

## **Introduction and Background**

To control rising healthcare costs, employers hire managed care organizations to control their health benefit costs. Most managed care organizations contract with pharmacy benefit managers (PBMs) to administer and run prescription drug coverage. The main goal of most PBMs is to control drug costs while administering a pharmacy benefit.

PBMs are responsible for processing drug claims, administrative services, formulary maintenance, pharmacy network management, and mail service pharmacy.

Mail service is offered through most major PBMs. The PBM may own its own mail order pharmacy or has the ability to contract with one or more.

However in its beginnings, mail service pharmacy did not develop as a marketing tool to lower healthcare costs and healthcare expenditures.<sup>1</sup> Rather mail-service was a concept built in the mid 20<sup>th</sup> century, to function in delivering medications to remote, inaccessible, and rural areas. In 1946, the first organized mail-order pharmacy service was established by the Veterans Administration with the goal of conveniently delivering drugs at no cost to veterans. The program proved to be a success as it expanded to serve millions of veterans who were unable to conveniently obtain their drugs through other means. In 1947, The National Retired Teachers' Association (NRTA) was established by Dr. Ethel Percy Andrus to assist retired teachers with their health services, including prescription drugs. Dr. Andrus then expanded her organization by forming The American Association of Retired Persons (AARP). In 1982, these two organizations joined together and NRTA became one of many divisions of AARP. One of its many services was providing prescription drugs to persons over 65, through mail-order drug delivery, which

proved to be an extremely beneficial service to many in the retired community. By 1985, it was operating ten pharmacy service centers within the United States.

As the success of non-profit programs, such as the AARP and the VA-mail service escalated, others saw profit opportunities in such programs. It was a novel idea that proved convenient and cost-effective for the consumer and economically advantageous to the insurance companies. Thus, beginning in the 1980s, mail-order began to develop commercially and proliferated into various areas. Its success mainly came from the national need to control the exponentially growing healthcare costs as well as the increasing numbers of the elderly who constantly required maintenance medications for chronic conditions.

The sweeping growth of mail-order pharmacies caused a backlash from retail pharmacies, which saw them as a threat to both their economic success as well as concerns about patient medication safety. This backlash prompted reports and studies from various organizations analyzing the costs associated with prescription drugs particularly within the Medicare and Medicaid population as well as comparative studies evaluating cost differences between community and mail-order pharmacy.

In a 1987 report by the United States General Accounting Office, prescription drug issues were assessed within the Medicare and Medicaid community, because around 2.2 million Medicare beneficiaries are also covered under the states' Medicaid program. (GAO).<sup>2</sup> In 1987, Medicare consisted of Part A and Part B. Part A offered coverage for inpatient hospital stays, while Part B mainly covered inpatient drugs and a small number of injectable outpatient drugs that were not to be self-administered. The majority of prescription drugs were covered under very expensive HMO plans that included

Medicare Part A, and Part B, which were paid for by additional premiums. According to data collected from 1980 to 1986, the cost of prescription drugs increased by 80%. More than 75% of individuals over age 65 were responsible for prescription drug usage and for over 30% of all drug prescription costs in the United States. Yet, almost 15.5% of persons aged over 65 could not afford to pay for their drug expenditures and ultimately did not get all of their prescriptions filled.

In a 1990 report entitled “*Choices in Prescription-drug Benefit programs: Mail versus Community Pharmacy Services*,” Kirking, examined the cost savings associated with the two different types of pharmacy settings.<sup>3</sup> The report pointed out that mail service pharmacy had grown from \$100 million in 1981 to \$1.5 billion in 1993 and maintained a 6% market share of the \$34 billion prescription market. According to Kirking’s report, this growth was attributed to assertions of cost savings by plan providers to plan members as well as increased drug benefits in employees’ compensation packages. Additionally, due to organized and efficient drug-utilization review and centralized billing procedures, mail-order claimed to significantly reduce administrative costs of employers. In view of that, the report attempted to validate the cost savings of such services by comparing specific costs associated with each particular service; mail-order and community pharmacy. Comparisons were done using three main components of direct prescription costs, including ingredient cost, dispensing fee, and administrative fees. Within all three categories, mail-service costs proved to be slightly lower than those associated with community pharmacy but the article acknowledged that other non-quantitative factors such as patient population characteristics and drug plan characteristics had to be taken into account in order to fully measure the cost variations.

For an example, typical mail service medications are usually those used as maintenance medications for chronic conditions such as hypertension and asthma. These conditions mostly afflict older patients, and thus mail order would be a good cost-saving option for that portion of the population, whereas for many younger patients mail-order would not be as cost-effective or even workable.

Kirking's findings indicated that mail-order pharmacy was cost-effective relative to the extent of its utilization. This meant that with large volumes of prescriptions it has some advantages due to "...economics of scale, lower occupancy costs because of non-retail locations, more efficient use of professional and technical personnel, and closer inventory control." Yet those cost containing strategies were offset by other costs incurred within a mail-order facility such as telephone usage and mailing costs. In addition, community pharmacies could achieve such advantages by also purchasing medications in bulk in order to obtain discounts and incentives from manufacturers. Hence, the report found that mail-order pharmacy did have certain cost-effective policies and savings but those savings were minimized with proper cost containing strategies in community pharmacies. Consequently, no explicit evidence or reliable data was found to effectively evaluate comparisons of costs within the two pharmacy drug distribution sectors.

