An Overview of Pharmacy Benefit Managers: Focus on the Consumer

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Executive Summary

This paper provides detailed background on the important role played by pharmacy benefit managers (PBMs) in reducing health plan prescription-drug costs while improving the quality of prescription-drug delivery and patient care. The United States spends more of its Gross Domestic Product on health care than 191 other countries, yet ranks 37TH in terms of health care quality. U.S. health care spending is expected to continue to grow faster than the economy.

The number of employers offering health care benefits continues to decline, with the cost of coverage more than doubling over the past ten years. High health care expenses can put companies operating in the U.S. at a competitive disadvantage. At the national level, each 1% increase in private insurance drug expenditures is the equivalent opportunity cost of 20,000 jobs. For an individual worker, going without health care or forgoing needed medications results in poorer health and reduced productivity.

PBMs are one solution to the challenge of controlling health care costs without compromising quality. Prescription-drug spending makes up 10% of total health care spending, or $307 billion annually. PBMs have been active since the 1980s in lowering overall prescription-drug costs while improving prescription-drug dispensing service and efficacy. They are hired by health insurance issuers and by plan sponsors such as HMOs, self-insured employer plans, and federal and state governments (e.g. Medicare Part D and Medicaid) to administer prescription-drug plans. Since plan sponsors determine the parameters of their coverage, savings will vary — but PBMs have reduced prescription-drug costs at many organizations by 15 to 40%. The Federal Trade Commission and other governmental agencies have independently determined that PBMs save the American public tens of billions of dollars each year. PBMs generate savings through a number of cost-reduction strategies including:

- **Negotiating discounts with pharmacies**
- **Negotiating rebates and discounts from drug manufacturers**
- **Creating formularies of preferred plan-covered prescriptions**
- **Encouraging use of generic drugs instead of branded products**
- **Using mail-order pharmacies**
- **Improving customer education tools**

PBMs also address the critical issues of drug safety and adherence. Not taking medications as prescribed (non-adherence) can lead to hospitalization or even death. The average cost of a hospital stay in 2009 was $17,271 and the economic burden (i.e., avoidable medical expenses) of non-adherence was estimated to be $290 billion. As with cost containment, PBMs employ a variety of techniques to ensure drug safety and adherence including:

- Drug Utilization Reviews — Identifying potential adverse reactions between prescriptions authorized by different physicians and picked up at different pharmacies. For every additional prescriber, the potential for such an adverse reaction increases 29%. Identifying problems with a particular drug or drug combination by systematically analyzing collected data.
- Encouraging the use of 90-day prescriptions for maintenance medications for chronic conditions.

- Refill reminders
- Patient coaching, counseling, and intervention
- Medication Therapy Management (MTM)

PBMs also have forward-looking programs to address both safety and cost issues. For specialty drugs, PBMs commonly employ separate in-house pharmacies that focus on these expensive drugs. Specialty, or biologic, drugs make up only 0.5% of prescriptions but now account for 11.8% of total drug outlays and are expected to grow by 15-20% per year. PBMs have been working with the Food and Drug Administration to develop a pathway to approve generic versions of these biologic products, which are anticipated to save between $42 and $108 billion in their first decade on the market. PBMs have also expanded the use of electronic prescribing and the integration of genetic testing and personalized medicine to ensure the right patient is receiving the right therapy at the right time.

Finally, PBMs have programs to address fraud, waste and abuse, which the Federal Bureau of Investigation estimates accounts for between 3 and 10% of total U.S. health care costs (up to $234 billion annually for fraud alone and $403 billion annually due to waste). PBMs carefully monitor patient needs and pharmacy dispensing and billing patterns, and use audit programs with advanced computer models to identify patterns of fraud.

The federal government and numerous state governments save by using PBMs to administer their pharmacy benefit plans. The Federal Employee Health Benefit Program(FEHBP), America's largest employer-sponsored health insurance program, has realized significant savings through its PBM with mail order of its members' prescriptions. For example, mail-order savings compared to retail for 4 common generics reached 50%, while the average savings for 14 brand-name drugs was 28%. Many state Medicaid managed care organizations contract with PBMs to administer their Medicaid prescription-drug plans. It is estimated that use of PBMs nationwide for these programs could save as much as $32.6 billion over the next decade. PBMs have also provided significant savings for Medicare. A PricewaterhouseCoopers study estimated that PBMs will save Medicare nearly $700 billion from 2008 through 2017.

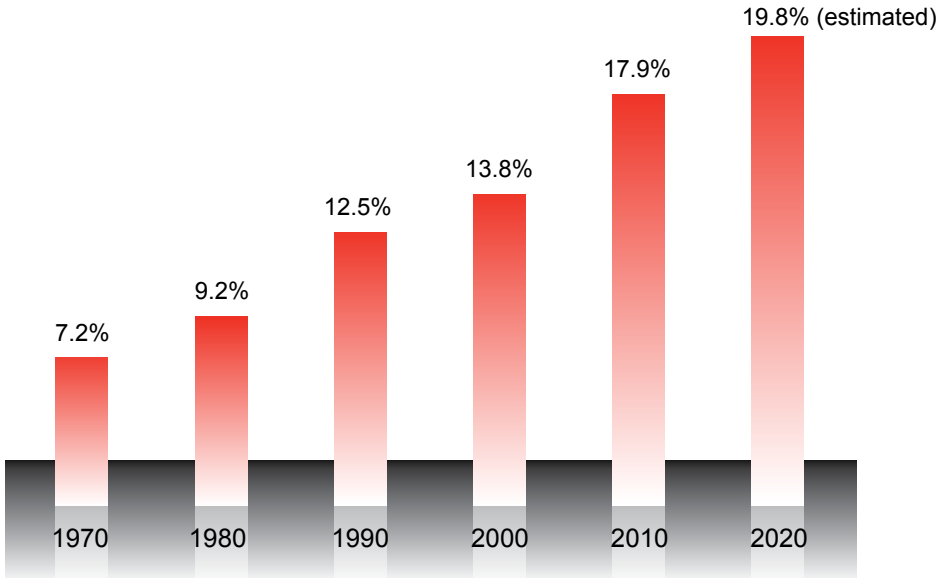
Because PBMs achieve savings in part by engaging in competitive reimbursement negotiations, pharmacy groups and other special interests have lobbied at the state and federal level to impose restrictions on PBMs. The benign stated purposes of such legislation (e.g., to empower payers by increasing disclosure and adding fiduciary responsibilities for PBMs) mask significant anti-competitive intentions on the part of industry proponents. These PBMs restrictions, if adopted by legislators, would have significant adverse consequences including higher costs due to decreased competition in the pharmaceutical industry, limitation of cost-saving mail order and generic substitution, and increased legal and insurance fees. This anti-PBM legislation could increase costs for pharmaceuticals over the next decade by as much as $360 billion for the private sector and $190 billion for Medicare Part D.

There is a consensus that U.S. consumers and employers are not receiving full value for the health care dollars they spend. Inefficiencies exist in every segment of health care. In the pharmaceutical segment, PBMs are a solution to this problem as they focus on reducing inefficiency, lowering drug costs and improving health outcomes. According to the Pharmaceutical Care Management Association, PBMs currently manage prescription-drug benefits for more than 215 million Americans with health coverage. It is estimated that the money PBMs saved employer sponsored plans in 2012 alone could cover the cost of 700,000 new jobs. Savings to plans, assuming adoption of best practices, could amount to an additional $500 billion over the next decade. PBMs have shown that it is possible to control costs while simultaneously improving prescription-drug delivery.

Introduction

The United States stands at a crossroads as it tries to rein in rocketing health care costs. Health care expenditures reached $2.7 trillion in 2011, representing 17.7% of the Gross Domestic Product (GDP).[1] This is more than a full percentage point increase from 16.6% GDP in 2008. Without changes to the current system, health care spending will continue to consume an ever expanding share of the American economy. As shown in Figure 1, with spending accelerating, annual health care expenditures are expected to reach $4.6 trillion or 19.8% of GDP by 2020.[2]

Figure 1
Health Care Expenditures as a % of GDP



Source: Centers for Medicare & Medicaid Services, National Health Statistics Group

This growth rate is being driven by a multitude of factors including: the passage of the Patient Protection and Affordable Care Act in 2010 which significantly expands the number of people eligible for Medicaid; an aging population that requires increased medical services; and an increase in the use of specialty drugs. New specialty drugs such as biologics offer great potential medical benefits but also represent a disproportionate amount of budgetary spending. On average, they cost 28 times more than non-specialty drugs.[3] The majority of health care expenditures in the United States can be attributed to hospital care (31%), physician / clinical services (21%), and prescription-drug costs (10%).[4]

Despite the discouraging overall health care outlook, opportunities remain for improvements and significant cost savings. According to some estimates, up to 30% of total health care expenditures could be eliminated without a change in quality.[5] One positive development, which has the potential to significantly rein in spiraling drug costs, is the expansion of pharmacy benefit management through PBMs. PBMs have been

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[1] Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, *National Healthcare Expenditure Projections 2010 - 2020*, July 28, 2011, pp. 1, 4.

[2] Ibid, p. 4

[3] Walgreens Health Initiatives, *Pharmacy Benefit Solutions 2010 Trend Report*, 2010, p. 8.

[4] Kaiser Family Foundation, "US Health Care Costs: Background Brief," March 2010, p. 1.

[5] Jules Delaune and Wendy Everett, *Waste and Inefficiency in the US Healthcare System*, New England Healthcare Institute, February 2007, pp. 7, 64.

lowering prescription-drug costs and improving health outcomes for consumers and employers through a variety of tools and techniques. Potential cost saving tools include expanding the use of generic drugs, better consumer education and greater operational efficiency in the delivery system. An analysis conducted by the IMS Institute showed the use of FDA-approved generic drugs over the past 12 years reduced national health expenditures by $1.03 trillion.[6] Other opportunities for savings come in reducing fraud, waste and abuse. The cost in 2010 was estimated to be $403 billion for waste and $70 to $234 billion for fraud. These items are expected to account for as much as $1.2 trillion of health care spending between 2010 and 2014.[7]

PBM efforts have slowed the growth in spending on prescription-drugs. Between 2008 and 2017, aggregate PBM savings (Medicare and non-Medicare) related to drug spending, are estimated at $1.3 trillion.[8] In 2008, this equated to an annual average savings of $1,090 for Medicare beneficiaries in private plans and $397 per person (non-Medicare) enrolled in a private health care plan.[9] A recent report by the IMS Institute showed spending on prescription-drugs declined from a 5.1% growth rate in 2009 to 2.3% in 2010.[10] This was the second lowest annual growth rate in 55 years. New PBM programs should continue this trend.

With their emphasis on drug safety and adherence (i.e. taking medications as prescribed), PBMs also improve clinical outcomes for patients. Eliminating non-adherence has the potential to save the U.S. health system $290 billion annually.[11] Customized patient outreach and counseling, refill reminders and home delivery for maintenance medications are some of the techniques used to achieve this goal. PBMs strive to contain costs while providing high-quality prescription-drug delivery and services.

Health Care and Prescription-Drug Costs in the United States

Compared to the other 30 democracies in the Organization for Economic Cooperation and Development (OECD), the United States spends the most on health care, with per capita costs more than double the average for these other industrialized countries.[12] On a per capita basis, the average American consumed $8,648 in health services in 2011.[13] This figure is projected to increase 62% to $13,709 by 2020. In a study conducted in 2010, the U.S. ranked last out of seven countries (behind Australia, Canada, Germany, Netherlands, New Zealand, and the United Kingdom) based on five different metrics including quality, efficiency,

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[6] Generic Pharmaceutical Association, “Savings: An Economic Analysis of Generic Drug Use in the U.S.” published report, September, 2011, p. 1.

[7] Express Scripts, *2010 Drug Trend Report: A Market and Behavioral Analysis*, April 2011, p. 8 and National Health Care Anti-Fraud Association, “Combating Health Care Fraud in a Post-Reform World: Seven Guiding Principles for Policymakers,” October 6, 2010, p. 4.

[8] PricewaterhouseCoopers, *Pharmacy Benefit Management Savings in Medicare and the Commercial Marketplace & the Cost of Proposed PBM Legislation, 2008 - 2017*, March 2007, pp. 1, 8, 9.

[9] Ibid, p. 10.

[10] IMS Institute for Healthcare Informatics, “The Use of Medicines in the United States: Review of 2010,” published report, April, 2011, p. 4.

[11] “Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease,” A *New England Healthcare Institute Research* Brief, August 2009, p. 1.

[12] Chris Peterson and Rachel Burton, *CRS Report for Congress U.S. Health Care Spending: Comparison with other OECD Countries*, September 17, 2007, p. 2.

