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Abt Associates Inc. 55 Wheeler Street Cambridge, MA 02138 Identification and Description of Industry Best Practices to Manage the Costs of Prescription Drugs

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1.0 Background and Introduction

Outpatient drug expenditures in both public and private programs have grown at a rate of 15% to 20% since the mid-1990s— more than double the rate of growth in total health spending (e.g., Medicaid total expenditures grew 7.7% per year from 1997 to 2000). Total prescription drug expenditures slightly exceeded 10% of total health care expenditures in 2002. Based on current rates of inflation, one forecast projects an increase of this share to above 14% by 2012. For working-aged adults, the share may be as high as 25%.¹ The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and CMS' 8th Scope of Work ² have focused additional attention on medications. While State Medicaid and other public-sector efforts to contain drug benefit costs have been well documented, information on the nature and effectiveness of private sector approaches is limited.

1.1 Objectives and Methods

Objectives

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) of the United States Department of Health and Human Services requested a preliminary study to identify and describe through case study techniques effective strategies and programs (best practices) developed by private sector organizations to manage the costs of prescription drugs. Candidate organizations included those that provide, manage, or fund prescription drug benefits (e.g. employers, managed care organizations (MCOs), including health maintenance organizations and preferred provider organizations, group practices, pharmacy benefits managers (PBMs), and purchasers) and have achieved positive results in controlling the growth of prescription drug costs. The objectives of this report are to summarize an environmental scan including conversations with experts and a literature review that helped identify the best practice organizations, to describe the case studies, and to identify cross-cutting themes that emerged from the cases.³

1.2 Literature Review

We conducted a literature review to identify examples of successful interventions and to aid in the identification of best practice organizations. We identified whether a study was of higher "quality" (in that it used a comparison group; appendix 1 describes our methods). In this section we discuss some of the most frequently used cost containment approaches identified among the higher quality studies in the review.

Formularies

A formulary is a list of covered drugs chosen by a health plan or a PBM's pharmacy and therapeutics committee based on effectiveness, safety, and cost considerations. Many health plans have tiered formularies, with drugs categorized by co-payment or co-insurance levels. A co-payment is a fixed dollar amount payment; co-insurance is a fixed percentage of drug cost. These

¹ Berndt ER. The US pharmaceutical industry: why major growth in times of cost containment? Health Affairs 2001. 20:100-114.

² The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, http://www.cms.hhs.gov/medicarereform/

³ The focus of the case studies was on program effectiveness in containing costs. Other potential intended and unintended consequences of these cost-containment policies, including effects on stakeholder satisfaction, access to prescription drugs, and the allocation of financial burden are not addressed in this study.

co-payment and co-insurance levels are intended to shift utilization from expensive brand name drugs to less expensive generic alternatives and also to discourage unnecessary utilization. In some cases, tiered formularies have more than two tiers in order to encourage the use of preferred brand drugs, with generic drugs placed in the first tier, preferred brand drugs placed in a second tier, and non-preferred brand drugs placed in a third tier. Formularies may be used in conjunction with many other cost intervention techniques, such as prior authorization or pharmacist intervention. The articles we reviewed, however, did not discuss the use of these other methods in tandem with formularies. Some health plans have closed formularies, in which the plan will only pay for a specific list of drugs; however, open formularies are more common.

Formularies were the most commonly studied cost intervention method identified in the review. The high prevalence of formularies suggests that they play an important role in managing prescription drug costs, but formularies clearly have limitations as a cost containment tool. Some researchers have suggested that consumers believe that lower cost drugs are of poorer quality and that they perceive a higher risk in using formulary drugs.⁴ Furthermore, physicians often see patients from multiple health plans and may therefore have difficulty keeping track of the differences.

The reason for the popularity of studying formularies may be attributable to the relative ease of studying them. Researchers only need access to the claims data of a health plan; they do not have to depend on surveys to compile results. Furthermore, formulary policy is relatively easily changed and may not have as long a lag time that the implementation of other interventions, such as a physician education program, might have. Motheral and Henderson point out that many published formulary studies are plagued by poor study design.⁵ Furthermore, many of the studies that appeared in our literature review were sponsored by either HMOs or PBMs. While bias favoring the publication of more studies with favorable than unfavorable results can occur regardless of sponsor, particular caution may be warranted when interested parties sponsor studies.

Seven of the intervention studies analyzed the effect of a change in formulary policy at an MCO. All of these articles used claims data from employee health plans to look at a change in formulary policy. Most of the articles used a quasi-experimental pre-post experiment design, while one used retrospectively collected claims data. The outcome measures that these articles analyzed included total drug costs, drug utilization rate, rate of continuation of medicine, generic utilization rate and the total number of prescription claims. Some of the articles examined a health plan's savings from increasing the number of tiers in the formulary, while others examined savings resulting from an increase in co-payment levels.

Three of these articles found that an increase in the number of tiers in the formulary or co-payments would decrease the cost to the health plan and decrease total prescription drug claims, especially in the second and third tiers.^{67,8} The four studies that examined the level of member co-payments

⁴ Rector TS, Finch MD, Danzon PM, et al. Effect of Tiered Prescription Co-payments on the Use of Preferred Brand Medications. Medical Care 2003. 41(3): 398-406.

⁵ Motheral B and Henderson R. The Effect of a Closed Formulary on Prescription Drug Use and Costs. Inquiry 1999-2000. 36(4): 481-91.

⁶ Fairman KA, Motheral B and Henderson RR. Retrospective, Long-Term Follow-Up Study of the Effect of a Three-Tier Prescription Drug Copayment System on Pharmaceutical and Other Medical Utilization and Costs. Clinical Therapeutics 2003. 25(12): 3147-61.

 ⁷ Motheral B and Fairman KA. Effect of a Three-Tiered Prescription Copay on Pharmaceutical and Other Medical Utilization. Medical Care 2001. 39(12): 1293-1304.

⁸ Joyce GF, Escarce JJ, Solomon MD, et al. Employer Drug Benefit Plans and Spending on Prescription Drugs. JAMA 2002. 288(14):1733-39. Oct.

found that the intervention groups paid higher co-payments for their drugs.^{6,7,9,10} However, results regarding whether a change in formulary policy resulted in patient's discontinuing their medication due to a higher co-payment amount were mixed.^{6,7,9,10}

In one example of a study that examined a change in formulary policy, the authors looked at the effect of an increase in brand drug co-payments from \$10 to \$15 in two-tier health plans at two employers. The comparison group in this study paid a \$5 co-payment for generic drugs and a \$10 co-payment for brand drugs throughout the study period (6 months pre and post intervention). Most drug claims for all therapeutic classes were studied, with some high cost and low frequency drugs excluded. Plan costs increased for the control group over the study period and decreased for the intervention group. Total ingredient costs increased for the control group and decreased in the intervention group, signifying that cost savings were not simply due to a shift in cost burden from the health plan to the enrollee. The number of claims increased in the control group and decreased in the intervention group, and the generic fill rate decreased for the control group while increasing 1% for the intervention group.¹⁰

In another example of a study that analyzed formularies as a cost containment tool, medical claims from 35 employers were used to estimate the effects on prescription drug costs of plan benefits with a wide variety of features, including co-payment and co-insurance rates for retail and mail order pharmacy, rules covering generic substitution, and rules governing exclusions of certain drugs.⁸ The authors concluded that "...(adding) an additional level of co-payment, increasing existing co-payments or coinsurance rates, and requiring mandatory generic substitution all reduced health insurance plan payments significantly." The relative impact of each intervention could not be assessed.

One article that studied a closed formulary found a significant impact on total costs and total number of claims when an employer plan switched from an open to a closed formulary.⁵ Furthermore, the generic fill rate increased from 45% to 49% for the intervention group while remaining constant for the control group. Members of the intervention group were more likely, though, to discontinue therapy after implementation of the closed formulary.

Although it is difficult to generalize about the cost savings potential of formularies due to the varying intervention techniques employed in the above examples, there is some evidence that formularies can yield significant cost savings.

Step Therapy

Some health plans use diagnosis-specific treatment protocols to advise physicians about the most cost-effective treatment method. Step therapy protocols specify the order in which treatment methods should be attempted. Only when the first, most cost effective method has failed, will the health plan approve payment for the next step.

Three step therapy programs were implemented and studied over two years in a 20,000-member plan.¹¹ The per member per month (PMPM) costs of the plan that had implemented the program were compared to a comparison group that did not have a step therapy program; the intervention group experienced a decrease in PMPM drug costs in three therapeutic categories of \$0.83 PMPM,

⁹ Huskamp HA, Deverka PA, Epstein AM, et al. The Effect of Incentive-Based Formularies on Prescription-Drug Utilization and Spending. N Engl J Med 2003. 349(23): 2224-32. Dec.

¹⁰ Motheral B and Henderson R. The Effect of a Copay Increase on Pharmaceutical Utilization, Expenditure, and Treatment Continuation. The Am J of Mang Care 1999. 5(11): 1383-94. Nov.

¹¹ Motheral, B, Henderson R and Cox E. Plan-Sponsor Savings and Member Experience With Point-of-Service Prescription Step Theapy. The Am J of Manag Care 2004. 10(7): 457-64. Jul.

while there was a \$0.10 PMPM increase in the comparison group. A member survey found that 30% of the members used the generic drug promoted by the first step of the protocol. Twenty-three percent of the members received a medical exception to use the brand drug. Seventeen percent received no medication while 16% paid the full retail price for the brand drug out of pocket. The authors pointed out that savings from a step therapy program should be compared against an evaluation of plan medical claims costs in order to understand the full economic consequences of the program.

Pharmacist Intervention

Given their interaction with both physicians and patients, pharmacists can play an important role in drug cost management. There is, however, often no formal relationship between the payer and the pharmacist unless the pharmacy is a mail order facility, and the pharmacist may not have an incentive to lead patients to more cost-effective medications.

One study examined a pharmacist intervention program in a primary care medical group that operated under a financial global risk contract with a health plan, so there was a financial incentive to manage drug costs.¹² The study examined a pharmacist intervention program on costs in eight therapeutic classes; the pharmacist analyzed drug utilization and created educational tools for physicians. In the year prior to the program, drug expenditures increased by 29.8% compared to a national increase of 10.6%. The increase in per member per year drug costs after implementation of the program was 1.7% in comparison to a national trend of 31.2% over the same time period, with savings resulting from both a decrease in average cost per claim and in drug utilization.

Physician Profiling

Individual physician's prescribing patterns can be compared to other physicians. The resulting profiles can indicate that the physician commonly prescribes a brand name drug when a less expensive generic drug is available. Profiles can show physician adherence to treatment guidelines and can provide guidance on how the physician can change prescribing patterns.

One study examined a physician profiling program at a staff-model managed care organization using a retrospective review of pharmacy claims to assess its impact on the drug costs of one therapeutic class --- selective serotonin reuptake inhibitors (SSRI).¹³ One report displayed physician specific prescribing patterns with respect to average cost per prescription, average number of prescriptions per patient and average total prescription costs per patient. A second quarterly report showed clinic and physician utilization patterns compared to benchmarks. Due to a decrease in utilization of the brand name SSRI drug, the average cost of SSRI drug therapy declined from \$2.43 per day of SSRI therapy before the program was implemented to \$2.16 per day after implementation. Research is needed at non-staff model health plans to further determine the merits of physician profiling.

Pill Splitting

Pill splitting aims to decrease the cost per prescription of a given drug. Many expensive prescription drugs are available in higher doses at a similar price as smaller doses, so if higher dose pills are prescribed and then split, a patient can receive treatment for as much as half the cost. However, physicians are hesitant to use this practice due to fears of non-compliance or inability to split drugs, and powdering or inaccurate splits can lead to inappropriate doses.

In one study of pill splitting, 11 frequently prescribed medications were identified for analysis based on their suitability for splitting to evaluate the cost savings a managed care organization might

¹² Walker S and Willey C. Impact on Drug Costs and Utlization of a Clinical Pharmacist in a Multisite Primary Care Medical Group.

¹³ Yokoyama KK, Doan QD, Godley PJ, et al. Effect of Physician Profiles and Academic Detailing on Cost and Utilization of Selective Serotonin Reuptake Inhibitors. J Managed Care Pharm 2003. 8(1): 23-31.

achieve through pill splitting.¹⁴ Pharmacy claims were retrospectively analyzed to determine how frequently these 11 mediations were split. The authors found that only 2% of potential savings were realized during the eight-month analysis period and determined that if these 11 pills were consistently split over one year, the savings to the health plan would have been \$259,500 (\$1.14 PMPM). Potential savings need to be compared to the costs of the physician and patient education programs that would be necessary to realize these savings. Furthermore, the potential cost savings described above assume that pills were split in every case in which they could have been split. However, consumer advocates and physicians both advocate non-mandatory pill-splitting programs, because pill splitting is not appropriate for all patients. Finally, it is possible that if pill splitting became a widespread practice, pharmaceutical companies would eventually adjust their pricing structure.

Dose Optimization

Dose optimization programs target the per-dose cost of medications. One study examined the cost savings from a dose optimization program of a management services organization at two large integrated delivery systems and several community-based provider groups.¹⁵ Fifteen frequently prescribed once-daily maintenance medications available in multiple strengths and with similar average wholesale prices were identified. Using a web-based therapeutic intervention application, pharmacy claims data were analyzed to identify prescriptions that were eligible for the dose optimization intervention. Pharmacists then generated a form that detailed the patient's current prescription and suggested an alternative prescription, a prescription for the alternative prescription and a letter from the clinician to the patient explaining the change in prescription. If the clinician felt that the dose change was appropriate, the new prescription and letter were mailed to the patient. During the six-month study period, the clinicians approved 49% of the interventions. Estimated annualized savings from these interventions were \$390,662, or \$1.67 per member per year.

The organizations in this study were operating under a risk contracting agreement with health plans, motivating them to manage the cost of prescription drugs. These organizations already had a large team of pharmacists and an established web-based module that analyzed prescriptions. Given these program costs, it would be useful to compare the costs of implementing these tools to the savings they would generate.

Health Information Technology

Handheld electronic prescription tools and computerized physician order entry systems (CPOE) can help influence physician decision-making.¹⁶ One study analyzed the cost savings generated from the implementation of a computerized decision support system (CDSS).¹⁷ Physicians in the intervention group were provided with a commercially available CDSS and entered a diagnosis into the CDSS to receive a list of potential prescriptions, with the most recent published evidence and comparative cost information provided for each. The savings during the six-month study period were estimated to be \$3,450 per clinician in the intervention group. While prescription drug costs increased in the comparison group at a rate consistent with the national trend, drug costs decreased by 11% in the intervention group.

¹⁴ Stafford R and Radley D. The Potential of Pill Splitting to Achieve Cost Savings. Am J Manag Care 2002. 8(8):706-12. Aug.

¹⁵ Calebrese D and Baldinger S. Dose-Optimization Intervention Yields Significant Drug Cost Savings. J of Managed Care Pharm 2002. 8(2). Mar-Apr.

¹⁶ Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment: Number 43. AHRQ Publication No. 01-E058, July 2001. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/clinic/ptsafety/

¹⁷ McMullin ST, Lonergan TP, Rynearson C, et al. Impact of an Evidence-Based Computerized Decision Support System on Primary Care Prescription Costs. Annals of Family Medicine 2004. 2(5): 494-498. September.

Because physicians receive so much information from pharmaceutical company representatives, CDSS have potential to diversify the educational material that physicians receive. To appeal to physicians, such material needs to be organized and conveniently provided. Computerized physician devices provide an additional benefit as excellent tools to enter prescribing data into a central database, which can aid health plans in their cost control efforts. Other electronic prescription tools have been used to support formularies, step therapy programs and prior authorization programs. These tools have the potential to coordinate and strengthen health plan efforts to manage prescription drug costs, decrease prescription errors, and to decrease administrative costs and billing errors.

Capitation

In capitated health care systems, physicians are held financially accountable for the costs that their patients incur, and they have a financial incentive to manage drug costs. In one study of capitation, a group of primary care physicians in a physician hospital organization was financially at risk for drugs; every physician received a target drug-spending amount for each patient in their panel.¹⁸ Actual drug expenditures for this group of patients were calculated at year-end, and physicians were held financially accountable for a portion of the spending that exceeded the target ---70% in the first year and 56% in the second. In the third year, instead of having to pay a portion of the excess, physicians were rewarded 40% of the savings if spending fell below the target. The results were mixed; when compared to just the primary control group, the capitation group saw a lower growth rate in spending over the entire study period, and as the financial risk to physicians diminished over the study period, drug-spending growth accelerated.

The strength of capitation as a cost containment strategy is constrained by the need for physician acceptance. Furthermore, patient demand for expensive drugs that they have seen advertised and a fear of litigation might influence physician prescribing behavior.

Summary

Most of the intervention studies that appeared in the literature review discussed the effects of formulary changes. Other methods that were discussed in this category of studies were step therapy, pharmacist interventions, physician profiling, electronic interventions, pill splitting, dose optimization, and capitation. Examples of widely used interventions are provided in Appendix 2.

An additional group of articles that discussed an institution's techniques for controlling costs but which did not provide sufficient information to assess the quality of the study design discussed a broader range of intervention methods. Twelve of the articles discussed formularies, 11 discussed physician education, 6 discussed electronic interventions, 5 discussed pharmacist interventions, 1 discussed capitation and 1 discussed step therapy. Other methods discussed were utilization review, prior authorization, and pill splitting. Most of these interventions were undertaken in an attempt to shift patients from brand name drugs to generic drugs.

It is not surprising that some articles targeted only a single therapeutic class or agent. Nine therapeutic categories --- NSAIDs/Cox 2, migraine, allergy, ulcer/GERD, hypertension, asthma, psychiatric, cholesterol, and diabetes --- encompassed 56% of spending by PBMs in the third quarter of 2003.¹⁹

Some articles reported increases in *generic dispensing rates* while others looked at increases in *generic substitution rates*. The generic dispensing rate is the percent of all prescriptions that are

¹⁸ Chernew M, Cowen ME, Kirking DM, et al. Pharmaceutical Cost Growth Under Capitation: A Case Study. Health Aff (Millwood) 2000. 9(6): 266-76. Nov-Dec.

¹⁹ Namovicz-Peat S, A Guide to Drug Cost Management Strategies, Atlantic Information Strategies, 2004, Washington, DC <u>www.AISHealth.com</u>.

generic, and generally ranges from the 40% to 55%. The generic substitution rate is the percentage of prescriptions that could be filled by bio-equivalent generics that are filled by generics. This rate is generally in the range of 85% to 95%. Another statistic that is commonly cited is the plan's PMPM prescription costs. This statistic can be deceptive if not adjusted for age and other factors. Furthermore, the definition of PMPM can vary by plan. Other statistics that are commonly cited are *per physician per month* drug costs and drug cost growth *trends*. *Trend* is the percentage increase in costs over the course of one year.

2.0 The Case Studies

In addition to the literature review, an environmental scan was conducted to locate those organizations that showed evidence of implementing interventions to manage prescription drug costs and which had achieved favorable results. The names of industry experts were retrieved from journals and articles that appeared in the literature review, from contact information in the article, and from on-line university or company data ("snowball sampling").²⁰ A number of individuals who were known by Abt staff to be industry experts were also contacted. Additional industry experts were identified from the first round of telephone conversations using the snowball information gathering technique. The background of the experts varied considerably and included affiliations with universities, MCOs, PBMs, consulting firms, purchasers, and other organizations. Based on our environmental scan, we identified a list of 32 organizations that qualified as potential best practices. Appendix 3 presents information obtained from the discussions with these experts.

We selected five "best practice" organizations: Tufts-New England Medical Center (T-NEMC), Pitney Bowes Inc., Medco Health Solutions Inc., Provider Service Network (PSN) and Kaiser Foundation Health Plan using the methodology described in Appendix 4.

- Tufts-New England Medical Center (T-NEMC) provides services to both adults and children, is a Boston, MA teaching hospital for Tufts University Medical School, and is known for its scientific research. Its independent practice association (IPA) participated in the study.
- Provider Service network, (PSN) in Boston, MA was a wholly owned subsidiary of CareGroup until 2005. In 2005, PSN became an independent firm, MedVentive, which provides services to the national hospital, provider, employer, and payer markets. The case focuses on the organization's activities while it was a part of CareGroup.
- The Kaiser Foundation Health Plan is a non-profit health plan located in Oakland, California. It owns and operates Kaiser Foundation Hospitals, its own pharmacies and warehouse, and purchases drugs directly from manufacturers.
- Pitney Bowes Inc. is a manufacturer of postage meters and other mailing equipment. Its headquarters are in Stamford, Connecticut, and the company ranked number 392 in the Fortune 500.
- Medco is currently one of the largest publicly owned pharmacy benefit managers (PBM) in the country, with headquarters in Franklin Lakes, New Jersey. It covers more than 60 million lives and processed more than 500 million prescriptions in 2004.

²⁰ Canadian Handbook on Health Impact Assessment. Available online at < http://www.hc-sc.gc.ca/hecssesc/ehas/publications/canadian_handbook/volume3/chapter_c_part3.htm>. 2005. Feb 22.

