ConsumersUnion
POLICY & ACTION FROM CONSUMER REPORTS

Written Statement of

Lynn Quincy, Director, Health Care Value Hub
George P. Slover, Senior Policy Counsel
Consumers Union

on

The State of Competition in the Pharmacy Benefits Manager and Pharmacy Marketplaces

Before the

Subcommittee on Regulatory Reform,
Commercial and Antitrust Law

Committee on the Judiciary
United States House of Representatives

November 17, 2015

Introduction

Consumers Union, the policy and advocacy arm of Consumer Reports,[1] appreciates this opportunity to provide our views on how the Prescription Benefit Management marketplace is functioning and whether it is delivering on its promised benefits for the health care system and for consumers.

We are an expert, independent, nonprofit organization whose mission is to work for a fair, just, and safe marketplace for all consumers, and to empower consumers to protect themselves.

As part of our work on behalf of consumers in health care, one important service we provide is to help consumers find the best value when purchasing prescription drugs. In 2004, we launched *Consumer Reports Best Buy Drugs*. This program uses evidence-based systematic reviews of prescription drugs to clearly demonstrate the efficacy and safety in over 30 categories of commonly used medicines.[2] What's more, we combine this information with reliable cost information – enabling consumers to truly identify the "best buy" for many drugs. To our knowledge, we are the only source of this type of information for consumers that is not supported by commercial funding.

As many have observed, consumers benefit when there is effective competition at all levels in the supply chain.

Unfortunately, the pharmaceutical marketplace, and the PBM marketplace in particular, is not functioning competitively. The PBM marketplace is highly concentrated – following the 2012 merger of Medco and Express Scripts, the top two PBMs control between 80 percent and 90 percent of the market for health plans sponsored by large employers, and 73 percent for plans sponsored by employers of any size.

The anticompetitive effects and risks of this high horizontal concentration are further increased by the vertically-integrated cross-ownerships and financial partnerships between PBMs, drug manufacturers, mail order services, and retail pharmacies.

PBMs administer prescription drug benefits for more than 235 million Americans.[3] PBMs can perform an important function in negotiating with

[1] Founded in 1936, *Consumer Reports* is an expert, independent, nonprofit organization whose mission is to work for a fair, just, and safe marketplace for all consumers, and to empower consumers to protect themselves. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Consumer Reports has over 8 million subscribers to its magazine, website, and other publications. Its policy and advocacy division, Consumers Union, works for health reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., the states, and the marketplace. This division employs a dedicated staff of policy analysts, lobbyists, grassroots organizers, and outreach specialists who work with the organization's more than 1million online activists to change legislation and the marketplace in favor of the consumer interest.

[2] http://www.consumerreports.org/health/best-buy-drugs/index.htm.

[3] http://www.pcmanet.org/about-pcma/about-pcma.

pharmaceutical manufacturers to help keep drugs more affordable. The PBM industry has also helped spur important innovations that have streamlined and modernized management of pharmaceutical delivery. They've helped propel the shift to generic drugs, encouraged the use of "step therapy," introduced techniques for improving medication adherence, and brought focus to safer use of drugs through monitoring of drug interactions and dosage reviews.

But to ensure that PBMs bring maximum benefit to the health care system and to consumers, it is important that PBMs act openly, and not on hidden conflicts of interest that skew their incentives.

Improved transparency of PBM business practices would better enable health insurance plans and self-insured employers to ensure that prescription drug formulary designs reflect appropriate safety, efficacy, and value considerations, without impeding consumers' ability to obtain the prescription drugs they need.

Ideally, effective regulation and effective competition work hand in hand. And the less we can rely on effective competition, the more important it is that regulation ensure effective transparency to reduce the potential for abuse.

Approximately 10 percent of our nation's health spending is for prescription drugs,[4] and clear, transparent information about clinical effectiveness and pricing are paramount in ensuring that we spend this money wisely. But, as explained below, the opaque business practices that are commonplace in the PBM industry can result in unfair arrangements between health plan sponsors and PBMs. Without a ready ability to audit these business practices, the arrangements can drive up costs for both plan sponsors and consumers; they also they have the potential to put the wrong prescription drugs into consumers' hands.