In a 1998 article, "*Does Mail-Order Pharmacy Really Deliver the Goods,*" mail-order service was once again questioned over its potential cost savings.<sup>6</sup> Despite its popularity among health plans and providers, mail-order began to be decried as a substandard level of service due to various practices that are seen as detrimental to the patient as well as the profession. Some claimed that the lack of face to face counseling

was not beneficial to patients. Opponents also claimed that mail-order pharmacists were not licensed within the state that they practice in.

Further studies were conducted about possible cost-savings with utilization of mail service pharmacy. In 1990, researchers at Brandeis University with University of Maryland Pharmacy School carried out a study that analyzed trends within the mail-order sector. Analysis revealed that mail-order pharmacy service consisted of 6% of all prescriptions and was growing at an enormous pace.<sup>4</sup> This growth was attributed to the development of mail service pharmacies in large retail chains.

Mail service prescription costs were further compared to community pharmacy costs. On average, each mail-service prescription cost \$42.32 with the average days supply being 76.6 days and had a \$0.561 charge per day's supply. By comparison, community pharmacies averaged \$15.19 per prescription with a 26 day supply averaged per prescription and a \$0.584 charge per day's supply. Once again, this data was not sufficient enough to competently assess the cost-effectiveness of each avenue because other factors were not taken into account.

Another 1993 article by Bashe and Murray in *Medical Marketing and Media* discussed certain challenges to mail service.<sup>5</sup> According to the article, mail-order's rate of growth was higher than any other "prescription channel," and the growth rate was predicted to grow 30% through 1995. This often took business away from community pharmacies and drew opposition by chain pharmacies led by the National Association of Retail Druggists (NARD), now the NCPA. Among their arguments was on the fact that many of the mail-order pharmacists were not licensed in the state in which they were

dispensing prescriptions as well as a lack of a face-to-face patient counseling that could have a negative affect on treatment outcomes.

One particular mail service provider, Medco grew at an unprecedented pace. Between 1991 and 1992, Medco's sales grew to \$1.8 billion. Medco provided mail service for over 1,255 companies and unions which totaled to almost 29 million beneficiaries.

The company claimed to serve both the needs of patients and manufacturers. Medco received significant manufacturer discounts while manufacturers maximized drug profits. These incentives were made available by manufacturers because of pharmacies' willingness to purchase in bulk as well as preferential exclusivity with certain medications. These preferred products were characterized as 'drugs of choice' to customers who achieved maximum savings. To maximize the discount, mail-order pharmacies attempted to persuade doctors to prescribe these preferred products within the Medco formulary in an effort to further increase the manufacturer's discounts. In addition, the company kept an extensive database of customer prescriptions in order to see patterns in prescribing certain drugs as well as side-effects and customer satisfaction queries. Similarly, Medco offered a detailed and efficient drug plan design that was individually molded to each patient in order for them to get the most efficient and cost-effective drug plan.

An added trend within the mail-order pharmacy sector was mandatory mail service among employers. This was further explored in an article published by Drug Topics entitled, "*The New Showdown: Community Pharmacy are Pulling Out All the Stops to Derail Mandatory Mail-Order Plans.*"<sup>10</sup> In order to contain rising healthcare

costs, employers began to require their employees to purchase maintenance drugs through mail service. This was mainly used for chronic medications with a 90 days supply, and was customarily paid for in two co-payments. Southwest, IBM, and Citigroup were some of the employers that began utilizing mandatory mail service within their companies. In addition, 54% of surveyed employers maintained their desire to implement the program in the future.

Supporters of mail service claim that consumers are much happier because of convenience, expertise, and price. The products are almost error-free due to the utilization of advanced technology aimed to verify each prescription with a better error rate than those of community pharmacies. Meanwhile, opponents of the requirement claim that many consumers are not satisfied with mail-order. The National Association of Chain Drug Stores asserts that many consumers would like a choice when it comes to prescription drugs and their associated services and are not happy with being obliged to buy drugs from mail-order.

A 2002 analysis by Diane West further clarified the growth of mail-order compared to retail. In her article entitled, "*Mail-Order Rx chips away at the retail sales,*" she analyzed that mail service claimed 17% of the market share and \$27 billion dollars of all prescription drug sales.<sup>7</sup> It had a largest gain of market share between 2000 and 2001, where it grew from \$20.6 billion to \$27.6 billion. This was comparatively smaller than the percentage of growth experienced by retail sales, which only increased by 10.6%. Analysis showed the rapid growth was due in part to pressure of employers to lower healthcare costs.

Another survey by the Pharmacy Benefit Management Institute reported various patterns among provider plans as seen in the Takeda Prescription Drug Benefit Cost and Plan Design Survey Report.<sup>8</sup> Mail-order pharmacy was shown to have grown in usage among employers along with mandatory mail order for chronic medications but the average brand reimbursement rates for mail order pharmacy have decreased from 86.80% in 1995 to 82.20% in 2001. Meanwhile, administrative-related fees were significantly lower for mail service. The average dispensing fee for mail order was \$0.23 per prescription compared with \$0.38 per prescription for community pharmacy. The survey also shows that drug utilization is increased through use of mail order pharmacy which is probably due to more cost effective strategies of pharmacy benefit managers to increase savings.

