

PBM FIDUCIARY DUTY AND TRANSPARENCY

Pharmacy Benefit Managers (PBMs) administer nearly every prescription drug insurance plan in the U.S.

The first PBMs were created by managed care organizations in the 1980s to apply managed care principles, such as provider networks and patient co-pays, to the drug benefit portion of health care plans. Through rapid growth in the 1990s, PBMs “emerged as the national standard for the administration of prescription drug insurance in the United States.”¹ The three largest PBMs manage drug benefits for over 200 million Americans – 95% of Americans with prescription drug coverage.² Today’s PBMs manage all aspects of a prescription drug benefit plan, including creating formularies of preferred medicines, negotiating with drug manufacturers for discounts and rebates, negotiating with pharmacies to establish retail networks for dispensing drugs, and establishing automated processes for determining (often called “adjudicating”) coverage eligibility at the point of sale. Each of the four largest PBMs operates its own mail order pharmacy to fill prescriptions directly.³

The PBM industry is highly concentrated

Through a period of consolidations in the last decade, the PBM industry has become dominated by three large companies. The three largest PBMs - Medco, Caremark and Express Scripts - administer 80% of insured prescriptions and 90% of insured mail order prescriptions.⁴ Each of these companies has annual revenues exceeding \$15 billion.

PBMs increase their profits by retaining payments from pharmaceutical companies to promote their drugs

Many opportunities and incentives for PBM practices that raise drug costs to consumers can be traced to their acceptance of payments (referred to as “rebates”) from pharmaceutical companies for increased sales of their most profitable products. As described by the Federal Trade Commission:

Pharmaceutical manufacturers recognize that having their drugs listed on the formulary or in a preferred spot on the formulary (as compared to competing drug products) will likely increase the drug products’ sales. . . . [P]harmaceutical manufacturers use “formulary payments” to obtain formulary status, and/or they use “marketshare payments” to encourage PBMs to dispense their drugs. Both payments are often specified as a percentage of the drug’s wholesale price (e.g., a percentage level of 10% means the manufacturer will pay the PBM 10% of a measure of the drug’s wholesale price multiplied by the quantity dispensed). Most industry members refer to these payments as

“rebates,” and they refer to the percentage level as the “rebate level.”⁵

PBMs profit from rebates by retaining some or all of them instead of passing the savings on to plans and consumers. Court documents establish that Medco Managed Care, while under the ownership Merck, was paid more than \$3.5 billion in rebates in 1997-99, the majority of which were not passed through to customer health plans.⁶ In 2004, New York Attorney General Eliot Spitzer filed suit against Express Scripts alleging that the PBM pocketed as much as \$100 million in drug rebates that should have gone to the state.⁷

Favoring Higher Priced Drugs

Higher rebates are paid on single-source brand name prescription drugs that do not have generic equivalents.⁸ Accordingly, PBMs “have an incentive to sell newer and higher priced single-source drugs, even when it may be more costly for the payer.”⁹ There is a growing body of evidence that PBMs favor single-sourced and brand name drugs over drugs with generic competition. According to estimates by the FTC, the top 25 brand drugs account for over 70% of the total payments by pharmaceutical companies to PBMs. Single-source brand drugs generally account for over 50% of the drugs dispensed to plan members by PBMs.¹⁰

Playing the Spread

PBMs increase their profits by “playing the spread” between the amount that is reimbursed by the PBM to a pharmacy for a prescription and the amount reimbursed to the PBM from a plan for the same prescription. Because each amount is independently negotiated and is normally kept secret from the other, the PBM can negotiate a higher reimbursement amount for itself than it pays to a participating pharmacy to dispense the prescription. For example, in one reported case a PBM billed an employer \$215 for a generic stomach medicine, Ranitidine, but paid the pharmacy only \$15 for the drug, pocketing the difference.¹¹

