INTERIM REPORT OF THE
DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

A REPORT ON PHARMACY BENEFIT MANAGER PRACTICES AND THERAPEUTIC INTERCHANGE

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

HOUSE DOCUMENT NO. 32

COMMONWEALTH OF VIRGINIA
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COMMONWEALTH of VIRGINIA

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TO: The Honorable James S. Gilmore, III

And

The General Assembly of Virginia

The report contained herein is provided pursuant to House Joint Resolution 574, passed by the 1997 General Assembly. This interim report provides information regarding the impact of pharmacy benefit manager firms (PBMs) on the Commonwealth's citizens and upon the health care market in Virginia.

The interim report also contains certain information on the PBM practice of therapeutic interchange. This is in response to the Task Force Studying the Practice of Therapeutic Interchange pursuant to House Joint Resolution 630, passed by the 1997 General Assembly. The Task Force was continued under House Joint Resolution 140, passed by the 1998 General Assembly, so that it may have the opportunity to review the findings of the HJR 574 study.

The interim report includes two studies.

The first study, conducted by the Mercatus Center at George Mason University, estimates the incidence in Virginia of one type of therapeutic interchange based on pharmacy benefit manager claims data, analyzes the impact of formularies on therapeutic interchange and reports on the pharmacy benefit management vendors used by major health insurers in Virginia.

The second study, conducted by the School of Pharmacy at Virginia Commonwealth University, is a literature review and summary description of the pharmacy benefit management industry. This study includes an annotated bibliography on pharmacy benefit management. The literature review also is supplemented by interviews with selected pharmacists, physicians, PBM employees, employers and patients.

The interim report executive summary also includes preliminary information from a citizen survey conducted by the School of Pharmacy at Virginia Commonwealth University on citizen perceptions estimating the annual incidence of therapeutic interchange. This study is not yet complete. It will be included in the final report.

Also included in the final report will be a survey of pharmacists and physicians conducted by the Mercatus Center at George Mason University. The survey will be used to determine the actual incidence of therapeutic interchange and the impact on physicians and pharmacists.

The final report to be delivered to the General Assembly before the end of February will include the surveys of citizens, physicians and pharmacists, will update studies in the interim report, if necessary, and will summarize all the information gathered on PBMs and the practice of therapeutic interchange.

Respectfully submitted,

Dennis G. Smith

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Department of Medical Assistance Services

An Estimate of the Annual Incidence of Therapeutic Interchange in the Commonwealth of Virginia During 1998

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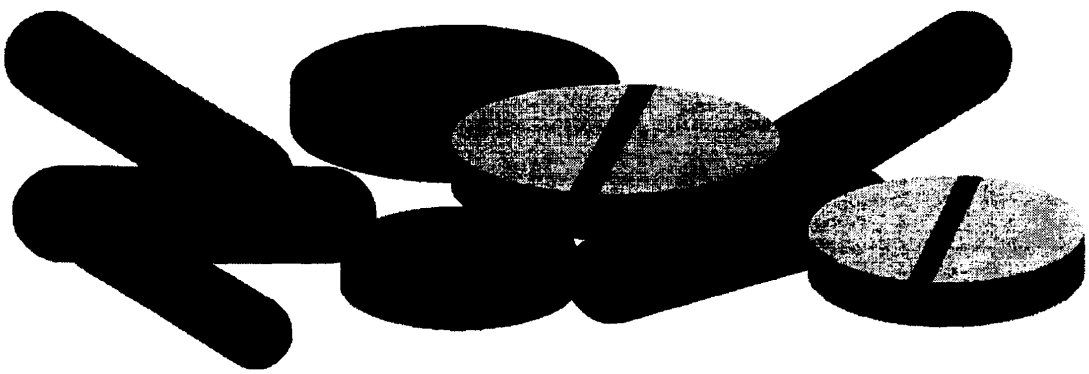

STUDIES PRESENTED BY THE COMMONWEALTH OF VIRGINIA'S DEPARTMENT OF MEDICAL ASSISTANCE SERVICES TO THE GOVERNOR AND THE GENERAL ASSEMBLY OF VIRGINIA

PURSUANT TO H.J.R. 574

Interim Report

January 1999

PREFACE

Growing emphasis on controlling spending growth for employee health benefits has propelled the growth of managed care in Virginia over the past several years. This emphasis has led to increased health plan competition based largely on price. Increased price competition has fueled innovation in the management of health costs--especially for health spending components experiencing above average cost growth. As one of the fastest growing components of health spending, pharmacy benefits have become subject to several new techniques designed to control spending growth. Techniques include mail order, formulary development, prior authorization, generic substitution, and therapeutic interchange.

The following two studies provide information on the changing face of pharmacy benefit management and estimates on the incidence of therapeutic interchange in the Commonwealth of Virginia. The first study, conducted by the Mercatus Center at George Mason University, estimates the incidence of therapeutic interchange based on pharmacy benefit manager claims data. The second study, conducted by the School of Pharmacy at Virginia Commonwealth University, is a literature review and summary description of the pharmacy benefit management industry.

The executive summary also includes preliminary information from a citizen survey conducted by the School of Pharmacy at Virginia Commonwealth University's Medical College of Virginia on citizen perceptions as a way of estimating the annual incidence of therapeutic interchange. This study is not yet complete. It will be included in the final report.

EXECUTIVE SUMMARY

The two manuscripts included in this report were commissioned by the Virginia Department of Medical Assistance (DMAS) as authorized by the Commonwealth's General Assembly per House Joint Resolution (HJR) 574 (1997). HJR 574 authorized DMAS to: (1) examine practices of pharmacy benefit manager firms (PBMs) on the Commonwealth's citizens, and (2) determine the affect of such practices on the Commonwealth's citizens and the overall healthcare market. The first study, Mercatus PBM Study, estimates the annual incidence of therapeutic interchange in the Commonwealth of Virginia by analyzing PBM pharmacy claims data. The Mercatus PBM Study also identifies health insurers in Virginia and how they are organized to manage their pharmacy benefit. The second study, VCU Literature Review, outlines the purpose and history of PBMs. The VCU Literature Review also identifies emerging issues in the management of pharmacy benefits. This executive summary also includes preliminary information from a VCU Citizen Survey on prescription drug coverage satisfaction and the extent of therapeutic interchange, but the study is not yet include and is not included in this report. The questions that follow summarize the most important findings from the studies.

Pharmacy Benefit Coverage in Virginia

1. What percent of Virginians with pharmacy coverage are satisfied with their prescription drug coverage?

- About 90 percent of all Virginians with pharmacy coverage report being satisfied with their prescription drug coverage (VCU Citizen Survey).

2. What percent of Virginians had pharmacy coverage in 1998?

- About 83 percent, or 5.6 million, of all Virginians are estimated to have had pharmacy coverage at any given time during the past year (VCU Citizen Survey & Mercatus PBM Study). There are an estimated 6.8 million Virginia residents (U.S. Bureau of the Census Estimate, July 1, 1998).

3. What percent of Virginians with pharmacy coverage used their pharmacy benefit during the past year?

- About 3.6 million, or roughly two-thirds, of all Virginians with pharmacy coverage are estimated to have used their pharmacy benefit during the past year (Mercatus PBM Study).

Health Insurers & Pharmacy Benefit Management in Virginia

4. Which Virginia health insurers hire PBMs to administer their pharmacy benefit management programs and which PBMs do they use?

- The left column in the following table lists health plans in alphabetical order. The right column lists the PBM vendor used by each health plan year (Mercatus PBM Study).

Health Insurers Contracting Out to PBM Vendors

Health Insurer	*PBM Vendor*
BC&BS of the National Capital Area	Merck-Medco Managed Care
Capital Care, Inc.	PCS
Cigna Health Corporation	PCS (indemnity)
George Washington University Health Plan	Advanced Paradigm
M.D. IPA & Optimum Choice, Inc.	Diversified Pharmaceutical Services
HealthKeepers, Inc.	Merck-Medco Managed Care
NYLCare Health Plans	Express Scripts, Inc.
OPTIMA Health Plan	Argus Health Systems, Inc.
PARTNERS Nat. Health Plans of NC, Inc.	Diversified Pharmaceutical Services
Peninsula Health Care, Inc.	Merck-Medco Managed Care
Physicians Health Plan, Inc.	Merck-Medco Managed Care
Priority Health Care, Inc.	Merck-Medco Managed Care
Sentara Health Plans, Inc. (SHP)	Argus Health Systems, Inc.
Trigon	Merck-Medco Managed Care
Southern Health Services, Inc.	Express Scripts, Inc.
United HealthCare of Virginia, Inc.	Diversified Pharmaceutical Services

5. Which Virginia health insurers use subsidiary PBMs for administering their pharmacy benefit management programs?

- The following table lists health insurers that have subsidiary PBMs for administering their pharmacy benefit management programs (Mercatus PBM Study).

Health Insurers Using Subsidiary PBMs
Aetna U.S. Healthcare, Inc.
Cigna Health Corporation (mail order)

6. Which Virginia licensed health insurers administer their pharmacy benefit management programs in-house?

- The following table lists health insurers that administer their pharmacy benefit management programs in-house (Mercatus PBM Study).

Health Insurers Managing PBM Activities In-House
Cigna Health Corporation (indemnity and PPO)
INOVA Community Health Plan
Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.
Prudential Health Care—Mid-Atlantic

The Practice of Therapeutic Interchange in Virginia

7. What are the different ways a therapeutic interchange can be initiated?

- There are four ways a therapeutic interchange can be initiated, based on the definition adopted by the Task Force Studying the Practice of Therapeutic Interchange. The four ways are *formulary exclusion, formulary inclusion, patient initiated and pharmacy financial incentive* therapeutic interchanges. *Formulary exclusion* describes interchanges made because the originally prescribed drug is not covered on the pharmacy plan formulary. *Formulary inclusion* describes interchanges made because the originally prescribed drug is not a preferred drug on the pharmacy plan formulary. *Patient initiated* are interchanges made upon request of the patient and can also be formulary exclusion or inclusion types of interchanges. *Pharmacy financial incentive* describes interchanges the pharmacy initiates as a result of financial incentives the pharmaceutical company has contracted to pay. Generally, pharmacy benefit

managers (PBMs) do not record therapeutic interchange cases where the originally prescribed drug is not on a formulary, the patient requests a different drug or the pharmacy initiates the interchanges as a result of financial incentives from pharmaceutical companies. PBM claims databases generally record *formulary inclusion* therapeutic interchanges. (Mercatus PBM Study).

