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LEVELING THE PLAYING FIELD IN THE PHARMACY BENEFIT MANAGEMENT INDUSTRY

Allison Dabbs Garrett and Robert Garis*

I. INTRODUCTION

Health care costs rose rapidly over the past several years¹ and are expected to continue to grow significantly in the future.² Prescription drug prices are one of the largest components of this increase, with spending on prescription drugs more than quadrupling since 1990.³ According to the Employee Benefit Research Institute, increases in prescription drug prices accounted for 16.7% of the total increase in health care spending in 2001.⁴ Legislators, health care professionals, insurance groups, and consumer groups have been engaged for many years in a quixotic debate over the health care crisis.

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¹ See Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, <http://www.cms.hhs.gov/statistics/nhe/historical/t2.asp> (last visited Jan. 28, 2005). In 2000, overall healthcare costs rose by 7.2%, while prescription costs rose by 16.4%; in 2001 overall costs rose 8.9%, while prescription costs rose 15.9%; in 2002 the numbers were 14.9% and 9.3%; and in 2003 the numbers were 7.7% and 10.7%, respectively. *Id.*; see also KAISER FAMILY FOUNDATION, PRESCRIPTION DRUG TRENDS 1 (2005).

² KAISER FAMILY FOUNDATION, COMPARING PROJECTED GROWTH IN HEALTH CARE EXPENDITURES AND THE ECONOMY 1 (2006), <http://www.kff.org/insurance/snapshot/chcm050206oth2.cfm>. Health care spending is currently increasing about 2.5% faster than the growth of the gross domestic product. *Id.*

³ See PRESCRIPTION DRUG TRENDS, *supra* note 1, at 1; see also *Improving Health Care: A Dose of Competition*, at 3 (July 2004), www.ftc.gov/reports/healthcare/040723healthcarerpt.Pdf; see also Prescription Drugs: Recent Trends in Utilization, Expenditures and Coverage at 1 (2004), http://ebri.new.matrixgroup.net/publications/ib/index.cfm?fa=ibPrint&content_id=493.

⁴ *But see* Prescription Drugs, *supra* note 3, at 1. (noting that the growth rate may be slowing somewhat); Bruce Shutan, *Prime Time for PBMs*, EMPLOYEE BENEFIT NEWS, Feb. 2004, <http://www.benefitnews.com/detail.cfm?id=5550&terms=%7Car%7C> ("Although employers are expected to face another year of double-digit health plan increases in the 12% to 15% range, they're gradually reining in prescription drug costs. The pharmacy trend rate fell to 15.3% from 17.7% between the spring and fall alone, according to Aon's recently published twice-annual Health Care Trends Survey").

One industry largely overlooked in the healthcare debate is pharmacy benefit management. Pharmacy benefit managers (“PBMs”) originated during the 1970s to serve as fiscal intermediaries by adjudicating prescription drug claims by paper and then, in the 1980s, electronically. When a health plan participant leaves a prescription at a pharmacy, the pharmacy verifies through the PBM that the participant has coverage, what copay is required, whether the plan covers the drug, and whether pre-approvals are required to fill the prescription. Once the prescription is filled, the pharmacy transmits details regarding the patient, health plan number, prescription, and price to the PBM. The PBM responds by approving or disapproving the transaction or by instructing the pharmacy to obtain additional information. The PBM then seeks payment from the health plan, whether self-insured or fully insured, and forwards the appropriate payment to the retail pharmacy.

The function of PBMs has changed over the years from simply processing prescription transactions to managing the pharmacy benefit for health plans.⁵ Today, PBMs negotiate drug discounts with pharmaceutical manufacturers, provide drug utilization reviews⁶ and disease management, and, in some instances, create a formulary that encourages or even requires health plan participants to use preferred formulary products to treat their conditions.⁷ A common structure is the three-tier plan. The first tier of co-payment, which is the lowest, typically provides for a copay of around \$10 for generic drugs. The middle tier, with a slightly higher copay, allows for the purchase of brand-name drugs that have been determined by the PBM to be the preferred brand drugs in the formulary for treating a particular disease or condition. The third tier, allows plan participants to purchase non-preferred brand drugs with the payment of the highest copay.

Within the United States, approximately two-thirds of all prescriptions filled pass through the hands of PBMs in one way or another. Over the past decade, significant changes have occurred in the PBM industry, but regulation of the PBMs has not kept pace with those

⁵ See, e.g., Regina Sharlow Johnson, *PBMs: Ripe for Regulation*, 57 FOOD & DRUG L.J. 323 (2002) (describing the functions of PBMs and the lack of an appropriate regulatory scheme); Dept. Health & Human Servs., *Report to the President: Prescription Drug Coverage, Spending, Utilization, and Prices* (April 2000).

⁶ Dep’t Health & Human Servs., U.S. Food & Drug Admin, *The Prescription Drug Marketing Act Report to Congress*, (June 2001); Sheila Shulman, *Pharmacy Benefit Management Companies (PBMs), Why Should We Be Interested?*, 14 PHARMACOECON 49 (1998).

⁷ Insurance Changes Alter Drug-Taking Behavior, <http://www.reflector.com/health/content/shared-auto/healthnews/drug/516324.html>; see also Dr. Haiden Huskamp, *Formularies and Cost Sharing Issues for Medicare Part D* (Oct. 8, 2004).

changes. Despite their involvement in the fulfillment of prescriptions, regulation of these entities is largely ad hoc. The PBMs' practices have been subjected to increasing scrutiny in the past few years and several states have attempted to regulate them in light of the dearth of federal regulation. In addition, PBMs, along with pharmaceutical manufacturers, are the targets of increased litigation.

The scrutiny of PBMs is likely to increase over the next few years. For example, the passage of the Medicare prescription drug bill involves PBMs in the administration of drug discount cards for seniors who lack prescription drug coverage and in the administration of various plans that provide the prescription drug benefit.⁸

According to an industry auditor frequently hired by health plans to audit their PBMs' performance, in more than 400 audits "we have never found a single situation where something wasn't wrong."⁹ Given the amount of litigation in the pharmaceutical and PBM industries, as well as attempts by the states to regulate the PBMs, change in the PBM industry is ineluctable.¹⁰ Yet, attempts at state regulation and the ad hoc constraints on behavior that litigation creates will not correct problems in the PBM industry quickly and efficiently. This article explores how the PBM industry operates, current regulations affecting the industry, problems within the industry, and provides alternatives to the current unworkable approach that will help to level the playing field between health plans and PBMs by reducing information asymmetry.

⁸ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 42 U.S.C. § 1395w-141 (2000); Medicare Prescription Drug Discount Card, Interim Final Rule and notice, 68 Fed. Reg. 69840 (Dec. 15, 2003).

⁹ Melissa Davis, *Medco, Peers Face New Test from Clients*, THESTREET.COM, (Oct. 24, 2004) http://www.thestreet.com/_yahoo/stocks/melissadavid/10190002_2.html. The auditor, Susan Hayes:

remembers one PBM waiting 10 months to carry out a contract change that would have saved its customer \$10 million—and then a long fight to recover the money. She remembers other PBMs refusing to supply information until their clients sued in court. She remembers PBMs retaliating against her company "big time" and one even banning her firm from auditing its contracts. . . . The industry needs to be overhauled.

Id.

¹⁰ See Davis, *supra* note 9 (in which co-author Robert Garis, predicts that "there is going to be a cataclysm in the industry").

II. THE PBM INDUSTRY

PBMs constitute a growing and lucrative industry. However, the industry is also quite complex. This Part will explore the PBM industry, discussing the basic attributes of PBMs, as well as the relationships PBMs have with health plans, pharmaceutical manufacturers, and retail pharmacies.

There are between forty and sixty PBMs operating in the United States, but most of these entities are small.¹¹ The industry is dominated by three firms: Caremark RX, Inc., Medco Health Solutions, Inc.,¹² and Express Scripts, Inc.¹³ PBM size can be measured in several ways: by the number of prescriptions they process, the dollar value of those prescriptions, or the number of covered lives (which is the industry terminology for the number of health plan participants a PBM serves). Caremark bought Advance PCS, another large PBM, in 2004 and together the combined entity serves 20% of the covered lives in the PBM market. Medco Health Solutions, Inc., serves another 12%, while Express Scripts, Inc., serves 10%.¹⁴

The PBMs' business model has proven extremely lucrative. In 2006, Express Scripts had a net income of \$474 million on revenues of \$17.7

¹¹ Improving Health Care, *supra* note 3 (estimating 60 PBMs); Robert F. Atlas, *The Role of PBMs in Implementing the Medicare Prescription Drug Benefit*, 2004 HEALTH AFFAIRS, (Oct. 28, 2004) at W4-504, 506, <http://content.healthaffairs.org/cgi/content/abstract/hlthaff.w4.504> (estimating 40-50 PBMs).

¹² Medco Health Solutions, Inc. is the successor in interest to Merck-Medco Managed Care, LLC. Regarding Merck Medco's history, see generally Nancy A. Nichols, *Medicine, Management, and Mergers: An Interview with Merck's P. Roy Vagelos*, HARV. BUS. REV. 113 (1994).

¹³ Joyce Frieden, *Consolidation, Lawsuits: Mail Order Rx Numbers May Be on the Rise*, OB/GYN NEWS, Apr. 15, 2004. The article describes the concentration of PBMs, stating:

The PBMs see the market differently. "This is a fairly fragmented industry," said Phil Blando, spokesman for the Pharmaceutical Care Management Association, a Washington-based trade association for PBMs. He noted that his organization has roughly 60 members, although "there is really a core group of seven or eight PBMs, none of which has more than the high teens in terms of market share or revenues." Besides the independent PBMs; several of the larger insurance companies have their own PBM units, he added.

Id.

¹⁴ *A Guide to Drug Cost Management Strategies*, from AIS's exclusive quarterly survey of PBMs conducted for *Drug Benefit News*, http://www.aishealth.com/MarketData/PharmBenMgmt/PBM_market01.html (last visited Jan. 18, 2007); see also Roy Harris, *The Year of Living Strategically*, CFO MAG., Jan. 2007, at 29, 31 (noting that currently, CVS is trying to acquire Caremark, a move that "in theory, might allow the company to help create better deals for consumers, while it gives itself new revenue opportunities").

billion,¹⁵ Medco Health Solutions, Inc. made \$630 million on revenues of \$42.5 billion during the same period,¹⁶ and Caremark RX, Inc. made \$1.1 billion on revenues of \$36.8 billion in 2006.¹⁷

PBMs profit: (1) from operating their own mail order pharmacies; (2) from providing services such as drug utilization review, rebate administration, and data mining; and (3) from negotiating with groups such as health plans, pharmaceutical manufacturers, and retail pharmacies. Through the process of negotiation with each group, the PBMs either make money or reduce expenses in various ways.

Typically, there are four ways that PBMs make a profit. First, they take a share of the “ingredient cost” by contracting to reimburse retail pharmacies for drugs at one rate, while charging health plans a higher rate. Second, PBMs receive the fees and rebates mentioned above from drug manufacturers.¹⁸ Third, the PBMs charge health plans a processing fee for each prescription filled.¹⁹ Finally, the PBMs compete to some degree with the retail pharmacies with which they contract. The PBMs each have a mail order branch and direct a portion of the pharmacy transactions through their own mail order branches. Some PBMs have also begun to offer their own discount cards to cash-paying patients who do not have health plans. This allows PBMs to generate additional revenue, while offering uninsured customers somewhat lower rates on pharmaceuticals.

The federal government has studied the role of PBMs several times over the past decade.²⁰ In the Medicare Modernization Act, passed in

¹⁵ EXPRESS SCRIPTS, INC. ANNUAL REPORT ON FORM 10-K FOR 2006, at 55, <http://www.secinfo.com/dr/ZUm.u2.htm>.

¹⁶ MEDCO HEALTH SOLUTIONS, INC. ANNUAL REPORT ON FORM 10-K FOR 2006, at 69.

¹⁷ CAREMARK RX, INC. ANNUAL REPORT ON FORM 10-K FOR 2006, at 44.

¹⁸ See *PBMs' revenue sources, rebate accounting procedures explained*, DRUG COST MANAGEMENT REPORT (Jan. 2003), http://findarticles.com/p/articles/mi_m0NIV/is_1_4/ai_97592327/print (describing access rebates, a type of rebate given for placing a particular drug on the PBM's formulary); Chris Nee, *Uncovering the Mysteries Behind Rebates*, DRUG COST MANAGEMENT REPORT (June 2002), available at http://findarticles.com/p/articles/mi_m0NKV/is_6_3/ai_87799122/print (describing the other amounts manufacturers pay to PBMs for marketing practices that increase their market share of particular drugs).

¹⁹ See Barbara Martinez, *Two Hats: Firms Paid to Trim Drug Costs Also Toil for Drug Makers*, WALL ST. J., Aug. 14, 2003, available at http://www.pbmwatch.org/update15_100703.html (describing the per transaction processing charge has decreased significantly over the past several years to between twenty and thirty cents per transaction from about one dollar per transaction).

²⁰ Cong. Budget Office, *Prescription Drug Pricing in the Private Sector*, at Glossary (Jan. 2007) [hereinafter CBO Report]; General Accounting Office, *Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies*

December of 2004, Congress included a provision requiring the Federal Trade Commission to study the mail order pharmaceutical business to determine whether the PBMs were engaged in self-dealing.²¹ The FTC issued its report in September of 2005, finding that self-dealing by the PBMs did not result in noticeably higher prices.²²

The dominant players in the PBM industry process the prescriptions dispensed to approximately 200 million Americans, thus earning huge annual profits.²³ Not only are PBMs extremely profitable, they also appear on Fortune's list of the fastest growing companies in America.²⁴ Although most large health plans turn to one of the dominant PBMs, there are at least twenty PBMs that have systems and retail pharmacy networks that can handle large health plans.

There are two main types of PBMs. The first is the full-service PBM that recommends plan design, handles all plan interaction with retail pharmacies, and negotiates rebates and other financial incentives with manufacturers. The second type, PBMs that are not full-service, sometimes contract out one or more of these functions to a third party. Each type of PBM negotiates with health plans and retail pharmacies and, directly or through a third party, with pharmaceutical manufacturers. The PBM also serves as the intermediary among these three groups.

(Jan. 2003) [hereinafter GAO-03-196]; Health Care Financing Admin., *Study of Pharmaceutical Benefit Management Industry*, at 41 (June 2001) [hereinafter Contract No. 500-97-0399/0097].

²¹ 42 U.S.C.A. § 1395w-101 (West 2004) (quoting Pub. L. 108-173, Title I, §110, Dec. 8, 2003, 117 Stat. 2174 (a)) ("The Federal Trade Commission shall conduct a study of differences in payment amounts for pharmacy services provided to enrollees in group health plans that utilize pharmacy benefit managers."); cf. Conference Agreement, 149 Cong. Rec. H. 11877 (2003). See also GAO-03-196, *supra* note 20 (noting that the purpose of the study was to determine whether self-dealing, which had been identified in an earlier, privately funded study, occurs); James Langenfeld & Robert Maness, *The Cost of PBM "Self-Dealing" Under a Medicare Prescription Drug Benefit* (Sept. 9, 2003), available at http://www.mpaginc.com/news/pbm_report.pdf.

