

**2014 ERISA Advisory Council
PBM Compensation and Fee Disclosure**

Patricia M. Danzon PhD
Celia Moh Professor
The Wharton School
University of Pennsylvania

I. Services Provided by PBMs

Pharmacy Benefit Managers (PBMs) are contracted as intermediaries by plan sponsors (employers and health plans) to manage the coverage of drugs dispensed to plan members by outpatient pharmacies. In addition to the most basic function of claims processing and paying pharmacies for drugs dispensed, PBMs usually also actively manage the pharmacy benefit with a view to assuring appropriate drug use, reasonable cost, safety and value for money. The specific functions of PBMs include:

- **Creating a network of contracted retail pharmacies:** PBMs negotiate discounted reimbursement rates with retail pharmacies in exchange for access to the PBM members' business. Without the services of a PBM, maintaining relationships with a wide network of retail pharmacies, in order to assure convenient access for beneficiaries, would be prohibitively expensive for many plan sponsors.¹
- **Processing pharmacy claims:** PBMs provide IT services to enable pharmacies to verify, in real time, whether a prescribed drug is covered by the plan and the member's co-payment. The pharmacy transmits the point of sale information to the PBM, which validates the claim, reimburses the pharmacy the contractually agreed amounts for the drug dispensed and the pharmacy dispensing fee. The PBM is reimbursed by the plan sponsor the contractually agreed amounts for these services. Such IT systems require significant up-front investments in fixed cost, but once established, can be expanded to broad usage, creating economies of scale for large PBMs.
- **Creating drug formularies to manage utilization and cost:** A formulary is a list of drugs that are covered by the plan, along with the member's co-payment for each covered drug and any restrictions on use. Common restrictions are: prior approval (a requirement that the doctor obtain approval from the PBM before the drug is reimbursed); and step edits (computerized requirements that the patient try a less expensive drug before a more expensive drug is approved for coverage). In designing formularies, a health plan or PBM uses a Pharmacy and Therapeutics Committee comprised of clinical pharmacists and physicians, who review the FDA-approved drugs in each therapeutic class, the evidence on each drug's effectiveness, safety, contra-indications and cost. PBMs structure formularies to balance coverage of an adequate range of drugs with cost to the plan sponsor and out-of-pocket cost to members. Most formularies now have three or four tiers. The lowest tier includes generics, with average retail co-pay of \$11; the second tier is preferred brands, with average retail co-pay of \$30; the third tier is non-preferred brands, with average retail co-pay of \$56 (PBMI, 2013). Some plans also have a fourth tier for specialty drugs, with a higher average co-payment or co-insurance percent of the price. Open formularies cover all approved drugs, but with different levels of patient cost-sharing. Closed formularies exclude specific drugs entirely from coverage. Very large employers may structure their own formulary. Smaller self-insured employers lack the necessary resources and expertise, and therefore usually choose one of several standardized formularies offered by a PBM or health plan, possibly with negotiated modifications.

¹ Large employers are more likely than small employers to use selective or limited pharmacy networks (PBMI, 2013). Many states have enacted Any Willing Provider laws that require PBMs to contract with any pharmacy willing to accept their fees, for their business that is governed by state regulation. Theory and evidence suggest that such laws lead to higher costs to consumers, by limiting PBMs' ability to contract selectively (see FTC CMS letter 3.7.14).

- **Negotiating drug rebates with pharmaceutical manufacturers:** PBMs' ability to influence drug utilization through formulary structure ("shift share") enables them to negotiate discounts/rebates off list prices of branded drugs from pharmaceutical manufacturers. PBMs' ability to influence utilization and hence to negotiate rebates is greatest in therapeutic classes with multiple, weakly differentiated branded drugs that are chemically unique but therapeutically very similar in efficacy and safety (close therapeutic substitutes). In such classes, the PBM can negotiate rebates in return for placing only two or three drugs on the preferred tier, because preferred tier drugs with relatively low cost-sharing tend to gain market share from non-preferred drugs with higher cost-sharing. In addition to use of differential cost sharing, PBMs can shift share towards preferred drugs by encouraging pharmacies to call the patient's doctor to authorize the switch or by calling the doctor directly if the drug is dispensed through the PBM's mail-order pharmacy.² These drug rebates are paid by electronic transfer from the drug manufacturer to the PBM. The pass-through of the drug rebates by PBMs to plan sponsors has been a contentious issue, but recent evidence suggests that most sponsors capture most of the rebates, thereby reducing the sponsor's total drug spend (see below). As with formulary design services, only the very largest plan sponsors would have the scale and expertise to individually contract with drug manufacturers for rebates. Most delegate this function to PBMs.
- **Mail-order pharmacy dispensing:** All of the major national PBMs have vertically integrated to offer mail-order pharmacy dispensing as an alternative to retail pharmacy dispensing, most commonly for maintenance medications. A PBM's mail-order pharmacy procures medications directly from drug wholesalers and/or manufacturers, eliminating the role and associated costs of retail pharmacy dispensing. Economies of scale exist in the mail order pharmacy business, as in retail pharmacy, due to such factors as inventory requirements, fixed capital costs of operation, scale-related pricing with drug wholesalers etc.

In addition to these traditional roles, the large national PBMs and some midsized PBMs have expanded their services to include:

- **Specialty pharmacy dispensing and related services:** Some specialty pharmaceuticals, including injectibles and infusions, require special handling and cold chain storage. As specialty pharmaceutical utilization has grown significantly, some PBMs have developed or acquired in-house specialty pharmacies, and now offer direct mail-order distribution, home infusion and related counseling to their members. For example, Express Scripts and CVS Caremark offer in-home infusion of specialty medications through their subsidiaries, Accredo and Coram, respectively. Note that drug infusions/injections that are done in a physician's office are covered by the patient's medical benefit, not the pharmacy benefit. PBMs' acquisition of specialty pharmacies are part of a strategy to expand their business to include the medical benefit side of drug spending.³
- **Drug utilization review (DUR):** PBMs offer DUR services, defined as authorized, structured, ongoing review of healthcare provider prescribing, pharmacist dispensing, and patient use of medication. DURs involve a comprehensive review of patients' medication data, to ensure appropriate prescribing and medication use, avoid potential drug interactions, and promote positive patient outcomes.⁴ Such reviews are required under some government programs such as Medicare and Medicaid.
- **Compliance and therapy management programs:** Many PBMs offer additional "value-added" services such as compliance and therapy management programs that help high risk patients stay on their medications and avoid drug-related complications.⁵ By improving compliance and reducing medication

² Pharmacies can do generic substitution (between generically equivalent versions for the same molecule) without the physician's permission, but therapeutic substitution (between different molecules) requires permission from the prescribing physician.