2.1 Tufts-New England Medical Center IPA Case Study

Description of the Organization

Tufts-New England Medical Center (T-NEMC), located in Boston, Massachusetts, is considered one of the country's leading medical institutions. T-NEMC consists of tertiary care facilities for children and adults with 390 staffed beds, research activities, affiliated health centers, and ambulatory services. T-NEMC is affiliated with Tufts University School of Medicine.

T-NEMC participates in most managed care plans that serve the Boston area, including the three largest, Tufts Health Plan, Harvard Pilgrim Healthcare and HMO Blue. Managed care penetration in Massachusetts is 31% of the total population, one of the highest rates in the country.²¹

This case study describes the pharmaceutical cost management strategies used in T-NEMC's adult medicine ambulatory clinics, which provide about 100,000 outpatient visits per year. These activities are delivered through the auspices of the T-NEMC Independent Practice Association (IPA), an organization of hospital and specialist physicians that was formed for the purpose of managing risk contracts with managed care plans. About half of the outpatient visits are associated with payers that have risk contracts and the remainder consists of Medicare, Medicaid, other types of insurance, and individuals without insurance coverage. Approximately 60% of the outpatient visits are provided annually through the primary care clinics, staffed by the 25 - 30 physicians in the General Medical Associates group practice, and the other 40% through the specialty clinics. The IPA's prescribing patterns follow a similar distribution.

Motivation For The Development Of Cost Management Programs

In 1997, the T-NEMC IPA negotiated its first risk contracts with local health plans, to be effective in 1998. Prior to this time, the financial performance of the ambulatory clinics had been worse than the non-risk-shared pharmacy budgets set with local plans, in part because the pharmacy budgets in these contracts did not accurately reflect the clinics' changing use of prescription drugs. The IPA undertook an in-depth study of pharmacy utilization shortly after the first risk contract was written; as a result, the risk contracts were negotiated to more realistic levels. The IPA leadership was also aware that, without active cost management, the national and clinic-specific trends in pharmacy spending posed a significant threat to the financial health of the IPA, which would be at risk for a considerable portion of the costs over the negotiated budget.

At the same time, the IPA leadership recognized that major changes had taken place in the clinic physicians' practice regarding use of prescription drugs. New drugs were becoming available at a fast pace that seemed likely to continue, requiring increasingly sophisticated decision-making regarding potential safety issues. While there was a growing ability to manage illness through drugs, there was a corresponding rise in risks. Furthermore, patients were increasingly at risk of encountering difficulty in complying with pharmacy regimes as the number of their prescriptions rose. Faced with these conditions, the IPA leadership and the Director of the T-NEMC Pharmacy Department saw the need for both access to clinical pharmacy consultation for physicians and patients and professional attention to pharmacy cost management. The Pharmacy Director saw the development of this role as a logical next step for facility-based pharmacists.

²¹ Massachusetts Department of Insurance, Total Membership as of 12/31/04.

The clinical environment was also a factor in shaping their thinking about how to solve these problems. Underlying this approach was the assumption that the IPA physicians were invested in using knowledge to inform their choices and would be responsive to evidence-based information that showed them what was happening within their medical practices.

The Decision-Making Process and the Choice Of Strategies

In 1998, based on the factors discussed above, the IPA leadership decided to hire a clinical pharmacist who would work full-time in the clinics, concentrating in the primary care clinics. The new pharmacist position was designed and co-funded by the IPA and the T-NEMC Pharmacy Department and would be responsible for clinical consultation and support as well as cost management. Although clinical pharmacists had had a presence in the clinics previously, it was not as full-time staff, but rather as faculty members whose major role was a commitment to the education of pharmacy students. Prior to establishment of this position, pharmacy cost issues were not managed separately and the pharmacy cost data available to physicians were based solely on feedback from the contracted managed care plans.

The clinical pharmacist is a member of the decision-making team of the IPA regarding pharmacy issues. The current process for determination of cost management interventions is highly participatory, as might be expected in an academic medical center. The IPA president and the clinical pharmacist identify potential interventions, based on review of clinic data, professional literature, national trends, and financial analyses of possible outcomes. After reviewing their recommendations with other physician leaders, they present them to the IPA physicians for further review and approval.

Several factors are considered in the process of designing an initiative. In addition to the fundamental criterion that the recommended practice has to be clinically sound, the IPA has determined that any cost management strategy has to be cost-effective for patients as well as the organization. Interventions that result in higher costs for patients are not pursued. The team also considers the extent to which the IPA is financially at risk, how the initiative will dovetail with other clinical activities, what the impact on T-NEMC's public profile might be, and the likelihood of success within the culture of the organization. In addition, the implementation of cost management activities is also sensitive to physician and patient needs. Interventions are focused on "new starts," not on asking physicians to change prescriptions for patients who are already on a drug for which the team has decided to recommend reduced use.

The overall strategy followed by the IPA is a focus on encouraging the use of generic and therapeutic substitution in place of high cost drugs. The overall financial goal has been to keep the rate of rise of drug costs at 10-11% per year, in an environment where the national and local trends have been about 15-20% per year.

The Cost Management Strategies

This section describes the cost management interventions conducted by the IPA.

Clinical Pharmacist Position

The respondents in this study identified establishment of the position of clinical pharmacist as the intervention most critical to the IPA's success in managing its pharmacy costs. It is seen as the

infrastructure upon which the other interventions are built. The position was carefully designed to provide clinical support to physicians and patients as well as to take a lead role in analyses and recommendations regarding cost-effective practices. Respondents reported that cost management interventions would have been less successful had the pharmacist not been fully integrated into clinic activities and housed in an office next to the clinic quarters.

The pharmacist provides individual clinical consultation to physicians, both formally through a Medication Clinic as well as informally through an "open door" policy that makes him available to physicians throughout the day. As part of the clinical team, he provides consultation to patients referred to his Medication Clinic and also provides counseling regarding access to pharmacy assistance programs for referred low-income individuals. He also gives presentations on specific drug and therapeutic topics at physician staff and resident meetings, contributes a column to the IPA's newsletter, and uses email to communicate current information to IPA physicians.

The pharmacist spends approximately 40 - 50% of his time on activities directly related to cost management activities. These activities include database management and analysis, financial analyses, management of the formulary information provided by the various health plans, research and development of recommendations for cost management interventions, and management of current strategies.

Physician Education and Information Activities

Educational and information activities are seen as key to changing prescribing patterns. The pharmacist makes about six presentations each year to the primary care medical staff, two or three each year to specialist staff, and monthly presentations to primary care residents on block rotations to the ambulatory clinics. The cost management topics for these meetings are in line with the priorities set within the IPA and clinic leadership in the process described earlier. Also during these meetings he distributes and discusses the utilization reports from the major health plans. Because the information in these presentations is considered crucial to clinic practice, the pharmacist meets individually with physicians who are unable to attend a presentation and goes over the same data and recommendations.

According to an IPA leader, these presentations are successful because they offer clinically sound, evidence-based recommendations, accompanied by data directly from the IPA's own utilization, and articulated in terms that are easily transferable into practice.²² The presentations are designed to provide sound information that is actionable. Questions and skepticism from physicians are addressed; sometimes the pharmacist has to conduct further data analyses to satisfy physician skepticism. The cost management initiatives are hammered out in this way, through sharing of data and discussion among staff.

These presentations have a significant impact on utilization; some changes have taken place almost directly after a presentation. The IPA has found that intellectual persuasion is critical in this environment where there are no other formal restraints on prescribing, such as, for example, a central pharmacy that could serve to review prescriptions based on institution policies.

²² The clinical drug information and recommendations provided are primarily based on evidence collected from clinical trial data. The sources are usually peer-reviewed medical journals, especially when comparative data between similar drugs is sought; journals frequently used include the New England Journal of Medicine, Journal of the American Medical Association, Annals of Internal Medicine, and Lancet. Another source is the Federal Drug Administration's website, which publishes full transcripts of advisory committee meetings and pre-marketing study data.

Physician education is also conducted through the pharmacist's column in the IPA newsletter, distributed about three times a year and through monthly email updates. The newsletter columns are focused strictly on cost management initiatives and are linked to the presentations. The monthly email updates provide about two pages of information on what is important in the pharmacy area, covering both clinical issues and cost.

Ambulatory Common Drug List (ACDL)

This tool was requested by the IPA physicians in order to have drug information conveniently available for use, in the face of the constant changes taking place in managed care formularies at that time. The clinical pharmacist and clinic leaders reviewed the IPA's drug utilization patterns and created a chart of 17 most used drug categories, within which two to four of the most cost-effective drugs are listed as options.²³ The chart also includes dosage information and a space for comments and is updated annually. While the initial ACDL was developed for primary care physicians, specialist versions were also designed. The ACDL chart is sized to fit easily into a lab jacket pocket, to make it easy for physicians to carry it with them. The ACDL continues to be used by the IPA specialists and their residents, although the Electronic Medical Record, discussed below, replaced it in the primary care clinics in 2001.

Electronic Medical Record (EMR)

While not specifically designed as a pharmacy cost management intervention, the adoption of the Electronic Medical Record in 2001 provided an opportunity to expand on the cost management activities in the clinics because of the system's formulary writing capacity. As a cost management tool, its strengths are that it is convenient, easy to use, and provides information continually to physicians at the point of care.

The clinical pharmacist programs formularies from four major health plans into the EMR once a year and updates the formularies as needed. A standard default formulary that emphasizes generics, established by the IPA, is also available on the device. Physicians get feedback through colorcoded recommendations when they key in the prescription they are considering: green=the drug is on all health plan formularies and is recommended, yellow=this drug is covered, but less costly alternatives exist, red=this drug is either not covered or is covered, but is the highest cost to the patient. The device's note capacity is used to provide customized messages for drug selections. For example, in situations where there is disagreement among formularies or when the health plan recommendation is not the lowest cost, either to the patient or to the IPA, a recommendation for use of another, less expensive, alternative is made. Also, the physician can request a list of lower cost alternatives for most drugs by selecting a "choose alternative" button.

Our respondents reported that, in addition to its value at the point of care, the EMR enables the pharmacist to retrieve and analyze critical information on drug trends, by payer as well as other variables within the practice, which has also had an impact on cost management. The ability to make changes and add notes quickly and easily also enables the pharmacist to respond quickly to new information. The IPA is now exploring electronic prescribing as a next step.

There was some early resistance to adoption of the EMR in general, which was primarily related to concerns about the amount of physician time necessary to complete documentation requirements,

²³ In considering cost-effectiveness, this group considers quality first. A drug is considered cost-effective when it is of equal quality to alternatives and meets the clinical need, is covered by all or most health plans, and when the out-of-pocket cost for the patient is no more than for alternatives.

according to our respondents. This was addressed by limiting its use initially to the problem list and medications for a practice standard. During the start-up period, the clinic triage nurses uploaded data for previously registered clinic patients to the EMRs to ease the transition to this technology.

Other Interventions

The IPA has conducted other activities that are important to how it has pursued its cost management goals. The results of these activities cannot be tracked financially, but are seen as additional contributions to the overall results.

The clinical pharmacist participates in medication coverage drug committees, such as pharmacy and therapeutic committees, of the various health plans in which the IPA participates. While this does not contribute to savings specifically, it gives the IPA a voice in health plan decisions about formulary alternatives and provides an opportunity for collaboration on cost management goals.

Over the years, the IPA has been responsive to changing attitudes among some IPA physicians regarding pharmacy industry detailing. Primary care physicians have become more cognizant of the effect detailing can have on what is prescribed and how it might have an adverse effect on the IPA budget. To address this, the group decided to limit detailer presence in the clinics. Now, physicians can see detailers in their own offices, should they choose, but not in the clinic areas. Physicians have become increasingly aware of the need to understand the specific advantages and disadvantages of "me, too" drugs. For example, as recent entrants in the field they may not have the same track record, may be more expensive, and are not necessarily better. While detailers can provide some information on specific drugs, the physicians see the clinical pharmacist as providing broader, more objective data on specific drugs and the field in general.

In 2002, distribution of drug samples in the primary care clinics was eliminated, which has also contributed to cost management. One reason to eliminate samples was the challenges of maintaining the quality control standards of accrediting organizations such as the Joint Commission for the Accreditation of Healthcare Organizations. While samples made access to medication easier for some low-income patients, the IPA leadership believed that the result was often a prescription for a more expensive drug than necessary. To compensate for the lack of samples to assist low-income patients to meet their needs, the clinical pharmacist provides information and assistance regarding pharmacy assistance programs.

Results of Cost Management Interventions

The T-NEMC IPA monitors the financial success of its interventions by tracking performance on several general measures and by using reports generated by the health plans with which it contracts. It monitors per-member-per-month (PMPM) costs against its contracted budgets with the major health plans. It also compares results against the health plans' network averages when that information is available and also monitors utilization of generic drugs. In addition to the performance data available from the health plans, the clinical pharmacist conducts financial analyses of specific initiatives established by the IPA. As noted earlier, all financial results are presented to the IPA physicians regularly in group meetings, the newsletter column, and printed information The general information given below relates to overall IPA performance, while the data on specific interventions focus on the performance of the primary care physician group, General Medical Associates.

Since 2000, the IPA has met its goals for overall performance. Annual financial performance has come in below health plan budgets, and the IPA's long-term, multi-year goal of keeping drug cost increases to about 10-11% annually has been achieved. The IPA also uses projections of future drug expenditures in ambulatory settings, published every January in the *American Journal of Health-Systems Pharmacy*, as a benchmark for setting a calendar year goal annually. Because of the patient and treatment mix in a medical center setting, the IPA combines projections for clinic and outpatient settings to establish its benchmark for the year.

Measures of utilization of generic drugs and adherence to health plan formularies also show that the IPA's performance has improved since the introduction of cost management strategies. Overall utilization of generic drugs has increased significantly as measured in the reports provided to the IPA by health plans. The IPA out-performed the network average in a major health plan in both 2003 and 2004 after trailing the average in preceding years; its rate increased from 43.6 % in 1999 to 57.1% in 2004. By 2004, the network utilization rate at the major health plan was 55.5% (1.5 percentage points below the IPA rate).

Data comparing the performance of the IPA physicians' adherence to the formulary to the full network of the same health plan show that the IPA's performance improved from 1999, when the network average was about 88.8% and the IPA's performance just slightly below, to surpassing the plan average from 2000 through 2004. In 2004, the IPA's rate was 96.4% while the network average was 95.7%.

The IPA tracked the outcomes of two specific initiatives carried out in the primary care clinics. Both focused on encouraging physicians to make more use of lower cost, equally effective drugs, one brand name and one generic. In one initiative, the use of a less expensive brand of Proton Pump Inhibitor (PPI) increased about 600% in about eighteen months. Prescriptions for PPIs made it a high-volume area and one where use was increasing, accounting for approximately 11% of the IPA drug budget for one major health plan in 2000, and a good target for cost management. At the start of the IPA's initiative to encourage the use of a generic option in 2001, typical retail prices for a 30-day supply of PPIs ranged from \$80 to \$220. From August 2001 to December 2002, prescriptions for the brand name alternative increased from 3.5% of all PPI claims to 24%, while prescriptions for the most popular brand name (Prilosec) decreased from 86% to 64%. The average cost per prescription in 2001 was \$157.17; this was reduced to \$137.38 in 2002, for a savings of about \$19.79 per PPI prescription during the time period.

In the second initiative, use of a generic SSRI antidepressant increased about 30% in two years. SSRI antidepressants are among the most-prescribed drugs in the IPA, accounting for about 8 - 9% of the IPA outpatient drug spending. An initiative that focused on encouraging use of a generic alternative resulted in an increase in utilization from 21% to 28% from April 2003 to May 2005, yielding a cost savings of \$567,000. During 2004 and 2005, two other popular antidepressants also became generic, and the rate of prescription for them has remained stable after an initial decline from 2003 to 2004.

Lessons Learned

The success of these cost management initiatives at the T-NEMC IPA confirms the IPA's theory that when physicians are made aware of drug prices and are persuaded of the availability of clinically sound, lower-cost options, they change their prescribing habits.

Key Success Factors

Our respondents identified several factors that they see as critical to success in future implementations of a similar approach to cost management. They perceive establishment of the clinical pharmacist position as a member of the IPA team to be most important; without this infrastructure, the initiatives would not succeed. Moreover, the role of clinical pharmacist must be integrated into the day-to-day operation, encompassing a consultative component that emphasizes quality of care, which will result in physicians' trust in the pharmacist's judgment and skills, rather than a single focus on cost management. The need for full integration cannot be over-emphasized; our respondents noted that the cost management initiatives launched by the IPA have been less successful among the specialty physicians than those in primary care in part because the specialty clinics are located in another building several blocks away.

The pharmacist's success relies on acceptance of his information by the IPA physicians. Over time the IPA has learned that appropriate selection of topics (as discussed earlier), as well as an agreed-upon approach to implementation of cost management practices, sets the foundation. For example, as noted, the IPA focuses on asking physicians to consider its recommendations for "new starts" of medications, which is much easier and less time-consuming clinically than asking physicians to switch medications for current patients. Also, initiatives have to be cost-effective for patients as well as the IPA. Our respondents noted that they have rejected initiatives that would result in lower costs for the IPA but would increase out of pocket costs for patients. In terms of communication, the IPA has learned that profiling individual physicians by drug utilization for cost management intervention is not as successful as group presentations and individual consultation.

Our respondents suggested that there must be a "start-up" period, during which the pharmacist will learn how best to interact with the practice in terms of communications and intervention implementation. The IPA pharmacist under discussion in this article estimated that he spent the first year developing his role in the clinics and gaining acceptance as a partner.

Replication

Our respondents reported that the approach described here could be transferred to other hospital settings. The major barrier is the cost of the pharmacist's salary, which requires a source of funding. A medical practice would have to have a critical mass of physicians and revenue to afford this expenditure. Risk contracts make the investment viable, while traditional fee-for-service practice does not create a similar incentive. At this IPA, the cost management advantages created by the clinical pharmacist benefit all payers (including, for example, indemnity contracts, managed care, Medicare beneficiaries and non-insured individuals) but are funded only by the managed care contracts.

Since only some large provider groups offer pharmacy residencies that provide exposure to cost management issues and technical training, another potential barrier is pharmacist training. It is, however, feasible to learn the cost management skills needed while on the job, through self-study and educational courses.

Looking to the Future

The separate activities of the T-NEMC cost management strategy have evolved over time. As noted earlier, the Electronic Medical Record mechanism is in many ways an expansion of the Ambulatory Common Drug List in that it provides information and guidance to physicians efficiently and conveniently. Our respondents reported that changing technology makes advances possible; for example, the next step might be progression from the EMR technology to adoption of electronic

prescribing. Also, initiatives around specific drugs changed as generic formulations became available or pricing changed.

Our respondents projected that the demographics, payer mix, and utilization in the ambulatory clinics are unlikely to change in the foreseeable future. While they don't envision the entrance of new "blockbuster" drugs to address common conditions into the market, they see increasing availability of high-cost biotechnology products that are used to treat low-incidence conditions and are beginning to plan how to manage their utilization effectively.

An important trend is the development of pay for performance models of financing from the federal government, health plans, and other payers. This direction toward payment for quality improvements in, for example, disease management and for conditions identified in the Health Plan Employer Data and Information Set (HEDIS[®]) measures, offers many challenges to providers in its requirements for screening, use of national guidelines, and public reporting. In these models, pharmacy costs will be integrated with other healthcare costs, and success is contingent on integration and synergy, not on performance within separate budgets.

Our respondents suggested that their experience in managing pharmacy costs has prepared them to continue to focus on cost-effectiveness as part of any financing model they undertake. The development of data collection and analysis systems and team management will be strengths in any future scenario.

2.2 Provider Service Network Case Study

Description of the Organization

Provider Service Network (PSN) was established in 1997 by the CareGroup Healthcare System, a large hospital/health care provider, in Boston, MA, to furnish contracting and medical management services to the hospitals and associations of physicians practicing in its recently-developed network of six tertiary and community hospitals in order to successfully manage risk contracts from payers. PSN operated as a wholly owned subsidiary of CareGroup until 2005, when it became an independent firm, MedVentive, which now provides services to the national hospital, provider, employer, and payer markets. This case study focuses on the organization's activities while it was, as PSN, working primarily with the CareGroup system. As a management services subsidiary, PSN expanded its services slightly beyond the founding CareGroup to include another healthcare system and several community-based physician group practices. It provided services to about 2,600 physicians who see approximately one million patients annually. Over 300,000 lives were covered through its managed care risk contracts with the three major payers in the Boston area.

The general development of PSN was strongly influenced by the structure of its managed care risk contracts. PSN focused on improved financial and clinical outcomes through intensive, data-driven management of health services under these contracts. PSN developed and managed a comprehensive utilization and financial reporting system for all healthcare services provided by physicians in the network, based on a data warehouse composed of eligibility data as well as medical and pharmacy claims data sent monthly to PSN by the three managed care plans.