Yet, in order for mail-service to function properly and deliver the promised savings, efficient plan and design structure needed to be implemented. A 2003 report in the Managed Care Journal by Kaye, pointed to the fact that certain conditions needed to be met for mail order savings to occur.<sup>9</sup> First, the drugs dispensed through mail-order should be indicated for chronic conditions and indicated on a drug benefit formulary blueprint. Additionally, the prescriptions should be paid for fully for a 90 day supply but not exceed 300 pills at one time in order to maximize the discounts but prevent waste. Similarly, in order to reach the highest degree of savings, generic use should be mandatory and all drugs should be given a correct average wholesale price in order maximize discounts that were provided by manufacturers. Similarly the prescription costs of drugs dispensed through mail order need to have an AWP of -22%, two co-payments and a \$2 dispensing fee in order to compete with the prices of retail drugs. To provide

savings, mail order has to have an AWP of -15%, a \$2 dispensing fee, and three co-payments. Yet an AWP of -15% serves as a disadvantage to the plan sponsor because it increases its costs.

The report also identified that many factors relating to mail order pharmacy savings deal with "...sociological issues and to the potential for increased utilization," such as termination rate of individuals within a company, which will affect contribution rates of the employee towards drug benefits. Employees contributed monthly to their benefit program that covered a 30 day supply of a medication. If the employee left the company after ordering a 90 day supply of a prescription and before they contributed a 90 day premium, most of the drug costs fell on the employer. Other factors mentioned include mail versus retail utilization rate, AWP discount rate difference, dispensing fee differences between mail service and community, and generic drug pricing in mail order. Furthermore, the article pointed out that a large amount of the revenue for pharmacy benefit managers was generated from sophisticated plan design of the benefit programs. This included maximum drug utilization reviews, aggressive AWP discounts, low dispensing fees, therapeutic interchanges, lower administrative fees, greater drug discounts and rebates, and unseen fees from manufacturers for generics.

One of the most controversial aspects associated with pharmacy is the generic dispensing rate, which is defined as the total percentage of prescriptions that are dispensed as generics. Various studies have shown that mail-order pharmacy has had a lower generic dispensing rate than retail pharmacies due to profit intentions of the pharmacy benefit managers. Pharmacy benefit managers are companies that have developed as an intermediary between plan sponsors and insurance companies. They

often provide an array of services that deal with administrative tasks which help clients with drug utilization, price controls, and an overall improvement of drug benefits. PBM's also take on the task of negotiating lower prices for drugs from manufacturers due to discounts and rebates provided through exclusivity. These arrangements for pharmaceuticals are offered on the basis that manufacturers will provide rebates and discounts on brand-name drugs sold in large quantities or ones that will capture a large portion of the market share for a particular disease.

This had been a source of controversy and was scrutinized in a study done by Wosinka and Huckman of the Harvard Business School.<sup>13</sup> The top five pharmacy benefit managers were analyzed for comparison of generic dispensing rates (AdvancePCS, Caremark, Express Scripts, Medco, and Prescription Solutions). Before the outcomes were analyzed, they were controlled for differences between therapeutic mixes due to the type and amount of medications being prescribed through the mail-order channel compared to the retail channel. The results were mixed. Among the most prescribed group of drugs, retail had a generic dispensing rate of 39.65% compared to mail-order which had a generic dispensing rate of 29.29%. The report claimed that the large difference was due to the type of drugs dispensed, such as statins, which, "...gets more than double the weight in the mail channel..." In all total therapeutic classes, retail had a 48.51% generic-dispensing rate while mail-order had a 38.79% rate, but after controlling for the discrepancy within indications resulted in a reduction of the gap in the generic-dispensing rate between the two channels to 1.26%. The 87% difference in generic-dispensing rate was shown to be a result of the lack of generic competitors for more acute drugs that are usually dispensed in a retail setting, while maintenance medications, that

are usually dispensing through mail-order have various generic competitors in the market mix. The rate of generic-substitution was also measured and mail-order was found to have a higher rate, due to the time allowed for mail-order pharmacists to call physicians and request less costly medication.

Pharmacy benefit managers can cause other problems within the pharmacy benefit sphere. These dilemmas could occur when a PBM's main goal is to profit on sales of drugs without looking out for the best interests of plan sponsors and patients. In 2003, a report by Langenfield was published that investigated what was considered "self-dealing" by pharmacy benefit managers and its impact on government healthcare costs.<sup>11</sup> This occurred as a result of pharmacy benefit managers sharing the role of both plan administrator as well as the owner of its mail-order pharmacy and thus created what was considered a conflict of interest. According to the analysis, the four largest pharmacy benefit managers own their own mail-order pharmacies from which they utilize various tactics in order increase their margins of profits. They usually start with 'therapeutic switching' where mail-order pharmacists gain permission from the doctor to alter a patient's prescription to a different drug that is more profitable for the PBM. This substitution usually involves a swap of a generic drug to a more expensive brand-name drug or for a single source brand name for which the mail-order business gains a better discount or rebate from the manufacturer. Additionally, some mail-order pharmacies tend to repackage drugs and sell them at a higher average wholesale price (AWP). This undertaking increases the price for the consumer by as much as 176%, but raises the profit margin to the PBM. Using cardiovascular drugs as a measure, the impact of PBM self-dealing resulted in a \$12,959,145, 988 expense which was the sum of under-

