/AIDS, and rheumatoid arthritis. Effective management is essential for these drugs; in 2020, nine of the 10 best-selling drugs by revenue will be specialty drugs compared with three out of 10 in 2010, and seven out of 10 in 2014. **Specialty pharmacies are estimated to save \$250 billion over the 10-year period from 2016-2025.**

Specialty drugs are prescribed for patients with a complex or chronic medical condition or a rare or orphan disease and may require advanced patient education. Additionally, specialty drugs typically have a high monthly cost, unique storage or shipment requirements, and are not stocked at a majority of retail pharmacies.

Specialty pharmacies play an important role in patient care. They provide 24/7 access to specially trained pharmacists and clinicians, physician consultations to address patient side effects, adverse reactions and non-adherence. Through these robust supports, specialty pharmacies increase patient adherence and dispense specialty drugs most efficiently and cost-effectively.

PBMs provide highly efficient mechanized mail-service pharmacies that supply home-delivered prescriptions with great accuracy and safety and at a substantial savings. Mail-service pharmacies typically provide 90-day prescriptions for drugs that treat chronic conditions. Consumers use mail-service pharmacies once they are stabilized on a medication, after having finished several 30-day prescriptions from their local drugstores. According to recent studies, mail service pharmacies will save consumers as much as \$60 billion over the ten year period from 2015-2024.xxi

PBMs Fight Fraud and Abuse

PBMs improve the safety and efficiency of the drug supply chain by exerting great efforts to combat fraud, waste, and abuse with respect to prescription drugs. PBMs use data analytics to identify fraudulent pharmacies and fraudulent patients and then go after the perpetrators. PBMs also perform audits, where records from pharmacies are compared to claims data records. Additionally, PBMs make site visits to ensure that a pharmacy reporting claims is actually occupying physical space and has customers.

To address increasing opioid abuse, PBMs are using sophisticated analytics to uncover patterns of potential fraud or abuse, and scanning for behavioral red flags to identify when someone may be inappropriately seeking opioids. To further combat opioid abuse, PCMA strongly supports use of pharmacy lock-in programs to allow payers to work with at-risk patients to choose a single pharmacy to dispense their controlled substances. We believe the practice maintains patient access to needed medications, but prevent inappropriate shopping for opioids.



PCMA also supports a number of other initiatives that we believe will help curb the current opioid crisis, such as requiring electronic prescribing for prescription opioids, and limiting prescriptions for acute pain to seven days.

Conclusion

PBMs evolved because they increase the value of prescription drug benefits. PCMA's member companies harness market forces and competition to corral drug costs and deliver high-quality benefits and services to their payer clients and enrollees. In its search for solutions to address high drug costs, PCMA believes the Committee would be best served to pursue policies that foster and encourage competition to keep prescription drug costs and pharmacy benefits more affordable for employers, enrollees, taxpayers, and government programs. Improving drug approval times and encouraging competition, as well as resisting the urge to unduly regulate PBMs and prescription drug benefits, will go a long way toward helping to constrain drug manufacturers' demonstrated impulses^{xxii} to price their products high.

Our companies welcome continuing discussion among all stakeholders to create a robust, sustainable market that will continue to deliver needed cures and treatments for patients who suffer through disease and chronic illness. PCMA looks forward to working with Congress to find additional ways to promote savings consistent with high-quality, high-value prescription drug benefits.

Thank you for the opportunity to submit this statement for the record.

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^{ix} Visante, Inc. Increasing Prices Set by Drugmakers; Not Correlated With Rebates, June 2017. Analysis prepared for PCMA

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