Lack of Transparency in PBMs

The PBM industry has come under fire for a number of anti-consumer practices, including:

(1) using opaque rebate schemes to inflate PBM profits;

(2) using opaque pricing spreads to inflate PBM profits;

(3) tailoring formulary designs and drug switching to inflate PBM profits; and

(4) steering plans and consumers to use of mail order for filling prescriptions even when consumers prefer to obtain prescriptions locally.

[4] Micah Hartman et al, National Health Spending In 2013: Growth Slows, Remains in Step with the Overall Economy, *Health Affairs*, December 2014.

Concern about these practices has resulted in litigation, in antitrust complaints, and in calls for reform.[5] In response, more than two dozen states have passed laws that attempt to regulate certain PBM practices.[6] However, many PBM contracts are not subject to state law, because most health benefits plans offered by self-funded employers are exempted from state regulation under ERISA.[7]

Based on its own examination of these issues, the ERISA Advisory Council last November unanimously called for the Department of Labor to require that PBMs disclose to health plan sponsors all forms of direct and indirect compensation received in connection with providing services to the health plan.[8] The Council found that increased disclosure would reduce potential PBM conflicts of interest and better enable health plan sponsors to assess the reasonableness of what they were being charged for PBM services. The Council also recommended that the Department of Labor issue guidance to assist health plan sponsors in more effectively auditing of PBM direct and indirect compensation.

As consumer advocates, we strongly support this effort to give plan sponsors greater ability to keep drug prices in check.

As detailed below, today's complex and opaque contract arrangements and pricing spreads result in increased costs to health plan sponsors and enrollees, and can lead to formulary designs that inappropriately steer consumers toward or away from certain medication choices that might be more suitable for their needs.

At the most basic level, accessible and transparent disclosures about PBM pricing practices will help employers and other plan sponsors ensure that drugs are priced more affordably and that the financial incentives facing consumers more accurately reflect the clinical safety and effectiveness of the drug.

[5] Mark Meador. "Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry through Regulation," 20 *Annals of Health Law*, 77 (2011).
[6] See State Laws Reforming the Practices of Pharmacy Benefit Managers, http://www.ncpanet.org/pdf.leg/nov12/pbm_enacted_legislation.pdf ; State Regulation of Pharmacy Benefit Management, http://www.approrx.com/media/documents/PUTT_State%20Regulations_061713a.pdf
[7] The Employee Retirement Income Security Act of 1974, or ERISA, establishes employee protections that apply to private employers that offer employer-sponsored health insurance coverage and other benefit plans to employees. ERISA does not require employers to offer plans; it only sets rules for benefits that an employer chooses to offer.
[8] Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure*, November 2014, https://www.dol.gov/ebsa/pdf/2014ACreport1.pdf.

Rebates

A rebate in the context of PBM practices refers to an incentive payment made by a drug manufacturer to the PBM based on how much the PBM increases the market share or sales of a drug. Rebate arrangements vary widely, and a PBM may not be required to disclose to plan sponsors the details of its rebate arrangements.

In some cases, it is possible that, unbeknownst to the plan sponsor, a PBM may pockets a substantial rebate, while imposing the full cost of the drug onto enrollees. For example, one industry analyst estimates that more than 80% of rebates are passed on to the health plan sponsors.[9] From that, we could conclude that the remaining 20% of rebates may never be passed on. In a more competitive and transparent environment, a PBM would not be able to retain rebates of this magnitude. Moreover, this figure does not even take into account rebate administrative fees that are often paid to the PBM by a drug manufacturer, which typically are not disclosed, or passed on.

Rebates based on volume metrics can undermine a PBM's role as an intermediary working on behalf of health plan sponsors to negotiate lower costs. This is especially the case when the PBM obscures the actual net costs of the drugs to the plan sponsor.

Lucrative rebate deals may encourage the placement of more expensive drugs onto a formulary. If profit considerations distort formulary design, they also undermine the consumer's – and the physician's – choice of drug based on the best medical evidence available, and the medical needs of that consumer.