Motivation for the Development of Cost Management Programs

In the 1990's, managed care organizations in Massachusetts used risk contracting with local providers as a means to engage providers in cost management. The expansion in the late 1990's to incorporate outpatient pharmacy benefits into risk-sharing agreements was a natural extension of this policy. Through its analysis of the potential contracts, PSN leaders recognized that the arrangements offered enough financial opportunity to support development of a pharmacy management program. In 1998, PSN launched its Pharmacy Risk Management Program to help physicians in the network manage the pharmacy budgets that were incorporated into the network's risk contracts. This program focused on pharmacy costs related to ambulatory services.

The Decision-Making Process and the Choice of Strategies

The PSN approach to decision-making about the choice of strategies is based on several principles. The central tenet is that the individual physicians retain autonomy for their own decisions. To achieve acceptance among physicians meant the program had to be credible and evidence-based, and cost management had to be secondary to the promotion and maintenance of quality of care. The process developed from this approach led to establishment of an infrastructure designed to promote participation, open discussion, and local accountability.

A pharmacy and therapeutics committee (P&T) consisting of physician leaders from every participating medical group, either sitting on the committee itself or one of the ten specialty subcommittees and PSN pharmacists, develops and maintains a formulary and approves pharmacy management guidelines. Two-thirds of the committee membership is physicians and one-third pharmacists. The P&T Committee is one means of balancing cost and quality in that the principles governing its deliberations are patient safety and efficacy first, and then cost. Another factor that focuses attention on quality first is that PSN is responsible for supporting the success of risk contracts that address all health services, so there is no financial incentive to deliver high savings without regard for quality in one area of service delivery because the rest of medical care and clinical outcomes are also at risk.

The PSN management recognized that provision of pharmacy clinical utilization reports would be insufficient to encourage physician participation in the interventions, since most physicians at the time were not aware of the different prices of medications and often relied on outside information, such as from drug manufacturers, for research information about pharmaceuticals. To address these conditions within a risk-contracting environment, PSN hired pharmacists with expertise in managed care clinical and financial issues to provide both clinical and cost management support to all medical groups. The creation of a staff of pharmacists was seen as an opportunity to establish managed care pharmacy expertise for the first time on the provider side of the relationships with managed care plans.

To complete the infrastructure within each risk unit, or independent practice association, primary care physicians were divided into groups or "pods" of six to twelve, with a local pod leader accountable for pod performance. The pods consist of physicians who may practice together or may be linked in some other way. These physicians meet regularly to discuss the recommendations from the P&T Committee and to review performance reports and other pharmacy initiatives at the site.

The Cost Management Strategies

This section describes the cost management strategies PSN has implemented in its work with the healthcare system.

Universal Drug Formulary

The PSN pharmacy and therapeutics committee established its Universal formulary in 1998, in an evidence-based process²⁴ that was designed to select the most effective and most cost-efficient drugs to be recommended for use through the health system. It started with just the top ten classes of drugs, but the health system physicians asked for more, until it reached the 100 page spiral-bound document it is now.

A few critical factors drove this development. The health plans with which the system contracted each had their own formularies, based on the acquisition costs and other business practices of that particular payer, leading to varying recommendations for drug use. PSN and the health system leaders recognized, however, that most physicians do not change their prescribing practices in

²⁴ A PSN pharmacist is assigned to lead the review. This professional conducts a literature review of peer-reviewed journal articles, the drug monograph, and the Academy of Managed Care Pharmacists dossier, and meets with the science liaison or representative of the manufacturer to collect that organization's information. The pharmacist asks local expert physicians within the network to review his draft drug monograph and incorporates their comments into the final document. New drugs are looked at within the context of the appropriate class. The document, which is sent to members well before the meeting, is presented to the P&T Committee for review and decision. Local experts in the particular area of medicine participate in the decision-making process.

response to their patients' health insurance coverage. Multiple formularies were confusing and many physicians stopped paying attention to any of them.

Furthermore, cost accounting for drugs under the risk contracts for each insurer was based on average wholesale price with an overall credit for health plan rebates. Rebate credits s were not specific to individual physician or network drug selection, but rather were allocated back as an average credit across all of a health plan's providers. Given that PSN was not likely to drive overall rebate dollars for any single health plan, prescribing choices based on average wholesale price were more likely to generate surplus for physicians under its risk contracts than choices based on the specific rebates for each health plan. This meant that PSN could use Average Wholesale Price as a single cost basis for prescribing across all health plans. This enabled the P & T Committee to develop a single formulary for use across all payers that would still optimize performance in each risk contract. PSN's financial incentives were to manage to the lowest average wholesale price through the development and use of their own all payer formulary rather than drive specific rebates through the use of specific health plan or pharmacy benefit manager formularies.

Respondents reported that once the P & T Committee became aware that they could use a consistent cost basis for decision making across all health plans, the development of an all payer formulary was simplified. The process would have been far more complex if the PSN had to always present different options for each health plan because of variations in rebates by payer. The committee did recognize that there would need to be some variations by payer, however, because of variations in co-payments and certain excluded drugs, but found that these exceptions were manageable. PSN supplies utilization data from pharmacy claims for all payers uniformly priced at Average Wholesale Price to the P& T Committee for its decision-making.

Another criterion the P & T committee uses in composing the formulary is that the drug selection has to be cost-effective for patients as well as for the health system. So, if a particular drug has a higher co-payment for patients in one of the managed care plans, the committee will add an alternative choice for physicians to select.

An additional advantage to the Universal formulary is that the AWP does not change frequently, while health plan formularies do change, to some extent because of evolving contracts for rebates. Physicians get very frustrated with this sort of change, according to the respondents. The PSN formulary only changes when absolutely necessary and the committee makes a conscious effort to select drugs that are likely to remain on the list for a long time. The committee only chooses drugs with wide coverage among the plans, that are good financially for patients, and that are unlikely to change because something in the market changes. The respondents reported that the final formulary contains the top 80-90% of most frequently prescribed drugs.

The printed document, a spiral-bound notebook that fits easily into a lab coat pocket, was designed to be physician-friendly. Co-payment and coverage information on Medicaid and another local managed care plan were added because physicians requested that information be close at hand as well, even though the network did not have a financial incentive to manage pharmacy cost under those contracts. PSN also added other information to the printed formulary document that facilitates its use, such as most common dose, cost per month based on AWP, clinical guidelines, and presentation of health plan co-payment structures and pre-authorization requirements to reduce "hassle factors" and increase efficiency. PSN established multiple modes of access to the material, including wall posters, access through the system's intranet, and capacity to be downloaded to a PDA. The printed book itself is updated annually, in order to remain current. Interim paper-based updates are sent out four times a year.

The rollout process of the PSN formulary emphasized to physicians that the Universal formulary was established by their colleagues as the most cost effective and highest quality guide to prescribing across all health plans and clinical categories. Physicians were told they did not need to look specifically to individual health plan formularies any more and that use of the PSN formulary actually optimized their potential financial return under all network risk contracts. Because it is based on AWP, the PSN formulary is also the most cost-effective option for patients who are not covered by insurer pharmacy benefits, such as Medicare beneficiaries and others who pay out-of-pocket. Since Medicare makes up about half of the average internist's panel, this was an additional incentive for physician adoption.

Reporting and Feedback

PSN designed a suite of 30 standardized pharmacy utilization and financial reports to support the Pharmacy Program. These reports aid in monitoring both cost and quality management. The data in the reports comes from the PSN data warehouse, which includes, as noted earlier, eligibility data and medical and pharmacy claims from the three major health plans, updated monthly. Aggregation across all payers yields more cases than those generated by the individual health plans, making the PSN reports more reliable, statistically, as a snapshot of prescribing patterns, than the individual health plan reports. Outliers are discarded to increase reliability. The reports compare performance by each risk unit to the system average and to the system's best performer, thereby encouraging healthy intra-organizational competition among the groups.

The reporting is adjusted for acuity, using a methodology for risk adjustment developed with DxCG, Inc., incorporating Diagnostic Cost Group models into PCP profiles. Without this, most physicians attribute high utilization to the fact that their patients are sicker. The ability to actually determine which physician's patients are sicker, and which are not, was a critical step in achieving success with the entire reporting system. Without physician buy-in to the methodology to adjust for level of illness, the reports would lack the level of credibility needed to change physician practice. Orientations to explain and support the validity of the risk adjustment model were presented to all medical groups by PSN staff in conjunction with the model's developers. Physicians who missed these meetings were asked to watch a video of the discussion.

The reports are available through a secure web-based format to physicians, administrators, pharmacists and others who need access in the health system. Reports have appropriate drill-down capacities, so users can work with detailed information as well as aggregated. The PSN clinical pharmacists are responsible for ensuring that the physicians in the medical groups understand and make use of the utilization and financial data, using whatever methods the particular groups select for this communication. They make presentations to small and large groups, meet individually or in pods for discussion, and target physicians with specific prescribing patterns. The respondents noted that reporting is key to managing compliance with the formulary and with other recommended practices. Using reports, the pharmacists can drill down to identify actionable issues with the physicians.

After the reporting system was developed, PSN staff were able to tell physicians that they needed to pay attention only to the PSN reports, rather than the multiple reports available from the health plans. Respondents noted that many physicians now do not even bother to open the health plan reports. Single reporting from PSN with higher numbers of patients per physician, a uniform cost basis and risk adjustment is far more meaningful to the physicians then health plan reports. Physicians also view single reporting as a convenience.

Counter-detailing

The PSN Pharmacy risk management program includes a staff of seven pharmacists who are assigned to the member IPAs and medical groups to provide consultation and physician education. Since success of the program depends on acceptance by physicians, the goal is to fully integrate these staff into the organizations so that the individual pharmacist is viewed as part of the medical group to which he is assigned. Pharmacists spend about 80% of their time with the client organizations and, in order to maintain that stability, are rarely re-assigned from one group to another. This allows the pharmacist to focus on the unique challenges of each group and modify PSN programs as needed to make them work for each customer.

The pharmacists serve as the primary drug information resource for physicians in the medical groups, not only for cost management issues. They offer education about new and current drugs, distribute and interpret the standardized pharmacy reports, assist in drug utilization review efforts and the development of local programs around pharmacy issues, and are involved with implementation of the PRISM[®] (see below) therapeutic interchange program. The methods they use to provide education and consultation are customized to the group's needs and preferences. For example, a pharmacist might meet with a group or a pod for an update, target the top twenty physicians who are outliers on reports, or go on one-to-one appointments. The ratio of pharmacists to physicians is variable, depending on what level of interaction the medical group wants, but might be estimated to be one to 500 physicians, with most attention to primary care physicians.

As mentioned earlier, PSN has incorporated a number of national guidelines into its formulary handbook and as a subject for physician education and consultation. PSN highlights the pharmacy recommendations in the guidelines that are relevant to its formulary and provides data to physicians about their use and results. This is part of physician education efforts and is designed to provide extensive information on drugs that are not highlighted or promoted by drug manufacturers. A respondent noted that PSN does not monitor or try to demand compliance with these guidelines, because most physicians are already familiar with them and some like to refine guidelines for themselves. This fits in with the PSN approach of providing data and explanations, but leaving the final clinical decisions up to the physicians.

The pharmacy program produces various materials that foster communication of the guidelines and recommendations, such as posters, handouts, small wall charts, and tear-off sheets that can be placed in patient waiting rooms. The materials that physicians might want to display or give to their patients are customized with the physician or medical group name.

Automated Therapeutic Interchange Program

PSN developed its automated therapeutic interchange program, PRISM[®], in 2000. Earlier, staff manually downloaded pharmacy claims that seemed appropriate for interchange monthly onto a compact disc and converted the file into a format that physicians could read more easily. Because that activity was tedious and time-consuming, PSN staff were limited to identifying a few interchange opportunities at a time. To improve this unwieldy system, PSN, in conjunction with a consultant, developed an automated filtering program through which all pharmacy claims are run. While the focus for PRISM[®] is the PSN Universal formulary, the filter program rules can be modified to work with any list of drugs.

The filter program identifies potential interchanges, including brand-to-generic or between brandname drugs, pill-splitting, and dosage consolidation. To streamline the program and make it userfriendly, PRISM[®] incorporates data that would be helpful to a physician's decision making, such as a history of all drugs the patient has been prescribed. Also, it excludes situations where a physician is unlikely to consider an interchange, such as when a drug that would have been recommended as an interchange has already been tried. The program also fully discloses the actual cost results of any recommendation. Additionally, the program allows its users to track the final outcome of each specific interchange thereby preventing future duplicate interchanges for physicians to have to review as well as preventing unnecessary patient disruptions.

The pharmacists assigned to medical groups can customize the reports according to the needs and priorities of each particular group. Information can be organized by a variety of categories, such as therapeutic category, specific interchanges, or potential cost savings, depending on what the group's priorities are. There are always more interchange opportunities than can be implemented, according to a respondent.

To make the intervention physician-friendly, PSN also developed materials that support physicians' communications with patients about interchange possibilities, including customized letters on physician letterhead and pre-printed prescription blanks for the recommendations.

Example of an Intervention at an Individual IPA

One IPA that participates in the pharmacy management program through PSN was included in the case study. This IPA takes part in the PSN cost management initiatives described above and also undertakes activities that are relevant to its individual environment. One recent local initiative has been to promote "pill-splitting" for a brand-name cholesterol-lowering drug among a group of patients for whom this drug is the best choice. This intervention takes advantage of the fact that the price per tablet does not significantly differ according to dosage strength. By taking advantage of this pricing, costs for the brand-name drug could be reduced almost to the price of the class's generic option.²⁵ Several studies have supported this approach, using laboratory testing to show that there is no effect on quality of care.

While not every medication can be split without potentially negative clinical outcomes, the medication in this case, atorvastatin (Lipitor), and selection of patients for the intervention indicated that it would be safe clinically.²⁶ The tablets are easily split, even without a pill splitter, and atorvastatin has a long half-life, so a precise daily dose is not critical. Also, the typical patient in this program is a middle-aged man being treated for primary dislipidemia; patients with physical impairments are not included, and physicians could exclude any other patients they believed would have difficulty with the program. Also, the clinical endpoint, LDL levels, is measurable. To date, no patient in the program has experienced an unexplained increase in serum LDL.

The PSN pharmacist and IPA leaders reviewed utilization data, used the PRISM[®] program to identify specific patients who met the criteria, and communicated the quality evidence to physicians. As a result, about 25% of all eligible patients have converted to prescriptions for the 20 milligram tablets and are splitting the tablets for daily 10 milligram doses. This conversion has saved approximately \$200,000 within the group's health plan budgets; if patients also had a

²⁵ A respondent observed that for some classes of drugs, the "pill-splitting" method can actually reduce costs to below that of the class's generic options.

²⁶ With the exception of Lipitor half-tabs, all other half-tab interventions conducted by PSN are for tablets that are scored and thus designed to be safely cut in half. A respondent noted that Lipitor tablets are oblong caplet-type tablets that just happen to cut very easily by hand.

financial incentive to convert, such as a lowered co-payment, the IPA and pharmacist estimate that as many as 50% of eligible patients would follow this approach.²⁷

Other Interventions

The leaders of the PSN pharmacy program as well as representatives from the member IPAs participate in the P&T Committees of the managed care plans with which the health system contracts and also sit on the P&T Committees of most of the hospitals in the system's network. Participation in managed care plan groups gives PSN and the IPAs a voice in decision-making and also provides information about possible future actions by the plans.

PSN leaders see membership on the hospital committees as a means to facilitate the extension of the Universal formulary into the hospital setting when appropriate, for example, influencing the choices of medications provided to patients at discharge. The less divergence between hospital and outpatient protocols, the more success is likely in attaining compliance with the PSN formulary. This is another step in aligning the environment to facilitate drug management efforts. One problem encountered in this area is that the hospitals and out-patient settings differ in terms of the acquisition cost for drugs, so that what might be cost-efficient for hospitals is not necessarily so in the out-patient setting.

Results of Cost Management Interventions

PSN monitors the overall success of its interventions by tracking financial performance against national drug trends, per-member per-month (PMPM) costs compared to managed care budgets, adherence to the Universal formulary, and therapeutic interchange completion rates as well as actual savings attributed to interchanges. Exhibit 1 below compares the PSN growth trend to a national benchmark from 1999 through 2004 and also shows the savings in pharmacy costs in the managed care risk contracts achieved by that performance. As can be seen, the trend in per-member per-year pharmacy costs within PSN and the healthcare network it supports has been well below the national benchmark. The PSN data in this table show the average trend across the network; however, some medical groups, or risk units, performed better than the average, and some worse. Cumulative savings across the network, compared to budgeted expenditures projected at the trend levels, total about \$76 million.

Year	PSN Growth	National	System-wide
	Trend	Growth Trend*	Savings
1999	9.8%	17.4%	\$6.7 million
2000	7.8%	16.2%	\$16.0 million
2001	14.1%	17.0%	\$19.5 million
2002	10.3%	18.5%	\$9.0 million
2003	5.8%	15.5%	\$14.9 million
2004	8.9%	14.0%	\$10.3 million
Total			\$76.4 million

Exhibit 1: Provider Service Network Pharmacy Cost Savings 1999 – 2004

*National Trending reference: Express Scripts Drug Trend Report

²⁷ The *Hartford Courant*, Hartford, CT, reported that ConnectiCare has reduced co-payment for members who are following a similar regime (June 9, 2005, ConnectiCare Introduces Pill-Splitting Program).

PSN respondents also reported that compliance with the Universal formulary increased from 63.0% in 1998 to 87.6% in December 2004. This increase reflects both improved attention to the formulary by network physicians, the success of PRISM[®] and a gradual expansion of the formulary to include commonly prescribed drugs. Adherence to the formulary contributes to the trends shown above.

Exhibit 2 below shows the cost savings associated with generic and therapeutic interchanges accomplished through use of the program. From its inception to the present, the savings through this intervention total about \$8 million in savings.

Year	Prism Interchange Savings
2001	\$1,793,442
2002	\$1,749,323
2003	\$1,360,198
2004	\$1,681,968
2005YTD	<u>\$1.504.974</u>
Total savings	\$8,089,905

Exhibit 2: PRISM[®] Network - Wide Cost Savings 2001 – 2005*

*Savings are calculated assuming use of the medication for 12 months. Savings from prescriptions used for more than 12 months are not included in savings for the following year(s).

Lessons Learned

Key Success Factors

The respondents identified several factors that they see as critical to the success they have achieved. Acceptance by the network physicians of the aims and activities of the pharmacy program is the most critical factor. To achieve this acceptance, the fundamental goals have to include both improving quality and the efficiency of prescribing. The program and staff have to be clinically credible and supportive of physicians' primary objectives. This sets a high standard for development of any specific activity and for the details of its design.

The emphasis on local accountability was also critical to success, and is a parallel to supporting physician autonomy in decision-making. Success in the pharmacy management program is the result of collaboration between the pharmacy expertise, organizational processes, and technical services provided by PSN and individual IPA leadership. Another critical factor is the alignment of financial incentives to encourage participation; the program makes sense to participants because the financial results are in concert with the other principles. Respondents noted, however, that the incentives for patients are not similarly aligned. If physicians knew that co-payments for patients would be reduced for their participation in interchange programs, these programs would be even more successful.

Inclusion of all medical groups in the P&T Committee sets the tone for a collaborative pooling of expertise. Design of the pod structure brings accountability to the individual level. The committee, access to on-site pharmacy expertise through an assigned pharmacist, and the pod organization create an infrastructure that is designed to maximize information transparency and individual participation in the pharmacy management process.

Respondents reported that the quality of the data and reporting is also a key factor. Since information is the common basis for discussion regarding goals and performance, data has to be accurate and presented in a clear format. Conclusions and recommendations have to be actionable.

The establishment of the Universal formulary is an example of creating an effective program that was more efficient than alternatives. Moreover, the Universal formulary corrected the "misalignment of incentives" that arose from adherence to multiple managed care formularies.

An overall goal is to make it as easy as possible for physicians to participate in the interventions. Viewed as a service and support to physicians, the program developed a partnership. The extent to which the PRISM[®] program accurately targets realistic therapeutic interchange possibilities is an example of a service that supports network physicians. In general, PSN staff regularly include features that "add value" for physicians participating in the program. Materials and documents are carefully designed to be easy-to-use, attractive, and to provide information beyond what might be expected from the health plans.

Respondents commented that the qualities of the pharmacist team are also critical. PSN recruits individuals who can quickly establish themselves as experts with physicians, can build credibility and rapport, are well-educated, and can present data and information objectively in the fashion that the different medical groups want it presented. The program pharmacists are all licensed and most have additional advanced degrees, such as a Master's degree in Business Administration or in Health Professions. Individuals who are more recent graduates have attended the now standard six-year programs and have doctorates in pharmacy. Respondents noted that the program maintains a staffing ratio of one pharmacist to about 500 physicians.

Critical Success Factors from an IPA Perspective

Leaders of one IPA with which PSN works participated in this case study. This IPA is considered to be one of the most successful among the health system network in management of risk contracts.

IPA leaders reported that the PSN cost management interventions have been successfully implemented within their organization. IPA leaders reported that the organization has managed to keep its annual incremental increases for the drug trend to about half that of the national average. These respondents stressed that the professional partnership and collaboration between PSN and the IPA was integral to that success. The IPA had developed an organizational cohesiveness among its members during many years of working together that facilitated the development and implementation of the pharmacy management program at its site. One basis for the cohesiveness is agreement that an important role for the IPA's administrative organization is to promote activities that alleviate the administrative burdens physicians face in practicing in the managed care environment.