8. What percent of Virginians report having experienced an approved therapeutic interchange during the past year?

- An estimated 3.0 percent of Virginians report having experienced an approved therapeutic interchange within the last 12 months. This estimate assumes a definition of therapeutic interchange to include formulary inclusion and formulary exclusion types of therapeutic interchange, but not patient initiated or pharmacy financial incentive therapeutic interchanges. The results are based on citizen recall and perceptions. (VCU Citizen Survey).

9. What percent of Virginians have experienced an approved therapeutic interchange during the past year?

- An estimated 0.4 percent of Virginians have had an approved *formulary inclusion* therapeutic interchange within the last 12 months (Mercatus PBM Study).

10. What percent of Virginians have experienced an attempted therapeutic interchange during the past year?

- An estimated 1.5 percent of Virginians have experienced an attempted *formulary inclusion* therapeutic interchange within the last 12 months (Mercatus PBM Study).

11. What percent of Virginians had prescriptions written that were identified as opportunities for a therapeutic interchange during the past year?

- An estimated 2.5 percent of Virginians had prescriptions written that were identified by PBMs as opportunities for a *formulary inclusion* therapeutic interchange within the last 12 months (Mercatus PBM Study).

INTRODUCTION

In 1997, the Virginia General Assembly passed House Joint Resolution (HJR) 574 (1997). HJR 574 requested the Virginia Department of Medical Assistance (DMAS) to:

1) examine practices of pharmacy benefit manager firms (PBMs) on the Commonwealth's citizens, and
2) determine the affect of such practices on the Commonwealth's citizens and the overall healthcare market.

Therapeutic interchange is a practice used by PBMs that is also of interest to the General Assembly. A special task force studying therapeutic interchange pursuant to HJR 630 (1997) recommended that the life of the task force be extended to consider the results of the PBM study. In response to both HJR 574 (1997) and 630 (1997), DMAS commissioned the following report to provide information useful for understanding the practice of therapeutic interchange in Virginia.

What is a therapeutic interchange?

The Special Task Force Studying the Practice of Therapeutic Interchange adopted the following definition of therapeutic interchange:

"Therapeutic interchange is the dispensing of a drug, by any person authorized by law to dispense drugs, that is a chemically dissimilar alternative for the drug initially prescribed. The alternative drug is expected to have the same clinical results and similar safety profile, when administered to patients in therapeutically equivalent doses as the drug initially prescribed, and is dispensed with the approval of the person who prescribed the initial drug, or their lawful designee."

No previous studies document the extent of therapeutic interchange in the Commonwealth of Virginia, and this report is the first known independent study on the practice of therapeutic interchange based on pharmacy benefit claims data.

Purpose of the Study

In this study, we:

1) estimate the incidence of therapeutic interchange in the Commonwealth of Virginia, and
2) identify insurers in Virginia who employ pharmacy benefit managers.

All pharmacy benefit claims data are from pharmacy benefit management (PBM) companies, health plans employing subsidiary PBM companies, or health plans that use in-house pharmacy benefit management techniques.

Report Outline

We organize the report into five chapters:

- The Introduction summarizes the purpose of the research.

- The Results chapter presents the information obtained from our statewide survey of pharmacy benefit claims data. We determine the incidence of therapeutic interchange as administered by pharmacy benefit management companies and health plans in Virginia.

- The Analysis chapter provides an analysis of several issues related to definitions of therapeutic interchange while presenting national data and cost data in order to better understand the underlying factors affecting pharmacy benefit management and the practice of therapeutic interchange.

- The Methods chapter describes the sampling methods used to obtain the raw data and estimating techniques used to reveal the therapeutic interchange process in Virginia.

- The Conclusion chapter highlights the most significant findings from the survey.

The report also includes four appendices:

- Appendix A provides an estimate of the number of Virginians with pharmacy benefit coverage by source of health plan. Source of health plan is defined as private employers, public employers, medical assistance (managed care), and medical assistance (state program).

- Appendix B provides estimates of the number of prescription opportunities, attempts and approved therapeutic interchanges in Virginia by the most prevalent drug therapy classes.

- Appendix C presents an estimate of the number of unique plan sponsors, the number of plan sponsors choosing to practice therapeutic interchange, and the number of subscribers in sponsor plans that provide financial incentives to encourage the practice of therapeutic interchange in Virginia.

- Appendix D contains the questionnaire that was transmitted to pharmacy benefit management companies and health plans with subsidiary or in-house pharmacy benefit management activities.

In addition to incidence estimates on the practice of therapeutic interchange and identifying insurers that employ PBMs, this research report provides an estimate of how many Virginians used their pharmacy benefit during the past year. All these estimates are provided in the Results chapter of this study.

RESULTS

Introduction

We divide this chapter into four sections. Section 1 presents estimates on the average number of Virginians who have health plan and pharmacy benefits coverage, and who use pharmacy benefits during the most recent year. Section 2 provides estimates of the total number of Virginians having at least one opportunity, attempt, or approved therapeutic interchange during the past year. Section 3 provides a comparison of Virginia-specific data obtained for this study with national survey data on the prevalence of therapeutic interchange by health plan. Section 4 identifies major insurers in Virginia, how they manage their pharmacy benefit (contract out to PBM companies, subsidiary pharmacy benefit manager, or in-house pharmacy benefit management), and identifies the pharmacy benefit management companies that health plans contract with to administer their pharmacy benefit.

Section 1: Pharmacy Benefit Characteristics of Virginians

According to the U.S. Bureau of the Census, Virginia had about 6.8 million residents in 1998[1], with an estimated 87%, or about 5.9 million citizens, covered by health insurance.[2] Findings from the Virginia Commonwealth University School of Pharmacy Citizen Survey suggest that over 5.6 million Virginians are

[1] U.S. Bureau of the Census. Estimated population of Virginia on July 1, 1998 is 6,791,345. [http://www.census.gov/population/estimates/state/st-98-3.txt]

[2] Report of the Special Task Force Studying the Practice of Therapeutic Interchange to the Governor and the General Assembly of Virginia. *A Study of the Practice of Therapeutic Interchange of Chemically Dissimilar Drugs in Virginia.* House Document No. 57. Commonwealth of Virginia, Richmond. 1998. p. 7.

enrolled in health plans that include a pharmacy benefit.[3] An estimated 3.6 million Virginians had prescriptions filled during the past year based on pharmacy benefit management claims data obtained for this study. [4] Table 1 is a summary presentation of these data.

Table 1	
Pharmacy Benefit Coverage and Utilization in Virginia	
1. Total Population (1998)	6,791,345
2. Estimated Population Covered by Health Plans	5,900,000
3. Estimated Population in Health Plans that Include a Pharmacy Benefit	5,600,000
4. Estimated Population Having Prescriptions Filled During the Past Year	3,600,000

Further detail for item number 3 above is provided in Appendix A. The *estimated population in health plans that include a pharmacy benefit* is separated into type of plan sponsor (private sector employers, public sector employers, and Medicaid) in Appendix A.

Section 2: The Number of Virginians With at Least One Opportunity, Attempt, or Approved Therapeutic Interchange During the Past Year

We identified two types of therapeutic interchange based on the definition adopted by the State Task Force Studying the Practice of Therapeutic Interchange. This study uses the "*formulary inclusion*" type of therapeutic interchange for purposes of this analysis and is explained as follows.

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[3] Michael A. Pyles, Ph.D. *Study to Determine the Impact of the PBM Practice of Therapeutic Interchange on Citizens of the Commonwealth of Virginia*, Virginia Commonwealth University. Draft, December 22, 1998

[4] The estimated population having prescriptions filled during the past year is based on data obtained from pharmacy benefit management companies, health plans with subsidiary PBMs, or health plans with in-house PBM activities representing about 25% of all Virginians with a pharmacy benefit during the past year. This is equal to about 20% of all Virginians.

The "*formulary inclusion*" type of therapeutic interchange only occurs when both the originally prescribed drug and the preferred drug to be interchanged are included on the pharmacy plan formulary. In addition, a "formulary inclusion" therapeutic interchange is generally initiated as a result of pharmacy benefit management activities. "Formulary inclusion" therapeutic interchange is also designed to change the prescribing behavior of physicians for prescriptions after an initially successful therapeutic interchange. Our estimates of therapeutic interchange opportunities, attempts, and approvals do not include subsequent therapeutic interchanges after the initial interchange.

A "formulary inclusion" therapeutic interchange also provides an economic benefit of lower prescription drug costs to the at-risk health plan. Economic incentives motivate health plans to encourage prescribers to substitute lower cost drugs for enrollees if, in the opinion of the plan's pharmacy and therapeutics (P&T) committee, the clinical effectiveness of both drugs is similar.

Another type of therapeutic interchange, "formulary exclusion," occurs when a prescriber writes a prescription for a drug and is later informed by the pharmacist, health plan, or patient that the originally prescribed drug is not covered on the pharmacy plan formulary. If the prescriber is aware of the formulary, he or she would usually not write a prescription for a non-formulary drug. In "formulary exclusion" cases of a therapeutic interchange, the consumer has a choice to either pay out-of-pocket for the originally prescribed drug or request the prescriber to authorize a substitute drug included on the pharmacy plan formulary. In this case, someone other than the health plan or pharmacy benefit manager would initiate the therapeutic interchange. This is reasonable, because economic incentives motivate consumers to encourage prescribers to prescribe a covered drug rather than an

uncovered drug. The economic benefit for substitution of a lower cost and equally effective prescription drug accrues to the at-risk consumer of prescription drugs.

