The Economic Benefits of Pharmacy Benefit Managers[1]

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I. Executive Summary

Health care spending in America is on an unsustainable trajectory. A variety of factors – including demographic changes, increased utilization of health care services, and high rates of chronic and complex disease – are driving rapid growth in health care spending. The Centers for Medicare and Medicaid Services (CMS) projects that the growth in prescription drug spending will average 7.1 percent per year from 2011 through 2020.[4] If costs per enrollee in Medicare and Medicaid grow at the same rate over the next four decades as they have over the past four decades, those two programs *alone* will increase from five percent of GDP today to 20 percent of GDP in 2050.[5] Escalating health care costs also make it more difficult for employers to provide quality health benefits to their workers and reduce employment and wages. Approximately 12 percent of employer costs today are for employee health benefits.[6]

Approximately one-half of adults in the U.S. have chronic diseases or complex health conditions.[7] This population segment accounts for 96 percent of drug spending[8] and 75 percent of total health care expenditures nationwide.[9] For the vast majority of chronic and complex diseases – 88 percent – drugs are a first, logical choice for medical intervention.[10] However, recent research from the New England Healthcare Institute reports that up to 50 percent of all U.S. patients do not take their medications as prescribed, and patients' non-adherence is estimated to cost up to $290 billion in "avoidable medical spending" every year.[11] Similarly, Express Scripts has estimated that pharmacy-related waste in health care spending exceeded

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[4] Centers for Medicare & Medicaid Services (2011), National Health Expenditure Projections 2010-2020, *available at* https://www.cms.gov/NationalHealthExpendData/downloads/proj2010.pdf.
[5] Peter Orszag, "Health Costs are the Real Deficit Threat," The Wall Street Journal, May 15, 2009.
[6] Toni Johnson, "Healthcare Cost and U.S. Competitiveness," Council on Foreign Relations, March 23, 2010, *available at* http://www.cfr.org/health-science-and-technology/healthcare-costs-us-competitiveness/p13325.
[7] Centers for Disease Control and Prevention, "Chronic Diseases and Health Promotion," *available at* http://www.cdc.gov/chronicdisease/overview/index.htm#ref2.
[8] David Snow (2010), "The Case for Smarter Medicine: How Evidence-Based Protocols Can Revolutionize Healthcare," p. 9, *available at* http://medco.mediaroom.com/index.php?s=17884.
[9] Ibid.
[10] Ibid., p. 10.
[11] New England Health Care Institute, "Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease," August 12, 2009, p. 1, *available at* http://www.nehi.net/publications/44/thinking_outside_the_pillbox_a_systemwide_approach_to_improving_patient_medication_adherence_for_chronic_disease.

$403 billion in 2010 alone and could exceed $1.2 trillion between 2010 and 2014.[12] The dual goal of containing drug spending and better managing the total costs of chronic conditions is key to addressing the nation's health care cost problem.

Pharmacy benefit managers (PBMs) help to lower health care costs. PBMs currently play a vital role containing costs and improving patient outcomes by serving more than 215 million Americans through health insurance plans, labor unions, private and governmental employers, and Medicare prescription drug plans.[13] PBMs improve prescription drug therapy management for patients and deploy a variety of tools to contain drug costs for payers. PBMs have evolved beyond their core service of prescription drug management to also focus on improving health outcomes and providing treatment solutions for patients with chronic and/or complex conditions.

PBMs' ability to contain spending will be critical in the coming years as health care reform expands coverage at a time of extreme budgetary pressures at both the federal and state levels. Health care reform also calls for several changes in the delivery of care, such as state health insurance exchanges and accountable care organizations (ACOs). PBMs are well placed to adapt to these changes and help spur innovation with their "wired" technology platforms that efficiently integrate prescription management at both mail order and retail and allow communication with pharmacists and physicians in real time for evidence based clinical management.

- **PBMs Reduce Drug Costs by Approximately 30 Percent Per Year**
  - Empirical evidence demonstrates that PBMs deliver cost savings for consumers, labor unions, employers, health plans and government programs. The benefits PBMs produce in containing costs have been thoroughly documented in studies by economists, government agencies such as the Congressional Budget Office (CBO), Government Accountability Office (GAO), and the Federal Trade Commission (FTC), health industry analysts, and clinical researchers. The Congressional Budget Office (CBO) estimated that PBMs have the potential to save as much as 30 percent in total drug spending relative to unmanaged purchasing.[14] Similarly, a more recent private-sector report estimates that PBMs will save plan sponsors and consumers almost $2 trillion (about 35 percent) from

[12] Express Scripts Drug Trend Report 2010, p. 8.

[13] Visante, "Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers," September 2011 ("Visante 2011"), p. 3. (A report prepared for the Pharmaceutical Care Management Association.)

[14] Congressional Budget Office, "Issues in Designing a Prescription Drug Benefit for Medicare," October 2002, Table 6 at 40 *available at* http://www.cbo.gov/ftpdocs/39xx/doc3960/10-30-PrescriptionDrug.pdf.

2012 to 2021, compared to drug expenditures made without PBMs in the following categories:[15]

Increased Use of Generics and Preferred Brands	11% – 16%
Manufacturer and Pharmacy Discounts	22% – 28%
Utilization Management and Adherence Programs[16]	-1% – 1%
Total	**30% – 40%**

- PBMs control drug spending primarily by leveraging their advanced technology platforms to make prescription management more efficient, driving higher use of generics and other lower cost medications, negotiating favorable drug prices from manufacturers and retail pharmacies, dispensing prescriptions via lower cost channels, such as mail-order pharmacies, and through evidence-based clinical programs.
- By helping to contain health care costs and improving patient outcomes, PBMs help public and private sector employers to offer more and better health benefits to their employees. Elsewhere, the benefits of PBM cost savings show up as lower prices for health care services, gains in effective wages, increased employment, and reduced spending for government payers.
- PBMs also help to rein in other health costs and improve health outcomes by boosting patient adherence to drug therapies,[17] detecting and closing gaps in care and preventing adverse drug interactions. Patient non-adherence is estimated to cost up to $290 billion per year – which represents about 13 percent of all health expenditures. A significant body of peer-reviewed literature shows that non-adherence takes a significant toll on health and leads to higher health care costs. For example, one estimate shows that non-adherence to prescribed medications accounts for nearly 20 percent of all hospitalizations and almost 125,000 deaths each year.[18] Research also indicates that patients who adhere to their medication regimens have better health outcomes and use fewer health care services – including urgent care and inpatient services – compared to patients who are non-adherent. Notably, researchers state that while improving medication adherence results in higher prescription drug costs, these costs are often more than offset by savings in other types of medical spending.[19]

[15] Visante 2011, p. 3 and Figure 5 at 17.

[16] Although there may be a net increase in drug utilization due to increased patient adherence, and therefore a "negative savings" in drug spending, there is an associated greater savings from an overall health care cost perspective since better medication adherence reduces other health care costs.

[17] See, e.g., O. Kenrik Duru, Julie A. Schmittdiel, et al. (2010), "Mail-Order Pharmacy Use and Adherence to Diabetes-Related Medications," *American Journal of Managed Care*, 16(1), 33, 37.

[18] Mediaplanet, "Medication Non-Adherence," March 2011, p. 10, *available at* http://www.cardinal.com/mps/wcm/connect/0ba69c00464d3b23b998fb690e45094f/Washington+Post+Special+Section+(March+2011).pdf?MOD=AJPERES&CACHEID=0ba69c00464d3b23b998fb690e45094f.

[19] One study found lower disease-related medical costs associated with higher medication adherence for patients with diabetes and hypercholesterolemia. (Michael C. Sokol, Kimberly A. McGuigan, et al. (2005), "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost," *Medical Care*, 43(6), 521.) Similarly, a 2011 *Health Affairs* study documented substantial cost savings from improved medication adherence for individuals with chronic vascular disease through reduced inpatient hospital days and emergency department visits. (M. Christopher Roebuck, Joshua N. Liberman, et al. (2011), "Medication Adherence Leads To Lower Health Care Use And Costs

- PBM's growing role in the clinical management of chronic diseases or complex health conditions is particularly important given that these patients account for approximately 96 percent of drug spending and 75 percent of total health care expenditures nationwide.

- **Medco and Express Scripts Save Clients Between $51 Billion and $87 Billion Per Year**
  - Simply analyzing the cost savings derived by Medco and Express Scripts – as estimated above using the 30 percent CBO savings estimate – we calculate that Medco and Express Scripts save plan sponsors and consumers roughly $51 billion per year.[20]
  - But Medco and Express Scripts estimate that they currently derive greater savings through larger discounts from drug manufacturers and retail network partners and benefit plans and consumers in other ways that would not be fully captured in the CBO estimates, such as their more extensive clinical offerings.[21] Therefore, Medco and Express Scripts estimate that together they save consumers roughly $87 billion per year.
  - To further quantify savings, we also compared the prices paid by Medco plan members at retail pharmacies to the usual and customary ("U&C") prices typically paid by cash-paying customers using data that Medco compiles in the ordinary course of business. As shown in Figure 1,[22] these data show that Medco plan members paid substantially lower prices than cash-paying customers. For brand drugs purchased at chain pharmacies, these data show that on average, the prices paid by Medco plan members during the 2008 to September 2011 period were 20 percent less than the prices paid by cash paying customers as measured by the U&C price. For generic drugs, the average price for Medco plan members was 57 percent less than the price paid by cash paying customers.

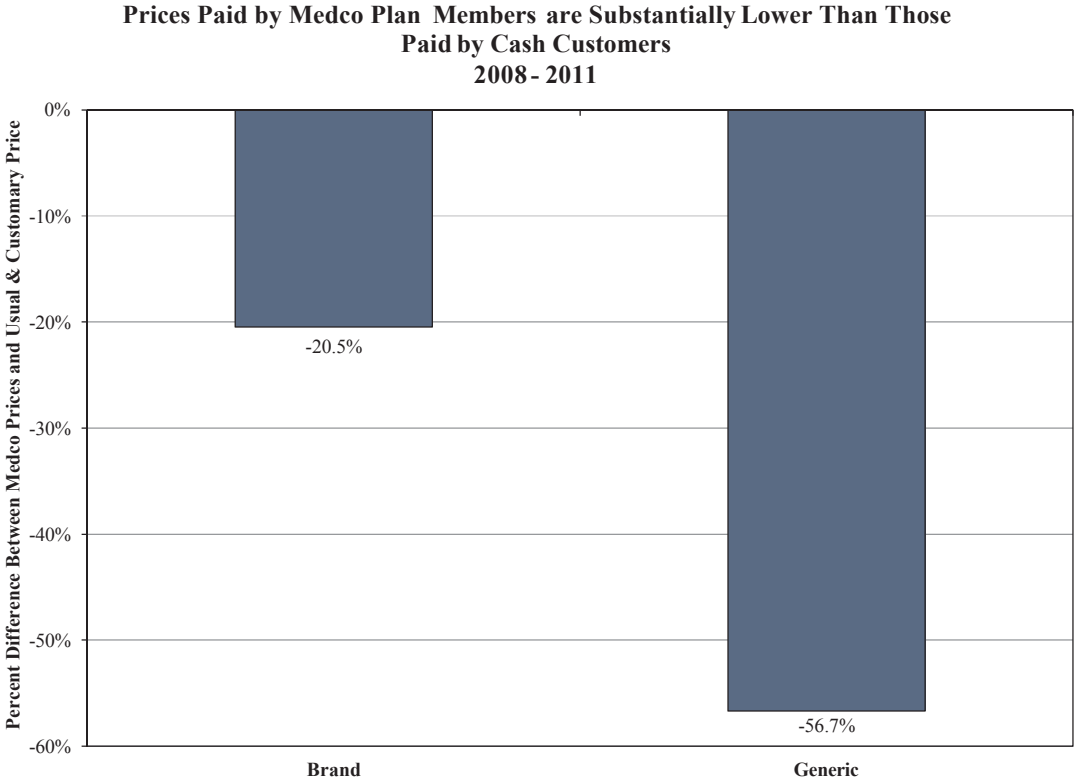
Despite Increased Drug Spending," *Health Affairs*, 30(1), 91, *available at* http://content.healthaffairs.org/content/30/1/91.full.pdf+html.) Another study found that patients with chronic myeloid leukemia (CML) who adhered to their medication more than 85 percent of the time have fewer hospitalizations than non-adherent patients, and the costs of the hospitalizations are lower, too: $3,758 vs. $44,498. (Eric Q, Wu, Nicolas Beaulieu, et al. (2010), "Healthcare Resource Utilization and Costs Associated with Non-Adherence to Imatinib Treatment in Chronic Myeloid Leukemia Patients," *Current Medical Research & Opinion,* 26(1), 61, 63-64.)

[20] Calculated as 30 percent of estimated Medco and Express Scripts AWP spending during 2010.

[21] For example, by integrating specialty pharmacies with core PBM functions, Medco and Express Scripts provide better coordinated care and have realized high rates of patient adherence, increased ability to close gaps in care, coordinate care for patients with co-morbidities, and provide other clinical benefits.

[22] Note: 2011 is through September 30, 2011. Source: Medco provided data file, ftc cash pay 20111011.xls.

Figure 1



- The savings delivered by Medco, Express Scripts, CVS/Caremark, SXC, Catalyst and other PBMs are passed on to public and private employers and labor unions in the form of lower prices for health care, to the federal government as a result of lower Medicare Part D costs, and to individuals who purchase insurance on their own. Based on the 2010 savings estimates provided by the companies, we estimate how these savings were distributed among the Medicare Program (Federal Government (Part D) + Medicare Beneficiaries), labor unions and employer and individual plans as summarized in Table 1 below.

Table 1

Medco and Express Scripts Estimated 2010 Client Savings Relative to Unmanaged Spending	
Medicare Program (Federal Government (Part D) + Medicare Beneficiaries)	$21.7 billion
Labor Unions	$3.5 billion
Employers and Individuals	$61.9 billion
TOTAL	**$87.1 billion**

- These cost savings are derived from a variety of sources. For example:

- Express Scripts uses data-driven models and other tools to curb health care costs stemming from non-adherence and increasing use of the most efficient and safest delivery channels. Express Scripts estimates that it saved each member $11 per year by moving them to value-enhanced pharmacies and up to $27 per year by elevating adherence rates for patients in its home delivery program.[23]
- The merging firms use a variety of tools to mitigate health care costs associated with chronic and complex conditions. Medco's Therapeutic Resource Centers (TRCs) are clinical programs that use specialized pharmacists and advanced systems to personalize pharmacy care for patients with chronic conditions and complex therapeutic needs. Medco estimates that TRCs closed more than 2.3 million clinical gaps in care in 2010 alone with estimated health cost savings of $900 million.[24]

As rising health care costs continue to confront both public and private payers, the need for innovative solutions becomes ever more pressing. By better containing health care costs and improving patient outcomes, PBMs help produce lower entitlement program spending and a healthier workforce. In some cases, PBM savings manifest themselves in the form of employers offering cheaper and/or better health benefits to their members. Elsewhere, the benefits show up as gains in effective wages, increased employment or reduced spending for cash-strapped government payers.