utilization with known substitution rates and AWP inflators between 2006 and 2013. The investigation also found that the total consequences for the government and ultimately to the consumer of such undertakings is \$26,062,520,405 using figures that organized generic dispensing rates by methods of payment, such as cash, Medicare, and Medicare. In addition, generic dispensing rates (GDR) were analyzed by the largest cities, and it was found that mail-order GDR was also lower than retail GDR 32.2% versus 38%. Evidence also found that PBMs were inflating AWP by repackaging larger units into smaller units and reselling at a higher price to the consumer in order gain a larger margin of profit.

Another scheme employed by pharmacy benefit manager companies operating a series of transactions known as differential pricing, or price spreads.<sup>12</sup> In a normal transaction between the pharmacy and plan sponsor, the pharmacy benefit manager serves as an intermediary. The PBM negotiates contracts between the pharmacists on the prices of drugs based on the average wholesale price (AWP) minus a discount from the manufacturer, from which the pharmacy is then compensated for along with a dispensing fee. The plan sponsor is later billed for each prescription as average wholesale price, which includes the drug ingredient costs, minus the discounts. Since the pharmacy benefit managers utilize two separate contracts between the pharmacies and between the plan sponsors, they have the ability to create different prices and costs in order to create larger profit margins. Given that there does not exist a fixed average wholesale price for drugs, pharmacy benefit managers can potentially alter the costs associated with drugs without knowledge by the pharmacies or plan sponsors. This can create a *spread*, or cash flow when the average wholesale price charged to plan sponsors is higher than the average

wholesale price reimbursed to the pharmacies. For example, generic drugs have a set maximum allowable cost (MAC) that is reimbursed to the pharmacy, and cannot be altered due to contracts. A pharmacy benefit manager could charge the plan sponsor a higher average wholesale price minus discount than the MAC, and thus create a profit for itself while creating a disadvantage to the plan provider. Thus PBM self-dealing is an issue that needs to be addressed in order to assure fairness in drug costs to both plan sponsors and consumers.

A 2005 article by Sipkoff, entitled “*Mail-Order Pharmacy Saves Money, Says PCMA, but at What Cost*” challenged the notion of savings in mail-order pharmacy.<sup>17</sup> The report claimed that mail service had an obvious savings benefit to consumers and providers but savings to health plans were not as clear. Mail-order was convenient to consumers, who were found to have above a 90% satisfaction rating in many prescription drug service categories.

Yet a study published by the Lewin group revealed savings for all groups, due to reduction in costs for each prescription claimed. This was due to lower administrative fees, ingredient costs, and dispensing fees. This contradicts the Journal of the American Pharmacists Association report which claimed an increase in costs to the health plans due to increases in costs for other factors that were crucial to mail-order pharmacy dispensing. The savings on ingredient fees and dispensing fees were offset by a loss due to lower co-payments from consumers. Therefore, no studies provide a concrete answer on the value of mail-order pharmacy to the consumer, employers, and health plans and thus further evidence needs to be established before a clear conclusion is developed.

Some further analysis was provided by the Federal Trade Commission to compare costs associated with pharmacies owned by pharmacy benefit managers and those that were not owned by mail service pharmacies. The report entitled, "*Pharmacy Benefit Managers: Ownership of Mail Order Pharmacies*," came up with several conclusions.<sup>19</sup> First, the study found that large PBM-owned pharmacies had lower prices on outpatient prescription drugs than did non-PBM-owned pharmacies that were also a large size, including for the most commonly prescribed drugs. This was found to be due to better negotiated contracts between PBM-owned mail order pharmacies and manufacturers that allowed for better discounts and rebates. Similarly, data were analyzed to compare the costs associated with retail-owned PBMs with mail service pharmacies and retail-owned PBMs without mail-order pharmacies. Data showed that for generics and brand name drugs with available generics, prices were lower at retail-owned PBMs and not lower for single source brand drugs. For the most commonly prescribed drugs, mail-order prices were significantly lower than retail prices during 2003. Additionally, the data attempted to analyze other aspects of mail order, such as generic dispensing rates, generic substitution, as well as repackaging. In large PBMs with mail-order pharmacies it was shown that they dispense a similar amount of generics as other drugs within the same therapeutic category, while retail-owned PBMs had a smaller ratio of generic dispensing. Generic dispensing rates among retail pharmacies were higher, 44% than those of mail order pharmacies that were owned by PBMs, 39%. Similarly, despite data showing cost savings to plan sponsors when therapeutic exchange was utilized, many PBM-owned mail service pharmacies did not substitute generics when they were available. Additionally, most PBMs did not resell repackaged drugs, with only one pharmacy

benefit manager company having a facility licensed by the FDA to repackage drugs. Contrary to other published reports, the repackaged drugs were not sold at a higher AWP, but rather at the customary price.