²² *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies*, Fed. Trade Commission (Sept. 6, 2005); see also GAO-03-196, *supra* note 20 (serving as an example of government agencies studying the PBM industry); Contract No. 500-97-0399/0097, *supra* note 20 (same).

²³ Improving Health Care, *supra* note 3, at 14.

²⁴ See *Market-share Analysis Shows Changing PBM Climate, Growth as Medco Spins Off*, (Aug. 29, 2003), http://findarticles.com/p/articles/mi0NKV/is_10_4/ai_107648547 (noting that "FORTUNE magazine's list of the 100 fastest growing companies [in 2003] . . . includes five PBMs or PBM parent companies among its 22 health care firms.").

A. *PBMs' Relationships with Health Plans*

Sponsors of group health plans include employers and unions. Employers may also make health maintenance organizations (“HMOs”) available to their employees. The HMOs also deal with PBMs to negotiate pricing for plan participants. Plan sponsors typically choose a PBM by sending a request for proposals (“RFP”) to several large PBMs. Most health plans retain a consultant from a high-profile firm such as Hewitt or Towers-Perrin to advise them during the RFP process. The primary concerns of the health plans typically include pricing, customer service, and pharmacy plan design.

Pricing is partially based on the reimbursement rate for prescription drugs. This rate is typically expressed as the Average Wholesale Price²⁵ (“AWP”) (a standard industry pricing that, curiously, is neither average nor wholesale) less a negotiated percentage for brand name drugs. AWP has been defined as:

A publicly available list price for sales of drugs by wholesales to pharmacies or other providers, the AWP is not the actual price that wholesales charge but is more like a sticker price in the automobile industry. The AWP is used as the basis for setting payment rates to pharmacies.²⁶

A related concept is the Average Manufacturer Price (“AMP”), defined as:

the average price paid to manufacturers for drugs distributed through retail pharmacies. It includes all forms of discounts given to wholesalers and to pharmacies, but it does not include rebates paid by manufacturers to third-party payers. The AMP is used to calculate the rebates that manufacturers of brand-

²⁵ Academy of Managed Care Pharmacy, *A Guide to Understanding Common Prescription Drug Pricing Terms*, at 5 (defining AWP as the price assigned to a drug and is listed in the *Red Book*, *First DataBank* or *Medispan*). AWP is a “suggested list price, and is typically not what is paid as buyers may negotiate lower prices through the inclusion of discounts, rebates or free products.” *Id.* AWP, which are used to establish reimbursement rates for drugs, are published in the *Drug Topics Red Book* and other sources. *Id.*; see *Floor Statement of United States Senator Chuck Grassley of Iowa* (Jan. 8, 2007), available at <http://www.senate.gov/~finance/press/Gpress/2007/prg010807.pdf>. (pointing out that a standing joke within the industry says the acronym stands for “Ain’t What’s Paid”).

²⁶ CBO Report, *supra* note 20, at Glossary.

name drugs are required to give to federal and state governments for sales to Medicaid beneficiaries.²⁷

In other words, the AMP is the price paid by wholesalers to drug manufacturers; the wholesaler then marks up the drugs and sells them to retail pharmacies.

For generic drugs,²⁸ the pricing is the Maximum Allowable Cost (“MAC”), which is often expressed as an aggregate discount off the AWP (for example, an aggregate discount on generics equal to or greater than AWP, such as 55%).²⁹ The MAC is “an upper payment limit on the ingredient costs for a multiple-source drug.”³⁰ While plan sponsors may operate under the illusion that the MAC is actually the maximum price allowable, there are often multiple MAC prices. PBMs use lower MAC prices to reimburse pharmacies, while higher MAC prices are charged to plan sponsors, increasing the spread retained by the PBM. PBMs can also increase their spreads by charging the plan sponsor a higher MAC price. For example, in a new contract between the plan sponsor and PBM, the PBM may give up more in rebate dollars while, unknown to the plan sponsor, the PBM starts using a MAC list with a higher unit price to maintain profit expectations. Pricing negotiations will also relate to the dispensing fee, which is a flat price per prescription paid to the pharmacies for filling the prescriptions and counseling the patients. In addition, pricing negotiations will deal with the rebates from pharmaceutical manufacturers that will be passed on to the plan sponsor, pricing for mail order fulfillment, drug utilization reviews and disease management, as well as administrative fees charged by the PBM for its services.

On January 1, 2005, Medicare changed its reimbursement approach from AWP to Average Sales Price (“ASP”). Although Medicare uses this

²⁷ *Id.*

²⁸ Generic drugs are also referred to within the industry as “multi-source drugs,” while brand name drugs are referred to as “single-source drugs.” See 42 U.S.C. § 1396r-8 (2000) and 42 C.F.R. §§ 405.517, 414.904 (2007).

²⁹ See Academy of Managed Care Physicians, *A Guide to Understanding Common Prescription Drug Pricing Terms* (defining MAC as the price that a health plan establishes as the “maximum cost per unit of medication (tablet, capsule, etc.) for that product Each health plan determines its own MAC, and uses its own formula to arrive at the MAC price.”). Health plan administrators do not have the time, systems, or considerable expertise that would be necessary to perform these calculations in house. Instead, each health plan contracts with the PBM for these services.

³⁰ CBO Report, *supra* note 20, at Glossary.

method, some non-governmental payers are also starting to use ASP.³¹ For example, several Blue Cross/Blue Shield plans peg their reimbursement rates to Medicare rates.³² Additionally, on January 1, 2007, pricing throughout the industry changed somewhat with the introduction of a new pricing approach as to state Medicaid programs. Under the Deficit Reduction Act of 2005,³³ Congress imposed a federal upper limit (“FUL”) on the federal matching funds that state programs receive.³⁴ Each drug’s FUL is now based on the AMP.³⁵ While the AMP does not apply to prices charged by the PBMs to health plans, it will likely become another accepted source for drug pricing and, if the AMP prices are lower, this may exert some downward pressure on the prices paid by health plans.

In addition to paying PBMs for the drugs purchased by plan participants, plan sponsors also pay PBMs for providing specialty pharmacy services. Specialty pharmaceuticals include “injectable and infusion therapies, high-cost (\$5,000 and up per patient per year) therapies, and therapies that require complex care.”³⁶ These drugs are typically very expensive and may require special handling, such as refrigeration.

Some PBMs also have mail order facilities and may try to shift plan participants to fulfillment of prescriptions through mail order rather than at retail pharmacies.³⁷ This approach is often used for maintenance drugs, such as those for hypertension, asthma, and diabetes to avoid a trip to a retail pharmacy and to lower the patient’s copay. When a PBM operates its own mail order facility, it can profit from a single transaction by processing the transaction as an intermediary and by receiving the dispensing fee and a markup on the drugs.

³¹ *Commercial Payers are Starting to Use Medicare’s Average Sales Price*, SPECIALTY PHARMACY NEWS (Mar. 2006), http://www.aishealth.com/DrugCosts/DBN_Medicare_Sales_Price.html.

³² *Id.*

³³ 42 U.S.C. § 1396r-8 (2000).

³⁴ 42 U.S.C. § 1396r-8(e)(4).

³⁵ See generally GAO, *Medicaid Federal Upper Limits*, GAO-07-239R, (Dec. 22, 2006).

³⁶ *Defining Specialty Pharmacy: Services, Markets and Player*, 3 DRUG COST MGMT. REP., No. 7 (July 2002).

³⁷ See 42 U.S.C. § 1395w-101 (2000); cf. Conference Agreement, 149 Cong. Rec. H. 11877 (2003). Concern over whether this occurs caused Congress to include in the Medicare Modernization Act, the following language: “The Federal Trade Commission shall conduct a study of differences in payment amounts for pharmacy services to enrollees in group health plans that utilize pharmacy benefit managers.” *Id.*

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Plan sponsors evaluating proposals from several PBMs are concerned with customer service elements of the bid package. Sponsors will review data concerning timeliness and responsiveness to contacts from plan participants and network pharmacies. Plan sponsors are also concerned with geo-access to network pharmacies, such that plan participants have access to conveniently located pharmacies. However, depending on the nature of the plan sponsor, the pharmacy network may be limited. For example, if the plan sponsor has a single facility, a nearby pharmacy may give better rates to the PBM in order to assure that plan participants patronize it. On the other hand, a plan sponsor with a geographically dispersed work force must assure that its employees have access to network pharmacies wherever they are located.

As part of the plan design aspects of the bid, PBMs often propose plan design features that should increase rebate payments to the PBM, drive up generic utilization rates, or require preapproval of high cost or frequently abused drugs.³⁸ The predominant plan structure is tiered. Under the tiered approach, the patient can obtain non-preferred drugs, but must pay a higher copayment. According to the Congressional Budget Office, a “formulary” is:

a list of drugs approved for coverage under a drug benefit. Pharmacy benefit managers (PBMs) working on behalf of health plans determine which drugs are therapeutically similar. Then, for such brand-name drugs with several close substitutes, PBMs negotiate with manufacturers for lower prices and rebates in return for placing the manufacturers’ drugs on their formularies.

The patients served by a PBM may have access to only those drugs on a formulary (in the case of a closed formulary) or may have access to all prescription drugs but at different levels of copayments or other conditions (in the case of an open formulary).³⁹

³⁸ Although the lack of transparency in the industry obscures the facts, PBMs may make more money creating incentives for consumers to purchase brand name drugs than by creating incentives for the use of generic drugs through a formulary.

³⁹ CBO Report, *supra* note 20, at Glossary. This CBO definition of “formulary” may not be entirely accurate. For example, for plan sponsors, it is unclear whether the PBM is actually negotiating for lower prices or just for rebates. Further, plan sponsors do not have

Under a formulary approach, the structure of the pharmacy plan provides for lower copays when preferred drugs are used. In theory, the health plan will receive better pricing because placement of the preferred drug on the formulary should help to drive market share increases for that individual drug.

In addition to providing for therapeutic substitution (drugs that address the same disease or condition in roughly the same manner), the formulary may require generic substitution. That is, the formulary may require plan participants to accept the generic drug, which is the chemical equivalent of the brand-name drug. For example, a generic cholesterol-reducing drug may carry a \$10 copay, while the brand-name drug may carry a \$20 copay. This provides an economic incentive to plan participants to choose the less expensive generic drug over the more expensive brand name drug.

Formularies can be designed not only to channel participants toward generic drugs, but also to channel participants to those drugs deemed most cost-effective for treating a particular disease or condition. Preferred drugs are those that the PBM's pharmacy and therapeutics ("P&T") committee selects for a given disease or condition, though it is unclear to what extent the selection is based on clinical merit as opposed to rebates. In addition, some formularies use therapeutic substitution, which is a switch to a drug that, while not chemically equivalent, has the same therapeutic effects as the prescribed drug.

The formulary may also be structured to maximize manufacturer rebates by causing plan participants to shift from one manufacturer's drug to another's.⁴⁰ In theory, maximizing rebates lowers the cost of the pharmacy plan for all plan participants, but this occurs only if the PBM

access to the information that would be necessary to determine whether the cost of rebatable drugs is actually lower than the cost of comparable drugs. *Id.*

⁴⁰ ANNA COOK & THOMAS KORNFELD ET AL., THE ROLE OF PBMS IN MANAGING DRUG COSTS: IMPLICATIONS FOR A MEDICARE DRUG BENEFIT 19 (2000). ("The ability of PBMs to manage utilization and substitute one drug for another on their formulary motivates manufacturers to offer rebates."). See also Advance PCS, Annual Report, (Form 10k-405) at 6 (June 29, 2000), <http://sec.edgar-online/2000/06/29/10/0000950134-00-005401/Section8.asp> ("We have historically derived our clinical revenues primarily from formulary rebates and volume discounts received from pharmaceutical manufacturers."); Robert B. Goldberg, *Managing the Pharmacy Benefit: The Formulary System*, 3 J. MANAGED CARE PHARM. 565-73 (1997).

passes those savings along to the plan. The judicious use of appropriate generic products also lowers plan costs.⁴¹

The various categories of drugs included in a health plan's formulary are called "tiers," with different copays and requirements for each tier. A typical plan may have four tiers, ranging from drugs that the P&T committee deems to be extremely cost effective and for which the copays will be the lowest, to those brand name drugs that have less costly alternatives. Differences in copays and pre-approval requirements are designed to influence plan participants, together with their doctors, to choose less costly alternatives, such as generic equivalents, for their diseases or conditions. Because these tiers influence market behavior, manufacturers may pay bigger rebates to the PBMs in connection with their administration of health plans that have more aggressive formularies.

B. PBMs' Relationships with Pharmaceutical Manufacturers

Generally, PBMs negotiate with pharmaceutical manufacturers for rebates associated with use of the manufacturers' brand-name drugs. In effect, the manufacturers pay PBMs to increase their market shares. For example, two drug manufacturers may have similar but competing drugs to treat asthma. The manufacturers may pay the PBM rebates or other funds for hitting sales targets or increasing the market share of an individual drug. The PBM may also receive rebates for placing the manufacturer's drug on its formulary, which will tend to shift usage to the preferred drug.

In addition to receiving rebates, PBMs are compensated by manufacturers for various services, such as distributing, adjudicating,

⁴¹ Academy of Managed Care Pharmacy ("AMCP"), *Comments Regarding the June 26, 2003 Joint FTC-DOJ Hearings on Health Care and Competition Law and Policy, (Pharmaceuticals: Formulary)* at 2 (Aug. 5, 2003) ("[A] well-desired, properly administered formulary will assist in the effective management of a patient's overall health care."). See also U.S. Senate Committee on Finance, *Providing Prescription Drug Coverage Through Medicare: The Role of Pharmacy Benefit Managers*, 106th Cong. (2000), at 4-5, in which testimony was given before the Committee that:

PBMs may develop relationships with manufacturers that provide lower pricing (through rebates) when a particular drug is on the formulary. The level of rebates will vary by manufacturer and prescription drug. In general, the level of the rebates increases if the PBM achieves a greater market share for a drug within a defined class of prescriptions with similar therapeutic effects.

Id.

and tracking drug-sample vouchers.⁴² PBMs may also receive marketing or educational money, administration fees⁴³ (fees associated with providing data to the pharmaceutical companies) for conducting pharmacoconomics studies, outcomes studies, and disease management studies. The amounts earned by the PBMs may be nothing more than disguised rebates, but because they are not characterized as rebates, they are not passed on to plan sponsors. AdvancePCS explains these other revenues as follows:

We also earn other revenue from pharmaceutical manufacturers for services such as formulary support services, outcomes studies and clinical trials. These services are negotiated separately with each pharmaceutical manufacturer and specify the services we are to perform and the revenues and fees we are to earn based on the delivery or completion of the services. We also earn revenues from our customers (primarily managed care organizations) for disease management services provided by Accordant, our wholly owned subsidiary. . . .⁴⁴

The PBMs' ability to negotiate effectively with manufacturers has been criticized in recent years. Some argue that the PBMs cannot negotiate effectively on a drug-by-drug basis because drug manufacturers insist on bundling the drugs and providing aggregate pricing.⁴⁵ Bundling may make it difficult to replace branded drugs with generic drugs as generics become available. If a competing brand drug enters the public domain when its patent expires, making generic equivalents available, the PBM should notify plan members to switch to the generic drug and save on co-payments. However, this rarely occurs.