[13] Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, *National Healthcare Expenditure Projections 2010 - 2020*, July 28, 2011, p. 4.

access to care, equity and the ability of patients to lead healthy productive lives. As this study notes, "the U.S. stands out for not getting good value for its health care dollars."[14]

Representative of the numerous criticisms of U.S. health care is this European opinion:

> America has a talent for wasting money on health care. It has devised many ingenious ways to do this. A patient may see many skilled specialists, none of whom coordinate with one another. Payment systems are unfathomably complex and highly variable. Doctors order duplicative or unnecessary tests. The country excels at treating sick people and does a horrible job keeping them from getting sick in the first place.[15]

Over the last four decades, the U.S. health care sector has experienced exponential growth: aggregate expenditures increased from $74.9 billion in 1970 to $2.7 trillion in 2011.[16] This represents a compound annual growth rate of 9.3% per year over a 40-year period. While some of the increase is attributable to an expanding population base, the growth in health expenditures far exceeds the change in population. During the same time period, the population grew at a rate of less than 1% annually from 210 million to 313 million people.[17] Along with other components of health care spending, prescription-drug expenditure growth accelerated sharply in the late 1990's and early 2000's. Drug expenditures reached a peak annual growth rate of 18.1% in 1999 before dropping back into the single digits in 2004.[18]

Adding to the growth in prescription-drug costs is the expanding use of specialty drugs. For example, while specialty drugs at Walgreens Health Initiatives, a PBM now owned by Catalyst Rx, are 0.5% of total prescriptions filled, they represent 13.4% of total prescription cost.[19] Undoubtedly, the use of specialty drugs will continue to increase, driven by the rising frequency of chronic illness. Chronic ailments represent 75% of total national health care spending with conditions such as high cholesterol and high blood pressure leading the list.[20] Despite the current economic crisis, national spending for prescription medicines in 2010 totaled $307 billion, an overall increase of 2.3% over 2009. Spending on branded drugs was down 0.7%, unbranded generic drugs rose 21.7%, branded generics were up 4.5%, and biologics increased 6.6% from the previous year.[21] (With generic drugs offering increased value over their branded counterparts, it is not surprising to see their share of prescription spending increasing.)

Large price increases for branded prescription-drugs have created significant pressure on overall prescription-drug costs. A recent study by the U.S. Government Accountability

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[14] The Commonwealth Fund, "U.S. Ranks Last Among Seven Countries on Health System Performance Based on Measures of Quality, Efficiency, Access, Equity and Healthy Lives," June 23, 2010, p.1.

[15] "U.S. Health Care Spending - Waste Measurements," *The Economist Online*, June 17, 2011.

[16] Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, *National Healthcare Expenditure Projections 2010 - 2020*, July 28, 2011 and historical data.

[17] Ibid.

[18] Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, *National Healthcare Expenditures 1960 - 2008*, 2008.

[19] Walgreens Health Initiatives, *Pharmacy Benefit Solutions 2010 Trend Report*, 2010, p. 8.

[20] Express Scripts, *2010 Drug Trend Report: A Market and Behavioral Analysis*, April 2011, p. 6

[21] IMS Institute for Health Care Informatics, *The Use of Medicines in the United States: Review of 2010*, published report, April 2011, pp. 6, 15.

Office (GAO) concluded the large price increases in branded products was largely attributable to the lack of therapeutically equivalent drugs for the same conditions and limited competition.[22] The average American consumed $880 of prescription-drugs in 2011, paying $182 out-of-pocket (21%) with the balance of $698 (79%) being covered by a third-party payer.[23] Private health insurance covers 41% of the total cost of prescription-drugs with 45% being funded by federal (Medicare and Medicaid) and state programs.[24] If government forecasts are accurate, public funding of prescription-drug plans will rise to 48% over the next decade.[25]

National health care costs are also increasing as the elderly population increases. One of the fastest growing segments of the population is Americans over age 60, which grew 24.6% between 2000 and 2010.[26] Not surprisingly, the number of prescriptions also increases with age — with the average senior taking between six or seven prescriptions a month.[27] While those 65 and older make up 13.2% of the overall population, they represented 42.9% of those individuals in the top 10% of health care expenditures.[28] The age 65+ demographic is expected to more than double from 2005 to 2050 (from 37 million to 81 million).[29] Health care costs, particularly pharmaceutical spending, will rise correspondingly.

As the total amount of health care spending rises, a greater portion of the burden falls on the struggling American workforce. While employer-provided insurance has long been the leading source of health care coverage in the country, its availability is declining. In 2011, 60% of firms offered health benefits, down from 69% in 2010.[30] The effects of cost increases are being felt by both employers and employees. Over the course of the last 10 years, premiums for employers have increased 108%, while worker contributions have risen 131%.[31] Figure 2 (on the next page) illustrates the dramatic increase in insurance premiums since 2001.

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[22] U.S. Government Accountability Office, “Brand-Name Prescription-Drug Pricing: Lack of Therapeutically Equivalent Drugs and Limited Competition may Contribute to Extraordinary Price Increases,” publication number GAO-10-201, December 2009, p. 2.

[23] Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, National Healthcare Expenditure Projections 2010 - 2020, July 28, 2011.

[24] Ibid.

[25] Ibid.

[26] U.S. Census Bureau, Percentage Increase of the 60+ U.S. Population from the 2000 Census to the 2010 Census, 2010, p. 1.

[27] Marie N. Stagnitti, “Average Number of Total (Including Refills) and Unique Prescriptions by Select Person Characteristics, 2006”, Medical Expenditure Panel Survey Statistical Brief No. 245, May 2009, p. 1.

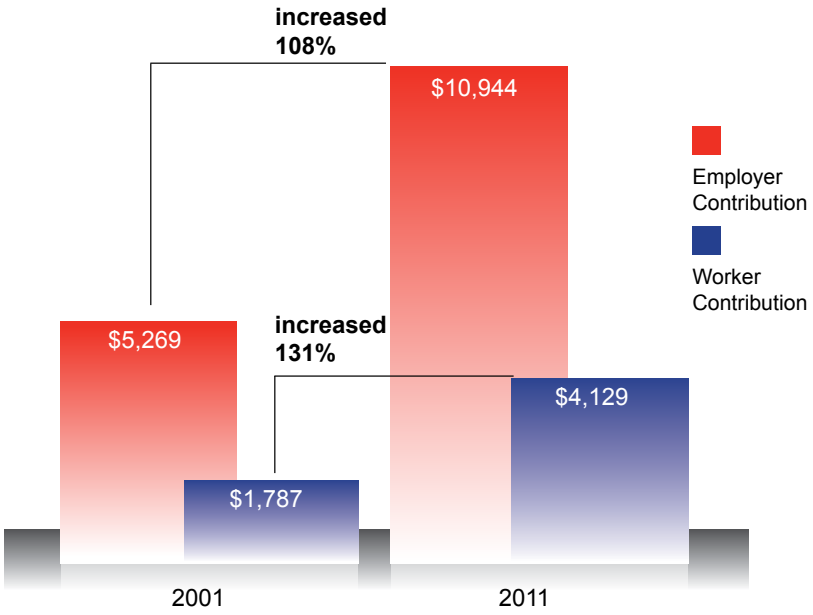
[28] Steven B. Cohen and William Yu, “The Concentration and Persistence in the Level of Health Expenditures Over Time: Estimates for the U.S. Population, 2008-2009”, Medical Expenditure Panel Survey Statistical Brief No. 354, January 2012, p. 2.

[29] Pew Research Center, “U.S. Population Projections: 2005-2050,” 2008, p.16.

[30] Kaiser Family Foundation and Health Research and Education Trust, Employer Health Benefits, 2011, pp. 2, 3.

[31] Ibid, pp.1, 4.

Figure 2
Cost of Employer Sponsored Plans



Source: Kaiser / HRET Survey of Employer-Sponsored Health Benefits, 2001-2011

Corporations operating within the U.S., both domestic and multinational, are often at a competitive disadvantage in the international marketplace as their health care expense burdens limit financial flexibility. This can be observed through industry growth rates: from 1985 to 2005, growth in industries with the highest levels of employer-provided health benefits lagged behind growth in industries with the smallest level of employer-provided health benefits.[32] Health care costs can also have a direct impact on a firm's ability to hire new employees. For example, each 1% increase in private insurance drug expenditures is equivalent to the cost of 20,000 jobs.[33] It is estimated that the savings generated by PBMs in 2012 alone represent the equivalent cost of 700,000 additional jobs.[34] Individual workers, whether or not insured, have been forced to forgo prescribed medications as a result of cost concerns.[35] Poor worker health results in increased absenteeism and diminished worker productivity. If health care costs are allowed to continue to rise, companies will be unable to expand their workforce and pursue market opportunities.

The Role of Pharmacy Benefit Managers

PBMs were created by managed care organizations in the 1980's in an effort to focus on pharmacy spending to reduce drug costs. Over the years, the industry has added a wide variety of cost-saving measures and recently has started to have a major economic impact on health care costs. PBMs, with their unique role as system mediators, are responsible for substantial shifts in the administrative style of health care. The physician, the patient, and the

[32] N. Sood, A. Gosh and J. Escare, "Employer-Sponsored Insurance, Health Care Cost Growth, and the Economic Performance of U.S. Industries," Health Research and Educational Trust, October, 2009, p. 1460.

[33] Pharmaceutical Care Management Association, Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers, September 2011, p. 3.

[34] Ibid, p. 3.

[35] Walgreens Health Initiatives, Pharmacy Benefit Solutions 2010 Trend Report, 2010, p. 13.

payer (otherwise known as the 3Ps) are closely connected in an interwoven web that strives to supply higher quality medical and drug services at a lower cost. Clients of PBMs are plan sponsors, which include managed care organizations, employer plans, Medicare Part D plans, labor funds, the Federal Employees Health Benefits Program, state government based health plans, and third-party administrators.

Over the last several decades, the PBM industry has grown substantially. In 1995, approximately 40 PBMs existed compared to more than 60 such companies today. According to the latest numbers from the Pharmaceutical Care Management Association, 215 million Americans (71% of the population) use PBMs to manage their prescriptions. Beginning in the 1980's, prescription-drug spending started increasing faster than spending on health care overall. As a result, an intense need for prescription management and savings emerged. Early on, PBMs primarily focused on reducing the costs of prescriptions through processing claims for a fee and through home delivery pharmacy services. By the 1990's, though, PBMs offered real-time electronic claim adjudication and worked with pharmacy networks that provided discounts. Today, PBMs keep drug costs affordable for their clients and patients through the use of sophisticated programs. Savings are achieved through the use of formularies, encouraging the use of less-expensive generic drugs, extensive data analysis, better patient compliance, drug therapy management, sponsored outcome research, and more efficient distribution services. A study by PricewaterhouseCoopers found that PBMs successfully reduced prescription-drug costs by an impressive 15- 40% depending on program prowess.[36] The study also showed that for private health plans, PBMs reduced the annual member cost by $397. These savings were even more substantial for Medicare beneficiaries in private plans — with yearly reductions of $1,090.

Choosing a Plan

While PBMs do not market their services directly to consumers, plan sponsors (e.g., the employer or managed care plan) work closely with PBMs to create unique details of coverage for their beneficiaries. Sponsors set parameters on what their plan will cover. This allows each individual sponsor to have a benefit tailored to fit its needs and values. Sponsors can select which drugs or classes of drugs they cover (formulary coverage), the quantity limit for a certain drug or for all prescriptions, copayment tiers, the kind of utilization review used and the pharmacy channel options.[37] In most cases, plan sponsors are allowed to decide whether to exclude weight loss drugs, "quality of life" drugs such as hair-growth medication, smoking cessation drugs, etc. By allowing plan sponsors to choose which drugs to cover, specific needs of employees may be taken into consideration more frequently. For example, plan sponsors may choose to cover non-sedating antihistamines for their employees if the company uses heavy machinery in its workplace. Additionally, selecting specific plans allows more control of cost saving by plan sponsors. The type of plans offered will determine the amount of savings available to the sponsor.

Cost Saving Strategies

As will be discussed in more detail later, it is estimated that $403 billion in pharmacy-related waste could be eliminated per year from the American system through more-efficient programs and stronger controls.[38] PBMs use a variety of tools to reduce the cost

[36] PricewaterhouseCoopers, Pharmacy Benefit Management Savings in Medicare and the Commercial Marketplace & the Cost of Proposed PBM Legislation, March 2007, p. 6.

[37] Pharmaceutical Care Management Association, *Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers*, Visante, Inc., September, 2011, p. 4.

[38] Express Scripts, *2010 Drug Trend Report: A Market and Behavioral Analysis*, April 2011, p. 8.

of medication to their members and other payers. In fact, three major federal agencies (CBO, GAO, and FTC) have all consistently determined that PBMs save Americans tens of billions of dollars.[39] The primary goal of PBMs is to ensure that members use the most-effective medication prescribed, in the correct dosage and taken as instructed. Following that, it is important that PBMs provide the most cost-effective treatment. This manages costs for members and employers through lower insurance premiums and reduces spending for the U.S. healthcare system overall. PBMs are able to generate savings for plan sponsors and patients through a number of avenues. These include:

(a) Negotiating Discounts With Pharmacies — By contracting with select pharmacies, PBMs are able to negotiate lower drug dispensing prices in return for steering their clients to these pharmacies. This targeting provides consumers with lower costs on prescription medication and provides participating pharmacies with increased business. As part of their negotiations with pharmacies, PBMs also encourage the use of generic drugs and provide their customers with a lower out-of-pocket cost for generics than for branded drugs.

(b) Utilizing Rebates From Drug Manufacturers — Due to their large size, PBMs negotiate with pharmaceutical companies in order to provide their clients cost savings through rebates. Pharmaceutical companies will provide rebates for their drugs if the PBM includes them as a "preferred" drug. This, in turn, allows customers to receive the drugs at a lower copayment.