[23] Express Scripts Drug Trend Report 2010, p. 16.
[24] Medco 2010 Annual Report, p. 2.

II. What Do Pharmacy Benefit Managers Do And How Do They Benefit the U.S. Economy?

A. U.S. health care spending is on an unsustainable growth trajectory and pharmacy benefit managers are well positioned to help meet this challenge.

The role of pharmacy benefit managers (PBMs) in containing prescription drug costs and improving management of chronic conditions is increasingly important to the U.S. economy. As discussed above, U.S. health care spending is on an unsustainable growth trajectory. PBMs help manage drug benefits for some 215 million Americans in both commercial and government health care programs.[25] Health care program sponsors contract with PBMs to process and pay prescription drug claims, to secure discounts and rebates from prescription drug manufacturers, and to manage broad networks of pharmacies including both community pharmacies and mail-order service pharmacies. PBMs also play an important clinical role in support of quality, cost-effective patient care by helping to ensure that patients take medications as prescribed; use the lowest-cost, clinically safe and effective medication; avoid taking multiple medications that may interact with one another adversely; and are incentivized to use the most cost-effective delivery channel, when appropriate. Appendix A provides an overview of the key functions PBMs perform in the management of drug benefits.

B. Medco and Express Scripts reduce health care costs for their clients by between $51 billion and $87 billion per year.

Consistent with the literature showing that PBMs generate large cost savings, Medco and Express Scripts have reduced health care costs for their clients by between $51 billion and $87 billion per year. Simply analyzing the cost savings derived by Medco and Express Scripts – as estimated using the 30 percent CBO savings estimate – we calculate that Medco and Express Scripts save plans and consumers roughly $51 billion per year.[26] But Medco and Express Scripts currently derive greater savings through larger discounts from drug manufacturers and retail network partners and benefit plans and consumers in other ways that would not be fully captured in the 2002 CBO estimates, including their more extensive clinical offerings that we describe

[25] Visante 2011, p. 3.
[26] Calculated as 30 percent of estimated Medco and Express Scripts average AWP spending for 2010.

below. Including these additional cost savings not included in the CBO estimate, Medco and Express Scripts estimate that they save consumers an additional $36 billion per year – or roughly $87 billion per year, in total.

Medco and Express Scripts estimated the savings generated for different types of plan sponsors during 2010 in three categories: (i) retail discounts, (ii) mail discounts, and (iii) rebates from drug manufacturers. Savings for the retail and mail channels represent the total client discount dollars off of Average Wholesale Price ("AWP") for each respective channel. Since AWP prices are similar to the prices paid by unmanaged cash paying customers at retail pharmacies, this method approximates the amount that PBMs save plan sponsors compared to unmanaged spending.[27] The calculation represents the entire discount realized by plan sponsors and consumers -- it does not attempt to apportion the discount between them. Savings for the rebate category represent the total dollars of rebates passed through to clients in each year. In addition to these three categories, Medco also estimated savings for a fourth category: savings from clinical programs. The savings for the clinical programs category are estimated by Medco using a claim-based methodology that compares the patient's claims activity before and after an intervention as a result of the various specific programs.[28]

The savings delivered by Medco, Express Scripts, CVS/Caremark, SXC, Catalyst and other PBMs are passed on to public and private employers and labor unions in the form of lower prices for health care, to the federal government as a result of lower Medicare Part D costs, and to individuals who purchase insurance on their own. Based on the 2010 savings estimates provided by Medco and Express Scripts, we estimate how these savings were distributed among the Medicare Program (Federal Government (Part D) + Medicare Beneficiaries), labor unions

[27] In studies of PBM savings, the reference prices for unmanaged plan members are frequently measured by the prices paid by cash-paying customers at retail pharmacies. (See, e.g., United States General Accounting Office, "Effects of Using Pharmacy Benefits Managers on Health Plans, Enrollees and Pharmacies," GAO-03-196, January 2003, ("2003 GAO Study"), *available at* http://www.gao.gov/new.items/d03196.pdf.) Medco has compiled information in the ordinary course of business on the usual and customary prices charged to cash-paying customers for a sample of brand and generic drugs over time. These data show that cash-paying consumers generally paid significantly more than AWP during the 2008 to 2010 for brand drugs and significantly less than the generic AWP for generic drugs. While the average discount from generic AWP was larger than the average premium over brand AWP, the fact that brand drugs account for substantially larger dollar volume of purchases implies that on an overall spending basis, the average difference between AWP and U&C prices is relatively small.

[28] The specific programs included in the Medco analysis include Concurrent Drug Utilization, POS Plan Management, Preferred Drug Step Therapy, Prior Authorization, Smart Rules, Rational Med, and Therapy Management. Medco receives fee income for some of its clinical programs. These fees are approximately $4.17 per eligible member per year across the Medco book of business. In comparison, the estimated clinical savings average approximately $385 per eligible member per year.

and employer and individual plans as summarized in Table 2 below. In addition, if the savings from Express Scripts Medicare plans were distributed similarly as those of Medco's plans, the $21.7 billion estimated Medicare savings could be divided further into savings of approximately $13.4 billion for the Federal Government (Part D) and $8.3 billion for Medicare beneficiaries.[29] Calculated savings to the federal government reflect lower government payments for the heavily government-subsidized Medicare Part D program. Specifically, the government experiences lower annual costs for Medicare Part D premium subsidies, reinsurance subsidies and low-income beneficiary subsidies (both premium and cost sharing) as a result of lower drug benefit costs. Furthermore, the government has reduced outlays for the retiree drug subsidy (RDS) whereby the government subsidizes a portion of total drug benefit costs for employers offering qualified drug coverage to Medicare beneficiaries. Medicare beneficiaries also directly benefit from lower premiums and/or lower cost sharing. Savings to employers and employees, as well as individuals purchasing insurance reflect lower premium and/or cost sharing as a result of lower drug benefit costs.

Table 2

Medco and Express Scripts Estimated 2010 Client Savings Relative to Unmanaged Spending	
Medicare Program (Federal Government (Part D) + Medicare Beneficiaries)	$21.7 billion
Labor Unions	$3.5 billion
Employers and Individuals	$61.9 billion
TOTAL	**$87.1 billion**

C. PBMs effectively deploy a variety of tools to reduce prescription drug spending

PBMs use multiple tools to contain prescription drug spending. A well-designed drug benefits program typically begins with a comprehensive formulary which lists the drugs that the plan will cover in each of many therapeutic categories. The formulary is compiled by the plan's Pharmacy and Therapeutics (P&T) Committee which is made up of pharmacists and physicians from different specialties who evaluate drugs in various therapeutic categories on a variety of

[29] A more detailed description of the methodology for allocating savings can be found in Appendix B.

criteria including effectiveness and safety.[30] Financial data also are considered in development of formularies, however, "[d]ecisions are based, first and foremost, on appropriate care for the member."[31] While PBMs consult extensively with plan sponsors in all areas of plan design, the final decisions are made by the plan sponsor, not the PBM. Given the formulary, and other elements of the plan design, PBMs drive down net drug costs by leveraging the volume of their customer bases, encouraging the use of lower cost products including generic drugs, conducting utilization management programs, and delivering medications to patients via low-cost, mail-order pharmacies. In 2010, the growth in prescription drug spending slowed to 3.5 percent. The Center for Medicare and Medicaid Services (CMS) has recognized the role of PBM tools, such as use of incentives to stimulate the use of lower cost generic drugs, in achieving this result.[32]

There is a diverse array of competitors in the PBM industry. The FTC's 2005 PBM Study estimated that about 40-50 PBMs operate in the US.[33] Similarly, the Pharmacy Benefit Management Institute's directory lists more than 40 members operating today.[34] While many PBMs are "stand-alone" independent firms – such as Express Scripts, Medco, Catalyst, SXC and MedImpact – other PBMs are affiliated with major health insurers or health plans (such as United Health, Aetna, CIGNA, and Kaiser). One of the largest PBMs, CVS Caremark, is a combination of a PBM and a retail drug chain, and another large retail drug chain Walgreens recently sold its PBM. These examples and many others show that plan sponsors have many diverse alternatives available when choosing a PBM.

In addition, the PBM industry is one where changes in business models and repositioning by competitors can have a significant impact on competition. For example, industry analysts estimate that Medco has recently lost as much as 33 percent of its revenue base, of that, approximately one-half is attributed to United Health's decision to take its PBM functions in-house, another eight percent of Medco's revenue base will now go to CVS (CalPERS, FEP, UAM), and the remaining eight percent will be divided up between other PBMs such as Prime

[30] Federal Trade Commission, "Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies," August 2005, ("2005 FTC Study"), pp. 10-11, *available at* http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf.
[31] 2005 FTC Study, p. 11.
[32] Sean P. Keehan, Andrea M. Sisko, et al. (2011), "National Health Spending Projections Through 2020: Economic Recovery and Reform Drive Faster Spending Growth," *Health Affairs*, 30(8), 1596, 1600, a*vailable at* http://content.healthaffairs.org/content/early/2011/07/27/hlthaff.2011.0662.full.pdf+html.
[33] 2005 FTC Study, p. v.
[34] Note, this may not include all PBMs as companies must pay a fee to be listed in PBMI's directory. (Pharmacy Benefit Management Institute, "PBM Directory," *available at* http://www.pbmi.com/pbmdir.asp.)

Therapeutics (BCBSNC) and others.[35] The Chairman and CEO of Medco, David Snow, discussed these and other recent examples of PBM innovation and competition.[36] Despite this variety of competitors, in some of the discussion that follows, we focus on specific programs and capabilities of the merging firms because we have more detailed information about their offerings. However, this disproportionate focus on the merging firms does not imply that the many other competitors in the marketplace do not also provide substantial benefits to consumers and plan sponsors.

1. Promote use of lower cost drugs

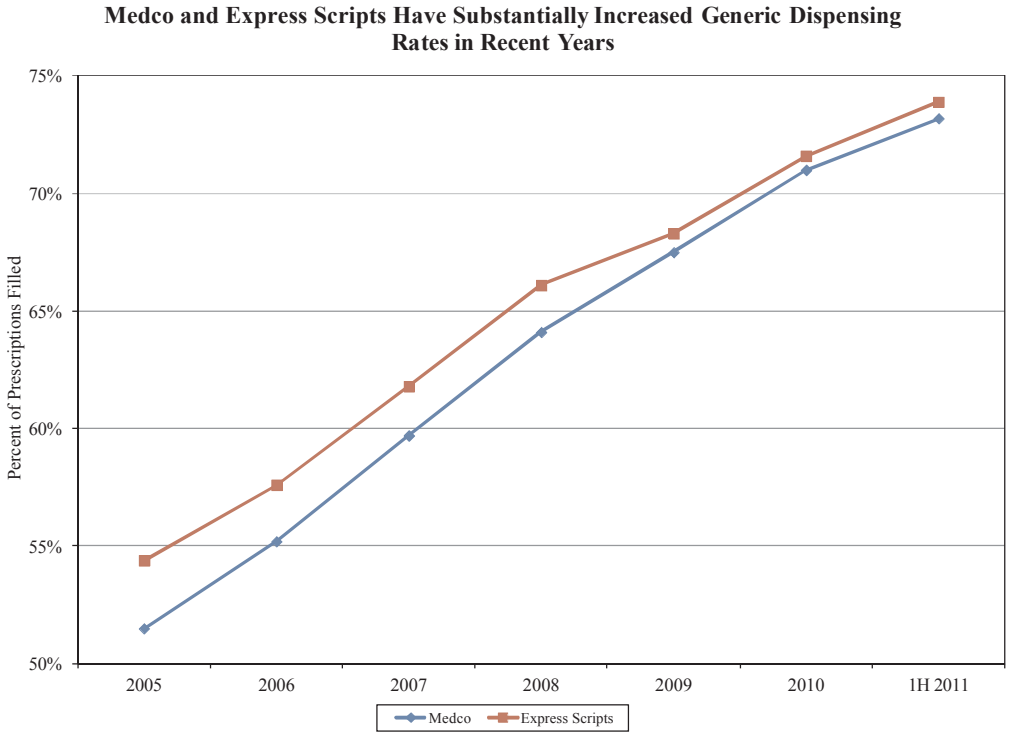
a) Driving Generic Drug Utilization

PBMs and health insurers increase the use of generics through a variety of benefit design and utilization management tools. As shown in Figure 2[37], Medco and Express Scripts have increased their generic dispensing rates significantly in recent years. In 2010, Medco's generic prescription dispensing rate reached 71 percent,[38] which resulted in incremental savings of $3.7 billion to Medco clients and members.[39] Express Scripts' generic dispensing rate was nearly 72 percent.[40] Medco estimates that its clients have realized cumulative savings of approximately $23 billion from increases in generic utilization since 2006.[41] These savings reflect both the effects of PBM tools that encourage generic utilization, and the increased availability of generic medications over time. Savings from increasing generic utilization have increased over time as the rate of price increases for brand drugs has far exceeded that of generic drugs – in 2009

[35] Morgan Stanley, "Healthcare Services & Distribution," July 28, 2011, p. 3.
[36] Written Testimony of David Snow Before the House Judiciary Committee, Subcommittee on Intellectual Property, Competition and the Internet, Hearing on the Proposed Merger Between Express Scripts and Medco, September 20, 2011, pp. 3-6.
[37] Sources: Medco Health Solutions 2007 10-K, p. 34; Medco Health Solutions 2010 10-K, p. 42; Medco Health Solutions 10-Q, June 25, 2011, p. 17; Express Scripts 2005 10-K, p. 33; Express Scripts 2007 10-K, p. 31; Express Scripts 2008 10-K, p. 36; Express Scripts 2010 10-K, p. 31; and Express Scripts 10-Q, June 30, 2011, p. 21.
[38] Medco Drug Trend Report 2011, p. 3.
[39] "Medco Chairman and CEO David Snow Addresses Shareholders, Highlighting Another Year of Growth, Innovation and Substantial Client Savings - With More to Come," Medco Health Solutions Press Release, May 24, 2011, *available at* http://medco.mediaroom.com/index.php?s=17872&item=40156.
[40] Express Scripts 2010 10-K, p. 31.
[41] "Medco Health Solutions Inc Q3 2011 Earnings Conference Call – Final Transcript," October 26, 2011, p. 4 *available at* http://seekingalpha.com/article/302339-medco-health-solutions-ceo-discusses-q3-2011-results-earnings-call-transcript.

average brand drug prices increased by over nine percent whereas generic drug prices rose by less than one percent.[42]

Figure 2



While the historical savings from generics are very substantial, there are additional opportunities to derive even greater savings – by maximizing the use of currently available generics and capitalizing on the upcoming "generic wave" which will affect many high-cost drug categories. Express Scripts estimates that the health care system could save $56.7 billion annually by achieving maximum generic fill rates within each therapy class for currently available generic drugs.[43] The savings potential from the use of generics in coming years will grow considerably: According to estimates, $89 billion in branded drug sales will lose patent protection over the next five years, and more than $50 billion in U.S. brand drugs – accounting for about 20 percent of current plan drug spending – will open to generic competition from late 2011 through 2013.[44]

[42] Medco Drug Trend Report 2010, p. 7.
[43] Express Scripts Drug Trend Report 2010, p. 9.
[44] Generic Pharmaceutical Association, "Savings Achieved Through Use of Generic Pharmaceuticals 2000-2009," July 2010, pp. 3-4 and Medco Drug Trend 2011, p. 48.