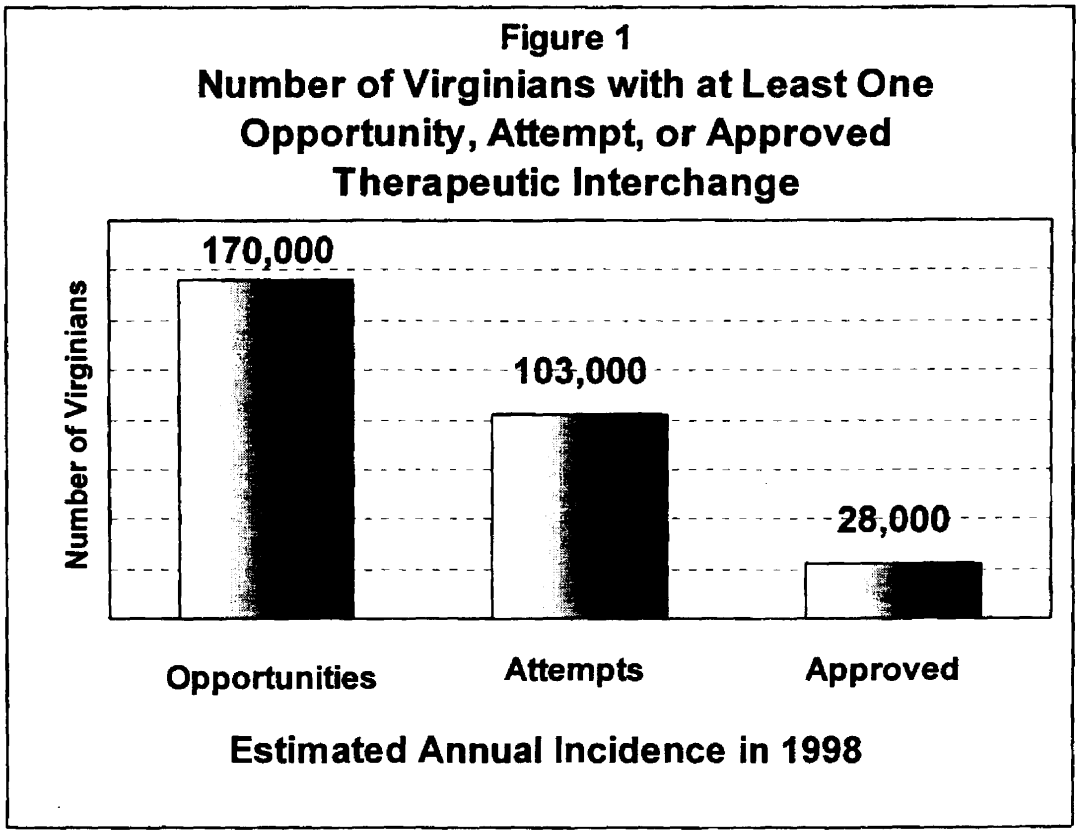
We note that other analysts may not recognize "formulary exclusion" as a type of therapeutic interchange. [5] Other analysts distinguish therapeutic interchange as a "*formal program set up to convince physicians that have been prescribing a certain drug to switch to the drug desired by the health plan.*" [6] Therapeutic interchange, under this definition, requires a conscious policy designed to persuade physicians to prescribe an alternative, yet chemically dissimilar, drug with a similar indication.

The definition adopted by the Task Force Studying the Practice of Therapeutic Interchange appears to provide a broader definition of therapeutic interchange than the industry. However, there are no compelling business reasons for pharmacy benefit managers to track formulary exclusion types of therapeutic interchange on their data systems, and therefore, pharmacy benefit managers do not generally recognize "formulary exclusion" as a therapeutic interchange. As a result, data obtained for this study only include the "formulary inclusion" types of therapeutic interchange. Annual incidence rates would likely be greater than estimated if it was possible to obtain data consistent with the Task Force definition of therapeutic interchange for this study.

The authors also wish to note that the data obtained for this study do not identify therapeutic interchanges initiated by patients or include those initiated by pharmacies that are provided financial incentives by drug manufacturers to conduct an interchange. Further discussion on the limitations of the data obtained for this study is provided in the Methods chapter.

[5] Namovicz-Peat S. Ed. *HMO & PBM Strategies for Pharmacy Benefits* AIS, Inc. Washington DC. 1998.
[6] Ibid. p. 19.

Figure 1 shows there were an estimated 170,000 Virginians with at least one opportunity for a therapeutic interchange during the past year in Virginia; potentially affecting about 2.5 percent of Virginians. An opportunity is a case where there are protocols approved by plan sponsors (employers, etc.) recommending a prescriber authorized substitution of one prescription drug for another.



The number of Virginians with at least one attempted therapeutic interchange during the past year is estimated to be 103,000; about 1.5 percent of all Virginians. An attempt is a case where a retail pharmacist initiated a discussion with the prescriber in order to request the prescriber to consider a therapeutic interchange.

An estimated 28,000 Virginians had at least one therapeutic interchange approved by prescribers in Virginia during the past year. The authors note that this estimate represents the number of Virginians affected by therapeutic interchange during the past year. It also represents a floor estimate of the number of prescriptions approved for therapeutic interchange during the past year. It is a floor estimate because some Virginians may have had more than one therapeutic interchange in the past year.

The therapeutic interchange incidence rate during the past year is estimated to be about 0.4 percentage points. In other words, an estimated 99.6 percent of Virginians did not have an alternative prescription drug attempted and approved for interchange by their prescriber during the past year.

Table 2 provides a summary of the drug therapy classes most affected by the practice of therapeutic interchange. It shows that pharmacists attempt therapeutic interchanges for about 60 percent of the total PBM identified opportunities. About 70 percent of opportunities and attempts occurred within three drug therapy classes (anti-hypertensive drugs, non-steroidal anti-inflammatory drugs, and H2 antagonist drugs) during the past year. Appendix B provides estimates of the number of therapeutic interchange opportunities, attempts, and approvals by therapy class.

Table 2		
Estimated Annual Therapeutic Interchange Prescription Activity in Virginia by Drug Therapy Class		
Drug Therapy Class	**Attempts as a Percent of Opportunities**	**Approvals as a Percent of Opportunities**
Anti-hypertensive	61%	15%
Non-Steroid Anti-Inflammatory	53%	11%
H2 Antagonist	61%	14%
Other Drugs & Devices	64%	27%

Section 3: Prevalence of Therapeutic Interchange Among Plans in Virginia

Therapeutic interchange was used in an estimated 56 percent of health plans in Virginia during 1998. This is consistent with national forecasts that therapeutic interchange would be used in 54.5 percent of health plans during 1998. [7] Nationally, the share of health plans using therapeutic interchange practices is estimated to have increased from 31.8 percent in 1996 to 54.5 percent in 1998. Health plan pharmacy directors also project that 61.4 percent of health plans in the U.S. will apply the practice of therapeutic interchange through 1999.[8] The Virginia percentage of health plans using therapeutic interchange may be similar to national trends based on the similarity of the Virginia data obtained for this study with national estimates for 1998.

[7] *Novartis Pharmacy Benefit Report: 1998 Trends & Forecasts.* Produced by Emron, Totowa, NJ, An IMS Company. p. 12.
[8] Ibid.

Section 4: Health Plan Pharmacy Management in Virginia

This section identifies major health insurers in Virginia and which pharmacy benefit management vendors they contract with to administer their pharmacy benefits. Health plans use several types of organizational arrangements to manage their pharmacy benefit. The different types of arrangements include health plans that:

- contract out their pharmacy benefit activities to pharmacy benefit management vendors that are independent of the health plan;
- manage their pharmacy benefit activities using a subsidiary pharmacy benefit manager; and,
- manage their pharmacy benefit activities in-house as a staff function within the health plan.

Table 3 is a list of major health plans operating in Virginia and the pharmacy benefit management vendor with which they contract to administer their pharmacy benefit.

Table 3	
Health Plans Contracting Out to PBM Vendors [9]	
Health Plan	***PBM Vendor***
BC&BS of the National Capital Area	Merck-Medco Managed Care
Capital Care, Inc.	PCS
Cigna Health Corporation	PCS (indemnity)
George Washington University Health Plan	Advanced Paradigm
M.D. IPA & Optimum Choice, Inc.	Diversified Pharmaceutical Services
HealthKeepers, Inc.	Merck-Medco Managed Care
NYLCare Health Plans	Express Scripts, Inc.
OPTIMA Health Plan	Argus Health Systems, Inc.
PARTNERS Nat. Health Plans of NC, Inc.	Diversified Pharmaceutical Services
Peninsula Health Care, Inc.	Merck-Medco Managed Care
Physicians Health Plan, Inc.	Merck-Medco Managed Care
Priority Health Care, Inc.	Merck-Medco Managed Care
Sentara Health Plans, Inc. (SHP)	Argus Health Systems, Inc.
Trigon	Merck-Medco Managed Care
Southern Health Services, Inc.	Express Scripts, Inc.
United HealthCare of Virginia, Inc.	Diversified Pharmaceutical Services

Table 4 is a list of major health plans operating in Virginia that manage their pharmacy benefit activities using a subsidiary pharmacy benefit manager.

[9] These data come from published sources including *HMO & PBM Strategies for Pharmacy Benefits* and world wide web sites [http://www.virginiabusiness.com/electro/hmos/dirlis.html] and [http://www.cigna.com/healthcare]

Table 4
Health Plans Using Subsidiary PBMs[10]
Aetna U.S. Healthcare, Inc.
Cigna Health Corporation (mail order)

Table 5 is a list of major health plans operating in Virginia that manage their pharmacy benefit activities in-house as a staff function within the health plan.