(c) Formularies — By using formularies, PBMs encourage brand-drug manufacturers to compete against other manufacturers who market similar, and therapeutically substitutable, medications. Tiered formularies, which include monetary incentives for the use of generics as well as preferred brands, can yield even more savings.[40] Step therapy is a cost-savings approach in which more-expensive drugs are covered only when the patient has first attempted less-expensive therapeutically equivalent products.[41] One example of step therapy is the use of over-the-counter non-steroidal, anti-inflammatory medications, such as ibuprofen or naproxen sodium, before a Cox-2 inhibitor like Celebrex® would be approved.[42]

(d) Generics — A branded drug has a patent life of 20 years. Once that term expires, the FDA can approve generic medications. By definition, generic medications are the same as brand medications "in terms of dosage, safety, strength, directions for administration, quality, purity, performance and intended use."[43] The cost of generics, however, is usually 60-80% less than the pharmaceutically equivalent branded drug. Generic medication costs decreased by 10.2% in 2010 while at the same time, branded medication prices rose 9.7%.[44] Sometimes generic drugs do not have a price advantage

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[39] Jonathan Orszag and Kevin Green, "The Economic Benefits of Pharmacy Benefit Managers," Compass Lexecon LLC, December 5, 2011, p.1.

[40] Pharmaceutical Care Management Association, *Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers*, Visante, Inc., September, 2011, p. 4.

[41] Jonathan Orszag and Kevin Green, "The Economic Benefits of Pharmacy Benefit Managers," Compass Lexecon LLC, December 5, 2011, pp. 15, 16.

[42] Jack Hoadley, "Cost Containment Strategies for Prescription-drugs: Assessing the Evidence in the Literature", Kaiser Family Foundation, March 2005, p. 4.

[43] Leigh Purvis, "Strategies to Increase Generic Drug Utilization and Associated Savings," *Insight on the Issues*, AARP, Public Policy Institute, December 2008, p. 1.

[44] Express Scripts, *2010 Drug Trend Report: A Market and Behavioral Analysis*, April 2011, p. 25.

due to the pricing concessions PBMs negotiate with brand manufacturers, which can significantly reduce the cost of their branded medicines. Therefore, a high Generic Fill Rate (GFR) is not always the least expensive option. In fact, PBMs manage drugs on a case-by-case basis in order to get the lowest prices for the best outcomes.[45] For 2012, projected aggregate savings of between 3.7% and 4.2% are expected from the eight major medications coming off patent including Boniva®, Lipitor®, Evista®, Lexapro®, Plavix®, and Singulair®.[46]

(e) Delivery Channel: Mail-Order Pharmacies — Savings are passed along directly to consumers through the use of mail-order pharmacies. PBMs often offer their customers the option of receiving prescriptions in the mail. This option may be especially beneficial for the elderly or for customers who live in rural communities without convenient access to a pharmacy. While some patients may prefer using their local pharmacy, this may not be the most cost-effective delivery mode, especially for medications treating chronic conditions. For acute conditions where it is imperative that treatment start as soon as possible, a local pharmacy can provide the medication faster (although perhaps not at the lowest cost). Mail order pharmacies offer their prescriptions at a discount, allowing customers to receive prescriptions at a lower cost. In addition, mail order prescriptions are frequently filled as a 90-day supply instead of a 30-day supply, making them less expensive (due to large quantity pricing) and more convenient (because refills are not needed as frequently). The increased efficiencies of mail-order pharmacies, through the use of computer-controlled quality processes, robotic dispensing machinery and advanced workflow practices, all contribute to reduced costs.[47] Studies have shown mail delivery of drugs saves money in three ways: better adherence could save $49.7 billion annually; improved drug mix (using generics whenever they are less expensive) could save $31 billion annually; and more favorable unit pricing and lower dispensing fees could save $7.6 billion annually.[48] Analysis of the data shows that mail-order pharmacies provide customers with some of the largest cost savings. Customers who use mail-order pharmacies instead of retail pharmacies save an average of 27% for branded drugs and 53% for generic drugs.[49] Without even counting Medicare part D savings, mail-order pharmacies will save U.S. plan sponsors and consumers $46.6 billion over the next decade.[50]

(f) Disease Management — PBMs have developed sophisticated programs which offer their customers services beneficial to maintaining overall health. In order to educate customers, PBMs frequently use disease management tools. Disease management, sometimes called Medication Therapy Management (MTM), involves ensuring that customers are aware of which drugs they are taking and what their effects may be. This is done by educating patients about their prescriptions. If patients have additional or follow-up questions, PBM staff pharmacists are available for consultation 24 hours a day, 7 days a week. To provide cost-effective care for chronic diseases, PBMs emphasize treatment protocols and changes in personal habits that focus on the entire spectrum of

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[45] Ibid, p.4.

[46] Walgreens Heath Initiatives, *Pharmacy Benefit Solutions, 2010 Trend Report*, 2010, p. 12.

[47] Pharmaceutical Care Management Association, *How Mail-Service Pharmacies Will Save $46.6 Billion over the Next Decade and the Cost of Proposed Restrictions*, Visante, Inc., February 2012, p. 8.

[48] Express Scripts, *2010 Drug Trend Report: A Market and Behavioral Analysis*, April 2011, p.9.

[49] U.S. General Accounting Office, *"Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies"*, January 2003, p. 4.

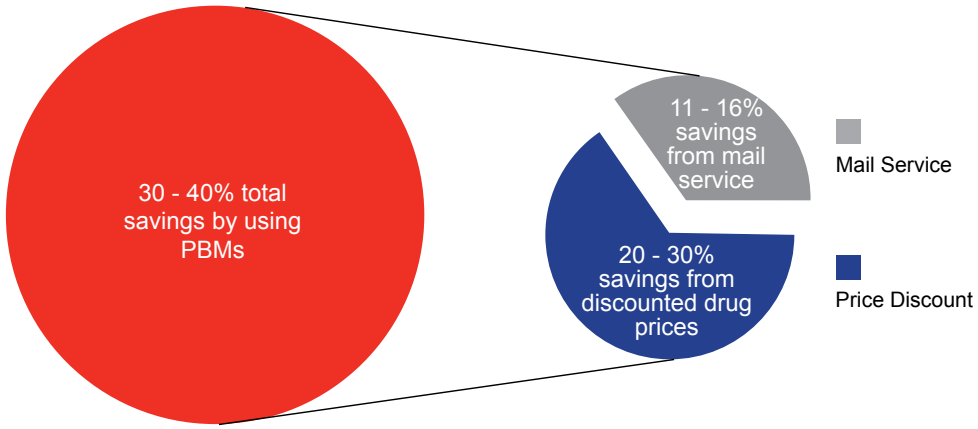
[50] Pharmaceutical Care Management Association, *How Mail-Service Pharmacies Will Save $46.6 Billion over the Next Decade and the Cost of Proposed Restrictions*, Visante, Inc., February 2012, p. 8.

care for a particular disease. Patient outreach involving refill reminders, feedback and follow-up are important aspects of MTM programs.[51]

(g) Drug Utilization Reviews — In addition to disease management techniques, PBMs employ drug utilization reviews (DUR). Utilization reviews involve evaluations of a patient's needs and current drugs in order to ensure that his or her prescriptions are correct. This may help customers cut down on the use of unnecessary prescriptions and ensure that the prescriptions being taken are safe, effective and at the correct dosage. DUR programs also check the patient's prescriptions for potentially dangerous drug interactions. These reviews are especially important for patients who take multiple prescriptions written by different physicians. For each additional physician who writes a prescription, the odds of an adverse drug event increase by 29%.[52] In addition, these programs can review the timing of prescription refills to highlight compliance for a particular drug regimen. Such reviews contribute to cost savings by ensuring that medications are not duplicated, are prescribed in the most effective dosage and duration and are diagnostically appropriate. DUR may encourage the pharmacist to use a generic medication, if one is available and not contradicted by the prescriber's orders. Reviews help to ensure that members are not taking unnecessary medications or purchasing medication they will not use. The use of prospective, real-time DURs significantly contributes to the effort to reduce pharmacy-related waste.

Customers of PBMs save, on average, $90 per member per year from step therapy, prior authorization and drug quantity management, and another $27 per member annually from mail-order prescriptions.[53] For a family of four, this translates into a savings of $470 per year. As shown in Figure 3 below, there are substantial savings (as a percentage of total prescription cost) available to plan sponsors and consumers by using PBM services vs. non-PBMs. Negotiated drug prices save users 20-30% in expenditures, with mail services reducing drug dispensing costs by another 11-16%. Altogether, PBM users can realize a total savings of 30-40% over what they would spend with non-PBMs.

Figure 3
Savings from Using PBMs



Data is from Visante, "Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers," released by PCMA (September 2011).

[51] Institute for the Study of Healthcare Organizations & Transactions, *PBMs And Chronic Disease*, March 2004, pp. 1,3,4

[52] J. Green, J. Hawley, and K. Rask, "Is the number of prescribing physicians an independent risk factor for adverse drug events in an elderly outpatient population?" *American Journal of Geriatric Pharmacotherapy*, March 2007, p.1.

[53] Express Scripts, *2010 Drug Trend Report: A Market and Behavioral Analysis*, April 2011, p. 16.

Regulation of PBMs

While PBMs are a relatively young industry, they are regulated at the state and federal level. States have exercised the ability to regulate PBMs in different ways. Nearly every state has considered legislation and 17 states have enacted laws to regulate PBMs. These PBM laws cover such issues as licensing, investigation, duties to clients, disclosure of financial terms with manufacturers, or the extent to which savings must be passed on to consumers.[54] Many of the enacted laws provide regulatory authority to the state's Insurance Commissioner. While each state differs in its regulation of PBMs, common themes include requiring PBMs to register with the state's Department of Insurance and requiring PBMs to submit to audits. Because state regulation of PBMs is relatively recent, particular state PBM regulatory laws often have unique features.[55] Maine's PBM oversight law, S.P. 194-L.D. 554 initially required PBMs to act as fiduciaries for their clients, but this fiduciary requirement was repealed in 2011. In Maryland, which has passed a series of PBM regulatory measures, PBMs must register with the Maryland Insurance Administration. Those registered as private review agents must undergo an examination by the Maryland Insurance Commissioner at least once every three years.[56] Maryland also has passed legislation which impacts PBM formularies, and a series of financial disclosure laws.[57] South Dakota, Connecticut, Georgia, Kansas, Louisiana, Maryland and Vermont all have legislation that requires PBMs to be licensed as third party administrators. Under typical state PBM laws, PBM mail-order pharmacies are required to be licensed and in good standing with the state boards of pharmacy in the states in which they operate. And, when shipping prescription-drugs to customers outside a state, PBM mail-order pharmacies must obtain nonresident licensure in 49 states.[58]

How Government Health Systems Benefit from PBMs

The current financial problems of the federal government and of state governments are exacerbated by increasing healthcare costs, including prescription medication expenses. Moreover, given the increasing number of aging and retiring baby boomers eligible for Medicare and the growing number of people eligible for Medicaid (due to high unemployment rates and changes in federal healthcare policy), the fiscal strain experienced by these programs will continue to mount. In 2010, Medicaid spending grew an average of 8.8% and Medicare grew by nearly 30% in the 2011 fiscal year.[59] In the same year, federal spending on Medicare and Medicaid reached over $926 billion.[60]

Fortunately, PBMs offer governments an opportunity to save money without cutting back on benefits or services provided to the citizenry. Indeed, many studies (including those cited in

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[54] Janet Brierton, *Regulation of Pharmacy Benefit Managers*, OLR Research Report, January 15, 2004, p. 1

[55] Colorado Department of Regulatory Agencies Office of Policy, Research and Regulatory Reform, *Pharmacy Benefit Managers*, Sunrise Report, October 15, 2004, pp. 2-5..

[56] Janet Brierton, *Regulation of Pharmacy Benefit Managers*, OLR Research Report, January 15, 2004, p. 2.

[57] Maryland Insurance Commissioner and Attorney General Announce the first Comprehensive Regulatory Scheme of Pharmacy Benefit Managers in the Nation, press release, April 17, 2008.

[58] Pharmaceutical Care Management Association, *How Mail-Service Pharmacies Will Save $46.6 Billion over the Next Decade and the Cost of Proposed Restrictions*, Visante, Inc., February 2012, p. 11.

[59] Vernon Smith et al. "Hoping for Economic Recovery, Preparing for Health Reform: A Look at Medicaid Spending, Coverage and Policy Trends," Kaiser Family Foundation, September 30, 2010 and N. Aizenman, "State Spending on Medicaid up Sharply," *The Washington Post*, October 27, 2011, pp. 6, 14.