As already explained, PBMs peddle their formularies to health plan sponsors. For large health plans, which may have more than one million covered lives, the potential increase in market share from adopting a PBM's formulary may give the PBM additional leverage with the drug

⁴² David M. Katz, *Drug Discount Peddlers*, CFO MAGAZINE, Oct. 28, 2005, <http://www.cfo.com/article.cfm/5079733?f=search>.

⁴³ *Id.* For example, the PBM may be paid to manage vouchers or coupons offered by the drug manufacturer. *Id.*

⁴⁴ Advance PCS, Annual Report, (Form 10k/A) at 52 (July 29, 2003), <http://sec.edgar-online/2003/07/29/0001193125-03-025659/Section8.asp>.

⁴⁵ John Carroll, *When Success Sours: PBMs Under Scrutiny*, 11 MANAGED CARE 20-26 (Sept. 2002), available at <http://www.badfaithinsurance.org/reference/GMDCPB/0031a.htm>.

manufacturers. And placing one manufacturer's cholesterol-lowering drug on the formulary as a preferred drug could help to shift market share away from competitors' drugs in the same therapeutic class.⁴⁶ For this reason, drug manufacturers may pay a combination of rebates, marketing fees, and administrative fees to PBMs in exchange for placement on a formulary or for providing marketing data to the manufacturers.

C. *PBMs' Relationships with Retail Pharmacies*

PBMs establish networks of pharmacies at which health plan participants can have their prescriptions filled. There is tension between having a broad network of retail pharmacies that provide plan participants with many retail choices to have prescriptions filled and creating a narrow network of pharmacies, although few PBMs establish restricted networks. Retail pharmacies are highly motivated to acquiesce to PBMs' pricing demands to assure that they will be included in the PBM's network of retail pharmacies, resulting in an increase in the pharmacy's market share. Exclusion from the network means that plan participants' claims cannot be processed automatically and the burden of additional paperwork will cause participants to avoid retail pharmacies that are not included in their network. The retail pharmacies are generally offered a "take it or leave it" deal to be included in the network, with only the largest pharmacy chains having any ability to negotiate with the PBMs.

PBMs offer a dispensing fee to each group of pharmacies that will be included in the network. The dispensing fee is a flat fee paid to the pharmacy that ostensibly compensates the pharmacy for overhead while providing some measure of profit. The dispensing fee charged to the plan sponsor may be higher than the dispensing fee paid to the retail pharmacies, meaning that the PBM keeps the spread as profit.⁴⁷

⁴⁶ *Id.*; see also Katz, *supra* note 42. Katz describes how Express Scripts, Inc., one of the three largest PBMs, removed Pfizer's Lipitor from its formulary in favor of Merck's Zocor. *Id.* This move was unusual, because Express Scripts noted that it was influenced by the fact that Zocor would soon come off of patent, meaning that generic equivalents should be available, whereas Lipitor had another eleven years left on its patents. *Id.*

⁴⁷ See Katz, *supra* note 42 (noting, "Another target of scrutiny is how PBMs can unduly profit from price spreads. In a typical arrangement, the manager at the PBM agrees with a corporate client on a guaranteed price that the client will pay for a drug. If the manager can hash out a lower price with the drugstore chain, the PBM pockets the difference"); see also Robert I. Garis & Bartholomew E. Clark, *The Spread: Pilot Study of an Undocumented Source of Pharmacy Benefit Manager Revenue*, 44 J. AM. PHARM. ASSOC. 15-21 (2004) (finding the

III. CURRENT REGULATION OF THE PBM INDUSTRY

Existing regulation of the PBM industry is a patchwork of state and federal laws and regulations from assorted government agencies, none of which has primary responsibility for regulating this important industry. However, because there is no single, comprehensive regulatory scheme, the industry has been left largely to its own devices with respect to several significant issues. Litigation and attempts at the state level to pass regulatory fixes have resulted in slow and inconsistent approaches to the significant issues affecting this segment of the health care industry. This Part will discuss federal and state regulation of the PBM industry.

A. *Federal Regulation of the PBM Industry*

There are many different federal regulations that affect the PBM industry, however no federal agency has overall responsibility for the industry's regulation. Further, existing regulations fail to address the concerns for fraud and self-dealing discussed in Part I of this article.

Among the federal regulations that address PBM behavior are the Medicare and Medicaid fraud and abuse statute⁴⁸ and anti-kickback rules.⁴⁹ Congress amended the statute in 1977 to expand its reach beyond bribes, kickbacks, and rebates by making any form of remuneration subject to the penalty provisions.⁵⁰ In 1980, Congress added the scienter requirement to allow individuals whose conduct is inadvertent to avoid prosecution.⁵¹ Conduct proscribed by the act must be knowing or willful for liability to attach.⁵² Penalties for violation of the anti-kickback law include up to five years in prison, criminal fines of up to \$25,000, and civil penalties of up to \$50,000.⁵³

"possibility of substantial and widely varying differences in the spread and spread percentage between PBMs for brand name and generic medications" and noting that "[a] more transparent business model for the PBM industry could produce better relations with PBM clients and business partners, including community pharmacies.").

⁴⁸ See Medicare-Medicaid Antifraud and Abuse Amendments, 42 U.S.C. § 1320a-7b(b)(1-3) (2000). The statute protects discounts or other price reductions as long as they are "properly disclosed and appropriately reflected." *Id.*; see also 42 C.F.R. § 1001.952(h) (2004).

⁴⁹ 42 U.S.C. § 1320a-7b (2000).

⁵⁰ See 42 U.S.C. § 1320a-7b(b)(1),(2) (2000); H.R. Rep. No. 95-393, at 53 (1977), reprinted in 1977 U.S.C.C.A.N. 3039, 3056.

⁵¹ See 42 U.S.C. § 1320a-7b(b)(1),(2) (2000); H.R. Rep. No. 96-1167, at 59 (1980), reprinted in 1980 U.S.C.C.A.N. 5526, 5572; see also H.R. Rep. No. 92-231, at 107 (1971), reprinted in 1972 U.S.C.C.A.N. 4989, 5093.

⁵² 42 U.S.C. § 1320a-7a(a)(7) (2000).

⁵³ 42 U.S.C. § 1320a-7b(b) (2000).

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The PBMs may, however, qualify for certain safe harbors under the anti-kickback rules.⁵⁴ The anti-kickback statute includes several statutory exemptions to prohibited activities.⁵⁵ The Office of the Inspector General of the Department of Health and Human Services was charged by Congress with drafting safe harbors to protect certain types of common payment practices from kickback liability. Accordingly, new safe harbors that apply to electronic prescribing were adopted in 2005.⁵⁶

Some scholars have noted the difficulty of applying these safe harbors to PBM activities.⁵⁷ These safe harbors may not, however, protect PBMs from liability for practices of the types discussed in Part IV of this Article, including channeling of prescriptions to their own fulfillment facilities, drug switching, kickbacks, and other pricing and rebate practices. Further, the effectiveness of these statutes to curb PBM behavior has been criticized, with one author noting: "Existing federal legislation aimed at eliminating healthcare fraud fails to redress the potential for conflicts of interest introduced by vertical integration."⁵⁸

In addition to the anti-kickback laws and the regulations implementing them, PBMs may also be subject to fiduciary duties under the Employee Retirement Income Security Act of 1974 ("ERISA").⁵⁹ ERISA applies to employee benefit plans created by employers "engaged in commerce or in any industry or activity affecting commerce."⁶⁰ It

⁵⁴ See 42 C.F.R. § 1001.952(h) (stating that an arms-length transaction qualifies for the safe harbor protection).

⁵⁵ See 42 C.F.R. § 1001.952 (exemptions to the anti-kickback statute include: properly disclosed discounts under a federal healthcare program; compensation paid to a bona fide employee; amounts paid by a vendor to a group purchasing organization if certain conditions are met; waivers of co-insurance by federally-qualified health centers; and remuneration paid as part of a risk-sharing arrangement). See generally Dept. of Health and Human Servs., *Federal Health Care Programs: Fraud and Abuse; Statutory Exception to the Anti-Kickback Statute for Shared Risk Arrangements*, 64 Fed. Reg. at 63,504 (Nov. 19, 1999).

⁵⁶ 42 C.F.R. § 1001.952.

⁵⁷ Greg Radinsky, *The Spotlight on PBMs: Federal Enforcement of the Anti-Kickback Statute on the Pharmaceutical Benefit Management Industry*, 36 J. HEALTH L. 213 (2003). See generally Mark Learn, *Applying Medicare and Medicaid Anti-Kickback Laws to Disease Management Programs: Ramifications for the Pharmaceutical Industry and a Regulatory Proposal*, 69 TEMP. L. REV. 245 (1996) (providing a general discussion of the anti-kickback rules and their possible application to PBM programs).

⁵⁸ Elizabeth L. Mitchell, *The Potential for Self-Interested Behavior by Pharmaceutical Manufacturers Through Vertical Integration with Pharmacy Benefit Managers: The Need for a New Regulatory Approach*, 54 FOOD & DRUG L.J. 151, 162 (1999).

⁵⁹ 29 U.S.C. § 1003(a) (2000); see also AccessRx Program, D.C. Stat. § 48-831.01(2001) (imposing a fiduciary duty on all PBM's to their covered entities).

⁶⁰ Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1003(a-b) (2000); see generally Peter J. Wiedenbeck, *ERISA's Curious Coverage*, 76 WASH. U. L.Q. 311 (1998)

provides that a fiduciary must “discharge his duties with respect to the plan solely in the interest of the participants and beneficiaries.”⁶¹ If the fiduciary fails to discharge its duties, the fiduciary is personally liable for money damages, restitution, and “such other equitable or remedial relief as the court may deem appropriate.”⁶² The Supreme Court has characterized the test for whether an entity is a fiduciary under ERISA as a functional test that depends on the control and authority exercised over the plan by the entity.⁶³ Regulation of PBMs under ERISA depends upon the characterization of PBMs as fiduciaries owing certain duties to plan participants. PBMs have resisted this characterization and routinely insist that a disclaimer of fiduciary status under ERISA be included in their contracts with health plans.

The question of whether fiduciary duties apply to PBMs under ERISA has been explored in numerous cases. For example, in *Glanton v. AdvancePCS Inc.*,⁶⁴ participants in several employer plans sued AdvancePCS alleging that the PBM had “secretly been keeping the spread between what it charge[d] the plans for drugs and what it [paid] suppliers.”⁶⁵ Plaintiffs argued that AdvancePCS was a plan fiduciary, as defined by ERISA, and that they had standing to sue AdvancePCS for breach of its fiduciary duty.⁶⁶ While only deciding the standing issue, the court noted: “It follows that plaintiffs here are authorized to sue AdvancePCS for breach of fiduciary duty.”⁶⁷

Similarly, in *Bickley v. Caremark RX, Inc.*,⁶⁸ the plaintiff brought a class action lawsuit alleging that Caremark was a plan fiduciary under ERISA and breached its various fiduciary duties.⁶⁹ According to the complaint, Caremark enriched itself “through undisclosed discounts, rebates, coupons and other forms of compensation from drug companies and pharmacies.”⁷⁰ Caremark had successfully moved to dismiss at the

(noting that ERISA does not apply to plans sponsored by the government and by churches).

⁶¹ 29 U.S.C. § 1104(a)(1) (2000).

⁶² 29 U.S.C. § 1109(a) (2000).

⁶³ See *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 262 (1993) (holding that entities that perform services for a plan but are not classified as fiduciaries under ERISA are not subject to money damages).

⁶⁴ 465 F.3d 1123 (9th Cir. 2005).

⁶⁵ *Id.* at 1124.

⁶⁶ *Id.* Whether an entity is specifically named as a plan fiduciary is not dispositive of the issue. Rather, it depends on the functions of the entity. *Id.*

⁶⁷ *Id.*

⁶⁸ 461 F.3d 1325 (11th Cir. 2006).

⁶⁹ *Id.* at 1326-27.

⁷⁰ *Id.* at 1327-28.

trial court level “based on lack of standing, failure to state a claim, and failure to exhaust administrative remedies.”⁷¹ Although the plan noted that participants had the right to sue for plan fiduciaries’ breach of their duties, the court explained that this language “merely recites plan participants’ general rights under ERISA and does not excuse a participant from satisfying the exhaustion requirement.”⁷² However, because the Eleventh Circuit concluded that the district court appropriately dismissed the complaint, it did not reach the specific issue of whether Caremark was acting as a plan fiduciary or whether Caremark’s alleged conduct violated its fiduciary duties.⁷³

Central States SE & SW Areas Health and Welfare Fund v. Merck-Medco Managed Care, LLC, was similar to *Bickley* in that the plaintiffs in consolidated class actions alleged that the PBM was a plan fiduciary and had violated its fiduciary duties.⁷⁴ The issue was whether plaintiffs had standing to sue the PBM. Plaintiffs alleged that Medco “systematically misused its fiduciary authority, and its management of formularies and drug-switching programs, among other purposes, (i) to increase the market share in specific drugs of its parent company Merck, and (ii) to divert rebates from drug manufacturers to itself, both at the expense of the Plans.”⁷⁵ At issue before the Second Circuit was whether a proposed class settlement was appropriate as to those class members that were self-funded plans; thus, the court did not reach the issue of whether the PBM was a fiduciary within the meaning of ERISA.⁷⁶

Whether the services of PBMs, or any other entity performing services for a plan, make that entity a fiduciary depends on the extent to which “he exercises any discretionary authority or discretionary control respecting management of such plan or exercises any authority or control respecting management or disposition of its assets . . . or . . . he has any discretionary authority or discretionary responsibility in the administration of such plan.”⁷⁷

PBMs generally insist on language in its contract with the plan sponsor specifically disclaiming fiduciary status. This type of language,

⁷¹ *Id.* at 1328.

⁷² *Id.* at 1329.

⁷³ *Id.* at 1326-27.

⁷⁴ 433 F.3d 181 (2d Cir. 2005).

⁷⁵ *Id.* at 187.