A 2005 report published by Teagarden of Medco entitled, “Dispensing Error Rate in a Highly Automated Mail-Service Pharmacy Practice,” in Practice Insights analyzed the dispensing error rate in community and mail-order pharmacies.<sup>15</sup> The study was aimed at promoting the use of automation and its benefits on reducing medication errors. The object studied was a large mail-order pharmacy that has a high utilization of automated dispensing and 21,252 prescriptions were studied. The results found 16 errors, with 14 of the errors being incorrect label directions, indicating human inaccuracies because these mistakes were made where automation was absent. No errors were due to incorrect medication or erroneous dispensing due to automation. The number of errors represented a mere 0.075% error rate for the total number of prescriptions. . In comparison to a retail setting, mail-order proved to be much more accurate. Retail pharmacies were found to have 77 errors out of 4481 prescriptions, indicating an error rate of 1.72%. Thus, automation was observed to play a key role in the accuracy of mail service prescriptions and therefore should be utilized in more settings.

In a 2005 report published by the Lewin Group, mail service pharmacy was scrutinized for its potential savings to the overall health system drug expenses within the next ten years.<sup>18</sup> The data were collected from two large sectors that accounted for 87% of the outpatient drug spending: the Medicare population and the non-Medicare insured population. The process employed exploring the potential spending on outpatient drugs using mail service in 2006 in both study groups as well as estimated the prospective shift

and potential savings associated with substituting retail pharmacies for mail service. The data were used from a 2002 survey provided by IMS Health and CMS' National Health Accounts as well a 2003 GAO report on Pharmacy Benefit Managers and a Takeda survey on drug benefits from the Pharmacy Benefit Management Institute to predict the trend in 2006 and savings until 2015.

As more promises of savings are made to employers, many employees are becoming required to obtain chronic medications through mail service. Yet some studies have shown that such tactics are forcing members to pay more than they would at a retail pharmacy. In an article in the Wall Street Journal in 2005, entitled "*Generic Drugs by Mail Can Be a Raw Deal*," Barbara Martinez, claims that certain drugs are costing members more money than they had expected.<sup>16</sup> General Motors was one company requiring its employees to utilize mail service without fully comprehending the complexities of pricing strategies used by such mail-order companies such as Medco. For example, through Medco mail service, ranitidine costs \$181.22 for a 90 day supply, whereas through a retail pharmacy, a 90 day supply costs a total of \$62.88. Drugs such as this ranitidine example are costing almost \$118.34 extra for plan sponsors and members. These extremely high generic prices may not have been fully understood or realized by employers, who still claim savings of \$80 million. Yet Medco claims that it is impractical to analyze savings using specific drugs but a full picture is needed because many of the savings are realized through manufacturer discounts on bulk products using average wholesale prices.

Several key discoveries were inferred from the report that supported the claim that mail service would continue to grow and save money. The numbers analyzed came from

assumptions that mail service is less expensive for payers compared with retail due to large volumes (90-day supplies) as well as a centralized, more efficient dispensing system that utilizes workflow to its maximum potential. This as well as lower ingredient costs lowers the cost to fill a prescription. According to the Takeda Prescription Drug Benefit Cost and Plan Design Survey Report, mail-service saves 20.4% in drug ingredient costs compared to that of retail which is 14.5%.

According to statistics, the 2005 trend of mail-order growth and reductions in healthcare costs were predicted to be \$6 billion by 2005. This represented \$2.2 billion from non-Medicare insured beneficiaries' savings on outpatient prescription drugs and \$2.8 billion from Medicare beneficiaries. Interestingly, another \$6.2 billion could potentially be saved if specific retail prescriptions for maintenance medications were transferred to mail service, making the total drug savings in 2006 be \$11.2 billion. In ten years, staying with the current trend of growth, healthcare savings would amount to \$78.9 billion, while with the predicted growth of mail-service pharmacy, savings would swell to an estimated amount of \$97.8 billion. Similarly, if mail-service maintained its current expansion, retail pharmacy would face an increase in drug spending, accumulating to \$2,550.4 billion from 2006 until 2015.

In 2006, the Lewin group once again reported on both savings in mail-order pharmacy as well the effects of laws that will limit the potential savings of mail service. This report entitled, "Mail-Service Pharmacy Savings and the Cost of Proposed Limitations in Medicare and the Commercial Sector," predicted the savings from 2007 to 2016 with full utilization of mail-order and the effect of legal interventions that will hinder the effectiveness of the cost savings associated with mail-order pharmacy.<sup>21</sup>

According to the research, due to the advent of mail-order service prescription drugs costs have begun to slow. In part, this occurred as a result of the effectiveness of pharmacy benefit managers, who, "...negotiating discounts from manufacturers and pharmacies; encouraging the use of more cost effective drugs such as generics or competing branded drugs within a therapeutic class; or expanding the use of efficient pharmacy channels such as mail service."