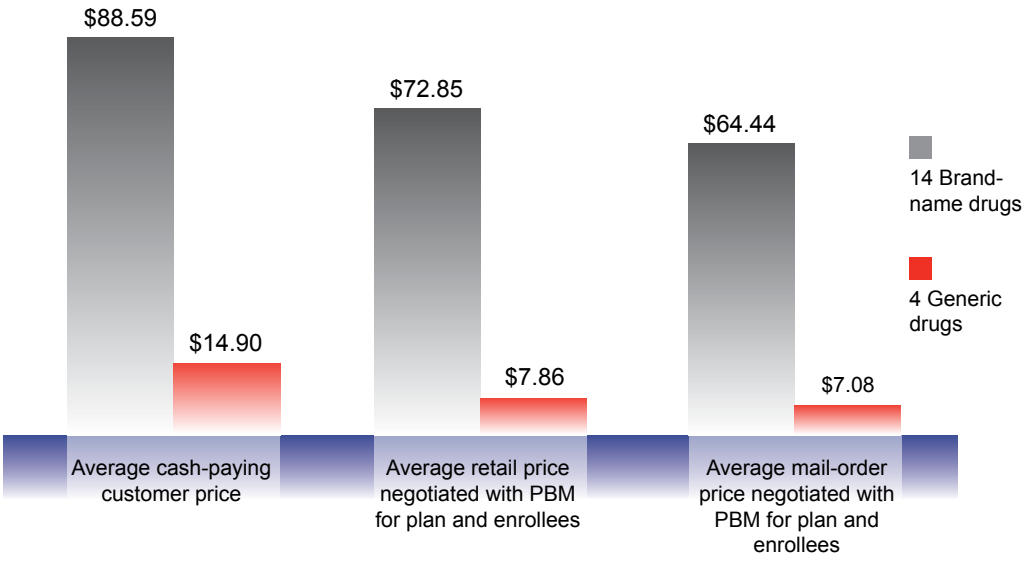
[60] Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, *National Healthcare Expenditures Highlights*, 2011.

this report) from both the public and private sectors have repeatedly confirmed that PBMs enable government programs to achieve substantial savings on their prescription spending.

Savings Generated for the Federal Employees Health Benefits Program

In 2003, the General Accounting Office (GAO) completed a report evaluating the impact PBMs had on the FEHBP, America's largest employer-sponsored health insurance program.[61] The study found that the decrease in prescription medication costs resulting from PBM usage was substantial. As shown in Figure 4, when comparing prices of 14 brand-name drugs with and without PBM negotiations, GAO found that PBMs produced prices averaging $72.85 versus $88.59, for average savings of approximately 18%. The average price fell $24.15 to $64.44 (a 20% savings) when the prescriptions were received through mail order. Additionally, when the average PBM mail order price of $7.08 for four generic drugs is compared to the average retail price of $14.90, the savings are over 50%. The study showed PBMs were also able to reduce prices by passing on rebates to the plans they covered, resulting in annual savings estimated between 3% and 9%.

Figure 4
PBM Discounted Prices Compared to Cash-Paying Customers



Source: U.S. General Accounting Office.

Medicaid Savings: Agreement Across Regional and Party Lines

The many challenges facing Medicaid have led policy makers to seek new methods to cut costs without reducing services. Consequently, a growing number of elected officials are coming to the conclusion that PBMs have the capacity to ease the financial burdens facing their Medicaid programs. For instance, New York Governor Andrew Cuomo announced his intention to use PBMs for New York's Medicaid program, which could save state taxpayers an estimated $350 million through 2015 and nearly $2.3 billion over the next decade.[62] Similar statements regarding PBM tools and usage have been issued by New Jersey Governor Chris Christie and Kentucky Governor Steve Beshear, whose states'

[61] The contents of this section are taken from: U.S. General Accounting Office, "Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies", 2003, p. 10.

[62] See Reuters, "Gov. Cuomo's Medicaid Proposal: PBM Tools Can Save $350 Million For New York," Press Release, February 25, 2011; New York Department of Health, "September 2011 Medicaid Update Special Edition", September, 2011; and the Lewin Group, Potential Federal and State-by-State Savings if Medicaid Pharmacy Programs were Optimally Managed, February 2011, pp. 20-21 .

project PBM-generated savings in Medicaid costs in the hundreds of millions dollars.[63] Additionally, approval for PBM utilization for Medicaid prescription management has been enacted in Texas which, like New York, could potentially save billions of dollars. According to one study, PBM usage and tools could lead to nationwide Medicaid cost reductions of almost $33 billion over the next decade, as shown in Table 1.

Table 1
Projected Savings if Medicaid Pharmacy was Optimally Managed

Year	Total Savings
2012	$2,645,209,301
2013	$2,702,821,959
2014	$2,976,671,958
2015	$3,261,168,728
2016	$3,332,196,983
2017	$3,404,772,233
2018	$3,478,928,173
2019	$3,554,699,228
2020	$3,632,120,577
2021	$3,711,228,164
10 Years total	**$32,699,817,304**

Source: The Lewin Group, "Potential Federal and State-by-State Savings if Medicaid Pharmacy Programs were Optimally Managed," February 2011.

Medicare, State Prescription Programs, and PBMs: Proven Success

Medicare Part D, which provides prescription-drug coverage for Medicare enrollees, became effective January 1, 2006. During the first year, 341 million prescriptions were filled at a cost of $47 billion.[64] By 2010, Medicare Part D covered 47.5 million individuals or 60% of all Medicare enrollees, with prescription costs reaching $61.7 billion. The average annual increase in the cost for Part D is expected to be as high as 9.7% through 2020.[65] Lawmakers have sought to employ a PBM model for these Medicare programs because of the savings PBMs have already generated for other organizations and programs, including state governments and Medicaid. For instance, PBM usage enabled Georgia to cut its pharmacy-cost growth from 26% to 16% from FY 2001 to FY 2002.[66] Also, when West Virginia entered into an agreement with Express Scripts to cover state employees, the state was able to realize a net savings of $7 million in just one year.[67]

The benefits PBMs provide to Medicare have been significant as well. A study by PricewaterhouseCoopers estimated that PBMs will save Medicare a staggering

[63] Pharmaceutical Care Management Association, "Gov. Christie: Modernizing New Jersey Medicaid Rx Will Help Save $41 Million," Press Release, (2011) and Reuters, " Modernizing Medicaid Rx with 'Innovative' PBM Tools Will Help Kentucky Save $375 Million," (July 8, 2011).

[64] Department of Health and Human Services, "Generic Drug Utilization in the Medicare Part D Program," OEI-05-07-00130, November 2007, pp. 1, 8.

[65] Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, *2011 Annual Report*, 2011, pp. 5, 9.

[66] Jack Hoadley, "Cost Containment Strategies For Prescription-drugs: Assessing The Evidence In The Literature," Kaiser Family Foundation, March 2005, p. 81.

[67] Ibid, p. 81.

$700 billion from 2008 through 2017.[68] Future estimates aside, current evidence also definitively illustrates PBM success with Medicare Part D, as the program has continually surpassed fiscal expectations, coming in under budget each year by optimally managing its prescription costs.[69]

PBM Clinical Services and How They Improve Patient Care

Since prescription-drugs account for a significant share of health care expenses in the U.S., it is critical that these drugs be managed with the goal of providing the greatest medical efficacy for members while reining in costs. Not taking medications as prescribed (non-adherence) can result in severe negative effects, including hospital admissions or even death. The average cost of a hospital stay in 2009 was estimated at $17,271 and non-adherence results in an estimated $290 billion per year of avoidable medical expenses.[70]

Clinical services provided by PBMs to their members include a variety of safety, adherence, educational, behavioral and informational resources. Many of these clinical services overlap in their goals of ensuring the best evidence-based healthcare and providing cost savings by obtaining the lowest prices on the most effective medicines available for each covered condition.

Increased Safety and Adherence Leads to Increased Health

Research to develop prescription medicines is intense and the FDA has strict standards regarding the safety and efficacy of those drugs. The clinical value of medicines that treat many high-prevalence diseases including diabetes, hypertension, high cholesterol, and congestive heart failure has been clearly demonstrated.[71] Treating medical conditions sub-optimally by prescribing: (1) medications in either too-low or too-high dosages; (2) medications without regard to contraindications for other conditions; or (3) drugs with dangerous interactions with other current prescriptions; can result in the worsening of a patient's condition. The same is true for patients not taking their medicines properly, i.e. non-adherence. To reduce the occurrence of these events, PBMs play an active role in managing the health care of their members in the following areas:

(a) Safety — Real-time drug utilization reviews are a powerful tool in managing safety for patients. These integrated systems are the key link between a pharmacist filling a prescription for a patient and that patient's complete pharmacy history. For example, no matter where a patient fills his prescription, Express Scripts runs more than 100 safety checks through its sophisticated adjudication process before the patient receives their medication.[72] Additionally, PBMs conduct ongoing research, using their pharmaceutical expertise along with their proprietary databases, to identify any problems related to a

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[68] PricewaterhouseCoopers, "Pharmacy Benefit Management Savings In Medicare and the Commercial Marketplace & the Cost of Proposed PBM Legislation, 2008-2017", March 2007, p. 1.

[69] Reuters, "PCMA: Part D Plans and PBMs Continue to Deliver Savings in Medicare," PR Newswire, August 4, 2011.

[70] See "Thinking Outside the Pillbox: A System-Wide Approach to Improving Patient Medication Adherence for Chronic Disease," A *New England Healthcare Institute Research* Brief August 2009, p. 1 and Jared Shelly, "Take Your Meds, Please!" HRE Online, October 16, 2011, pp 1, 3.

[71] M. Sokol, K. McGuigan, R. Verbrugge, and R. Epstein. "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost," *Medical Care*, June 2005, pp. 524-525.

[72] George Paz, "Written Testimony Before the House Judiciary Committee, Subcommittee on Intellectual Property, Competition, and the Internet Hearing on 'The Proposed Merger between Express Scripts and Medco'", Express Scripts, September 20, 2011, p. 3, 7.

particular drug or combination of drugs. This can be an important first line of defense for a patient. For example, Express Scripts was able to identify "serious safety concerns with Vioxx® more than six months before the FDA withdrew market approval."[73] In another well-publicized case described by the *Wall Street Journal* "the 16,690-person study by pharmacy-benefits company Medco Health Solutions, Inc. suggests that people who combine a heartburn pill like Nexium® or Prilosec® with Plavix® at their doctors' direction have a 50% higher risk of a heart attack or other cardiac event compared with those taking Plavix® by itself."[74] This is a case of a medication used to treat the side effects (heartburn) with one drug (Plavix®) having the potential to create a devastating, potentially lethal, condition that may not have been discovered without the use of the PBM review process.

Through greatly enhanced dispensing accuracy, the use of highly automated mail-order pharmacies also contributes to patient safety. The dispensing error rate for these systems is 0.071%, or 1 in every 1,416 prescriptions. Retail pharmacy error rates are closer to 1 in every 50 prescriptions (2.0%).[75] Considering that the FDA reports a death every day and 1.3 million people injured per year from medication errors, this reduction has significant safety implications.[76]

(b) Adherence — The World Health Organization describes poor adherence as "any deviation from the prescribed course of medical treatment."[77] In terms of medication, this can include not filling the initial prescription, not taking the medication in the proper dosage or at the appropriate time as prescribed, and discontinuing the medication when directed to continue. To a dispassionate observer, it may seem obvious that non-adherence results in increased risks of negative health outcomes, especially for those with chronic diseases.[78] For any individual there may be a myriad of reasons for not adhering to the prescribed regimen including cost, side effects, cultural beliefs, cognitive impairments, the challenges of managing several prescriptions for chronic diseases simultaneously or a belief that the medication is not necessary because the individual does not feel "sick." Improving adherence rates is a complicated issue, as illustrated by the process described in Figure 5 on the next page.

[73] Ibid.

[74] Alicia Mundy and Jared Favole, "Plavix Study Faults Mixing Pills," *Wall Street Journal*, November 12, 2008, p. B2.

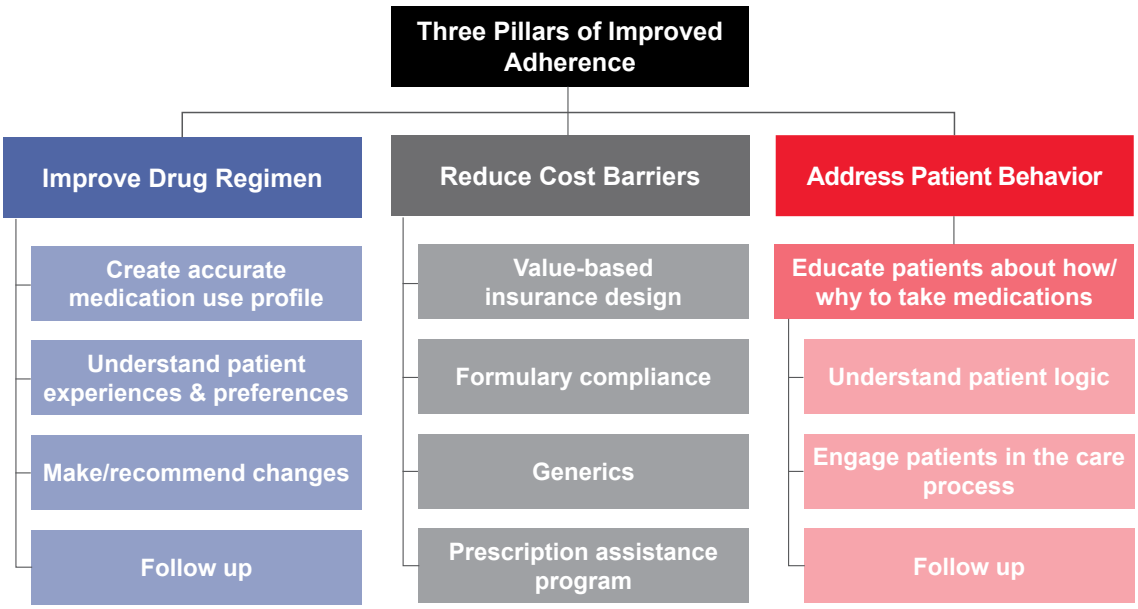
[75] J.R. Teagarden et. al. "Dispensing Error Rate in a Highly Automated Mail-service Pharmacy Practice," *Pharmacotherapy*, 2005, pp. 1,629 -1,635.