³ CVS Caremark Q1FY2014 Earnings Call Transcript accessed at <http://www.morningstar.com/earnings/earnings-call-transcript.aspx?t=CVS&pindex=4>

⁴ <https://www.prxn.com/docs/PRxN%20DUR.pdf>

⁵ Express Scripts FY2013 10-K filing accessed through SEC EDGAR Database

errors, such programs aim to reduce the need for costly medical interventions. The PBM's access to real time pharmacy data enables them to more effectively manage such programs.

II. Alternatives Available to Sponsors

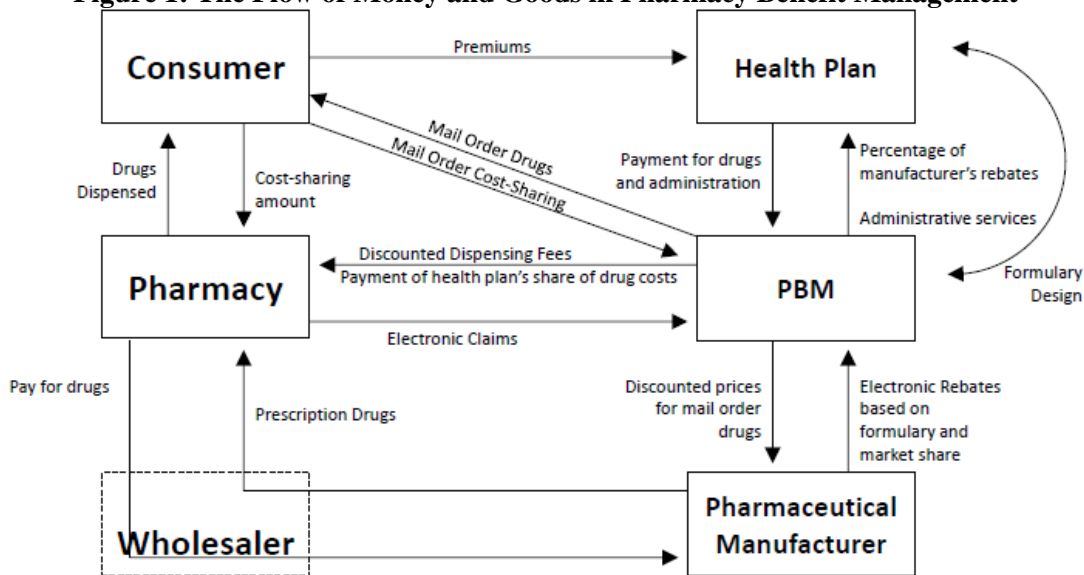
A plan sponsor has three options for performing the essential functions of operating a pharmacy benefit, including selecting a formulary of covered drugs, setting patient cost sharing, contracting with and paying pharmacies for drugs dispensed. First, the sponsor may “carve in” these functions to the health plan that administers the sponsor’s health benefit. Several large health plans own and operate their own, in-house PBMs and/or contract with independent PBMs (see Section III below). Second, the sponsor may “carve out” the full spectrum of services to an independent PBM. Third, very large employers may conduct some of the core formulary-related PBM services in-house, outsourcing to a PBM only the basic pharmacy network management and claims processing that are subject to large economies of scale. The evidence suggests that small employers are more likely to carve in pharmacy benefit management to their health plan administrator: 66% of small employers contract for their PBM through a health plan administrator and only 30% contract with a PBM directly, whereas for large employers 30% contract through a health plan and 65% contract directly with a PBM (PBMI, 2013).

II. The PBM Business Model: How PBMs Make Money

Overview

Figure 1 shows the flow of money and goods in pharmacy benefit management. Pharmaceutical manufacturers typically sell their drugs to wholesalers, such as McKesson and Cardinal Health, which distribute the drugs to pharmacies, including independent and chain retail pharmacies and PBMs’ mail order pharmacies, which dispense the drugs to patients. PBMs develop and manage formularies, contract with and reimburse retail pharmacies, contract with and collect rebates from drug manufacturers, and dispense drugs through their mail order pharmacies. They are compensated by plan sponsors for these services. Each stage of this supply chain incurs costs and adds a markup or margin, to cover these costs. The functions of PBMs include not only claims processing but also managing the choice and cost of drugs on the formulary and the costs of the distribution chain.

Figure 1: The Flow of Money and Goods in Pharmacy Benefit Management



1. Pricing and Spreads on Retail Pharmacy-dispensed Drugs

Single-Source Brand Drugs Pharmaceutical manufacturers typically sell their on-patent brand drugs to wholesalers at the manufacturer's list price, usually *Wholesale Acquisition Cost (WAC)*, net of any discounts for prompt payment etc. Manufacturers also supply their list price(s) to third party database companies, such as Medi-Span.⁶ The third-party database companies calculate *Average Wholesale Price (AWP)* based on the standard formula $WAC+20\%$.⁷ If the manufacturer lists both a WAC and a Suggested Wholesale Price (SWP), Medi-span states that it will set AWP at the manufacturer's SWP. Thus for on-patent brand drugs AWP is a list price that is usually higher than and roughly proportional to what the wholesaler actually paid, but the relationship between AWP and WAC or actual wholesaler acquisition cost is not necessarily strict proportionality. Wholesalers distribute and sell drugs to pharmacies, adding a small (roughly 2-3%) margin.