PBMs use a variety of tools to encourage the use of generic drugs when appropriate. One tool PBMs use to motivate members to utilize generic drugs is tiered copayments. These are explicit incentives to consumers to choose lower-cost drugs.[45] Some plans waive copayments altogether for generic drugs.[46] Another method is to require members to pay the full-price difference between a generic and branded drug if they refuse the generic alternative. Medco found that plans with a strong "pay the difference" program achieved higher substitution rates (61.2 percent) compared to plans without a "pay the difference" requirement (52.8 percent).[47]

PBMs also can influence generic utilization through the extensive use of mail-order pharmacy services, which enables PBMs to influence more directly generic substitution and offer generic alternatives shortly after they enter the market. When a new generic medication is introduced to the market, PBMs will often stock the medication prior to its introduction date, communicate with physicians and patients about the new product, and convert prescriptions from the branded drug to the generic on an expedited basis as soon as the medication is available.[48] Medco found that new generics entering the market replaced 92.4 percent of their brand name counterparts through its mail-order pharmacy within the first week of release, compared to a substitution rate of 54.1 percent achieved at retail pharmacies.[49] Over the course of the first year of introduction of a generic, retail pharmacies had a lower generic dispensing rate than Medco; such lower generic dispensing rates resulted in approximately $430 million higher health care costs.[50]

PBMs also increase generic dispensing rates through communications with both physicians and plan members. Some plans offer physicians periodic "report cards," which track generic prescribing behaviors. With the assistance of its PBM, one large Medco customer used this tool to increase its generic dispensing rate by 12 percentage points, resulting in savings of 18 percent in total plan cost for the employer and out-of-pocket savings for the company's

[45] Pharmacy Benefit Management Institute, "PBM 101 White Paper Series: Drug Benefit Management Strategies," 2009 ("PBM 101"), p. 3 and 2005 FTC Study, p. 11.
[46] PBM 101, p. 6.
[47] David B. Snow (2007), "Maximizing generic utilization: The power of pharmacy benefit management," *Journal of Generic Medicines*, 5(1), 27 ("Snow 2007"), 32.
[48] Ibid., p. 33.
[49] Snow 2007, p. 33 and Figure 4. Further, Medco reported during the first week of its release in 2007 the generic for Ambian, zolpidem, Medco mail-order pharmacy achieved a generic substitution rate of 97 percent, 20 percentage points higher to retail pharmacies' generic substitution rate of 77 percent over the same period. (Medco Drug Trend Report 2008, p. 10.)
[50] Snow 2007, pp. 33-34.

employees.[51] Similarly, Medco found that plan members who were presented cost savings options through an online tool were more likely to convert to a generic medication. In fact, 51 percent of those studied converted to a generic drug, and an additional seven percent converted to a lower-cost therapeutic equivalent drug; each conversion yielded an average annual savings of $171 per member.[52]

b) Therapeutic Interchange

Two plans surveyed by the GAO reported savings ranging from one percent to 4.5 percent from therapeutic interchange programs, where a clinically appropriate and less costly alternative drug was dispensed.[53] PBMs use therapeutic interchange programs to encourage physicians and patients to use formulary or preferred formulary drugs.[54] Therapeutic interchanges are programs where PBMs identify a suitable substitute drug in the same therapeutic class – even if not chemically equivalent – as the originally prescribed drug.[55] The interchange for a substitute drug can be either branded-to-branded or branded-to-generic, depending upon the physician's final approval.[56] When a prescribed drug is identified by a PBM as having a therapeutic equivalent on the PBM's formulary, the PBM contacts the prescribing physician and offers the opportunity to prescribe the substitute medication.[57]

c) Prior Authorization, Step Therapy, and Refill-too-Soon

Express Scripts estimates that plans that make use of the full range of clinical programs including step therapy, prior authorization, and others, can save roughly 11 percent of annual drug costs compared to plans that use none of these programs.[58] Similarly, Medco estimates that

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[51] Ibid., pp. 36-37.
[52] Ibid., pp. 36-37. On generic savings see also, Visante 2011, p. 11-13 and Jack Hoadley, "Cost Containment Strategies For Prescription Drugs: Assessing The Evidence In The Literature," Kaiser Family Foundation, March 2005, pp. 32-33, *available at* http://www.kff.org/rxdrugs/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=51885.
[53] 2003 GAO Study, p. 13.
[54] 2005 FTC Study, p. 13 and 2003 GAO Study, pp. 13-14.
[55] 2005 FTC Study, p. 13.
[56] Ibid.
[57] PriceWaterhouseCoopers, "The Value of Pharmacy Benefit Management and the National Cost Impact of Proposed PBM Legislation," July 2004, ("PWC 2004"), p. 7 (A report prepared for the Pharmaceutical Care Management Association.) and 2005 FTC Study, p. 13.
[58] Written Testimony of George Paz Before the House Judiciary Committee, Subcommittee on Intellectual Property, Competition and the Internet, Hearing on the Proposed Merger Between Express Scripts and Medco, September 20, 2011, p. 3.

its clinical programs have saved roughly $305 per eligible member per year during the 2008 to 2010 period.[59] Prior authorization (PA) is a process by which the PBM must approve a physician's or patient's request for a drug before the plan sponsor will pay for it. In some instances, physicians must give clinical justification for the prescription prior to receiving approval,[60] while in other instances drugs not included in the PBMs' formulary require PA.[61] These authorizations, which are often required for medications that are particularly expensive or prone to misuse, can help control drug costs.[62] A GAO study found that PA produced savings ranging from one percent to six percent of plan spending for drugs that either were not dispensed or were substituted with less costly alternatives, for particular plans that were studied.[63]

Step therapy is a plan design tool in which the plan will only cover more expensive drugs if patients try and fail therapy with less expensive alternatives, such as generic drugs, over-the-counter drugs, or less expensive brand drugs.[64] Express Scripts estimates that its step therapy efforts can produce savings of $30 or more per member each year.[65] One study analyzing 2005 data reported that a step therapy effort requiring patients to use a generic antidepressant prior to use of a brand-name drug resulted in drug cost savings of nine percent for the entire class of antidepressants, equal to approximately $1.8 billion in the first year of the intervention.[66]

To limit overuse – or fraudulent diversion – of medications, nearly all PBMs use refill-too-soon interventions. These measures prevent a patient from refilling a prescription until a certain percentage of the prior prescription is exhausted.[67]

2. Negotiate lower net drug costs for customers

The key economic role of PBMs in negotiating favorable prices from drug manufacturers has been discussed in many studies.[68] PBMs have significant negotiating leverage because they

[59] Medco receives fee income for some of its clinical programs. These fees are approximately $4.17 per eligible member per year across the Medco book of business.
[60] 2005 FTC Study, pp. 13-14. *See also,* PBM 101, p. 6.
[61] PWC 2004, p. 13.
[62] 2005 FTC Study, p. 14 and 2003 GAO Study, p. 13.
[63] Ibid.
[64] 2005 FTC Study, p. 14. *See also,* PBM 101, p. 7.
[65] Express Scripts Drug Trend Report 2010, p. 16.
[66] Jeffrey D. Dunn, Eric Cannon, et al., (2006), "Utilization and Drug Cost Outcomes of a Step-Therapy Edit for Generic Antidepressants in an HMO in an Integrated Health System," *Journal of Managed Care Pharmacy*, 12(4), 294.
[67] Pharmacy Benefit Management Institute, "Prescription Drug Benefit Cost and Plan Design Report 2010-11," 2010, p. 34.

are able to pool large volumes of prescription drug purchases across their entire customer bases, and because they can influence the use of particular drugs within a therapeutic class through preferred placement on a formulary and other incentives for consumers. It is this unique ability to influence consumer and prescriber behavior that gives PBMs a major advantage over other large participants in the distribution chain such as retail chains and drug wholesalers in negotiating discounts and rebates.

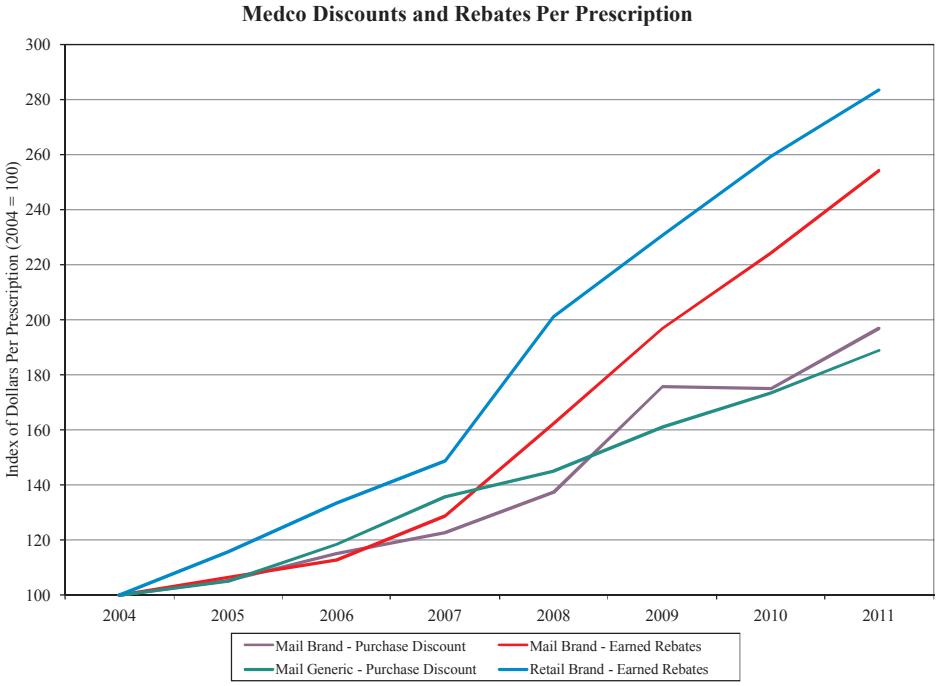
Based on an annual survey of health plans, the average rebate collected per prescription for each brand name drug dispensed at retail increased from $2.57 in 2007 to $7.87 in 2010; the average rebate collected for brand name drugs dispensed via mail order rose from $10.79 in 2007 to $25.97 (or an increase of $3.59 to $8.65 based on a 30-day supply) in 2010.[69] Similarly, data on the actual rebates and discounts negotiated by Medco with drug manufacturers and wholesalers also provides strong evidence that such rebates and discounts have increased substantially as Medco has grown over time (see Figure 3).[70]

[68] See, e.g., 2005 FTC Study; Department of Justice and Federal Trade Commission "Improving Health Care: A Dose of Competition," July 2004, Chapter 7, *available at* http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf; Federal Trade Commission, "FTC-DOJ Hearings on Health Care and Competition Law and Policy – Panel Discussion: Pharmacy Benefit Managers," June 26, 2003, *available at* http://www.ftc.gov/ogc/healthcarehearings/030626ftctrans.pdf; 2003 GAO Study; Patricia Danzon (2000), "Making Sense of Drug Prices," *Regulation*, 23(1), 56 *available at* http://www.cato.org/pubs/regulation/regv23n1/danzon.pdf; Benjamin Klein and Andres Lerner (2008), "The Law and Economics of Bundled Pricing: LePage's, PeaceHealth and the Evolving Antitrust Standard," Antitrust Bulletin 53(3), 555; United States Department of Health & Human Services, "Report to the President Prescription Drug Coverage, Spending, Utilization, and Prices," April 2000, Chapter 3, *available at* http://aspe.hhs.gov/health/reports/drugstudy/chap03.htm; Özden Gür Ali and Murali Mantrala (2010), "Pharma Rebates, Pharmacy Benefit Managers and Employer Outcomes," Health Care Management Science, 13(4), 281.

[69] Pharmacy Benefit Management Institute, "Prescription Drug Benefit Cost and Plan Design Report 2010-11," 2010, p. 29.

[70] Note: 2011 is as of July 2011 forecast. Source: Medco provided data file, Medco Scale Trend Statistics (Aug 2011) Vers 3.xls.

Figure 3



While the potential cost saving benefits of PBM bargaining power have been widely recognized, some critics of PBMs have argued that some PBMs may have monopsony power in their dealings with retail pharmacists.[71] These claims reflect a basic confusion between buying power, which likely benefits plan sponsors and consumers, and monopsony power which has the potential to harm consumers. The FTC has clearly recognized this crucial distinction and the potential benefits of increased buying power in the PBM industry specifically in its statement regarding the 2004 Caremark acquisition of AdvancePCS.[72] In particular, the FTC states:

> We also considered whether the proposed acquisition would confer monopsony (or oligopsony) power on PBMs when they negotiate dispensing fees with retail pharmacies. It is important not to equate market concentration on the buyer side with this kind of power. For example, a shift in purchases from an existing source to a *lower-cost, more efficient* source is not an exercise of monopsony power. Nor do competition and consumers suffer when the

[71] See, e.g., Statement of Dan E. Gustafson, Before the House Committee on the Judiciary, Subcommittee on Intellectual Property, Competition and the Internet, Hearing on The Proposed Merger between Express Scripts and Medco" September 20, 2011, p. 14-15. Monopsony is a structure of a market in which there is one buyer facing many sellers. It is the opposite of monopoly where one seller faces many buyers.

[72] Statement of the Federal Trade Commission, *In the Matter of Caremark Rx, Inc./AdvancePCS*, File No. 031 0239, pp. 2-3, *available at* http://www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf (note omitted).

