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Joanna Shepherd

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The Fox Guarding the Henhouse: The Regulation of Pharmacy Benefit Managers by a Market Adversary

Joanna Shepherd[1]

ABSTRACT

Pharmacy benefit managers (PBMs) save Americans billions of dollars each year by lowering both the prices that consumers pay for prescription drugs and the prices that health plans pay for drug coverage. As I explain in this Article, however, new regulatory developments in some states threaten to undercut competition in the PBM industry and disrupt the cost-savings PBMs currently generate. The regulatory scheme that was adopted by Mississippi in 2011, and that is currently under legislative consideration in several other states, shifts regulatory control of PBMs from the neutral Insurance Commissions to the states' Boards of Pharmacy. The fundamental problem with this structure is that the Boards of Pharmacy are made up of pharmacists, the direct market adversaries of PBMs. In several different areas of the prescription drug market, PBMs and pharmacists are in direct competition over profits. Thus, the pharmacist-controlled Boards of Pharmacy have both the incentive and the opportunity to exert their regulatory authority in ways that benefit pharmacies at the expense of PBMs; reductions in PBMs' profits generally lead to more profits for pharmacists. Indeed, I describe two important regulatory changes that the Board has enacted in its first two years that harm PBMs and benefit pharmacies. The power to regulate a market adversary gives pharmacists unprecedented power and will undercut competition in the prescription drug market. I explain how this regulatory scheme will not only hurt the PBM industry, but will also increase the prices that consumers and third parties pay for prescription drugs.

TABLE OF CONTENTS

INTRODUCTION 2
I. BACKGROUND ON PHARMACY BENEFIT MANAGERS 4
A. The Role of Pharmacy Benefit Managers 4
B. Structure of the Pharmacy Benefit Management Industry 6
C. Benefits of Pharmacy Benefit Management 7
II. REGULATION OF PHARMACY BENEFIT MANAGERS 9
A. The Need for Regulation 9
B. History of Regulatory Efforts 11
A. Regulation by the Board of Pharmacy 13
1. Mississippi 13

[1] Associate Professor of Law, Emory University School of Law

2. Proposals in Other States 14
B. Economic Analysis of Regulation by a Market Adversary 15
1. Disclosure of Sensitive Business Information 18
2. Imposing a Fiduciary Duty on Pharmacy Benefit Managers 19
CONCLUSION 22

INTRODUCTION

Although most people have never heard of a "pharmacy benefit manager," 95% of insured Americans have prescription drug coverage that is administered by one.[2] Pharmacy benefit managers (PBMs) act as the middlemen among pharmacies, drug manufacturers, insurers, and consumers with prescription drug coverage. They influence how much consumers pay for drugs, which pharmacies they use, and even which drugs they take. By negotiating discounts with pharmacies and manufacturers, substituting less expensive drug alternatives when appropriate, and filling prescriptions for chronic conditions by mail, PBMs save consumers and third parties that pay for prescription drugs billions of dollars each year.[3]

However, recent regulatory developments in some states threaten to disrupt the PBM industry and the cost savings they currently produce for consumers of prescription drugs. The regulatory scheme currently in place in Mississippi—and under legislative consideration in several other states—gives regulatory control over PBMs to the states' Boards of Pharmacy. Although this regulatory scheme is innocuous on its face, pharmacists—who serve on the Boards of Pharmacy—are market adversaries of PBMs. In several different areas of the prescription drug market, PBMs and pharmacists are in direct competition over profits. Thus, the pharmacist-controlled Boards of Pharmacy have both the incentive and the opportunity to exert their regulatory authority in ways that benefit pharmacies at the expense of PBMs. Indeed, although the Mississippi Board of Pharmacy has only had regulatory authority over PBMs for a little over a year, examples of regulations that harm PBMs have already emerged. Unfortunately, this regulatory scheme will do more than just hurt the PBM industry, it will also increase the prices that consumers and third parties pay for prescription drugs.

PBMs administer the prescription drug benefits for health plan sponsors such as employers, labor unions, and Health Maintenance Organizations (HMOs). PBMs engage in various activities to manage their clients' prescription drug benefit efficacy and costs. For example, PBMs negotiate discounts on prescription drug prices from pharmacies in exchange for the pharmacy's placement on the preferred network for plan participants. PBMs also negotiate discounts and payments from drug manufacturers in exchange for the manufacturers' drugs placement on the preferred list of medication for various ailments. In addition, PBMs interact electronically with pharmacists that are filling prescriptions to substitute generic drug substitutes or lower-priced alternatives when

[2] Letter from Maureen K. Ohlhausen, Acting Dir., Office of Policy Planning, Fed. Trade Comm'n et. al. to Senator Richard L. Brown, North Dakota Senate 4 (Mar. 8, 2005), *available at* http://www.ftc.gov/os/2005/03/050311northdakotacomnts.pdf [hereinafter Letter to Senator Richard L. Brown].

[3] CONG. BUDGET OFFICE, ISSUES IN DESIGNING A PRESCRIPTION DRUG BENEFIT FOR MEDICARE 14, 40 tbl. 6 (2002), *available at* http://www.cbo.gov/ftpdocs/39xx/doc3960/10-30-PrescriptionDrug.pdf.

appropriate. These practices that are central to the PBM business model produce lower prices for prescription drugs. Indeed, research shows that consumers with PBM-administered prescription drug coverage pay between 15% and 50% less for drugs than do non-insured customers buying the exact same drugs.[4]

Yet, despite evidence of the significant cost savings that PBMs generate for consumers and health plan sponsors, critics of the PBM industry have successfully lobbied state legislatures for increased regulation of these companies in recent years. These regulations include a variety of rules related to licensing, investigations, duties to clients, disclosures of financial terms with manufacturers, and the extent to which savings must be passed on to consumers. Until 2011, despite the various regulatory schemes, all states gave regulatory authority over PBMs to a neutral insurance commission. In 2011, Mississippi became the first and only state to shift regulatory authority over PBMs from the Insurance Commission to the Board of Pharmacy. The Board of Pharmacy is composed entirely of pharmacists.[5] Legislatures in Oregon, Hawaii, and Oklahoma are currently considering proposals to allow the state Boards of Pharmacy to regulate PBMs. In the last legislative session, Washington, New Hampshire, Alabama, and Louisiana considered similar proposals.

The fundamental problem with this regulatory scheme is that PBMs are the direct market adversaries of pharmacies in several segments of the prescription drug market. For example, when PBMs negotiate price discounts for prescription drugs at network pharmacies, they put direct pressure on the profits of both network and non-network pharmacies. In addition, when PBMs attract customers to mail-order pharmacies with lower drug costs, they reduce the number of prescriptions filled at retail pharmacies. Granting Boards of Pharmacy regulatory control over PBMs creates an inherent conflict of interest by giving pharmacists regulatory control over their natural competitors in the marketplace. Under this new regulatory scheme, a Board has both the incentive and the power to exercise its regulatory power in ways that weaken PBMs' competitive positions, and in turn, benefit pharmacies. The power to regulate a market adversary gives pharmacists unprecedented power and will severely undercut competition in the prescription drug market. Moreover, this regulatory scheme will increase the prices of prescription drugs for both consumers and health plan sponsors.

Even though the Mississippi Board of Pharmacy has only had regulatory authority over PBMs for a little over a year, two regulations have already emerged that harm PBMs and benefit pharmacies. First, the Mississippi Board of Pharmacy has the power both to require PBMs to turn over sensitive financial information and to share that information with pharmacies. This practice will benefit pharmacies by giving them business information about their market adversaries and it will weaken the PBM industry and produce significant harms for consumers and health plan sponsors.

Second, on January 23, 2013, the Mississippi Board of Pharmacy enacted a rule imposing a fiduciary duty on PBMs. PBMs' new fiduciary status will compel them to adopt certain defensive measures, curb various cost-saving practices, incur additional

[4] FED. TRADE COMM'N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES 36 (2005), *available at* http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf.

[5] Press Release, Pharmaceutical Care Management Association, Mississippi State Board of Pharmacy Backs Down After PCMA Threatens Lawsuit (2013), *available at* http://www.pcmanet.org/2013-press-releases/mississippi-state-board-of-pharmacy-backs-down-after-pcma-threatens-lawsuit.

legal and administrative costs, and increase the reporting of sensitive business information. As a result of these changes, the cost of prescription drug coverage administered by PBMs will increase. Moreover, many of the consequences of a fiduciary duty will undermine PBMs' competitive positions in the prescription drug market relative to retail pharmacies that do not have fiduciary status. Thus, the newest regulation further demonstrates that the Board is utilizing its regulatory authority to disadvantage PBMs while benefitting pharmacies.