Drug Switching

PBMs can favor higher priced drugs through drug switching. Drug switching, or “therapeutic substitution,” occurs when a doctor prescribes one drug and the PBM requests to change the prescription to a different drug of similar therapeutic value. The PBM can profit off of the switch if the second drug has a higher rebate value or mark up than the initially prescribed drug. In May 2006, Medco took a charge of \$163 million in its first quarter to cover a proposed settlement of federal charges that it defrauded customers by shorting, changing and canceling their prescriptions.¹² In a three-month period, Medco 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).¹³ In 2002, AdvancePCS sent letters encouraging doctors to switch patients from a generic ulcer drug costing 20 cents a days to Celebrex, which cost ten times as much.¹⁴ Also in 2002, AstraZeneca paid ExpressScripts \$500,000 to call 22,000 doctors and ask them to switch their patients to Nexium from Prilosec, after Prilosec became available in a cheaper generic form.¹⁵

Drug Repackaging and Mark Ups

PBMs that own their own mail order pharmacies can profit by repackaging drugs and selling the repackaged items at higher prices than the original average wholesale price set by manufacturers. One study found, for example, “15 instances when the branded drug Celebrex was repackaged and the unit price for the repackaged drug exceeded the original manufacturer’s per unit price by more than 7% and as much as 176%.”¹⁶ A 2004 report of the Vermont State Auditor found that Express Scripts marked up state employee benefit drug prices by as much as 111%, costing Vermont taxpayers \$1.85 billion in one year.¹⁷

Contract terms have not been sufficient to protect plans from excessive PBM profiteering

Some sophisticated plans negotiate contracts that include provisions for sharing rebates between the PBM and the plan sponsor and provide for audit rights that allow them to verify whether they receive the payments for which they contract.¹⁸ But the extent of such contract terms varies with the bargaining and power and sophistication of plans.¹⁹ “[A] PBM might receive a discount from a manufacturer on a particular drug and not pass any of it on to the health benefit provider, keeping the difference for itself.”²⁰

Lack of Transparency

It is often the case that buyers cannot discipline PBM profiteering because they do not know the extent to which it is practiced. In most cases, plans do not have access to PBM rebate agreements and other side deals. PMS have often claimed that these agreements are “trade secrets,”²¹ although some contracting parties have achieved access to the agreements and the First Circuit Court of Appeals has rejected trade secret claims. As the federal District Court in Maine explained, PBMs “introduce a layer of fog to the market that prevents benefits providers from fully understanding how to best minimize their net prescription drug costs.”²²

In 2003, Maine passed the first transparency and fiduciary duty law²³

The Maine law was upheld in all particulars in 2005 in a unanimous decision by the U.S. Court of Appeals for the First Circuit.²⁴ The court specifically upheld the rights of states to regulate the practices of PBMs by imposing contract transparency and conflict of interest requirements, to establish a state fiduciary duty owed by PBMs to client health plans, and to require that savings based on volume discounts be passed through to client health plans and thence to consumers.²⁵ On June 5, 2006, the U.S. Supreme Court rejected a request by the pharmacy benefits management industry that the Court consider the constitutionality of a Maine law.²⁶ In rejecting the writ of certiorari, the Supreme Court ended the litigation over Maine’s law, which will now be enforced.

Other states have followed suit

Since the Maine law was enacted, many other states as well as the District of Columbia have passed similar laws. The D.C. statute was recently upheld (reversing an earlier decision enjoining the law) based on the 1st Circuit decision.²⁷ Both the Maine and DC laws require the PBM to act as a fiduciary, require transparency and pass-through of rebates and other payments and savings, restrict drug-switching and conflicts of

interest, and establish guidelines for drug-switching and other practices. Maryland passed a series of PBM reform measures in 2008 including legislation addressing transparency, registration, drug-switching, pass-through of rebates, and pharmacy contracts. Iowa, South Dakota and Vermont also have PBM laws that seek to address transparency, conflicts of interest disclosure, greater transparency on rebates and other payments, and include more limited fiduciary language (requiring “fair dealing” or “reasonable care and diligence”, “fair and truthful under the circumstances”). Several other states have more limited laws governing registration and/or payment provisions including Kansas, Mississippi, North Dakota, Rhode Island, Tennessee and Connecticut. Arkansas and Georgia have enacted a “Pharmacy Bill of Rights” which outlines audit and payment requirements. Louisiana does not have a law, but in 2006 completed a PBM recruitment RFP process requiring fiduciary responsibility.²⁸