> increased bargaining power of large buyers allows them to obtain lower input prices without decreasing overall input purchases. This bargaining power is procompetitive when it allows the buyer to reduce its costs and decrease prices to its customers.
> …
> At most, the acquisition is likely to increase the bargaining power of the merged PBM and to increase its shares (and correspondingly reduce the pharmacies' shares) of the gains flowing from contracts between the PBM and the pharmacies. It is likely that some of the PBM's increased shares would be passed through to PBM clients. Although retail pharmacies might be concerned about this outcome, a reduction in dispensing fees following the merger could benefit consumers.[73]

In addition to recognizing this conceptual difference between buying power which can benefit consumers and monopsony power, there also is no empirical basis for believing that modest reductions in payments to retail pharmacies that the merged firm may be able to negotiate would result in financial difficulties for pharmacies or a significant reduction in the marketplace output of pharmacy services. In fact, the aggregate gross profits of pharmacies reported by the US Census Bureau have increased by 37.4 percent from $43.5 billion in 2004 to $59.8 billion in 2009, even though pharmacy reimbursement rates have trended down over this period.[74] To illustrate the small magnitude of any potential impact on pharmacies, even if we assume that (say) 25 percent of the publicly disclosed estimated $1 billion in annual savings to plan sponsors and consumers came from lower reimbursement to retail pharmacies, the resulting $250 million in annual savings would constitute less than one-half of one percent of the estimated pharmacy industry gross profit of $60 billion per year.

In addition, if the primary concern of some analysts is for the health of independent pharmacies (rather than the entire retail pharmacy sector), several additional points must be recognized. First, public policy should focus on overall economic efficiency and consumer welfare, not protection of any particular type of pharmacy.[75] Second, PBMs have no economic

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[73] Ibid. Similarly, a joint report by the FTC and Department of Justice stated, "One panelist noted that a large customer base enables the largest PBMs with the most covered lives to drive the market share of any one pharmaceutical drug product and, therefore, obtain the lowest prices from pharmaceutical manufacturers." (Department of Justice and Federal Trade Commission, "Improving Health Care: A Dose of Competition," July 2004, Chapter 7, p. 11, (note omitted) *available at* http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf.)

[74] Adam J. Fein, "2010-11 Economic Report on Retail and Specialty Pharmacies," Pembroke Consulting, December 2010 ("Fein 2010"), Exhibit 24 at 33 and US Census 2009 Annual Retail Trade Report, Gross Margin, March 31, 2011, *available at* http://www.census.gov/retail/.

[75] It is widely recognized that some retail pharmacy groups have been strident opponents of PBM cost containment tools for many years. Such opposition has included strong advocacy for state and Federal legislation that would

incentive to benefit other retail formats at the expense of independent pharmacies. A diverse and competitive pharmacy industry helps PBMs achieve their business goals of providing convenient and affordable retail networks to plan sponsors. More than 60,000 retail pharmacies – which represent more than 95 percent of all United States retail pharmacies – participate in one or more of Express Scripts' and Medco's networks.[76] The independent pharmacies' membership in the Express Scripts and Medco networks plays an important role in their business, driving a large amount of incremental customer traffic to their stores. As another example, PBM care innovations allow independent pharmacies to deliver enhanced levels of service to their customers. For example, as discussed below, Medco has partnered with community pharmacies in innovative programs to help them achieve better adherence results for their patients.

Some PBM opponents also have argued that the cost savings PBMs generate from their ability to negotiate favorable deals with pharmaceutical manufacturers and retail network partners often are not passed through to plan sponsors.[77] However, this reflects a misunderstanding of typical PBM contracting practices and the economics of the industry. PBM contracts with plan sponsors typically require that PBMs pass on a very large fraction of the savings they negotiate with drug manufacturers and retail network partners. For example, Medco's 10-K reports that it passed through to its customers 87.5 percent of manufacturer rebates in 2010.[78] The economic evidence also indicates that plan sponsors who prefer contract structures with such high rates of pass-through are able to negotiate for such contracts. For example, in its recent 2011 letter commenting on proposed PBM regulation in Mississippi, the

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make PBM tools significantly less effective. The FTC has opposed such legislation on numerous occasions. See, for example, Federal Trade Commission, Letter to Honorable James L. Seward, August 8, 2011, p. 2, *available at*, http://www.ftc.gov/os/2011/08/110808healthcarecomment.pdf. Federal Trade Commission, Letter to the Honorable Mark Formby, March 22, 2011, pp. 2-3, 8, *available at* http://www.ftc.gov/os/2011/03/110322mississippipbm.pdf.

[76] Express Scripts 2010 Annual Report, p. 6; Express Scripts 2010 10-K, p. 2; and Medco Health Solutions 2010 10-K p. 9.

[77] For example, David Balto recently argued that "there is little reason to expect a dominant PBM to pass on savings to consumers." (David Balto, "Step Up to the Plate: FTC Needs to Stop the Express Scripts-Medco Merger," TheHill.com, November 2, 2011, *available at* http://thehill.com/opinion/op-ed/191497-step-up-to-the-plate-ftc-needs-to-stop-the-express-scripts-medco-merger.) *See also,* Statement of Dan E. Gustafson, Before the House Committee on the Judiciary, Subcommittee on Intellectual Property, Competition and the Internet, Hearing on The Proposed Merger between Express Scripts and Medco, September 20, 2011, p. 16.

[78] Medco Health Solutions 2010 10-K, p. 55. Similarly, Express Scripts stated in its 2010 10-K that "Historically in the PBM industry, competition in the marketplace has also caused many PBMs, including us, to reduce the prices charged to clients for core services and share a larger portion of the formulary fees and related revenues received from pharmaceutical manufacturers with clients." (Express Scripts 2010 10-K, p. 16.)

FTC staff reiterated that "competition affords health plans substantial tools with which to safeguard their interests" in contracting with PBMs.[79]

For other categories of PBM savings, such as increased mail order and generic dispensing, pass-through of savings occurs automatically under existing contracts, because mail order and generic drugs are substantially less costly for plan sponsors. In addition, for those categories of cost savings that are not subject to such "automatic" pass-through mechanisms, such efficiencies reduce the PBM's costs, allowing it to compete more aggressively in the marketplace. Economic analysis indicates that such efficiencies also are likely to benefit consumers over time as they increase the incentive and ability of the firm to reduce prices, provide better products, and expand output in other ways.

3. Lower costs using mail order pharmacy

Mail order pharmacies allow PBMs to offer lower prices on prescription drugs, achieve higher rebates through improved formulary compliance, increase generic dispensing rates, and automate systems for reviewing prescriptions to elevate rates of adherence to chronic medications and detect other gaps in care. According to Medco data, clients using Medco's mail order pharmacy more than 40 percent of the time in 2008 saw absolute drug costs decline year-over-year – completely offsetting the effects of inflation and increased utilization.[80] Indeed, Medco projects that the use of mail order will produce more than $1.93 billion in savings to Medco clients in 2012.[81] Express Scripts estimates savings of up to $27 per member each year have been realized from the use of mail order.[82]

Health plan members also benefit from generally lower co-payments at mail order and the convenience of receiving a 90-day supply of their prescriptions delivered to their homes. For

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[79] Federal Trade Commission, Letter to the Honorable Mark Formby, March 22, 2011, p. 2, *available at* http://www.ftc.gov/os/2011/03/110322mississippipbm.pdf. In addition to the different contract options offered by Medco and Express Scripts, there are numerous competing PBMs in the marketplace that aggressively promote their services based on a high degree of "transparency" to potential clients (e.g., Navitus, Catalyst Rx) There are also many external consultants whom offer expertise and sophisticated tools to assist plan sponsors in evaluating PBM offerings. Notably, both Medco and Express Scripts have recently been certified as meeting the standards of business transparency adopted by the HR Policy Association, an organization representing the chief human resource officers of more than 325 large private sector employers in the United States. ("HR Policy Association Announces 2012 PBM Transparency In Pharmaceutical Purchasing Solutions Participants," September 13, 2011, *available at* http://www.hrpolicy.org/downloads/2011/11-119%202012%20TIPPS-Certified%20PBMs%20Press%20Release.pdf.)

[80] Data provided by Medco.

[81] Ibid.

[82] Express Scripts Drug Trend Report 2010, p. 16.

example, recent survey data show that under the most common plan design in 2010, the average copayment for a 90-day supply of medication from mail order was $53.63, compared to a copayment for a 30-day supply at retail of $25.93, making the mail option more economical for the patient over the 90-day comparison period ($25.93x3=$77.79).[83] One study found that nearly 80 percent of employers did not have to pay dispensing fees when using mail-order pharmacies, compared to the average $1.62 dispensing fee at retail pharmacies.[84]

Medco, Express Scripts and other PBMs can offer low-cost mail-order pharmacies because they operate such facilities at a large scale and leverage efficiencies through automated dispensing pharmacies. They can additionally utilize on-line ordering, integrated voice-response systems, and point-of-care technologies.[85]

The efficiencies of mail-order pharmacies and PBMs are well recognized by CBO, GAO, the FTC, and the research community. A 2003 GAO study found the average price of prescriptions through mail order was 27 percent below the average cash price consumers would pay at a retail pharmacy for brand name drugs, and 53 percent below the retail cash price for generic drugs.[86] The FTC, citing its own research, has stated that "Mail order pharmacies typically are less expensive than retail pharmacies, for both health plans and consumers."[87] U.S. officials also have recognized the benefits of mail-order pharmacies and PBMs. In a letter to state governors earlier this year, HHS Secretary Kathleen Sebelius listed mail order as one way states could purchase drugs more effectively for their Medicaid programs.[88] The FTC has also highlighted the benefits of PBMs and mail-order pharmacies in letters sent to both Mississippi and New York government agencies in 2011.[89]

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[83] Pharmacy Benefit Management Institute, "Prescription Drug Benefit Cost and Plan Design Report 2010-11," 2010, p. 18.
[84] Fein 2010, p. 38.
[85] Mail-order pharmacies are able to review, record, and interpret incoming prescriptions, screen for interactions based on each patient's drug history profile, resolve benefit issues with rules set by plan sponsors, resolve clinical or prescription clarification issues with physicians, and collect co-payments from patients. Image-based technology is used to improve access to prescription orders and increase processing efficiency. Following order processing, prescriptions are approved for dispensing and electronically routed to one of the firm's mail-order dispensing pharmacies, which are networked into one integrated systems platform. Automated technology is used to dispense tablets and capsules, as well as original packaging. (Medco Health Solutions 2010 10-K, p. 8.)
[86] 2003 GAO Study p. 4.
[87] Federal Trade Commission, Letter to Honorable James L. Seward, August 8, 2011, p. 2, *available at*, http://www.ftc.gov/os/2011/08/110808healthcarecomment.pdf.
[88] U.S. Department of Health & Human Services, "Sebelius Outlines State Flexibility and Federal Support Available for Medicaid," February 3, 2011, *available at* http://www.hhs.gov/news/press/2011pres/01/20110203c.html.
[89] Federal Trade Commission, Letter to the Honorable Mark Formby, March 22, 2011, *available at* http://www.ftc.gov/os/2011/03/110322mississippipbm.pdf and Federal Trade Commission, Letter to Honorable

4. Manage specialty drug spending

PBMs can play a vital role in the management of specialty drugs. In general, the utilization of specialty drugs – drugs for complex medical conditions that require special handling either in delivery from pharmacy to the patient or in administration of the medication, or both – has grown rapidly in recent years and is projected to continue as the fastest growing category of drug spending.[90] Express Scripts estimates that by 2014, specialty drug spending will constitute 22 percent of total worldwide drug spending and up to 40 percent of U.S. drug spending, including both medical and pharmacy spending.[91] Because of this rapid current and projected growth, health plan sponsors increasingly face serious challenges in managing spending on high-cost biologics and other specialty medications.

One factor underlying specialty drug spending is the growth in patients with chronic or complex conditions, which can require highly innovative and expensive medications to treat. Roughly 50 percent of U.S. adult population is treated for a chronic or complex condition,[92] and those conditions represent 96 percent of drug costs in the U.S. and 75 percent of medical expenses.[93] A 2005 study estimates that poor management of chronic and complex conditions can lead to $350 billion in unnecessary health care costs annually.[94]

Specialty pharmacies have evolved in order to address the needs of some of the most complex and costly patient conditions within this category of chronic medication users. Some PBMs have integrated wholly-owned specialty pharmacies to complement their mail-order pharmacies to achieve many of the similar economies of scale and scope that are associated with

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James L. Seward, August 8, 2011, *available at*, http://www.ftc.gov/os/2011/08/110808healthcarecomment.pdf. The FTC also noted several potential economic benefits from integrating complementary functions such as PBM operations and mail order pharmacies within a single firm, including the elimination of "double markups" in the supply chain, savings in transactions costs and better alignment of incentives. (2005 FTC Study, p. xvi.)

[90] See, e.g., Fein 2010, Exhibit 37 at 53.

[91] Express Scripts Drug Trend Report 2010, p. 5. Similarly, USA Today recently reported that specialty drugs represent the fastest growing segment of employer health plan spending. (Julie Appleby, "Specialty drugs offer hope, but can carry big price tags," USA Today, August 22, 2011, *available at* http://www.usatoday.com/money/industries/health/drugs/story/2011/08/Specialty-drugs-offer-hope-but-can-carry-big-price-tags/50090368/1/)

[92] David Snow (2010), "The Case for Smarter Medicine: How Evidence-Based Protocols Can Revolutionize Healthcare," p. 9, *available at* http://medco.mediaroom.com/index.php?s=17884. *See also,* Centers for Disease Control and Prevention, Chronic Diseases and Health Promotion, *available at* http://www.cdc.gov/chronicdisease/overview/index.htm#ref2.

[93] David Snow (2010), "The Case for Smarter Medicine: How Evidence-Based Protocols Can Revolutionize Healthcare," pp. 9-10, *available at* http://medco.mediaroom.com/index.php?s=17884.

[94] David Snow, "Healthcare Reform: The Future is Now," May 14, 2010, p. 4, *available at* http://www.colorado.edu/mcdb/goldlab/Slide%20Decks/19.%20David%20Snow%20slides.pdf .

mail-order pharmacies, but focused specifically on dispensing specialty medications and managing patients with chronic conditions.