This Article proceeds as follows. In Section I, I describe the role of PBMs in administering prescription drug coverage and the structure of the PBM industry. I also discuss empirical evidence that shows that PBMs produce significant benefits to consumers and health plan sponsors by lowering both the prices of prescription drugs and the cost of prescription drug coverage. In Section II, I discuss the specific arguments that critics make in their demands for more regulation of the PBM industry and the empirical evidence showing that more regulation is unnecessary. I also briefly describe the history of federal and state regulatory efforts toward the PBM industry. In Section III, I discuss the existing regulatory scheme in Mississippi and the current proposals in Oregon, Hawaii, and Oklahoma to grant Boards of Pharmacy regulatory authority over PBMs. Then, I present an economic analysis of these approaches and explain why granting regulatory authority to a market adversary will undercut competition in the prescription drug market. As a result of these approaches, both consumers and health plan sponsors will pay more for prescription drugs and prescription drug coverage.

I. BACKGROUND ON PHARMACY BENEFIT MANAGERS

Many private sector entities that offer medical insurance also offer prescription drug coverage to their members. These health plan sponsors may include employers, labor unions, Health Maintenance Organizations (HMOs), and other entities. Health plan sponsors often hire PBMs to manage prescription drug benefits for their members. Ninety-five percent of Americans with prescription drug coverage receive their benefits through a PBM.[6]

In this section, I describe the role of PBMs in administering prescription drug coverage and the structure of the PBM industry. I also discuss empirical evidence that shows that PBMs produce significant benefits to consumers and health plan sponsors by lowering both the prices of prescription drugs to plan participants and the overall cost of prescription drug coverage to the health plan.

A. The Role of Pharmacy Benefit Managers

PBMs engage in various activities to manage prescription drug benefits for client health plans. First, PBMs assemble networks of retail pharmacies where plan participants can easily fill prescriptions by simply providing a copayment (copay).[7] When a consumer presents a prescription to the pharmacist at a retail pharmacy, the pharmacist inquires whether the consumer has prescription drug benefit coverage. If there is coverage, the pharmacies' computer systems ensure that the prescription is filled according to the

[6] Letter to Senator Richard L. Brown, *supra* note 2, at 4.
[7] *See* FED. TRADE COMM'N, *supra* note 4, at 1.

consumers' specific coverage plan. The consumer pays the retail pharmacy the copayment that is due according to the plan. PBMs negotiate specifics of this plan. More specifically and most importantly, PBMs negotiate the price for prescription drugs at the retail pharmacy. The prescription drugs are then paid for by a combination of consumer payments (copays, deductibles, or co-insurance) and health plan sponsors' payments to the pharmacy.[8] By harnessing the buying clout of the many consumers covered by client sponsors' prescription drug plans, the PBMs can negotiate discount prescription drug prices for both health plans and consumers.[9]

Second, PBMs work with health plan sponsors to create the list of preferred drugs for different medical conditions (the formulary) for which the plan will provide coverage. The health plan offers participants incentives, such as lower copayments, to use the formulary drugs.[10] As a result, drugs listed on the formulary face considerable consumer demand, and in turn, produce significant sales for drug manufacturers. Manufacturers negotiate with PBMs to obtain formulary status for their drugs. The primary bargaining tools that manufacturers wield in these negotiations are price discounts and rebates that drug manufacturers pay to PBMs to have their drugs listed on the formulary. Drug manufacturers compete intensively with each other for formulary status, and thus the rebates or discounts can often be substantial.[11] The PBMs then use these rebates to lower prices for the formulary drugs. As a result of this negotiation between PBMs and drug manufacturers, both consumers and health plans pay lower prices for prescription drugs.[12]

Third, many PBMs employ mail-order pharmacies to keep prescription drug costs low. Many prescription drug plans encourage covered consumers to fill prescriptions for ongoing, chronic conditions through mail-order pharmacies. These pharmacies can offer discounts because of the efficiencies they achieve by high-volume dispensing and the dispensing of longer, 90-day prescriptions. In addition, when PBMs own a mail-order pharmacy, they can ensure that customers receive formulary drugs, generic substitutes, or cheaper alternatives when appropriate in order to keep prescription drug prices low. Indeed, empirical research has shown that mail-order pharmacies offer prescription drugs at significantly lower prices than their retail counterparts.[13]

Fourth, PBMs process and pay prescription drug claims for their health plan sponsor clients. That is, they ensure that when a consumer with prescription drug coverage fills a prescription at a pharmacy, the pharmacy and drug manufacturers receive the correct payments or reimbursements. PBMs can offer significant savings through the economies of scale they achieve in claims processing. As of 2011, the top three PBMs each manage about 20% of the almost four billion prescriptions dispensed in the U.S. every year, requiring large, sophisticated infrastructures.[14]

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[8] *Id.*
[9] Thomas Gryta, *What is a 'Pharmacy Benefit Manager?,* WALL ST. J. (Jul. 21, 2011), http://online.wsj.com/article/SB10001424053111903554904576460322664055328.html.
[10] FED. TRADE COMM'N, *supra* note 4, at 6.
[11] *Id.* at 6-7.
[12] *Id.* at iv-v.
[13] *Id.*; U.S. GEN. ACCOUNTING OFFICE, EFFECTS OF USING PHARMACY BENEFIT MANAGERS ON HEALTH PLANS, ENROLLEES, AND PHARMACIES 10-11 (2003) [hereinafter GAO REPORT], *available at* http://www.gao.gov/cgi-bin/getrpt?GAO-03-196.
[14] Gryta, *supra* note 9.

Finally, PBMs may perform various other services to efficiently manage the pharmacy benefits of consumers. For example, as pharmacists fill prescriptions, PBMs' computer systems check for drug interactions among a consumer's current prescriptions, determine whether a generic version of a prescribed drug is available, calculate whether enough days have passed before a prescription can be refilled, analyze physician prescribing patterns, and provide treatment information and monitoring of covered individuals with certain chronic diseases.[15]

B. Structure of the Pharmacy Benefit Management Industry

Approximately sixty PBMs operate in the United States today.[16] Industry experts estimate that 95% of patients with prescription drug insurance coverage receive their benefits through a PBM.[17] This translates into more than 215 million Americans with prescription drug coverage administered by PBMs.[18]

Although the relative size or market share of PBMs vary according to the specific measure used—i.e. prescriptions per year or individuals covered—the market is generally considered to have at least ten significant competitors.[19] The three largest PBMs—Medco Health Solutions, Express Scripts, and CVS Caremark—account for roughly 20% of the almost four billion prescriptions dispensed in the U.S. every year.[20] Express Scripts and Medco have recently merged, increasing market concentration among the largest PBMs. However, several PBMs owned by insurers and retailers, as well as smaller stand-alone PBMs, have become viable competitors to larger PBMs that have traditionally had a stronger market presence.[21] Indeed, these smaller PBMs are increasingly winning employer accounts away from Medco, Express Scripts, and CVS Caremark.[22] The intense competition in this market has forced PBMs to lower the prices of their services in order to remain competitive, resulting in declining PBM profit margins in recent years.[23]

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[15] FED. TRADE COMM'N, *supra* note 4, at 1-2.

[16] Letter to Senator Richard L. Brown, *supra* note 2, at 4. The Pharmacy Benefit Management Institute lists forty eight PBMs in its online directory. However, the directory may be under-inclusive as a fee is required for inclusion. *See PBM Directory*, PHARMACY BENEFIT MANAGEMENT INSTITUTE, http://www.pbmi.com/pbmdir.asp (last visited Jul. 9, 2013); *see also* FED. TRADE COMM'N, *supra* note 4, at 1-2.

[17] Letter to Senator Richard L. Brown, *supra* note 2, at 4.

[18] *See* VISANTE, PHARMACY BENEFIT MANAGERS (PBMS): GENERATING SAVINGS FOR PLAN SPONSORS AND CONSUMERS 3 (2011).

[19] This market is defined as the market for full-service PBM services to health plan sponsors; it does not include any PBM services provided to health plans, as they do not typically offer the same capabilities and services as the PBM services to health plan sponsors. *See* FED. TRADE COMM'N, STATEMENT OF THE FEDERAL TRADE COMMISSION CONCERNING THE PROPOSED ACQUISITION OF MEDCO HEALTH SOLUTIONS BY EXPRESS SCRIPTS, INC. (2012), *available at* http://www.ftc.gov/speeches/rosch/120402expressmedcostatement.pdf.