Retail pharmacies make money by marking up the drug price and adding a dispensing fee. In a cash transaction to a self-pay patient, this marked-up price would be charged in full to the patient when the drug is dispensed. One way that a PBM reduces costs for sponsors is by negotiating discounts on the pharmacies' usual and customary drug mark-ups and dispensing fees. The PBM is then reimbursed by the plan sponsor at a negotiated, contract price for the drugs and administration of the retail pharmacy claims. These contractually agreed prices for drugs, from PBMs to pharmacies and from sponsors to PBMs, are typically expressed as a percentage of a widely available list price benchmark, most commonly AWP. For example, the PBM may reimburse pharmacies for drugs at AWP minus 18% plus a \$1 dispensing fee. These payment rates at which PBMs reimburse pharmacies are not generally known to plan sponsors. The PBM contracts for reimbursement from the sponsor at a somewhat smaller discount off AWP, say AWP minus 16% plus a \$2 administration fee per script. The difference between the sponsor's payment rate to the PBM and the PBM's payment rate to the pharmacy is known as the "retail spread" and is a significant source of PBMs' net revenue.

Generics In the US, most oral generics are rated by the FDA as bio-equivalent to and substitutable for the reference brand drug ("AB-rated").⁸ Pharmacies are authorized to substitute any AB-rated generic for the brand, even if the script is written for the brand, unless the physician explicitly requires the brand. The pharmacy is therefore the decision-maker with respect to generic substitution and specifically, which generic product to dispense. Generic manufacturers compete for market share by offering generics to pharmacies at large discounts off the list price. Large generic firms also often distribute generics directly to large pharmacies, eliminating the wholesaler role. As a result of direct generic discounting, AWP is a poor indicator of actual acquisition cost of generics to the pharmacy. A recent CBO report found discounts to pharmacies on generics can exceed 80-90% of their AWP list price.⁹ This occurs because the AWP list price is usually set at a relatively high level when the first generic is launched; over time, generic entry and competitive discounting drives down actual acquisition prices but there is no incentive to lower list prices.

PBMs typically reimburse pharmacies for generics based on *MAC* pricing (maximum allowable cost), which is based on the PBM's estimate of generic acquisition cost to pharmacies, net of discounts. The MAC reimbursement is the same for all generic versions of a product (defined by molecule-form-strength). MAC reimbursement incentivizes pharmacies to use the lowest cost generic available as this will provide them with the greatest margin. Over time, PBMs revise down the MAC, based on their evidence of actual pharmacy acquisition cost for generics, thereby capturing (some of) the savings from competitive discounting by generic manufacturers to pharmacies. Unlike AWP, which is a list price schedule set by third-party database companies,

⁶ According to Medi-Span's official pricing policy, drug manufacturers most often provide a Wholesale Acquisition Cost (WAC) but sometimes a Direct Price (DP) and/or a Suggested Wholesale Price (SWP).

⁷ Wolters Kluwer Health Average Wholesale Price (AWP) Policy, http://www.medispans.com/sites/all/themes/wkh/assets/pdf/pre/WKH_AWP_Policy.pdf

⁸ Bioequivalence includes that the generic has the same active ingredient, dosage form and strength and essentially the same absorption and bioavailability as the originator. Generics must also comply with Current Good Manufacturing Practices (cGMP) standards.

⁹ January 2007 CBO Paper, Prescription Drug Pricing in the Private Sector, <http://www.cbo.gov/publication/18275>

each PBM sets its own MAC reimbursement prices for pharmacies (Eberle, 2008). According to the 2013-2014 PBMI Report, the majority of PBM contracts with plan sponsors (75%) bill for generics based on MAC pricing, and the remainder bill for generics based on a discount off AWP. PBMs can earn a spread on generics dispensed through retail pharmacies, as they do on brand drugs. However, retail pharmacies also capture some of the discounts on generics.

Several other price metrics are used in pharmaceutical reimbursement but are less common than AWP and MAC for PBM business:

Average Manufacturer Price (AMP) is the weighted average price at which manufacturers sell to the retail class of trade, net of all rebates except those given for Medicare Part D. Manufacturers are required to report AMP to CMS, which uses AMP to calculate Medicaid rebates. Because AMP is a price that reflects most rebates, it is considered confidential and is not publicly available.

Average Sales Price (ASP) is the weighted average price at which manufacturers sell infusion and injectable specialty drugs that are dispensed in physician offices or hospital outpatient departments and are covered under Medicare Part B (or the private patient's medical benefit). Manufacturers are required to report ASP to CMS on a quarterly basis. CMS calculates reimbursement under Medicare Part B as ASP+6%. ASP is publicly available and is also widely used by private payers for specialty drug reimbursement under their medical benefit.

Weighted Average Manufacturer Price (WAMP). Since 2011 CMS publishes online a WAMP for generics that are available from at least three manufacturers.¹⁰ CMS has proposed to base Medicaid drug reimbursement to pharmacies for multi-source generics at 175% of AMP.¹¹

National Average Drug Acquisition Cost (NADAC). Since 2012 CMS publishes NADAC, which is the national average acquisition cost for retail community pharmacies for drugs, based on a survey of independent and chain retail community pharmacies, intended for possible use by Medicaid agencies. The NADAC is an invoice-based measure, so it omits off-invoice rebates received by pharmacies.

Both NADAC and WAMP are relatively new and so far not widely used. They may be used in the future by public and some private payers, as they are publicly available and may provide a more accurate measure of generic acquisition cost for pharmacies than AWP.

However, it is important to note that once a pricing measure becomes widely used for reimbursement, this pricing measure may be modified to influence reimbursement. For example, AWP did originally approximate the actual average wholesale price. But once it became widely used as a basis for pharmacy and physician reimbursement for drugs, AWP over time became an inflated list price while actual wholesale prices were set at discounted levels.