Express Scripts has extended its PBM benefit management tools to specialty drugs, which often fall under a patient's medical benefit rather than under the outpatient pharmacy benefit. Express Scripts estimates that 55 percent of specialty drug spend occurs under a patient's medical benefit.[95] Industry analysts have identified various advantages to plan sponsors from moving specialty drug spending to the pharmacy benefit, including "better contracting and purchasing of drug product and potentially improved patient outcomes from higher compliance as the PBM would work with the specialty drug manufacturer to negotiate rebates in exchange for formulary position, helping manage patient utilization and assurance of payment."[96]

Specialty pharmacies will likely achieve even greater cost savings with the evolution of "biosimilars" when innovator patents expire. There are 46 biotech products with patent expirations through 2020, totaling $42.3 billion in potential savings from biosimilars.[97] Biosimilars present a large opportunity for cost savings to patients and plan sponsors given the rising costs of branded specialty drugs. PBMs and their integrated specialty pharmacies will play a critical role in encouraging utilization of biosimilars, helping plans and patients realize significant savings.

5. Manage pharmacy network reimbursement

Another tool PBMs use to manage prescription drug benefits is pharmacy network cost management. PBMs contract with retail pharmacies and negotiate payment rates for covered drugs on behalf of a plan sponsor.[98] A GAO study that examined the pharmacy benefits for federal employees illustrates how successful PBMs have been in negotiating with retail pharmacies. The study found the average price PBMs negotiated for drugs from retail pharmacies was about 18 percent below the average cash price customers would pay at retail pharmacies for 14 selected brand-name drugs.[99] The price differential was even greater for

[95] Express Scripts Drug Trend Report 2010, p. 18.
[96] Citigroup, "Pharmacy Benefits Managers and Distributors," January 27, 2011, p. 29.
[97] U.S. Drug spend estimates are based on IMS Health data for 2009, manufacturer reported U.S. sales or a percent of manufacturer reported worldwide annual sales of the drug. Market availability of biosimilars based on expected patent expiration dates current as of November 2010 plus two years. Changes may occur due to litigation, patent challenges, or other factors.
[98] 2005 FTC Study, pp. 3-4.
[99] 2003 GAO Study, p. 9.

generic drugs, with PBMs negotiating costs 47 percent below the average cash price for four selected generic drugs.[100] As shown in Figure 1 above, Medco data confirm that Medco plan members continue to receive much larger discounts than cash-paying customers. For brand drugs purchased at chain pharmacies, these data show that on average, the prices paid by Medco plan members during the 2008 to September 2011 period were 20 percent less than the prices paid by cash paying customers as measured by the U&C price. For generic drugs, the average price for Medco plan members was 57 percent less than the price paid by cash paying customers.

Retail pharmacies are willing to offer these discounts to be included in a PBM's network because they will realize substantial incremental sales from plan members that are managed by the PBM, including both pharmacy sales and sales of other products carried in their stores. Pharmacies often compete by offering discounts depending on the size of the PBM's member base; pharmacies offer greater discounts to earn the business a plan or PBM may offer.[101] Since PBMs often manage benefits for many health plans covering a large number of plan members, individual health plans typically benefit from the additional bargaining power that a PBM can bring to the negotiation of pharmacy network reimbursement contracts.[102] Express Scripts also has estimated savings of up to $11 per member each year by incentivizing customers to use retail pharmacies that offer lower prices.[103]

6. Efficiencies from PBMs advanced technology platforms

As discussed above, many of the efficiencies provided by PBMs, are facilitated by their "wired" technology platforms that efficiently integrate prescription management at both mail order and retail and allow communication with pharmacists and physicians in real time for efficient evidence based clinical management. PBMs have made major contributions to industry efficiency and patient care by continually innovating their pharmaceutical care technology and information systems.

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[100] Ibid.
[101] 2005 FTC Study, p. 5 and United States Department of Health and Human Services Office of Inspector General, "Memorandum Report: Medicare Part D Pharmacy Discounts for 2008," OEI-02-10-00120, November 17, 2010, *available at* http://oig.hhs.gov/oei/reports/oei-02-10-00120.pdf.
[102] See, 2005 FTC Study, p. 5.
[103] Express Scripts Drug Trend Report 2010, p. 16.

7. Detect fraud and abuse

Prescription fraud and abuse – which can be perpetrated by individuals as well as pharmacies – affects all stakeholders, and translates into higher premiums and out-of-pocket costs for consumers.[104] Approximately one percent of prescription drug costs are estimated to result from fraud, waste, and abuse, resulting in hundreds of millions of dollars in unnecessary health care costs.[105] With nearly four billion prescription drug claims processed per year, detecting and preventing fraud and abuse is crucial to controlling overall health care spending.[106]

PBMs use real-time claims processing to try to identify fraud immediately. Additionally, PBMs operate advanced programs to monitor claims at the patient, pharmacy, and physician level to try to identify fraud and abuse after it has occurred. PBMs can identify individuals who fill multiple prescriptions at multiple pharmacies as likely fraud candidates or flag a pharmacy whose claims jump sharply in a given period of time.[107] PBMs also audit their contracted pharmacies to ensure they are not engaging in fraud and abuse.[108] Examples of pharmacy fraud include manipulating the coding and payment system to receive higher reimbursement, or overcharging payers for drugs dispensed.[109] These efforts will likely be even more effective with the combined data and technology of the merged firm.

Express Scripts and Medco employ many sophisticated tools to combat and prevent fraud, waste and abuse (FWA). Express Scripts' FWA program features the identification of potential problem pharmacies, members, and prescribers with unusual or excessive utilization patterns. Express Scripts estimates that implementing their FWA program has the potential to

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[104] 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, *available at* http://www.sas.com/resources/asset/health-insurance-third-party-white-paper-nhcaa.pdf.

[105] Pharmaceutical Care Management Association, "Fraud, Waste, and Abuse Detection in Retail Pharmacy: The Drugstore Lobby vs. Employers," July 2011, p. 1, *available at* http://pcmanet.org/images/stories/uploads/2011/July2011/PCMA_Fraud_Waste_and_Abuse_in_Retail_Pharmacy_July_2011.pdf.

[106] IMS Health Channel Distribution by Prescriptions, April 7, 2011, *available at* http://www.imshealth.com/deployedfiles/ims/Global/Content/Corporate/Press%20Room/Top-line%20Market%20Data/2010%20Top-line%20Market%20Data/2010_Distribution_Channel_by_RX.pdf.

[107] Statement for the Record of the Pharmaceutical Care Management Association Submitted to the United States House Of Representatives Committee On Ways And Means Subcommittee On Oversight, Hearing on Improving Efforts to Combat Health Care Fraud, March 2, 2011, p. 1, *available at* http://waysandmeans.house.gov/UploadedFiles/PCMASubmissionForTheRecord1.pdf.

[108] Ibid.

[109] Pharmaceutical Care Management Association, "Fraud, Waste, and Abuse Detection in Retail Pharmacy: The Drugstore Lobby vs. Employers," July 2011, p. 2, *available at* http://pcmanet.org/images/stories/uploads/2011/July2011/PCMA_Fraud_Waste_and_Abuse_in_Retail_Pharmacy_July_2011.pdf.

provide substantial cost savings to clients. A return on investment of approximately 3:1 ($0.88 PMPY) may be achieved through the FWA program's proactive analytics, data mining, and investigational services.[110] In 2010, Express Scripts' Network Audit program audited more than one million claims resulting in more than $58 million in overpayments identified and credited to clients.[111] Express Scripts has referred over 300 member, physician, and pharmacies to law enforcement in 2011.[112]

D. PBMs' clinical programs can improve health outcomes and lower overall health care costs

Medication is broadly recognized as a vital and effective tool for preventing and treating a broad array of health conditions -- prescriptions are the first line of defense for nearly 90 percent of illnesses.[113] However, research shows that there are widespread problems with how medications are used. One study estimates that 50 percent of all U.S. patients do not take their medications as prescribed and in other cases needed drugs are not prescribed.[114]

Patient non-adherence to prescribed medication therapy is estimated to cost up to $290 billion per year – which represents about 13 percent of all health expenditures.[115] A significant body of peer-reviewed literature shows that non-adherence takes a significant toll on health and leads to higher health care costs. For example, non-adherence to prescribed medications accounts for nearly 20 percent of all hospitalizations and almost 125,000 deaths each year.[116] Research also indicates that patients who adhere to their medication regimens have better health outcomes and use fewer health care services – including urgent care and inpatient services – compared to patients who are non-adherent. Notably, researchers state that while improving medication adherence results in higher prescription drug costs, these costs are often more than offset by

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[110] Data provided by Express Scripts.
[111] Ibid.
[112] Ibid.
[113] David Snow (2010), "The Case for Smarter Medicine: How Evidence-Based Protocols Can Revolutionize Healthcare," p. 10, *available at* http://medco.mediaroom.com/index.php?s=17884.
[114] World Health Organization, "Adherence to Long-Term Therapies: Evidence for Action," 2003, pp. 7, 156, *available at* http://www.who.int/chp/knowledge/publications/adherence_full_report.pdf.
[115] New England Health Care Institute, "Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease," August 12, 2009, p. 1, *available at* http://www.nehi.net/publications/44/thinking_outside_the_pillbox_a_systemwide_approach_to_improving_patient_medication_adherence_for_chronic_disease.
[116] Mediaplanet, "Medication Non-Adherence," March 2011, p. 10, *available at* http://www.cardinal.com/mps/wcm/connect/0ba69c00464d3b23b998fb690e45094f/Washington+Post+Special+Section+(March+2011).pdf?MOD=AJPERES&CACHEID=0ba69c00464d3b23b998fb690e45094f.

savings in other types of medical spending.[117] One study found lower disease-related medical costs associated with higher medication adherence for patients with diabetes and hypercholesterolemia; the authors found that every dollar spent on diabetes medication saves $7 in medical costs (see Figure 4).[118] Similarly, a 2011 *Health Affairs* study documented substantial cost savings from improved medication adherence for individuals with chronic vascular disease through reduced inpatient hospital days and emergency department visits.[119] Drug spending accounts for approximately 10 percent of total health care spending nationwide while hospital and physician services together account for roughly 50 percent of expenditures.[120] By addressing the 10 percent of spending through better adherence, less waste, and greater use of lower cost treatments, PBMs can also help reduce the 50 percent of national spending to yield an amplified savings effect.

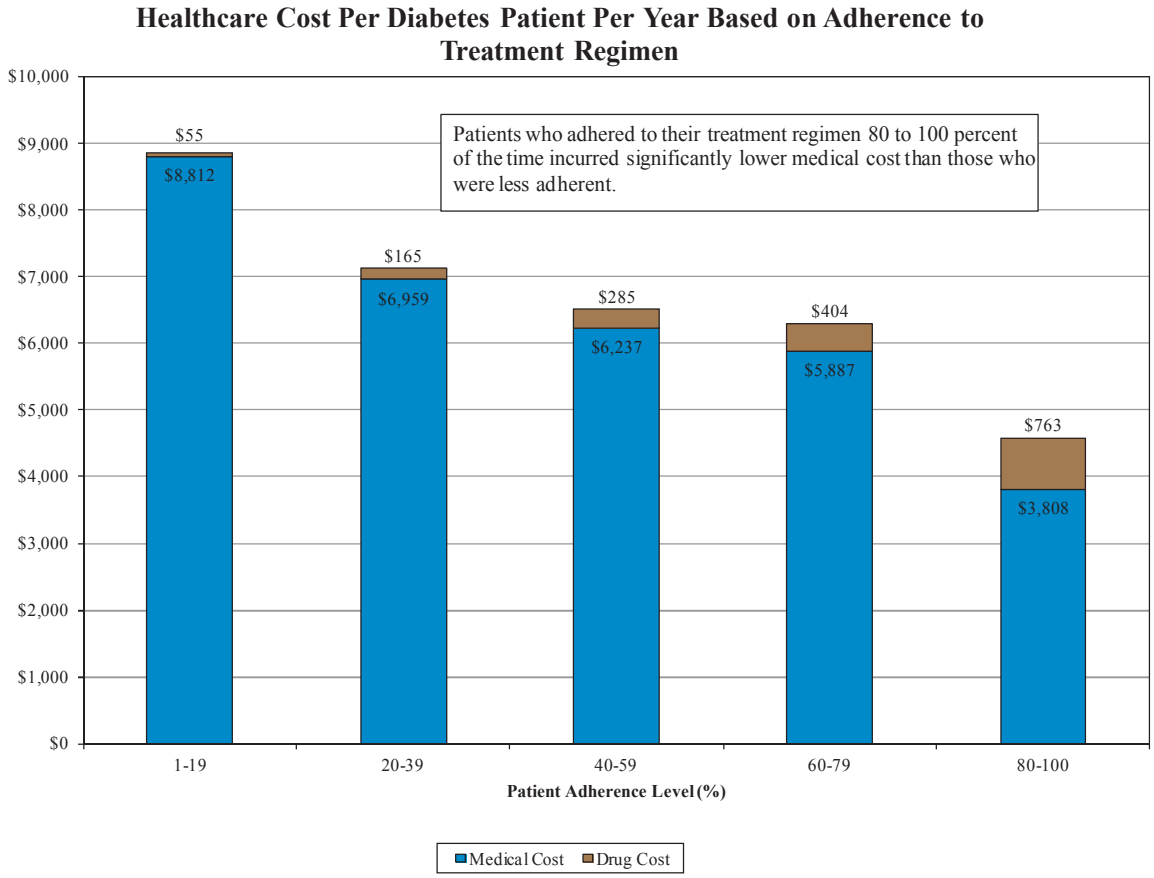
[117] One study found lower disease-related medical costs associated with higher medication adherence for patients with diabetes and hypercholesterolemia. (Michael C. Sokol, Kimberly A. McGuigan, et al. (2005), "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost," *Medical Care*, 43(6), 521.) Similarly, a 2011 *Health Affairs* study documented substantial cost savings from improved medication adherence for individuals with chronic vascular disease through reduced inpatient hospital days and emergency department visits. (M. Christopher Roebuck, Joshua N. Liberman, et al. (2011), "Medication Adherence Leads To Lower Health Care Use And Costs Despite Increased Drug Spending," *Health Affairs*, 30(1), 91*, available at* http://content.healthaffairs.org/content/30/1/91.full.pdf+html.) Another study found that patients with chronic myeloid leukemia (CML) who adhered to their medication more than 85 percent of the time have fewer hospitalizations than non-adherent patients, and the costs of the hospitalizations are lower, too: $3,758 vs. $44,498. (Eric Q, Wu, Nicolas Beaulieu, et al. (2010), "Healthcare Resource utilization and Costs Associated with Non-Adherence to Imatinib Treatment in Chronic Myeloid Leukemia Patients," *Current Medical Research & Opinion,* 26(1), 61, 63-64.)

[118] Source: Michael C. Sokol, Kimberly A. McGuigan, et al. (2005), "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost," *Medical Care*, 43(6), 521, Table 2 at 525 and Figure 1 at 526 *available at* http://www.americanhealthstrategy.com/pdfs/Resources/Evidence%20Based%20Literature/Impact%20of%20Medication%20Adherence%20on%20Hospitalization%20Risk%20and%20Healthcare%20Costs.pdf.