[20] Gryta, *supra* note 9.

[21] FED TRADE COMM'N, *supra* note 19, at 3. For example, Costco unveiled its own PBM in early 2013; with almost 450 Costco pharmacies and annual prescription drug revenues of approximately $1.6 billion, it promises to be a significant competitor in the PBM industry. *Costco Unveils Its Own PBM*, DRUG CHANNELS (Jan. 17, 2013), http://www.drugchannels.net/2013/01/costco-unveils-its-own-pbm.html.

[22] FED. TRADE COMM'N, *supra* note 19, at 3-5.

[23] *Id.* at 2.

C. Benefits of Pharmacy Benefit Management

PBMs produce significant benefits for consumers and health plan sponsors by lowering both the price of prescription drugs to plan participants and the overall plan costs of prescription drug coverage. Moreover, PBMs improve health outcomes by making prescription drugs more affordable, thus allowing more Americans to take their medications as prescribed.

Consumers with prescription drug coverage administered by PBMs pay significantly lower prices for prescription medication. PBMs negotiate significant rebates from drug manufacturers by offering their drugs exclusive formulary status in exchange for rebates. PBMs also harness the buying clout of their many enrolled consumers to negotiate discounts at retail pharmacies. Consumers benefit from these negotiated rebates and discounts by paying lower prices for prescription drugs.

Several studies have measured the rebates PBMs are able to negotiate with drug manufacturers.[24] Based on an annual survey of health plans, the average rebate that PBMs negotiated from drug manufacturers in 2012 was $16.70 per prescription for each brand name drug dispensed at a retail pharmacy.[25] That is, PBMs were able to negotiate a payment of $16.70 *each* time a prescription for a brand name drug was dispensed to one of their covered consumers. Similarly, the average rebate that PBMs negotiated for each prescription of a generic drug dispensed at a retail pharmacy was $6.13.

Other studies have examined the discounts PBMs negotiate with retail pharmacies.[26] A study by the U.S. General Accounting Office (GAO) that explored pharmacy benefits for federal employees found that PBMs were able to negotiate significant discounts on both brand name and generic prescriptions.[27] PBMs were able to negotiate prices on brand name drugs that were, on average, 18% less than the prices that non-covered consumers paid for the same drug at the same retail pharmacies.[28] Negotiated discounts on generic drugs were even greater; PBMs negotiated prices that were, on average, 47% less than the prices non-covered consumers paid for the same generic drugs at retail pharmacies.[29]

Most contracts between PBMs and plan sponsors require that PBMs share with the plan sponsor a very large fraction of the discounts they negotiate with manufacturers and pharmacies.[30] As a result, the rebates and cost savings negotiated by PBMs have led to significantly lower health plan costs and lower drug prices for consumers. [31] The FTC has

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[24] FED. TRADE COMM'N, *supra* note 4, at 44-55; PHARMACY BENEFIT MANAGEMENT INSTITUTE, 2012-2013 PRESCRIPTION DRUG BENEFIT COST AND PLAN DESIGN REPORT, 29 (2012), *available at* http://benefitdesignreport.com.

[25] PHARMACY BENEFIT MANAGEMENT INSTITUTE, *supra* note 24, at 29.

[26] FED. TRADE COMM'N, *supra* note 4, at 36; GAO REPORT, *supra* note 13, at 9.

[27] GAO REPORT, *supra* note 13, at 9.

[28] *Id.*

[29] *Id.*

[30] FED. TRADE COMM'N, *supra* note 4, at 57-58.

[31] Although there has been some dispute about the extent to which PBMs pass on the cost savings they negotiate from drug manufacturers to plan sponsors and consumers, research indicates that a significant portion of the savings are shared. A decade-old study by the FTC reported that even when there was less competition in the PBM industry, PBMs passed on over 50% of the cost savings to health plan sponsors. FED. TRADE COMM'N, *supra* note 4, at 57-60. However, as competition for sponsor contracts has intensified, evidence suggests that PBMs have agreed to share more of the cost savings to remain

found that, compared to customers without prescription-drug insurance, customers with PBM-administered prescription drug coverage paid 15% less for brand name drugs that did not have generic alternatives.[32] Similarly, customers with PBM-administered drug coverage paid 25% less for brand name drugs that did have generic alternatives.[33] The difference in prices was greatest for generic drugs: insured customers paid 50% less for generic drugs than did non-insured customers buying the exact same drugs. [34]

In addition to lowering the prices that consumers pay for prescription drugs, PBMs have employed several other tools to reduce both prescription drug spending and overall health care spending. Many PBMs have reduced drug spending by increasing the use of generic drugs. Generic drugs are bioequivalent to brand name drugs; they contain the same active ingredients as brand name drugs, and are chemically identical in strength, concentration, dosage form, and route of administration.[35] However, generic drugs are substantially less expensive: the average total prices for generic drugs are approximately 25% of the prices of brand name drugs that have no generic alternative.[36] By substituting generic drugs for brand name drugs when appropriate, PBMs have lowered prescription drug spending for covered consumers.[37]

PBMs' use of mail-order pharmacies also significantly reduces prescription drug spending. Mail-order pharmacies produce various cost saving, including the realization of economies of scale by dispensing larger prescription sizes (i.e. 90-day instead of 30-day), dispensing more formulary drugs that produce manufacturer rebates, and increasing substitutions from brand name to generic drugs.[38] These cost savings have translated into significant savings for consumers. The average price that consumers and health plans paid for brand name generic drugs dispensed from mail-order pharmacies was 27% less than the price that consumers without prescription drug coverage paid at retail pharmacies for the exact same drugs. [39] For generic drugs, mail-order pharmacies dispensed drugs that cost 53% less than what consumers without prescription drug coverage paid at retail pharmacies.[40]

PBMs also reduce prescription drug spending with various other cost-saving approaches. Some PBMs employ therapeutic interchange programs to substitute

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competitive. For example, the 2010 financial statements from one major PBM indicate that the company passed on 87.5% of the drug manufacturer discounts to customers. MEDCO HEALTH SOLUTIONS, ANNUAL REPORT (FORM 10-K) 55 (2010). In 2010, Medco Health Solutions reported receiving $5.8 billion in rebates from brand-name pharmaceutical manufacturers. Only 12.5% of total rebates were retained by Medco, while 87.5% were passed back to Medco's clients. *Id.* Similarly, Express Scripts stated in its 2010 Form 10-K, "Over the last several years, competition in the marketplace has also caused many PBMs, including us, to reduce the prices charged to clients for core services and share a larger portion of the formulary fees and related revenues received from pharmaceutical manufacturers with clients." EXPRESS SCRIPTS, ANNUAL REPORT (FORM 10-K) 19 (2010).

[32] FED. TRADE COMM'N, *supra* note 4, at 36.

[33] *Id.*

[34] *Id.*

[35] *Id*. at 61.

[36] On average, generic drugs cost less than half the price of brand name drugs that do have generic alternatives. *Id*. at 28.

[37] *Id*.

[38] *See*, *e.g.*, *id*. at 23-40.

[39] GAO REPORT, *supra* note 13, at 9.

[40] *Id.*

clinically appropriate and less costly drugs with physician approval.[41] Others use a prior authorization process that requires the PBM to approve the dispensing of certain drugs before the health plan sponsor will pay for it.[42] Similarly, step therapy plans require patients to try less expensive drugs before the plan sponsor will pay for more expensive drugs.[43] Most PBMs employ various other utilization controls, such as limits on frequent refills, to control costs.[44]

PBMs' cost-cutting tools produce significant savings for consumers. Estimates of the magnitude of PBMs' cost-savings range from 30%[45] to 35%[46] of total prescription drug spending. More affordable prescription drugs may mean that more Americans will be able to afford to take their medication as prescribed. Higher priced prescription drugs result in more people skipping doses or not filling prescriptions at all.[47] Thus, by saving consumers money, PBMs are also improving health outcomes and, in many cases, they may be saving lives.

II. REGULATION OF PHARMACY BENEFIT MANAGERS

Despite the substantial cost savings outlined in the previous section, PBMs also face substantial criticism. In this section, I discuss the specific arguments that critics make in their demands for more regulation of the PBM industry and the evidence showing that more regulation is unnecessary. I also briefly describe the history of federal and state regulatory efforts toward the PBM industry.