For example, formularies that once placed the popular brand-name heartburn drug Nexium (now a generic) on its preferred-brand list could have been steering consumers toward using that drug because the PBM had negotiated a rebate deal with a manufacturer. In 2014, we estimated that a month's supply of 20-mg of Nexium might have a total cost (health plan plus consumer's cost-share) of about $240. But another drug, equally safe and effective, and in the same class as Nexium, was an over-the-counter generic called omeprazole. A similar quantity of this drug could be bought for just $17, or even less – no prescription needed.[10]

In a perfect world, rebates based on prescription volume metrics should be eliminated. We believe there's no way to structure rebates that does not essentially constitute a form of kickback. In the intermediate term, we recommend strengthening transparency requirements so that the net cost that the PBM pays, after all rebates are factored in, is disclosed to plan sponsors.

---

[9] Adam J. Fein, Pembroke Consulting. January 2014. 2013-14 *Economic Report on Retail, Mail and Specialty Pharmacies.*

[10] See "Got heartburn? The best treatment for you" Consumer Reports Online, March 2014 available at: http://www.consumerreports.org/cro/2014/03/find-the-best-heartburn-treatments/index.htm.

Pricing Spreads

Another source of profit for PBMs is pocketing what can be a significant price difference between what a PBM actually pays a pharmacy for a prescription drug and what it charges the health plan sponsor and consumer.[11] This pricing difference is known as the "spread." To get this spread, the PBM often anchors what the plan sponsor is charged using a pricing reference list such as the Manufacturers' Average Cost list, or "MAC."

Unlike volume discounts or rebates, which may be shared with plan sponsors and consumers, plan sponsors and consumers are not typically told of, and do not typically share in, the price spread – it is a "hidden mark-up" revenue mechanism. Moreover, this pricing scheme adds another layer of complexity to an already complex chain of supply, distribution, and pricing. Thus, even in rare cases where transparency around spread pricing is written into a PBM contract, it can be difficult, if not impossible, for the health plan sponsor to police.

Some savvy plan sponsors have begun to prohibit hidden pricing spreads in their contracts with PBMs. Following the lead of the Medicare program in 2009, many have adopted straightforward "pass-through" pricing, wherein the PBM fully discloses the actual price it pays the pharmacy. The PBM then either passes the discount on to the plan sponsor, charging a transaction fee instead, or it shares an agreed-upon proportion of the transparent price spread. All things considered, we find this fee-based mechanism to be preferable. It is simpler, easier to administer, and less vulnerable to manipulation and gamesmanship. It also promotes competition among PBMs by allowing a plan sponsor to more easily compare drug prices offered in its plan against those from other plans.

As a byproduct, the higher potential profits connected to spread pricing could give PBMs an additional financial motivation to favor and push the greater use of generics, but this is not a compelling reason to support this mechanism. Spread pricing is too susceptible to PBM manipulation, and too difficult for plan sponsors and others to monitor. We could find no credible evidence that the size or amount of hidden PBM pricing spreads increases the rate of generic prescription use. And there is already sufficient incentive for the use of generics, as their underlying cost is a fraction (often 10% or less) of the cost of the brand name drugs. Generic pricing should adhere as closely as possible to this underlying cost, and those savings should be disclosed to and passed on to consumers.

Formulary Design and Drug Switching

Formulary design is an essential component of pharmacy management. Formularies can be successful at compelling doctors and consumers to choose effective, less expensive medicines. However, when formulary design is used to amplify the benefits to the PBM of rebate concealment and spread pricing profits, it ill serves plan

[11] *See, e.g.*, "Painful Prescription," Fortune Magazine, Oct. 10, 2013, http://fortune.com/2013/10/10/painful-prescription/.

sponsors and consumers.

Drug switching is a practice where the doctor has prescribed one drug for a patient, but the PBM uses "therapeutic substitution" and changes the prescription to a different drug it deems to be of similar therapeutic value. When structured appropriately, PBM intervention in this process can serve the dual beneficial purposes of saving money while ensuring that consumers get an effective and safe medication for their treatment.