Three specific interventions were highlighted. One of the first regulatory interventions that were mentioned was an act that would prevent restrictive contracting with only one exclusive mail service. This would impose a regulation that 'any willing mail service pharmacy' could be utilized by a plan to eliminate selective contracting. Thus, health plans would have to involve any provider that abides by the standards and terms of network participation. This would decrease competitiveness among the providers because many plan providers would contract with several mail-order pharmacy providers and eliminate a single preferred mail-order pharmacy. This would cause a "shift in volume from operations," that would reduce the incentives of manufacturers to provide discounts for bulk orders and thus cause an increase in outpatient prescription costs by 2-4% or around \$7.30 for brand and \$2.67 for generics drugs. For consumers of prescription drugs, the 'any willing pharmacy' mandate would cause an increase of \$10 billion in the next 10 years for insured commercial users and \$13 billion in the next 10 years for Medicare beneficiaries. Annually, this would result in an additional expenditure of \$15-31 billion between 2007 and 2016.

The second scenario requires consumer cost sharing to be equivalent whether the prescription is filled through mail service or retail, eliminating the promise of lower costs

to consumers when their prescriptions are filled through mail service, as well as the incentive to purchase drugs through mail service. In addition, the law would mandate that benefit plans allow the consumer to purchase the same 90-day supply of drugs at any retail pharmacy. As a result of this, between 2006 and 2017, prescription costs would increase by \$40 billion among both Medicare and commercially insured beneficiaries.

Additionally, the Lewin group provided a comprehensive scenario of the total impact of healthcare costs when all three changes are mandated. The combination of uniform cost sharing, 90-day retail, and any willing pharmacy would increase mail service prescription costs by 6.1% from 2007-2016, and \$47 billion for beneficiaries.

More studies were conducted to analyze the cost savings associated with mail service pharmacy. One of those reports was written by Johnsrud at the University of Texas at Austin in 2006 and attempted to evaluate whether mandatory mail-order saves money for providers of pharmacy benefits.<sup>20</sup> The analysis attempted to utilize available literature that provided information on both perceptions of users and providers of mail-order pharmacy along with qualitative evidence of cost savings on outpatient prescription drugs. The results did not turn out to be explicit due to the lack of empirical based, peer-reviewed reports on the subject matter but more of opinion and subjective qualitative analyses.

Most plan sponsors believed that mail service has an advantage in cost-containment based on literature asserting benefits due to economies of scale that provide larger discounts from manufacturers and thus lower costs on prescription drug products, smaller administrative and facility fees due to a centralized system that provides greater productivity for less money, and a greater rate of substitution due to more time to call

doctors and encourage cost-containing drugs. For consumers, this means lower co-payments, smaller deductibles, convenience, as well as comprehensive over the phone patient counseling. However, studies on customer satisfaction lacked sufficient sample sizes and diversity that prevented reporting adequate generalizable results. In the end, the findings showed that customer satisfaction is high in both mail service and community pharmacies, depending on individual preferences.

Investigations on savings also lack significant and objective peer-reviewed studies that could provide a satisfactory answer. The study attempted to identify literature that provided detailed information on cost savings to the plan sponsor, which is usually the employer or a union that provides drug benefits to the consumer. Many of the studies were outdated such as a report published by the Centers for Medicaid and Medicare during the 1980s that compared costs associated with each sector of pharmacy. Results indicated price per day costs of both mail service and retail pharmacies were similar but were deficient in evidence because many mail service pharmacies studied provided incomplete data and thus the results were mostly formulated on averages. Another report mentioned within Johnsrud's study was an analysis written by the U.S General Accounting Office that used a specific federal health plan called the Federal Employees Health Benefits Program to compare drug costs. The study used a very small sample of 36 community pharmacies in 3 states and only compared 18 different products in 30 day supplies. The results showed savings of 27-53% to plans and consumers over cash prices at community pharmacies. In addition, savings of only 18-47% were shown when members used the FEHBP over cash prices. Thus mail service showed more significant savings over retail prices although there was once again a lack of sufficient data. Similar

studies were conducted by PriceWaterhouse Coopers and the Federal Trade Commission but also lacked satisfactory comparisons and data that could adequately contribute to cost comparisons. However, Johnsrud did mention one comprehensive study within his report that was organized by Virginia Commonwealth University which used data from a health plan consisting of 100,000 members and using 44,800 claims and 201 different products, which had a larger representative mix than other studies up to that point. The evidence pointed to an increase in costs to the plan sponsor while simultaneous savings to consumers. This was due to the fact that the plan spent 3.8% more due to excessive reductions in co-payments and deductibles. In other words, the savings to consumer were offset by the cost to the plan itself. But the estimated total drug benefits costs decreased by 7.8% with utilization of mail service pharmacy.

Johnsrud concluded that such a lack of well-written, published literature is due to the limited data provided by pharmacy benefit managers who often utilize the data for their own applications. In addition, many assumptions are made in regards to savings and specific costs associated with mail service which do not take into account various quantitative and qualitative factors and thus produce erroneous data and conclusions by plan administrators. Thus an actual measure of savings for plan sponsors can only be concluded through thorough investigation of pharmacy drug benefit design that is written during contract negotiations in order see specific details of the plan. Without that kind of specific data, results show that the, "...the savings commonly attributed to the mail order component may be more of a by-product of the pharmacy benefit design (e.g., co-payments levels or day-supply requirements) rather than mail order efficiencies, in particular."