⁷⁶ *Id.*

⁷⁷ 29 U.S.C. § 1002(21) (A) (2000).

though, is not dispositive.⁷⁸ Arguably, PBMs do exercise discretionary authority by virtue of the adjudicatory function they perform with respect to pharmacy claims by plan participants. The effects of the application of ERISA to PBMs' activities include prohibitions under ERISA on self-dealing,⁷⁹ the application of fiduciary standards to the PBMs,⁸⁰ and subjection of the PBMs' activities to reporting and disclosure obligations under ERISA.⁸¹

One state law, Maine's Unfair Prescription Drug Practices Act ("UPDPA"), provides that PBMs are fiduciaries and, as such, have to disclose conflicts of interest and remuneration from (and other types of financial arrangements with) manufacturers.⁸² UPDPA makes each PBM a "fiduciary" to its client and requires disclosure of any conflicts of interest and any remuneration to the PBM by a prescription drug manufacturer or labeler.⁸³ The Act also mandates disclosure of other types of information upon request,⁸⁴ as well as disgorgement of any profits inuring from self-dealing.⁸⁵ Violation of the UPDPA is considered a violation of Maine's Unfair Trade Practices Act.⁸⁶ In *Pharmaceutical Care Management Assoc. v. Rowe*, PBMs successfully challenged their characterization as fiduciaries, arguing that Maine's UPDPA was preempted by ERISA.⁸⁷ However, on appeal, the First

⁷⁸ *Glanton v. ALCOA Prescription Drug Plan*, 465 F.3d 1123 (9th Cir. 2005) (citing *Kayes v. Pac. Lumber*, 51 F.3d 1449, 1458-61 (9th Cir. 1995)).

⁷⁹ 29 U.S.C. § 1106 (2000); *but see* Karen Lee, *Need for PBM Firewalls Comes Tumbling Down*, (Mar. 1, 2002), http://findarticles.com/p/articles/mi_km2922/is_200203/ai_n6927610/print.

⁸⁰ 29 U.S.C. §§ 1104-1105 (2000).

⁸¹ 29 U.S.C. §§ 1021-1031 (2000).

⁸² Act to Protect Against Unfair Prescription Drug Practices, ME. REV. STAT. ANN. tit. 22, § 2699 (2005). The "covered entities" referred to are the PBM's health plan provider customers. *Id.* at (1)(A).

⁸³ *Id.* at (2)(G). *Accord* 320 ILL. COMP. STAT. ANN. 55/25 (West Supp. 2007) (providing that PBMs must disclose any "conflict(s) of interest" with the state's Medicaid program).

⁸⁴ ME. REV. STAT. ANN. tit. 22 § 2699(2)(D).

⁸⁵ *Id.*

⁸⁶ *Id.* at § 2699(4).

⁸⁷ 307 F. Supp. 2d 154 (D. Me. 2004) (holding that ERISA preempts Maine's UPDPA). *See also* 29 U.S.C. § 1144(a) (2000) (stating that ERISA "shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan"). *See generally* Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., 519 U.S. 316, 325 (1997) ("[w]here a State's law acts immediately and exclusively upon ERISA plans . . . or where the existence of ERISA plans is essential to the law's operation" ERISA supersedes the state law); N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 658 (1995); FMC Corp. v. Holliday, 498 U.S. 52, 58-59 (1990); Shaw v. Delta Airlines, 462 U.S. 85, 98 (1983).

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Circuit held that Maine's UPDPA did not "relate to" ERISA plans and therefore was not preempted by ERISA.⁸⁸

In addition to ERISA, the Health Insurance Portability and Accountability Act⁸⁹ ("HIPAA") governs the use of protected health information⁹⁰ while providing for limited regulation of PBMs.⁹¹ Agreements between "covered entities," such as health plans and other organizations that provide services to the covered entity, are required to assure the confidentiality and protection of the private health information.⁹²

The False Claims Act ("FCA") also provides a basis for targeting PBMs practices that may be fraudulent.⁹³ The liability of PBMs under the FCA can be direct liability or indirect liability.⁹⁴ PBMs can also have liability under the Medicaid rebate program, in that the PBM may overstate the price offered to it by the manufacturer if the PBM fails to take into account "certain payments for benefits provided to PBMs by the pharmaceutical manufacturers. . . ."⁹⁵ The FCA, while useful in regulating the PBM industry, is not co-extensive with the industry's business. Individuals who are health plan participants are generally not beneficiaries under Medicare or Medicaid.⁹⁶ Because no claim is made to the government in such cases, the FCA would not apply. The ability of

⁸⁸ Pharm. Care Mgmt. Assoc. v. Rowe, 429 F.3d 294, 305 (1st Cir. 2005).

⁸⁹ See 42 U.S.C. § 1395 (2000) (requiring a written contract between a health plan or other covered entity and the service provider).

⁹⁰ See 45 C.F.R. § 164.501 (2000) (defining protected health information as any information that can be linked to a particular individual).

⁹¹ *Id.*

⁹² See The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (1997). See generally Steven D. Morgan, *Implementing the HIPAA Transaction Standards in Managed Care Pharmacy Settings*, 16:1 HEALTH L. 14 (Nov. 2003).

⁹³ See False Claims Act, 31 U.S.C. § 3729(a) (2000) (prohibiting knowingly presenting a false or fraudulent claim for payment to the government, a prohibition that applies to a large number of PBM transactions, if not to all of them following the enactment of a Medicare prescription drug benefit by Congress).

⁹⁴ See 31 U.S.C. § 3729. Liability under the FCA extends to those who submit false claims or cause false claims to be submitted. This broad coverage of the FCA includes those who submit a claim to another, who then submits a false claim. See, e.g., U.S. of America ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Group, Inc., 400 F.3d 428, 447 (6th Cir. 2005) (interpreting the FCA); U.S. of America ex rel. Totten v. Bombardier Corp., 380 F.3d 488 (D.C. Cir. 2004) (same); U.S. of America ex rel. Sarasola v. Aetna Life Ins. Co., 319 F.3d 1292, 1301 (11th Cir. 2003) (same).

⁹⁵ James G. Sheehan, *Prescription Drug Plans, Fraud Schemes, and the False Claims Act*, 17 TAXPAYERS AGAINST FRAUD 18, 21 (1999).

⁹⁶ See 31 U.S.C. §§ 3729-3733 (2000) (the False Claims Act does contain *qui tam* provisions).

the FCA to limit behavior by the PBM is therefore limited to situations where the government has been defrauded.

Even the Racketeering Influenced and Corrupt Organization Act (“RICO”)⁹⁷ provides a statutory basis for attacking PBM practices.⁹⁸ In *Morse v. Bankers Life & Casualty Co.*,⁹⁹ plaintiffs brought a RICO claim against a PBM. The judge allowed a multi-count fraud action to proceed against several defendants, including a PBM.¹⁰⁰

In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act (“MMA”).¹⁰¹ The MMA created Medicare Part D, which provides for a prescription drug benefit for Medicare Part A and Part B recipients. Prescription drug plans (“PDPs”) offered as part of the MMA must provide beneficiaries with an adequate retail network as well as information about out-of-area coverage. Formularies and drug utilization reviews used in or conducted by these PDPs must meet the requirements set forth under the MMA. PBMs are regulated by the Centers for Medicare & Medicaid Services (“CMS”) under the MMA. CMS is a federal agency within the U.S. Department of Health and Human Services that is responsible for administering Medicare and working with the states to administer state Medicaid programs. CMS regulates the PBM industry under the MMA by establishing regulations regarding rebates, discounts, formularies, mail order, reporting, dispensing fees, and networks.¹⁰² CMS also has the right to review marketing materials prepared under Medicare Part D.¹⁰³ Thus, the MMA (through CMS) regulates the activities of the PBMs that

⁹⁷ Racketeering Influenced and Corrupt Organization Act, 18 U.S.C. §§ 1961-1968 (2000).

⁹⁸ See 18 U.S.C. § 1962(c) (2000). RICO makes it unlawful “for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity.” *Id.* “Racketeering activity” includes, among other offenses, wire and mail fraud. *Id.*; see also *Libertad v. Welch*, 53 F.3d 428, 441 (1st Cir. 1995) (holding that, a plaintiff must plead under RICO’s § 1962(c) the following elements: “(1) conduct; (2) of an enterprise; (3) through a pattern; (4) of racketeering activity”); *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 268 (1992) (holding that predicate acts must be the proximate cause of the plaintiff’s injury); *Reves v. Ernst & Young*, 507 U.S. 170, 176 (1993) (holding that the “conduct” element “requires some participation in the operation or management of the enterprise itself”); *United States v. Turkette*, 452 U.S. 576, 580 (1981) (holding that the “enterprise” must be “a group of persons associated together for a common purpose of engaging in a course of conduct”).

⁹⁹ No. 99 C 0193, 2000 WL 246245 (N.D. Ill. Feb. 2000).

¹⁰⁰ *Id.*

¹⁰¹ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, tit. XI, 117 Stat. 2066 (2003).

¹⁰² 42 C.F.R. § 403.806 (2005); 42 C.F.R. § 423.562 (2005); 42 C.F.R. § 423.871 (2005).

¹⁰³ 42 C.F.R. § 423.50 (2005).

are implementing the Prescription Drug Plans. Medicare, Medicaid, SCHIP, and TriCare are all subject to anti-kickback regulations that apply to PBMs.¹⁰⁴

Additionally, the Food and Drug Administration (“FDA”) published draft regulations about advertising and other promotional practices by PBMs in 1998. The FDA administers the Federal Food, Drug, and Cosmetic Act (“FDCA”)¹⁰⁵ and the regulations implementing it by regulating labeling¹⁰⁶ and promotional activities¹⁰⁷ by manufacturers. The FDA’s “Draft Guidance, therefore, tries to fit these relationships between PBMs and manufacturers into the categories of labeling and manufacturer promotion.”¹⁰⁸ The FDA was concerned about the effects of PBM promotional practices on patient health, as PBMs engage in practices such as drug switching.

Other federal agencies also provide some level of oversight. For example, the Office of the Inspector General of the Department of Health and Human Services participates in the oversight of the PBM industry by issuing compliance guides¹⁰⁹ and providing certain types of safe harbors relating to prescriptions.¹¹⁰ In addition, the Department of Justice enforces the laws and regulations that apply to the PBM industry. It does so by investigating allegations of wrongdoing, negotiating consent orders that relate to anti-kickback laws under Medicare, Medicaid, and TriCare, the military’s benefit plan.

Further, the Federal Trade Commission (“FTC”) provides some oversight of the PBM industry through regulation of business combinations within the industry, its implementation of the regulations

¹⁰⁴ 42 U.S.C. § 1320a-7(b). The terms “kickback” and “bribe” are not defined in 42 U.S.C. § 1320a-7b.

¹⁰⁵ Federal Food, Drug, and Cosmetic Act, 29 U.S.C. §§ 301 (2000).

¹⁰⁶ 21 C.F.R. § 202.1(l)(2) (2000) (stating that labeling “disseminated by or on behalf” of the manufacturer constitutes labeling for the purposes of the Act).

¹⁰⁷ 21 C.F.R. § 202.1(k) (defining regulated advertisements as those “issued or caused to be issued” by the manufacturer).

¹⁰⁸ Johnson, *supra* note 5, at 337 (quoting James G. Sheehan, *Fraud and Abuse in the Marketing of Ethical Pharmaceuticals Through Pharmacy Benefit Management Programs*, 15 FOOD DRUG COSM. & MED. DEVICE L. DIG. 49, 52 (1998)).

¹⁰⁹ 67 Fed. Reg. 62057-03 (Oct. 3, 2002). See generally, *OIG Pharma Guidelines have Implications for PBMs, Payers*, (July 11, 2003), http://findarticles.com/p/articles/mi_m0NKV/is_7_4/ai_105645099.

¹¹⁰ 42 C.F.R. § 1001.952.

regarding antitrust conspiracies,¹¹¹ and its implementation of the Federal Trade Commission Act's prohibition of "unfair methods of competition"¹¹² and "unfair or deceptive acts or practices."¹¹³ The FTC administers the Hart-Scott-Rodino Act, which requires pre-merger notification to the FTC.¹¹⁴ Also, the FTC issues regulations and guidance to the PBM industry in the area of consumer advertising.¹¹⁵

Finally, federal antitrust laws apply to PBMs, just as to other entities. Antitrust claims have been brought under section 16 of the Clayton Act¹¹⁶ which allows "[a]ny person, firm, corporation, or association" to seek injunctive relief against threatened loss or "damage by a violation of the antitrust laws . . ."¹¹⁷ and under section 1 of the Sherman Act, which prohibits "[e]very contract, combination . . . or conspiracy, in restraint of trade."¹¹⁸

B. State Regulation of PBMs

State oversight of PBMs falls under the aegis of several state agencies. These include boards of pharmacy, state insurance commissioners, and state Medicaid agencies. State boards of pharmacy regulate PBMs only to the extent that the PBM operates a mail order or internet fulfillment facility in the state.¹¹⁹ In these states, the PBM is

¹¹¹ Ruth Barber Timm, *The Intraenterprise Conspiracy Doctrine and the Pharmaceutical Benefit Management Industry: A Proposed Exception to the Copperweld Holding*, 31 VAL. U. L. REV. 309 (1996).

¹¹² 15 U.S.C. § 45 (2000) (prohibiting "unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices. . .").

¹¹³ *Id.*

¹¹⁴ Hart-Scott-Rodino Act, Pub.L. No. 94-435, 90 Stat. 1383, 1390 (1976). The Hart-Scott-Rodino Act lays out a three-part test for pre-merger notification to the FTC. *Id.*

¹¹⁵ See Staff of the Federal Trade Commission, *In the Matter of Request for Comments on Agency Draft Guidance Documents Regarding Consumer-Directed Promotion*, Public Hearing Dkt. No. 2004D-0042, Comments Before the Dept. of Health & Human Serv. Food & Drug Admin. (May 10, 2004).

¹¹⁶ Clayton Act, 15 U.S.C. § 26 (2000).

¹¹⁷ *Id.*

¹¹⁸ 15 U.S.C. § 1 (2000). See also *NYNEX Corp. v. Discon, Inc.*, 525 U.S. 128, 133 (1998) (holding that to be violative of this provision, the action must unreasonably restrain trade); *U.S. v. Container Corp. of Am.*, 393 U.S. 333, 337 (1969) (holding that price fixing has been held to be a per se violation of Section 1 of the Sherman Act); *U. S. v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 223 (1940) (same); *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977); *Eichorn v. AT&T*, 248 F.3d 131, 140 (3d Cir. 2001) (holding that even if the actions complained of are per se illegal, the plaintiff must still allege and prove an antitrust injury).

¹¹⁹ See NCPA Model Bill, *Pharmacy Benefit Manager Licensure and Solvency Protection Act*, <http://www.nlarx.com/modelleg/pdfs/NCPA-PBMBill.pdf>. The National Community Pharmacists Association ("NCPA"), the industry organization that represents independent

regulated like any other retail or mail order pharmacy facility. Some states regulate claims processing performed by PBMs.¹²⁰ State Medicaid agencies also regulate claims processing and drug utilization review services by the PBMs.¹²¹ Finally, states may regulate the activities of PBMs through their consumer protection laws, such as unfair competition laws and consumer fraud laws.¹²² For example, many states have antitrust laws based on the Uniform State Antitrust Act.¹²³ States may also have their own versions of anti-kickback laws. These laws prohibit pharmacists from accepting payments for referrals or to promote the sales of goods or services.