2. Mail Order Pharmacy Business

Most large PBMs own and operate a mail-order pharmacy. For this mail-order business, PBMs purchase drugs from wholesalers (or directly from some generic manufacturers) and dispense to their members through the mail. Accepting mail dispensing is usually voluntary for patients and is used primarily for maintenance medications that a patient takes for a several months or more. When PBMs dispense directly from their mail pharmacies, they eliminate the margin and dispensing fee usually paid to a retail pharmacy, although of course the PBM incurs some dispensing and mail costs. Dispensing through their own mail order pharmacy can strengthen a PBM's ability to ensure patient adherence to treatment and formulary compliance, using their in-house pharmacist to contact physicians to switch patients to preferred brand drugs or get prescriptions renewed. Greater ability to shift share can yield larger rebates on brands. The PBM mail-order pharmacy also captures the

¹⁰ February 2, 2012 Federal Register, Vol 77, No. 22, Medicaid Program; Covered Outpatient Drugs; Proposed Rule, <http://www.gpo.gov/fdsys/pkg/FR-2012-02-02/pdf/2012-2014.pdf>

¹¹ December 2013 GAO Report, Medicaid Prescription Drugs, <http://www.gao.gov/assets/660/659833.pdf>

discounts from generic manufacturers that would normally accrue to the retail pharmacy. Discounts on generics have become an increasingly important source of revenue for PBMs as for retail pharmacies, as the generic share of prescriptions has grown to over 80 percent in the US. Because mail-order business is more profitable for PBMs than retail pharmacy business, PBMs typically incentivize enrollees to use mail order, by offering 90-day rather than 30-day prescription fills, with a 90-day mail co-pay that is only roughly two-times rather than three-times the 30-day co-retail co-pay.¹² For patients, mail order can provide convenience as well as lower co-pays. Use of mail-order has been strongly opposed by the retail pharmacy industry, leading to restrictive legislation in some states.

3. Manufacturer Rebates

As discussed in section I, PBMs negotiate rebates with brand manufactures in return for preferred formulary placement and increase in market share of their drugs. PBMs contracts with plan sponsors usually specify the percentage of rebates retained by the PBM vs. passed through to the sponsor. Manufacturers transmit rebates to PBMs electronically, based on actual usage of the manufacturer's drugs by PBM enrollees over the preceding time period. The PBM transmits the contractually agreed upon share of rebates to the sponsor (or offsets it against revenue due), and books the share it retains as a reduction to the cost of revenues.¹³

Over time, rebates have declined as a share of PBMs' annual profits. In 2003, Medco retained \$1.59 million in rebates (>50% of total rebates) on \$1.52 million of gross profit, meaning 104.6% of Medco's gross profit came from rebate retention. By 2011, Medco retained only \$757 million in rebates (12.1% of total rebates) on \$4.62 billion of gross profit, meaning rebates only accounted for 16.4% of Medco's gross profit (FY2004 and FY2011 SEC 10-K filings).¹⁴ This decline in retained rebates probably reflects several factors. First, the potential to capture brand rebates has declined over the last decade with patent expiries on many blockbuster drugs and erosion of brand sales by generic. In 2004, generics accounted for 57% of prescriptions in the US; by 2013, the generic share of all prescriptions was 86%.¹⁵ Second, an increasing share of total drug sales is for specialty drugs which are typically differentiated and not considered substitutable by doctors and patients. Since PBMs have less ability to shift share for specialty drugs, they are less able to negotiate rebates. Third, the Medicare Part D program established in 2006 required transparency and pass-through of manufacturer price concessions.¹⁶ A study conducted by the Office of the Inspector General found that on average, PBMs administering Part D plans retain less than 1% of negotiated rebates.¹⁷ These practices on Part D programs may have spilled over to private plans. Fourth, litigation may have reduced PBMs' capture of rebates¹⁸ and competition among PBMs promotes pass-through to plan sponsors. The PBMI Report (2013) shows that contracts with plan sponsors provide for a variety of different mechanisms for rebate pass-through, which complicates comparison across plans. In 2013 only 6% of large employers reported capturing no rebates, compared to 25% of small employers. Note, however, any conclusions from such evidence are tentative because there may be offsetting decreases in other types of compensation to the PBM, to make up for their retention of rebates. The notion that retained rebates are less important to overall PBM profitability is underscored in Medco's FY2004 SEC 10-K filing, which states "the impact on profitability from the increase in generic utilization, particularly in mail order, more than offsets the impact from lower rebate retention on brand name prescriptions." This point is also made in

¹² Pharmacy Benefit Management Institute 2013-2014 Prescription Drug Benefit Cost and Plan Design Report

¹³ Express Scripts FY2013 10-K filing accessed through SEC EDGAR Database

¹⁴ Medco Health Solutions FY2004 & FY2011 10-K filings accessed through SEC EDGAR Database

¹⁵ IMS Health, Medicine use and shifting costs of healthcare, April 2014,

http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Secure/IIHI_US_Use_of_Meds_for_2013.pdf

¹⁶ Social Security Act SEC. 1150A. [42 U.S.C. 1320b-23]

¹⁷ OIG Report, Concerns with Rebates in the Medicare Part D Program, March 2011

¹⁸ In a 2004 suit, Medco was accused of switching patients from Lipitor to the higher list price drug, Zocor, in order to gain higher rebate revenue on Zocor. The resulting settlement deemed it illegal for a PBM to incentivize a patient to switch to a drug that is more expensive for the plan sponsor (Freudenheim, 03/13/2003)

Express Scripts' investor presentations, which reveal that while rebates drove EBITDA growth in the 1990's, increases in generic utilization accounted for the majority of EBITA growth in the 2000s.¹⁹

4. Other sources of PBM revenue

- **Flat administrative fees per member or per transaction:** Some PBMs charge plan sponsors a flat administrative fee per member or per transaction. Such administrative charges could be (partly) in lieu of spread margins and rebate retention.
- **Consulting fees:** PBMs offer consulting services to plan sponsors, including auditing claims data to look for cost saving opportunities or a custom formulary design for a specific client. These services may be bundled in with other fees or billed separately.
- **Other value added services:** Some PBMs charge administrative fees for providing programs for plan members including compliance and disease management programs. Again, these services can be bundled in with other fees or billed separately.