Potential for savings

Although the Maine PBM law was the first to be enacted, because the PBM industry was successful in halting implementation of that law for several years, there isn’t yet a track record measuring its effectiveness in cutting costs. However, in South Dakota, where the law was not challenged, well over \$800,000 was saved in state health insurance costs in a single year as the direct result of the more transparent business model required by its law.²⁹ In Arkansas, an audit of the PBM managing the state employee health program determined the state was overcharged almost \$500,000 in just a 3 month period of time. The state ultimately issued a new transparent RFP for state business, lowering pharmacy expenses and directly saving the state over \$13 million.³⁰

Several recent reports have pointed to the value of transparency requirements in achieving savings for state government. A plan prepared for the Governor of Oregon by the Heinz Family Philanthropies recommended Oregon “require the greatest level of transparency possible” as well as annual audits of the PBMs and insurance companies the state contracts with to insure that rebates are passed through.³¹ A report to the Illinois Commission on Government Forecasting and Accountability recommended the state stop using PBMs entirely, and at a minimum require a fiduciary relationship. By directly negotiating pharmacy benefits in its state employee health plan instead of paying a PBM \$2.81 per enrollee per month to negotiate on its behalf, the report estimated savings of \$1.35 per claim or about \$10 million per year.³² The University of Michigan, in an attempt to deal with skyrocketing drug costs, dropped the five benefit managers it had been working with, hired a single new manager that has less control over how the drug plan is administered, and imposed strict new rules. These changes enabled UM to hold its drug spending to \$43 million in 2003, or \$8.6 million less than it would have paid under the previous plans.³³

¹ PricewaterhouseCoopers, *HCFA Study of the Pharmaceutical Benefit Management Industry*, HCFA Contract No. 500-97-0399/0097, 5 (June 2001).