The National Association of Health Insurance Commissioners's ("NAIC") Health Insurance and Managed Care Committee created the Pharmaceutical Issues Working Group to consider state-level and other regulation of PBMs. The NAIC drafted model legislation on prescription drug benefit management activities. The ability of NAIC members to

pharmacies, has developed model legislation providing for state boards of pharmacy and insurance commissioners to monitor the activities and financial stability of PBMs. *Id.* The NCPA believes that PBMs are practicing pharmacy and should, therefore, be regulated as pharmacies. *Id.* The NCPA's model bill provides for a license specifically for PBMs. *Id.*

¹²⁰ FLA. STAT. ANN. § 627.6131 (West 2005).

¹²¹ See 42 C.F.R. § 456.722(a) (2000). The regulation states:

Each Medicaid agency, at its option, may establish, as its principal (but not necessarily exclusive) means of processing claims for covered outpatient drugs, a point-of-sale electronic claims management (ECM) system to perform on-line, real-time (that is, immediate) eligibility verifications, claims data capture, adjudication of claims, and to assist pharmacists and other authorized persons (including dispensing physicians) in applying for and receiving payment.

Id. The regulations go on to set minimum systems functional requirements. *Id.* at 456.722(b) & (c).

¹²² See, e.g., ARIZ. REV. STAT. ANN. § 44-1521 (2007); CAL. BUS. & PROF. CODE § 17200 Ch. 2-A (2007); CONN. GEN. STAT. § 42-110b (2007); DEL. CODE ANN. Tit. 6 § § 2511, 2531 (2007); FLA. STAT. ANN. §501.201 (2007); 815 ILL. COMP. STAT. ANN. 504/1 (West 1998); IOWA CODE ANN. § 714.16 (West 2007); LA. REV. STAT. ANN. §§ 51:1410, 15:1410 (2007); ME. REV. STAT. ANN. Tit. 5, §205-A (2007); MD. CODE ANN., COM. LAW. § 13-101 (West 2007); MASS. GEN. LAWS ANN. Ch. 93A, §1 (West 2007); NEV. REV. STAT. ANN. § 598.0903 (West 2007); N.Y. GEN. BUS. LAW §§ 349-350, 63(12) (McKinney 2007); N.C. GEN. STAT. ANN. § 75-1.1 (West 2007); OR. REV. STAT. ANN. § 646.605-646.656 (West, 2007); 73 PA. CONS. STAT. ANN. § 201-1 (West 2007); TEX. BS. & COM. CODE ANN. § 17.47 (Vernon 2002); VT. STAT. ANN. tit. 9 § 2451 (West 2007); VA. CODE ANN. § 59.1-196 (West 2007); WASH. REV. CODE ANN. § 19.86.010 (West 2007).

¹²³ See, e.g., ARIZ. REV. STAT. ANN. § 44-1401 (2007); CAL. BUS. & PROF. CODE § 17200 Ch. 2-A (2007); D.C. CODE § 28-4501 (2007); FLA. STAT. ANN. §542.15 (2007); KAN. STAT. ANN. § 50-101 (2007); LA. REV. STAT. ANN. § 51:121 (2007); ME. REV. STAT. ANN. tit. 5, § 205-A (2007); MASS. GEN. LAWS ANN. Ch. 93A, § 1 (West 2007); MICH. COMP. LAWS ANN. § 445.771 (West 2007); N.J. STAT. ANN. § 56:9-1 (West 2007); N.Y. GEN. BUS. LAW § 340 (McKinney 2007); TENN. CODE ANN. § 47-25-101 (West 2007); WIS. STAT. ANN. § 133.01 (West 2007).

affect the regulation of PBMs is limited, however, because state insurance commissioners may only regulate health insurers. Arguably, unless a health plan is capitated, the PBM is not providing health insurance.¹²⁴ For these reasons, state insurance commissioners have only a limited ability to influence the activities of PBMs.

In addition, to the extent that a PBM assumes some of the risk associated with a particular pharmacy plan, state departments of insurance may regulate the entity.¹²⁵ PBMs may also be regulated by state departments of insurance depending on the structure of the pharmacy plans the PBMs design for their health plan clients. In some instances, PBMs may charge a flat fee or a fee per covered life, agreeing to assume the risk that the actual pharmaceutical expenses will exceed this fee. The contract between the health plan and the PBM might also be negotiated to require that a portion of the PBM's fee is placed "at risk" and depends on the PBM's performance. For example, AdvancePCS describes its rebate guarantees as follows:

Agreements with certain health plan sponsor customers contain provisions that require us to obtain a minimum rebate per claim from pharmaceutical manufacturers in order to generate additional savings for health plan sponsor customers. Failure to achieve the minimum rebate per claim results in an obligation by us to the health plan sponsor customer. The obligation is equivalent to the difference between the actual rebate per claim obtained and the minimum stated in the health plan sponsor customer agreement, which is then multiplied by the number of claims processed in a specified period. We continually monitor the health plan sponsor customers' rebate per claim and recognize

¹²⁴ MASS. GEN. LAWS ANN. Ch. 176D, §3B (West 2007) (enacting "any willing provider" statutes that apply to pharmacy networks, as well as other types of networks). *See, generally* Ky. Assoc. of Health Plans, Inc. v. Nichols, 227 F.3d 352, 363 (6th Cir. 2000), *aff'd sub nom.* Ky. Assoc. of Health Plans, Inc. v. Miller, 538 U.S. 329 (2003) (holding that an "any willing provider" law did not violate ERISA's preemption of state laws).

¹²⁵ *See State Insurance Commissioners Weigh PBM Regulations This Month*, MANAGED CARE MAG. (Mar. 2000), <http://www.managedcaremag.com/archives/0003/0003.states.html>. PBMs sometimes enter into capitated agreements with health plans under which the PBM charges a fixed, or capitated, fee for all covered lives. *Id.* Under this type of arrangement, the PBM assumes the risk of losses in excess of amounts charged. *Id.* When PBMs enter into capitated agreement, they may become subject to regulation by the state's insurance commission. *Id.*

a liability when it appears unlikely the average rebate per claim will meet or exceed the stated minimum.¹²⁶

Existing agencies and state regulations have been insufficient to address the issues identified in Part IV of this article. For these reasons, several states have proposed new legislation that specifically targets PBMs. PBMs have fought against these proposed disclosure statutes, which have often been supported by retail pharmacies.¹²⁷

Thus, some states have considered, but not yet adopted, legislation patterned on the NCPA's model bill.¹²⁸ In several other instances, statutes regulating at least some of the PBMs' business practices or requiring the licensure within the state have been considered.¹²⁹

The District of Columbia also passed a law to regulate PBMs.¹³⁰ The Access Rx Act, as it is known, requires PBMs to act as fiduciaries, to notify health plans of any conflicts of interest, to pay over all payments or rebates received from drug manufacturers, and to disclose all financial terms with manufacturers upon request.¹³¹ That Act is now in litigation and its effective date has been suspended by a court injunction. The Pharmaceutical Care Management Association sued the District of Columbia and was granted injunctive relief because the United States District Court for the District of Columbia found that plaintiffs would suffer irreparable harm if the District of Columbia was allowed to enforce the Act.¹³² The plaintiff specifically challenged those portions of the act that imposed fiduciary duties on PBMs¹³³ and required them to

¹²⁶ Advance PCS, Annual Report (Form 10-Q), at 54 (Aug. 13, 2003), <http://sec.edgar-online.com/2003/08/13/0001193125-03-036190/Sectin9.asp>.

¹²⁷ Rob Eder, *Nothing More 'transparent' than PBM Posturing—Prescription Benefit Management*, DRUG STORE NEWS (Sept 22, 2003), http://findarticles.com/p/articles/mi_m33374/is-12-25/ai_108969842/print.

¹²⁸ See, e.g., H.B. 493, 421st Leg. (Md. 2006); H. File 1989, 84th Leg. (Minn. 2005); H.B. 1374 (N.C. 2005); H.B. 714 (Pa. 2005); S.B. 828 (S.C. 2005).

¹²⁹ See, e.g., H.B. 171 (Ala. 2006); S.B. 483, 580 (Conn. 2006); H.B. 516 (Del. 2006); H.B. 31 & S.B. 1440 (Haw. 2005); S.B. 2799 (Ill. 2006); H.B. 160 & S.B. 181 (Iowa 2005); H.B. 5442 & S.B. 2697 (Miss. 2006); S.B. 2697 (Miss. 2006); H.B. 1247 N.H. 2006); S.B. 1291 (N.J. 2006); S.J. Memorial 22, 47th Leg. (N.M. 2006); H.B. 2392 (Okla. 2006); S.B. 2247 (R.I. 2006); S.B. 2847 & H.B. 2971 (Tenn. 2006); SB. 261 (Vt. 2006); H.B. 945, 2473 (Va. 2006); H. Con. Res. 81, 78th Leg. (W. Va. 2006).

¹³⁰ D.C. CODE § 48-831.01 (2001) *et seq.*

¹³¹ *Id.*

¹³² Memorandum Opinion Granting Plaintiff's Motion for Injunctive Relief (Dec. 21, 2004), *Pharmaceutical Care Mgmt. Assoc. v. The District of Columbia*, CV 04-1082 (D.D.C.). The plaintiff argued that the Act was preempted by ERISA and that the Act violated the Takings and Commerce Clauses of the United States Constitution. *Id.*

¹³³ D.C. CODE § 48-832.01 (2001).

make certain financial disclosures.¹³⁴ The Access Rx Act also regulates PBMs' drug switching practices.¹³⁵

Additionally, Georgia passed legislation in 2002 that requires licensure of PBMs as pharmacies and allows for inspection of PBM premises, whether located in Georgia or elsewhere.¹³⁶ In 2006, Georgia passed another law that provides for audit rights by third party payors dealing with PBMs.¹³⁷

Numerous other states have passed statutes regulating PBMs, including Kansas, which passed legislation in 2006 that requires PBMs to register with the state's insurance commissioner.¹³⁸ Also, Maryland passed a law in 2003 that requires the State's Insurance Department to examine PBMs at least triennially.¹³⁹ Louisiana also regulates PBMs as a third party administrator under state insurance regulations.¹⁴⁰ Similarly, Mississippi has subjected PBMs to some oversight by the state Insurance Department. Mississippi's Pharmacy Benefit Prompt Pay Act, passed in 2006, requires PBMs to file financial statements with the state Insurance Department, use nationally recognized pricing databases, and pay claims within fifteen days.¹⁴¹ North Dakota requires that PBMs register as an administrator with that state's insurance department, disclose ownership of the PBM, comply with certain requirements regarding drug substitution, offer to health plans a transaction fee without sharing payments received from drug manufacturers, and allow health plans to audit the PBM's books.¹⁴² Rhode Island also requires PBMs to register as third party administrators and to file annual reports with the state insurance commissioner that includes a complete description of all financial arrangements between the PBM and other entities, such as drug manufacturers.¹⁴³ Additionally, South Dakota requires registration of the PBM as a third party administrator, requires the PBM to perform its duties in the exercise of good faith and fair dealing, requires the PBM to

¹³⁴ *Id.* at § 48-832.01(c)(1)(A).

¹³⁵ *Id.* at § 48-832.01(d).

¹³⁶ GA. CODE ANN. § 26-4-110.1 (West 2007).

¹³⁷ GA. CODE ANN. § 26-4-118 (West 2007).

¹³⁸ KAN. STAT. ANN. § 40-3821 (2006).

¹³⁹ MD. CODE ANN., INS. § 15-10B-20 (2007).

¹⁴⁰ LA. REV. STAT. ANN. § 22:3031 (2007).

¹⁴¹ MISS. CODE ANN. § 73-21-126 (2007).

¹⁴² N.D. CENT. CODE § 26.1-27-02-07 (2007).

¹⁴³ R.I. GEN. LAWS § 27-29.1 (2007).

disclose rebate and other revenues, and gives the health plan audit rights.¹⁴⁴

Finally, Maine passed a law regulating PBMs in June of 2003.¹⁴⁵ The Maine law provides that PBMs are fiduciaries and must act “with care, skill, prudence and diligence and in accordance with the standards of conduct applicable to a fiduciary in an enterprise of like character and with like aims.”¹⁴⁶ Under the statute, the PBM must provide all financial information requested by the health plan and must transfer to the plan any payments received from drug manufacturers for drug substitutions.¹⁴⁷

In September of 2004, the PBM industry group, the PCMA, filed suit in the United States District Court in Maine seeking to enjoin the law on the basis of ERISA preemption. The PBM industry argued before the law’s passage that it would destroy the competitive market for drugs, compromise PBM trade secrets, conflict with ERISA and FEHBA, violate the takings and due process clauses of the United States and state constitutions,¹⁴⁸ and would have allowed unfettered enforcement under state unfair trade practices acts.¹⁴⁹ Maine’s law, like that of the District of Columbia, would have characterized PBMs as fiduciaries. As a fiduciary, the PBM would have disclosure obligations and would be prohibited from self-dealing. PBMs have fought characterization as fiduciaries in the past.¹⁵⁰ When PBMs negotiate with health plans they typically insist on a provision that specifically states that they are not plan fiduciaries, though the contract language is not dispositive of the issue. Maine’s law was an example of legislators’ attempt to divide and conquer. The law would have grandfathered and exempted some PBMs, while others would have been subject to all of the law’s provisions.

¹⁴⁴ S.D. CODIFIED LAWS § 58-29E (2007).

¹⁴⁵ ME. REV. STAT. ANN. tit. 22, § 2699 (2007).

¹⁴⁶ *Id.* at § 2699(2)(A).

¹⁴⁷ *Id.* at § 2699(2)(D).

¹⁴⁸ See *Pharmaceutical Care Mgmt. Assoc. v. Rowe*, 307 F. Supp. 2d 164, 178-79 (D. Me. 2004), *aff’d* 429 F.3d 294 (1st Cir. 2005), *cert. denied*, 126 S. Ct. 2360 (2006) (finding that mandatory disclosure requirements under Maine’s UPDPA could destroy the value of the PBMs’ trade secrets); *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1003-04 (1984); see also *Philip Morris, Inc. v. Reilly*, 312 F.3d 24, 47 (1st Cir. 2002) (*en banc*) (holding that the protection afforded by the Takings Clause includes protection of intangible property, such as trade secrets).

¹⁴⁹ Milt Freudenheim & Robert Pear, *More Disclosure for Drug Plans*, N.Y. TIMES, July 19, 2003.

¹⁵⁰ See *In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 398 (3d Cir. 2000).

In addition to passing legislation to rein in PBMs, states can affect PBMs through their own contracting processes.¹⁵¹ When a state sends a request for proposals (“RFP”) to the various PBMs, the state can require the PBMs to promise a degree of pricing transparency, reporting, and audit rights. When the low-cost PBM is selected, the state’s contract with that PBM should include the pricing and reporting provisions necessary to assure appropriate pricing, transparency, and audit rights.