III. PBM Market Overview and Entry

The efficient functioning of the PBM industry for plan sponsors relies on competition. This section provides some evidence on concentration and entry, as one indicator of competition. Defining PBM market shares is problematic because some PBMs outsource some services, usually claims processing, to other PBMs, which leads to significant double counting when counting shares of covered lives or total claims processed. CVS Caremark calculated market shares for 2013 based on annual PBM revenue as shown in Table 1²⁰:

Table 1: PBM Market Shares, by 2013 Revenue

PBM	Market Share by 2013 PBM Revenue
Express Scripts	33%
CVS Caremark	26%
OptumRx	12%
Prime Therapeutics	5%
Catamaran	5%
Humana	5%
MedImpact	3%
Cigna	3%

Market share based on annual revenue understates the role of companies such as Argus Health Systems that processes claims for other PBMs and plan sponsors, but captures a small share of total market revenue.²¹ Atlantic Information Services (AIS) reports estimated 2014 PBM market shares based on claims processed (Casey, 2013):

¹⁹ Express Scripts Investor Presentation, Bank of America Merrill Lynch 2014 Healthcare Conference, May 13, 2014, <http://phx.corporate-ir.net/phoenix.zhtml?c=69641&p=irol-presentations>

²⁰ CVS Caremark 2012 Analyst Day Presentation, http://media.corporateir.net/media_files/irol/99/99533/dec2012/CVS_Caremark_2012_Analyst_Day-Per_Lofberg_Presentation.pdf

²¹ DST Systems FY2013 10-K filing accessed through SEC EDGAR Database

Table 2: PBM Market Shares, by Claims Processed

PBM	Expected Market Share by 2014 Claims Processed
Express Scripts	27%
CVS Caremark	19%
OptumRx	12%
Argus Health Systems	11%
Catamaran	10%

The large PBMs also play a major role as Prescription Drug Plans (PDPs) that administer the Medicare Part D program. There is significant overlap between the top Medicare PDP sponsors and the top PBMs. The top 8 PDP sponsors by total PDP lives are shown in Table 3:²²

Table 3: PDP Market Shares, by PDP Lives

Part D Plan Parent	Total PDP Lives	Market Share
UnitedHealth Group, Inc.	5,165,940	22%
CVS Caremark Corporation	4,178,699	18%
Humana Inc.	3,769,934	16%
Express Scripts Holding Company	2,708,871	12%
Aetna Inc.	1,625,387	7%
WellCare Health Plans, Inc.	1,350,379	6%
CIGNA	1,230,583	5%
WellPoint, Inc.	431,528	2%

Based on the Table 1 measures of market shares by annual revenue, the 2 largest independent PBMs account for almost 60% of the market, and the 4 largest PBMs account for 76%. The PBM industry has become more concentrated over the last decade through a series of mergers and acquisitions that created the three largest publically owned, independent PBMs. Express Scripts acquired Wellpoint's wholly owned NextRx PBM in 2009²³ and then merged with Medco in 2012.²⁴ CVS and its PBM, PharmaCare, merged with Caremark Rx in 2006²⁵ to become CVS Caremark and later acquired Longs Drug Stores' PBM, RxAmerica, in 2008.²⁶ Catamaran was born as the product of SXC Health Solution's 2012 acquisition of Catalyst,²⁷ which had previously purchased Walgreens Health Initiatives in 2011.²⁸

²² CMS May 2014 MA/PDP Enrollment by Plan, CMS.gov

²³ Wellpoint Press Release, December 1, 2009, <http://phx.corporate-ir.net/phoenix.zhtml?c=130104&p=irol-newsArticle&ID=1360094&highlight=>

²⁴ Express Scripts Press Release, April 2, 2012, <http://phx.corporate-ir.net/phoenix.zhtml?c=130104&p=irol-newsArticle&ID=1360094&highlight=>

²⁵ CVS Caremark Press Release, <http://info.cvscaremark.com/newsroom/press-releases/cvscaremark-merger-closes-creating-nations-leading-pharmacy-services-company>

²⁶ CVS Caremark Press Release, October 29, 2008, <http://info.cvscaremark.com/newsroom/press-releases/cvs-caremark-successfully-completes-tender-offer-longs-shares>

²⁷ Catalyst Health Solutions Press Release, July 2, 2012, http://phx.corporate-ir.net/phoenix.zhtml?c=96579&p=irol-newsArticle_pf&ID=1711470&highlight=

²⁸ Catalyst Health Solutions Press Release, March 9, 2011, http://www.businesswire.com/news/home/20110309005921/en/Catalyst-Health-Solutions-Acquire-Walgreens-Health-Initiatives#.U4_bUPIdXhA

Several large health plans have attempted to develop their own PBMs to compete with the large independent PBMs. OptumRx is the wholly owned PBM of United Healthcare and primarily provides PBM services to United's clients. Prime Therapeutics is a large national PBM co-owned by 13 non-profit Blue Cross Blue Shield Licensees and serves primarily the members of these health plans. Large for-profit health insurers Humana, Cigna, and Aetna all operate their own captive PBMs, but outsource some services to third party PBMs. Catamaran has grown quickly since the 2012 SXC/Catalyst merger. Catamaran offers purely fixed fee per transaction pricing with clarity on rebates and other fees²⁹. MedImpact offers clients full disclosure on rebate administration.³⁰ Members of the HR Policy Association, an organization that represents large employers, have negotiated an exclusive agreement with Prime Therapeutics, including clear pass through pricing with no undisclosed PBM mark-ups and 100% pass through of pharmaceutical rebates, pricing all inclusive of services including clinical programs and utilization management, and the option for additional savings through narrowing the pharmacy network.³¹ This evidence indicates significant consolidation over time in the PBM industry, and also some attempts at competitive entry, mainly by large health plans, some of which continue to rely partly on external PBMs.