A. The Need for Regulation

Critics of the PBM industry argue that the PBM business model creates fundamental conflicts of interest. They argue that these conflicts of interest arise as a result of the incentives created both by PBMs' contracts with drug manufacturers and retail pharmacies and by PBMs' ownership of mail-order pharmacies. As a result, critics argue that more regulation of the PBM industry is needed to protect the interests of consumers and plan sponsors.

Critics allege that the rebates drug manufacturers pay to PBMs to have their drugs listed on the formulary create incentives for PBMs to heavily favor certain drugs over others.[48] This could be detrimental to consumers and plan sponsors if the favored drugs

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[41] *See, e.g.*, FED. TRADE COMM'N, *supra* note 4, at 10-14.
[42] *See, e.g.*, *id.*
[43] *See, e.g.*, *id.*
[44] *See, e.g.*, *id.*
[45] CONG. BUDGET OFFICE, *supra* note 3, at Table 6 at 28. The "Average Value of Drug Benefit" is the estimate of PBM savings.
[46] VISANTE, *supra* note 18, at 5.
[47] William Sage et al., *Why Competition Law Matters to Health Care Quality*, 22 HEALTH AFFAIRS 31, 35 (2003). ("when costs are high, people who cannot afford something find substitutes or do without. The higher the cost of health insurance, the more people are uninsured. The higher the cost of pharmaceuticals, the more people skip doses or do not fill their prescriptions").
[48] Letter from Senator Mark Montigny, Legislative Association on Prescription Drug Prices, to Chairman Deborah Platt Majoras, Fed. Trade Comm'n (May 11, 2005) ("Our own experience as state legislators dealing with state agencies which must negotiate with PBMs has shown that PBMs often act contrary to the

either cost more or provide inferior therapeutic benefits as compared with other alternatives.

Similarly, critics claim that PBMs' confidential contracts with retail pharmacies create potential conflicts of interest. For example, they argue that PBMs can unfairly increase the spread—the difference between the prices plan sponsors pay for a drug and the amount the PBM reimburses the retail pharmacy—to increase PBM profits.[49] This could harm pharmacies, plan sponsors, and consumers by generating overpayments from plans and reduced payments to retail pharmacies.

However, the largest controversy involves PBMs' ownership of mail-order pharmacies. Critics assert that by both administering the pharmacy benefits for plan sponsors and dispensing drugs via their mail-order pharmacy, PBMs have the opportunity to create various "self-dealing" arrangements to increase their profits.[50] For example, PBMs could encourage plans to adopt certain payment structures that steer consumers to purchasing more drugs from the PBM-owned mail-order pharmacy.[51] In addition, critics allege that PBMs can persuade their mail-order pharmacies to dispense more brand name drugs or expensive drugs that yield higher rebates from drug manufacturers.[52] Finally, PBM opponents allege that PBM-owned mail-order pharmacies increase their profits by repackaging drugs and selling them at a higher price.[53] All of these practices could be harmful if PBMs' increased profits came at the expense of consumers.

In response to these allegations, several government entities—The Federal Trade Commission (FTC), the General Accounting Office (GAO), and the Congressional Budget Office (CBO)—have analyzed the PBM industry to determine whether any of these alleged conflicts of interest produce undesirable consequences for consumers and plan sponsors.[54] The studies all conclude that PBMs benefit consumers and health plan sponsors by significantly reducing the prices that consumers pay for prescription drugs.[55]

In response to the specific allegations by critics, both the FTC and GAO found that PBMs pass on a significant portion of the payments they receive from drug manufacturers.[56] In fact, the GAO concluded that PBMs' sharing of manufacturer payments reduce total annual drug spending by as much as 9%.[57] Similarly, the GAO

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interests of the buyers they represent. . . . PBMs often direct individuals to drugs that provide the PBM with the highest rebates, and the greatest margins, while failing to pass those savings on to purchasers.").

[49] *See, e.g.*, Robert I. Garis & Bartholemew E. Clark, *The Spread: Pilot Study of an Undocumented Source of Pharmacy Benefit Manager Revenue?*, J. AM. PHARMACISTS ASS'N 15-21 (2004).

[50] JAMES LANGENFELD & ROBERT MANESS, THE COST OF PBM "SELF-DEALING" UNDER A MEDICARE PRESCRIPTION DRUG BENEFIT 30-31 (2003), *available at* http://www.reducedrugprices.org/read.asp?news=325.

[51] FED. TRADE COMM'N, *supra* note 4, at xviii.

[52] *See* Press Release, Nat'l Ass'n Of Chain Drug Stores, NACDS Applauds Bipartisan Bills to Confront PBM Tactics and Protect Pharmacy Choice for Patients (2011), available at http://www.nacds.org/Home/TabId/107/PostId/149/nacds-applauds-bipartisan-bills-to-confront-pbm-tactics-and-protect-pharmacy-choice-for-patients.aspx.

[53] *See* LANGENFELD & MANESS, *supra* note 50, at 1, 5-6, 11-13.

[54] FED. TRADE COMM'N, *supra* note 4, at 27-36; GAO REPORT, *supra* note 13, at 10; CONGRESSIONAL BUDGET OFFICE, *supra* note 3, at 40.

[55] FED. TRADE COMM'N, *supra* note 4, at 27-36; GAO REPORT, *supra* note 13, at 10; CONGRESSIONAL BUDGET OFFICE, *supra* note 3, at 40.

[56] FED. TRADE COMM'N, *supra* note 4, at 57-60. GAO REPORT, *supra* note 13, at 11-12.

[57] GAO REPORT, *supra* note 13, at 11-12.

found that PBMs achieved significant discounts for drugs purchased at retail pharmacies; customers with PBM-administered drug coverage paid 18% to 47% less than non-covered consumers paid for the same drug at the same retail pharmacies.[58]

In regards to the allegations concerning PBM-owned mail-order pharmacies, the FTC found no evidence of self-dealing arrangements. It found that PBM-owned mail-order pharmacies generally are no less likely to substitute generic drugs for brand name drugs than are either retail pharmacies or mail-order pharmacies not owned by PBMs.[59] Similarly, it concluded that there is no evidence that PBM-owned mail-order pharmacies substitute more expensive drugs for therapeutically similar cheaper drugs.[60] Finally, the FTC found that PBMs rarely dispense repackaged drugs through their owned mail-order pharmacies, and, as a result, the financial impact of repackaging is negligible.[61] Both GAO and FTC found that as a result of PBMs' cost-saving practices, the prices that consumers paid for prescription drugs dispensed from PBM-owned mail-order pharmacies are significantly less than the prices of drugs dispensed from retail pharmacies.[62]

B. History of Regulatory Efforts

Despite the lack of evidence, suspicion of PBMs has led both state and federal governments to pursue various frameworks for regulating the PBM industry.[63]

In general, the federal government's efforts to regulate the PBM industry have been much less expansive than the states' efforts.[64] The FTC, the federal agency tasked with promoting consumer protection and eliminating anti-competitive business practices, has focused its oversight of PBMs on pursuing antitrust issues related to the PBM industry.[65] Beyond that, many FTC officials believe it is unnecessary to regulate the PBM industry and are openly opposed to such regulation.[66] The Department of Labor, the government agency that regulates employee benefit plans, has not sought to regulate the PBM industry.[67] Indeed, some regulatory scholars believe it would be impossible for preexisting regulatory agencies to effectively monitor the nuanced commercial interactions that allow PBMs to lower healthcare costs;[68] they fear that misguided administrative actions by regulators that do not fully understand the complexity of the PBM industry and business model could have a negative impact on the integrity of the healthcare system.[69] Some advocate for the creation of an entirely new federal regulatory

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[58] *Id*.
[59] FED. TRADE COMM'N, *supra* note 4, at 65-70.
[60] *See id.* at xii.
[61] *See id.* at xiii.
[62] *See id.* at 27-36; GAO REPORT, *supra* note 13, at 10.
[63] *See* Kevin C. Green, *Regulation of Pharmacy Benefit Managers: An Economic Analysis of Regulation and Litigation as Agents of Health Care Change* 9 (January 2008), http://works.bepress.com/kevin_green/1.
[64] *See id*.
[65] *Id*.
[66] The FTC has written numerous papers discouraging any additional regulation of the PBM industry. *Id*. at 11.
[67] *Id*. at 9.
[68] *See* Mark Meador, *Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry Through Regulation*, 20 ANNALS OF HEALTH L. 77, 109 (2011).
[69] *Id.*

agency devoted to monitoring the PBM industry.[70] However, the creation of such an agency is unlikely given government concerns that the costs of bureaucratic red tape would negate the savings that the PBM industry presently provides to consumers.[71]