Table 5
Health Plans Managing PBM Activities In-House[11]
Cigna Health Corporation (PPO and indemnity)
INOVA Community Health Plan
Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.
Prudential Health Care—Mid-Atlantic

[10] Ibid.

[11] Ibid.

ANALYSIS

"Formulary exclusion" therapeutic interchanges are not reflected in the data obtained for this study because pharmacy claims data systems generally do not record whether the original drug prescribed is included on the formulary. As a result, the pharmacy benefit management industry does not generally recognize the "formulary exclusion" type of therapeutic interchange included in the definition adopted by the Task Force Studying the Practice of Therapeutic Interchange. "Formulary inclusion" therapeutic interchange is a growing practice nationally[12] and is likely a growing practice in Virginia. Although we cannot identify empirically whether "formulary exclusion" therapeutic interchange is a growing practice in Virginia, there is survey information on "open" vs. "closed" formulary trends nationally. This chapter provides an analysis of national trends on the prevalence of "open" vs. "closed" formularies.

Formulary Designs

A formulary is a list of drugs available for pharmacy benefit subscribers and approved by a managed care organization or pharmacy benefit manager for coverage based on safety, clinical effectiveness, and cost. Formularies were originally designed for use in a hospital in-patient setting as a way to control costs while maintaining patient quality of care.

[12] *Novartis Pharmacy Benefit Report: 1998 Trends & Forecasts.* Produced by Emron, Totowa, NJ, An IMS Company.

Formularies are generally labeled according to coverage, consumer cost sharing arrangements, and preferred drug policies/protocols. Pharmacy benefit plans designed to provide a broad selection of drugs with small, uniform co-payments, and no preferred drug policies/protocols are referred to as "open" formularies. Pharmacy benefit plans designed to offer a narrower selection of drugs within a therapeutic class are generally referred to as "closed" formularies. There are a potentially infinite number of hybrid plans falling in between these "open" and "closed" formulary ideals. The hybrids can be referred to as "partially-closed," "partially-open," or "selective" formularies.

Factors Causing Increases in Market Penetration for "Closed" Formulary Designs and Therapeutic Interchange Practices

Market penetration of formulary systems in the outpatient or ambulatory setting has increased rapidly over the past decade. We believe two factors are responsible for the rapid market growth. First, employers who sponsor health plans with pharmacy benefit coverage for their employees became more cost sensitive during the past decade making them more prudent consumers with their health care budget.

Secondly, the development of increasingly powerful and sophisticated information systems, including point of service transactions, have made it easier to tailor and effectively implement a formulary system for employers in order to help meet their health benefit budget constraints. These two factors have also combined to create market innovations such as therapeutic interchange. Therapeutic interchange, as one of several economizing techniques practiced by pharmacy benefit managers, helps employers to maximize the range of benefits included in employee health plans by creating pharmacy budget savings that can be used to finance an expansion of other health benefits for employees.

Formulary Changes Nationally

National trends regarding increased use of "closed" formularies have mirrored national trends of increased use of "formulary inclusion" therapeutic interchange as budget-driven employers seek ways to maximize health benefit coverage for employees.

A national survey sponsored by Novartis Pharmaceuticals Corporation, the Novartis Pharmacy Benefit Report: 1998 Trends & Forecasts, provides information on the prevalence of "closed" formularies reported by employer benefits managers and health maintenance organizations. They conclude: "*Employers and HMOs agree that the trend is toward more restrictive designs, and, already, a higher percentage of HMOs describe designs as closed . . .*"[13]

The national survey showed that the percent of HMOs describing formulary designs as "closed" increased from 25% in 1996 to a forecasted 37% by the year 1999. Employers also forecast an increase in formulary designs as "closed" from 12.5% in 1996 to 18.8% by the year 1999. These increases are offset by a declining percentage of self-described "selective/partially closed" formulary designs.

In 1997, employer benefit managers also reported that 10.5% of employers use "*no coverage for nonformulary drugs*" as a way of sharing the cost of pharmaceutical care with employees. If the percent of employees matches the percent of employers subject to "*no coverage for nonformulary drugs*" as a

[13] *Novartis Pharmacy Benefit Report: 1998 Trends & Forecasts.* Produced by Emron, Totowa, NJ, An IMS Company. p. 12.

technique for cost sharing, the share of pharmacy benefit subscribers subject to "formulary exclusion" therapeutic interchange nationwide could be small.

It is difficult to determine the incidence of the "formulary exclusion" type of therapeutic interchange nationally. On the one hand, we have projections of increased use of "closed" formularies nationally over the next year. On the other hand, only one in ten employers use "formulary exclusion" as a way of sharing pharmacy costs with employees. The above survey data indicates that the number of pharmacy benefit subscribers affected by "formulary exclusion" therapeutic interchange could be small. However, it is difficult to evaluate the validity or reliability of the data absent a more careful review of the survey and methods. It would also be difficult to generalize about these practices in Virginia based on national trends given the Novartis Report findings that: "*During the past few years, wide regional variations have existed in the way formulary management techniques have been applied . . .*"[14]

Projected Cost Trends for Employer Pharmacy Benefits

Employer pharmacy benefit budgets are likely to be strained in the future. There are several factors contributing to this trend. The factors, in projected order of impact, are: 1) an increase in the number of new prescription drugs receiving U.S. Food & Drug Administration (FDA) approval (new drugs), 2) an increase in the per-subscriber use of more expensive drugs within a therapy class (therapeutic mix), 3) an increase in general prescription drug price inflation (inflation), and 4) an increase in the general per-subscriber use of prescription drugs (utilization). [15]

Data published by Express Scripts in their Drug Trend Report, June 1998 show the components of company prescription drug cost trends over the past four

[14] Ibid. p. 12.
[15] Express Scripts-Value Rx, 1997 Drug Trend Report. June 1998. p. 3.

years. The largest component of drug costs during this period was due to new drugs. New drugs accounted for just over 40 percent of the per member per month (PMPM) pharmacy cost increases for Express Scripts clients over the period 1993 to 1997. FDA approvals for new molecular entities have roughly doubled over the past four or five years.[16] The FDA approval trend is likely to continue given the growing number of investigational new drug and new drug applications entering the approval pipeline. The new drug component is the largest and least controllable of all cost increase components, especially for health plans with open formularies. Consumers of health care services will want their health plans to cover costly new drugs as they are approved by the FDA.

The second largest component of PMPM cost increases during the period 1993 to 1997 was therapeutic mix. Therapeutic mix accounted for just over 17 percent of the total increase in per member per month pharmacy costs for Express Scripts clients. Therapeutic interchange is one technique designed to reduce the therapeutic mix share of total PMPM cost increases.

General inflation was the third largest component of PMPM month pharmacy costs, accounting for about 15 percent of the total increase in per for Express Scripts clients during the 1993 to 1997 period. Inflation is largely a function of market factors and is based on average wholesale price. Volume discounts by large purchasers of prescription drugs are one technique for reducing this component of pharmacy budget increases.

The fourth largest component of pharmacy benefit cost increases is utilization. Utilization accounted for almost 10 percent of the per member per

[16] FDA Center for Drug Evaluation and Research: Fact Book 1997, p. 22. FDA's Fiscal Year 1999 Justification of Estimates for Appropriations Committees and Performance Plan, p.150.

month (PMPM) pharmacy cost increases for Express Scripts clients over the period 1993 to 1997.

Consistent with the experience documented by Express Scripts, we expect per member per month pharmacy benefit costs to continue to increase from 9 to 16 percent per year for the foreseeable future. Pharmacy benefit management techniques designed to provide equivalent quality of care at lower costs can be expected to continue as employer health benefit plans face overall budget constraints. These techniques include therapeutic interchange.

METHODS

Survey Instrument Development

The survey instrument was developed and administered by the Mercatus Center project research team. A copy of the survey instrument is included in Attachment D of this report. The survey included 11 questions for all pharmacy benefit management companies and health plans with subsidiary or in-house pharmacy benefit management activities identified in Tables 2, 3, and 4 in the preceding Results chapter. After the Project Director completed the first draft of the survey instrument, it was circulated for review and comment to the members of the Mercatus Center project research team. Almost all comments received from the research team were incorporated into the survey instrument. The second draft survey instrument was then circulated for review and comment to research experts at the Department of Medical Assistance and Services (DMAS). Almost all comments received from DMAS survey experts were incorporated into the survey instrument.

Sample Selection and Contact Procedures

All pharmacy benefit management companies or health plans with subsidiary or in-house pharmacy benefit management activities were asked to complete the survey. Letters of introduction and explanation about the research project were sent to all pharmacy benefit management companies and health plans with in-house pharmacy benefit management activities that were identified in the preceding chapter. The letters were generally addressed to operations officers at the Vice President level. In cases where there were no operations contacts listed,

Presidents or CEOs received the letters. Letters were sent out on November 4. Follow-up telephone calls were made three to four working days after Mercatus Center researchers mailed the introduction letters. If addressees or contacts did not respond to the first telephone call, Mercatus Center researchers initiated up to five telephone calls over a one to two week period before ending the attempts to discuss the survey questions. Survey instruments were e-mailed or faxed after establishing contact with the company official assigned to respond to the survey.

Response Rate

The response rate was significant. Confidentiality agreements with respondents do not allow us to identify companies responding to the survey. However, responses received account for about 25 percent of all pharmacy benefit subscribers in Virginia during the past year. This covers about 20 percent of all Virginians.