Also, the IPA leadership has strong views on the importance of management of pharmacy costs as a priority, given the dramatic increases in these expenditures in recent years. For this IPA, pharmacy costs are now equal to costs associated with hospital care; recognizing this, an orientation program given to new physicians, including interns and residents, includes a "Managed Care 101"

component that includes the importance of addressing pharmacy issues. Nevertheless, even with these advantages of commitment and focus, it took time and effort to build trust and credibility among the membership about the specific pharmacy program activities.

These leaders see the P & T Committee as an extremely valuable component within the pharmacy management program because it expands the scope of expertise available to any one IPA within the system in terms of discussion, professional review of evidence, and ultimate consensus on recommendations. The P & T Committee is recognized as a panel of locally known experts, whose opinions and judgments on other matters are already respected within the health system, thus giving the Committee's conclusions and recommendations important credibility among IPA physicians.

IPA representatives observed that, initially, many physicians challenged the committee recommendations, preferring to depend on their own professional experience regarding drug selection rather than on the Committee's recommendations. To some extent, the PSN P&T Committee and the concept of the Universal formulary were seen as another regulatory organization trying to impose itself on physician decision-making. Over time, however, as the recommendations have proven to be clinically sound, and the group has been able to meet its financial objectives regarding the risk contracts, IPA physicians have come to trust the Committee and the Universal formulary.

Respondents reported that other aspects of the PSN interventions are integral to their capacity to meet their objectives. The pod structure has been a major key to their success. This structure streamlines the flow of pharmacy information to busy physicians, providing information more efficiently than alternatives, such as distribution of printed reports or newsletter articles, would. An IPA leader chairs a monthly meeting with pod leaders to review information from the P&T Committee, to address clinical as well as cost issues on the agenda, and to go over the PSN-developed reports. The PSN pharmacist is part of the process and attends both the leaders' meeting and the individual pod monthly meetings as well as meeting with individual physicians as needed.

The PSN reports are seen as critical to management of the risk contracts. The IPA leadership does not review utilization reports generated by the managed care plans in the pod process and has recommended to its physicians that they ignore these reports, believing that the health plan reports are of little value in assisting physicians to meet the goals specified in the risk contracts. Respondents also commented that the PSN data system is used for other clinical interventions as well; for example, recently, when certain drugs were removed from the market suddenly, the IPA could use warehoused data to identify and contact every patient in the plan with those prescriptions.

Because the focus of this IPA is on affecting physician prescribing practices, with the goal of supporting physicians to make appropriate initial prescription decisions, the PRISM[®] program is viewed as a monitoring device which makes it possible to carry out corrective action. Respondents cited the effectiveness of the PRISM[®] program in terms of data quality and the ease with which physicians can complete an intervention, using the pre-printed prescription form and an explanatory letter to the patient. Within this IPA, physicians see mention on the PRISM[®] listings as reminders about pharmacy priorities and tend to modify their practices in response. This effect probably generates additional savings related to PRISM beyond specific patient substitutions directly from the system.

Replication

Although the concepts of the PSN interventions are applicable within many medical environments that are involved with risk contracts or similar incentive structures, the respondents called attention

to two issues on particular. As mentioned earlier, upfront investment is required; an organization considering this approach has to plan for a start-up and development period. Also, access to historical claims data was very important for PSN in its development of its Universal formulary and in the PRISM[®] program. Respondents noted that during development of the formulary, information about prescribing patterns within the network and at different partner organizations influenced decision-making. There were times when the P & T Committee would decide not to exclude a drug from the formulary because there was already so much use throughout the network that exclusion would be extremely disruptive. Without utilization information, the Committee deliberations would have been less efficient, in that time would have been spent discussing literature and evidence about drugs that no-one uses or excluding drugs where there is already high use. It is critical to the formulary development process that the committee understands existing utilization patterns and the implications of their recommendations.

Access to historical claims should be established as a provision in contracts with payers; for commercial plans, members sign releases when they enroll that allow data to be shared for management purposes.

Looking to the future

The PSN managers reported that they expect their strategies to continue to be applicable. However, they noted that there is a national trend among commercial payers to be less interested in involving providers in managing pharmacy costs. Rather than creating incentives for physicians to manage these areas, commercial payers are moving toward consumer incentives, some of which result in cost-shifting. While consumer incentives are effective, the respondents questioned how much further this method could go before the costs become too much for some individuals, resulting in unequal access to care, or before employer groups find the requirements on employees disruptive. Another issue is how these incentives affect quality of care.

Respondents also observed that it is not yet known how the inclusion of Medicare Part D in health plans will affect pharmacy cost management in that market. At this point in the Part D implementation, physicians and medical groups do not appear to fully understand the implications of the program and what opportunities for participation in cost management will be created.

2.3 Kaiser Permanente Medical Care Program Case Study

Description of the Organization

Kaiser Foundation Health Plan, Inc. is a nonprofit health plan, with headquarters in Oakland, California. The Health Plan serves the health care needs of members in nine states and Washington, D.C., and has a national membership of about eight million. The Health Plan owns and operates Kaiser Foundation Hospitals as well as its own pharmacies and warehouses. The Plan purchases drugs directly from manufacturers, using its market power to negotiate prices.

In California, the Health Plan is structured as a group-model HMO. It contracts with two physician organizations, the Permanente Medical Group Inc., in northern California, and the Southern California Permanente Medical Group, in the southern portion of the state, totaling about 11,000 physicians, to provide health care services to six million members. About thirty medical centers participate in the program. The plan's name in California reflects the partnership between the health plan and the medical groups.

The Kaiser Foundation Health Plan provides to its members pharmacy benefit coverage that is equivalent to benefits offered by its competitors. This case study describes drug management strategies that originated with the Kaiser Foundation Health Plan's California program and the two medical groups. Since that time, these strategies have been adopted throughout the Kaiser system, but this case study focuses on the activities in California.

Motivation for the Development of Cost Management Programs

As a managed care plan that must compete with others for membership, the Kaiser Foundation Health Plan has focused on cost-effectiveness for many years. The plan's formulary of preferred drugs reflects that principle. In the 1970's and 1980's, plan administrators encouraged the use of generic drugs whenever possible; later, the Plan worked with the medical groups to increase therapeutic substitutions as well. In 1999, the pharmacist and physician leadership recognized that trends in pharmaceutical markets, such as the proliferation of medications that compete for massmarket shares and the growing use of mass advertising by manufacturers, were affecting drug utilization in the plan. Although the plan's generic and therapeutic substitution efforts were continuing to be successful and would be maintained, a different approach was needed to address this new challenge.

This new strategy involves focused efforts by the program to use an evidence-based approach to drug use management with the goals of improving clinical practice and outcomes in conjunction with managing utilization. The evidence-based approach had already been adopted by clinicians in the Permanente Medical Groups for aspects of their clinical practices. Applying the principles of evidence-based medicine to pharmaceuticals was an extension of that approach. The aim of this strategy is to establish information, tools, and techniques that enable physicians to select the right drug for an individual or no drug, if the clinical evidence suggests that to be the most efficacious approach, at the right time.²⁸

²⁸ The lead reviewer assesses information from peer-reviewed literature, guidelines from the specialty medical societies, The Medical Letter on Drugs and Therapeutics, and similar sources for presentation to the committee. Local experts

Although the medical group physicians had always been partners with the pharmacy group in development of the health plan's formulary and in the activities of the P & T Committee, the new strategy further cemented these working relationships. The focus on issues around guidelines for clinical management, choices among multiple drugs and treatments, and decision-making regarding the interpretation of clinical evidence could only be guided by clinical experts. The goal was to establish a systematic approach that promotes appropriate and individualized treatment for every patient. A fundamental principle underlying this process is preservation of the physicians' role to make the final decisions for their patients.

The fact that Kaiser Foundation Health Plan, Inc. purchases its drugs directly from manufacturers gives it unusual power to manage drug costs, since approximately 75 to 80% of the cost of a pharmacy benefit, in most health plans, is the actual acquisition cost of the drugs. Drug cost management at Kaiser requires that broad clinical care decisions regarding drug utilization then be coordinated with the supply chain, including acquisition, inventory, and distribution, to achieve successful implementations. The plan's ability to make multi-year commitments to high volumes of the drugs it deems most effective for large numbers of people gives it substantial market power in negotiations with manufacturers. The financial value of the plan's utilization interventions is enhanced because of the effects on acquisition costs.

The Decision-Making Process and the Choice of Strategies

An infrastructure to implement the new strategy was established first in each of the two California regions in 1999; the leadership group was called the Drug Utilization Action Team (DUAT) in the southern region and the Drug Utilization Group (DRUG) in the north. By 2000, all medical centers in the two regions had similar committees. The role of the committees is to establish regional or medical center priorities, select initiatives, and oversee and support implementation to achieve results. These committees are made up of physicians who are medical directors, chiefs of specialty services, members of the regional P & T Committee, and pharmacy operations leaders.

A drug use management team, responsible to both California regions, identifies potential initiatives through analysis of utilization data, assessment of new clinical evidence from literature, or other changes to the environment, such as announcements that a generic form of a drug will be introduced, or a new drug is entering the market. Wide variations in prescribing performance and high cost implications are two of the criteria used for selecting potential initiatives. This team presents the proposals, along with monitoring methods and projected results, to the DUAT and DRUG groups. Although cost implications are considered in identification of proposed initiatives, the assessment and implementation processes deemphasize the financial issues and emphasize the clinical evidence and clinical appropriateness.

The Cost Management Strategies

This section describes some of the methods that the drug use management program uses to moderate drug costs. Approximately ten to twelve initiatives targeting specific populations of patients are conducted each year; with three or four ongoing at any one time. Respondents reported that, generally, one project is in the planning stage, two are in full implementation, and a fourth is

in the particular medical area participate in the review and will often write articles on the subject to be distributed to their colleagues.

winding down. Limiting the number of concurrent initiatives is a key aspect of the program's implementation strategy.

A staff of about thirty drug education coordinators, all trained pharmacists, assists in various implementation tasks depending on the initiative, serves as an expert resource for education and consultation to physicians, and also provides counter-detailing. A drug education coordinator is assigned to every medical center, with the goal of being fully integrated into the center's medical team. These staff are critical to the drug management efforts because they are the "face" of the pharmacy aspects of the program at the medical centers.

The intended financial results of the Kaiser strategy around drug use management can be expressed in three ways. Some initiatives result in *cost savings*, where measurable changes in drug costs can be tracked year after year. If, during the first year of a program, comparable costs are down, the differences are defined as savings. A second category is *cost avoidance*, where trends in spending are halted or reversed. For example, an initiative that has reduced use of antibiotics for cold and flu by 30% over the past five years is deemed avoidance. The third category is *maintenance*, or staying at the current and appropriate utilization; for example, continuing to emphasize use of generic drugs in order to keep the issue current in physician decision-making. Since the launch of the program, a variety of initiatives have been conducted. Several types are described in the following sections.

Staying with Proven Therapies

A respondent reported that maintaining the use of an existing drug that has been proven to be the highest quality therapy is frequently the most cost-effective approach. In many drug categories, new entrants into the market are more expensive than older medications. For example, one drug use management initiative involved assessment and recommendation of the antidepressant fluoxetine, which is the generic form of the brand-name drug Prozac. Just before the generic fluoxetine became available, according to a respondent, Prozac had about 30% of the total national market of selective serotonin reuptake inhibitors (SSRI) antidepressants. In recent years many more antidepressants have entered the market and have been the subjects of intense advertising. The program has continued to assess alternatives, but has found fluoxetine to be generally most effective. The result is that, at the health plan, utilization of the generic is now at 60% of all prescriptions for SSRIs and 75% of all new prescriptions for the SSRIs, higher than the brand-name equivalent at its peak. In the national healthcare sector, however, the generic fluoxetine comprises just 10% share of the market, a much lower share now than the brand-name form had several years ago.

A second example involves treatment of hypertension. The drug management program leaders report that the literature has strongly recommended that a class of generic medications, thiazide diuretics, are among the best treatments for hypertension and should probably be the first line treatment for most patients without complicating conditions. Many patients require a combination of thiazide diuretic and ACE inhibitor medications; failure to improve on these medications can result in use of more expensive drugs in the Angiotensin II Receptor Blockers (ARBs) class.

The program leaders recognized that failure to comply with initial medication regimes was often the root cause of prescriptions for the more expensive drugs. To improve compliance, the program recommended use of a generic medication that combines a thiazide diuretic and an ACE inhibitor in a single tablet, thereby avoiding some difficulties patients have around compliance, for example, forgetting which and how many pills they have taken. The recommendation was also positive for patients, since they are charged just one co-payment for the medication, compared to two co-payments for the non-combined drugs. The number of patients treated with this combination has

grown from 10,000 in early 2004 to 40,000 in July 2005. The plan's HEDIS[®] scores on hypertension control²⁹ have improved by 9.5 percentage points in two years.

The program managers expect that by increasing hypertension control through early intervention, the plan physicians will reduce use of ARBs. A similar objective, to decrease the use of ARBs in patients who have never been prescribed ACE inhibitors and thiazide diuretics, is also being pursued in 2005: those prescriptions were reduced from 16.6% among new patients in the first quarter of the year to 13.4% in the second quarter. A program manager reported that the savings achieved by increasing appropriate use of thiazide diuretic and ACE inhibitor medications will be directed toward further development of those programs as well as better treatment of patients who require ARB medication.

In these and other similar situations, the drug program uses an extensive communication campaign to remind physicians about the value of these generic or older lower-cost brand-name drugs, since they are marketed little, if at all, by manufacturers. Kaiser maximizes the financial benefits of this situation through its purchasing capacity. For example, expecting that the health plan will be committed to fluoxetine for several years, Kaiser can enter into multi-year contracts to purchase high volumes of the drug, thereby using its market power to reduce the purchase price.

Another reason to stay with proven therapies arises from clinical concerns. A respondent observed that it can take several months for good academic peer review literature, which is critically important in the assessment process, to be available to the healthcare community after a new drug is introduced. Material available from manufacturers' clinical trials may not discuss that trials were limited to specific populations and whether the drug has the same effects on all others is not known. In such a situation, in a population the size of Kaiser's membership, the health plan is likely to see the side effects that were not discovered in clinical trials that focused on more limited populations. Unless a new drug addresses life threatening illnesses, like cancer or AIDS, the Kaiser policy is to be more circumspect with respect to adoption, measuring the interventions and identifying the outcomes before recommending it for use.

Stratification for Appropriate Use

Emphasizing the appropriate use of drugs for individualized treatment plans has resulted in use of stratification for drug use management. Several years ago, the program decided to study and promote the appropriate use of arthritis drugs, especially for patients who were at risk of developing gastrointestinal bleeding as a result of using nonsteroidal anti-inflammatory drugs (NSAIDs). COX-2 Inhibitors, a type of NSAID which lessens the risk of bleeding, had been introduced recently and utilization of these drugs, such as Vioxx and Celebrex, was growing very rapidly, although they were much more expensive than traditional NSAIDs.

Clinical evidence at the time indicated that most patients were at very low risk of serious bleeding and could be treated safely with a traditional NSAID. To be able to make more specific recommendations to physicians, the Drug Management group decided to pursue further research and worked with researchers in rheumatology at Stanford University School of Medicine.³⁰ This

²⁹ A measure in The National Committee for Quality Assurance's Health Plan Employer Data and Information Set (HEDIS[®]).

³⁰ Cheetham, T. Craig, Levy, Gerald, and Spence, Michele. Predicting the Risk of Gastrointestinal Bleeding Due to Nonsteroidal Antiinflammatory Drugs: NSAID Electronic Assessment of Risk in *The Journal of Rheumatology* 23;30:10, 2241-2244.

team developed an automated tool to identify patients at risk of bleeding by analyzing Kaiser data for 300,000 patients who were using NSAID drugs at the time. Using this risk stratification model, the drug management group was able to identify the small number of patients (5%) who were at high risk for bleeding and could benefit from the new COX-2 Inhibitors. Patients who were not at risk and did not need the more expensive drug were prescribed appropriate medications for their conditions. The results were that 5% of Kaiser patients being treated with NSAIDs were prescribed COX-2 Inhibitors while in other settings, the market share for COX-2 drugs, until recently, was about 45% and in some other closely managed HMOs, about 25%. More recent data, from July 2005, shows that 15% of the NSAID prescriptions dispensed nationally in a recent week were for COX-2 drugs (the only one left on the market is Celebrex), while at Kaiser, fewer than one per cent (0.5%) were for a COX-2 drug.³¹

A respondent estimated the financial results of this program, which was motivated very much by concerns about quality as well as the potential dramatic increases in utilization. Given the plan's cost structure and population, each percentage point difference in market share was worth about \$1 million in each of the two California regions. Thus, using the earlier data cited above about market shares, Kaiser's costs were approximately \$20 million to \$40 million lower in each region compared to other health insurance and health maintenance organizations.

A therapeutic substitution program that was geared toward increasing use of a recommended drug for lowering cholesterol, lovastatin, a generic, also made use of a risk stratification approach. Not only were patients transferred quickly from the brand-name version of the medication (Mevacor) to lovastatin, but the drug management program also received agreement from physicians to transition patients who were currently on other brand-name statins to the recommended drug. To do this, it was necessary to stratify these patients in order to determine the correct dosage of lovastatin. Patient data gathered through the information system from the laboratory, pharmacy, and hospital, as well as the outpatient setting, made it possible for the drug management staff to categorize patients into eight groupings and to make individualized recommendations which could then be reviewed by the responsible physicians.

The conversion process included clinical oversight: a pharmacist consulted with the patients at the time of the initial conversion, and patients had laboratory testing after eight weeks for the drug management team to review results. If a patient did not return in eight weeks, health plan staff contacted them. Physicians were aware that the conversions were taking place and were very attentive to the process and to the response of their patients. As it does with all conversions, the drug management group also monitored the "flip rate," that is, the number of patients who have been transitioned to the preferred drug but who then call their physicians about their experiences and request return to the original medication. This feedback loop also provided valuable information about the effects of the initiative.

The final result was that the drug management program succeeded in its objectives for the conversion and also in providing evidence to physicians that now lead them to choose lovastatin in preference to other statins for initial prescriptions. At the present time, in the two California regions, lovastatin accounts for just less than 83% of all statin prescriptions; it accounts for 95% of all new prescriptions for statin medications. In contrast, national data on statin use reports that lovastatin accounts for just 7% of all statin prescriptions.³²

³¹ Market share data from IMS Health Weekly Retail Channel information, July 9 – July 15, 2005.

³² Market share data from IMS Health Weekly Retail Channel information, July 9 – July 15, 2005.

Cost Avoidance

Emphasizing the appropriate use of drugs results in cost avoidance. During the last five years, the drug management program has reduced the inappropriate use of antibiotics during cold and flu season by about 30%. Again, education and communication campaigns continue to be used to remind physicians about the wise use of antibiotics and to support them to find "teachable moments" with patients to educate them about the appropriate use of antibiotics. A respondent reported that, at the time of the case study discussion, the program was preparing for the upcoming cold/flu season. The group is following a planning process similar to that of other campaigns.

To prepare for the upcoming season, the drug management group reviews the performance of the previous few seasons, studies the utilization data, examines new clinical evidence from literature and other sources, and identifies any new opportunities for increasing appropriate use. The group consults with infectious disease specialists and adult and pediatric primary care physicians regarding the evidence and options. This year, for example, new research findings that antibiotics are ineffective for ear infections in children and bronchitis for adults further supports previous evidence about antibiotic use for these conditions. The group will next design specific campaigns, which may differ in targeting. For example, they may be directed differently for adult and pediatric primary care physicians or aimed broadly to all physicians or to the highest prescribers to remind physicians of appropriate use.

Physician Education and Information Activities

Drug management leaders reported that information, education, and communication are key to achieving the group's goals. The most critical issue is that the infrastructure and decision-making process represent a partnership between the medical and pharmacy organizations, resulting in initiatives that are sound clinically and grounded in analysis of local utilization as well as other professional evidence. The close collaboration in the decision process sets the tone for that partnership throughout the organization. Physicians from relevant specialty areas have an important role in educational campaigns; their support for recommended medications is another form of evidence regarding efficacy. These specialist "champions" work with the drug education coordinators to provide evidence and information to the medical staff. Physicians receive feedback on departmental and individual performance along with summaries of the evidence and information from Kaiser medical experts in the field; questions and challenges are addressed openly in a process that is based on sharing of data and discussion.

The drug management leaders reported that they use a variety of techniques to conduct information campaigns, using various communication modes, such as videoconferences, teleconferences, emails, and extensive printed materials, as well as borrowing from well-known mass marketing techniques, such as use of promotional items, paycheck stuffers, and flyers. Pens, pads, and even envelope openers, with serious and humorous messages (for example, "Luv'n lovastatin" on an envelope opener), are used to remind physicians of the recommended drugs. Physicians also are provided with materials, such as scripts and exam room posters that help them to educate patients about the medications and the reasons for selection, or the reasons for not using a prescription drug for treatment. An individual campaign is designed for every initiative, incorporating the techniques and methods that the drug program leaders think have the best chance of succeeding with the particular topic.