PBMs compete on their ability to save their plan sponsors money and improve value on their pharmacy spend, as well as competing on margins. For example, Express Scripts mentions in a recent earnings call, "...marketplace factors provide an important opportunity for Express Scripts to assist our patients and clients in lowering healthcare costs while driving better clinical outcomes. Obviously, our tools and programs to control costs are needed now more than ever."³² Morningstar points out that "Express Scripts' operating income accounts for well less than 1% of its clients' overall health-care costs. If Express Scripts can lower its clients' health-care costs by even a few percentage points more than the competition, it will justify the company's margins and facilitate market share gains."³³ Such value based competition underscores that point that it could be counterproductive for sponsors to focus solely on driving down a PBM's operating income, if this leads the PBM to skimp on effort to constrain drug costs.

PBMs can be accredited by URAC, an independent, non-profit organization that reviews PBMs, in addition to other health care organizations.³⁴ URAC reviews PBMs' contract terms and pricing structures, pharmacy networks, drug utilization management capabilities, formulary management, patient safety and customer service. All of the large PBMs have received full accreditation from URAC.

IV. Employer Contracting with PBMs

As noted earlier, a plan sponsor has three options for performing the essential functions of managing a pharmacy benefit. First, the sponsor may "carve in" these functions to the health plan that administers the sponsor's health benefit. For example, United Healthcare can provide the full range of PBM services through its OptumRx PBM, but Humana partners with claims processor Argus Health Systems to administer its pharmacy benefit (Humana Argus Agreement). Second, the sponsor may "carve out" the full spectrum of services to a PBM. Third, very large employers may conduct some of the core formulary-related PBM services in-house, outsourcing to a PBM and/or large national pharmacy chain only the claims processing and other functions that are subject to large economies of scale. Smaller employers are more likely to contract with their health plan administrator for their pharmacy benefits, whereas large employers are more likely to contract directly with a PBM (PBMI 2013).

²⁹ Catamaran FY2013 10-K filing accessed through SEC EDGAR database

³⁰ MedImpact website, <https://www.medimpact.com/>

³¹ HR Policy Association Website, http://www.hrpolicy.org/initiatives_pharmadirect_index.aspx

³² Express Scripts Q3FY2013 Earnings Call Transcript accessed at <http://www.morningstar.com/earnings/earnings-call-transcript.aspx?t=ESRX>

³³ Morningstar Express Scripts Analyst Report, March 29, 2012, <http://analysisreport.morningstar.com/stock/archive?t=ESRX®ion=USA&culture=en-US&productcode=MLE&docId=542527>

³⁴ URAC Website, <https://www.urac.org/accreditation-and-measurement/accreditation-programs/all-programs/pharmacy-benefit-management/>

Employers choosing to contract for PBM services may seek proposals from several PBMs, possibly using a third party benefits consultant to assist in the PBM selection process. A basic PBM proposal typically includes:

- Any per claim-based fees e.g. for claim processing, dispensing, prior authorization etc.;
- The reimbursement rate to be paid to the PBM for brand and generic drugs, at retail and mail order, usually expressed as a % of AWP for brands and % of MAC for generics;
- Share of drug rebates to be passed through to the employer vs. retained by the PBM.

The PBMI (2013) study provides recent survey evidence on some dimensions of the experience of large (>5,000 employees) and small firms ($\leq 5,000$ employees) with PBM contracting (PBMI, 2013). This report is based on a broad sample of employers that represents most size classes, geographies and industries; however, it is not a random sample of employers and not all employers responded to all questions, so findings may not be fully generalizable. Nevertheless, this survey provides the best currently available evidence on PBM contracting with employers. The median dispensing fee for 30 day retail prescriptions is \$1.50, and \$0 for mail-order prescriptions. The average reimbursement level is AWP-16% for branded 30 day retail drugs and AWP-22% for branded mail-order drugs. The average reimbursement level for generics is AWP-65% for 30 day retail and AWP-61% for mail-order. This evidence implies that sponsors do typically capture some of the larger profits earned by PBMs on mail-order dispensing. MAC pricing for generics is used by 75% of employers for 30 day retail prescriptions and 70% of employers for mail-order prescriptions. The majority of employers receive a share of manufacturer drug rebates. Some contracts provide a percentage of actual rebates to the plan sponsor; other contracts guarantee a flat minimum level of rebates per prescription or per rebateable drug (preferred tier brands). Different ways of calculating rebates complicate comparison across contracts. The mean and median employer shares of drug rebates were 60% and 80% for retail dispensed drugs, for employers with a rebate share arrangement that responded to this question.³⁵

The PBMI study also highlights differences in negotiated pricing between large and small employers. Large employers received higher retail discounts on branded and generic drugs, paid lower dispensing fees, and were more likely to receive manufacturer rebates than smaller employers. All of these differences were found to be statistically significant. There were no significant differences by employer size for mail or specialty discounts.

Given the common use of AWP-x% as a measure of the price the sponsor pays to the PBM for branded drugs, this can often be compared across proposals. Comparing generic prices across proposals may be less precise because PBMs' MAC prices may differ. Most PBMs do not disclose to employers either the price that they pay to retail pharmacies or drug acquisition costs for their mail operations, which makes the PBM spread non-transparent to sponsors. As noted above, a group of very large employers has negotiated for this information from some PBMs.

PBMs also sometimes take risk by guaranteeing a certain level of savings on drug costs compared to the sponsor's expenditures in the previous year. It is difficult to determine how common such arrangements are.³⁶ It is also unclear whether such arrangements would benefit sponsors, because reduction in pharmacy spending could result in higher costs in other areas and/or reduction in benefits to consumers.

A few employers have experimented with contracting directly with retail pharmacy chains as an alternative to PBM services. One example is Caterpillar, who negotiated a direct contract with two large pharmacy chains to dispense prescriptions to its members (Bisping, 04/26/2010). Caterpillar still contracted with a PBM to perform claims processing. Other PBM market evidence, including Wellpoint selling their in-house PBM to Express Scripts and Humana and Cigna contracting with PBMs to perform claims processing, suggest that the economies of scale in some basic PBM functions make it inefficient to completely forego PBM services.