IV. IMPACT OF THE LACK OF TRANSPARENCY AND INADEQUATE REGULATION

The PBMs are the common counterparty with health plans, retail pharmacies, and drug manufacturers. Thus, no single entity of these entities knows the economics of the transactions with the other counterparties. This lack of transparency has created an environment in which PBMs may engage in practices that involve self-dealing or that are prohibited under various laws. Examples of these practices include drug switching, channeling certain prescriptions to the PBMs’ own mail order or specialty pharmacies, and certain rebate and pricing practices. The PBMs, which are ostensibly hired by health plans as the agents for those plans to negotiate with manufacturers and retail pharmacies, hide from their own clients what they pay for prescriptions and often fail to disclose appropriate information regarding rebates.¹⁵² One industry expert who has studied PBMs for years stated:

What seems clear from this navigation of the PBM maze is that prescription benefit plan sponsors (either private employers or government entities) should insist on full disclosure of cash flows to and through the PBM that is administering their drug benefit. Without this level of scrutiny, the plan sponsor cannot be sure if its PBM is providing a good service for a fair price or is acting primarily in its own interest.¹⁵³

¹⁵¹ See generally Kimberley Fox et al., *State Pharmacy Discount Programs: A Viable Mechanism for Addressing Prescription Drug Affordability?*, 60 N.Y.U. ANN. SURV. AM. L. 187 (2004).

¹⁵² Davis, *supra* note 9. (“[T]he giant PBMs continue to hide plenty from their own clients in the name of competition. Many PBMs refuse to show exactly what they pay for prescriptions because, they say, manufacturers—and not customers—would benefit from such knowledge.”).

¹⁵³ Robert I. Garis et al., *Examining the Value of Pharmacy Benefit Management Companies*, AM. J. HEALTH-SYS. PHARMACISTS, 81, 85 (2004).

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The PBM industry argues that legislation mandating disclosure will harm the PBM industry and reduce the discounts that the PBMs are able to negotiate on behalf of health plans. This argument is based on a study performed on behalf of the Pharmaceutical Care Management Association by PriceWaterhouseCoopers, stating that disclosure of this type "is not required of other healthcare organizations. In a competitive environment, the ability to negotiate in confidentiality is paramount. Without such confidentiality, competition, and the benefits derived from it, is eroded. Those benefits include lower costs achieved through a competitive model."¹⁵⁴

Yet, this argument is contradicted by South Dakota's recent experience. As noted previously, in 2004, South Dakota passed transparency legislation of the type opposed by the PCMA.¹⁵⁵ Despite the passage of the legislation, pharmacy prices in South Dakota appear to be no higher than prices elsewhere. In addition, although PBMs fought the legislation by arguing that they would be forced to leave South Dakota, none have done so since the legislation's enactment.

PBMs are concerned that transparency legislation would require the *public* disclosure of information such as: (1) agreements with manufacturers regarding rebates, discounts, and incentives; (2) agreements favoring one manufacturer's product over another; (3) agreements regarding whether a product will be placed on (or removed from) a formulary list; and (4) agreements regarding how much the PBM bills the client or reimburses the pharmacy.¹⁵⁶ In other words, if transparency legislation were passed, the PBMs would be forced to compete on the basis of price, rather than on the basis of obfuscation. The PBMs argue the manufacturers and retail pharmacies would be less willing to negotiate aggressively with PBMs if they knew that the agreement would be made public.¹⁵⁷

David Balto, former policy director for the Federal Trade Commission's Bureau of Competition, has observed that these PBM arguments "are inconsistent with economic theory, antitrust law and common sense To the contrary, greater transparency will enhance

¹⁵⁴ *The Value of Pharmacy Benefit Management and the National Cost Impact of Proposed PBM Legislation*, at 16 (July 2004).

¹⁵⁵ S.D. CODIFIED LAWS § 58-29E (2007).

¹⁵⁶ *The Value of Pharmacy Benefit Management and the National Cost Impact of Proposed PBM Legislation*, at 16 (July 2004).

¹⁵⁷ *Id.* at 17.

competition and lower prices.”¹⁵⁸ Economists generally agree that transparent pricing ensures survival of the best firms and will result in lower prices as the firms compete with each other for market share.¹⁵⁹ An antitrust attorney recently characterized PBMs as having an oligopoly and contended that it is “patently absurd” to assume that manufacturers would stop offering rebates if transparency were increased.¹⁶⁰ Arguably, the market power that PBMs wield stems both from market share and also from the paucity of information available to those who deal with the PBMs.¹⁶¹

Transparency can be especially important in controlling costs in the healthcare arena, as has been demonstrated in other fields. For example, in *FTC v. Indiana Federation of Dentists*,¹⁶² the Supreme Court found that a conspiracy among dentists to refuse to provide x-rays to managed care providers suppressed competition.¹⁶³ Where a third party, even a buying consortium, acts as an intermediary between willing buyers and

¹⁵⁸ See Eder, *supra* note 127.

¹⁵⁹ Jack Gynn, President & CEO, Fed. Res. Bank of Atlanta, Keynote Address at the Carter Center Conference on “Transparency for Growth in the Americas” (May 4, 1999):

[T]he benefits of transparency . . . far outweigh the costs; that in the long run all of these things lead to greater economic growth and stability; and that the benefits ultimately accrue to the individual and society as a whole. . . . [I]n a market for goods in which quality varies and in which the seller has more information about the quality of the goods being offered than the buyer, good products and bad products must sell at the same price. When buyers have no way to distinguish between products — when they are forced to assume the worst — the market price tends to be the lemon price, and good sellers eventually leave the market. Thus do bad cars, bad money — bad whatever — drive out the good.

“The purchaser’s problem . . . is to identify quality.” [Professor] Akerlof said, “There may be potential buyers of good quality products and there may be potential sellers of such products in the appropriate price range; however, the presence of people who wish to pawn bad wares as good wares tends to drive out the legitimate business. The cost of dishonesty, therefore, lies not only in the amount by which the purchaser is cheated; the cost also must include the loss incurred from driving legitimate business out of existence.”

Id.

¹⁶⁰ See Eder, *supra* note 127.

¹⁶¹ See, e.g., *Bates v. State Bar of Ariz.*, 433 U.S. 350, 377-78 (1977) (noting that restrictions on pricing transparency “increase the difficulty of discovering the lowest cost seller” and “perpetuate the market position of established” sellers); DENNIS W. CARLTON & JEFFREY M. PERLOFF, *MODERN INDUSTRIAL ORGANIZATION* 431 (2000).

¹⁶² 476 U.S. 447 (1986).

¹⁶³ *Id.* at 454-55.

sellers dealing on an arm's length basis, this can constrain the buyers and sellers from independently reaching an appropriate price.¹⁶⁴

Aside from the economic argument regarding the pricing impact of non-transparent business practices, there have been several suggestions, primarily in litigation against the PBMs, that these entities engage in a number of illegal business practices. These include drug switching,¹⁶⁵ channeling prescriptions to entities owned by the PBMs, and various other rebate and pricing schemes. A number of lawsuits have been brought around the country against the PBMs for these practices.

A. Drug Product Switching

The business model used by PBMs allows them to engage in drug product switching, which occurs when a prescription is switched from one drug to another that has similar therapeutic characteristics and will not change the patient's health outcome differently than the first drug. Switching can occur because of the influence PBMs exercise on doctors¹⁶⁶

¹⁶⁴ *Kartell v. BCBS of Mass.*, 749 F.2d 922, 924 (1st Cir. 1984) (noting that Blue Cross intervened in the market to keep buyers and sellers from reaching arm's length agreements on pricing and service); *see also Austin v. BCBS of Ala.*, 903 F.2d 1385, 1391 (11th Cir. 1990). In *Austin*, the court noted that where the purchaser sets pricing, it may be predatory pricing. *Id.* The issue identified by the *Austin* court was "whether, standing alone, Blue Cross' use of its market power to gain lower rates for its subscribers from hospitals violate[d] the Sherman Act." *Id.* at 1390. The *Austin* court looked to *Travelers Insurance Company v. Blue Cross of W. Pa.*, 481 F.2d 80 (3d Cir. 1973), *cert. denied*, 414 U.S. 1093 (1973), in which the Third Circuit stated:

In its negotiating with hospitals, Blue Cross has done no more than conduct its business as every rational enterprise does, i.e., get the best deal possible. This pressure encourages hospitals to keep their costs down; and, for its own competitive advantage, Blue Cross passes along the saving thus realized to consumers. To be sure, Blue Cross' initiative makes life harder for commercial competitors such as Travelers. The antitrust laws, however, protect competition, not competitors; and stiff competition is encouraged, not condemned.

Id. at 84.

¹⁶⁵ Milt Freudenheim, *Medco to Pay \$29.3 Million to Settle Claims of Drug Switching*, N.Y. TIMES, Apr. 27 2004 at C1.

¹⁶⁶ Victoria Stagg Elliott, *Physicians Say No to Automatic Therapeutic Drug Substitutions*, 44 AM. MED. NEWS, Jan. 8, 2001, <http://www.ama-assn.org/amendnews/2001-01-01h1120101.htm>; *cf.* AM. MEDICAL ASSOC., CODE OF MEDICAL ETHICS § 8 (2006-2007) (stating that physicians must not allow their professional judgment to be influenced by inappropriate outside persuasion); American Medical Association Opinion E-8.06, *Prescribing and Dispensing Drugs and Devices*, <http://www.ama-assn.org/ama/pub/category/8483.html> (same).

and individual consumers through advertising¹⁶⁷ and through the PBM's disease management businesses.¹⁶⁸ Some scholars have written about the practice of switching¹⁶⁹ as a possible violation of the anti-kickback law.¹⁷⁰

The states have been active in suing PBMs to curb perceived pricing abuses and to recover for past abuses. For example, in April of 2004, attorneys general from twenty states settled claims under state deceptive trade practices laws against Medco Health Solutions, Inc.¹⁷¹ The complaint alleged unfair trade practices and that Medco encouraged therapeutic switching, or switching patients from a lower cost or generic drug to a brand name drug to allow the PBM to earn higher rebates or incentive payments. According to the lawsuit, Medco did not pass its savings from therapeutic switching on to patients or health plan sponsors. Eliot Spitzer, in response, stated: "This case shows how [PBMs] previously hid from consumers, doctors and health plans that they were switching prescriptions to promote their own profits."¹⁷² Health plans are concerned about drug switching because, although the drugs may address the same condition, a switch from one drug to another often requires follow-up testing and office visits, all of which come at a cost to the plan.

The suit settled in April 2004, with Medco agreeing to pay \$20.2 million to the states, \$6.6 million in fees and costs, and \$2.5 million to patients.¹⁷³ The Consent and Stipulation entered into by Medco prohibits

¹⁶⁷ PR Mansfield et al., *Direct to Consumer Advertising is at the Crossroads of Competing Pressures from Industry and Health Needs*, BRITISH MEDICAL J. 330:5-6 (Jan. 1, 2005), available at <http://www.chspr.ubc.ca/node/116>.

¹⁶⁸ Bruce Ingersoll, *Drugs: FDA to Watch Drug Switching, Sales Practices*, WALL ST. J., JAN. 6, 1998, at B1 (stating that the idea behind disease management programs is that non-compliance with prescription drug regimes is likely to result in higher costs to the health plan because lack of compliance can lead to emergency room visits or hospital stays).

¹⁶⁹ See Mark A. Hall, *Institutional Control of Physician Behavior: Legal Barriers to Health Care Cost Containment*, 137 U. PA. L. REV. 431, 467-74 (1988); see also Learn, *supra* note 57, at 249; Thomas N. Bulleit, Jr. & Joan H. Krause, *Kickbacks, Courtesies or Cost-Effectiveness?: Application of the Medicare Anti-kickback Law to the Marketing and Promotional Practices of Drug and Medical Device Manufacturers*, 54 FOOD & DRUG L.J. 279, 309 (1999).

¹⁷⁰ 42 U.S.C. § 1320a-7b(b) (defining "remuneration" as "including any kickback, bribe or rebate").

¹⁷¹ See Press Release, New York Attorney General, *19 States Settle Deceptive Trade Practices Claims Against Medco Health Solutions* (Apr. 26, 2004), http://www.oag.state.ny.us/press/2004/apr/apr26b_04.html.

¹⁷² *Id.*

¹⁷³ Press Release, U.S. Dep't of Justice, *The United States Settles Its Anti-Fraud Claims for Injunctive Relief and 20 State Attorneys General Settle Unfair Trade Practices Claims Against*

the company from soliciting drug switches in situations where the PBM benefits at the expense of these other parties. Medco also agreed to take certain prospective steps, such as disclosing to prescribers and patients any financial incentives Medco has for drug switching.¹⁷⁴ In addition, Medco must comply with certain forward-looking disclosure obligations, must establish processes to obtain express permission to switch drugs, must monitor the health effects of drug switches, and must adopt the code of ethics of the American Pharmacists Association.¹⁷⁵

The Prescription Access Litigation Project, the American Federation of State, County, and Municipal Employees, and the AFL-CIO filed another significant lawsuit in 2003 against Advance PCS, Express Scripts, Medco Health Solutions, and Caremark.¹⁷⁶ The plaintiffs alleged that the PBMs negotiated lower prices with drug manufacturers, but failed to pass those cost savings on to the plans they represented, artificially inflating prices.¹⁷⁷ According to the President of AFSCME, "It's corporate greed like this that is chipping away at the paychecks of hard working men and women across the country."¹⁷⁸

B. Channeling Prescriptions to PBM-Owned Businesses

The use of mail order as a prescription fulfillment channel has increased in the past few years and litigation relating to mail order fulfillment by PBMs is likely to increase in the near future.¹⁷⁹ For health plan participants, mail order provides convenience and can also provide for a lower copay, as the copay for a ninety-day supply of drugs will generally be less than the copays for three thirty-day supplies. Concerns about mail order fulfillment exist largely because the major PBMs operate their own mail order facilities, giving them an additional opportunity to profit from transactions by health plan participants.

Medco Health Solutions (Apr. 26, 2004), <http://www.usdoj.gov/usao/pae/News/Pr/2004/apr/medcoinjunctivereliefrelease.pdf>.

¹⁷⁴ *Id.*

¹⁷⁵ American Pharmacists Association, *Code of Ethics for Pharmacists* (adopted Oct. 27, 1994), <http://www.aphanet.org/AM/Template.cfm?Section=Home&CONTENTID=2654&TEMPLATE=/CM/HTMLDisplay.cfm>.

¹⁷⁶ *AFSCME v. AdvancePCS*, No. BC 292227 (Cal. Super. Ct., Los Angeles Cty. Apr. 4, 2003).

¹⁷⁷ *Id.*

¹⁷⁸ Press Release, AFSCME, *Pharmacy Benefit Managers Charged with Inflating Prescription Drug Prices Lawsuit Alleges Secret Deals between PBMs & Pharmaceutical Companies* (Mar. 18, 2003), <http://www.badfaithinsurance.org/reference/LMCOPBM/0010a.htm>.