Generalization of Responses to Experience of All Virginians

The estimated population having prescriptions filled during the past year is based on data obtained from pharmacy benefit management companies, health plans with subsidiary pharmacy benefit management, or health plans with in-house pharmacy benefit management activities representing about 25 percent of all pharmacy benefit subscribers in Virginia during the past year. Generalization of the estimates in this research can be made to the extent that PBMs and health plans that did not respond have similar experiences to respondents. The information received for this study may be generally representative of therapeutic interchange experiences in Virginia. At a minimum, the Mercatus Center research team believes the results of this study are representative for about one-quarter of Virginians enrolled in a pharmacy benefit plan during the past year.

Reliability of Responses

Responses are considered reliable for two reasons. Mercatus Center researchers made themselves available to clarify any issues in cases where respondents had questions concerning the survey instrument. Secondly, the responses are actual pharmacy benefit claims data records, and not the perceptions of pharmacy benefit managers. Data reported are routinely used to analyze pharmacy claims data for business management purposes.

Operational Definition of Therapeutic Interchange

The operational definition of a therapeutic interchange used for this study is a "formulary inclusion" type identified in the Results chapter of this study. A "formulary inclusion" type of therapeutic interchange requires that both the original and substitute drugs be available on the health plan's pharmacy benefit formulary. In addition, a "formulary inclusion" therapeutic interchange is generally initiated as a result of pharmacy benefit management activities.

Estimating Procedures

The survey instrument was designed to accept flexible periods that corresponded to the latest complete year of available data for each individual PBM or health plan. This was done to increase the ease of responding to the survey and potentially improve the response rate. Consequently, the data were reported based on different periods of time for each respondent. As a result of this difference, it was necessary to develop a method to make the data from different time periods equivalent and comparable. In order to determine an average annualized enrollment in any given health plan, it was necessary to convert enrollment point estimates into annualized averages.

Equivalence and comparability were made possible by developing estimates using linear interpolation techniques. In this study, linear interpolation was used to estimate pharmacy plan enrollment changes between two time periods and assuming that the rate of change is constant. For example, if pharmacy plan enrollment increased 50% over a six-month period, the average monthly increase in enrollment over that period is assumed to be about 8.33 percentage points (50 divided by 6 = 8.33%) of the total enrollment.

Mid-year estimates for the most recent 12-month period were used as a proxy for the average annual plan enrollment. For example, if the 1st month enrollment was 100,000 and the 12th month enrollment was 200,000 for a company, the mid-year enrollment estimate would be 150,000.

Mid-year enrollment estimates are needed to calculate annual incidence rates because the number of Virginians subject to therapeutic interchange data are reported for the most recent 12-month period by respondents. For example, if 1,500 Virginians had an approved therapeutic interchange during the most recent 12-month period and the mid-year enrollment estimates were 150,000, the therapeutic interchange incidence rate would be 1 percent.

Limitations

There are several limitations to the use of this study. The most important limitation to this study is the difficulty of generalizing about therapeutic interchange practices in states other than Virginia. Pharmacy benefit management practices are known to vary considerably by state and region.[17] For example, therapeutic substitution (substituting prescription drugs without the authority of the prescriber) is illegal in Virginia. Therapeutic interchange (the prescriber

[17] *Novartis Pharmacy Benefit Report: 1998 Trends & Forecasts.* Produced by Emron, Totowa, NJ, an IMS Company. p. 8.

authorized substitution of prescription drugs) is legal in Virginia. In states where therapeutic substitution is legal, the practices of substituting drugs may be considerably different.

It is difficult to generalize about Virginia's therapeutic interchange practices in the future because the pharmacy benefit management market is dynamic. Therapeutic interchange techniques are continually refined and changed as new drugs are approved by the U.S. Food and Drug Administration, as human knowledge about cost- and clinical-effectiveness of therapeutic drugs increases, and as computerized systems become more sophisticated. [18]

Another limitation is that this study does not capture "formulary exclusion" type of therapeutic interchanges. It is difficult to determine the full extent of therapeutic substitution by including only the "formulary inclusion" type of therapeutic interchanges. The Analysis chapter that precedes this chapter provides national information on the dynamics of change with regard to formularies.

A final limitation is that this study does not capture cases of therapeutic interchanges initiated by patients or initiated by large pharmacy chains that receive financial incentives from drug manufacturers to encourage interchanges for their prescription drug products.

[18] Drug Benefit Trends, *Drug Information Services in the Managed Care Setting*. 9(8):28-30,36-40, 1997.

CONCLUSIONS

The goals of this research report were: (1) to provide estimates of the incidence of therapeutic interchange practices in the Commonwealth of Virginia using pharmacy benefit claims data and, (2) to identify insurers in Virginia who employ pharmacy benefit managers.

About 1.5 percent of Virginians had a "formulary inclusion" therapeutic interchange attempted during the past year. Pharmacy benefit data indicate that pharmacists take action on about sixty percent of all therapeutic interchange opportunities.

Best evidence suggests that about 0.4 percent of Virginians experienced an approved "formulary inclusion" type of therapeutic interchange during the past year. This estimate is based on pharmacy benefit management and health plan claims data.

In short, incidence rates for attempted and approved "formulary inclusion" therapeutic interchanges were low in Virginia during 1998.

APPENDICES

APPENDIX A

Estimated Number of Virginians With Pharmacy Benefit Coverage by Health Plan Sponsor					
	Private[19] Sector Employers and Other	Public[20] Sector Employers	Medicaid[21] (Managed Care)	Medicaid[22] (State Program)	Total
Virginians with Pharmacy Benefit Coverage	4,400,000	600,000	107,000	485,000	5,600,000

[19] This estimate is a residual after subtracting public sector and Medicaid estimated enrollment from the total. The estimate also includes health plan subscribers with individual policies and Medicare supplemental policies that include prescription drug coverage.

[20] U.S. Department of Labor, Bureau of Labor Statistics, Philadelphia Regional Office. *Ready Facts Catalog*. The BLS estimates there were 599,700 persons employed by government in Virginia during July 1998. [ftp://ftp.bls.gov/pub/special.requests/philadelphia/fax_9535.txt]

[21] Department of Medical Assistance Services (DMAS) Web page. [http://www.state.va.us/~dmas/98%20facts.htm.] Latest estimates show 20,005 enrolled in the HMO Options program, and 86,983 enrolled in the HMO Medallion II program.

[22] Latest DMAS statistics show a total of 591,644 Medicaid recipients in the Commonwealth of Virginia. This statistic is a residual of total Medicaid recipients less the total number of Medicaid managed care recipients.

APPENDIX B

Estimated Annual Therapeutic Interchange Activity in Virginia by Drug Therapy			
Drug Therapy Class	**Est. Number of Opportunities**	**Est. Number of Attempts**	**Est. Number of Successes**
Antihypertensive	72,000	44,000	11,000
Non-Steroid Anti-Inflammatory	40,000	21,000	4,500
H2 Antagonist	18,000	11,000	2,500
Anti-Lipemic	14,000	9,000	3,000
Respiratory	12,000	7,500	2,000
Contraceptive	12,000	8,000	4,000
Other Drugs & Devices	14,000	9,000	5,000
Total Estimate	**182,000**	**109,500**	**32,000**

Figure B-1

Anti-hypertensive drugs are commonly prescribed to treat persons with high blood pressure. There are over 30 different drugs used to control high blood pressure. Common anti-hypertensive subclasses include angiotensin converting enzyme (ACE) inhibitors, calcium channel blockers, diuretics, vasodilators, and B-Andrenergic (beta) blockers.

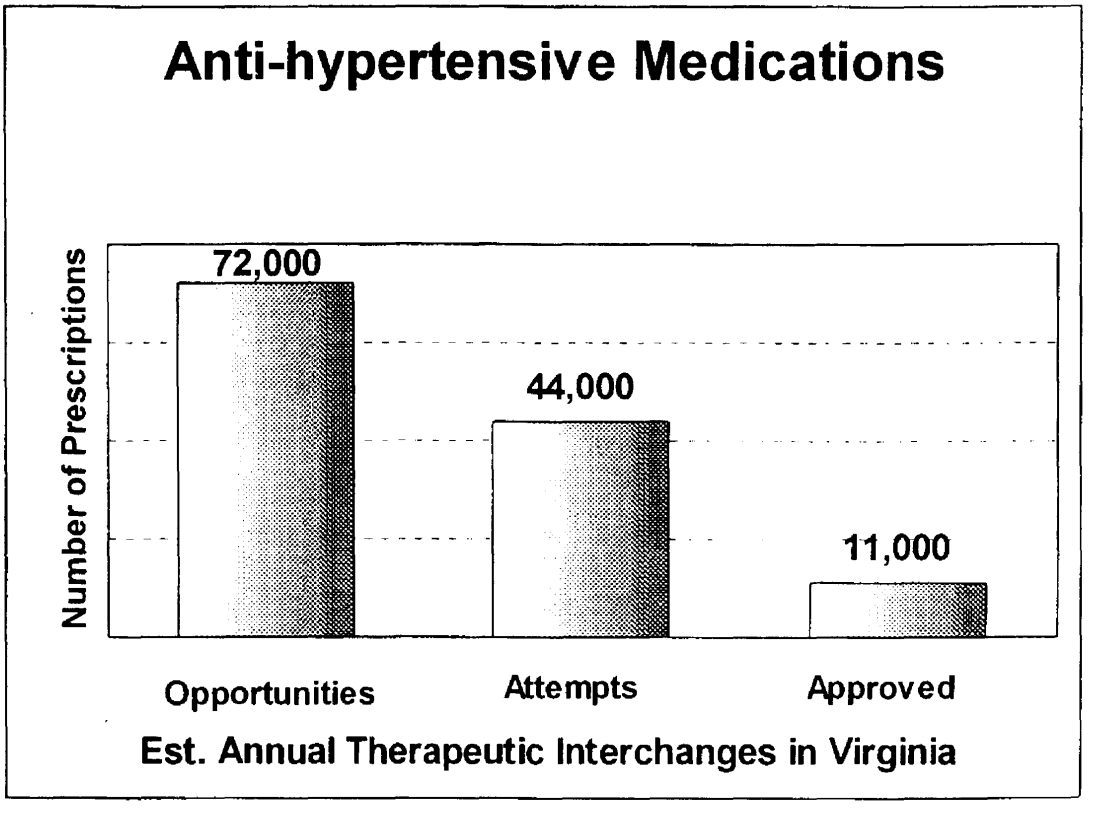


Figure B-2

Nonsteroidal anti-inflammatory drugs (NSAIDs) are one form of therapy that can be used to reduce mild inflammation as well as ease pain due to arthritis and other related conditions. There are several different drugs including aspirin, ibuprofen, ketoprofen and naproxen. It is very difficult to predict which patients will respond positively to the various types of NSAIDs. These medications are often substituted with one another.