The federal government's reluctance to regulate PBMs has encouraged the critics of PBMs to turn to the states for PBM regulation. [72] Over the past decade, nearly every state has considered legislation to regulate PBMs, and seventeen states have enacted some regulation.[73] The states have chosen different aspects of PBMS to regulate, including information disclosure licensing, investigations, duties to clients, and rebate sharing.[74] The diversity of regulatory structures enacted in different states has caused redundant, complex litigation.[75]

Still, there are two common themes that unify PBM regulation across most states.[76] First, almost all states require PBMs to register with their state's insurance commissioner.[77] Second, states generally require PBMs to submit annual audits.[78] Beyond these common themes, states' regulatory frameworks contain numerous idiosyncratic features distinguishing them from other states.[79]

III. REGULATORY AUTHORITY OVER PHARMACY BENEFIT MANAGERS

Despite the assorted regulatory environments that PBMs face in different states, all states that have elected to regulate PBMs have done so through their Insurance Commission. However, in 2011, Mississippi became the first and only state to shift regulatory authority over PBMs from the Insurance Commission to the Board of Pharmacy.[80] Legislatures in Oregon, Hawaii, and Oklahoma are also considering proposals to allow the state Boards of Pharmacy to regulate PBMs. In the last legislative session, Washington, New Hampshire, Alabama, and Louisiana considered similar proposals.[81]

In this section, I discuss existing and proposed regulatory schemes that grant Boards of Pharmacy regulatory authority over PBMs. Then I present an economic analysis of these approaches and explain why granting regulatory authority to a market adversary threatens competition in the prescription drug market. As a result of these approaches,

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[70] *Id*.
[71] *See* Letter from Susan S. DeSanti et al., Director Office of Policy Planning, Fed. Trade Comm'n, et. al. to Mark Formby, Representative, Mississippi House of Representatives 4 (Mar. 22, 2011), *available at* http://www.ftc.gov/os/2011/03/110322mississippipbm.pdf [hereinafter Letter to Mark Fornby].
[72] EDWARD C. LAWRENCE ET AL., AN OVERVIEW OF PHARMACY BENEFIT MANAGERS: FOCUS ON THE CONSUMER 15 (2012), *available at* http://www.rxobserver.com/wp-content/uploads/2012/05/lawrencestudy.pdf.
[73] *Id.*
[74] *Id*.; Green, *supra* note 63, at 9.
[75] Meador, *supra* note 68, at 109.
[76] *See* LAWRENCE, *supra* note 72, at 14.
[77] *Id*.
[78] *Id*.
[79] *Id*.
[80] Pharmaceutical Care Management Association, *supra* note 5.
[81] Express Scripts, *Pharmacy Benefit Manager (last session)* (on file with author); Express Scripts, *Pharmacy Benefit Manager (this session)* (on file with author).

both consumers and health plan sponsors will pay more for prescription drugs and prescription drug coverage.

A. Regulation by the Board of Pharmacy

Prior to 2011, all states placed regulatory authority over PBMs with a neutral insurance commission.[82] The state insurance commissioners are either political appointees or elected officials that have nothing to gain or lose from regulatory decisions that affect PBMs.[83] Several states, however, have recently taken steps to shift regulatory control of PBMs away from insurance commissioners and to the state Boards of Pharmacy.[84] Unlike the neutral insurance commissions, the Boards of Pharmacy are composed of pharmacists that are the direct market adversaries of PBMs.[85]

1. Mississippi

On April 26, 2011, Mississippi Governor Haley Barbour signed Senate Bill 2445 amending the Mississippi Pharmacy Practice Act.[86] This law shifted regulatory authority over PBMs from the Mississippi Insurance Commissioner to the Mississippi Board of Pharmacy. Under the new amendments, PBMs need to clear several regulatory hurdles to legally operate in Mississippi. The law requires PBMs to obtain a license from the Board of Pharmacy,[87] and to submit annual balance sheets and income statements to the Board of Pharmacy.[88] Although these requirements do not differ substantially from what was required of PBMs prior to enactment of the new amendments,[89] the critical difference is that PBMs must turn over the necessary information to the Board of Pharmacy instead of a neutral insurance commission. Of greater concern is that the new amendments to the Mississippi Pharmacy Practice Act allow the Board to conduct financial examinations of PBMs' businesses,[90] and require PBMs to share potentially sensitive business information with the Board.[91] Although the Act specifies that PBMs will not be required to disclose proprietary information, it provides no guidance on what is considered proprietary. Thus, the scope of protection for sensitive financial information is unclear. Moreover, the Board of Pharmacy is permitted to share the business information it

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[82] *Id.*
[83] *Id.*
[84] *Id.*
[85] *Id.*
[86] *Id.*
[87] "The board shall be responsible for the control and regulation . . . of pharmacy benefit managers . . . ." MISS. CODE ANN. § 73-21-83 (West 2013). The initial licensure fee for pharmacy benefit managers shall be set by the board but shall not exceed Five Hundred Dollars ($ 500.00). *Id*. The licensure period lasts from January 1st to December 31st annually. *Id*.
[88] MISS. CODE ANN. § 73-21-157 (West 2013). These financial documents are due "by March 1 or within sixty (60) days of the end of [the PBM's] fiscal year if not a calendar year." *Id*.
[89] Letter from George Dale, Commissioner of Insurance, Mississippi Insurance Department, to All Pharmacy Benefit Managers Operating in the State of Mississippi, Bulletin No. 2007-1 (2007), available at: http://www.mid.ms.gov/bulletins/20071bull.PDF.
[90] MISS. CODE ANN. § 73-21-159 (West 2013).
[91] *See* MISS. CODE ANN. § 73-21-157 (West 2013). The amendments include the following clause limiting the type of information PBMs must disclose the Board of Pharmacy: "However, no pharmacy benefit manager shall be required to disclose proprietary information of any kind to the board." *Id*.

obtains from PBMs with any health plan sponsor, pharmacist, or pharmacy.[92] As I explain in the next section, allowing the Board to share sensitive business information with pharmacies, the market adversaries of PBMs, threatens to undercut competition in the PBM industry and increase the cost of both prescription drugs and prescription drug coverage. These amendments to the Mississippi Pharmacy Practice Act include a sunset provision repealing these regulatory changes on July 1, 2013.[93]

2. Proposals in Other States

Legislation currently under consideration in Oregon, Hawaii, and Oklahoma would alter regulatory structures for monitoring PBMs by shifting power to the States' Boards of Pharmacy. In the last legislative session, Washington, New Hampshire, Alabama, and Louisiana also considered similar proposals.[94] The regulatory provisions in the proposed legislation are similar to those enacted in Mississippi.

On January 14, 2013, the Oregon Representative Committee on Health Care introduced House Bill 2123, which would require the Oregon Board of Pharmacy to regulate PBMs.[95] The proposed legislation would require PBMs conducting business in Oregon to obtain a license from the Oregon Board of Pharmacy.[96] It would alter PBMs' pricing schemes by requiring PBMs "to permit covered individuals to fill mail-order prescriptions at a retail community pharmacy [sic] in the same manner and at similar price that individuals fill orders at mail-order pharmacies."[97] Thus, this provision would eliminate the market advantage that PBMs' mail-order pharmacies currently have over retail pharmacies.