¹⁷⁹ Judith A. Waltz, *Multimillion Dollar Settlement Signals Government's Increased Scrutiny of Pharmaceutical Industry*, 13 DRUG BENEFIT TRENDS 15, 15-16 (2001), <http://www.medscape.com/viewarticle/414901>.

Fulfillment through mail order facilities operated by the PBMs can increase costs to health plans in several ways. First, generic dispensing in PBM-owned facilities is increasing and mail tends to employ higher spreads on generic drugs than retail pharmacy dispensing.¹⁸⁰ The enhanced generic spread in mail order fulfillment comes in addition to the rebates PBMs receive for brand drug dispensing. Second, PBMs may channel patients toward higher-priced drugs through switching. The mail order facility has a call center whose task is to contact physicians and switch patients to the “preferred” (rebateable) drugs. Third, they may also fulfill prescriptions for high-priced specialty pharmaceuticals themselves. Fourth, they may channel prescriptions through their own fulfillment facility, rather than to the facility that can fill the prescription the most inexpensively. Fifth, they charge the plan for processing the transaction, both as a PBM and as a fulfiller. Sixth, waste is higher for mail order fulfillment because plan sponsors pay for a ninety-day supply of a prescription that may or may not work for a particular participant.¹⁸¹ If the prescription does not work, the participant must then have another prescription filled.

A study that was funded by retail pharmacies noted that PBMs might steer participants to higher priced drugs on which the PBMs earn higher rebates.¹⁸² For example, a mail order facility may be less inclined to channel a participant toward a generic drug, when the PBM that owns the mail order facility makes more in rebates on the brand name drug. Another area of increased profits relating to PBM mail order practices

¹⁸⁰ Press Release, Caremark Rx, Inc., *Caremark Rx, Inc. Reports Second Quarter 2006 Earnings: Company Raises Full Year 2006 Earnings Guidance* (Aug. 8 2006), <http://sec.edgar-online.com/2006/08/08/0001193125-06-164865/Section2.asp> (stating “Mail pharmacy revenues increased 11% to \$3.2 billion and mail pharmacy claims were 15.2 million, up 5% from the second quarter of 2005.”); Press Release, *Express Scripts, Inc., 9.5 Million Shares Repurchased During the Quarter* (July 26, 2006), <http://phx.corporate-ir.net/phoenix.zhtml?c=69641&p=irol-newsArticle&ID=888008&highlight=> (“As a result of the success of our formulary strategy, and strong underlying trends for continued growth in generic utilization, specialty pharmacy and home delivery, we are raising our 2006 earnings guidance.”); Press Release, *Medco Health Solutions, Inc., Medco Reports Second-Quarter 2006 GAAP Earnings of \$0.56 per Share* (Aug. 4, 2006), <http://www.alacrastore.com/storecontent/newstex/PRN-000510024901> (“The sequential increase in EBITDA per adjusted prescription was driven primarily by an 80 basis point increase in the generic dispensing rate at mail, an increase in adjusted mail penetration, and stronger Accredo Health Group margins.”).

¹⁸¹ Norman V. Carroll et. al., *Comparison of Costs of Community and Mail Service Pharmacy*, 45 J. AM. PHARM. ASSOC. 336, 336-43 (2005) (“The available evidence suggests that the wastage rate for mail service pharmacies is about two times greater than that for community pharmacies.”).

¹⁸² Langenfeld, *supra* note 21.

would be inflation of AWP by use of relabeled drugs, although this is less prevalent today than it was a few years ago. Another concern is whether the PBMs allow for a three-month prescription to be filled only at their own mail order facilities.¹⁸³

Because of the concerns about the potential for self-dealing in cases where the PBM owns a mail order facility, Congress required the Federal Trade Commission to study these issues. This "Conflict of Interest Study" reviewed whether there are cost differences between prescription drugs dispensed by mail in PBM-owned mail order pharmacies and those that are not owned by PBMs. The Federal Trade Commission's study was released in August of 2005.¹⁸⁴

The study found a link between increases in prescription drug costs and a PBM's activities as both manager of a plan and operator of its own mail order pharmacy.¹⁸⁵ For example, generic substitution rates tended to be higher when PBMs filled the prescriptions using mail order pharmacies owned by others than when PBMs filled the prescriptions using their own mail order pharmacies.¹⁸⁶

Other reviews of the mail order industry have concluded, however, that health plans' mail order costs tend to be higher than their retail costs.¹⁸⁷ This is because the plan sponsor typically agrees to allow participants to obtain a ninety-day supply for the equivalent of two co-payments rather than three. This loss of a co-payment "has become a major cost to health plans."¹⁸⁸ Although mail order fulfillment was less expensive for health plan participants, "[f]rom the health plan's perspective, the loss of copayments in the mail service benefit was greater than the savings on ingredient costs and dispensing fees."¹⁸⁹

¹⁸³ 10 Federal News, *Antitrust Scrutiny Likely to Increase for PBM Mail-Order Arrangements*, *Lawyers Say*, No. 12 (Mar. 24, 2004), available at <http://www.badfiathinsurance.org/reference/GMCOPBM/0043a.htm>.

¹⁸⁴ FTC, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* (Aug. 2005), <http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf>.

¹⁸⁵ See Langenfeld, *supra* note 21.

¹⁸⁶ *Id.*

¹⁸⁷ Bartholemew E. Clark et. al., *Poster Presentation: Implications of Incentives Increasing Mail-Service Pharmacy Utilization*, Academy Health Annual Research Meeting (June 26-28, 2005), http://chpe.creighton.edu/chpe/snapshots/garis/Snapshot_Garis.pdf.

¹⁸⁸ Carroll, *supra* note 181, at 336.

¹⁸⁹ *Id.*

C. Rebate and Pricing Schemes

Various lawsuits have alleged that PBMs perpetrate several types of schemes, including schemes relating to rebates, formulary decisions, mail order decisions, and spreads. For example, in *In re Warfarin Sodium Antitrust Litigation*, a manufacturer of generic prescription drugs alleged that the manufacturer of name-brand drugs had paid rebates to PBMs to assure that the name brand rather than the generic oral anticoagulant drug was prescribed.¹⁹⁰ The district court refused to grant a motion to dismiss, ruling that the plaintiff had stated a claim for commercial bribery.¹⁹¹

In *Mulder v. PCS Health Systems, Inc.*, the trial court certified a class comprised of plans administered by PCS Health Systems.¹⁹² The PBM moved for summary judgment arguing that it was not a fiduciary for purposes of ERISA.¹⁹³ The district court agreed¹⁹⁴ with the PBM's argument that claims processing, formulary establishment, rebate processing, and drug utilization reviews did not render the PBM a plan fiduciary under ERISA. The court noted that the concept of a fiduciary under ERISA is elastic; an entity might meet the definition of fiduciary for certain purposes, but not for others.¹⁹⁵ The court then examined each of the areas listed above to determine whether PCS was operating as a fiduciary in performing those services.¹⁹⁶ With respect to claims processing, the court noted that other courts had held that processing was sufficient to prove that an entity was operating as a fiduciary,¹⁹⁷ but distinguished those cases by noting that those entities also controlled the related cash reserves while PCS did not control the reserves and did not exercise discretionary authority.¹⁹⁸ Regarding the role of the PBM in the establishment of the formulary, the court held that the fiduciary duty requirements of ERISA do not apply where the plan sponsor makes plan

¹⁹⁰ 214 F.3d 395 (3d Cir. 2000).

¹⁹¹ *Id.*

¹⁹² 216 F.R.D. 307 (D.N.J. 2003) (certifying the class to pursue claims for kickbacks and unlawful rebates, but limited the class to participants in plans that the same PBM administered).

¹⁹³ *Id.*

¹⁹⁴ 432 F. Supp. 2d 450 (D.N.J. 2006).

¹⁹⁵ *Id.* at 454.

¹⁹⁶ *Id.*

¹⁹⁷ *Id.* at 456 (citing *Sixty-Five Sec. Plan v. Blue Cross & Blue Shield*, 583 F. Supp. 380 (S.D.N.Y. 1984); *Greenblatt v. Prescription Plan Servs. Corp.*, 783 F. Supp. 814 (S.D.N.Y. 1992)).

¹⁹⁸ *Id.* (noting that merely following the terms of the plan document does not constitute an exercise of discretionary authority).

design decisions rather than the PBM.¹⁹⁹ Similarly, with respect to rebate services provided by PCS, the court stated, "PCS did not acquire fiduciary status or have discretionary authority over plan assets simply by contracting to receive its compensation for services through drug manufacturer rebates."²⁰⁰ This role in negotiating rebates on behalf of the plan did not, in the court's view, give PCS control or authority over plan assets.²⁰¹ And with respect to the drug utilization reviews provided by PCS, it was the participants' doctors who made the ultimate decisions regarding which drugs to prescribe.²⁰² Based on this analysis, the court granted the PCS's motion for summary judgment.²⁰³

Additionally, in Vermont, the State Auditor wrote to the Attorney General requesting an investigation of Express Scripts, the PBM for state government employees. She noted that Express Scripts "may be pocketing hidden profits averaging 43 percent from certain drug prescriptions."²⁰⁴ The State Auditor's office had performed sample testing in July of 2004 and concluded that on some drugs, Express Scripts was costing the state nearly \$2 million per year by pocketing these hidden profits.²⁰⁵

Further, in 2004, the U.S. government accused Medco of defrauding federal customers by only partially filling, switching, or even destroying their prescriptions.²⁰⁶ These practices violate the False Claims Act, which prohibits billing for services that were not provided.²⁰⁷ Medco was also alleged to have violated the Anti-Kickback Act of 1986²⁰⁸ by receiving payment from drug manufacturers for favoring their drugs and by paying a corporation to rely exclusively on Medco's services.²⁰⁹ The two

¹⁹⁹ *Id.* at 458.

²⁰⁰ *Id.* at 459-60.

²⁰¹ *Id.* at 460.

²⁰² *Id.* at 461.

²⁰³ *Id.*

²⁰⁴ *Vermont May be Paying Hidden Drug Profits: Pharmacy Benefits Manager mark up drug prices by as much as 111 Percent*, THE GREEN MOUNTAIN EYESHADE (Office of the Vermont State Auditor, Montpelier, VT) (Spring 2004), at 1.

²⁰⁵ *Id.*

²⁰⁶ *U.S. v. Merck-Medco Managed Care, L.L.C. and Medco Health Solutions, Inc., et. al.*, Nos. Civ.A.00-737, Civ.A.99-2332 (E.D. Pa. Sept. 23, 2004); David S. Cloud, *US Targets PCS and Merck-Medco in Investigation of Marketing Practices of Pharmaceutical Makers*, WALL ST. J. EUR., Mar. 8, 2000, at 28, available at 2000WL-WSJE 2947415; see also James G. Sheehan, *Fraud and Abuse in the Marketing of Ethical Pharmaceuticals Through Pharmacy Benefit Management Programs*, 15 FOOD DRUG COSM. & MED. DEVICE L. DIG. 49, 52 (1998).

²⁰⁷ False Claims Act, 31 U.S.C. § 3729 (2000).

²⁰⁸ 41 U.S.C. § 51 (2000).

²⁰⁹ *U.S. v. Merck-Medco Managed Care, L.L.C.*, 336 F. Supp. 2d 430, 436 (E.D. Pa. 2004).

related cases were settled in October of 2006 for \$155 million.²¹⁰ In addition to paying the fine, “the United States required that Medco enter into a corporate compliance agreement with the Office of Inspector General, Department of Health and Human Services; and with the Office of Inspector General of the Office of Personnel Management.”²¹¹

D. Anticompetitive and Deceptive Practices

In Alabama, North Jackson Pharmacy, a class plaintiff, filed suit against Express Scripts and Medco Health Solutions, Inc., for violating the Sherman Act in using “anticompetitive practices” against small retail pharmacy operators.²¹² The plaintiffs alleged that the PBMs, acting as middlemen, forced retail pharmacies to accept unconscionable reimbursement rates.²¹³ The judge denied the defendants’ motion to dismiss the plaintiffs’ second amended complaint, finding that the complaint provided the defendants with fair notice of the nature of the claims made against them.²¹⁴

E. Kickbacks

In the *Medco* lawsuit filed by the U.S. government, the U.S. Attorney alleged that Medco was engaged both in paying and accepting payments in violation of anti-kickback laws.²¹⁵ As noted above, Medco was accused of violating the Public Contracts Anti-Kickback Act²¹⁶ by receiving payment from drug manufacturers for favoring their drugs and by paying a corporation to rely exclusively on Medco’s services.²¹⁷

The Office of the Inspector General of the Department of Health and Human Services announced in December of 2006 that it had entered into an agreement under which Advance PCS would pay \$137.4 million to the government “and enter into a 5-year corporate integrity agreement to resolve its liability for allegedly soliciting and receiving kickbacks from pharmaceutical manufacturers and paying kickbacks to potential

²¹⁰ Press Release, U.S. Department of Justice, *Medco to Pay U.S. \$155 Million to Settle False Claims Act Cases* (Oct. 23, 2006), http://www.usdoj.gov/opa/pr/2006/October/06_civ_722.html.

²¹¹ *Id.*

²¹² *North Jackson Pharmacy, Inc. v. Express Scripts*, 345 F. Supp. 2d 1279 (N.D. Ala. 2004).

²¹³ *Id.*

²¹⁴ *Id.*

²¹⁵ Katz, *supra* note 42.

²¹⁶ 41 U.S.C. § 51 (2000).

²¹⁷ *Merck-Medco*, 336 F. Supp. 2d at 436.

customers to induce them to contract with the company. This settlement represents the first of its kind with a PBM."²¹⁸

V. SUGGESTED SOLUTIONS

Given the pervasiveness of issues with respect to PBMs, including the lack of transparency, the complexity of industry audits, and the lack of a meaningful regulatory scheme, other solutions should be explored. Under a public sector approach, state agencies that contract with PBMs in connection with Medicare and Medicaid could insist on transparency. There are several private sector approaches that could assist health plans in assuring that the terms of their agreements with their PBMs are the best possible. Under a private sector approach, groups of several large plans could cooperate to contract with a PBM of their choice, while insisting on transparency. A single health plan or a single PBM could also address these issues in unique ways. Standardized contracting has also been suggested as an approach to these issues with PBMs.

As mentioned, a public sector approach would require state agencies that contract with PBMs to insist on transparency as part of the contracting process. Jeffrey Lewis, Executive Director of the Heinz Family Philanthropies, has proposed this approach to achieve transparency and lower prices in the drug-purchasing arena and agreed to provide seed money to help states establish a public sector, non-profit PBM.²¹⁹ The Heinz Family Philanthropies worked with nine states and the District of Columbia to create a nonprofit PBM to manage prescription plans.²²⁰

The advantages and disadvantages of the Heinz approach were discussed in a report by Health Policy and Payer Relations,²²¹ which noted: "For manufacturers, the non-profit PBM idea has pros and cons. The upside is that a manufacturer will only have to negotiate with one

²¹⁸ Office of Inspector General, *OIG Reports More than \$38 Billion in Savings and Recoveries for FY 2006*, OIG NEWS at 2 (Dec. 5, 2006), http://209.85.165.104/search?q=cache:LD_ArikPqwJ:oig.hhs.gov/publications/docs/semiannual/2006/PRSemianual%2520Final%2520FY%25202006.pdf+OIG+kickback+PBM&hl=en&gl=us&ct=clnk&cd=1.