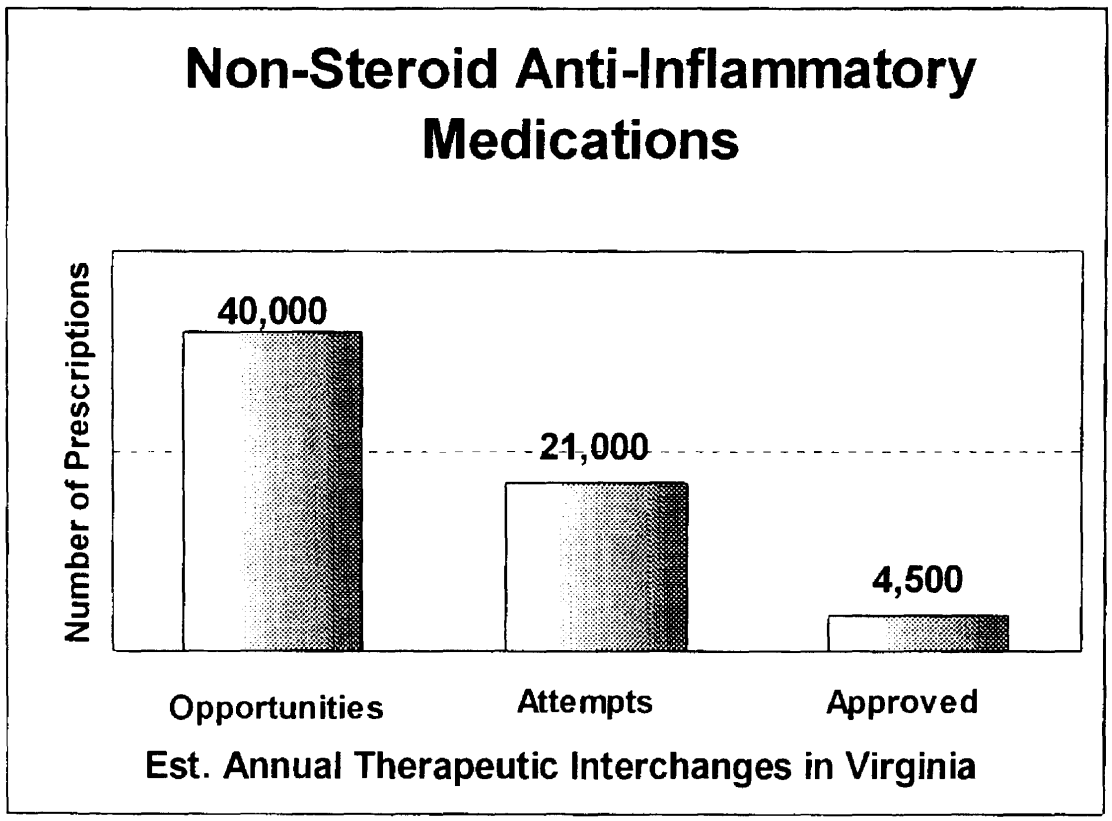


Figure B-3

H2 antagonist drugs are commonly prescribed to treat persons with gastrointestinal problems, especially gastroesophogeal reflux disease (backup of stomach acids in esophagus). There are several drugs in this therapy class. Gastrointestinal problems can be caused by drugs sold by prescription and over the counter.

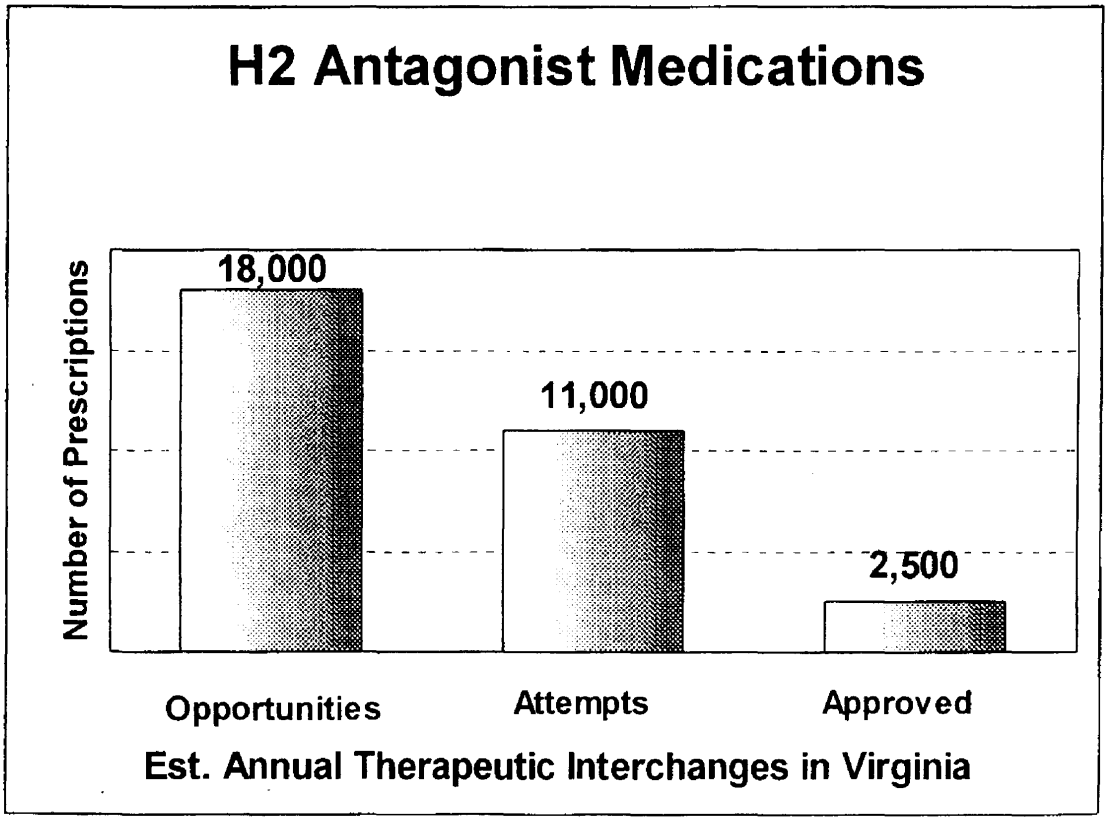


Figure B-4

Respiratory drugs are commonly prescribed to prevent asthma. There are about a dozen drugs on the market. They are generally taken daily to control inflammation, swelling and mucus secretion that underlie asthma symptoms. Anti-inflammatories can be inhaled or taken orally but are considered safer when inhaled. Inhaled steroids work primarily in the lungs and pose far smaller risks than oral versions of the drugs.

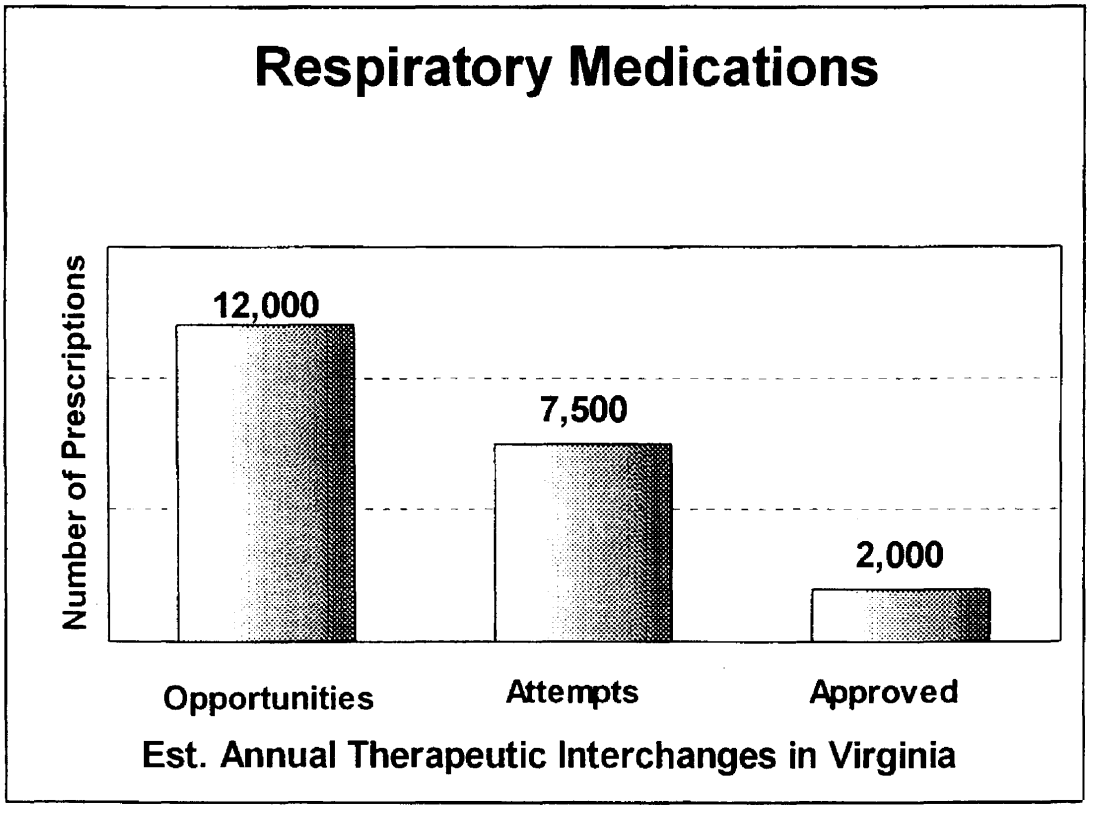


Figure B-5

Anti-lipemic drugs are commonly prescribed to treat persons diagnosed with high cholesterol. There are several drugs available for treatment including bile acid sequestrants, gemfibrozil, reductase inhibitors, and niacin. Reducing cholesterol generally involves lifestyle changes including a low-fat diet and controlling weight. Prescription drugs can lower total and LDL cholesterol and triglyceride levels, while increasing the beneficial HDL cholesterol.