On January 17, 2013, both Oklahoma and Hawaii introduced legislation altering the states' regulation of PBMs.[98] Hawaii's legislation grants the Board of Pharmacy relatively open-ended regulatory authority over PBMs by allowing the Board "to adopt rules . . . to regulate all pharmacy benefit management companies."[99]

In addition to requiring PBMs to "obtain a license from the State Board of Pharmacy,"[100] Oklahoma's legislation specifically grants the Board the ability to demand proprietary business information from PBMs. It would allow the Board to demand disclosures from PBMs and, as necessary, "subpoena witnesses and information."[101] It would also require PBMs to disclose sensitive financial information including "the difference in the amount paid to providers for prescription services rendered to covered individuals and the amount billed by the pharmacy benefits manager to the covered entity or plan sponsor to pay for prescription services rendered to covered individuals."[102] In

[92] MISS. CODE ANN. § 73-21-159 (West 2013).
[93] MISS. CODE ANN. § 73-21-83 (West 2013); MISS. CODE. ANN. § 73-21-157 (West 2013); MISS. CODE ANN. § 73-21-159 (West 2013).
[94] Express Scripts, *supra* note 81.
[95] H.B. 2123, 77th Leg. Assemb., Reg. Sess. (Or. 2013).
[96] *Id*.
[97] *Id*.
[98] H.B. 63, 27th Leg. Assemb., Reg. Sess. (Hi. 2013); H.B. 2100, 54th Leg. Assemb., Reg. Sess. (Ok. 2013).
[99] H.B. 63, 27th Leg. Assemb., Reg. Sess. (Hi. 2013)
[100] H.B. 2100, 54th Leg. Assemb., Reg. Sess. (Ok. 2013).
[101] *Id*.
[102] *Id*.

other words, Oklahoma's legislation explicitly allows the Board of Pharmacy to demand confidential information about the business practices of PBMs.

B. Economic Analysis of Regulation by a Market Adversary

The amended Mississippi Pharmacy Practice Act creates an inherent conflict of interest by giving pharmacists regulatory control over their natural competitors in the marketplace. The power to regulate a market adversary gives pharmacists unprecedented power and will undercut competition in the prescription drug market. Moreover, this regulatory scheme will increase the prices of prescription drugs for both consumers and health plan sponsors.

Pharmacists and PBMs are market adversaries in two different areas of the prescription drug market. First, pharmacists and PBMs negotiate prices that plan sponsors will pay for prescription drugs at retail pharmacies; the lower the price that PBMs can negotiate, the lower the profits for pharmacies. Second, retail pharmacies directly compete with PBM-owned mail-order pharmacies for prescription drug sales; the more prescription drugs sold by mail-order pharmacies, the fewer drugs sold by retail pharmacies.

Because PBMs are the direct market adversaries of pharmacies in several segments of the prescription drug market, pharmacists have the incentive to take actions that benefit themselves at the expense of PBMs. Reductions of PBMs' profits generally lead to more profits for pharmacists. By granting the pharmacist-controlled Mississippi Board of Pharmacy regulatory authority over PBMs, the amended Act grants pharmacists the power to act on these incentives. That is, under the amended Act, the Board has both the incentive and the authority to exercise its regulatory power in ways that weaken PBMs' competitive positions, and in turn, benefit pharmacies.

Indeed, because PBMs' mail-order pharmacies are direct competitors to retail pharmacies, Mississippi's PBM regulatory framework is similar to allowing a board composed of taxi drivers to regulate a market competitor, private town car companies. Imagine the consequences if the taxi board had the authority to set rules governing the town car business model or demand confidential business information from town car companies. The taxi board would have both the incentive and the ability to take regulatory measures that competitively disadvantaged town car companies while benefitting taxi drivers. The incentives facing the pharmacist-controlled Board of Pharmacy are no different than the incentives facing a taxi board.

There are numerous ways that the Mississippi Board of Pharmacy can exploit this regulatory power to establish rules and practices that give pharmacists a competitive advantage at the expense of the PBM industry. The Board of Pharmacy could establish various rules or practices that improve pharmacists' bargaining position as they negotiate with PBMs for retail prescription drug prices. Similarly, the Board could establish rules that restrict cost-saving practices that attract consumers to mail-order pharmacies and away from retail pharmacies. In the next sections, I discuss two concrete examples that demonstrate how the Mississippi Board of Pharmacy has already established rules and practices that competitively disadvantage PBMs while benefiting pharmacists: requiring

PBMs to turn over sensitive financial information and imposing a fiduciary duty on PBMs.

Unfortunately, the Board's recently adopted regulations not only reduce the profitability of PBMs, they also hurt consumers and sponsors. Future Board practices will have the same impact.[103] PBMs' business strategies that reduce profits for pharmacies—negotiating price discounts at retail pharmacies and implementing cost-saving practices at mail-order pharmacies that attract customers away from retail pharmacies—also lower the prices that consumers and health plans pay for prescription drugs. Thus, by restricting these business strategies in an effort to improve pharmacists' profits, the Board would increase the prices that health plan sponsors and consumers pay for prescription drugs.

In a letter addressing the likely consequences of allowing the Mississippi Board of Pharmacy to regulate PBMs, the Federal Trade Commission opined on the wisdom of allowing boards to regulate market adversaries:

> Although we offer no specific recommendations on the ideal structure for regulating PBMs, it is our understanding that no other state has placed PBMs under the regulatory control of its pharmacy board. Because pharmacists and PBMs have a competitive, and at times, adversarial relationship, we are concerned that giving the pharmacy board regulatory power over PBMs may create tensions and conflicts of interest for the pharmacy board. [104]

Similarly, the Federal Trade Commission has opposed regulatory boards composed of market participants in other industries. *In the Matter of North Carolina Board of Dental Examiners,*[105] the North Carolina State Board of Dental Examiners "determined on its own that teeth whitening was a practice that could be performed only under the supervision of a dentist and used the imprimatur of state authority to drive lower-priced non-dentists from the relevant market."[106] The board consisted of six licensed dentists, one licensed dental hygienist, and one consumer member.[107]

In their analysis of the regulatory framework of the North Carolina Board of Dental Examiners, the FTC stated that when a state regulatory body is controlled by participants in the very industry it purports to regulate, "common sense and economic theory . . . dictate the conclusion that Board actions in this area could be self interested."[108] The FTC questioned the board's ability to regulate the North Carolina dental industry in an unbiased fashion given the economic and political pressures influencing the members of the board.[109] The FTC also noted the lack of supervision of the board's decision making by impartial state actors.

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[103] Letter to Mark Fornby, *supra* note 71, at 4.
[104] *Id*. at 5.
[105] Opinion of the Commission, North Carolina Board of Dental Examiners, Docket No. 9343 (Feb. 8, 2011), *available at* http://www.ftc.gov/os/adjpro/d9343/110208commopinion.pdf.
[106] *Id*. at 2.
[107] *Id*. at 4.
[108] *Id*. at 13.
[109] *Id*.

The United States Supreme Court has also recognized the danger of regulatory boards composed of market participants pursuing their own interests rather than the interests of the state.[110] In *Patrick v. Burget*,[111] a surgeon in Oregon declined an invitation to join a local medical clinic and instead began an independent practice in competition with the clinic.[112] Subsequently, the surgeon experienced difficulties "in his professional dealings with clinic physicians."[113] These difficulties ultimately culminated in the local hospital's peer-review board terminating the surgeon's privileges to use the hospital on the ground that petitioner's care of his patients was below the standard of the hospital.[114] The peer-review board consisted of members of the local medical clinic that the surgeon had declined to join.[115] The surgeon filed suit alleging that the peer-review board violated the Sherman Act by initiating proceedings in order to reduce competition rather than to improve patient care. The Court ruled in favor of the surgeon and noted that a member of a private regulatory body "may be presumed to be acting primarily on his or her own behalf."[116] The Court added that state supervision is necessary to ensure regulatory bodies actually further state regulatory policies.[117]

The design of Mississippi's PBM regulatory framework is as troubling as the regulatory frameworks discussed in *Patrick* and *North Carolina Board of Dental Examiners*, and could raise antitrust issues similar to those in *Patrick*.[118] Mississippi's Board of Pharmacy is controlled by pharmacists that oppose the PBM industry. As was suggested by the FTC and Supreme Court, it is safe to assume that the members of a professional board that are market adversaries to the groups they are charged with regulating will act in their own self-interest. Moreover, there are no statutory safeguards to protect the PBM industry when members of the Board of Pharmacy pursue policies benefitting pharmacists at the expense of the PBMs. Mississippi has no program to actively supervise the Board of Pharmacy's decisions; there is no Mississippi statute that

[110] The Supreme Court has held that the Sherman Act cannot be used "to restrain state action or official action directed by a state;" however, when regulating anti-competitive activity, the Federal Government must ensure that private parties claiming state-action immunity from Sherman Act liability are in fact acting in the interest of the state. Patrick v. Burget, 486 U.S. 94, 100 (1988). It can be difficult to assess whether a regulatory board is acting in the interest of the state and should be immune from Sherman Act liability. The Court uses a two pronged test to evaluate whether the actions of a board should be deemed state action and thus shielded from the antitrust laws: first, the Court considers whether the challenged activity is "clearly articulated and affirmatively expressed as state policy;" second, the court considers whether the anticompetitive conduct is "actively supervised by the State." *Id*.