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- ² AIS Market Data, Pharmacy Benefit Management, PBM Market Share, Top 25 Pharmacy Benefit Management Companies and Market Share by Membership, as of 2nd Quarter 2007. Accessed on April 15, 2008 at http://www.aishealth.com/MarketData/PharmBenMgmt/PBM_market01.html.
- ³ James Langenfeld & Robert Maness, *The Cost of PBM 'Self-Dealing' Under a Medicare Prescription Drug Benefit* (September 9, 2003).
- ⁴ David Balto, former Assistant Director in the Bureau of Competition of the Federal Trade Commission and attorney advisor to Chairman Robert Pitofsky, Testimony Before the House of Representatives, State of Washington (January 20, 2006), at p. 3. See also National Community Pharmacists Association, Legislative and Government Affairs. Available at http://www.ncpanet.org/leg_gov/notes_from_capitol_hill/2004/december.shtml (last viewed May 19, 2006).
- ⁵ Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies*, viii (2005).
- ⁶ Milt Freudenheim, NY Times, *Documents Detail Big Payments by Drug Makers to Sway Sales* (March 13, 2003).
- ⁷ Michael Gormley, CBS news (August 4, 2004). Available at <http://www.cbsnews.com/stories/2004/08/04/health/main634035.shtml> (last viewed May 9, 2006).
- ⁸ Drugs that do have generic equivalents are referred to as “multi-source.” For example, Zoloft is a single-source brand antidepressant; Prozac is a multi-source brand antidepressant that has fluoxetine (the active ingredient in Prozac) as a generic equivalent. FTC (August 2005) at vi.
- ⁹ Langenfeld 1.
- ¹⁰ FTC 2005 at ix.
- ¹¹ Robert Garis & Bartholomew Clark, Journal of the American Pharmacists Association, *The Spread: Pilot Study of an Undocumented Source of Pharmacy Benefit Manager Review* (Jan/Feb. 2004).
- ¹² Health Care, *Medco Settle with Feds* (May 5, 2006). Available at <http://www.thestreet.com/stocks/healthcare/10283796.html> (last viewed on May 11, 2006).
- ¹³ Milt Freudenheim, NY Times, *Documents Detail Big Payments by Drug Makers to Sway Sales* (March 13, 2003).
- ¹⁴ Barbara Martinez, The Wall Street Journal, *Pharmacy-Benefit Managers at Times Toil for Drug Firms* (August 14, 2002).
- ¹⁵ Martinez.
- ¹⁶ Langenfeld at 1.
- ¹⁷ Elizabeth Ready, The Green Mountain Eyeshade, *Vermont May Be Paying Hidden Drug Profits* (Vol. 1, Issue 2 2004).
- ¹⁸ FTC 2005 at ix-x.
- ¹⁹ David Balto, former Assistant Director in the Bureau of Competition of the Federal Trade Commission and attorney advisor to Chairman Robert Pitofsky, Testimony Before the House of Representatives, State of Washington (January 20, 2006), at 3 (“those who have the resources for monitoring the PBMs have in some cases done so, but their success has been mixed. Often even sophisticated buyers have had to turn to litigation to vindicate their rights.”).
- ²⁰ *PCMA v. Rowe*, 429 F.3d 294, 298 (1st Cir. 2005), cert.den. 126 S.Ct. 2360, ___ U.S. ___ (2006).
- ²¹ See Colorado 8, 16.
- ²² *PCMA v. Rowe*, 2005 WL 757608 at *2 (D. Me. 2005), affirmed 429 F.3d 294.
- ²³ An Act to Protect Against Unfair Prescription Drug Practices, 22 M.R.S.A. § 2699 (UPDPA). The UPDPA regulates pharmacy benefit managers and contracts for pharmacy benefits management and imposes on PBMs certain fiduciary duties and required practices including notice of conflicts of interest, drug switching and other transparency requirements.
- ²⁴ *PCMA v. Rowe*, 429 F.3d 294 (1st Cir. 2005).
- ²⁵ *PCMA v. Rowe*, 429 F.3d at 316.
- ²⁶ *PCMA v. Rowe*, 126 S.Ct. 2360, ___ U.S. ___ (2006).
- ²⁷ The US District Court for the District of Columbia upheld the similar D.C. statute based on this line of cases, finding that the legal claims brought by PCMA were identical to those in the Maine litigation and that the First Circuit decision was controlling, *Pharmaceutical Care Management Association (PCMA) v. District of Columbia*, Civil Action 04-1082 (RMU) (3/6/2007).
- ²⁸ “Potential Savings on Pharmacy Benefit Management Costs,” Illinois Commission on Government Forecasting and Accountability, prepared by Winkelman Management Consulting (April 2006) at 15.
- ²⁹ Email communication between Deborah Bowen, then South Dakota Insurance Commissioner, and RxPlus Pharmacies, February 2006; confirmed in telephone communication between Debra Bowen, now SD Social Services

Director, and Ann Woloson of Prescription Policy Choices (August 7, 2006 email communication from Ann Woloson).

³⁰ Presentation by Mark Riley of the Arkansas Pharmacists Association to the National Conference of State Legislatures to the NCSL Health Committee, August 6, 2007, Boston, Massachusetts.

³¹ The Oregon Blueprint: Coordinated Contracting of Prescription Drugs – A Fiscal and Policy Strategy for the State of Oregon,” by Jeffrey R. Lewis, Heinz Family Philanthropies (July 2006) at 11-12.

³² “Potential for Savings on Pharmacy Benefit Management Costs,” Illinois Commission on Government Forecasting and Accountability, prepared by Winkelman Management Consulting (April 2006) at 11-16.

³³ Katz, David. “Drug Discount Peddlers” CFO.com 10/28/05

<http://www.cfo.com/printable/article.cfm/5079733?f=options> and Saxl, Michael. “Making PBMs Work for North Dakota” <http://www.legis.nd.gov/assembly/59-2005/docs/saxlpresentation.ppt>