³⁵ Pharmacy Benefit Management Institute 2013-2014 Prescription Drug Benefit Cost and Plan Design Report

³⁶ Express Scripts FY2013 10-K filing accessed through SEC EDGAR Database

Potential conflicts of interest

Various sources of conflict of interest have been alleged against PBMs, especially those that own mail-order pharmacies that compete with retail pharmacies. In 2005 the FTC reported on their in-depth study of the self-dealing allegations related to PBM ownership of mail pharmacies. The FTC obtained proprietary data on contracts and claims paid from 2002-3. The FTC concluded that “These data provide strong evidence that .. PBMs’ ownership of mail-order pharmacies generally did not disadvantage plan sponsors....these allegations (of self-dealing arrangements) are without merit” (FTC, 2005).

Retention of rebates by PBMs also allegedly leads to conflict of interest, specifically, that the PBM has incentives to encourage members to take a drug with a higher net cost to the plan sponsor because the PBM receives a larger rebate. A 2004 case accused Medco of switching patients from the cholesterol treatment Lipitor to similar, but higher cost, Zocor, in order to gain higher rebate revenue on Zocor. The resulting settlement deemed it illegal for a PBM to incentivize a patient to switch to a drug that is more expensive for the plan sponsor (Freudenheim, 2003). More generally, the decline in brand rebates absolutely and as a major PBM revenue source has reduced this potential conflict. Because PBMs make larger margins on generics and generics are available for an increasing number of drugs, PBMs’ incentives are now aligned with those of sponsors, to encourage generic substitution whenever possible.

Another potential conflict arises from the fact that the PBM’s retail spread is usually a fixed percentage of the drug’s list price. In theory, this implies that PBMs have little incentive to control the rate of increase in drug prices or to prefer drugs with lower list prices, as the PBM margin increases as drug prices increase. This potentially perverse incentive may be mitigated by the fact that controlling the growth of client drug spending is a competitive proposition of PBMs. However, to be effective, this requires that sponsors are able to evaluate the effectiveness of PBMs at controlling drug spending. In most cases, this seems unlikely. PBMs do not generally take financial risk for the rate of growth of total drug spending, which would eliminate this conflict of interest but could also lead to excessive controls on patient access.

A fourth potential conflict of interest may arise from the ability of PBMs to set reimbursement rates for both competitor retail pharmacies and their captive mail-order pharmacies, and to steer utilization between the two. Abrams (2007) has argued that large PBMs artificially keep retail pharmacy reimbursements for generic drugs high in order to protect margins in their mail order business, which is the more profitable channel for PBMs. The PBMI study indicates that employers using AWP pricing pay PBMs slightly higher prices for generics dispensed through-mail order (AWP-61%) compared to retail (AWP-65%); however, this difference was not statistically significant and may be of little practical importance because the study also found that the majority of employers use MAC pricing for generics. The FTC study found that employers pay lower prices on mail order and, overall, rejected the allegation that PBMs’ ownership of mail order pharmacy harms their customers (FTC, 2005).

V. **PBM Transparency Reporting for Medicare Part D and ACA Qualified Plans: Application to ERISA Plans**

The Affordable Care Act (ACA) requires specific disclosures by PDPs administering Medicare Part D plans and by PBMs participating in qualified health plans in federal or state health insurance exchanges, including:³⁷

- The aggregate amount of all price concessions including rebates earned on behalf of the patient from drug manufacturers, wholesalers, or pharmacies;
- The aggregate amount of price concession passed onto the health plan sponsors
- The aggregate amount of the difference between what the PBM pays to retail and mail pharmacies and what is paid by the health plan

These required disclosures are in aggregate, so the PBM is not required to provide information on specific manufacturer contracts or pricing for specific customers or products. The PBM is required to make these disclosures to CMS and, for the ACA, to the health plan, which is required to maintain confidentiality.

Evaluation of requiring spread and rebate transparency reporting for ERISA plans

Potential benefits of reporting

The proposal to require similar transparency reporting by PBMs to ERISA sponsors presupposes that this market is not functioning well and that requiring more transparency would improve competition and benefit sponsors, but the precise problems and how reporting might improve them are unclear. The evidence from PBMI (2013) and other sources does indicate that larger employers manage their pharmacy benefit more actively and get somewhat better contract terms than do small employers for retail pharmacy drugs but with no significant differences for mail order and specialty drugs. Some very large employers are also able to negotiate more transparency on contract terms. It may seem unsurprising that small employers appear to fare worse. For 79% of small employers, the person managing their pharmacy benefit spends less than 25% of time on this function (PBMI, 2013), compared to 58% for larger employers. If limited information and expertise is leading to poor contracting, requiring more transparent reporting for all ERISA employers, as is required for Part D and ACA plans, might improve information and enhance employers' ability to make informed choices and get the best value from their PBM contracts, especially for small employers. In theory, savings might include reducing the spreads charged by PBMs on retail and mail order drugs, and getting a larger share of rebate dollars.

However, PBMI (2013) also reports that 66% of small employers contract for their PBM services through their health plan administrators. These administrators should be sophisticated, well-informed purchasers of PBM services, since some operate their own PBMs and/or contract with independent PBMs themselves. Given this reliance on health plan administrators, the apparently inferior PBM contracting performance of small employers seems unlikely to simply reflect their own lack of information. Other possible explanations include: imperfect agency by health plan administrators; diseconomies of small scale of their PBMs and/or the small employer business; or simply differences in contract design and cost allocation that are not captured by the PBMI (2013) analysis. FTC (2005) emphasizes that PBM contracts differ in how they structure fees and charges. For example, contracts where PBMs retain a larger share of rebate dollars may charge lower fees for other services.

The available evidence is thus suggestive but inconclusive on what information problems exist in employer contracting with PBMs, if any; the causes of these problems; and how/whether additional PBM reporting requirements might improve market functioning.

³⁷ Social Security Act SEC. 1150A. [42 U.S.C. 1320b–23]. Medicare Part D reporting has been required since the start of the program.