[111] *Id*.

[112] *Id*.

[113] *Id*.

[114] *Id*.

[115] Patrick v. Burget, 800 F.2d 1498, 1503-04 (9th Cir. 1986) *rev'd*, 486 U.S. 94 (1988).

[116] *Patrick*, 486 U.S. at 101.

[117] *Id.* at 100-01.

[118] The Supreme Court "established a rigorous two-pronged test to determine whether anticompetitive conduct engaged in by private parties should be deemed state action and thus shielded from the antitrust laws. First, the challenged restraint must be one clearly articulated and affirmatively expressed as state policy. Second, the anticompetitive conduct must be actively supervised by the State itself. Only if an anticompetitive act of a private party meets both of these requirements is it fairly attributable to the State." *Id*.

provides for direct judicial review of the Board of Pharmacy's actions.[119] Although the PBM industry can challenge decisions by the Board of Pharmacy in court, until a court rules, PBMs will suffer substantial financial losses and consumers and health plan sponsors will pay more for prescription drugs.

Thus, under the amended Mississippi Pharmacy Practice Act, the Mississippi Board of Pharmacy has both the incentive and the opportunity to exert its regulatory authority in ways that benefit pharmacies at the expense of PBMs. Even though the Board has only had regulatory authority over PBMs for a little over a year, two examples of regulations that harm PBMs have already emerged.

1. Disclosure of Sensitive Business Information

The first example of a regulation by the Mississippi Board of Pharmacy that competitively disadvantages PBMs while benefitting pharmacies is the Board's ability to demand sensitive business information from PBMs. This business information includes not only standard financial statements such as balance sheets and income statements, but also "any other information relating to the operations of the pharmacy benefit manager required by the board."[120] Although the Act specifies that PBMs will not be required to disclose proprietary information, it provides no guidance on what is considered proprietary. Thus, the scope of protection for sensitive financial information is unclear.

Moreover, the amended Act gives the Board the power to share PBMs' financial information with pharmacists, the direct market rivals of PBMs: "The board may provide a copy of the financial examination to the person or entity who provides or operates the health insurance plan or to a pharmacist or pharmacy."[121]

Thus, the amended Act grants the Board of Pharmacy the power to require PBMs to turn over sensitive financial information, and then allows the Board to share that information with pharmacies. This practice will benefit pharmacies by giving them business information about their market adversaries while weakening the PBM industry and producing significant harms for consumers and health plan sponsors.

As an initial matter, if the Board requires PBMs to turn over additional financial information than was previously required, the collection, preparation, and presentation of the additional information will increase costs for the PBMs. [122] These costs will likely be passed on to health plans and consumers.

More importantly, if the Board forces PBMs to turn over sensitive financial information, it will reduce PBMs' bargaining power to negotiate discounts with pharmacies and rebates with drug manufacturers, thus increasing drug prices for consumers. Both pharmacies and drug manufacturers are less likely to offer the same price terms to PBMs when they know their rival pharmacies or manufacturers can learn

[119] The decisions of a State board are only shielded from the antitrust laws if the board is "actively supervised by the State itself." *Id*. The lack of any mechanism enabling the State of Mississippi to monitor the decisions of the Mississippi Board of Pharmacy suggests the Mississippi Board of Pharmacy's regulatory actions will not be shielded from the antitrust laws.

[120] MISS. CODE. ANN. § 73-21-159 (West 2013).

[121] *Id*.

[122] Letter from James Cooper, Acting Director, Office of Policy Planning, Fed. Trade Comm'n, et. al., to Senator James L. Seward, New York Senate, 4 (March 31, 2009*), available at* http://www.ftc.gov/os/2009/04/V090006newyorkpbm.pdf. [hereinafter Letter to James L. Seward].

the specifics of the arrangement. When rivals can see the arrangement and offer the same or better terms, it blunts the incentive to offer PBMs favorable terms in the first place.[123] Moreover, pharmacies and manufacturers will be less likely to offer "deals" when they know that everyone they do business with can see the terms of the deal and will likely demand the same terms.[124] Finally, uncertainty about rivals' offerings induces pharmacies to offer greater discounts and manufacturers to offer greater rebates to try to outdo the "unknown" deals.[125] But when the arrangements are no longer unknown, this incentive to outdo unknown price terms disappears. Hence, disclosure of sensitive financial information will reduce the discounts and rebates that PBMs can pass on to consumers and health plan sponsors. As a result, prescription drug spending will increase.

Indeed, federal antitrust agencies have explained how sharing information among competitors can harm consumers; it "can blunt a firm's incentive to offer customers better deals by undercutting the extent to which such a move would win business away from rivals" and "also can enhance a firm's incentive to raise prices by assuaging the fear that such a move would lose customers to rivals."[126]

Thus, granting the Board the power both to require PBMs to disclose sensitive business information and to share that information with pharmacies will reduce competition in the market for prescription drugs. Pharmacies and manufacturers will no longer compete as effectively for PBMs' business when business arrangements are no longer private. Moreover, PBMs will no longer be able to intensely compete for contracts with health plan sponsors by offering exclusive prices that they were able to negotiate with pharmacies and drug manufacturers.

Finally, the increase in drug prices and reductions in competition could spill over to states beyond Mississippi. PBMs' business practices are likely similar across states so that disclosing information about PBMs' practices in Mississippi will inform pharmacies and manufacturers about PBMs' practices in other states. They can use the information from Mississippi for their benefit in other states. For example, pharmacies and drug manufacturers in Alabama may demand the same pricing arrangements as PBMs negotiated in Mississippi. Thus, disclosure of sensitive financial information in Mississippi could reduce competition across the industry and cause prescription drug prices to increase nationwide.

2. Imposing a Fiduciary Duty on Pharmacy Benefit Managers

The most recent example of the Mississippi Board of Pharmacy exploiting its regulatory authority to disadvantage PBMs is the imposition of a fiduciary duty on PBMs. Adopted by the Board of Pharmacy on January 23, 2013, the new amendment to the Mississippi Pharmacy Practice Regulations states that PBMs "shall operate to the best interest of the patient or citizen of Mississippi, including costs related to the patient or

[123] Letter to Mark Fornby, *supra* note 71, at 7.
[124] *Id*.
[125] *Id*.
[126] U.S. DEPARTMENT OF JUSTICE AND FEDERAL TRADE COMMISSION, HORIZONTAL MERGER GUIDELINES § 7 (2010) (describing anticompetitive effects of coordination among rivals), *available at* http://ftc.gov/os/2010/08/100819hmg.pdf.

citizen."[127] A duty to act in the "best interest" has been interpreted by courts to be a fiduciary duty;[128] thus, this new regulation gives PBMs a fiduciary duty to covered consumers. As a fiduciary, a PBM would owe consumers a duty of loyalty by acting "on behalf of the principal and only for his benefit."[129] This fiduciary duty includes a "duty to give information" that is independent of any disclosure requirements contained in the statute or private contracts and a "duty to account for profits" that may require PBMs to share more of their profits with health plan clients.[130]

Fiduciary duties generally exist in situations where contracts cannot easily solve potential conflicts of interest. In these situations, the threat of litigation that accompanies a fiduciary duty can deter opportunistic behavior.[131] However, the PBM marketplace is not one in which contracts generally fail to protect against opportunistic behavior. Health plan sponsors can enter into any contract they choose, and because of the intense competition among PBMs for contracts with health plan sponsors, the sponsors have considerable leverage to obtain desired contract terms.[132] As a result, the sponsors can require a limited fiduciary duty for PBMs or the disclosure of sensitive business information in the contract.

Even though health plan sponsors could contract for a fiduciary duty for PBM partners, many would choose not to because of the established consequences of this heightened legal duty. A fiduciary duty entails a broader set of legal obligations than those typically specified in PBM contracts. With the new legal obligations come new litigation risks; PBMs could be liable in tort actions in addition to being subject to liability claims for breach of contract.[133] These new litigation risks will increase certain legal, administrative, and operating costs for PBMs. PBMs, in turn, will pass on these additional costs to health plan sponsors and consumers, increasing the cost of prescription drug coverage.

First, the increase in the risk of litigation for fiduciaries will increase certain legal and administrative costs for PBMs. The legal obligations accompanying a fiduciary duty present new uncertainties and complexities. PBMs will either expand the efforts of their existing litigation departments or consult with outside counsel to help them understand

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[127] 2012 MS REG TEXT 313748 (NS).