However, drug switching can also be motivated by pure financial self-interest on a PBM's part – in pursuit of manufacture rebates, or spread pricing, or targeted discounts. In 2006, for example, Medco paid $163 million to settle federal charges that it defrauded customers by shorting, changing and canceling their prescriptions. In a three-month period, Medco had persuaded doctors to switch more than 71,000 prescriptions from Lipitor, made by Pfizer, to Zocor, a more costly drug from Merck (then Medco's owner).[12]

In May 2015, Medco paid $7.9 million to settle federal charges that it took kickbacks in exchange for identifying AstraZeneca's product Nexium as the "sole and exclusive" proton pump inhibitor on certain of its formularies. AstraZeneca had previously agreed to pay $7.9 million for its role in the kickback scheme. As the Justice Department noted in announcing the settlement, "Hidden financial agreements between drug manufacturers and pharmacy benefit managers can improperly influence which drugs are available to patients and the price paid for drugs."[13]

Formulary design must be fully transparent to the health plan sponsor. Assignment to formulary tiers, as well as the rules for therapeutic substitution, must reflect the best medical evidence regarding clinical effectiveness and safety, followed by the fully transparent bottom-line cost reflecting all rebates, other fees, and the actual price pharmacies are paid for generics. This will help ensure that formulary design is not swayed by the relative prospects for PBM revenue or profits on one drug over another.

Mail Order Services

When properly designed and offered as a choice for consumers, not as a mandatory measure, a PBM's mail order delivery option can provide consumers with cost savings, convenience, and potentially improved medication compliance.

However, it is critical to employers and other health plan sponsors, and to consumers, that PBMs not use mail order services as a vehicle for further opaque drug switching driven by rebates or generic spread pricing, or other anticompetitive self-dealing.

[12] "PBM Fiduciary Duty and Transparency," Prescription Policy Choices, www.policychoices.org.
[13] http://www.justice.gov/opa/pr/medco-pay-79-million-resolve-kickback-allegations.

Our main concern, as also identified by industry analysts, is that PBMs who provide their own mail order services have the opportunity to both set the price of a drug for mail-order using a different reference pricing or MAC list than they do with retail pharmacies, and then also determine how much they will charge the plan sponsor. Plan sponsors are likely to be unaware of this pricing mechanism, and unaware that different reference price lists are being used to determine how much the plan sponsor will pay for an enrollee's medications. For example, one recent survey of employers found that a quarter of them said they did not know what pricing mechanism was in place for mail order services provided by their PBMs.[14]

These and other concerns have already prompted several states to pass legislation to regulate aspects of pharmacy mail order.[15] Transparency around mail order services is an important part of any effort to make PBM practices better understood by employers, other plan sponsors, and consumers – and to give them a basis for comparison and choice.

The new regulations by the Centers for Medicare and Medicaid Services for Medicare Part D, scheduled to take effect for contract year 2016, should help. The final rule will promote increased price transparency by requiring Part D plans and their PBMs to make available to pharmacies contracted in their networks the reimbursement rates for drugs under Maximum Allowable Cost pricing standards.

Conclusion

As currently structured, the highly convoluted drug supply and pricing chain offers too many opportunities for deception by PBMs and may be raising costs for consumers. The high levels of concentration and vertical integration in the PBM marketplace increase those risks.

As an indication of how substantial the cost of price spreads and rebates can be, in 2009 the U.S. Military's health care provider, TRICARE, estimated it could save more than $1.7 billion dollars by negotiating its own pharmacy benefits instead of using a PBM for its nine million covered lives.[16]

But it is often the case that employers and other health plan sponsors – let alone

[14] Pharmacy Benefit Manager (PBMs): *Generating Savings for Plan Sponsors and Consumers*, Visante, September 2011, 3. Available at: http://pcmanet.org/images/stories/uploads/2011/Sept2011/pbms%20savings%20study%202011%20final.pdf.

[15] Adam J. Fein, Pembroke Consulting. *Economic Report on Retail, Mail and Specialty Pharmacies*, January 2014. 2013-14.

[16] Kevin Schweers, *Community Pharmacists Hear Mail Order Complaints; Debunk PBM Myths*, NCPA Commentary (Sept. 23, 2009), http://www.ncpanet.org/advocacy/pbm-resources.

consumers – lack the tools to discipline PBM profiteering, because they do not know the extent to which it is practiced. In most cases, plan sponsors do not have access to PBM rebate agreements and other contract terms.

Consumer Union supports efforts to more effectively enable purchasers, government enforcers, and consumer watchdog organizations to better monitor prevailing, average, and actual pricing so there is meaningful access to pricing information by which to judge the effectiveness of PBMs in negotiating good net prices for prescriptions.

We appreciate the Subcommittee's attention to this issue of profound importance to our health care system and to consumers.