Potential harms of reporting

The proposed reporting requirements would themselves entail administrative costs for PBMs that would likely be passed on to employers. More significant, such reporting could have unintended consequences and competitive harms:

Competitive Harms There are significant grounds for concern that transparency reporting requirements could result in some PBMs knowing the terms that their competitors are offering, which could reduce rather than increase fair competition in the highly concentrated PBM industry. Such anticompetitive effects could apply not only to the PBM's own terms but also to its contracting with individual pharmacy chains or drug manufacturers. The latter risks are mitigated if reporting of retail spreads and rebate dollars is at the aggregate level, not for individual drugs or specific pharmacy contracts. However, aggregate reporting requirement could lead to demands for audit, to assure compliance, which could reveal more competitively sensitive data about pharmacy and manufacturer contracts.

Of much greater concern is the risk of divulging competitively sensitive data about the PBMs' own costs and contract terms to competitors, particular related to the mail order business. There is always a concern that information about a competitor's prices can undermine competition and promote tacit collusion in concentrated industries. In the case of PBMs, concerns about unfair competitive advantage are particularly acute because of different and overlapping business models, specifically, that health plans are both customers of independent PBMs and competitors whose own PBMs compete for the business of employers.

To illustrate, consider the case where an independent PBM such as ExpressScripts is required to report its retail and mail order spreads to an employer that is also considering contracting for PBM services with its health plan administrator. The employer would naturally pass on the ExpressScripts data to its health plan administrator, which operates its own in-house PBM that competes with ExpressScripts. This would give the health plan's PBM unfair insights into its competitors' costs and contracting terms.

Further, PBMs contract with retail pharmacies but PBMs also operate mail order pharmacies. These PBM mail order pharmacies are an important competitive check on the increasingly concentrated retail pharmacy sector. If PBMs are required to reveal cost and spread information on their mail order business, this information would likely be divulged to retail pharmacy chains that compete with PBMs' mail pharmacies.

Non-comparable "Data" Because some PBMs own retail pharmacies and most PBMs own mail-order pharmacies, their reporting of "acquisition costs" and spreads for these pharmacy services would be transfer payments created for accounting purposes, rather than "arms length", commercial prices. It would be competitively inappropriate to compare these transfer prices with true commercial prices of less vertically-integrated PBMs. Moreover, such transfer pricing "costs" are more likely to lead to challenges and demands for audit, which increases the risk of disclosure of competitively sensitive information.

Importance of preserving confidentiality of generic acquisition costs The interests of plan sponsors and PBMs are currently strongly aligned to drive the utilization of generics, which provide very large savings for employers/consumers. There is a risk that transparency might reduce PBM margins on generics sufficiently to undermine their incentives to encourage generic utilization and discounting. This risk is greatest for generics that PBMs buy and dispense through their mail-order pharmacy. Protecting the confidentiality of generic acquisition prices is essential to preserve competitive discounting by generic companies, which is hugely beneficial to consumers.

Preserving appropriate agency incentives If the PBM business were so transparent that any savings they made e.g. on brand rebates would be fully passed through to plan sponsors, their incentives to look for such savings would be undermined. Further, since rebates are usually related to the restrictiveness of formulary choice, the contractual promise of a specified level of rebates by a PBM cannot be meaningfully evaluated without information on restrictions on drug choice. There is a risk that simple rebate reporting could lead employers to focus on maximizing their rebate dollars, ignoring the effects of restrictive formularies that generate rebate dollars on employees' choice, health outcomes and value for money.

Attempts to base reimbursement on cost can be counterproductive Transparency requirements that attempt to set actual reimbursement for drugs at the pharmacy's or PBM's actual cost or acquisition price may have unintended consequences, leading to higher real costs or manipulated prices. As noted above, once AWP was widely adopted as a basis for reimbursement, it became distorted as a measure of actual average wholesale price. Similarly, the use of ASP reimbursement for physician-dispensed drugs contributes to high list prices and discourages competitive discounting. The general point is that any widespread attempt to tie reimbursement to a measure of the provider's cost will likely lead to distortions in that "cost".

Conclusions: A better understanding of what problems exist in employer contracting with PBMs and how the proposed transparency reporting would address these problems is needed. The risks of requiring PBM transparency reporting to ERISA employers are considerable. Although similar reporting requirements have existed for Medicare Part D to CMS, this is a very different context: the risks of competitive harms and disclosure of competitively sensitive information are less. ERISA employers are much more numerous and are in situations that could lead to inappropriate disclosure of confidential PBM information and/or could reduce competition in this highly concentrated industry.

Employers do need better information to evaluate PBMs' performance. To achieve this objective requires metrics to evaluate the PBM's performance in controlling total drug spending, of which the PBM's compensation is a small fraction. For example, if PBM A charges 10% more for administering the drug benefit than PBM B, but PBM A also reduces wasteful drug spending by 10%, the extra administrative cost would be worth paying for. Such performance metrics might include measures of drug spend growth, risk adjusted, normalized for national trends, patient choice and patient cost-sharing. A carefully designed and validated set of metrics, including PBM performance and relevant costs, could assist employers in evaluating their PBM options and have pro-competitive effects on the industry.

References

- Abrams, Lawrence W, (January 24, 2007). “Pharmacy Benefit Managers As Conflicted Countervailing Powers”
Watsonville: Nu-Retail.
- Bisping, Todd N, (April 26, 2010). “Caterpillar Breaks New Ground Managing the Prescription Drug Supply
Chain”. Plainsboro: *American Journal of Managed Care*.
- Casey, Tim, (March 19, 2013). “PBMs: A Wall Street View”. *First Report Managed Care*
- Eberle, Brent J. and Alan Van Amber, (December 1, 2008). “Your PBM's MAC List Impacts Your Bottom
Line”. *Managed Healthcare Executive*.
- Freudenheim, Milt, (March 13, 2003). “Documents Detail Big Payments by Drug Makers to Sway Sales”. New
York: *The New York Times*.
- Pharmacy Benefit Management Institute (PBMI). 2013. “2013-2014 Prescription Drug Benefit Cost and Plan
Design Report.”
- U.S. Federal Trade Commission (FTC). 2005. “Pharmacy Benefit Managers: Ownership of Mail-Order
Pharmacies.” August 2005.
- U.S. Federal Trade Commission (FTC). 2014. Letter to CMS. March 7, 2014.