One of the most detailed reports came from Johnsrud in the March 2007 edition of the Journal of Managed Care Pharmacy.<sup>24</sup> Its purpose was to give as a quantitative comparison of mail order as compared to community pharmacy due to shortages of comprehensive reports. Major areas that were evaluated included member and plan sponsor cost per day of drug therapy, the generic dispensing rates, as well as the cost per unit for the top 20 drugs. The information was collected from two health plans in Texas in 2004 and the data were utilized to obtain specific quantitative measures of costs and payments among members and providers.

The average daily cost of thirty different drug products was compared between the two distribution methods. For both plans, mail order was found to have a lower average cost for members than community pharmacy. Plan A members paid 36.4% of all costs while members who utilized community pharmacies paid almost 41.5%. In Plan B, members were responsible for 26.3% of mail order expenditures and 35.9% of community pharmacy costs. For all types of drugs, including generics and brand, and in both health plans, the portion of member cost was greater in community pharmacies than mail order pharmacies while plan sponsors had a higher average daily cost through mail order. For example, for brand name drugs purchased from mail service pharmacies, plan sponsors had an average \$75 co-payment for brand name drugs, while having a \$67 co-payment for brand name drugs in community pharmacies. Additionally, for generic drugs, plan sponsors paid an average \$63 through mail service and only \$52 for community. Thus, most of the member savings that were accumulated through utilization of mail service pharmacy were due to transfer of payments to the plan sponsors.

In addition, generic dispensing rates were also quantified on comparative grounds, where the rate in community pharmacies was higher than that of mail order pharmacy. For example in Plan B, the rate in mail service was 24.1% whereas in community, the rate was 32.7%. Likewise generic prices per unit were also compared for the top twenty drugs on the market. The results pointed to the fact that only 45% of the top twenty drugs measured in cost per unit turned out to be cheaper when using mail service compared to community pharmacy. For example, omeprazole cost \$1.66 compared to \$3.02 in a community pharmacy, while fluoxetine cost \$1.07 by mail and \$0.53 when dispensed from community pharmacies, which indicated results varied among the top twenty categories while leaning toward lower prices in mail order pharmacy. Thus contrary to published reports, almost half of the twenty generic drugs resulted in higher costs by mail versus community practice. This was likely the result of contracts and deals between PBMs and manufactures that created incentives for brand name drugs and did not guarantee lower prices for generics. Overall, total drug costs for the top twenty generic products were higher in community pharmacy as opposed to mail service pharmacy. Thus, according to the study, most benefits of mail service were advantageous to the member while creating a conundrum for the plan sponsor.

A 2006 article published by the Journal of Managed Care Pharmacy analyzed three new policy amendments in the State of Michigan to investigate their impact on community pharmacies.<sup>23</sup> The three policy changes included the inclusion of a mandatory mail service pharmacy, the authorization to allow importation of pharmaceuticals across states, and a reduction in the dispensing fee for pharmacies for

Medicaid prescriptions. Mandatory mail service was shown to have the largest economic effects on community pharmacies in Michigan.

Michigan was one of few states that allowed exclusivity for mail order companies and did not permit community pharmacies to distribute mail prescriptions, which resulted in a large reallocation of prescriptions from Michigan other states. This impacted heavily on the economics in the state of Michigan. The author cited a study from Millman USA in conjunction with PCMA that evaluated the consequences of a bill presented by Michigan lawmakers that legalized the usage of mail by community pharmacies. This would permit community pharmacies to distribute 90 day supplies of maintenance medications similar to mail service pharmacy firms and grasp a large percentage of prescription drug market share. The result of that study illustrated an increase in cost per capita for employers, "...due to loss of discount pricing leverage for pharmacy benefit managers (PBMs) and 14% (\$4 per capita) from the difference in community versus mail-service pharmacy pricing." The Millman report pointed to \$145 million in savings from mail-service pharmacy, which was deduced from a savings of \$30 per capita for 5 million individuals. Yet, the author identified the data to not have sufficient evidence to make such assumptions and thus could be utilized only to presume savings.

Thus, a more conclusive analysis was performed to investigate these policy changes. Before the data were applied, certain assumptions were formulated. It was assumed that Michigan spent approximately \$6 billion on prescription drugs at 2000 community pharmacies. This was for around 56,399 prescriptions per pharmacy with an average price of \$51.44 per prescription.

The advent of mandatory mail pharmacy in some plans had put a dent into the sales of community pharmacies because it shifted their volume to other out of state mail pharmacies. The program attributed an estimated 12.5% loss of sales for community pharmacies, which was around \$375,000 in losses per pharmacy. This resulted in a \$2,625,000 loss in net sales and a gross margin loss of \$603,750 which produced a profit loss of \$15,000. Accordingly, these data was utilized to calculate the total losses for the state of Michigan when mandatory mail order is applied to the entire population of community pharmacies in Michigan. It was found that if \$6 million was spent on drugs and a 12.5% sales loss could be attributed to mandatory mail service, then Michigan pharmacies would record a \$750 million loss in sales and consequently a \$172.5 million loss in gross margin and a \$30 million loss in total prescription net profits. In addition, the losses accrued by each pharmacy impacted employment in the area. This resulted in a reduction of employment in Michigan of 1,880 jobs and amounted to \$33,750 of lost employee payroll.