²¹⁹ Maine House Democrats, <http://www.maine.gov/tools/whatsnew/index.php?topic=housedems+news&id=1243&v=Article>.

²²⁰ Milt Freudenheim, *States Organizing a Nonprofit Group to Cut Drug Costs*, N.Y. TIMES, Jan. 14, 2003, <http://query.nytimes.com/gst/fullpage.html?res=9A06E1DC1231F937A25752C0A9659C8B63&sec=&spon=&pagewanted=all>.

²²¹ Health Policy and Payer Relations, *Issue Analysis: Medicaid PDLs and Supplemental Rebate Restrictions* (2003), http://www.parexelonpolicy.com/images/PAREXEL_Issue_Analysis_PDLs.PDF.

entity, instead of nine separate states. However, the existence of one entity representing nine states, including two large ones, means that negotiations are for higher stakes.”²²² Although this approach was suggested in 2002, and the coalition of states was formed in early 2003, there has been little reported progress to date.

The first approach would be for a single employer to form its own captive PBM. This approach would require the employer to have a sufficient number of covered lives to interest drug manufacturers in negotiating directly with it. The approach will work only where the employer has several million covered lives, a number not even approachable by Wal-Mart, the nation’s largest employer, with 1.3 million employees in the United States.²²³ Unfortunately, this approach requires a level of expertise that far exceeds the in-house knowledge of executives of even the largest benefits plans in the United States.²²⁴ A second type of employer that might be able to use this approach is one that has a large number of employees in one particular area. The percentage of employees associated with the employer in the particular area might be sufficient to move the market share in that market.

Another approach that a single employer could take is to change the situs of its health plan to a state that mandates transparency.²²⁵ For example, a law passed by South Dakota in 2004 requires each PBM to “perform its duties exercising good faith and fair dealing toward the covered entity”²²⁶ and to “disclose to the covered entity, the amount of all rebate revenues and the nature, type, and amounts of all other revenues that the pharmacy benefits manager receives from each pharmaceutical manufacturer or labeler with whom the pharmacy benefits manager has a contract.”²²⁷ One approach to the problem is for health plans to transfer their situs to South Dakota or another state that has favorable transparency and fiduciary duty legislation. This transfer

²²² *Id.*

²²³ See <http://www.walmartfacts.com> (“Wal-Mart employs 1.8 million associates worldwide, including 1.3 million in the United States.”) (last visited Sept. 26, 2007).

²²⁴ Katz, *supra* note 42. (“With all the criticism of pharmacy benefit managers, it’s fair to ask whether they’re still needed at all. Handling drug benefits in house, however, is not in the cards. ‘Somebody’s got to adjudicate the claims,’ says Ron Lyon, national pharmacy practice leader with Towers Perrin, adding that PBMs do still provide substantial discounts.”).

²²⁵ Act to Provide for the Regulation of Pharmacy Benefits Management, H.B. 1311, 79th Leg. Assem., Reg. Sess. (S.D. 2004).

²²⁶ *Id.* at § 3.

²²⁷ *Id.* at § 4.

would enable the plan to insist upon full disclosure under applicable state laws.

Another private sector approach is for a PBM to develop a niche in which it markets a completely transparent plan. Some small PBMs have already begun to do so. According to the New York Times, “[s]ome small benefit managers have begun selling ‘transparent’ drug plans, promising to inform customers about all their dealings with manufacturers, rather than base their business on a web of complex rebates, discounts and incentive arrangements with drug makers.”²²⁸

Yet another approach is for a group of plans to work together to form a non-profit PBM that provides complete transparency to plans. A private sector approach to PBMs would require one or more private employers to have the capability to process prescription transactions, either directly or indirectly, through a third-party processor. The private sector PBM would have to serve as an intermediary between the plans it serves, retail pharmacies, and drug manufacturers. Perhaps the most daunting aspect of this would be the creation of the system to handle the transactions. The most likely source for the system would be an existing small PBM that has already invested in the creation of a scalable system. That PBM could be purchased through a joint venture arrangement among the plans, the system could be licensed, or the plans could simply pay a processing fee calculated on a per-covered life or per-transaction basis. Some PBMs already exist that charge solely on a per-person or per-transaction basis, with no other cash flow to the PBM. One example, and probably the most experienced transparent PBM, is Pharmaceutical Technologies, Inc./National Pharmaceutical Services, which has existed since 1994. Other new PBMs that have adopted the transparent model are Innoviant and Envision. All are full-service PBMs that provide rebate contracting. These PBMs typically provide detailed rebate accounting and may take a disclosed portion of the rebate (for example, 20-30%) as service fees.

Standardized contracting has been suggested as another way to address the lack of transparency in the industry. A loose affiliation of health plans calling itself the Rx Collaborative is administered by Towers Perrin.²²⁹ Another, the Health Policy Association, is run by Hewitt

²²⁸ Milt Freudenheim & Robert Pear, *More Disclosure for Drug Plans*, N.Y. TIMES, July 19, 2003, <http://query.nytimes.com/gst/fullpage.html?res=9E05E7D7113CF93AA25754C0A9659C8B63&sec=health&spon=&pagewanted=print>.

²²⁹ Katz, *supra* note 42. According to a recent article:

Associates.²³⁰ This group originally approached manufacturers directly to solicit pricing net of rebates.²³¹ More than 50 Fortune 500 companies in the group originally insisted on price transparency, including complete disclosure of all PBM revenue sources and negotiating pricing directly with the manufacturers.²³² Yet, despite the manufacturers' general willingness to work with the plans, the administrative hurdles associated with this approach proved insurmountable.²³³

Some large employers, members of the HR Policy Association, are experimenting with the idea of a group purchasing arrangement.²³⁴ Group purchasing arrangements always carry antitrust concerns. The Department of Justice has issued guidance to companies in the form of Horizontal Merger Guidelines²³⁵ and Statements of Antitrust Enforcement Policy in Health Care.²³⁶ The 1992 Horizontal Merger Guidelines discuss monopsonies (situations where a single buyer is able "to depress the price paid for a product to a level that is below the

[T]he Rx Collaborative pledges that members will seek financial and contractual protections in their drug-benefit agreements, according to a Towers Perrin publication. Among them are price transparency via "full disclosure" of PBM revenue sources; "100 percent pass-through of rebates, discounts, and dispensing fees"; and enough information to audit the PBM.

Id.

²³⁰ *Id.*

²³¹ *Why the Plans of a Major Drug Purchasing Coalition Did Not Work*, DRUG BENEFIT NEWS (Oct. 25, 2005), http://www.aishealth.com/DrugCosts/DBN_Drug_coalition_didn't_work.html.

²³² *Id.*

²³³ *Id.*

²³⁴ Davis, *supra* note 9. Davis states:

The embattled pharmacy benefit management industry could soon face competition from its own customers. For years, major employers have simply trusted PBMs . . . [b]ut some big companies have grown frustrated by the industry's lack of transparency and have come to doubt that the professed savings are real. Thus, dozens of companies . . . have joined forces in an effort to directly negotiate with drug manufacturers for discounts on their own. The HR Policy Association, which formulated the idea, calls the group "the largest private-sector drug purchasing coalition ever assembled." . . . The potential group buyers have surfaced at a time when drug costs are soaring and PBMs face intense government scrutiny for their pricing and business practices.

Id. at 1.

²³⁵ U.S. Dept. of Justice & FTC, *Horizontal Merger Guidelines* (1992).

²³⁶ U.S. Dept. of Justice & FTC, *Statements of Antitrust Enforcement Policy in Health Care*, at 54 (Aug. 1996); FTC & U.S. Dept. of Justice, *Antitrust Guidelines for Collaborations Among Competitors* (Apr. 2000).

competitive price and thereby depress output.”²³⁷ Concerns regarding development of monopsony power may exist if several very large employers were to band together to form a purchasing consortium. To the extent that the group has sufficient purchasing power to affect prices and output within the pharmaceutical industry, we should be concerned that investments in innovation would decrease.

The Department of Justice and FTC issued their joint *Statements of Antitrust Enforcement Policy in Health Care* in 1993. With respect to group purchasing arrangements (“GPAs”), Statement 7 provides that “[m]ost joint purchasing arrangements among hospitals or other health care providers do not raise antitrust concerns. Such collaborative activities typically allow the participants to achieve efficiencies that will benefit consumers.”²³⁸ GPAs raise antitrust concerns only where the GPA creates a monopsony, or power purchaser, that can exercise market power with respect to the product or service²³⁹ or where the GPA facilitates price fixing.²⁴⁰

Given the choice, plan sponsors will likely focus on their core businesses, rather than take a hands-on role in the pharmacy benefit.²⁴¹ Sponsors need information adequate to make rational decisions about PBM value to create a market solution to transparency. To assess the value of the PBM, a sponsor must know the true cost of the PBM service, obviously more than the published per-transaction (administration) fee, charged to the sponsor by the PBM.

The PBM takes three cash flows in the process of administering prescription plans: PBMs retain a portion of the rebates (“RR”), spread pricing (“SP”), and the per-prescription (or per-member) administration fees (“ADM”). The PBM administration fees assessed are specified in the contract and are not subject to variation in any given contract period. We

²³⁷ See generally Willard K. Tom, David A. Balto & Neil W. Averitt, *Anticompetitive Aspects of Market-Share Discounts and Other Incentives to Exclusive Dealing*, 67 ANTITRUST L.J. 615 (2000); David A. Balto, *Networks and Exclusivity: Antitrust Analysis to Promote Network Competition*, 7 GEO. MASON L. REV. 523 (1999).

²³⁸ U.S. Dept. of Justice & FTC, *Statements of Antitrust Enforcement Policy in Health Care* at Statement 7 (Aug. 1996).

²³⁹ *Id.*

²⁴⁰ *Id.*

²⁴¹ Plan sponsors that wish to take a more active role should be prepared to hire a cadre of specialists capable of auditing and overseeing the plan. These sponsors would also have to contract out the processing of pharmacy claims, administration of their formulary, negotiating with drug manufacturers and setting up a pharmacy network.

can express the terms below in a mathematical expression describing total cost of the PBM service:

$$RR + SP + ADM = \text{Cost of the PBM service}$$

Experienced consultants have watched the PBM industry, under increasing pressure from the sponsors, give up a larger share of rebates to sponsors. Therefore, PBMs have decreased the amount of rebate retained (“RR”) as a portion of cash flow. In order for PBMs to meet quarterly Wall Street expectations, they have increased spread pricing (“SP”), mainly on generic drugs. Generic drug pricing is particularly difficult to evaluate because generics typically have multiple prices and the sponsor routinely lacks adequate information on a reasonable price range. Complicating this system is the fact that some PBMs have several different MAC price lists. The revised equation represents the current state of PBM cash flows (*i.e.*, cost of PBM service):

$$\downarrow RR + \uparrow SP + \rightarrow ADM = \text{Cost of the PBM service}$$

A market solution to PBM transparency requires the sponsor to have sufficient knowledge to purchase PBM services rationally, with information on price and quality. The following suggestions are intended to facilitate the sponsor’s PBM selection and monitoring, by positioning the plan sponsor to demand information previously overlooked in contract negotiations. When a plan sponsor circulates a request for proposals (“RFP”) to several PBMs, the RFP should require the PBMs responding to it to represent that they will comply with each of the following items. The sponsor might even attach to the RFP a form of contract and require each PBM responding to the RFP to represent that it will sign a contract in the form attached.

First, the sponsor should demand that the PBM provide a copy of all the electronic prescription transactions performed for the sponsor in each billing cycle. The PBM is in the business of transmitting electronic transactions; it can easily remove personal information from the transactions and deliver the requested information to the sponsor. PBMs have sometimes warned sponsors that retrieving these transactions will be very expensive. This argument is untenable. The PBM must have aggregated the transactions in order to bill the sponsor. The Appendix lists information that the plan sponsor should request.

Second, the PBM should be required to provide the sponsor with the generic drug price list (“MAC”) and all subsequent updates to that MAC list. This step would probably require the sponsor to sign a

confidentiality agreement with the PBM. Spreads generated by the PBM on generic drug pricing likely represent the greatest challenge to sponsors in the next several years. Having both the transactions and the generic price list allows the sponsor to spot-check the prices being billed. As stated earlier, it is quite likely that the plan sponsor will have a third party check the pricing in a comprehensive exam. With the sponsor's data now available, a periodic exam of the firm's data by an outside vendor could prove to be a worthwhile investment.

Third, the PBM should be required to provide the sponsor with accounting in adequate detail for the sponsor to confirm rebate payments. This information would, likely, require a confidentiality agreement by the sponsor. Pharmacy transactions exist in exquisite detail; it is only reasonable to demand a straightforward accounting of the payments that the sponsor's transactions earned. PBMs often try to limit plan sponsors to auditing only transactions involving a select list of drugs or to auditing only transactions involving a small number of drugs. The plan sponsor should insist that it or its designated auditor have complete access to all information needed.

VI. Conclusion

The PBM industry has largely escaped public scrutiny because few members of the public know of its existence or understand its processes. It is one of the most powerful industries in the health care arena today, yet it is ineffectively regulated by a patchwork of federal and state laws. The most promising areas of legislation, disclosure statutes, have been vehemently resisted by the PBMs. Further, these disclosure statutes are far from an optimal solution, as different states pass different statutes.

Despite the issues in this industry, the federal government does not appear poised to create a comprehensive regulatory scheme. Because of the lack of appropriate regulation, a private sector solution appears to be the best solution available at this time for health plans.

For health plans to negotiate effectively with PBMs, they must arm themselves with the information necessary to level the playing field. The current regime of information asymmetry prevents health plans from negotiating the best terms possible with PBMs. The suggestions provided in this article give health plan managers guidance regarding the tools they need to equip themselves to negotiate more effectively with PBMs in the future. In the absence of these steps, PBMs will be able

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Leveling the PBM Playing Field

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to take advantage of health plan payors, resulting in higher pharmaceutical costs for America's employers and plan participants.

APPENDIX

Suggested data elements to request from the PBM

NDC (National Drug Code)
Date dispensed
Drug name & strength
Quantity dispensed
Days supply
NABP # (Pharmacy Provider ID number)
Generic Flag (Generic/Brand identifier)
Ingredient Cost (Amount billed to the sponsor for drug ingredient)
Dispensing Fee (Amount paid to pharmacy for dispensing)
Co-payment Amount (Co-payment paid by member)
Amount Due from sponsor = (Ingredient Cost + Dispensing Fee) - (Co-payment)
Reversal Flag (Reversal/Credit of transactions)
Mail/retail pharmacy indicator
Generic Product Indicator (GPI)