Other Interventions

Other interventions contribute to the management of pharmacy costs at the health plan as well. As mentioned earlier, for many years the health plan has used a formulary, or preferred drug list, and
also has focused on generic substitution. The use of a preferred drug list contributes significantly to cost management; however, health plan physicians are not required to comply with these recommendations and can write any prescription without any restrictions such as prior authorization requirements. Regarding generic substitution, in California the drug management program has agreements with the physician groups about the quality of generic drugs to be acquired and processes of implementation. Once these standards are met, physicians are informed of an intended conversion in order to permit additional discussion if needed. Although there are some exceptions, when the conversion is more clinically complex, most conversions can be implemented very rapidly because of the high degree of system support and the integration of health plan pharmacies within the plan.

The health plan has also minimized physician drug detailing by manufacturers. The drug management program has not been able to quantify the savings from this decision, but observed increases in utilization of specific drugs following a "natural experiment" at a large medical center where detailing was initially banned and then briefly permitted. The plan, in general, also does not accept or distribute free samples from manufacturers. Instead, the plan provides "starter packs" of medications that allow patients a brief tryout on recommended medications that are less well known to the general public. For example, starter packs have been used to acquaint patients with famotadine as an intervention for gastrointestinal symptoms, and with inhaled cortical steroids such as Qvar for asthma.

Results Of Cost Management Interventions

The drug management program measures its results through monitoring of individual initiatives against goals and against national utilization of the medications, the per-member per-month prescription costs, and generic utilization rates.

The Kaiser Foundation Health Plans in five locations, including northern and southern California, Ohio, Mid-Atlantic States, and Colorado, had the lowest per-member per-month prescription costs of all health plans enrolled in the NCQA Quality Compass[®] in 2003. The Southern and Northern California health plans placed first and third, respectively, with PMPM costs of \$22.73 and \$24.87. The drug program managers estimate that the plan spends about \$500 million less annually than a competitor serving a comparable population. Much of this value can be attributed to the plan's high use of generic drugs. The health plan's generic utilization rate is between 75% - 85%, compared to a range of 45% - 55% among other health plans, with managed care plans averaging about 55%. While the program tracks generic utilization for management purposes, it is not used as a measure internally; utilization of specific medications is measured, but no physicians are measured by their overall generic utilization. From a cost perspective, however, transition from brand-name to generic therapies offers enormous savings, as patients move from medications of \$3.00 per tablet, for example, to generics where the cost is \$0.10 to \$0.30 per tablet.

The results of individual initiatives that illustrate several ways the health plan has been able to achieve its financial results were discussed earlier.

Lessons Learned

Key Success Factors

Our respondents identified several factors that they believe have contributed to their success in managing drug costs. Using an evidence-based approach is critical because the philosophy at Kaiser is to rely on intellectual persuasion and on physicians' commitment to the most appropriate and best medical care. Evidence-based medicine was introduced at Kaiser approximately fourteen years ago. Although some physicians challenged it at the time, concerned about a "cookbook" approach to medicine, it has been adopted for some aspects of medical care. Respondents reported, though, that evidence itself is not sufficient to ensure success of initiatives; rather, the collaboration and support of local experts adds to that likelihood. Recommendations have to be supported by local specialists and physician leadership, and must be credible on a patient-specific basis.

The planning process itself is a key to success. A respondent noted that the program has a planning process that emphasizes the importance of consensus among all affected parties, and once consensus is reached on an initiative and how the program will be implemented, all support it. Another respondent observed that communication skills are critical in working in this environment where discussion and challenges are integral to the decision-making process.

The program relies on distribution of data among stakeholders as a means to engage physicians in discussion of alternatives and review of practice patterns. Data quality is critical. A respondent reported that data to be presented to physicians must be as close to 100% accurate as possible, because poor data results in skepticism, loss of credibility, and failure to gain agreement with goals. The pharmacy management program made large investments in data quality for this reason. It has perfected tracking of laboratory results and prescription use, to be able to discuss specific patients and outcomes with physicians, and to develop feedback loops on outcomes for initiatives. The effectiveness for patients of many drugs can be measured through laboratory tests, and to the extent that it is possible, the program uses them. A respondent commented also that the more patient-specific the information is, the more credible it is with physicians.

Individual, unblinded performance reports on specific initiatives are distributed to each medical department for discussion and review. All initiatives are monitored in relation to goals specified during the planning process. Being able to feed information back quickly is also important. For reports, recent data are far more persuasive than data that are months old. New, good information also makes administrative action possible. At the health plan, information on prescriptions filled at the plan's pharmacies is available within fifteen hours after close of business. This gives the program staff the ability to look quickly at physicians and other staff regarding circumstances or decisions that led to undesired results, such as increased dispensing rates of non-preferred drugs. A respondent noted that the rapid feedback permits the program to spot supply chain problems and other systems issues early.

Another key to success is limiting the number of initiatives being implemented at any one time. A respondent observed that if too many projects are active at the same time, it becomes hard for the recipients of all that information to remember the key messages. The program sponsors about four initiatives concurrently, organizing communication campaigns that stress these messages for three to four months. One respondent characterized these concentrated, intense communication campaigns as "overwhelming force." Program leaders have found that they are usually able to achieve about 90% of an initiative's goal in a few months; after that, the staff evaluate the results and decide whether to conduct a "clean-up" campaign to complete the goal or whether their time

and efforts would be more effectively used starting the next initiative. The communication techniques used in the campaigns, described earlier, are also considered critical to success.

The presence of drug education coordinators is indispensable to the program's success. These pharmacists bring pharmaceutical expertise to the medical center physicians, support and implement initiatives through education and consultation, distribute and interpret data, and work with their assigned center or group on local initiatives. The drug management program has demonstrated that when the organization, or a part of it such as a medical center, is under-invested in human resources, drug costs are higher, savings are worse, and performance is worse. When the program does strategic planning, the management team looks at whether they have sufficient staff at each medical center to complete the initiatives.

Replication

The Kaiser Permanente Health Plan is widely recognized as having a unique place in healthcare. Many observers see its unusual organizational arrangements, as a fully integrated delivery system and direct purchaser of drugs, and long history as characteristics that set it apart from more "typical" medical settings. The respondents for this case study noted, however, that many aspects of the plan's approach to drug use management can be replicated in other settings. They see collaboration between physicians and the pharmacy program and availability of accurate data as the key ingredients to adoption of these methods. These resources make it possible to evaluate evidence, gain support of opinion leaders, communicate messages, and monitor and report outcomes. Collaborative relationships can be developed through many means, and access to high quality data is also feasible to achieve. One respondent noted about the need for collaboration and physician leadership that local medical societies, and similar organizations, are potential leaders for locally driven initiatives.

Nevertheless, there are aspects to the Kaiser organization that may have made its achievements more easily accomplished than in other settings. The direct links between clinical decisions about preferred drugs and the ability to negotiate purchase prices magnifies the value of the plan's initiatives; additionally, some initiatives are facilitated by the fact that the plan also offers in-house pharmacies. Further, the long history of collaboration among physicians and the plan administrators is, in part, due to self-selection among the individuals who choose to work there.

Looking to the Future

The respondents reported significant challenges ahead for the program. The program is just starting to become involved with the use of medications among specialty physicians. Because of the health plan's size, there are sufficient numbers of specialists to make statistical analyses of prescribing practices possible. Program leaders intend to exp and the evidence-based approach to target pharmaceuticals commonly used by specialists.

Drug program leaders are also exploring increased use of self-care for patients. The program staff is starting to look at how to identify which patients can be appropriately transitioned to over-thecounter products and which patients continue to need prescription drugs and medical management. For example, program leaders estimate that perhaps 40% - 60% of patients with gastro-intestinal conditions can be transitioned from prescription drugs. The task over the next three years will be to identify those patients who do not have GI disease, but have occasional symptoms that lead them to seek medical care, and to identify those patients who do have GI disease and need medical attention. Many of the individuals in the former category do not need long-term medications, but could be helped with over-the-counter alternatives and/or life style changes. Respondents also reported that the program will soon have to address the implications of biologic drugs and of the industry's advances in pharmacogenomics. Further use of risk stratification is also expected. The wide-spread adoption of the electronic medical record will change methods for physician education; it will be possible to embed evidence and decision-making support into the computer, so information can pop up at the point of prescribing, the most effective time to provide the information.

2.4 Pitney Bowes Inc.

Description of the Organization

Pitney Bowes Inc. produces postage meters and other mailing equipment, provides shipping and weighing systems, online postage services, facilities management services, and develops software to manage shipping, transportation and logistics for customers. The company has about 35,000 employees and ranks as #392 in the Fortune 500.

Pitney Bowes Inc. is self-insured for the health benefits it offers to employees, retirees, and their families. The Global Health Benefits Office of Pitney Bowes is responsible for the design and management of health benefits for the company and contracts with Caremark RX, Inc., a pharmacy benefit management firm (PBM) to provide benefit management services for the program. The pharmacy benefit that is described in this case study covers approximately 52,000 lives, comprising 20,000 employees, 2,500 retirees, and their families.

Motivation for The Development of Cost Management Programs

Pitney Bowes management decided to modify its pharmacy program in 2000 as part of a general review of the health benefit programs it offered to employees and retirees. Pharmacy costs were escalating, and the company was looking for ways to both make the costs of the benefit more stable, so that regular changes to the benefit would not be necessary, and to slow the rate of increase, if possible. The company was not seeking to make extensive reductions in pharmacy expenditures. Most importantly, the company viewed its health benefits as a critical component in employee morale and satisfaction with the work environment and thus as a key factor in productivity.

At the same time, employee surveys showed that employees were not aware of the actual cost of health benefits. Employees tended to have a narrow view, perceiving their co-payments as the cost of care, without recognition of the firm's payment for the bulk of the benefit. For example, if a co-payment doubled from \$10.00 to \$20.00, employees saw their cost doubling but did not notice that the firm was also experiencing sharp cost increases and that a change in co-payment policy was a necessary response to escalating expenditures. As a consequence, employees might be bewildered and angry at increases in their contribution without understanding that the company's share was also rising. The company managers decided to confront that lack of knowledge among employees and to educate them about the total picture. In the face of possible continuing changes in the benefit structure because of escalating healthcare payments, dissatisfaction with the benefit would likely grow.

The Decision-Making Process and the Choice of Strategies

As they thought about the nature of the problems they faced, two managers in the health benefits group became interested in consumer-directed healthcare, that is, a new approach to healthcare benefit design that has at its center the premise that consumers are best equipped to manage their own health coverage, and carried out a review of literature on the topic. Because little historical data was available to them for claims analysis, the managers decided to take a more theoretical approach, based on their literature reviews.

Other principles also contributed to the focus on a consumer-centered model. Managers believed that more restrictive plan designs bring the pharmacy plan, in essence the employer, into the medical decision-making process, which should only include the patient and his doctor. The team felt strongly that it is inappropriate for the employer to enter that relationship; and also believed that such involvement led to employee dissatisfaction and, from that, potentially reduced productivity. The team also wanted to encourage the relationship between employees and pharmacists for education about the use of medications and about alternatives to a prescribed medication, if need be.

A respondent reported that the expected impact on the workplace was also a critical consideration. The team believed that they needed to reduce the "hassle" factor that more complicated arrangements tended to impose on employees; this, too, was seen as a potential source of dissatisfaction and also could lower productivity. Their experience suggested that complicated benefit structures required significant time to be spent by employees as they negotiated among physicians, health plans, and pharmacists in order to comply with rules and procedures or to fill their individual needs within a set a rules. Much of this time, a respondent commented, takes place at work and can easily affect productivity. He noted that a previous experience with the introduction of step therapy had led to a sharp increase in complaints and time during working hours spent on calls to the call center.

Based on all these considerations, managers decided to adopt a benefit design that they term a "consumer strategy," that encourages employee's participation in decisions about their care and would raise their awareness of the cost. Rather than offer a benefit designed to provide only the lowest-cost options, managers decided to establish a plan that provides choice and an economic structure that draws attention to the different prices for medications. To this end, the managers decided to offer a broad formulary that includes most medications, making a wide range of medications available to employees. To give employees economic incentives to become involved in drug decisions, a three-tiered co-insurance program replaced the former three-tiered co-payment structure. Since members paid a fixed percent of their price of the prescription instead of a fixed dollar amount, members were more likely to be aware of the cost of the drug. Generic drugs are included in the first and least expensive tier, brand-name drugs without generic equivalents are in the second tier, and brand-name drugs that have generic equivalents are in the third tier.

Several other factors were considered in the benefit design. The company wanted members to become good consumers but not to be burdened with an open-ended liability. For this reason, the plan limits out-of-pocket costs by establishing a maximum level for employee costs; beyond that level, co-insurance requirements are waived. The company also decided to offer employees an opportunity to "buy up," or purchase a modified version of the plan that provides drugs at lower co-insurance and a lower out-of-pocket maximum ceiling. Plan designers believed that members with expectations of higher drug costs would be interested in this option.

Another consideration was the reaction of retirees to the new benefit plan. When company representatives met with groups of retirees, they found that retirees were nervous about coinsurance and the new unpredictability of their cost share. Most of all, they worried about being embarrassed financially when they went to pick up drugs at the pharmacy. In response, to ease into the new program, a co-payment structure was retained for the mail order program for the first two years of operation.

In concert with this design and consumer-centered philosophy, the company decided not to purchase any cost management interventions offered by the PBM. For example, the company does not have programs for generic or therapeutic substitution or for step therapy. The company does

purchase utilization management programs that are geared toward patient safety, such as efforts to identify potential drug interactions. Also, as part of this, the plan provides only a small encouragement for use of mail order, because the firm believes that the one-on-one discussion with a pharmacist is a valuable interchange that can make use of a "teachable moment" to assist employees with their concerns, such as how to use specific medications or to discuss lower-cost alternatives to an expensive medication. The primary services provided by the PBM are adjudication and processing of claims, a customer service call center, educational and communication services, clinical safety programs, and formulary recommendations.

At the time of the program's launch, a respondent reported, the managers had little data and so did not have much expectation for favorable financial results. As noted earlier, the primary goal was to gain stability from escalating costs in the program.

The Cost Management Strategies

The design and structure of the Pitney Bowes pharmacy benefit is the primary cost management intervention. An education and information program for employees is a vital complement.

Plan Design

Employees are asked to share costs in the form of three tiers of co-insurance, as described earlier. The standard plan requires a 10%, 30%, and 50% co-insurance for prescriptions in the three tiers, with a cap on out-of-pocket expenditures of \$1,500 per person per year. Employees can "buy up" for \$125 a year to a plan with lower co-insurance levels of 10%, 25%, and 35% and a cap on out-of-pocket expenditures of \$1000 per person per year, which is divided into \$500 at retail pharmacies and \$500 via the mail program. About 25% of employees have chosen to participate in this "buy up" programs where a floor amount is set for co-insurance, so a member pays a set amount if the co-insurance total falls below a particular limit, such as \$10, on a specific drug. The management had two reasons for keeping the co-insurance percentage the same no matter the actual price of the drug: it signified that the company would be fair in asking employees for only the stated percentage, as cost-sharing and management hoped that the resulting very low co-insurance levels for some generic medications would be an incentive for employees to consider them.

As noted earlier, the company does not use cost management interventions such as step therapy and generic or therapeutic substitution programs available through the PBM. And, although it offers an incentive, i.e., a 90-day supply for two co-insurance payments required for 30-day supplies, for the use of mail order pharmacy service, the company does not aggressively promote the program because of the conviction regarding the importance of the relationship between employee and pharmacist. Mail order penetration is low --- about 11% for 2004 among active employees.

The benefit also includes a telephone case management program for employees in need of specialty drugs in order to assure appropriate use of medications. This program provides counseling and education regarding use of the drugs, and staff will contact the individual if a prescription has not been refilled to find out why and to offer assistance. The hotline is available 24 hours a day, 7 days a week. While the program is not seen specifically as a cost management intervention, the focus on appropriate use and safety also addresses cost-effectiveness.

Education and Information

Education and information are critical to supporting employees in understanding and exercising their choices in their use of the plan. Our respondents reported that the partner PBM at the time when the program was introduced, AdvancePCS, which was subsequently acquired by Caremark RX, provided extensive educational services, including printed material and on-site meetings for employees to inform them about the new pharmacy benefit during the implementation period. Currently, the company encourages employees to call the customer service line offered by Caremark RX, or to use the Caremark RX website, with any questions. As a back-up to that system, employees can contact the company's own benefits telephone service line if they are not satisfied with the response from Caremark RX. A respondent from that service reported that almost all the employee calls regarding the pharmacy benefit are related to eligibility and administrative issues, such as loss or non-receipt of a benefit identification card; in 2004, fewer than ten appeals were made through the benefits grievance system.

The Caremark RX website offers extensive personalized information to employees, such as lists of prescribed medications, information about the medications, and options for lower-cost alternatives, such as generics. In a continuation of efforts to make employees aware of the costs of prescriptions, a receipt is printed and attached to every prescription bag that reports the full drug price, the price the company paid, and the employee's contribution through their co-insurance payment.

Pitney Bowes also purchases a corporate membership to WebMD, a website that delivers health information. The company makes this website available to employees, retirees, and their families as a critical component of the corporate wellness programs, primarily as a source of self-paced learning. The site also provides extensive information on pharmacy issues.

Other Cost Interventions

In 2001, the company began to use predictive modeling to examine combined medical and pharmaceutical claims and expenditures. Managers became aware of the approach when they learned that staff of an HMO with which they contracted used it to forecast future expenditures, and thus insurance rates, more accurately than the company had been able to do. They decided to use the forecasting method to identify targets for healthcare interventions that could avoid the predicted large outlays. The firm contracted with two firms to analyze their healthcare experience, working with DxCG, Inc., a vendor that provides predictive modeling, to analyze claims and pharmacy data and to forecast future expenditures, and with Medical Scientists, Inc., which uses a software modeling approach based on hybrid Artificial Intelligence, to understand healthcare patterns driving future high cost. Among its results, Medical Scientists, Inc. identified that individuals with diabetes, asthma, and cardiovascular disease who had poor medication compliance were at high risk of becoming high-cost claimants in the medical plan.

In response, the company launched a variety of interventions, such as education, free or low-cost screenings, information and education services from health plans, and pricing for medications, to address the healthcare needs of employees in these categories. Drugs used in treatments for the three conditions were made available at the first level of co-insurance (10%), in order to encourage employees whose irregular use of medications put them at high risk of increased illness to follow treatment regimens.³³

³³ Alice Dragoon, "An ounce of prediction," <u>CIO Magazine July</u> 1, 2004 Issue.

Pitney Bowes also operates eight on-site medical clinics at the company's locations to provide emergent primary care services; 73% of the company's employees use the clinic at least once each year. When medications are dispensed, they are almost always generic. A respondent reported that employees' use of the clinics offers "teachable moments" regarding the use of generics as appropriate medications; by receiving generic medications for a course of illness free of charge, employees are encouraged to become familiar with the use of generics in other situations as well.

Results of Cost Management Interventions

The respondents reported that they have accomplished the goals they set for the pharmacy benefit. Employees have become more astute about the cost of medications and are making reasonable decisions. Also, the company is no longer in the position of interfering with the physician – patient relationship. The benefit design has facilitated communication between patients and their doctors, with the pharmacist serving as an educator. Lastly, the benefit has stabilized, so there is no need to go back annually and make further changes.

The company monitors results of the benefit quarterly. The primary reason for monitoring so frequently is because the benefit design is innovative; managers want to ensure that it is performing within boundaries that are comparable to the outside marketplace. All claims data from Caremark is transferred into a database maintained by an outside vendor, in order to protect the privacy of employees. The benefit managers have direct access to the database via an internet connection.

In terms of financial results, a respondent reported that the overall goal has also been achieved. The company believes that it has achieved financial results using its economic model that would have otherwise required a tightly managed model that they worry would have created significant employee relations problems.

The company uses per-member per-month (PMPM) costs, the drug trend, generic dispensing rate, and generic substitution rate as measures. The PMPM, which is calculated on the costs of all prescription drugs as well as specialty medications, for 2004 was \$32.10 for the active, non-retiree population, compared to \$29.50 in 2003 and \$26.40 in 2002. The drug trend for 2004 was 8.8%, compared to a national benchmark of 11.9%.³⁴

For 2004, the generic dispensing rate was 48%. A respondent noted that this rate could be higher if the company employed more aggressive benefit management techniques, such as step therapy; however, since the company never had a goal of increasing the rate to a certain percent, they are satisfied with that number.³⁵ The generic substitution rate for Pitney Bowes in 2004 was 91%, compared to a national benchmark of 92% for retail and 93% for mail order programs.³⁶

A respondent reported that expenditures for medications for individuals with asthma and diabetes also decreased. This was quite unexpected, since the program was designed to encourage the use of medications in the hope that patients would avoid more expensive healthcare services, such as

³⁴ CMS has projected that the national drug trend for 2004 was 11.9%. Stephen Heffler et al, "U.S. Health Spending Projections for 2004-2014," <u>Health Affairs</u> 23 February 2005.