[119] M. Christopher Roebuck, Joshua N. Liberman, et al. (2011), "Medication Adherence Leads To Lower Health Care Use And Costs Despite Increased Drug Spending," *Health Affairs*, 30(1), 91*, available at* http://content.healthaffairs.org/content/30/1/91.full.pdf+html.

[120] Centers for Medicare & Medicaid Services (2011), National Health Expenditure Projections 2010-2020, *available at* https://www.cms.gov/NationalHealthExpendData/downloads/proj2010.pdf.

Figure 4



PBMs improve patient health outcomes using programs that help optimize the selection of appropriate drugs, avoid prescribing errors, and help ensure that patients adhere to their prescribed therapy. Medco and Express Scripts both have developed proprietary evidence based clinical programs to promote safe, effective, and appropriate use of specialty and non-specialty drugs. For example, Medco has devoted substantial resources to employ specialist pharmacists with extensive training in the medications used to treat particular chronic and complex conditions. Express Scripts' Consumerology initiative applies advanced behavioral science to identify and change common behaviors that prevent patients from adhering to their prescription medications.

Medco's Therapeutic Resource Centers (TRCs)

Medco Therapeutic Resource Centers operate based on the theory that specialization leads to better pharmacy care for members with chronic and complex conditions. Medco

specialist pharmacists receive additional specialized training in the chronic conditions that are generally associated with significant medical costs and resulting gaps in care, such as diabetes, heart disease, asthma and cancer. The pharmacists that focus on a particular disease category practice together in TRCs dedicated to that disease category to facilitate research and sharing of knowledge and expertise among pharmacy staff in a particular specialty. Most of Medco's TRC pharmacists now have up to five years of working experience in their specialty.

Medco TRCs deploy 1,100 specially trained pharmacists who provide treatment support to improve patient outcomes in high-cost clinical areas, including diabetes, cardiology, neurology/psychiatry, pulmonary conditions, and oncology. Specialist pharmacists within the TRCs can reach out to a patient to provide support and counseling, clarify any confusion regarding treatment regimen, and assess and address any barriers that may be impeding access to care. The model is designed to address medication safety and gaps in care, specifically:

1. Omissions of essential therapy (e.g. patient with diabetes not on cholesterol lowering medications);
2. Adherence with essential therapy (e.g. patient with diabetes not taking oral hypoglycemic medications); and
3. Omissions of essential laboratory testing (e.g. patient with diabetes not getting a routine blood test to gauge how well patients are managing the disease).

1. Promoting appropriate medication use and improving medication adherence

PBMs promote appropriate medication use and improve medication adherence through a variety of approaches. Medco used its TRCs to close more than 2.3 million clinical gaps in care[121] in 2010 *alone* with a projected savings of approximately $900 million.[122] Patients under the care of Medco TRCs consistently have higher compliance rates with evidence-based quality-of-care metrics than patients receiving traditional pharmacy care. For example, Medco estimates that its TRC interventions lowered the health care costs of patients with hypertension by $700

[121] Gaps in care include non-adherence to prescribed therapy and omissions (when a clinically appropriate therapy is not prescribed or initiated).
[122] Medco 2010 Annual Report, p. 2.

per patient annually compared to traditional pharmacy.[123] Medco found similar effects for patients that used its cardiovascular TRC.[124]

Similarly, Medco's analysis indicates that TRCs have made significant improvements in care for patients with diabetes, which is generally accepted as one of the most pervasive, preventable, and treatable chronic conditions nationwide. A recent Medco analysis of 600,000 patients showed that TRCs closed 81 percent of gaps in care related to patients with diabetes not adhering to diuretic medications.[125] The same analysis demonstrated that TRCs closed 74 percent of gaps in care related to patients with high cholesterol not adhering to statin medications.[126]

Similarly, Express Scripts found significant improvements in adherence over a control group in a trial of over 4,500 members taking maintenance medications for diabetes, high blood pressure/heart disease and high cholesterol.[127] To improve adherence, Express Scripts has predictive models for chronic conditions to identify specific patterns and characteristics that indicate, in advance, whether an individual member is at increased risk for non-adherence.[128] This helps the company create proactive programs to increase adherence among patients identified as not likely to take their drugs as prescribed.[129] Such tools include an automated

[123] Medco TRC Update, 2009, p. 2.
[124] Kenneth Klepper (2010), "Perspectives: Closing Gaps in Care with Advanced Pharmacy," p. 15 *available at* http://medco.mediaroom.com/index.php?s=17884.
[125] "New Data: Advanced Pharmacy Model Significantly Reduces Gaps in Care for Patients with Chronic and Complex Conditions; Improves Clinical and Financial Outcomes," Medco Health Solutions Press Release, November 21, 2008, *available at* http://medco.mediaroom.com/index.php?s=17872&item=28015.
[126] Ibid.
[127] Express Scripts Drug Trend Report 2010, p. 17.
[128] For example, Express Scripts Vice President of Research Sharon Frazee stated: "The things we learn from the predictive models allow us to design better programs that help all of our patients and clients that pay for our services. You have to continually look for insights that can lead to better solutions that benefit everyone. … Combined with the organization's advanced understanding of human behavior, the results are adherence scores that are far more accurate, informative and actionable than previously possible.'" ("Prescribing a Healthier Life," *available at* http://www.sas.com/success/expressscripts.html.) *See also,* Express Scripts Drug Trend Report 2010, p. 15.
[129] For example, Express Scripts chief scientist Bob Nease recently reported their studies have identified four types of patients whom do not adhere to their prescriptions. "'The first is people who simply forget to take their medications every day. The second is a different kind of issue, which is procrastinating on getting a renewal. … There's a much smaller fraction of patients who have issues with costs and they benefit from moving to a lower-cost drug or a lower-cost delivery channel or pharmacy. In the fourth case, there are patients who have real clinical issues: they think the drug is not working, they think it has side effects, or they're feeling medicalized.' Nease said once the cause is identified for non-adherence to therapy, solutions can be presented. 'So for people with who have a hard time remembering to take their medications, we give them reminders. … We help people get renewals if they need it. For people who are having issues with costs, we help them find a lower-cost option. And then for patients who have side effects or think the drug is not working, we can connect them with one of our pharmacists.'" (Jim

voice messaging system to remind patients at risk of non-compliance to refill their prescriptions, and a pilot program called "GlowCaps" which remind patients to take their medication daily with blinking or beeping caps, which can also report patient use data back to Express Scripts.[130] Express Scripts also has a home delivery program that allows members the choice of using Express Scripts' mail-order pharmacy or a retail pharmacy. According to Express Scripts, adherence is up to eight percent higher for patients in this program[131] and savings are estimated at $27 per member per year.[132]

Other studies have found similar conclusions.[133] For example, a study of three drug classes – antidiabetics, antihyperlipidemics, and antihypertensives – found that compliance for taking medication prescribed by a doctor was 7 to 8 percent higher for people using mail order.[134]

Retail Pharmacy-Based Approaches

PBMs are also piloting programs that help retail pharmacists improve adherence among their customers. For example, Medco's assessment of a 26-week program with community pharmacies throughout Illinois showed improved adherence. The initiative used a clinical database which identified 2,400 patient adherence gaps and the patients' local pharmacists were then sent "gap in care" alerts.[135] Community pharmacists received training to improve patient counseling and use of these techniques improved adherence for 74 percent of the discovered gaps.[136] By applying these techniques, community pharmacists filled 48 percent more prescriptions and closed 27 percent more adherence gaps than a control group of pharmacies.[137]

Doyle, "Why won't up to half of patients take their medicine?" St. Louis Post-Dispatch, September 2, 2011, *available at* http://www.stltoday.com/business/local/article_d0eaccb6-2a51-500f-b878-980ae4813963.html.)

[130] Citigroup, "Pharmacy Benefits Managers and Distributors," January 27, 2011, p. 30.

[131] Express Scripts 2009 Annual Report, p. 7.

[132] Express Scripts Drug Trend Report 2010, p. 16.

[133] See, e.g., Julie A. Schmittdiel, Andrew J. Karter, et al. (2011), "The Comparative Effectiveness of Mail Order Pharmacy Use vs. Local Pharmacy Use on LDL-C Control in New Statin Users," *Journal of General Internal Medicine,* 1(26), 1; O. Kenrik Duru, Julie A. Schmittdiel, et al. (2010), "Mail-Order Pharmacy Use and Adherence to Diabetes-Related Medications," *American Journal of Managed Care*, 16(1), 33, 33, 37; J. Tang and R. Faris (2008), "Exploring the Impact of Different Dispensing Systems on Medication Compliance and Persistence in Multiple Sclerosis Patients using Pharmacy Claims Data," *Journal of the International Society for Pharmacoeconomics*, 11(3), A144.

[134] O. Kenrik Duru, Julie A. Schmittdiel, et al. (2010), "Mail-Order Pharmacy Use and Adherence to Diabetes-Related Medications," *American Journal of Managed Care*, 16(1), 33, 33, 37.

[135] Medco Health Solutions Illinois Pilot Project.

[136] Ibid.

[137] Ibid.

The initiative's success in Illinois has prompted Medco to expand the program to New Mexico and Florida.

2. Improving adherence and health outcomes from specialty pharmacy management

As mentioned earlier, some PBMs, have integrated specialty pharmacy services as a component of overall PBM services in order to provide clinical and cost management for patients taking specialty drugs. Specialty pharmacy medications have unique characteristics; they often require that the pharmacist engage in significantly more patient and physician interaction, in addition to other services that are specific to the product being dispensed, such as intravenous administration, unique packaging, and courier service delivery due to temperature requirements of the drug compound. Through the integration of specialty pharmacy as a component of PBM services, with the added benefit of targeted clinical management of complex chronic diseases, patients enjoy a higher level of care, which results in positive patient outcomes. For example, Medco combines its TRCs with its Accredo Health Group specialty pharmacy unit to offer teams of specialized pharmacists, registered nurses, and patient service representatives that dispense and monitor specialty drugs to patients and provide additional educational services, such as how to self-administer specialty medications and how to cope with side effects.[138]

Such efforts allow PBMs to provide an integrated package of services to patients and plan sponsors, leading to improvements in care. For example, many patients with chronic and complex diseases take a number of different medications for both their primary condition and other conditions they may have. In a traditional non-integrated setting, some of these medications might be filled by a retail pharmacy, some by the PBMs mail order pharmacy, and some by an independent specialty pharmacy. However, none of these pharmacists may have the complete picture on all the medications the patient is taking and whether the patient is adhering to their therapy regimen.

In contrast, the integration of pharmacy benefits under the PBM umbrella implies that all patient data is combined and pharmacy care can be coordinated by PBMs to screen for adverse drug interactions, review patient dosing and adherence with all medications, provide coordinated

[138] Medco Health Solutions 2010 10-K, pp. 8-9.

counseling on ways to improve care or adherence or avoid side effects, contact and counsel physicians on these issues, and so on.

Research shows that distribution of medication through specialty pharmacies with focused clinical management often produces better outcomes when compared with retail pharmacy. Studies indicate that specialty pharmacies improve adherence, thereby reducing utilization of costly health care services. For example, a retrospective analysis examined pharmacy and medical claims for rheumatoid arthritis (RA) patients and compared health care costs and outcomes for specialty and retail pharmacy customers.[139] The study found that patients who filled RA medications through a specialty pharmacy had:

- 16 percent higher adherence rate
- $1,534 lower annual medical costs, other than prescription drugs
  - 5.9 percent fewer patients had an office visit
  - 2.3 percent fewer patients had an ER visit
  - 1.3 percent fewer patients were hospitalized

3. Reducing inappropriate medication use and medication errors with drug utilization review and mail order

One of the ways PBMs promote safe and effective use of medications by patients is by sharing drug utilization information across the retail, mail order, and specialty drug dispensing platforms. The sharing of a patient's drug utilization history with pharmacists at the point of care through a PBM's IT infrastructure, irrespective of the dispensing environment, plays a key role in the avoidance of potential drug/drug interactions and inappropriate use of medications. Utilizing this IT infrastructure overcomes the limitations of having only a single pharmacy's drug information for the patient or relying on a patient or caregiver's recall of a current prescription regimen to check against for potential medication issues.

PBMs' drug utilization review (DUR) programs identify adverse drug interactions and suggest effective therapies. DUR can take many forms, including reviews related to drug-age, drug-gender, drug-allergy, drug-gene, as well as drug-drug. DUR programs examined by a peer-

[139] Jane Barlow, et al., "Impact of Specialty Pharmacy Management on Medication Compliance, Medical Utilization, and Costs for Patients with Rheumatoid Arthritis" presentation at the American College of Rheumatology's 73rd Annual Meeting, October 16, 2009.

reviewed study found these tools achieved an average savings of 6.9 percent on total drug spend.[140]

Mail order pharmacies automate the entire process of dispensing prescription drugs, resulting in fewer dispensing errors that may put patients at risk. One study in the *Journal of the American College of Clinical Pharmacy* found that highly automated mail service pharmacies dispensed prescriptions with 23-fold greater accuracy than retail pharmacies.[141] The mail service error rate was zero in several of the most critical areas, including dispensing the correct drug, dosage, and dosage form.

4. More effective medication use from pharmacogenomics research

Thanks to scientific and technological breakthroughs, pharmacogenomics is widely recognized to hold promise for identifying optimal medications and doses based on individuals' genetic information. For example, the American Medical Association has stated that pharmacogenomics has the potential to lead to tailored drug therapy allowing for more powerful medications, less adverse side effects, and more accurate doses dependent on the patient.[142] In 2010, the National Institutes of Health announced plans to spend $161.3 million over five years to expand its Pharmacogenomics Research Network.[143]

Some industry analysts project that PBMs will play a pivotal role in applying genetics to health care benefits management. Some PBMs such as Medco have been investing heavily to increase their capabilities and expertise in these areas.[144] Medco has invested substantial resources in recent years to facilitate the use of pharmacogenomic tools through close integration of pharmacogenomic testing into pharmacy benefit management. Medco's personalized medicine programs identify plan members who may benefit from such genetic testing, provide comprehensive information resources to the physician and the member to evaluate the potential

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[140] William J. Moore, (2000), "System wide Effects of Medicaid Retrospective Drug Utilization Review Programs," *Journal of Health Politics, Policy and Law* 25(4): 653, as cited in Jack Hoadley, "Cost Containment Strategies For Prescription Drugs: Assessing The Evidence In The Literature," Kaiser Family Foundation, March 2005, *available at* http://www.kff.org/rxdrugs/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=51885.