[76] Food and Drug Administration, Medication Error Reports, web site accessed February 2012.

[77] "Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease," A *New England Healthcare Institute Research* Brief, August 2009, p.1.

[78] Ibid, pp. 1-2.

Figure 5
Improving Patient Adherence



Source: Avalere Health, NEHI Analysis

Research shows that 58% of patients who are non-adherent to therapy actually think they take their medication as prescribed.[79] Not surprisingly, several studies have documented that non-adherent patients have significantly higher rates of both hospitalization and mortality.[80] Because of this, PBMs focus much of their attention on clinical services that increase adherence and target conditions that require long-term pharmacological treatments. They have developed programs and approaches that have proven to be effective with a wide variety of member populations. Examples of recent successes include:

- Applying behavioral science to promote healthy behaviors — Express Scripts, using behavioral sciences and patient history, has determined there is a real gap between what individuals intend to do and their actual adherence behaviors.81 As a result, the company provides targeted services to its members making it easier for them to follow-through with their intended, health promoting behaviors. This includes reminding patients of the nearest network pharmacy, encouraging mail delivery of 90-day fills for their maintenance medications, and using the most effective and lowest-cost drug before a more expensive one (step therapy).82

- Intensive chronic disease management to improve outcomes — Under disease management initiatives, PBMs communicate regularly with members being medicated for one of several high-prevalence conditions such as diabetes, cancer, heart disease and stroke. These conditions are targeted because chronic conditions are responsible for $1.7 trillion of healthcare spending annually and because they affect a large segment of the population nationwide.[83] Medco established Therapeutic Resource Centers, where

[79] Express Scripts, *2010 Drug Trend Report: A Market and Behavioral Analysis*, April 2011, p. 42.

[80] "Thinking Outside the Pillbox: A System-Wide Approach to Improving Patient Medication Adherence for Chronic Disease," A *New England Healthcare Institute Research* Brief, August 2009, p. 2.

[81] Express Scripts, *2010 Drug Trend Report: A Market and Behavioral Analysis*, April 2011, p.15.

[82] Ibid, pp. 16, 46.

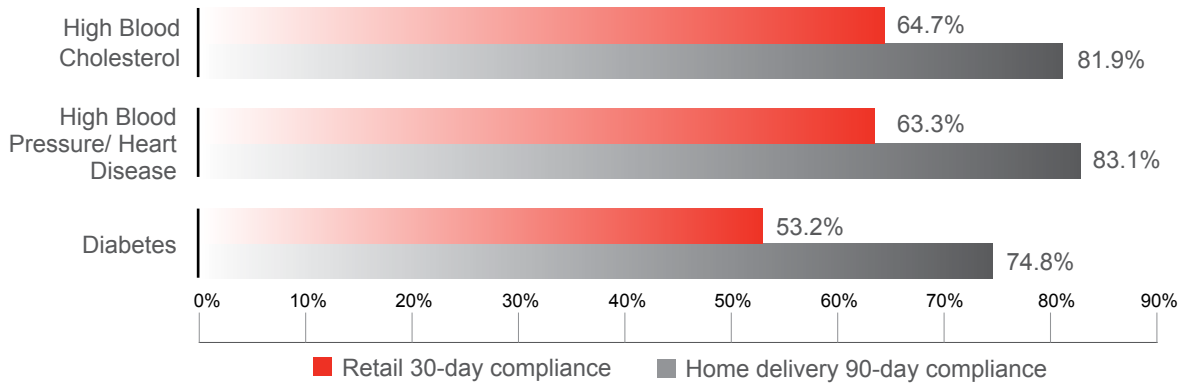
[83] Walgreens Health Initiatives, *Pharmacy Benefit Solutions 2010 Trend Report*, 2010, p. 10.

over 1,000 pharmacists specially trained in specific disease areas such as cancer, diabetes, heart disease and asthma are readily available to consult with members. The extended training includes an emphasis on co-morbidities (i.e. the effect of all the other diseases an individual patient might have in addition to the primary disease of interest) and side effects. Training also focuses on improved communication skills so the pharmacists can better advise members to improve outcomes. According to one observer, the essence of the centers is individualized medicine — understanding each patient's response to medications, medication gaps, right-dosing and gaps in care.[84]

- At home medical management to reduce hospital readmissions — Nearly 70% of adverse health events after a hospitalization are related to medical management. Recently, CVS Caremark, in conjunction with Dovetail Health, developed a hospital readmission prevention plan. By receiving in-home consultations with a clinical pharmacist shortly after discharge, high-risk patients will get a 90-day plan which "includes a comprehensive drug therapy review, care plan development to mitigate the greatest readmission risk factors such as chronic illness management, health coaching and care coordination with the patient's health care provider."[85] The program will hopefully reduce readmission rates, improve clinical outcome and create an opportunity for cost savings.

Adherence to medication regimens for patients suffering from chronic conditions has been shown to improve with the use of home delivery of medication. When treating diabetes, high blood pressure, heart disease, and high cholesterol there are dramatic improvements in adherence with a 90-day mail delivery fill over that of a retail pharmacy 30-day fill, as illustrated in Figure 6. One study demonstrated that when adherence to medication regimens was high, overall healthcare spending decreased. This lowered the cost of additional outpatient care, emergency room visits and hospitalizations. Most likely, the savings are underestimated since the study did not include skilled nursing care outside of the hospital or the non-deductible expenses incurred by those caring for a patient who is unexpectedly hospitalized or incapacitated. The research also found that the risk of hospitalization was dramatically lower when adherence increased.[86]

Figure 6
Patient Compliance With 30-Day Retail vs. 90-Day Home Delivery



Source: Express Scripts, *2010 Drug Trend Report: A Market and Behavior Analysis*, p.10

[84] Tomas Reinke, "Large PBMs Transform Old Business Models," *Managed Care*, October 2009, p. 21.

[85] "CVS Caremark Announces Agreement with Dovetail Health to Develop Hospital Readmission Prevention Program," *New York Times*, September 29, 2011.

[86] M. Sokol, K. McGuigan, R. Verbrugge, and R. Epstein, "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost," *Medical Care*, June 2005, p. 524-525.

The Future of Clinical Services

PBMs continue to evolve to serve their clients and members by improving clinical outcomes and reducing costs. Further efforts are expected in the next several years, especially in the following area:

- Specialty Pharmacy Drug Management — Specialty drugs represent the fastest growing segment of drug spending. These drugs (often biopharmaceuticals) are used to treat difficult-to-manage, complex diseases and frequently require special handling and storage. A number of new products come onto the market annually. Specialty drugs often are novel therapies for previously untreated conditions. Many of these drugs are used at earlier points in disease progression (such as for rheumatoid arthritis), contributing to the nearly 20% increase in spending for these drugs in 2010 over 2009.[87] Specialty drugs are expensive. Although they account for 11.8% of total drug costs, they make up only 0.5% of prescriptions written. The average cost of a specialty drug in 2009 was $2,213 — an eye-opening 28 times that of the average non-specialty drug.[88]

Until recently, most medications have been chemically synthesized, small-molecule compounds. In the last few decades, medically active large molecules isolated from a biological source or biopharmaceuticals (e.g. proteins, peptides, monoclonal antibodies, hormones, nucleic acids, etc.), have become commercially successful. These drugs, which include self-injectables, often have special data and handling requirements and may necessitate a high level of support for patients on use. Because of this, more than 88% of health plans use specialty pharmacies to administer these products.[89] Specialty pharmacies offer a more focused expertise for these more difficult to handle drugs. They manage patient care and monitor side effects, which can be significant with these drugs, and evaluate efficacy of treatment. The specialty pharmacy at Express Scripts, for example, utilizes a "high-touch" care model which integrates a patient coordinator, specialty nurse, case worker and an on-call pharmacist into a patient care team. In addition to negotiating with the manufacturer for discounts, PBM specialty pharmacies can facilitate access to manufacturer assistance programs for those patients who need help covering their portion of a drug's costs.[90]

The PBM industry has been active in working with the FDA in developing a pathway to approve biogenerics, the generic versions of biopharmaceuticals. In the future, the development of biogenerics and biosimilar drugs hopefully will result in significant savings to patients — similar to what generic small-molecule drugs have offered. It is estimated that when such products enter the marketplace, savings from $42 to $108 billion will be realized during the first 10 years.[91] The Biologics Price Competition and Innovation Act of 2009, which creates a framework for FDA approval of follow-on biologics, became

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[87] Express Scripts, *2010 Drug Trend Report: A Market and Behavioral Analysis*, p. 91.

[88] Walgreens Health Initiatives, *Pharmacy Benefit Solutions 2010 Trend Report*, p. 8.

[89] Pharmacy Quality Management, "The Benefits of Full-Service Specialty Pharmacies," URAC Specialty Pharmacy White Paper, 2011, p. 8.

[90] J. Sammer, "Specialty Drugs Driving Pharmacy Benefit Costs", *Society for Human Resources Management*, April 4, 2011.

[91] Generic Pharmaceutical Association, "Savings: An Economic Analysis of Generic Drug Use in the U.S.", September 2011, p. 7.

law in March of 2010.[92] For these reasons, it is imperative that PBMs find effective ways to manage costs. New approaches to managing extremely high costs will continue to develop, including the following initiatives:

- Health Information Technology — Health information technology encompasses a vast amount of development, from electronic medical records to the real-time reviews mentioned earlier. Of particular interest to PBMs is the increasing use of electronic prescribing. In order to increase adherence and safety, "data on patients and on relevant medications must be available at the point of prescriptions and at every point of patient follow-up."[93] Increasing the use of e-prescribing will require an investment in technology and the education of prescribers by PBMs, and increased integration of health care information. Currently 52% of office-based physicians use e-prescribing, up from only 10% in 2008.[94] With financial incentives for physicians (included in the recent financial stimulus bill), it is expected that the use of this important tool will increase to more than 75% of prescribers over the next five years.

- Personalized Medicine — Genetic testing and pharmacogenomics, often referred to as personalized medicine, are at the cutting edge of pharmaceutical research. This research provides opportunities to identify optimal medications and doses based on individualized genetic profiles. Determining which biomarkers (bodily substances which are indicators of a biological or pathological state) to test requires the integration of evidence from molecular biology, oncology and other disciplines. PBMs have the skill, experience and motivation to make this happen. The urgency of this effort is underscored by the fact that the oncology pipeline now contains approximately 300 Phase II or higher candidates with the potential for testing against a biomarker.[95]

Because some tests are costly and could be inappropriately used, clinical policies for genetic testing and test utilization management help eliminate waste associated with nonspecific tests. By taking advantage of these tools, plan sponsors are able to base health care decisions on constructive, evidence-based guidelines. With all of the positive news developing in pharmacogenomics, PBMs are acutely aware that the regulatory and commercial complexities of tandem development of drugs and diagnostics are still emerging.[96]

Community Pharmacies and PBMs

Community and independent pharmacies have been vocal in their opposition to PBMs. These pharmacies fear that PBM efforts to reduce prescription-drug prices will shrink their sales and profit margins. Furthermore, they believe PBM support of mail-order services threatens to keep patients away from their traditional community pharmacy. Community pharmacy opposition to PBMs increased in 2006, following the passage of Medicare Part D legislation, which allowed private companies to administer prescription-drug plans for Medicare recipients.[97] Contrary to community pharmacy perceptions, though, the number of community pharmacies continues to increase, and pharmacies themselves are thriving.

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[92] "The Future Role of Biosimilars and Follow-on Biologics in Health Care," *ASHP Advantage e-Newsletter*, January 2011, p. 1.

[93] "Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease," A *New England Healthcare Institute Research* Brief, August 2009, p. 8.

[94] P. Dolan, "Office Based Doctors Warm to E-prescribing," American Medical Association amednews.com, November 28, 2011 and W. Dunham, "E-prescribing to Soar with New Spending," Reuters, March 16, 2009.