³⁵ While standard benchmark figures do not exist for this statistic, PBMs and health plans who do use more aggressive cost management techniques report generic dispensing rates in the low 50s while averages tend to run from the mid to high 40s.

³⁶ Steven Heffler et al, "U.S. Health Spending Projections for 2004-2014," <u>Health Affairs</u> 23 February 2005.

emergency and hospital care, if they had ready access to appropriate medications. In fact, while reductions in medical expenditures were most significant, pharmacy expenditures decreased as well. Patients with diabetes showed an average decrease of 7% in their cost of drugs and those with asthma showed a 12% decrease. Reduced use of rescue medications and medications to treat complications accounted for the results.

Lessons Learned

Key Success Factors

The respondents saw several factors as contributing to the success they have achieved. The company's approach of openness about the benefit is viewed as critical. A respondent noted that employees understand easily how the benefit works in terms of procedures. Employees are also encouraged to use the PBM helpline and websites for information, which makes navigating the benefit easier as well. And, the company has established a set of procedures with the PBM that enables customer service representatives to override co-insurance rules when it is medically appropriate. For example, if a physician believes that a brand-name drug that is listed in the third tier is better for the employee than a generic in the first tier, the representative can approve the co-insurance at the second tier level rather than the third.

Another positive factor is the result of the decision not to place a floor on co-insurance. The fact that the co-insurance percentage is applied even if the price of a drug is low, such as \$8.00, creates something of a "wow factor," in that employees are surprised and likely to talk about a co-insurance charge of just \$.80. This has resulted in positive, informal communication among employees about the benefit. A respondent noted that the use of a floor on co-insurance implies to employees that the company is taking savings for itself and not sharing them with the member.

Now that employees understand the benefit, they also research information using the educational sources available. A respondent noted that some employees have learned about the discount the company receives from the retail price by comparing their prices to estimates available on the internet and now recognize that that discount is also passed on to employees. Some employees have also realized that drug prices vary among retail outlets, according to a respondent, and may be using that information to select their pharmacies.

Respondents noted that the implementation process was also critical to their success. The PBM managed a smooth introduction, including dealing with the various health plans with which the firm contracts, hosting on-site meetings, having identification cards ready, providing education, and ensuring that employees were aware of the telephone helpline and website as information sources. Sensitivity to specific is sues that were of concern to employees was also critical to a smooth implementation. As mentioned earlier, to ease the transition to co-insurance, the company retained a co-payment approach to use of the mail order program for two years before converting to co-insurance for that as well. This was done primarily in response to concerns expressed by retirees, who were anxious about not knowing what their cost would be at a pharmacy and very worried that they would be financially embarrassed.

Respondents also noted that balancing the costs of the medications with consideration of the impact on medical conditions is critical to design of the program. It is impossible to look at the pharmacy benefit separate from the medical benefit. When viewed together, a manager can begin to understand the tradeoffs that are made and is likely to make different decisions than if just looking at the pharmacy benefit alone.

Replication

Respondents reported that the key factor in adopting this approach is willingness to set various coinsurance rates and to be open and direct with group members about the benefit. They also noted that selection of a PBM is critical, because the PBM will be administering a program that differs from many other groups. Respondents suggested that companies consider site visits to potential PBMs, to understand if there is agreement about philosophy and the level of service employees would get.

As was discussed earlier, management of the benefit requires an ability to understand the pharmacy program as it relates to the medical program and therefore to understand the trade-offs related to cost management options. The fact that the director of Global Health Benefits is a physician facilitates this process for Pitney Bowes.

Looking to the Future

Respondents reported that they expect to stay with the current program because it has proven effective. They are currently considering ways to expand the concept of lowering the cost of access to medications for specific conditions. For example, they are exploring ways to increase appropriateness of care for depression and how to facilitate access to counseling and medications.

They are also aware of the rapid increase in biotechnology drugs. They have elected to remain with their current system of contracting with a vendor that offers 24-hour access to counseling and drug information and of using co-insurance similar to other brand-name drugs.

The company is also planning to introduce a Health Savings Account plan that is expected to attract about 10% of the employees. This introduction might have implications for the pharmacy program because the Health Savings Account plans are expected to attract individuals in very good health and with few medical costs. A Health Savings Account program requires that medical, pharmacy, and mental health benefits be coordinated through a single administrator, which means that the healthiest individuals are likely to leave the current pharmacy program for enrollment in the new program. If that happens, both average utilization and costs will increase in the pharmacy program.

2.5 Medco Health Solutions, Inc. Case Study

Description of the Organization

Medco Health Solutions is a publicly-owned pharmacy benefit manager (PBM) with corporate headquarters in Franklin Lakes, New Jersey. Medco was started in 1983 as a mail order pharmacy, and in 1985, after acquiring PAID Prescriptions, a company which pioneered the use of prescription drug cards at retail pharmacies, became the first pharmacy benefit manager to provide both mail-order and retail pharmacy services to clients. In 1993, Medco was acquired by Merck & Company, which owned Medco until 2003, when it became an independent company again. Medco competes for clients with other firms in the benefit management industry. Currently, the company is one of the largest PBMs in the country; it covers more then 60 million lives and processed more than 500 million prescriptions in 2004. About 80 million of these prescriptions are filled by the company's mail-order operation, which is the largest in the U.S.; the remaining 420 million are filled through Medco's network of more than 50,000 retail pharmacies. Medco is #48 in Fortune Magazine's 2005 ranking of the top 500 U. S. companies.

Medco's clients include health insurance companies, managed care plans, and federal and state employee and retiree plans, as well as private groups such as individual employers and unions that are self-insured and contract directly with a PBM for the pharmacy benefit portion of employee and member health benefits. The services Medco provides to these clients include pharmacy network and management, adjudication and payment of claims, formulary designs, consultation services that assist in plan design, clinical programs, quality and safety programs, cost management services, mail order services, and negotiations with manufacturers for favorable prices and rebates.

Motivation for the Development of Cost Management Programs

Medco's interest in cost management programs is driven by the needs of its market, that is, its client organizations. Customers have always sought ways to restrain expenditures while still providing benefits that are perceived as valuable by their employees and members. As the cost of offering pharmacy benefits increases, however, customers' interest in assistance is also on the rise. Customers are not all alike in their interests and concerns about cost; they also differ in terms of the constraints each has on its abilities to make changes in benefit packages the y provide. Medco and others in the pharmacy benefit management field have developed a variety of interventions that can be applied flexibly to meet customers' needs.

The Decision-Making Process and the Choice of Strategies

Cost management strategies fall into two categories: those embedded in the benefit design the customer selects and others that result from specific techniques Medco uses to manage its customers' pharmacy benefits. Medco gives customers a wide range of choices about how the elements of their benefit or plan design can be assembled to achieve cost management goals. Plan design includes elements such as the defined scope of the benefit, the comprehensiveness of the preferred drug list or formulary, the extent to which they require their members and employees to share the costs of individual features in the form of coinsurance, co-payments, and deductibles, and the breadth of the pharmacy network and the use of mail order pharmacy services.

There are multiple choices within these elements that enable customers to focus on specific cost concerns. For example, a customer may want to encourage employees to use generic medications when possible. There are several options within the components in plan design that can achieve that, so a customer can choose the mechanisms that fits their needs, perhaps choosing to offer a broad formulary, rather than a restrictive one, but having co-payments that make it significantly more expensive for employees to purchase non-generic drugs. The final plan design for a customer reflects a series of such decisions, which consider the goals of the customer in offering the benefit, the constraints on the scope of its decision-making power in the area of health benefits, and the relationship between the customer organization and its members or employees. Another factor that clients take into consideration in their plan designs is the financial impact of drug manufacturer rebates on the costs of drugs it purchases for its members. In general a broader formulary will provide higher total rebate value to a plan sponsor; however, a plan may be able to earn higher rebates on some products with narrower content if the formulary content is complemented with aggressive plan design parameters such as substantial copay differences or coverage rules that drive market share to the preferred, formulary drugs.

Medco also provides services and programs to actively manage the implementation and use of customers' pharmacy benefits. In these programs, Medco takes steps to implement the more subtle decisions in the benefit design, such as additional means to encourage members to use specific drugs, to ensure that access to certain drugs is cost-effective, or that drugs are used safely and appropriately. Medco works with members, physicians and other health providers, and pharmacists in these activities. Some management programs are embedded in the company's core offerings to client organizations; others are available for an additional cost. These interventions make use of internal resources such as data processing and claims adjudication capacities, extremely rapid processing times, extensive databases of patient information, claims and utilization data, and expert information technology and clinical personnel.

As part of the decision-making process with clients, Medco advisors work with each health plan or employer to design a program of techniques that address that organization's needs. Medco advisors use computer modeling, based on aggregated pharmacy claims, other medical care utilization, and other factors such as demographics, to estimate what specific clients' financial savings would be if certain cost management techniques are implemented. For example, if a client wants to add a deductible or increase a co-payment for certain drugs, Medco can predict approximately how many people would be affected, what the savings to the client would be and the additional cost or savings to the member.

Within Medco, the Product and Business Development Group is charged with assessment and development of new ideas for cost management strategies, although ideas may arise anywhere within the company and be submitted to the group for evaluation. Staff in the Department of Medical Affairs assesses the clinical implications of these ideas and also submits them for review by the company's pharmacy and therapeutics committee (P&T), a board of eight independent pharmacy and healthcare experts, to ensure that the strategies are clinically responsible. The recommendations then may be presented to one or more of Medco's multiple client advisory groups, independent bodies made up of representatives from specific segments of clients, for review and input. Finally, the company reviews recommendations and makes the business decisions regarding value and priority of the recommendations.

Cost management issues are also considered during a decision process that determines how changes in pharmaceuticals, such as introduction of new drugs, will be addressed. The Department of Medical Affairs chairs an interdisciplinary group, called the Pipeline Committee, which develops the strategies Medco will use to manage these changes both clinically and financially. During the process, in addition to many other aspects of strategy, the group identifies what it considers to be the most appropriate currently available cost management or utilization management programs for each new drug. These recommendations are then reviewed by the P&T Committee to assure clinical appropriateness. The final step is the development of an implementation strategy.

The Cost Management Strategies

This case study describes two cost management strategies that have had significant success in reducing prescription drug costs for Medco's clients. As noted earlier, Medco offers a wide array of choices in benefit design and benefit management programs to meet the varying needs and constraints of clients. The following descriptions provide some information regarding the extent to which various methods can be used to achieve cost management goals.

Mail Order Programs

Medco's mail order pharmacy is the largest private sector mail order operation in the country, filling about 80 million prescriptions per year. The mail order benefit is an integral part of all of Medco's benefit offerings. The mail order program covers medications that can be safely sent by mail or delivery service and which do not need to be filled immediately. It is particularly useful for chronic maintenance drugs. Clients also can choose to purchase another program called the retail refill allowance (RRA), which establishes strong financial incentives for members to use the mail program for a narrower list of medications than what is covered through the standard mail program. The standard mail program is described first and the RRA program follows it below.

Program managers reported that covered drugs provided through the standard mail program cost six to eight percent less than if the prescriptions are filled through retail pharmacies. This is because of lower wholesale costs, fewer dispensing fees, and the economies of scale and increased efficiencies of processing compared to retail settings, as well as the effects of programs designed to increase generic utilization and adherence to the client's chosen formulary. Member utilization of this program depends on what financial incentives, such as co-payment or co-insurance structures, the client organization has adopted for its members. For example, many clients offer a reduced co-payment charge to members who use mail order; often setting the mail order co-payment for a 90 day supply less than what the co-payments would be for an equivalent supply from a retail pharmacy. Respondents estimated that a range of 10 to 40% of total prescriptions for individual clients are filled through this program. This is significantly lower than the full potential for mail order use, which can be as high as 89.3%³⁷ of all prescriptions, but varies widely depending on the demographics in a client group.

The mail order program is also a platform for other cost management interventions, such as generic substitution, which is bolstered in many states by regulations. Moreover, a staff of pharmacists associated with the mail order program carry out efforts that encourage therapeutic interchange and resolve more complicated generic substitution situations. These interventions are discussed in the next section on increasing the use of generics.

Another potential financial benefit of the mail order program is that high generic substitution rates are achieved quickly after a drug becomes generic. For example, Medco respondents reported that

³⁷ Medco staff analyzed their client organization with the highest mail penetration and reviewed the potential penetration if all maintenance prescriptions were moved to mail in addition to what was already there. This analysis yielded a potential mail penetration rate of 89.3%.

seven days after Neurontin (an epilepsy medication) became available through a generic, the mail order pharmacy reached a 92 percent generic substitution rate for prescriptions submitted during the period. In comparison, the retail channel had only achieved a 40 percent generic substitution rate during the period, according to analyses done by Medco using the company's claims billing system. Six months after the generic drug became available, the mail order rate was 94 percent in comparison to a 78 percent rate at retail pharmacies. This substitution rate at the mail order program was achieved through review of the prescriptions submitted and outreach to physicians and members to change prescriptions for Neurontin to the generic drug.

The standard mail order program provides a wide range of customer services to encourage members to use the program. Prescriptions can be submitted by mail or fax by a provider, and refills can be ordered by mail, phone, or through an internet site. Delivery is designed to be convenient and safe. Customer service representatives and pharmacists are available to answer member questions 24 hours a day, 7 days a week. Furthermore, respondents reported that a recent study³⁸ found that errors are less frequent at Medco's mail order pharmacies, which are highly automated, than at retail pharmacies. Respondents noted that one source of errors that occur in retail pharmacies is demand peaks at certain hours that create a higher likelihood of human dispensing error; mail order facilities do not have this problem because they are able to spend more time on a prescription since the member is not waiting for the prescription to be filled immediately.

To gauge the program's acceptance, overall satisfaction with the mail order program is monitored quarterly by surveying randomly selected members who use it. These individuals are asked, "What is your overall satisfaction with Medco Home Delivery Service?" Among those surveyed, 96% report that they are satisfied.

Retail Refill Allowance Program (RRA)

This program aims to increase the use of the mail-order pharmacy program among members by establishing significant financial incentives to do so, accompanied by extensive member education and customer support via mailings, telephone, and online information. About 200 clients and approximately six million members currently participate. The program design requires that higher co-payments or co-insurance levels be imposed on members who continue to use the retail pharmacy channel beyond a specific number of allowed refills for medications covered in the program. Client organizations set the refill limits and the financial incentives; clients can choose any co-payment or co-insurance level, or can choose to require that members pay 100% of the cost from the retail pharmacy after limits are reached, to motivate members to use the mail program. In order to use the program successfully, an organization has to have the ability to change its co-insurance and co-payment structure and the willingness to impose new costs that are substantial enough to affect member decision-making.

The list of medications included in the RRA program represents about 80% of maintenance prescription volume. Professionals in Medco's Department of Medical Affairs develop the list, using clinical and service criteria. Only drugs for conditions where the duration of therapy will exceed one year are included. It must be clinically appropriate to use a long-term, or 90-day, supply rather than 30-day; for example, those drugs that require that the user be monitored frequently by a physician during therapy are not included. Also excluded are drugs that have limitations on

³⁸ The study was conducted by Medco and designed to parallel a 2003 Auburn University study on pharmacy dispensing errors in the retail community pharmacy. The results were presented at the 2004 conference of the American Pharmacists Association.

dispensing, such as day supply regulations or chemical stability issues, or limitations on supply, where product availability is a concern for some reason.

A respondent reported that enrollment in the RRA program can increase mail order utilization from the current rate of 10% to 40% for the standard mail program to between 50% and 85% of the prescriptions obtained by a client's members. The clients that attain the highest utilization are likely to cover an older population with a significant group of retirees, and the lower rate would involve a younger population with more acute rather than maintenance prescription use. An extensive communications strategy targeting members during the implementation period and continuing for the length of the program is critical to success; utilization of the mail program is 15% - 20% higher when the communications process is used compared to when it is not, according to a respondent. The type of communications available to be provided during the introductory period includes printed materials, such as letters to educate members about the benefits of the program and to provide the materials needed to transfer appropriate prescriptions, cost comparison charts, and "frequently asked questions" materials. Member and Pharmacy Service representatives are available to provide phone support to individuals, pharmacists, and physicians about the program. Also, members can access the medco.comTM internet site for information, and can receive personalized messaging through the site. Medco also offers communications that can be sent automatically, reminding the recipient of the potential cost savings of the mail program, when members continue to use retail pharmacies.

Communications and education, customer service, and a financial benefit to the user are critical to success for a program that uses financial penalties to steer individuals towards a process that is new and unfamiliar to them. However, a respondent noted that member satisfaction is high when those conditions are met, and that members will then expand their use of the mail program to include other maintenance drugs that do not have the same financial penalties associated with them. Results from the satisfaction survey process described earlier, which polls mail order users, show that it is typical for overall satisfaction with the mail order program to decline the first quarter after the RRA program is introduced at a client organization, but it then rises to an equal or greater rate than was found before the move to the RRA program.

Increasing the Use of Generics

Medco has always emphasized the use of generic drugs, and many of the company's cost management initiatives are geared toward furthering the use of generics both as substitutions for brand-name drugs that have the equivalent molecular structure and as alternatives, where generics differ molecularly but are determined to have the same therapeutic effects as specific brand-name medications.

However, there continue to be significant challenges in this area. While consumers have become more accepting of generic drugs, some continue to view generics as inferior to brand names. This opinion contributes to the demand for brand-name drugs and to rising drug costs. Secondly, physicians are not prescribing generics as often as is possible from a clinical perspective, especially in the area of therapeutic interchange. And, manufacturers of brand-name drugs target both groups with advertising designed to create awareness of these particular brand names.

These barriers are important to Medco's approach to generic utilization because of customer considerations. For employers and similar groups such as unions, member satisfaction is extremely important; member complaints and dissatisfaction affect benefit managers' ability to address cost management. Any strategy needs to address potential member satisfaction. A respondent emphasized that the aim of many of the generic promotion strategies is to engage the member in the

decision process, make the member aware of the discrepancy in cost of therapies, and to encourage a dialog between the member and the prescribing physician regarding which drugs are most cost effective. On the other hand, commercial health plans, according to a Medco respondent, are very concerned about the satisfaction of network physicians. Any strategy targeting generics also has to be concerned about that.

Benefit Plan Design Options

As noted earlier, because the client base is diverse in terms of priorities and constraints in decisionmaking, any broad strategy Medco undertakes has to offer choices among possible interventions. Many opportunities are available within plan design options to encourage the use of generics. Customers can select formularies that favor generic drugs while still meeting Medco's clinical standards. Customers also can structure cost-sharing (co-payments and co-insurance) arrangements to encourage use of generics through financial incentives. Currently, Medco is seeing a shift away from flat co-payments toward co-insurance. The use of co-insurance has several benefits: a stable co-insurance rate is easier for customers to administer year to year, a percentage share of medication costs increases actual cost-sharing, and as members' out-of-pocket costs go up, they become more aware of the cost of the benefit. The latter also encourages members to participate in the prescription process with their physicians in order to seek lower cost alternatives.

Clients can choose to encourage the use of generic equivalents through a "Member Pay the Difference" program. In this program, if a prescription is written for a branded drug for which there is a generic equivalent available, and the member rejects the generic option, the member pays the difference in price between the two medications. Since the FDA has determined that the drugs are bioequivalent, members are asked to bear the financial burdens of their choices. The program also addresses situations in which a physician specifically requests on the prescription form that the brand-name drug be dispensed as written (DAW). A "hard" version requires the member to pay the difference even if a physician makes this request; in the "soft" version the member is not charged under these particular circumstances. A respondent estimated that about half of Medco's clients have selected the "soft" version, possibly to avoid the possibility of member and physician dissatisfaction discussed above. A respondent observed that the current status is an opportunity for further efforts to educate Medco clients on the clinical soundness and financial value of a more stringent requirement.

Two other possible interventions within plan design include elimination of co-payments for generic drugs to create a strong financial incentive toward use of generics and implementation of a step therapy program for specific brand-name drugs, which requires members to try a generic medication before use of a specific brand-name drug in the same class is paid for.

Formulary Management Programs

From a benefit management perspective, Medco offers many programs designed to encourage increased use of preferred drugs, both generic and preferred brand name. Two of these programs are Therapeutic Interchange (TI) and Formulary Coverage Review (FCR). This section will describe how the program works with generics.

About 20 to 25 non-formulary brand drugs are targeted for therapeutic interchange. Two factors that determine candidates for the TI program are: first, clinical assessments by Medco's P&T Committee that these drugs are "generally interchangeable," which means the interchange would not result in any difference in clinical outcome or need for additional clinical monitoring, and second, a financial assessment. There is a long list of drug pairs that Medco's P&T consider generally interchangeable, so the assessment by Medco's Formulary Consulting Department of the

value of the potential interchanges to customers is critical to the decision. Some interchanges direct physicians toward generic alternatives and some toward lower-priced brand-name drugs. Interchange opportunities that come into the mail order program are identified at receipt; before the prescription is filled, Medco pharmacists call physicians to discuss the generic or preferred brand options. For the retail pharmacy channel, Medco staff identify opportunities by reviewing claims tapes weekly. Medco then contacts these physicians, asking if the physician would consider changing the prescription to the preferred generic or brand drug for the next refill. If the physician agrees to the interchange the member is sent a letter for use at the next refill. This program is voluntary: the physician, pharmacist, and member may decline a suggested interchange.