[141] J. Russell Teagarden, Becky Nagle, et al. (2005), "Dispensing Error Rate in a Highly Automated Mail-Service Pharmacy Practice," *Journal of the American College of Clinical Pharmacy*, 25(11), 1629, 1633.

[142] American Medical Association, "Pharmacogenomics," *available at* http://www.ama-assn.org/ama/pub/physician-resources/medical-science/genetics-molecular-medicine/current-topics/pharmacogenomics.page.

[143] "NIH Expands Network Focused on How Genes Affect Drug Responses," National Institutes of Health, September 7, 2011, *available at* http://www.nigms.nih.gov/News/Results/pgrnIII_20100709.htm.

[144] See, e.g., Deutsche Bank, "Rx Benefit Manger Survey Straight from the Minds of Key PBM Decision Makers," June 30, 2010, pp. 5, 26-27.

benefits of testing, and coordinate the testing, laboratory analysis, and feedback of testing results to the member's physician.[145] Medco's specialist pharmacists and genetic counselors with advanced training and experience are available to assist physicians and patients with interpreting test results and considering therapy changes.[146] The identification of promising member candidates for these programs is facilitated by the analyses of PBM databases of pharmacy and medical claims which permit insights into medications prescribed, other drugs that patients may be taking, any genetic testing results, and the overall health status of patients.[147]

Medco research shows that this type of close integration of pharmacogenomic testing into pharmacy benefit management can be an important step in facilitating wider use of pharmacogenomic research. For example, Medco conducted a survey of over 10,000 physicians with the American Medical Association (AMA) regarding attitudes toward gene testing. They found that although 98 percent of respondents believed genetics affect drug response, only 10 percent considered themselves informed enough about pharmacogenomic testing to use it with their patients.[148] Further, the 10 percent of doctors who believed they were well informed were twice as likely to order the genetic tests for their patients as doctors who were merely aware of pharmacogenomics.[149] Accordingly, Medco concluded that clinician education initiatives would be key to encouraging the wider adoption of pharmacogenomic tools.

Some PBMs also are taking the lead in determining how the use of pharmacogenomic testing will benefit patients in selecting the most appropriate drug treatment. For instance, a study conducted by Medco Research Institute and the Mayo Clinic found a simple genetic test reduces the rate of hospitalization for patients on the widely prescribed blood thinner, warfarin,

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[145] Medco Health Solutions, "Our Programs," *available at* http://www.medcohealth.com/medco/corporate/home.jsp?ltSess=y&articleID=CorpPM_PersonalizedMedicine.

[146] Ibid.

[147] Jane Barlow, "Gene Testing Stakes a Claim in the Health Benefits marketplace," *Formulary*, July 15, 2011, ("Barlow"), p. 3, *available at* http://formularyjournal.modernmedicine.com/formulary/Pharmacoeconomics/Gene-testing-stakes-a-claim-in-the-health-benefits/ArticleStandard/Article/detail/679086.

[148] Ibid. Similarly, cardiologist Eric Topol, Director of Scripps Translational Science Institute in La Jolla, has described the important role played by PBMs in advancing pharmacogenomics: "While physicians and the life science industry have done little to advance the use of testing for drug-gene interactions, now the pharmacy benefit managers (PBMs) Medco and CVS/Caremark, which collectively administer the employer prescription plans for nearly 100 million Americans, are stepping up. They are introducing wide-scale genotyping for certain drugs, like Plavix or Tamoxifen, and many anti-cancer medications. … It has caught the medical community by surprise, but may be just the thing that is needed to bring the marked progress in genomics forward for patients." (Adam J. Fein, "PBMs, Not Physicians, Stepping Up for Genomics," Drug Channels, August 24, 2010, *available at* http://www.drugchannels.net/2010/08/pbms-not-physicians-stepping-up-for.html.)

[149] Barlow, pp. 3-4.

by nearly one-third.[150] Similarly, Medco discovered patients who use Plavix, another widely prescribed blood thinner, in combination with heartburn medications increase their risk of heart attack by 74 percent. This allowed the company to place safety warnings in its system to alert pharmacists to potential danger even before the FDA issued an advisory.[151] For Medco pharmacy patients, this discovery resulted in a 28 percent reduction in the use of this combination of drugs.[152] Another study conducted by the Medco Research Institute found the breast cancer drug tamoxifen is ineffective in women who have certain genetic variations that affect how the drug is metabolized.[153]

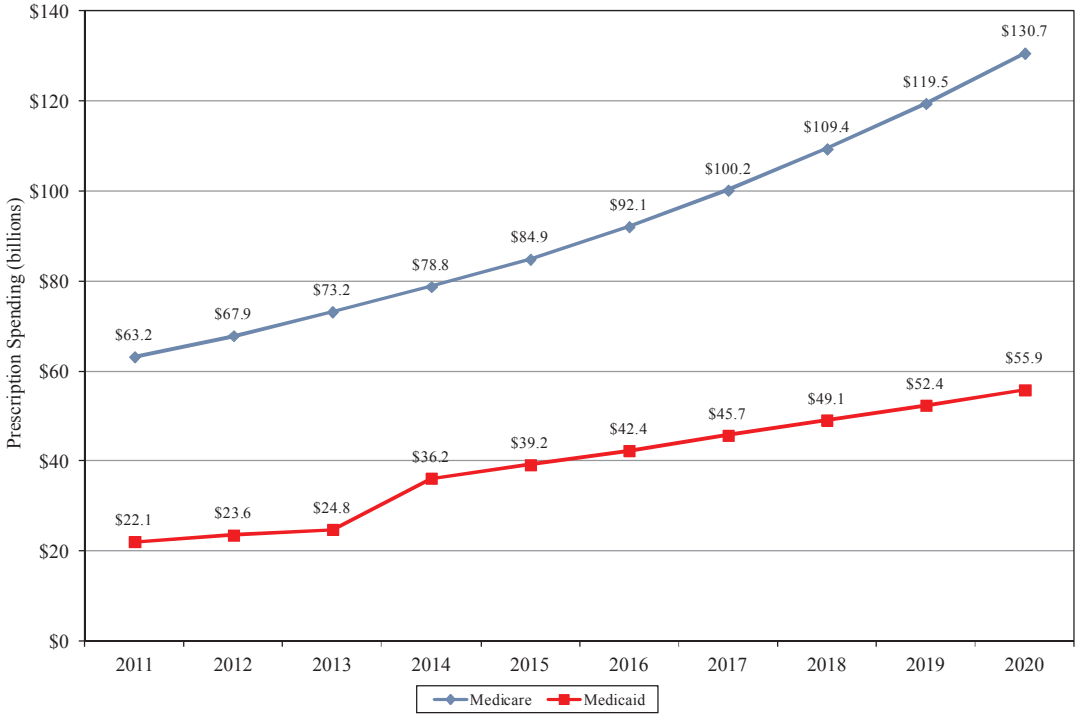
E. Benefits from PBMs in Medicare

A large portion of prescription drug spending – more than one-third – is through government programs, such as Medicare and Medicaid.[154] Spending on these programs is rising rapidly. The Centers for Medicare & Medicaid Services (CMS) projects that federal prescription drug spending will climb 7.2 percent per year from 2015 through 2020 (Figure 5) due to a variety of factors including the expansion of public health coverage under the Affordable Care Act and the continued aging of the U.S. population.[155] In light of this dramatic growth in prescription drug spending, and the intense budgetary pressures at both state and federal levels, the use of effective tools to ensure that these dollars are spent efficiently is critical.

[150] Medco 2010 Annual Report, p. 5.
[151] "New study: A Common Class of GI Medications Reduce Protection Against Heart Attack in Patients Taking Widely Prescribed Cardiovascular Drug," Medco Health Solutions Press Release, November 11, 2008, *available at* http://medco.mediaroom.com/index.php?s=17872&item=28012.
[152] Based on a Medco analysis of Medco data.
[153] Ronald E. Aubert, Eric J. Stanket, et al., "Risk of Breast Cancer Recurrence in Women Initiating Tamoxifen with CYP2D6 Inhibitors," presented at 2009 American Society of Clinical Oncology (ASCO) Annual Meeting, May 30, 2009, *available at* https://www.medcoresearchinstitute.com/community/oncology/tamoxifen.
[154] Kaiser Family Foundation, "Prescription Drug Trends," May 2010, p. 2, *available at* http://www.kff.org/rxdrugs/upload/3057-08.pdf.
[155] Sources: Centers for Medicare & Medicaid Services (2011), National Health Expenditure Projections 2010-2020, *available at* https://www.cms.gov/NationalHealthExpendData/downloads/proj2010.pdf and Sean P. Keehan, Andrea M. Sisko, et al. (2011), "National Health Spending Projections Through 2020: Economic Recovery and Reform Drive Faster Spending Growth," *Health Affairs*, 30(8), 1596, 1600, a*vailable at* http://content.healthaffairs.org/content/early/2011/07/27/hlthaff.2011.0662.full.pdf+html.

Figure 5

CMS Projected Prescription Drug Expenditures in Medicare and Medicaid 2011 - 2020



Last year, 34.5 million people, out of Medicare's 47.5 million total beneficiaries, chose to participate in Medicare Part D drug plans.[156] At the core of the Medicare Part D program is the notion that health plans and PBMs will compete against one another, innovating new ways to control costs, and lowering costs for both Medicare beneficiaries and the federal treasury. From the inception of planning for Part D, Congress chose to have private sector health plans and PBMs administer the program. The goal was to leverage PBMs' established skills and tools, purchasing arrangements with pharmaceutical manufacturers and vast pharmacy networks, rather than to reinvent these assets.

In 2009, Part D program spending reached $52.5 billion, which included monthly subsidies to plans, reinsurance for high-cost enrollees, premiums and cost sharing for LIS enrollees, and payments to employers that continue to provide drug coverage to retirees who are

[156] 2011 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, May 13, 2011, p. 4 and Table IV.B8 at 181, *available at* https://www.cms.gov/reportstrustfunds/downloads/tr2011.pdf.

Medicare beneficiaries.[157] Although Part D expenditures are increasing, data show that program spending growth is slower than anticipated. CMS data indicates the average Medicare Part D prescription drug plan premium in 2012 will drop from the original 2003 estimate of $41 to a far lower average of $30.[158] PBMs play a significant role in containing costs of the Part D program using the programs and tools described above.

According to PricewaterhouseCoopers, PBMs are on track to save Medicare and its beneficiaries $469 billion from 2006-2015 relative to unmanaged drug expenditures (Table 3).[159]

Table 3

Savings Resulting from Medicare PDPs Using PBM Tools as Esimated by PriceWaterhouseCoopers

	2006	2007	2008	2009	2010	2006-2015
Unmanaged* Drug Expenditures by Part D Enrollees	$105.0	$114.3	$124.8	$136.4	$149.4	$1,642.0
Total Drug Expenditures by Medicare Part D Enrollees**	$75.0	$81.7	$89.1	$97.4	$106.7	$1,173.0
Total Savings Achieved by Medicare Part D Plans	$30.0	$32.7	$35.6	$39.0	$42.7	$469.0

Notes: *Unmanaged drug expenditures are equivalent to retail pharmacy purchases with no pharmacy benefit management support.
**Total drug expenditures on Part D include both the government share and the share paid by Medicare beneficiaries in the form of premiums, copayments/coinsurance and other out-of-pocket costs. Part D enrollees include individuals covered by PDPs or MA-PDPs.

One of the primary reasons Part D program costs have been lower than expected year after year is greater than anticipated generic drug use.[160] The CBO concluded that the use of generic medications in Medicare Part D saved beneficiaries and the program about $33 billion in 2007, while an additional $14 billion in savings was expected as first-time generics enter the

[157] Medicare Payment Advisory Commission, "Report to Congress: Medicare Payment Policy," March 2011, Chapter 13, p. 318, *available at* http://medpac.gov/chapters/Mar11_Ch13.pdf.
[158] "PCMA: Part D Plans and PBMs Continue to Deliver Savings in Medicare," PCMA News Release, August 4, 2011, *available at* http://pcmanet.org/pcma-part-d-plans-and-pbms-continue-to-deliver-savings-in-medicare.
[159] PriceWaterhouseCoopers, "Medicare Part D: An Assessment of Plan Performance and Potential Savings," January 2007 ("PWC 2007"), Exhibit 3, *available at* http://pcmanet.org/images/stories/uploads/2007/01/2008-03-25_Research_PwC20Medicare20Savings20and20Generics20Report20200620Jan202007.pdf. (A report prepared for the Pharmaceutical Care Management Association.)
[160] Department of Health and Human Services Office of Inspector General, "Generic Drug Utilization in the Medicare Part D Program," November 2007, p. i, *available at* http://oig.hhs.gov/oei/reports/oei-05-07-00130.pdf.

market through 2012.[161] For each percentage point increase in overall generic utilization, Part D drug spending falls by an estimated $12 billion over the 2007 to 2015 period. If PDPs were able to increase their generic dispensing rate by five percentage points, savings could increase by $58 billion over the 2007 to 2015 period.[162]

In addition to the PBM tools discussed above, PBMs' ability to negotiate contracts that increase consumer usage of generics also is an important driver of increased generic utilization in Part D. An OIG study of six selected Part D sponsors and their PBMs found that PBMs negotiate pharmacy contracts that encourage generic utilization and other cost saving measures. Specifically, the OIG study found that:[163]

- Certain PBM-pharmacy contracts allow additional payments to the pharmacy if it achieved certain levels of generic drug use among Part D beneficiaries
- Several sponsor-PBM contracts include benchmarks ("generic effective rates") requiring PBMs to provide a minimum average discount for generics among its network pharmacies
- PBM-pharmacy contracts often contain clauses paying pharmacies the lesser of a cash price or the negotiated Average Wholesale Prices (AWP) discount-based reimbursement

In addition to encouraging patients to use generics, PBMs in Part D can encourage therapeutic substitution, in which higher-cost drugs are substituted in favor of lower-cost, generic equivalents. CBO estimates that if single-source brand-name prescriptions in seven classes in Part D had been switched to generic drugs from the same class, prescription drug costs would have been reduced by $4 billion in 2007, or seven percent of total payments to plans and pharmacies in that year.[164]

As with commercial plans, another source of PBM savings in Part D is through the use of mail-order pharmacies. A study published in the *Journal of Medical Economics* found that Part D beneficiaries who received their diabetes medications through a mail-service pharmacy achieved greater adherence than those using retail pharmacies – 49.7 percent vs. 42.8 percent,

[161] Congressional Budget Office, "Effects of Using Generic Drugs on Medicare's Prescription Drug Spending," September 2010, p. ix, *available at* http://www.cbo.gov/ftpdocs/118xx/doc11838/09-15-PrescriptionDrugs.pdf.
[162] PWC 2007, p. i.
[163] United States Department of Health and Human Services Office of Inspector General, "Memorandum Report: Medicare Part D Pharmacy Discounts for 2008," OEI-02-10-00120, November 17, 2010, pp. 5-6, *available at* http://oig.hhs.gov/oei/reports/oei-02-10-00120.pdf
[164] Congressional Budget Office, "Effects of Using Generic Drugs on Medicare's Prescription Drug Spending," September 2010, p. viii, *available at* http://www.cbo.gov/ftpdocs/118xx/doc11838/09-15-PrescriptionDrugs.pdf.

respectively.[165] Medication adherence in Medicare Part D presents a challenge to ensuring positive patient outcomes, as described earlier. Specific to Medicare, improving adherence to medications has been shown to offset spending in other areas of Medicare, specifically Part A and B costs, based on recently published peer-reviewed research.[166] One study concluded that implementation of Part D was followed by "significant reductions" in non-drug medical spending, particularly on acute- and post-acute care for elderly Medicare beneficiaries with limited prior drug coverage.[167]

F. PBM cost savings and clinical benefits enhance consumer welfare, employment, competiveness and economic growth

From an economic perspective, health insurance is a cost of hiring workers, just as wages and salaries are. At roughly 12 percent of payroll, health care typically is one of the most costly benefit expenses for employers.[168] Accordingly, reducing the growth of health costs increases the quantity of labor demanded by employers at given levels of wages and benefits. On the supply side of the labor market, most workers are willing to accept somewhat lower wages and salaries to receive attractive health care benefits. Accordingly, when health care cost growth is reduced, the benefits to workers typically reflect a combination of more and better benefits, increased wages and increased employment.