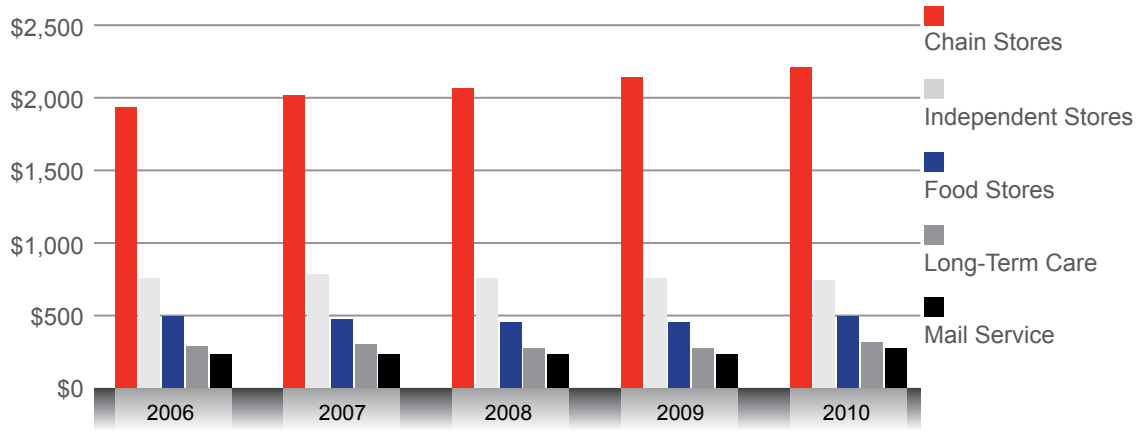
[95] Medco, *Drug Trend Report*, 2011, p. 7.

[96] "Companion Diagnostics: A Business Area Fraught With Challenges Ahead," *The Pink Sheet Daily*, March 15, 2011.

[97] Ibid.

Mail order pharmacies fill 7.2% of outpatient prescriptions, with 59.1% filled at chain pharmacies, 20.4% filled at independent pharmacies, and 13.3% filled at food store pharmacies. As seen in Figure 7 below, all four pharmacy channels have experienced similar growth rates between 2006 through 2010, indicating equal access by consumers. The push to restrict mail-order pharmacies appears to be simply an effort to increase sales and earnings for independent and chain pharmacies at the expense of the consumer.[98]

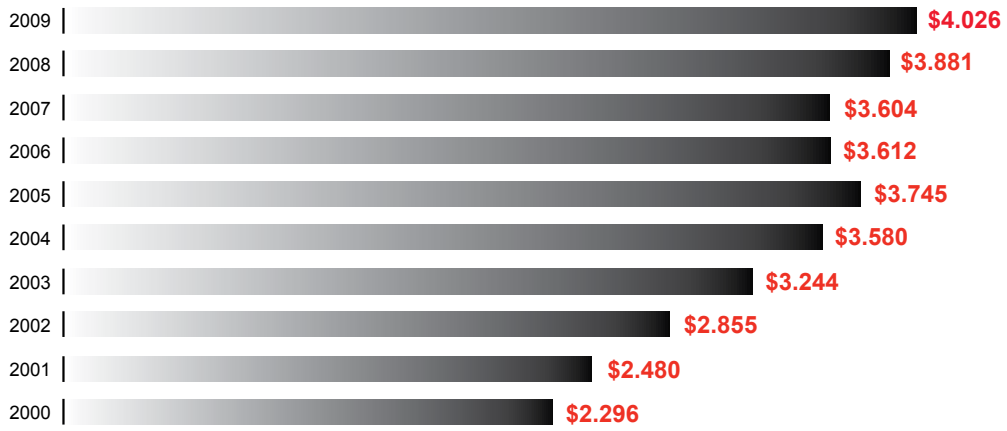
Figure 7
Average Sales per Store for Independent Community Pharmacies (in thousands of $)



Source: National Community Pharmacists Association, *2010 NCPA Digest*.

Independent community pharmacies have a $93 billion share of the total prescription-drug market, with 93% of their revenues coming from prescription-drug sales. Over the last two years, the number of independent and community pharmacies has actually increased by 336 stores nationwide to 23,064.[99] Between 2008 and 2009, the average annual number of prescriptions filled by independent community pharmacies rose from 62,379 to 64,635 (an increase of 3.6%). This increase in volume helps to explain the upward trend in average sales per store reported in Figure 8.[100] Over the span of a decade, the average store sale level has increased by 75% even with the recent economic recession. Independent community pharmacies have experienced positive annual sales growth in eight out of the ten most recent years.

Figure 8
Average Sales per Store for Independent Community Pharmacies (in millions)



Source: National Community Pharmacists Association, *2010 NCPA Digest*.

[98] IMS Health, Channel Distribution by Prescriptions, April 2011.

[99] National Community Pharmacists Association, *2010 NCPA Digest*.

[100] Ibid.

In addition to experiencing increased sales, independent community pharmacies have also been performing within their historical norms for operating and profit margins.[101] As reported in Table 2 on the next page, they have experienced fairly consistent profitability over the last ten years.[102] Gross profits ranged from a low of 22.8% in 2006 to a high of 24% in 2004. Since 2006, when the Medicare Part D program was implemented, independent and community pharmacies have seen gross profits increase from 22.8% to 23.8%, with the latter being the second highest figure over the previous ten years. Net operating income trends display similar characteristics as those of the gross profit margin. While reaching a decade low net operating income of 2.8% (as a percentage of sales) in 2006, pharmacies have rebounded nicely with annual gains each year between 2007 and 2009. The ability to control operating expenses has had a significant impact on maintaining profitability.

Table 2
Financial Performance of Independent Community Pharmacies

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Sales	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Cost of Good Sold	76.6%	77.0%	76.5%	76.0%	77.9%	76.4%	77.2%	76.8%	76.8%	76.2%
Gross Profit	23.3%	23.0%	23.5%	24.0%	22.1%	23.6%	22.8%	23.2%	23.2%	23.8%
Payroll Expenses	12.2%	12.5%	13.1%	13.2%	12.2%	13.4%	13.6%	13.7%	13.5%	14.1%
Other Operating Expenses	7.9%	6.9%	6.6%	6.8%	6.3%	6.5%	6.4%	6.5%	6.5%	6.4%
Total Expenses	20.1%	19.4%	19.7%	20.0%	18.5%	19.9%	20.0%	20.2%	20.0%	20.5%
Net Operating Income	3.2%	3.5%	3.8%	4.0%	3.6%	3.7%	2.8%	3.0%	3.2%	3.3%

Source: National Community Pharmacists Association, *2010 NCPA Digest*.

Aside from these financial metrics, an important gauge of the health of retail pharmacies is their ability to serve patients. In rural communities, as opposed to suburban and urban settings, pharmacies often act as one of the only medical providers in the immediate area. These are often independent pharmacies, since rural areas do not typically provide the economic incentives to attract chain stores. In these situations, the pharmacy's role can expand beyond prescription filling and may include bandaging wounds and referring patients to specialists for medical care. One measure of a pharmacy's ability to continue fulfilling these needs is to evaluate the access patients have to its services. Rural pharmacy participation in Medicare Part D prescription plans is strong, with a median participation rate of 88.9%. With such a high participation rate, access to in-network pharmacies is good. Of those pharmacies that do not participate in 100% of Medicare Part D plans, half of them have a competing pharmacy located within ten miles.[103] Only 16% of those pharmacies that do not participate in 100% of Medicare Part D plans are more than 20 miles from another pharmacy. Based solely on rural areas, 70% of Medicare beneficiaries live within 15 miles of a retail pharmacy participating in their Medicare Part D plan.

It is important to recognize that community pharmacies are not powerless in contracting with PBMs. More than half of all community pharmacy locations are comprised of the

[101] Ibid.

[102] Ibid.

[103] Department of Health and Human Services, Office of Inspector General, *Retail Pharmacy Participation in Medicare Part D Prescription-drug Plans in 2006*, June 2007.

largest nine pharmacy companies, led by CVS, Walgreens, and Rite Aid. With their significant market shares, each large retail chain has individual negotiating power with PBMs.[104] Depending on sales volume and market share, these large pharmacies can also negotiate directly with manufacturers and wholesalers for discounts and rebates.[105] Independent pharmacies also have the option to join Pharmacy Services Administration Organizations (PSAOs) in order to combine and leverage their collective strength. PSAOs are supported by drug wholesalers (who act as middlemen between drug manufacturers and retail pharmacies) to negotiate and administer contracts between independent pharmacies and PBMs. The five largest PSAOs include 13,500 independent pharmacies.[106] Finally, independent and community pharmacies can be part of as many PBM networks as they desire. These relationships are not exclusive.

Combating Fraud, Waste and Abuse in Drug Distribution

Impact on the Consumer and Health System

Fraud, waste and abuse are three major problems plaguing the U.S. health care system. These afflictions are pervasive, severe and affect every sector of the system, ranging from management to drug distribution. The result is higher costs to all participants — patients, medical providers, insurance companies, plan sponsors, and taxpayers. Consumers, especially the uninsured or underinsured, are exposed to greater health risks if they cannot afford the proper medications due to higher overall out-of-pocket expense. To put the situation in perspective, the Pharmaceutical Care Management Association (PCMA) estimates 1% of total prescription-drug costs can be attributed to fraud, waste and abuse.[107] For the whole health system, the costs are much larger. The FBI believes that between 3% and 10% of total health care expenses are attributed to these three problems.[108] In dollar terms, fraud alone represents a staggering $70 billion to $234 billion in additional health care costs each year.[109] These estimates, as large as they may appear, probably still significantly understate the size of the problem. For example, a recent study by Express Scripts found the cost of pharmacy-related waste (as explained in more detail later) in 2010 amounted to nearly $403 billion. This is money spent that did not yield any incremental health returns.[110]

Defining the Terms and Combating the Problems

Since the 1990s, a multitude of fraudulent, wasteful and abusive practices in health delivery have been detected and monitored. To better inform the reader, the following section provides some working definitions and examples of basic terms as they are being employed in this study.

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[104] "PoweRX 50," *Drug Store News*, May 2, 2011.

[105] Health Strategies Consultancy, "Follow the Pill: Understanding the U.S. Pharmaceutical Supply Chain," Kaiser Family Foundation, March 2005, p. 17.

[106] "In Their Own Words: Changes are in Store for PBM /Wholesaler Deals," *Drug Benefit News*, June 25, 2010.

[107] Pharmaceutical Care Management Association, "Fraud, Waste, and Abuse Detection in Retail Pharmacy: The Drugstore Lobby vs. Employers," Press Release, July 2011, p.1.

[108] Ibid, p.1.

[109] National Health Care Anti-Fraud Association, "Combating Health Care Fraud in a Post-Reform World: Seven Guiding Principles for Policymakers," October 6, 2010, p. 4.

[110] Express Scripts, *2010 Drug Trend Report: A Market and Behavior Analysis*, p. 8.

Fraud, the intentional deception or concealment of medical information for financial gain, is widespread in our health care system and costly. Dishonest medical practitioners can bill for services not provided or willfully misrepresent the nature of their services in order to receive higher compensation. Pharmacies may participate in drug switching, where lower-cost drugs are dispensed but claims are submitted for higher-cost versions.[111] Even worse, some unethical pharmacists have billed insurers for phantom prescriptions, receiving payment for prescriptions that are not actually filled. There are instances of organized criminal networks creating phantom pharmacies which turn in prescription claims for payment. Other examples of fraudulent behavior include: diverting narcotic prescriptions to the black markets for illegal sale; inflating drug prices; billing the patient a higher co-pay for services or drugs than required under the plan benefits; falsifying a patient's medical condition to justify unwarranted tests, procedures or prescriptions; and billing for more expensive medical services than were actually performed.[112] Pill flipping — switching Medicaid patients from a less expensive form of a generic drug (such as a tablet) to a more expensive form (such as a capsule) — can cost the public millions of dollars. Between July 2001 and 2005, a national chain made these kinds of substitutions for three generic drugs to increase their Medicaid revenue.[113] As a result of legal action, the company has agreed to pay back $18.6 million to the U.S. government and $16.4 million to the participating state Medicaid programs.

With respect to prescription-drugs, the simplest kind of waste is when drugs are prescribed but not administered or taken properly. Patients may fail to pick up their prescribed medicine or unilaterally suspend use of one or more of their medications for a host of reasons — including side effects, cost, interactions and simple neglect. On the manufacturer side, certain drugs may be discontinued and excessive stock has to be destroyed. Moreover, physicians may erroneously prescribe drugs that are ineffective or ignore generic drugs that are less expensive and just as effective as a brand-name prescription. Waste in the drug distribution system can be viewed as: channel waste (waste associated with visiting a pharmacy to pickup prescriptions rather than lower-cost mail order); drug mix waste (choosing a higher-cost brand-name drug over lower-cost generics); and non-adherence waste (patients not taking their medication as instructed). Express Scripts estimates these three types of wastes account for $88 billion, $57 billion, and $258 billion respectively in health care costs.[114]

The problem of abuse is closely associated with waste because it describes inappropriate utilization of health care services. Abuse differs somewhat from fraud in that abusive actions deviate from responsible medical practice but are not necessarily criminally motivated. It comes in many different forms. Nonmedical use of prescription-drugs by young adults is a rapidly rising epidemic, with more than 15 million people using psychotherapeutic drugs recreationally.[115] This represents three times the estimated number of people illegally using cocaine. The Centers for Disease Control and

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[111] Pharmaceutical Care Management Association, "Fraud, Waste, and Abuse Detection in Retail Pharmacy: The Drugstore Lobby vs. Employers," Press Release, July 2011, p. 2.

[112] D. Lubby, D. Geiger and A. Lopez, "Pharmacy Fraud, Part Two: A Clear Prescription," *Fraud Magazine*, July / August 2007.

[113] Medicaid Lawsuit is Settled by Walgreens," *Chain Drug Review*, June 30, 2008.