A similar communication process is used with DAW prescriptions. Medco staff identify prescriptions in the retail pharmacy channel where the physician has ordered DAW by reviewing claims tapes weekly. Medco then sends a fax to these physicians, asking if the physician would consider changing the prescription to the generic equivalent drug for the next refill. Prescriptions with a DAW order that come into the Medco mail order program are identified at receipt; before the prescription is filled, Medco pharmacists call physicians to discuss the generic option.

Many factors influence the success rate of the TI program. Overall this voluntary program has about a 35 to 50% success rate. A respondent suggested that one barrier to success is that some physicians do not respond to Medco within the time frame needed, and since the program is voluntary, Medco cannot stop processing the prescription. Also, some physicians simply do not want to agree to the interchange before discussing the alternative with the patient. Despite this concern, the patient acceptance of this program is very good. After the interchange, because it is a voluntary program, patients can contact Medco and ask Medco to contact their doctors for a return to the prior medication; but only about 5% do so.

All interchanges are shifts to lower cost drugs. Medco projects that the savings for the therapeutic interchange programs will total \$30 million for 2005. Further value is produced by driving improved formulary compliance, thereby enhancing Medco's ability to negotiate rebate contracts with manufacturers. These contracts are worth over \$3 billion annually. More than half of Medco members are enrolled in its TI program. Therapeutic Interchange impacts approximately 600,000 to 1 million claims annually. Although this is a small proportion of total claims, it affects not only generic utilization but also overall formulary compliance programs that drive the overall formulary rebate value. Of the TI interchanges, about 40% to 50% are from a single source brand (i.e. where a generic is not available) to a therapeutically equivalent generic of a different of drug.

Formulary Coverage Review (FCR) has enrolled about 16 million lives since its launch in January 2004. This program differs from Therapeutic Interchange in that a coverage review is required before selected non-formulary drugs would be covered by a plan. The program focuses on a very selective list of non-formulary drugs where potential for cost savings is high. At the time of the case study data collection, the program included Proton Pump Inhibitor medications, selective serotonin reuptake inhibitors (SSRI) antidepressants, and cholesterol lowering medications. The program is similar to step therapy in that it requires use of a generic or preferred brand before the non-preferred is covered. The Medco claims adjudication system does not allow the initial prescription to be filled either at the retail pharmacies or the mail program. Information then goes to the Medco pharmacists who contact physicians to inform them about the plan rule that the member would have to pay out-of-pocket for the medication, unless there is a clinically valid reason for coverage of the non-formulary drug. If physicians do not agree to a change to the formulary generic or brand, they are asked to complete a coverage review. However, physicians agree to the

change about 90% to 95% of the time. Medco respondents reported that customers can save up to 30% to 50% of the cost of specific drugs in this program if the prescriptions not been reviewed.

Education and Communication

As noted earlier, many members and physicians are not fully knowledgeable about generics. To raise awareness of the availability and benefits of generics, Medco has developed a variety of educational programs directed toward members, physicians, and pharmacists. The efforts are intended to work in concert, educating all stakeholders.

Educational communications directed toward members provide highly individualized information about a member's use of medications, the costs to themselves and the plan sponsor, information about generic options, and the potential savings they can achieve. This information is delivered by mail, the internet, and telephone counseling, using Explanation of Benefit (EOB) statements, the Medco website *Medco.com* which has individual account information, targeted "opportunity" letters, and Medco pharmacists who reach out to specifically targeted individuals. Medco managers believe that raising members' awareness of costs and options to save money encourages them to discuss these issues with their physicians.

Medco has developed several programs designed to educate physicians about generic options. "Generics First" is a counter-detailing program, where skilled pharmacists meet with highprescribing pharmacists to discuss the use of generic alternatives as an option for specific conditions. This is a new program and is conducted in cities where there is a concentration of interested clients. Another program, which is also a counter to manufacturers' promotional efforts, provides samples of generics to physicians to encourage their use with patients who are just starting therapy. The program is continually evolving, depending on what can be procured from manufacturers, but currently includes samples for proton pump inhibitors (PPIs), ACE inhibitors, beta blockers, selective serotonin reuptake inhibitors (SSRIs), nonsteroidal anti-inflammatory drugs (NSAIDs), non-sedating antihistamines (NSAs), and two diuretics. And finally, Medco produces physician practice summaries, based on claims data, that profile individual physicians' prescription patterns and benchmark against peers in the same specialty. The report, which also goes to health plan customers, measures performance from the standpoint of generic prescribing and formulary compliance.

Medco uses its claims adjudication system to communicate with pharmacists. It alerts the pharmacist with a message whenever a generic equivalent or generic alternative is available for a prescription that the pharmacist has just entered. Medco also sends report cards to pharmacists that summarize performance on generics utilization, and compares performance to other pharmacies.

Other Interventions

Utilization Management

Medco respondents reported that significant cost savings can be achieved through management of utilization. The primary focus of the utilization management programs is patient safety, where Medco strives to ensure that patients receive the appropriate drug at the correct dose and for the right period of time. While the goal of the program is to minimize adverse drug events and to avoid drug interactions and allergies, it also leads to cost savings.

The concurrent drug utilization review (DUR) program is administered directly through the claims adjudication system, looking for many different kinds of potential adverse drug events, such as

dosing above the maximum dose, drug-drug interactions, therapy duplications, early refills which could lead to overlapping therapy, and drug allergy based on the patient's past history. The system also identifies certain drugs that are inappropriate for elderly patients and some drugs that can have adverse effects when the accumulated dose over time reaches a certain level. About one quarter of prescriptions generate one of these kinds of alerts. Medco also has a retrospective DUR program, which reviews patients' prescription histories over time to assure clinical appropriateness of therapy to detect therapy duplications and potential abuse of narcotics.

Savings can occur when a prescription is reduced, changed to another drug, or cancelled. Medco estimates that four to five percent of clients' drug spending is saved with these alerts, though the level of savings depends on the demographics of the member population, the client's formulary, and the mix of member prescriptions.³⁹

Clients can also purchase an enhanced patient safety program, called Rational Med. This program integrates prescription data with comprehensive medical claims and selected laboratory data provided by the health plan or employer. With this additional data, Rational Med search engines can look for drug-disease interactions with a high degree of sensitivity as well as drug-drug interactions. This service is particularly useful if a patient is seeing multiple doctors for multiple conditions, since specialists treating separate conditions may not be aware of all therapies a patient may be taking for multiple conditions.

Results Of Cost Management Interventions

A Medco manager observed that "There are no home runs in cost management, only singles," meaning that cost savings are a matter of the accumulation of various interventions. This section provides financial results for the strategies described in previous sections. However, results have not been calculated for many of the specific interventions because the programs are designed to work in concert and to support larger objectives.

Mail Order Program Results

As noted earlier, the standard mail order program is able to save about six to eight percent on the cost of drugs through lower acquisition costs, fewer dispensing fees, and increased efficiencies compared to the retail pharmacy sector. Recent data from Medco show that members are increasingly turning to the mail program: among Medco clients, the percentage of total drug spending associated with the mail program rose from 34.3% for calendar year 2003 to 39.6% for 2004.⁴⁰

Also, as noted earlier, clients enrolled in the retail refill allowance program experienced significant increases in mail order use. Clients enrolled in the standard mail order program typically use mail order at a rate of 10% to 40% of total prescriptions, while those enrolled in the RRA program use mail order at a rate of 50% to 85%. The drug trend for the clients who are enrolled in the RRA program was far below the national drug trend for 2003 and the projected trend for 2004, as can be seen in Exhibit 3 below. In 2003, the national drug trend was 13.4 percent, while the trend for

³⁹ Savings are calculated based on claims, calculating the difference between the costs of the initial drug and the costs associated with the drug, if any, actually dispensed.

⁴⁰ Medco Drug Trend Report, May 2005, p. 30.

clients enrolled in the RRA program was 6.9 percent. Almost the same gap was maintained in 2004, when the projected national drug trend was 11.9 percent and the drug trend for Medco clients enrolled in the RRA program was 6.4 percent.

	2003	2004
National Trend*	13.4	11.9
RRA Program Clients	6.9	6.4

Exhibit 3: Comparison of Drug Trends between National and RRA Program Clients

Source: Discussion with Medco respondents

*National drug trend as projected by the Centers for Medicare and Medicaid Services⁴¹

Increasing Use of Generics

Medco has not assessed separate results for the cost management interventions related to its efforts to expand the use of generics. However, Medco data show that the average generic dispensing rate for Medco clients increased from 43.8% in 2003 to 46.3% in 2004.⁴² For the second quarter of 2005, the generic dispensing rate reached 51.0%.⁴³

The overall drug trend for Medco has decreased from 12.9% for 2002 to 8.5% for 2004.⁴⁴ The increase in generic use is seen as an important factor in a slowdown in growth of the unit cost of drugs, a key driver of the drug trend. Annual increases in unit costs have slowed from 8.3% for 2002 to 3.1% for 2004. Two drivers of unit cost, price inflation and therapy mix, are affected by increased use of generics. Specifically, while prices for brand-name drugs increased 6.7% during 2004, prices for generic drugs increased only 0.5%. At the same time, a higher proportion of generic drugs were dispensed, as noted in the change in dispensing rates. The result of both trends, more use of drugs for which prices rise more slowly, has been a slowing in the growth of unit cost over time.⁴⁵

One Employer's Experience

One employer client participated in the case study. This employer has been a Medco client for more than ten years and has about 27,000 lives covered under the Medco drug benefit, including both retirees and employees. This employer participates in the retail refill allowance program (which promotes the use of the mail-order pharmacy) and does formulary coverage review for three classes of drugs. This client also has an incentive formulary with significant penalties. The organization had experienced high rates of increase for several years, culminating in an increase of 26% on a PMPM basis in 2002. The trend slowed to about 4% in 2003. In 2004, the company introduced extensive plan changes; for 2004, the trend on a PMPM basis was

-15.7%. These changes included several programs discussed in the case study, including Formulary First coverage review and retail refill allowance, as well as a customized formulary, additional step therapy rules, and exclusion of antihistamines.

⁴¹ Stephen Heffler et al, "U.S. Health Spending Projections for 2004-2014," <u>Health Affairs</u> 23 February 2005.

⁴² Medco Drug Trend Report, May 2005, p. 30.

⁴³ The information on 2005 is found in Medco's News Release regarding second quarter earnings, July 26, 2005.

⁴⁴ Medco Drug Trend Report, May 2005, p. 7.

⁴⁵ Medco Drug Trend Report, May 2005, p. 29.

Lessons Learned

Key Success Factors

Respondents reported that effective communication techniques to support members in their understanding of their benefits and the use of economic incentives are two keys to success in implementing the cost management activities discussed in this case study. Member engagement is seen as critical, whether the cost management programs are voluntary or mandatory. Education and information were mentioned as part of all the cost management strategies discussed in this case study. For example, as was noted earlier, patients may erroneously view generic equivalents as being inferior, although the FDA has determined that they are equivalent. Effective communication strategies are needed to challenge the perception that generics are inferior. A respondent reported that a combination of financial incentives and aggressive education, from both the employer and Medco, is critical in moving the generic dispensing rate for an individual client from the high 40's to low 50's.

Medco's information system was also identified as important to success. The system has a single information platform where all the data and all rules reside. This makes it possible to conduct analyses and carry out modeling efforts very rapidly in response to questions or concerns. This capacity is very important in working with clients; Medco account advisors can quickly calculate the outcomes of possible changes in benefit management or plan design, such as deductibles, a narrower pharmacy network, or rules for cost management. These systems also make possible rapid communication with pharmacists in order to enforce plan design elements and very targeted communications to members about drug utilization and generic alternatives.

The mail-order pharmacy program was seen by several respondents as very important in reducing cost trends for many clients. The cost savings accrue from multiple sources. As previously mentioned, drugs purchased through the mail-order pharmacy are acquired at a lower cost than at the retail pharmacy. Additionally, the value of the mail-order pharmacy is enhanced because it makes other cost management programs more effective. Since Medco pharmacists handle the individual prescriptions, the formulary coverage review and therapeutic interchange programs are more effective for the company's clients than what would be available in a retail setting. Medco pharmacists, as employees, have a stronger incentive to see these programs succeed.

The discussion with the client also gave insight into Medco's key success factors. The client reported that Medco is able to provide data of exceptional quality. The drug (such as new drugs coming onto the market) and utilization data provided by Medco enables this client to make informed decisions about which strategies will work best for their managed population. Furthermore, the quality of Medco's data is perceived to be key to the particularly smooth implementation of the cost management strategies at this firm. The client, who noted that his organization is very sensitive to the frustration that employees might encounter if a new program is not implemented correctly, valued this.

Replication/generalizability

Any organization can purchase the type of cost management services described here from Medco and other firms in the pharmacy benefit management field. However, a respondent reported that the organization's philosophy toward the pharmacy benefit is critical in determining what kind of strategies can be pursued. If a client firm believes that it cannot ask its members to suffer some disruption, and to change behaviors, then the options for intervention are very limited. Most safety programs, such as described in the section on Utilization Management, are easily acceptable, and while they are primarily geared towards safety, there are also cost savings. Another important issue is that organizations need to be prepared to undertake a number of activities to improve cost management. At this time, cost management results from many separate activities, each yielding returns that, in the end, can add up to significant savings.

Looking to the Future

The respondents had several comments about how cost management strategies might be affected in the future. A respondent observed that there will be a number of changes in the area of generic drugs next year when the patents of many well-known brands will expire, and generic equivalents will enter the markets. Among some classes of highly used drugs, such as SSRIs and drugs for lowering cholesterol, generic equivalents will be available for several well-known brand name drugs. Other factors that may generate interest in generics are the voluntary reduction in advertising by manufacturers and the development of more stringent guidelines from the Federal Drug Administration on drug advertising and physician detailing. As advertising decreases, both physicians and consumers may become more aware of generics.

The respondent noted that more client organizations are expressing interest in programs that encourage the use of generics, perhaps because clients are more comfortable when their members have choices. Now that there is more than one choice in several classes, and the potential financial savings are clear, clients may be more drawn to emphasizing generics. Another respondent observed that emphasis on promotion of generics as alternatives to brand name drugs will grow.

There are likely to be changes in the services available through the mail order program. A respondent noted that there is a growing need to provide special services for members with complicated health conditions. New programs are likely to be added, also, as the utilization of specialty drugs grows. Individuals using these medications require a variety of services, such as specialized counseling, that are currently not provided through the program.

A respondent noted that the increased use of e-prescribing has the potential to facilitate drug cost management because it enables organizations to provide physicians with education about prescription alternatives at the point of decision-making. Not only are e-prescribing tools effective as communication vehicles, but they also decrease the administrative costs of processing a drug claim. There remain challenges, however, to the wide-spread implementation of e-prescribing tools, for the cost of implementing the tools is borne entirely by the physician while many of the benefits accrue to the pharmacy benefit manager (through decreased drug costs) and member (through decreased co-payments).

A respondent observed that the development of "personalized" medications will require new ways to deliver benefits. For example, recently the Federal Drug Administration approved use of a genetic test that will begin to make individualized dosing feasible. As drug manufacturers make use of these types of testing approach, and as more tests become available, the ability to calibrate dosing will increase. This progress will challenge PBMs and similar organizations to develop means to adapt to these changes.

3.0 Discussion

3.1 Overview Of Interventions And Results

The five organizations employed a number of interventions. In this section we provide an overview of these interventions and the results achieved.

The key interventions of the **Tufts-NEMC IPA** included a full-time clinical pharmacist position to provide clinical support to physicians and patients and take the lead in recommending and supporting cost management practices. Tufts-NEMC used physician education and information initiatives including presentations and newsletters to change prescribing patterns. Tufts-NEMC implemented a common drug list to help physicians select the most cost-effective drugs and correct dosages from among multiple health plan formularies. The organization leveraged its existing electronic medical record to provide color-coded drug formulary recommendations to physicians and to facilitate drug trend analysis. Other interventions include limiting detailing and free drug sample distribution, and participation on the P&T committees of the managed care plans and hospitals with which the health system contracts.

With respect to cost savings, since the year 2000 Tufts-NEMC has met its multi-year goal of keeping drug cost increases to about 10-11%. Overall utilization of generic drugs has increased significantly, and the IP out-performed the network average in a major health plan in both 2003 and 2004. Physicians' formulary compliance improved over time, and IPA performance with a Proton Pump Inhibitor (PPI) and a generic SSRI antidepressant improved.

PSN designed an evidence-based universal (all payer) formulary to support physicians' prescribing needs and, with its single cost basis, encourage cost effective decision-making. PSN developed a 'suite' of standardized pharmacy utilization and financial reports to support the Pharmacy Program. Its incorporation of DxCG risk adjustment enhanced its credibility with physicians, and its web-based format leverages the latest health information technology. PSN's Automated Therapeutic Interchange Program also leverages HIT to identify potential interchanges (brand-to-generic, between brand-name drugs, pill-splitting, and dosage consolidation) that are cost-effective. PSN's counter-detailing programs employ pharmacists to provide consultation and physician education; because pharmacists are the primary source of drug information, the likelihood of cost-effective clinical decisions increases. Additionally, PSN leaders participate on P&T and hospital committees.

From 1999 through 2004, PSN's per-member per-year pharmacy cost trend within PSN and its network has been well below the national benchmark. Cumulative savings of \$76 million compared to budgeted expenditures projected at the trend levels were realized across the network. From 1998 to 2004, universal formulary compliance increased substantially. Cost savings associated with generic and therapeutic interchanges since 2001 total approximately \$8 million.

For clinical reasons and because new market entries are often more expensive, wherever appropriate, **Kaiser** stays with proven therapies. The health plan's objective is to continue the use of existing cost-effective drugs proven to be of the highest quality through an extensive communication campaign to remind physicians about the value of these drugs. Kaiser's "stratification for appropriate use" intervention emphasizes the appropriate use of drugs for individualized treatment plans using risk stratification for drug use management. Through physician education and communication campaigns, the health plan's cost avoidance program emphasizes that the appropriate use of drugs results in cost avoidance. Kaiser emphasizes the importance of physician education and information activities through a partnership between its medical and pharmacy organizations to design initiatives that are clinically sound. Other interventions include a formulary focusing on generic substitution, and minimization of drug detailing by manufacturers.

The Southern and Northern California Kaiser plans placed first and third, respectively, in the NCQA Quality Compass[®] in 2003 with PMPM costs of \$22.73 and \$24.87 and plan managers estimate that Kaiser spends \$500 million less annually than a competitor with a comparable population. Kaiser's generic utilization rate is between 75% - 85%, with managed care plans averaging about 55%.

Pitney Bowes, as an employer, has focused its cost management on its pharmacy benefit, with an innovative educational program for its employees as a vital complement. Pitney Bowes has implemented a three tiered co-insurance benefit with very low co-insurance levels for some generic medications. Telephone case management for specialty drugs with a 24/7 hotline enhances the program's appeal. The company partners with its PBM to provide educational services and a website with personalized employee information, and also makes WebMD available to employees. Pitney Bowes also uses predictive modeling to examine combined medical and pharmaceutical claims and expenditures, to identify high-risk individuals with diabetes, asthma, and cardiovascular disease with poor medication compliance, and to implement a variety of risk reduction interventions. Finally, Pitney Bowes' on-site medical clinics offer "teachable moments" regarding the use of generics.

Pitney Bowes indicates that its overall financial goal has been achieved. The PMPM, calculated using all prescription drugs (including specialty medications) for 2004 was \$32.10 for the active, non-retiree population, compared to \$29.50 in 2003 and \$26.40 in 2002, with a drug trend for 2004 of 8.8%, vs. an 11.9% CMS projection for that year. Pitney Bowes' 2004 generic dispensing rate was 48% and their generic substitution rate was 91% (vs. a national projection of 92% for retail and 93% for mail order programs). There was an average decrease of 7% in the cost of drugs for patients with diabetes and 12% among those with asthma.

Medco's mail order benefit is a key component of cost management offerings due to lower costs, fewer dispensing fees, economies of scale, higher efficiency than retail processing, and specific programs that use mail order as a platform for such interventions as generic substitution. Medco's retail refill Allowance Program increases the use of the mail-order pharmacy program with financial incentives, member education and customer support. Medco increases the use of generics by providing customers formularies that favor generic drugs while meeting Medco's clinical standards. Their "Member Pay the Difference" program requires members to bear the financial burdens of their choices. Medco offers a plan that eliminates co-payments for generic drugs and which requires members to try a generic medication before specific a brand-name drug in the same class is paid for. Medco offers Therapeutic Interchange (TI) and Formulary Coverage Review (FCR) programs to encourage increased use of preferred drugs, both generic and preferred brand name. Medco's Education and Communication programs target members, physicians, and pharmacists. Finally, the organization offers utilization management focusing on patient safety – minimizing adverse drug events to avoid drug interactions and allergies, which also leads to cost savings. Medco's enhanced patient safety program, Rational Med, integrates prescription data with comprehensive medical claims and selected laboratory data provided by the health plan or employer.