[128] *See* Poe v. Summers, 11 So. 3d 129, 136 (Miss. Ct. App. 2009) ("A fiduciary duty exists 'where one person or institution assumes a trust relationship with another, such that the former, as a matter of choice or legal obligation, assumes the responsibility to act in the *best interest* of the latter, even to the detriment and peril of the *best interests* of the former.'") (emphasis added); *see also* BLACK'S LAW DICTIONARY (9th ed. 2009) (defining fiduciary duty as "a duty to act with the highest degree of honesty and loyalty toward another person and in the *best interests* of the other person") (emphasis added).

[129] *See* RESTATEMENT (SECOND) OF AGENCY §§ 377386 (1958) (regarding duties of care and obedience) and §§ 387395 (duties of loyalty); J. Dennis Hynes, *Freedom of Contract, Fiduciary Duties, and Partnerships: The Bargain Principle and the Law of Agency*, 54 WASH. & LEE L. REV. 439, 443 (1997).

[130] *See* RESTATEMENT (SECOND) OF AGENCY § 381 (duty to give information) and § 388 (duty to account for profits arising out of employment, subject to contract, general duty to convey profits to principal).

[131] For example, fiduciary duties often arise in situations involving professional services. *See, e.g.,* Packard-Bamberger & Co., Inc. v. Collier, 771 A.2d 1194, 1203 (N.J. 2001) (attorneys); Carluccio v. 607 Hudson St. Holding Co., 57 A.2d 452, 453 (N.J. 1948) (real estate agents); Fasolo v. Bd. of Trustees of Div. of Pensions of New Jersey Treasury, 464 A.2d 1180, 1187 (N.J. Super. Ct. App. Div. 1983) (trustees).

[132] FEDERAL TRADE COMMISSION, *supra* note 4, at 57-60.

[133] *See* 2012 MS REG TEXT 313748 (NS).

their new status and advise them on certain defensive business practices to adopt in order to avoid litigation.[134]

Second, liability concerns may deter PBMs from engaging in certain cost-reducing practices. For example, because fiduciaries cannot profit at the expense of their clients, PBMs may be concerned that owning a mail-order pharmacy and employing incentives to direct covered consumers to that pharmacy will be interpreted as profiting at the expense of their clients.[135] Because mail-order pharmacies are able to offer lower priced prescription drugs,[136] deterring PBMs from utilizing mail-order pharmacies will increase the prices that consumers and health plan sponsors pay for prescription drugs.

PBMs may be hesitant to contract at all with certain health plan sponsors because of the increased litigation risk that accompanies their fiduciary duty in these relationships. For example, sponsors that wish to provide only a limited network of retail pharmacies or place fewer preferred drugs on their formularies may expose PBMs to claims for breach of duties of care and skill if these arrangements appear to depart from best industry practices.[137] Similarly, health plan sponsors may allege a breach of fiduciary duty if PBMs negotiate rebates from manufacturers or discounts from retail pharmacies that are less favorable relative to the terms negotiated by other PBMs or by the same PBMs in contracts with other health plan sponsors.[138] If PBMs agree to contract with health plan sponsors despite the fiduciary duty, they will only be willing to incur the increased litigation risk if they receive higher fees from health plan sponsors. These fees will increase the cost of prescription drug coverage for consumers.

Moreover, fiduciary status will impose additional reporting requirements on PBMs that would likely lead to the disclosure of sensitive business information.[139] As previously discussed, such disclosure will undermine competition in the PBM industry and increase prescription drug prices for consumers and health plan sponsors. It will also competitively disadvantage PBMs while benefitting pharmacies.

Thus, imposing a fiduciary duty on PBMs will compel these companies to adopt certain defensive measures, curb various cost-saving practices, incur additional legal and administrative costs, and increase the reporting of sensitive business information. As a result of these changes, the cost of prescription drug coverage administered by PBMs will increase. Moreover, many of the possible consequences of a fiduciary duty, such as a reduction in the utilization of mail-order pharmacies or increased reporting of sensitive business information, will undermine PBMs' competitive positions in the prescription drug market relative to retail pharmacies that do not have fiduciary status. That the Board of Pharmacy would impose a fiduciary duty on PBMs when a heightened legal duty is unnecessary—health plan sponsors' contracts can already safeguard against opportunistic behavior and even contractually impose a fiduciary duty on PBMs—demonstrates that the Board is exploiting its regulatory authority to disadvantage PBMs while benefitting pharmacies.

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[134] Letter from Maureen K. Ohlhausen, Director, Office of Policy Planning, Fed. Trade Comm'n, et al to Senator Nellie Pou, New Jersey General Assembly, at 5 (April 17, 2007*), available at* http://www.ftc.gov/be/V060019.pdf. [hereinafter Letter to Nellie Pou].
[135] *Id*. at 6.
[136] GAO REPORT, *supra* note 13, at 9.
[137] Letter to Nellie Pou, *supra* note 134, at 6.
[138] *Id*.
[139] Letter to James L. Seward, *supra* note 122, at 9-10.

Indeed, no state regulatory agency has ever independently enacted a rule imposing a fiduciary duty on PBMs. Over the past decade, there have been bills introduced in over thirty states that sought to impose a fiduciary standard on PBMs.[140] However, legislatures in twenty nine of these states decided against imposing a fiduciary duty after considering the likely consequences. Maine, in 2003, is the only state that enacted such a law, but that law was subsequently repealed by the Maine legislature in 2011.[141] The District of Columbia also enacted a fiduciary provision in a 2004 law. That law, after years of litigation, was unanimously overturned by the U.S. Court of Appeals in 2010.[142]

CONCLUSION

PBMs save Americans billions of dollars each year by lowering both the prices that consumers pay for prescription drugs and the prices that health plans pay for drug coverage. However, new regulatory developments in some states threaten to undercut competition in the PBM industry and disrupt the cost savings PBMs currently generate. The regulatory scheme that was adopted by Mississippi in 2011 and is currently under legislative consideration in three other states—Oregon, Oklahoma, and Hawaii—shifts regulatory control of PBMs from the neutral Insurance Commissions to the states' Boards of Pharmacy. The fundamental problem with this structure is that the Boards of Pharmacy are made up of pharmacists, the direct market adversaries of PBMs. In several different areas of the prescription drug market, PBMs and pharmacists are in direct competition over profits. Thus, granting Boards of Pharmacy regulatory control over PBMs creates an inherent conflict of interest by giving pharmacists regulatory control over their natural competitors in the marketplace. Under this new regulatory scheme, the Board has both the incentive and the power to exercise its regulatory power in ways that weaken PBMs' competitive positions and, in turn, benefit pharmacies. The power to regulate a market adversary gives pharmacists unprecedented power and will severely undercut competition in the prescription drug market.

Unfortunately, this new regulatory scheme does more than just undermine competition in the PBM industry, it will also increase the prices that consumers and third parties must pay for prescription drugs. Total annual prescription drug spending in the U.S. is currently around $263 billion, but industry estimates suggest that this number would be at least $100 billion more if it were not for PBMs' cost-saving practices.[143] It would be reckless for states to enact or maintain regulatory schemes that threaten to undo

[140] LAWRENCE, *supra* note 72, at 15.
[141] ME. REV. STAT. tit. 22, § 2699 (West 2011).
[142] In *Pharmaceutical Care Management Association v. Dist. of Columbia*, the D.C. Circuit held that ERISA preempted provisions of the District of Columbia's Access Rx Act requiring PBMs to act as fiduciaries, to disclose conflicts of interests, to disclose the costs of prescribed drugs and substitute drugs, and to transfer any benefit received as the result of prescription drug substitution. 613 F.3d 179 (D.C. Cir. 2010). The D.C. Circuit held that imposing a fiduciary obligation on PBMs would impermissibly impact employee benefit plans in the District of Colombia and impede Congress' goal of national employee benefit plan uniformity. *Id.*; *Appeals Court Rules that ERISA Preempts Prescription Drug Law*, 38 TAX MGMT. COMPENSATION PLAN. J. 274 (2010).
[143] Estimates of PBMs' cost savings range from 30 to 35% of total prescription drug spending, suggesting that total drug spending would be $376 to $404 billion without PBMs' cost saving practices. Congressional Budget Office, *supra* note 3, at 40 (Table 6); VISANTE, *supra* note 18, at 5.

these cost savings and increase prescription drug prices in our current state of ever-increasing healthcare costs.