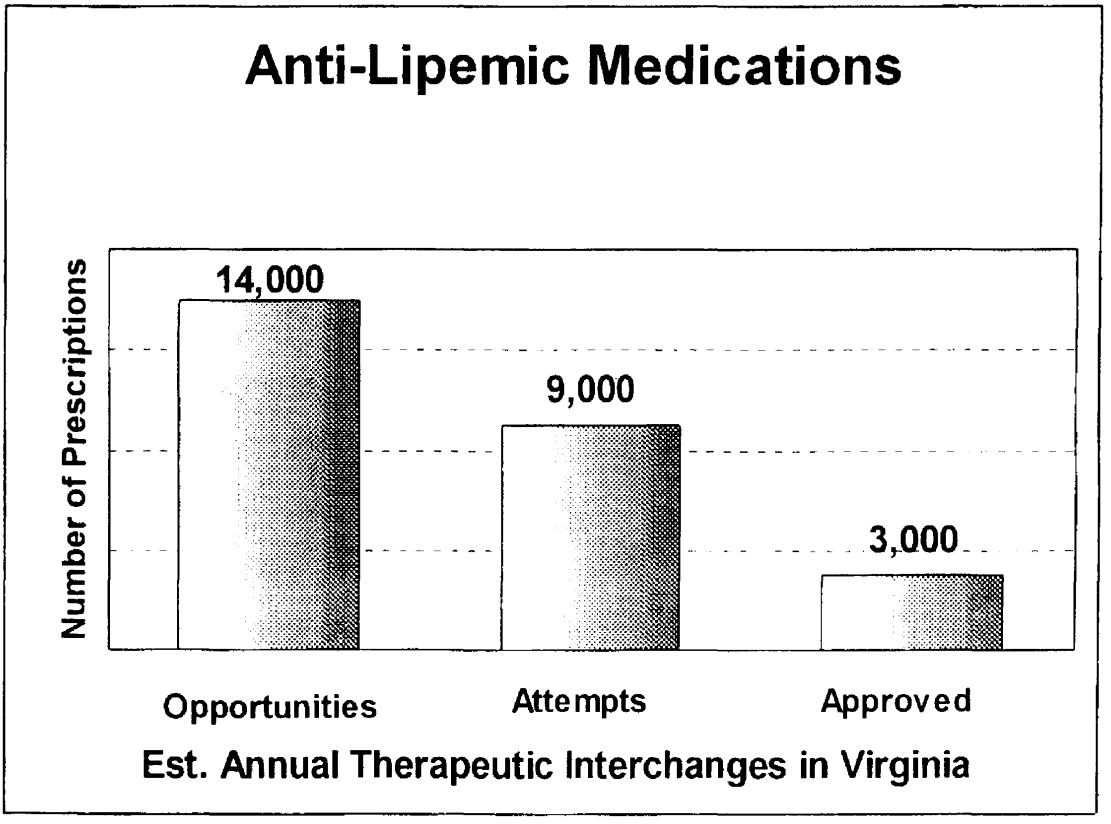
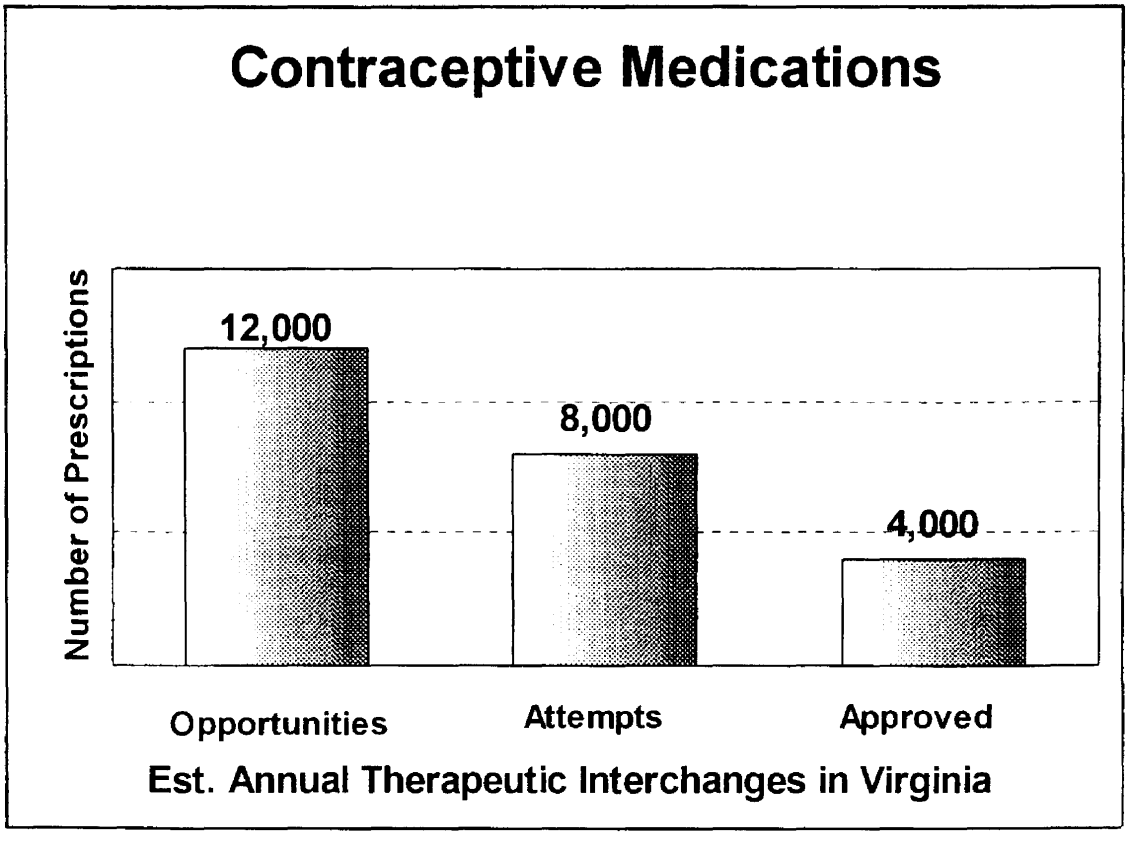


Figure B-6

Contraceptive drugs are prescribed to prevent pregnancy. There are about 10 drugs commonly prescribed by physicians.



APPENDIX C

The following are estimates of the number of unique plan sponsors, the number of plans that include the practice of therapeutic interchange, and the number of subscribers in sponsor plans that provide financial incentives to encourage the practice of therapeutic interchange in Virginia.

Estimated Number of Plan Sponsors Using Therapeutic Interchange During the Past Year in Virginia			
	Estimated Number of Number of Plan Sponsors	Estimated Number of Plan Sponsors That Choose to Use TI	Number of Subscribers in Sponsor Plans with Incentives for TI
Number	110	70	3,000,000

APPENDIX D

COMMONWEALTH OF VIRGINIA
THERAPEUTIC INTERCHANGE QUESTIONNAIRE

QUESTIONS 1-9	Private Sector Employees	Public Sector Employees	Medical Assistance Subscribers (Medicaid)	Other	Total
1. How many subscribers in VIRGINIA are currently enrolled in your PBM plans?					
2. How many subscribers in VIRGINIA were enrolled in your PBM plans one year ago?					
3. How many subscribers in VIRGINIA have received prescription drugs from your company during the most recent 12 month period? (Please specify the 12 month period)					
4. How many subscribers in VIRGINIA presented prescriptions at least once for drugs that were eligible for therapeutic interchange? (Again during the same, most recent 12 month period)					
5. How many subscribers had a pharmacist or other authorized agent of the pharmacy, PBM, or insurer initiate (request) a therapeutic interchange in VIRGINIA (Again during the same, most recent 12 month period)					
6. How many subscribers had a therapeutic interchange prescription filled in VIRGINIA (Again during the same, most recent 12 month period)					
7. What percentage of subscribers in VIRGINIA are in pharmacy benefit plans with financial incentives designed to encourage therapeutic interchange?					
8. How many unique PBM plans or contracts are currently administered for employers in VIRGINIA?					
9. What percent of unique PBM plans or contracts include the practice of therapeutic interchange for employers in VIRGINIA?					

QUESTION 10:
Please provide copies of policies and practices used by your company with regard to therapeutic interchange. Do policies and practices regarding therapeutic interchange differ by contracted group (i.e., private sector employees, public sector employees, medical assistance enrollees)?