Recent Medco data show an increase in members' use of the mail program; percentage of total mail order drug spending increased from 34.3% for calendar year 2003 to 39.6% for 2004. Drug trend in

the RRA program was far below the national drug trend for 2003 and the projected trend for 2004; in 2003, the national drug trend was 13.4 percent, while the trend for clients enrolled in the RRA program was 6.9 percent. In 2004, when the projected national drug trend was 11.9 percent, the drug trend for Medco clients enrolled in the RRA program was 6.4 percent. Medco data show that the average generic dispensing rate for Medco clients increased from 43.8% in 2003 to 46.3% in 2004. For the second quarter of 2005, the generic dispensing rate reached 51.0%. The overall drug trend for Medco has decreased from 12.9% for 2002 to 8.5% for 2004, with annual increases in unit costs slowing from 8.3% for 2002 to 3.1% for 2004. Medco has seen a slowing in the growth of unit cost over time. The employer highlighted in the Medco case study had experienced high rates of increase for several years, culminating in an increase of 26% on a PMPM basis in 2002. The trend slowed to about 4% in 2003. In 2004, the company introduced extensive plan changes; for 2004, the trend on a PMPM basis was –15.7%.

3.2 Cross-cutting Themes

Several cross-cutting themes emerge from the studies presented above. In this section we identity and comment on these themes. These include:

- Identifying areas where there are opportunities for savings,
- Influencing institutional partners,
- Creating physician commitment,
- Facilitating physician compliance,
- Facilitating patient compliance, and
- Health information technology.

Identifying Areas Where There Are Opportunities for Savings

Some cost savings interventions may have (at least initially) nothing to do with physician or patient behavior. For example, there are efficiencies to be gained in the process by which medications are 'delivered' to the patient; mail order is less expensive than alternatives. As another example, lower prices for a given therapy can be achieved by pill-splitting, which is a strategy that does not work by changing patient utilization but is based on lower costs per prescription. Similarly, dose optimization also targets the per-dose cost of medications.

Another area where there are opportunities for savings is the choice of less costly therapies. Most of the organizations used some form of generic promotion to achieve cost savings; generic promotion is a widely accepted cost savings technique. There is generally room for increased used of generics; one reason is that they are not as profitable as brand names, so less advertising is devoted to them. In addition, drug companies attempt to delay the "brand name to generic" cycle by preventing their drugs from going off patent through techniques such as only slightly changing the dose or the molecule. Formulary management programs, step therapy, and stratification for appropriate use are other examples of encouraging the selection of less costly medications.

Focusing on key populations is another opportunity for achieving savings. Health Information Technology (HIT) helps to identify such opportunities.

Create Influence On Institutional Partners

In the complicated matrix of relationships that health care is today, partnerships become increasing valuable. Examples of this in pharmacy cost management are the partnerships that two organizations mentioned regarding pharmacy and therapeutics committees. By working closely with

partners outside of their own organizations, these entities reported significant influence on the work of these committees.

Creating Physician Commitment

Partnerships between physicians and pharmacists play a critical role. The two health plan cases have full-time clinical pharmacists and have developed strong partnerships between their medical and pharmacy organizations. This relationship is a collaborative one in which the pharmacist is perceived by physicians as a colleague whose input is highly respected. An important component of these partnerships is some form of educational program. Some of the same techniques used by drug companies (e.g. a form of counter-detailing), have proven useful to managers of pharmacy costs. Some of these case studies show the need for pharmacy expertise directed at the physician level; accurate information delivered by a trusted source is viewed as critical. Targeted information to inform physicians becomes increasingly important as therapies themselves become more complex. Concerns about drug interactions, for example, highlight the need that physicians have for complex information provided by a by a pharmacist who is a "full-service" resource. The physician-pharmacist partnership also helps facilitate physicians' practice of evidence-based medicine.

These case studies suggest that cost alone may not be a principal motivator of physician behavior. Physicians may have little awareness of drug costs. Some of the cases suggested that physicians may be much more responsive when the overall context of concerns about quality of care is emphasized, in contrast to only addressing cost management. In addition, the use of risk adjustment (e.g. DxCGs) mentioned in one case, can help to build credibility with physicians.

Physicians not surprisingly find multiple formularies frustrating. Interventions that assist physicians in coping with this problem can leverage an opportunity for cost savings by providing tools that simplify prescribing. Reducing physicians' exposure to pharmaceutical manufacturers' efforts to promote the utilization of high-cost drugs can be very effective. Both health plans, by limiting detailing and drug sample distribution, have achieved results in this area.

Facilitating Physician Compliance

Risk sharing is one way to encourage physician compliance, and a respondent at one organization mentioned how this created an environment conducive to pharmacy cost containment. Another way to encourage physician compliance is to provide physicians with tools that make their work easier. Examples include formulary simplifiers such as the universal formulary and common drug lists described in some of the cases. Again, HIT can be useful in this context, for example by identifying potential drug interchange opportunities and by supporting the production of physician-friendly reports, as described above.

Facilitating Patient Compliance

A number of the interventions involve some form of patient (or consumer) education. Advertising is powerful and some of the cost savings interventions involve strategies for countering this technique of drug companies to increase or maintain brand name utilization. One organization mentioned case management as an opportunity to educate patients and obtain their buy-in. Financial incentives may work for patients as well as for physicians. Tiered co-pays worked well for one of the organizations. For another, financial incentives for mail order and for the use of lower-cost drugs have proven successful.

Health Information Technology

Health information technology (HIT) has become increasingly important in a variety of health care areas. These case studies highlight numerous uses of increasingly sophisticated HIT in pharmacy

cost containment. The increasing integration of pharmacy data with medical data is a key driver of success in this area. HIT plays a key role in many of the cross-cutting themes, from enabling sophisticated reports incorporating risk adjustment to providing support for physician education. Sophisticated HIT depends upon high quality data; as one of the organizations emphasized, this builds credibility with physicians.

Other Observations

In addition to the broader themes described above, some additional specific points are evident:

- Few if any of the interventions that were described were developed and implemented instantaneously. There was always significant startup time in developing a program.
- Benchmarks are increasingly used in many fields to improve performance. In pharmacy cost management, there is a dearth of good benchmarks.
- The commonly used metric known as "trend" is not always uniformly defined. Some plans calculate drug trends after the consumer cost share is deducted, while others do not. Denominators inconsistently include elders, and sometimes specialty drugs are not included.

3.3 Strengths And Limitations Of The Study

The present study has both strengths and limitations. Strengths include the characteristics of the selected companies, the iterative method of data collection, and access to senior executives at each organization. The organizations selected as case studies represent a broad range of entities including a provider, an HMO, a PBM, an employer, and a provider of specialty pharmaceutical support services. This enabled us to present not only a variety of cost containment strategies, but perspectives on these strategies from a variety of major types of stakeholders.

Our data collection process entailed a combination of on-site and telephone methods. Because we tape recorded the discussions, we were able to formulate follow-up questions that enabled in-depth follow-up probing. Finally, we obtained access to senior executives at each organization, who provided not only broad, high-level perspectives but also access to operational managers to provide detail as needed.

At the same time there were some limitations to the study. While the five selected cases represent a diverse group of organizations, there are limits to the inferences that may be made from a relatively small number of organizations in a large area of application. Not every type of existing cost containment technique is illustrated by these organizations.

3.4 Suggestions For Future Research

While the case studies in this report describe innovative techniques in cost containment, the field could benefit from further research in this area. Key questions include: which interventions are effective, and what are the ancillary impacts of cost containment interventions? Some of the cross-cutting themes discussed above have implications for future research.

Identifying Areas Where There Are Opportunities for Savings

A database of drug claims could be used to simulate the cost impact of various behavioral changes, such as a ten percent increase in the use of generics, a fifteen percent decrease in dispensing fees due to increased use of mail order, and a ten percent reduction in ER use for asthma due to disease management. Simulations could identify promising intervention areas, especially for populations of interest to ASPE.

Creating Physician Commitment

Future research could entail expanding the current study to developing further case studies of the implementation of cost-containment initiatives with an emphasis on key success factors in specific areas. One area would be to conduct a literature review of best practices regarding influencing physician behavior, for example.

Health Information Technology

HIT is an area of rapid change and in which it is particularly important to stay current. Studies of specific HIT initiatives and how they affect the quality and cost of drug therapy are needed. Abt, for example, has conducted an analysis of a pilot study of the use of a computerized system that provides patient drug history to clinicians in the emergency room.

Data Needs For Cross-Sectional And Pre/Post Intervention Studies

The present qualitative study can generate research questions that a quantitative research design could test. Some examples include: How may HIT be deployed to further increase savings? What forms of patient and physician education work best? How can physicians become engaged in various interventions? Do interventions that appear to work well in the short-term also work well in the long run?

Many Medicaid programs have carved out their drug benefits to PBMs for at least some populations, and the PBMs have instituted various cost containment initiatives. Pre/post studies of implementation of cost-containment initiatives to identify impacts on costs and other outcomes would be informative. Ideally, independent parties would conduct these studies. ASPE, for example, could fund this type of research.

What existing or soon-to-be existing data can be used to rigorously identify and evaluate best practices? A design for assessing the effect of different containment strategies on drug utilization and costs is the cross-sectional study. Databases that contain claim and utilization data from multiple entities (e.g. health plans) would be most useful. Such databases would enable evaluation of the results obtained by applying different types of interventions to obtain cost savings. The results of each entity could be risk adjusted, and literature reviews and discussions with organizations contained in the databases could be used to identify characteristics of interventions employed.

For example, the Federal Employee Health Benefits Plan (FEHBP) could be used to model drug utilization as a function of individual and plan characteristics to examine whether certain plan strategies had a measurable impact on utilization. Other data sources that contain drug claims for individuals in multiple plans could also support such analyses. The full implementation of the Medicare Part D program will open up new avenues for research using claims and utilization data to conduct the type of study described with FEHBP data above. Examples of other databases to be explored include those of Thompson/Medstat (MarketScan), PharMetrics (now part of IMS, which was bought by VNU), and i3Magnifi (formerly Ingenix, now part of United Healthcare).

Ancillary Impacts

Cost containment can have both intended and unintended consequences. While it is important to contain costs, future research should also consider the impact of cost containment strategies on clinical outcomes, patient satisfaction, and physician satisfaction. Numerous avenues exist for examining clinical performance in the inpatient setting (e.g. CMS Hospital Quality Initiative⁴⁶),

⁴⁶ Hospital Quality Initiative, http://www.cms.hhs.gov/quality/hospital/

although fewer data are available for outpatient quality analyses. With respect to member satisfaction, the widespread use of the Consumer Assessment of Health Plans (CAHPS)⁴⁷ initiative offers opportunities to measure health plan members' perspectives on care. A study with an explicit focus on physicians' perspectives on cost containment and best practices could help provide information necessary to increase physicians' compliance.

⁴⁷ Agency for Healthcare Research and Quality, http://www.ahrq.gov/qual/cahpsix.htm

Appendix 1

Literature Review

The literature review encompassed both peer-reviewed and non-peer reviewed journal articles. Internet searches of policy organizations, corporate websites, and Google News were also used as online sources to find current information on companies that were implementing cost-containment strategies. The Knight Ridder Collection newspaper archive, Atlantic Information Service's *Drug Benefit News*, and *A Guide to Drug Cost Management Strategies* were also used to find potential best practices organizations.⁴⁸ We limited our search to materials that had been written in 1999 or later. The review of peer-reviewed journals was conducted using the abstract databases PubMed, Business Source Premium, the Biomedical Reference Collection and International Pharmaceutical Abstracts. The search terms that were used in the literature review targeted articles that reviewed or discussed cost containment strategies.

The abstracts identified from searching these databases were reviewed and articles that appeared relevant were retrieved. Project staff then reviewed these articles for examples of organizations that had implemented cost containment strategies. The names and, where available, contact information for individuals who were industry experts, were also retrieved. Finally, the bibliographies were reviewed for additional articles to obtain.

The 102 articles reviewed were categorized as follows:

- 1. *Intervention study:* The article involved a comparative study or an experiment to determine if a cost containment strategy achieved positive results (18 articles).
- 2. *Unknown methods study:* The article reviewed and discussed a cost containment strategy and identified cost savings, but did not define the methods used to evaluate the strategy (25 articles).
- 3. *Non-specific study*: The article generally discussed cost containment strategies without identifying cases of cost savings at a specific organization (38 articles).
- 4. *Contacts-only study:* The article yielded industry expert contact information but no information about cost management strategies (21 articles).

Intervention studies and unknown methods studies had the potential to ultimately provide examples of potential best practice case studies. Non-specific and contacts-only studies were useful mainly as educational material and as sources of expert contacts.

The intervention studies provided the best resources for information about cost intervention strategies. The cost containment methods analyzed in these articles are discussed in the body of this report. The findings from the studies using unknown methods are very briefly summarized. The other types of articles are not discussed.

⁴⁸ Namovicz-Peat, S. A Guide to Drug Cost Management Strategies. Atlantic Information Strategies 2004. www.AISHealth.com.

Appendix 2

Summary Of Potential Cost Containment Strategies

In pursuing this objective through peer-reviewed and other forms of literature, we identified many examples of what forms of interventions were believed to work. Following is a list of potential strategies for managing pharmaceutical costs.

Pharmacy Benefit Strategies to Control Costs*		
Strategy	Definition	
Analysis	Review of claims data to update formulary and trend analysis and reporting	
Capitation	Physician financial incentives to monitor pharmaceutical budgets.	
Compliance monitoring	Any technique to encourage patients to take their medications as prescribed	
Co-payments	A fixed amount of money per prescription paid by the enrollee when filling a prescription; 'tiered' co-payments are often used to encourage generic or therapeutic substitution	
Co-insurance	Similar to a co-payment, except the amount is a proportion of the total drug cost rather than a fixed dollar amount.	
Counter-detailing/MD Education	Used by MCOs and other payers to educate physicians about certain drugs. Source of information can include product literature and pharmacist intervention.	
Dosage optimization	Reviewing dosages patients are receiving and adjusting them to recommended levels.	
Disease management	Grouping patients by disease category and using treatment protocols (including drugs) to standardize care	
Drug utilization review	Retrospective or concurrent/prospective monitoring to identify problems with prescribing patterns	
Electronic prescription tools	Algorithm-based prescribing aids may decrease costs and medical errors and which are implemented on a range of platforms including handheld devices to computerized physician order entry systems	
Edits/alerts	Claims processing system algorithms that generate messages on benefit policies, drug interactions and other administrative and safety data	
Formulary	A compendium of covered drugs. Indicates which drugs are covered by co- payment amount. Open formularies contain preferred but not mandatory choices. Closed formularies require approval (prior authorization) when drugs not listed are prescribed. There are many other gradations.	
Generic substitution	Switching to a non-brand name molecular equivalent compound	
Mail order	Enabling members to purchase drugs by mail rather than in a pharmacy	
OTC substitution	The offering by a health plan to cover an over-the-counter alternative to a prescription drug	
Patient education	Through a variety of sources (pharmacist, internet, literature) providing information directly to patients about therapeutic options	
Pill splitting	Taking advantage of lower prices by purchasing higher dosage units and cutting them to the correct dose	

Pharmacy Benefit Strategies to Control Costs*		
Strategy	Definition	
Physician incentives	Monetary mechanisms to encourage certain physician behaviors. Examples include capitation arrangements or report cards showing drug utilization patterns and which may be have financial impact	
Physician profiling	Sharing with physicians reports on their prescribing patterns (without financial incentives)	
Step therapy	Treatment protocols advising the physician the order of choice for a particular set of prescription products	
Therapeutic substitution	A non-bioequivalent drug promoted by a health plan	

*Based on Namovicz-Peat S, A Guide to Drug Cost Management Strategies, Atlantic Information Strategies, 2004, Washington, DC <u>www.AISHealth.com</u> and from the results of the environmental scan.

Appendix 3

Summary Of Expert Discussions

Some experts were able to recommend specific organizations that they saw as achie ving cost savings. Other experts emphasized that it was difficult to name organizations for a number of reasons. The most common reason cited was the lack of transparency at pharmacy benefit management companies. Some suggested that the proprietary nature of the operations of some of these companies makes it difficult to assess who is and who is not a leader in achieving drug cost savings. Some experts indicated that little material has been published beyond anecdotal stories and marketing material and that rigorous evaluations of cost management techniques are difficult to obtain.⁴⁹ This pointed out the need in the development of the case studies to seek as much objective data as possible from the organizations selected.

Other experts were hesitant to name organizations that managed drug costs because they felt that the emphasis should be on total cost of care, not just drug costs. These experts were quick to point out that an increase in drug expenditures could mean a decrease in other health care costs. Finally, some experts were concerned that the quality of health care was being compromised in the pursuit of cost management strategies.

The amount of information that we were able to gather from experts about potential best practice organizations varied greatly. As mentioned, the lack of transparency was an impediment, and experts often named potential best practices without being able to cite solid evidence to back up their referrals. Anecdotal reasons were cited more often than specific cost cutting strategies that had quantifiable results. For example, one expert recommended an organization because "...they manage their physicians well". Another expert recommended another organization because this organization was "...not afraid to be on the cutting edge and try something new." In the cases where we were able to gather information on specific cost management techniques, the information came from an individual who was either a current or former employee of the organization, or had an affiliation with the organization.

The questions in the expert discussions focused on naming institutions that had achieved cost savings. However, some experts found it easier to talk in general terms about the individual techniques (not the specific organizations) that were likely to result in cost savings. Most experts emphasized the role of generics, either through direct generic substitution or through therapeutic interchange, in controlling prescription drug costs. There was less consensus on other techniques. One expert felt that educating physicians was essential to contain prescription drug costs. Another expert emphasized proper claims adjudication.

One expert at a potential best practice organization mentioned that the information systems support provided at that organization is essential to their success. By supporting the physician educational process, the electronic medical record has been a key contributor to cost savings. This individual also said that his organization's research suggests that the effects of simultaneous multiple interventions are difficult to sort out and, therefore, limit the inferences that can be made about the impact of specific single interventions.

⁴⁹ A review of the literature on drug cost containment strategies was published by the Kaiser Foundation. (Hoadley, J. Cost Containment Strategies for Prescription Drugs: Assessing the Evidence in the Literature, March, 2005. http://www.kff.org/rxdrugs/7295.cfm) The author points out the paucity of peer-reviewed studies of cost-containment and the fact that "evidence of effectiveness has been reported – often in quite general terms - in various industry newsletters or reports produced by different industry organizations."

Following is a list of expert comments on a variety of relevant topics:

- There is a lack of innovation in cost management efforts for employer-managed retiree drug benefits.
- Group purchasing is a key means for employers to manage costs.
- Specialty pharmaceuticals are an area to track for innovative cost management ideas.
- One employer purchasing group plays a coordinating role between its members' MCOs and their PBM; it reviews all prescriptions on a 24-hour basis, obtains benchmark data, and conducts yearly audits of the PBM.
- There is a need for evidence-based formularies.
- Quantity limits are a useful tool, as is a six-month moratorium on new drugs until safety and efficacy basic data are available.
- Disease management programs can have an effect on drug utilization.

Finally, it should be recalled that our key objective for these discussions was to obtain specific referrals to potential best practice organizations.

Appendix 4

Case Study Selection and Data Collection Approach

Based on our environmental scan, we identified a list of 32 organizations that qualified as potential best practices. The organizations were included on this list because they were either referred by at least one expert in a discussion or had published relevant data in a journal or news article. For each of these 32 organizations, when available, we obtained information on what interventions they had implemented from articles, the internet, or during a discussion. We used the same methods to obtain 'outcomes' information on savings. If we spoke to someone at the organization, we also noted whether the organization indicated interest in participating as a case study if we were to select it. Finally, we counted how many referrals an organization received. Finally, for the near final group of organizations a 'qualification' process was used to determine the suitability of each organization for inclusion in the final set of five case studies. This qualifying process involved identifying potential discussants (e.g. pharmacy director, medical director, operations), characteristics of the organization, pharmacy benefits, interventions in place, available measures, evidence of cost savings, and the willingness of organization to be a case study. An additional factor considered in selecting organizations was their performance relative to data compiled by the Academy of Managed Care Pharmacy.⁵⁰

To conduct the case studies, we constructed a flexible protocol for each organization. Two studies were conducted on-site (Tufts-NEMC IPA and PSN) and the others by telephone. Key contacts were identified at each site, with these individuals identifying additional associates with whom to have discussions. Respondents were asked for permission to audiotape the sessions to aid the write-up of the cases. Between two and three staff were present during each session to conduct the discussions using the protocol, to run the tape recorder, and to take notes. Respondents were asked for supporting documentation wherever possible. The key contact at each organization reviewed a draft of their organization's study report for accuracy.

⁵⁰ Academy of Managed Care Pharmacy. http://www.amcp.org/amcp.ark?c=pr&sc=xE42EBA1011D2071ACB3F0991E002B7EF> 2005. Feb 24.