There has been a significant amount of economic research on the effects of high and rising health care costs on economic performance. Many employers cite the high cost of providing health care as a significant impediment to providing comprehensive benefits to their

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[165] Lihua Zhang, Armen Zakharyan, et al. (2011), "Mail-Order Pharmacy Use and Medication Adherence among Medicare Part D Beneficiaries with Diabetes," *Journal of Medical Economics*, 14(5), 562.

[166] Bruce Stuart, Amy Davidoff, et al. (2011), "Does Medication Adherence Lower Medicare Spending among Beneficiaries with Diabetes?" *Health Services Research*, 46(4), 1180.

[167] J. Michael McWilliams, Alan Zaslavsky, et al. (2011), "Implementation of Medicare Part D and Nondrug Medical Spending for Elderly Adults with Limited Prior Drug Coverage," *Journal of the American Medical Association*, 306(4), 402, 407-8.

[168] Toni Johnson, "Healthcare Cost and U.S. Competitiveness," Council on Foreign Relations, March 23, 2010, *available at*: http://www.cfr.org/health-science-and-technology/healthcare-costs-us-competitiveness/p13325; "Employer Health Insurance Costs and Worker Compensation," The Henry J. Kaiser Family Foundation Snapshots: Health Care Costs, February 2011, *available at* http://www.kff.org/insurance/snapshot/Employer-Health-Insurance-Costs-and-Worker-Compensation.cfm; and David Cutler and Neeraj Sood, "New Jobs Through Better Health Care," Center for American Progress, January 2010, *available at* http://www.americanprogress.org/issues/2010/01/new_jobs_health.html.

employees and even to increased hiring.[169] Recent studies have also concluded that reducing the cost of quality patient care will make American businesses more competitive – creating a healthier, more productive workforce, preserving existing jobs, and creating new jobs in the future.[170] In June 2009, President Obama's Council of Economic Advisers released a large scale economic study of the benefits to the economy of health care reform that slows the rate of growth of health care costs. They estimated that slowing the annual growth rate of health care costs by 1.5 percentage points would produce economic benefits of the following types:[171]

- Increase real gross domestic product (GDP) by more than two percent in 2020 and nearly eight percent in 2030;
- Increase household income for a family of four by $2,600 by 2020 (in 2009 dollars), and $10,000 by 2030;
- Raising employment by approximately 500,000 workers each year; and
- Dramatically improve future federal budget deficits because the federal government pays for a large and increasing fraction of health care.

The cost savings and other benefits produced by PBMs would be expected to produce similar categories of economic benefits. In many cases, such cost savings show up in the form of public and private sector employers and plan sponsors offering more and better drug benefits to their members. In other cases, they will show up as gains in effective wages or reduced spending for cash-strapped government payers. By containing costs and improving patient outcomes, PBMs improve competitiveness and consumer welfare, while easing fiscal burdens on employers and government health programs.

PBM savings benefit the federal government via lower Medicare Part D costs and will also reduce subsidy payments for low-income individuals in plans sold through the state-based

[169] Increases in health insurance costs for small business are often cited as a reason for not hiring. Dennis Tootelian, director of the Center for Small Business at Cal State Sacramento said, "If healthcare costs and other costs go up, it's going to make it more difficult for small businesses to hire." (Duke Helfand, "Health insurance rate hikes hitting California small businesses could hurt state's economic recovery," Los Angeles Times, May 26, 2010, *available at* http://articles.latimes.com/2010/may/26/business/la-fi-smallbiz-insurance-20100526.) Similarly, the 2011 Chase Economic Outlook Study, released in June 2011 reported that 72% of companies surveyed regarding their economic outlook and hiring plans were "very concerned" about rising health care costs; and the remaining 27% were "somewhat concerned." (JPMorgan Chase & Co., "2011 Chase Economic Outlook Study," June 2011, p. 2.)

[170] See, e.g., David Cutler and Neeraj Sood, "New Jobs Through Better Health Care," Center for American Progress, January 2010, *available at* http://www.americanprogress.org/issues/2010/01/new_jobs_health.html; Katherine Baicker and Amitabh Chandra (2006), "The Labor Market Effects of Rising Health Insurance Premiums," *Journal of Labor Economics*, 24(3), 609; and David M. Cutler and Brigitte C. Mandrian (1998), "Labor Market Responses to Rising Health Insurance Costs: Evidence on Hours Worked," *The Rand Journal of Economics*, 29(3), 509.

[171] Executive Office of the President Council of Economic Advisers, "The Economic Case for Health Care Reform," June 2009, p. i.

health insurance exchanges created by the Affordable Care Act beginning in 2014. Lower drug benefit costs in the exchanges will reduce federal expenditures because the federal government will subsidize premiums and cost sharing for low-income beneficiaries in the exchanges.

The FTC staff also highlighted the importance of PBM efficiencies to consumers in its August 2011 opposition to a proposed New York bill that would reduce PBMs ability to contain costs using mail order pharmacies. The FTC stated: "For some consumers, increased costs may mean higher out-of-pocket prices for prescription drugs. For other consumers, it may mean that prescription drug benefits are curtailed or eliminated. Scaled-back drug benefits are likely to create pressing financial concerns for many consumers, and may even lead to additional health problems. As an article in *Health Affairs* noted, 'when costs are high, people who cannot afford something find substitutes or do without. The higher the cost of health insurance, the more people are uninsured. The higher the cost of pharmaceuticals, the more people skip doses or do not fill their prescriptions.'" [172]

III. Conclusions

As health care costs continue their relentless upward march at a time of economic hardship and severe budget pressures, the need for innovative solutions continues to grow. The benefits provided by PBMs in containing costs and improving health outcomes have been thoroughly documented in studies by economists, government agencies such as the CBO, GAO, and FTC, health industry analysts, and clinical researchers. In addition, Express Scripts and Medco have each established a long track record of successful operations in their "core" PBM functions, and each has also made substantial investments to develop unique and innovative capabilities that are delivering positive results to plan sponsors and patients.

By containing costs and improving patient outcomes, PBMs reduce the cost of providing effective drug management solutions. In some cases, such cost savings manifest themselves in the form of public and private sector employers and plan sponsors offering better health benefits to their members. Elsewhere, the benefits will show up as gains in employment and effective wages or reduced spending for cash-strapped government payers. In addition, patients also benefit substantially from improvements in the quality of pharmacy care.

[172] Federal Trade Commission, Letter to Honorable James L. Seward, August 8, 2011, p. 4, *available at*, http://www.ftc.gov/os/2011/08/110808healthcarecomment.pdf.

Appendix A: PBM Functions

PBM Functions	Description
Claims processing and fulfillment	PBMs provide technological platforms to communicate with pharmacists and physicians in real-time for efficient claim processing.
Plan design	PBMs work with plan sponsors to develop drug benefit program plans that incentivize compliance with the plan's formulary through copayments, coinsurance, and/or deductibles. These incentives can include differential copayments, denial of coverage for non-formulary drug purchases, and other incentives for use of mail-order pharmacies.
Generic dispensing	PBMs help control costs by increasing usage of generic medications. Some of the tools PBMs use to encourage generic utilization include mail order and plan design that incentivizes use of generics.
Negotiate favorable drug pricing with drug manufacturers and wholesalers	PBMs often negotiate substantially larger rebates and discounts than wholesalers or retailers. The contracts between PBMs and drug manufacturers often provide that the pharmaceutical manufacturer will pay a rebate for being placed on a formulary, and additional rebates if the PBM can achieve certain specified sales or market share targets, and preferred placement of certain drug products on the PBM's formulary. PBMs typically pass through a large fraction of such rebates to plan sponsors.
Retail pharmacy network management	PBMs contract with retail pharmacies and negotiate reimbursement rates for covered drugs on behalf of a plan. In general, the PBM negotiates a discount rate on payments to retail pharmacies as a discount off of the average wholesale price or maximum allowable cost of a drug plus a dispensing fee.
Therapeutic interchange	Therapeutic interchange programs are used by PBMs to identify opportunities to substitute with a safe and effective, lower-cost therapeutic alternative. The interchange for a substitute drug can be either branded-to-branded or branded-to-generic; either way, physician approval is required.
Drug utilization review (DUR)	PBMs' DUR programs review how physicians prescribe drugs and how patients utilize those drugs. Reviews can be done two ways: concurrently or retrospectively. Concurrent DURs check for drug interactions between prescribed drugs to limit adverse reactions, prescribed duplicative therapies and early or late refills (an indicator for over/under consumption) by the customer.

	Retrospective DURs allow PBMs to identify physicians with a tendency to prescribe high-cost drugs when there are opportunities to prescribe therapeutic alternatives that provide safe, cost-effective therapy.
Clinical prior authorization	Prior authorization requires that a physician/patient receive PBM approval for a drug before it is covered by a plan sponsor. These authorizations are often required on medications that are particularly expensive or prone to misuse.
Step therapy	Step therapy is a plan design tool in which the plan will only cover more expensive drugs if patients fail on less expensive therapeutically-equivalent alternatives such as generic drugs, over the counter drugs or cheaper brand drugs.
Refill-too-soon intervention	Refill-too-soon interventions prevent a patient from filling a prescription until a certain percentage of the prior prescription is exhausted. Nearly all PBMs use refill-too-soon interventions to limit overuse of medications that may unnecessarily increase costs to employers.
Efficiencies of mail order pharmacy	PBMs are able to lower costs for clients through use of mail-order by taking advantage of purchasing scale, increased use of generic drugs, higher rebates through formulary compliance, and highly automated systems for reviewing prescriptions for compliance issues and dispensing the medications.
Management of specialty drug spending	PBMs often employ specialist pharmacists with extensive training in the medications used to treat particular chronic and complex conditions.
Detecting fraud and abuse	PBMs monitor claims to detect patterns of potential abuse or fraud.

Appendix B: Calculating the Historical Savings Distributions

Historical savings delivered to customers, including the federal government, were provided by Medco and Express Scripts. The savings estimates provided by Medco were somewhat more detailed, allowing a more detailed allocation of savings for the Medicare drug benefit programs as described below. The savings amounts determined for the federal government, Medicare beneficiaries and employers/individuals were estimated using the quantified savings estimates provided by the companies along with company-specific historical experience with their commercial and Medicare Part D covered lives.

Background on Part D Financing

The Medicare Part D drug benefit is heavily subsidized by the federal government which pays approximately 74.5% of the nationwide premium cost of a statutorily defined "standard benefit" for all Part D enrollees (direct subsidy payments and reinsurance payments). The federal government subsidizes other Part D costs through reinsurance payments and low-income subsidy (LIS) premium contributions and LIS cost-sharing. Medicare beneficiaries pay for the remaining portion of the cost of the drug benefit in the form of beneficiary premiums and cost sharing. Medicare beneficiaries also pay the full amount of the cost of drug coverage for "enhanced" benefits which are the portion of drug coverage that exceeds the statutorily defined benefit for Part D.

The federal government incurs additional Part D-related costs by subsidizing retiree drug coverage provided by employers (Retiree Drug Subsidy or RDS). The government subsidizes 28% of allowable costs for this program.[173]

Allocation of savings across lines of business

The savings estimates were distributed to savings in the Part D program, savings for retiree drug subsidy (RDS) program and RDS employers, labor unions and savings in the group market and individual market. These were allocated using the estimated percent drug spending in each of these areas. In Table 2, the employer/individual savings represent the savings allocated to the group and individual markets. For the individual market, we assume that the health plan sponsor passes the full amount of savings through to the consumer. For group plans, we assume health plans pass through the full amount of the savings to employers who then share some portion of those savings with employees. For the RDS program, the portion of the savings that was attributable to employers and beneficiaries was allocated to the employer/individual savings group.

Distribution of Part D savings between Medicare beneficiaries and the Federal government

[173] Subsidy payments equal 28 percent of each qualifying retiree's allowable prescription drug costs between the applicable cost threshold and cost limit. Allowable costs are actual incurred costs (i.e., net of discounts rebates, and similar price concessions).

In order to distribute the Part D savings between the federal government, employers and beneficiaries, savings were determined separately for the Part D program and the RDS program. The federal portion of the Part D costs includes government spending on premiums, reinsurance and LIS payments. Beneficiary savings include savings for their portion of premium payments and cost-sharing as well as savings attributable to enhanced benefits. In order to determine the total federal contribution for premiums, reinsurance and LIS premium and cost-sharing payments, historical data were used to determine the portion of federal payments to total gross costs based on historical LIS membership in the plans. The savings were then allocated to the federal government based on the estimation of their total contribution to Part D gross costs.

RDS program savings were allocated to the government and to employers who would pass savings to enrollees. While the government contribution for allowable costs is 28%, we used organization specific historical information to determine the federal contribution of total costs for RDS supported plans. We then allocated the federal portion of savings to the government for the RDS program and the remaining portion of the savings was allocated to employer/individual savings in Table 2.

The total savings to the federal government for Part D was calculated by combining the portion of the Part D program savings and RDS savings attributable to the federal government.