[114] Express Scripts, *2010 Drug Trend Report: A Market and Behavior Analysis*, p. 8.

[115] Laxmaiah Manchikanti, "National Drug Control Policy and Prescription-drug Abuse: Facts and Fallacies," *Pain Physician*, May 2007, p. 400. He reports that in 2005, 6.3% of all young adults between the ages of 18 to 25 were abusing prescription drugs.

Prevention believes annual deaths from non-prescription painkillers has reached almost 15,000 annually — more than those from heroin and cocaine combined.[116] Another less destructive but nevertheless costly example includes medical providers and consumers inflating medical costs by prescribing or purchasing drugs that are non-essential to their treatment regimes, especially when the parties are aware of effective over-the-counter alternatives. A key factor in abusive incidents is that consumers are often purchasing higher-cost prescription-drugs simply because they are covered by insurance plans where over-the-counter drugs are not.

Receiving Increased Government Scrutiny

Government agencies have instituted new policies, with coordination from industry, to reduce or eliminate inappropriate practices in drug distribution. Among the tools are the False Claims Act which allows the government to pursue civil actions to impose severe penalties for participants committing fraud and abuse. The Health Insurance Portability and Accountability Act of 1996 was designed to provide better protection for patient privacy, thus combating potential fraudulent use of confidential information.[117]

The problems stemming from fraud, waste and abuse in pharmaceutical drug distribution have recently been receiving increased scrutiny by various law enforcement agencies. For example, the U.S. Department of Justice (DOJ) considers fraud eradication one of its foremost priorities.[118] Given the enormous scope of these problems, industry members are working with federal and state agencies to aggressively confront organized offenders, better educate consumers and strengthen general oversight of pharmacy programs and the drug distribution process. Without a carefully coordinated and concerted effort by all participants in the health care industry, there will be little chance of lowering the costs stemming from these practices.

The DOJ has identified prescription analgesics such as oxycodone as the most common target of abuse. It has urged managed care organizations and PBMs to carefully monitor patient needs and purchasing patterns.[119] Establishing real-time data sharing between pharmacies and prescribers to detect drug-seeking behavior, multiple refills at many locations, early refills, etc. is a useful strategy for preventing abuse at the pharmacy point-of-sale. The Academy of Managed Care Pharmacy has recently developed several programs that attempt to balance patient access with abuse prevention using drug monitoring programs. One method is to restrict “patients suspected of abuse to receiving medications from one prescriber and one pharmacy or chain of pharmacies.”[120]

The Role of PBMs in Combating Fraud, Waste and Abuse

Being on the front line of the drug delivery system, PBMs are keenly aware of the exigency to identify and combat health care fraud and waste. These companies have established audit programs or departments that are dedicated to the review and

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[116] Devlin Barrett and Timothy Martin, “Pain Pill Suppliers Should ‘Self-Police’,” *Wall Street Journal*, March 1, 2012, pp. B1, B10.

[117] InformedRx, “General Medicare Compliance Training Slides”, December 23, 2009, p. 73.

[118] Lanny Breuer, Speech delivered at the American Health Lawyers Association and Health Care Compliance Association’s “2011 Fraud and Compliance Forum,” September 26, 2011.

[119] Laxmaiah Manchikanti, “National Drug Control Policy and Prescription-drug Abuse: Facts and Fallacies,” *Pain Physician,* May 2007, p. 419.

[120] Academy of Managed Care Pharmacy (AMCP), “Fraud, Waste and Abuse in Prescription-drug Benefits,” October 2011, p. 2.

analysis of problematic claims. Utilizing information from automated fraud detection software, auditors investigate the validity of these claims by conducting follow-up communications with pharmacies, physicians and patients to identify patterns of fraud. They also use advanced computer algorithms and are instituting even more secure electronic prescribing systems to detect fraud before payments are actually made. Among the effective tools PBMs have available are drug utilization reviews that search for inappropriate or fraudulent use of drugs. These programs offer both real-time and retrospective reviews. Thus, rather than chasing payments after they are made, PBMs are proactive, stopping fraud before it imposes a real cost. Prior experience has shown that loss recovery is usually more difficult, ineffective and time-consuming than stopping fraud at an earlier stage.

Many experts believe real-time data analysis is a key factor in audit processes to ensure timely fraud prevention. Auditors routinely screen for abuse with drugs that require prior authorization. These drugs require the physician to certify medical necessity prior to the prescription being filled. Auditors also perform routine on-site audits so as to be in a better position to uncover phantom pharmacies, discrepancies between inventories and prescriptions and failure to comply with insurance plan restrictions or regulatory requirements. *Fraud Magazine* cites a recent case where a PBM auditor identified inconsistencies between a patient's medical history and disease parameters versus the dispensed drug.[121] The auditor flagged the incident and eventually discovered systematic diagnostic code switching, which led to sanctions against the perpetrating pharmacy. A combination of advances in fraud detection technology, compliance training and audit programs allow PBMs to efficiently target fraudulent practices in drug distribution.

Another fraud prevention tool is comprehensive employee training on the latest developments in fraud detection during company-wide information sessions. By requiring employee attendance at these training programs, PBMs are able to make sure that up-to-date information on drug distribution fraud is shared with the entire staff and to encourage whistle blowing if any suspicious activity is spotted. For example, one company, InformedRx, has electronically published the company's compliance material in which it describes its current policies and tools for detecting fraud and abuse. In so doing, it better educates the public and discourages certain members of society from attempting fraud in the first place, as they realize the odds of getting caught are rising. The ongoing effort of PBMs to abide by and advocate legislative anti-fraud policies is instrumental in the prevention of fraud in drug distribution.

To counter the problem of waste, PBMs are actively sponsoring research studies to investigate the causes of patient non-adherence behavior. One recent survey confirms that patients do understand and appreciate actions that may lower their prescription waste.[122] The study found that 82% of patients using brand-name medications preferred generics, 70% of patients going to retail pharmacies actually preferred the convenience of home delivery and 40% of patients buying at more-expensive retail pharmacies were willing to switch to a lower-cost retail pharmacy if one was available. Traditional efforts at combating waste have been focused on educating consumers on the merits of low-cost alternatives and offering incentives for behavior changes. However, this report indicates patients already possess sufficient knowledge of strategies that could drastically reduce

[121] D. Luby, D. Geiger and A. Lopez, "Pharmacy Fraud, Part Two: A Clear Prescription," *Fraud Magazine*, July/ August 2007.

[122] Express Scripts, *2010 Drug Trend Report: A Market and Behavioral Analysis*, pp. 13-14.

prescription-drug waste. Thus, by focusing on helping patients align their medical needs with appropriate behavior, waste can be effectively reduced.

CVS/Caremark, Express Scripts and other companies in the PBM industry are constantly improving their pharmacy dispensing processes to increase patient adherence and compliance with drug therapy to improve outcomes and to lower waste. These programs include working with other health care professionals for trial periods where medications are studied for their efficacy and side effects, as a prelude to prescribing long-term drug therapy for patients.

PBMs, acting in conjunction with federal and state-level programs, have made significant progress in combating fraud, waste and abuse. They are also actively engaged in cross-disciplinary discussions with other industry participants and government policymakers to coordinate new ways to address these problems. In December, 2011, OptumRx sponsored a roundtable conference that gathered federal agency representatives and managed care professionals to explore current / future solutions. Increased levels of mutual access to relevant data, including information on frequent opiate users at a particular pharmacy, would be highly beneficial in detecting abuse. Programs for physician and consumer education and compliance training for PBMs were among topics discussed. Joshua Stein of OptumRx summed up the current situation:

> "Pharmacy benefit managers can and do play an important role fighting prescription-drug fraud, waste and abuse by creating their own programs and tools that can quickly identify irregularities and potential issues. By working with law enforcement, we are able to help ensure that the dollars allocated by the federal government and employers are actually used to help Americans live healthier lives."[123]

HINDERING PBMS WITH COSTLY MANDATES HURTS PATIENTS

Many recent legislative initiatives, both at the state and federal level, have sought to impose mandates and restrictions upon PBMs with the ostensible goals of empowering payers and consumers. Proponents and authors of anti-PBM legislation argue that imposing disclosure and fiduciary responsibility on PBMs, subjecting PBMs to increased regulation and putting limitations on PBM tools will reduce costs for their clients. For example, some proposals want to limit the use of mail-order pharmacy prescription filling services and curtail the encouragement of generic drug substitution for branded drugs. However, a closer examination of the consequences of such bills reveals that their economic impact would be the opposite of what proponents claim; the bills will result in higher prices for consumers and decreased competition in the pharmaceutical industry. Proponents of such legislation are often representatives of groups from whom PBMs negotiate their savings. These groups have a vested interest in keeping pharmaceutical prices high. Listed below are some of the proposed anti-PBM legislative concepts and the likely outcomes if they come into effect.

Limiting Mail Order Pharmacies

One of the primary ways PBMs can save clients money is through the offering of mail-order prescription services. In addition to cost-savings, mail prescription filling has the value of convenience and enhanced patient safety due to high automation and a low error rate.

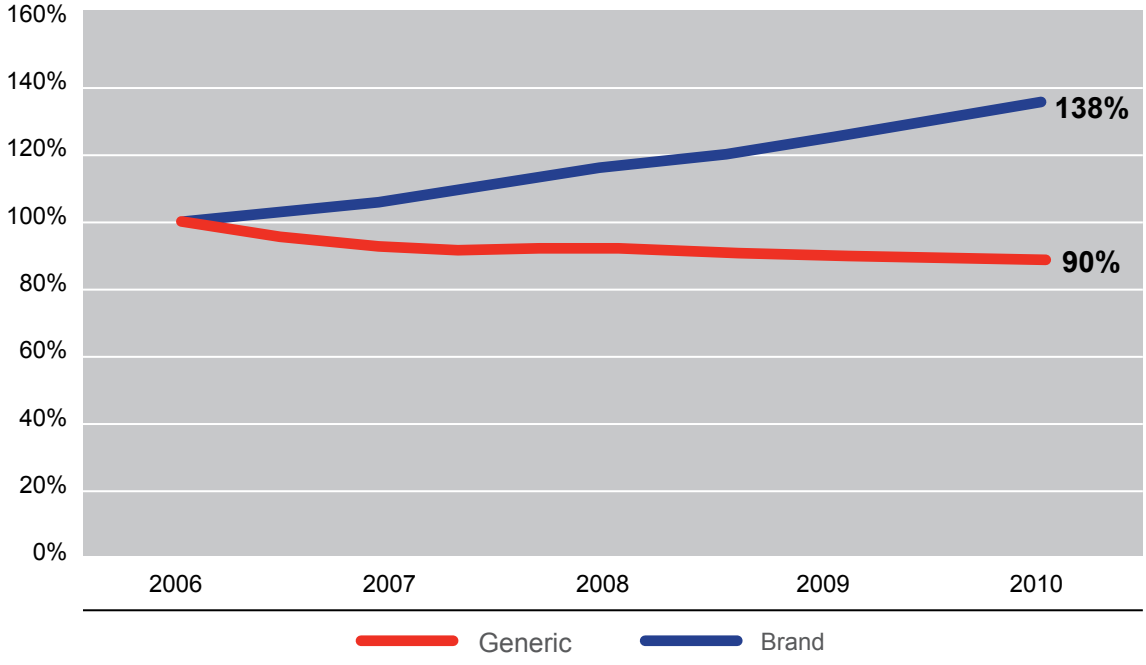
[123] Market Watch, "Policy and Industry Experts Push for Coordinated Solutions to Reduce Prescription-drug Fraud Waste and Abuse," *Wall Street Journal*, December 8, 2011.

As previously noted, the GAO published a report detailing the benefits of PBM use for the FEHBP. One of the major findings was the savings that resulted from mail-order pharmacy usage ranged between 27% to 53% when compared with purchasing the same generic and branded drugs from retail pharmacies.[124] Despite the profound need to lower prescription-drug costs, legislation has been proposed seeking to limit the methods through which PBMs encourage the use of mail order.[125] While the legislation at first appears intended to give consumers more choice by allowing them to visit pharmacies of their choosing, it could actually force them to use only retail pharmacies. Thus, the result would be higher costs and less competition. Not including Medicare Part D, it has been estimated that each 1% decrease in the use of mail-order pharmacies would raise prescription costs nationally by $2.3 billion over a ten year period.[126]

Restricting Generic Substitution

Another method PBMs employ to lower costs is encouraging the use of generic drugs instead of their more expensive branded counterparts. This is particularly significant from a cost-savings perspective. Generic drugs are generally 60-80% less expensive than their brand counterparts, have not experienced the same rapid price increases.[127] In fact, a 2011 study by the GAO comparing commonly used generic and branded drugs revealed that the costs of the branded drugs rose 38% over the last 4 years while the costs of generics actually declined 10% over the same time period, as depicted in Figure 9.[128]

Figure 9
Price Increases of Branded Drugs vs. Generics, 2006 – 2010



[124] U.S. General Accounting Office, "Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies," 2003, p. 4.

[125] See Virginia House Bill No. 405 (2006) and Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics, "Letter to the Hon. James L. Seward," August 8, 2011.

[126] Pharmaceutical Care Management Association, *How Mail-Service Pharmacies Will Save $46.6 Billion over the Next Decade and the Cost of Proposed Restrictions*, Visante, Inc., February 2012, p. 13.