In a 2006 article, Carroll addressed various issues with current analyses of savings due to mail-service pharmacies.<sup>22</sup> In the report, Carroll attempted to delineate various characteristics that are essential for a complete review and analysis of savings. He pointed to the importance of using actual claims data to study savings instead of making use of contract pricing that would only provide estimated savings as well take account of waste that can be a factor in mail service due to the large volume of medication that is given at once. Contract pricing can conceal actual numbers and cause misleading results because some pharmacy benefit managers have been shown to exaggerate prices for sponsors using tactics such as repackaging and inflating the average wholesale price.

Furthermore, the review has to include a large sample of both products and providers that could serve as a representative for a larger illustration. These studies should be peer-reviewed by professionals and published in qualified journals to enhance the validity of the report.

Carroll cited several reports that exemplified inadequate analysis. Other than one study that was peer-reviewed and widely published in a medical journal, most were typically written by consulting groups. The Lewin group was used as an example of a consulting firm hired by the Pharmaceutical Care Management Association to study cost savings associated with mail service pharmacy. Three sources were utilized in the study, including Merrill Lynch, PricewaterhouseCoopers, and the General Accounting Office. All three resources claimed savings for mail order pharmacy ranging from 5%-11.5%, yet they did not provide sufficient verification on the basis of the savings or use a representative sample of products to deduce these conclusions.

### **Objective**

The aim of this study was to measure the impact of mail service pharmacy on plan sponsors. Mail order pharmacy has grown significantly in recent years due to increasing demands to reduce healthcare costs. In some settings, mail order is mandated pharmacy option for employees. Various studies have examined cost savings of mail order to consumers. Moreover, the numerous studies previously cited do not provide a clear, definitive picture of whether savings exist for the sponsor. Thus after an extensive literature review of available publications, further evaluation is required to assess the impact of mail service pharmacy on plan sponsors.

Temple University was interested in assessing potential savings to plan sponsors through utilization of mail order pharmacy in one employer-based health plan. Our main

objective was to provide a comprehensive analysis of the costs to plan sponsors for the top 50 maintenance medications in both mail order and retail settings. Most of the drugs were maintenance medications used for chronic conditions, such as diabetes, hyperlipidemia, and asthma average daily costs and percent savings were calculated and compared between the two settings.

### **Methods**

After being turned down by numerous employers and insurers, we were able to secure the cooperation of a large, diverse employer with 5,200 covered employees representing janitors, bus drivers, professors, physicians, secretaries, and administrators.

We conducted a comparative study to analyze costs to a plan sponsor for the top 50 maintenance medications in both retail and mail order settings. Maintenance medications for chronic conditions are the most common types to be delivered through mail order.

The analytics team at a large PBM provided claims information for the top 50 prescription drugs delivered through both mail order and retail for an employer from 7/1/2008 through 6/30/2009. For each category, information supplied included the total number of prescriptions for each drug, the total number of retail and mail days, and net costs. This was the amount charged to the plan sponsor per day for a particular medication. Additionally, daily savings and percent savings were calculated for each drug.

This information was used to generate a series of evaluations to estimate potential savings associated with mail order pharmacy.

### **Results**

*Tables attached.*

Among the top 50 maintenance medications, 66% were generic drugs. Out of the top 50 total drugs, 38 of them were less expensive to the plan sponsor through the mail order setting. Only 12 medications provided savings to the plan sponsors when purchased through a retail setting. Among the top 17 brand name drugs in the analysis, all but one of the drugs (Xalatan) provided savings to the plan sponsor with mail service utilization. In the generic drug category, 22 out of 33 medications, demonstrated potential savings to plan sponsors through mail service.

As hypothesized, mail order provided savings to plan sponsors among the top 50 maintenance medications. Among all provided chronic prescriptions drugs, average total saving was ¢0.14 per day. When calculated for 30 days and 90 days, savings averaged to \$4.13/day and \$12.40/day. Furosemide 20mg as associated with the largest percent saving (100%) among all drugs while Pantaprazole 40mg had the smallest percent saving (1%). Thus mail savings ranged from 1-100% among the top 50 medications.

Among brand name drugs, mail savings ranged from 5.24% for Prevacid 30mg to 58% for Proair HFA inhaler. Among brand name drugs, average total saving was ¢0.38 per day. When calculated for 30 days and 90 days, savings averaged to \$11.30/day and \$33.80/day.

Generic drugs provided a savings of \$0.02 per day. When calculated for 30 days and 90 days, savings averaged to \$0.45/day and \$1.36/day.

Thirteen medications or 26% of all drugs did not offer savings to the plan sponsor. In fact, these drugs were more expensive through the mail order setting. These included Simvastatin 20mg, Metformin 500mg, Omeprazole 20mg, Simvastatin 40mg, Lisinopril

10mg, Atenolol 50mg, Sertraline 50mg, Xalatan 0.005% eye drops, Metformin 1000mg,  
Folic acid 1mg, Metoprolol Tartrate 25mg, Clonazepam 0.5mg, and Ibuprofen 600mg.

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