[127] Consumers Union, "Generic Drugs: The Same Medicine For Less Money," *Consumer Reports Health.org.*, undated, pp. 5, 6.

[128] U.S. Government Accountability Office, "GAO-11-306R Prescription-Drug Price Trends," February 10, 2011, p. 19.

Moreover, a recent study on behalf of the Generic Pharmaceutical Association (GPhA) conducted by IMS Health outlined savings greater than $734 billion to the health care system from 1999 through 2008 as a result of generic drug substitution.[129] Yet, despite the cost benefits resulting from generic drug substitution and PBM encouragement of this practice, certain PBM-related legislation actually contains stipulations that could hamper PBMs in their ability to encourage generic-drug use. The FTC took note of this, writing to state legislators to warn them a bill contained language 'that potentially burdens certain substitutions of generic drugs for brand name drugs."[130]

Forcing Disclosure of Confidential Operating Information

The subject of disclosure is one of the most strongly contested issues in the PBM legislative debates. Proponents argue that greater disclosure about the operations of PBMs is necessary to ensure payers and patients receive the benefits to which they are contractually entitled and have sufficient knowledge to measure PBM performance. Thus, proponents insist it is necessary for PBMs to disclose highly sensitive information, such as their agreements with drug manufacturers concerning rebates, price negotiations, formulary placement, product selection and selection of preferred drugs.[131]

These types of disclosures are not required of other health care organizations. And, disclosure of such sensitive information would severely limit the ability of PBMs to negotiate with drug companies. Confidentiality is vital for ensuring that drug manufacturers bid aggressively in order to be placed on formularies or have their products receive preferred status.[132] As the FTC points out, if this type of information were made public the incentives for aggressive bidding would greatly diminish, while the opportunities for tacit collusion would also greatly increase — both of which would lead to higher drug prices. The same is true concerning negotiations between PBMs and pharmacies.[133] Following any mandated disclosure, PBMs would be incapable of securing price concessions from pharmacies if they all knew what reimbursements others were getting. PricewaterhouseCoopers calculates the new disclosures would increase drug costs by 4.1%, or $127 billion, over the period 2008-2017.[134] This would be financially devastating and could cause hundreds of thousands of individuals to lose their health insurance.

Imposing Fiduciary Standards on PBMs

Bills proposing increased disclosure requirements for PBMs often contain language requiring PBMs to assume fiduciary responsibility to clients. The justification for imposing fiduciary

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[129] See IMS Institute for Healthcare Informatics and IMS Health, "SAVINGS: An Economic Analysis of Generic Drug Usage in the U.S." September 2011, P. 2. and U.S. Food and Drug Administration, "Generic Drug Roundup" April 2010, p. 1.

[130] Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics "FTC Staff Comment to the Hon. Terry G. Kilgore Concerning Virginia House Bill No. 945 to Regulate the Contractual Relationship Between Pharmacy Benefit Managers and Both Health Benefit Plans and Pharmacies," October 2006, p. 9.

[131] PricewaterhouseCoopers, "Pharmacy Benefit Management Savings in Medicare and the Commercial Marketplace & the Cost of Proposed PBM Legislation 2008-2017," March 2007, pp. 11-13.

[132] Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics, "FTC Staff Comment to the Hon. Terry G. Kilgore Concerning Virginia House Bill No. 945 to Regulate the Contractual Relationship Between Pharmacy Benefit Managers and Both Health Benefit Plans and Pharmacies," October 2006, p. 8.

[133] Ibid, p. 13.

[134] PricewaterhouseCoopers, "Pharmacy Benefit Management Savings in Medicare and the Commercial Marketplace & the Cost of Proposed PBM Legislation 2008-2017," March 2007, pp. 13, 15, 16.

standards on PBMs is the assumption that doing so would be beneficial for consumers and would ensure that PBMs act in good faith. However, as is the case for other PBM-directed proposals, the FTC believes the mandated fiduciary rules would actually prove detrimental to consumers as the costs would inevitably rise if the rules were implemented.[135]

In a fiduciary role, the duties and nature of the relationship between PBMs and their health care clients would be significantly altered as PBMs become subject to greater potential liability.[136] A fiduciary duty normally refers to a person or organization who handles financial assets (e.g. pension funds) on behalf of someone else. The fiduciary label would considerably alter the current "arm's length" contractual agreements between PBMs and their clients and subject PBMs to onerous conditions including:

- Extending responsibilities and duties held by health plans onto PBMs
- Complicating or contradicting various contractual duties and agreements which had previously been clearly defined and understood
- Exposing PBMs to breach of duties claims
- Creating conflicting obligations between PBM clients (employers) and their ultimate beneficiaries, the patients[137]

To counteract this added burden, PBMs would likely: 1) increase their liability insurance spending; 2) reduce some of their cost-saving measures in case these would expose them to expanded legal risks; and 3) stop doing business in states which pass such laws.[138] These actions would result in higher prices for consumers. The first option would result in greater administrative costs (to be passed on to employers, consumers, and taxpayers), while the second would lead directly to higher drug prices. PricewaterhouseCoopers estimates that requiring PBMs to become fiduciaries would increase drug costs by 3%, or an additional $92 billion, over a decade.[139] Maine, the only state to have imposed a fiduciary requirement on PBMs, repealed the law in 2011 since it reduced competition and increased prices.

Any-Willing-Provider Legislation

Any-willing-provider (AWP) legislation requires managed care organizations to accept any provider who agrees to the plan's terms and conditions. For PBMs, this means that they must include in their network all pharmacies willing to accept the terms offered. These so-called "freedom of choice" laws are promoted as a way to maximize competition. But, like much of the anti-PBM legislation, the unintended consequences

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[135] Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics," Letter to the Hon. James L. Seward," March 31, 2009, p. 10.

[136] PricewaterhouseCoopers, "Pharmacy Benefit Management Savings in Medicare and the Commercial Marketplace & the Cost of Proposed PBM Legislation 2008-2017," March 2007, pp. 14, 15.

[137] See Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics, "Letter from FTC staff to New Jersey Assemblywoman Nellie Pou," April 17, 2007, p. 5. and PricewaterhouseCoopers, "Pharmacy Benefit Management Savings in Medicare and the Commercial Marketplace & the Cost of Proposed PBM Legislation, 2008-2017," March 2007, p. 15.

[138] Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics, "Letter from FTC staff to New Jersey Assemblywoman Nellie Pou," April 17, 2007, pp. 2, 5, 6.

[139] PricewaterhouseCoopers, "Pharmacy Benefit Management Savings in Medicare and the Commercial Marketplace & the Cost of Proposed PBM Legislation 2008-2017," March 2007, p. 2.

of such bills are the exact opposite. A FTC study analyzing AWP proposals determined that, if enacted, the legislation would, "limit competition undermine freedom of choice and increase the cost of pharmaceutical services." Pharmacies would no longer have an incentive to compete by developing innovative proposals.[140] A 2009 study on the impact of AWP legislation on drug expenditures at the state level did indeed find an increase in private plan pharmaceutical drug expenditures. In states with pharmacy-specific AWP laws, per capita spending on pharmaceuticals was more than 6% higher than in states without such legislation. This increase was attributed to the inability to selectively contract with a set group of pharmacies and an increase in administration costs as a result of contracting with more providers.[141] A recent analysis of AWP legislation at the state and federal level concluded that such laws "lead to less competition and higher prices for consumers while providing no compensating benefits. Selective and exclusive network contracting is a fundamental part of the competitive process which leads to minimizing cost and maximizing consumer welfare."[142]

Unnecessary Regulation

In responding to various state legislators regarding proposed disclosure measures, the FTC argued that current market mechanisms are already sufficient to address many of the concerns put forward. For instance, it noted that health plans already have the ability to negotiate for greater disclosure and audit rights from PBMs. It concluded that "Allowing competition among PBMs is more likely to yield efficient levels of payment sharing, disclosure, and price than contract terms mandated by government regulation."[143] Moreover, while the FTC does acknowledge that pricing information is needed for consumers to make informed decisions, it notes that the payments PBMs receive from drug companies are only one aspect which is factored into the how PBMs charge their clients. The FTC believes that requiring the disclosure of such information is analogous to requiring firms to reveal underlying cost structure to consumers, which is not needed for the generation of competitive market outcomes.[144] While it might help Whirlpool to know how much Frigidaire is paying for steel for their appliances, it certainly would not help the consumer looking to buy a refrigerator.

Another problem arising from recent legislation targeting PBMs is the lack of clarity in some of the language, including sections affecting confidential proprietary business information. The response to such uncertain business and legal standards would likely lead to even greater protective measures and less deployment of cost-saving tools on the part of PBMs.[145] Should such restrictive legislation come into effect, costs could increase as much $360 billion in the commercial sector and $190 billion for Medicare part D.[146]

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[140] Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics, "Letter to Patrick C. Lynch, Attorney General and Juan M. Pichardo, Deputy Majority Leader, Senate," State of Rhode Island, April 8, 2004, pp 1-3, 5.

[141] Christine Piette Durrance, The Impact of Pharmacy-Specific Any-Willing-Provider Legislation on Prescription-drug Expenditures, *Atlantic Economic Journal*, December 2009, pp. 409-423.

[142] Jonathan Klick and Joshua D. Wright, "The Anti-Competitive Effects of "Any Willing Provider," *Laws, Legal Backgrounder*, March 23, 2012, p.3.

[143] Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics, "Letter to the Hon. James L. Seward," March 31, 2009, p. 6.

[144] Ibid, p. 10.

[145] Ibid, pp. 3, 7, 8.

[146] Pharmaceutical Care Management Association, Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers, September 2011, p. 3.

Concluding Remarks

Health care spending in the U.S. is on an unsustainable trajectory. We are facing a "perfect storm" with a weak economy, an aging population, high unemployment, more people eligible for government coverage under the Affordable Care Act and the rise of promising but expensive specialty drugs. All factors are providing strong upward pressure on health care spending. As a result, the costs of health care paid by both employers and employees have more than doubled over the last ten years. The real challenge facing health care today is to not just rein in or reduce these ever escalating costs, but to do so without compromising the quality of medical service. There have been estimates that as much as 30% of total health care costs could be eliminated with no change in quality.

This study has highlighted how PBMs work to control prescription-drug costs while still enhancing patient care. Drug costs are kept affordable and accessible through a variety of mechanisms: promotion of generic drugs over their branded counterparts; mail order pharmacies; creation of formularies; better consumer education; negotiating discounts with pharmacies; negotiating rebate programs with drug manufacturers; and drug utilization reviews. All have been shown to be effective tools for controlling costs. As previously discussed, PBMs have successfully reduced prescription-drug costs by an impressive 15% to 40% depending on program prowess. PBMs have been actively working with the FDA to develop a framework for the development of biogenerics, which are forecasted to save consumers between $42 billion and $108 billion in their first decade on the market. Government agencies including the CBO, GAO, and FTC have all confirmed that PBMs generated savings in the tens of billions of dollars.

PBMs enhance patient care and adherence using a multi-pronged approach. Drug safety and adherence are addressed by: drug utilization reviews to catch potential adverse drug interactions; analyzing systematically collected data to identify dangerous drug combinations; encouraging the use of 90-day prescription for chronic conditions; patient coaching; counseling, education and interventions; and helping with management of chronic diseases. Reviews of real-time patient data identify previously unknown drug related problems.

PBMs are looking to the future to identify new avenues to be even more effective. Recent studies estimate that up to $403 billion in pharmacy-related waste per year could be eliminated in the U.S. through more efficient programs and stronger controls. In conjunction with federal and state governments, PBMs are making progress fighting fraud, waste and abuse. Automated fraud detection software, including advanced computer models, identify patterns of fraud allowing PBMs to take corrective action when it counts the most.

Recently, at both the federal and state levels, there has been heavy lobbying by special interest groups for new legislation to impose restrictions on PBMs. Although supporters ostensibly want to empower their members, these bills often have significant, unintended consequences. Indeed, the end result of such legislation would be decreased competition in the pharmaceutical industry and higher costs to plan members. Limitation of mail order and generic substitution, along with higher legal and insurance bills would all contribute to increased costs. Maine has already repealed its fiduciary requirement for PBMs because of just such cost-increasing effect. Any-Willing-Provider legislation has also increased prescription costs at the state level. Should unnecessary PBM-restrictive legislation be widely imposed, it has been estimated that costs could increase as much $360 billion in the commercial sector and $190 billion for Medicare Part D.

Brick and mortar pharmacies, fearing for their future, have also lobbied strongly against mail-order pharmacies. Our examination of financial data clearly shows, however, that independent and community pharmacies in this country are growing and thriving. The push to restrict mail-order pharmacies is simply an effort to maintain or increase profits for independent and chain pharmacies at the expense of consumers.

Each and every dollar spent on health care should bring its full value to consumers and plan sponsors. For what Americans are spending, we should have one of the top health care systems in the world. The PBM industry's goal of keeping drug costs affordable for their sponsoring employers and consumers through the use of sophisticated programs is one that has a history of success. If best practices were adopted by all plans, PBMs could generate savings of up to $500 billion over the next decade. New efforts and programs offer the opportunity for even greater savings while maintaining and improving the health of their plan members.