QUESTION 11:
Attached is a table with six columns. Please provide a report (preferably in the Excel spreadsheet format) that includes the following information. Please note: we have designed the table in a format to avoid the reporting of competitive or proprietary information on specific drugs and PBM practices. The data you provide on the prevalence and incidence of therapeutic interchange will be reported in the aggregate for VIRGINIA. *We will not share your specific information with anyone.*

- **The first column is a listing of drug classification categories.**
- **The second column is to indicate whether therapeutic interchange has EVER been attempted for any drug in the associated drug category during the most recent 12 month period in VIRGINIA (please specify Yes or No).**
- **The third column provides a count of the average monthly number of prescriptions filled for the most recent 12 month period in VIRGINIA (per 1,000 members per month).**
- **The fourth column provides a count of the number of prescriptions eligible for therapeutic interchange during the most recent 12 month period in VIRGINIA (per 1,000 members per month).**
- **The fifth column provides a count of the average monthly number of prescriptions where a pharmacist initiated (requested) a therapeutic interchange for the most recent 12 month period in VIRGINIA (per 1,000 members per month).**
- **The sixth column provides a count of the average monthly number of prescriptions where a therapeutic interchange was successfully completed for the most recent 12 month period in VIRGINIA (per 1,000 members per month).**

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Impact of Pharmacy Benefit Management (PBM) Firms on Patients and Pharmacists - A Literature Review and Responses from Personal Interviews

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PREFACE

This is a study requested by the Virginia State Legislature under House Joint Resolution No. 574 which requests the Virginia Department of Medical Assistance Services (DMAS) to *examine the practices of pharmacy benefits manager firms on the Commonwealth's citizens and upon the health care market.* Since some of the "practices" of interest are not restricted to PBMs and are common among most managed prescription benefit plans, this study will focus on pharmacy benefit practices whether they are conducted by PBMs, insurance companies, pharmacy drug chains, health maintenance organizations, or any other entity that manages prescription benefits. The study consists of several sections.

The background section recounts how the evolving health care environment led to the need for PBMs. The next section describes the pharmaceutical benefit and how it is managed. The following section defines PBMs and lists the characteristics of PBMs. The impact of PBMs on physicians, pharmacists, and patients is then depicted, and empirical evidence demonstrating the effect of PBMs on cost and quality are presented. The study concludes by listing some of the difficulties associated with managing the pharmaceutical budget. The appendices contain an annotated bibliography of important papers relating to the topic and the notes of informational interviews conducted by researchers with selected experts.

TABLE OF CONTENTS

EXECUTIVE SUMMARY

Pharmaceutical costs have increased dramatically over the last two decades. They are currently the fastest growing component of medical care. As a result, payers, such as employers and government, have become increasingly concerned with the amounts they pay for drugs. Pharmacy benefit managers (PBMs) have evolved to meet the need to control prescription drug costs.

PBMs attempt to manage the costs of prescription drugs by reducing the costs of the drug product, by reducing the cost of the pharmaceutical service, or by reducing the total number of prescriptions used. PBMs serve as intermediaries between plan sponsors (those who pay for prescription drug benefits for their employees or members) and retail pharmacies. The services they provide include claims processing and adjudication, developing networks of retail pharmacies that will dispense prescriptions for plan members for a discounted fee, negotiating rebates on drug product costs with drug manufacturers, and managing the quality of prescribing and dispensing through drug utilization review and provider profiling. In addition, they work with plan sponsors to design the drug benefit. This includes determining how much of the cost of prescriptions employees will be asked to pay, which drugs will be covered, whether mail order pharmacies will be used, and whether patients will be given economic incentives to use lower cost alternatives such as mail order pharmacies, generic drug products, and preferred formulary drug products. In recent years, PBMs have added disease state management and outcomes research services.

Five companies account for over 80% of patients covered by PBMs. Pharmaceutical manufacturers own three of these (although one is currently being purchased by a pharmacy chain). Two are independently owned. Managed care organizations and drugstore chains also own PBMs. A number of companies that do not call themselves PBMs do, in fact, manage prescription benefits. That is, they engage in the same practices and fulfill the same functions as PBMs. For purposes of this report, these firms are considered to be PBMs.

Most PBMs operate nationally. Therefore most of the trends and practices of PBMs probably apply to their operations in Virginia. However, there is little published or publicly available information specific to the operation of PBMs in the Commonwealth.

Physicians are most affected by PBMs through restrictive formularies and therapeutic interchange programs. Restrictive formularies limit the drugs for which the PBM will provide reimbursement. If physicians prescribe drugs not included on the formulary, patients have to pay all, or a greater portion, of the cost of the drug. Therapeutic interchange is a practice in which PBMs attempt to persuade patients, physicians, and pharmacists to switch from the drug prescribed by the physician to a chemically different product. This drug is usually one that is believed to have the same therapeutic effect as the original drug and one for which the PBM either receives a larger rebate or is charged a lower price. Both restrictive formularies and therapeutic interchange effectively limit the physician's choice of drug. Because of this, physicians argue that PBMs interfere with their ability to practice medicine. PBMs point out that physicians frequently do not prescribe as they should based on prescribing guidelines established by experts from organizations such as the Agency for Healthcare Policy and Research (AHCPR). Therefore the use of formularies and

therapeutic interchange can standardize care and improve the quality of prescribing as well as hold down drug costs. However, there is little empirical research demonstrating that formularies actually improve either the quality or costs of prescribing.

PBMs have had a major impact on pharmacists. PBMs have been instrumental in computerizing the claims processing, adjudication, and payment process. This has resulted in more efficient operation of both pharmacies and plan sponsors. On the other hand, much of the savings that PBMs generate for plan sponsors has come through reductions in pharmacy fees. (The fee is the amount which pharmacies receive for dispensing the product. It does not include the cost of the drug.) The latest research indicates that it costs a pharmacy around $6 to dispense a prescription and that the average fee paid by PBMs is around $2.23. In addition, PBMs channel prescription volume away from retail pharmacies and to mail order pharmacies. One possible consequence of this situation has been that the number of retail pharmacies nationwide has declined by about 12% since 1990. The number of independent pharmacies, which depend more heavily on prescription sales than do chain, grocery store, and mass merchandising pharmacies, has declined by 34%. Although a cause and effect relationship has not been established between PBM practices and the decline of independent pharmacies, an argument can be made that the current PBM-influenced environment puts independents at a disadvantage. In the current environment, all pharmacies have had to accept lower dispensing fees in an effort to maintain their customer base. Smaller pharmacy organizations have difficulty negotiating better fees because they lack bargaining power. Larger chains are more able to negotiate good terms with PBMs than single independents or small groups of pharmacies. Recognizing this, the larger chain pharmacies have consolidated and bought out smaller chains and independents in an attempt to gain sufficient size to allow them to negotiate better with PBMs. A major concern for pharmacists is that PBMs have reduced pharmacy fees to the point that pharmacists can no longer afford to provide patient care services, such as prevention of medication errors and compliance counseling, which could dramatically improve patient health and reduce overall health care costs. Little research has addressed the impact of therapeutic interchange and restrictive formulary policies on pharmacies or pharmacists.

Evidence of the impact of PBMs on patients is both contradictory and meager. Patient satisfaction surveys indicate that patients are generally satisfied with their drug benefit plans but that satisfaction declines as patients gain more experience with a plan. PBMs, like most pharmacies, have on-line systems which screen for adverse drug reactions and interactions whenever a prescription is processed. The PBM's system provides an extra measure of protection for patients using multiple pharmacies because the PBM database includes prescriptions from all of the pharmacies which the patient uses. Anecdotal reports indicating that a few patients have experienced, or been put at risk for, substantial harm as a result of therapeutic interchanges initiated by PBMs have not been substantiated by empirical research.

A number of studies have attempted to estimate the savings that a plan sponsor realizes when contracting with a PBM. The majority of estimated savings come from reductions in retail pharmacy fees and from discounts and rebates negotiated with drug manufacturers. Another substantial amount comes from generic substitution. Lesser amounts come from drug utilization review, prior approval, and formulary programs. Some of these savings estimates must be viewed skeptically because (1) the estimates are based on data provided by the PBMs being evaluated and

(2) empirical research suggests that programs which limit patients access to drugs may save drug costs but increase use and costs of other health care services. The high rate of PBM use and interviews with benefit managers suggest that plan sponsors are convinced that PBMs save them money.

BACKGROUND

Changes in Prescribing and Dispensing

In recent years, the prescribing and dispensing of prescriptions has changed significantly. In the past, physicians prescribed medications for patients without much concern for drug cost or interference from others. Physicians were free to choose whatever medications they thought would most benefit a patient. Pharmacists filled drug prescriptions according to physician specifications and the pharmacist's own professional expertise. Patients bore the cost of their prescriptions out of their own pocket, an expense that was generally affordable. However, the rising cost of prescription drugs and the subsequent involvement of managed care and pharmacy benefit managers has made prescribing and dispensing more complicated.

Now, patients visit a physician who prescribes a medication from an approved list of drugs (i.e., a formulary). The formulary is developed by third-party payers such as employers, managed care organizations (MCOs), and pharmacy benefit managers (PBMs) to restrict insurance reimbursement to lower priced, "equally effective"[1] drugs. If a physician wants to select a drug that is not on the formulary, the physician might be required to call the third party payer to get permission. To receive this "prior authorization," the physician usually telephones to an automated system which prompts him/her through a sequence of interactive menus that asks for a list of patient related information. After the physician completes the interactive menu, permission is either granted or denied, or a connection is made to a pharmacist for further details. If the nonformulary drug is not part of a prior authorization program, the patient may be required to pay for all or a portion of the drug cost. Physicians who prescribe more nonformulary medications than norms established by the third party payer are at risk of being charged a financial penalty as part of a risk-sharing contract or may even be excluded from managed care contracts altogether.

When visiting a pharmacy, the patient is often required to visit a "network" pharmacy to have the prescription filled. Pharmacy networks are groups of pharmacies that contract with a third party payer to make services accessible to plan members over a wide geographic area. Pharmacies in the network must accept lower dispensing fees, and are encouraged to dispense generic and formulary drugs, and call physicians to change some prescriptions originally prescribed by the physician to other drugs considered "therapeutically similar or equivalent." Therapeutically equivalent drugs are usually cheaper for the prescription plan to reimburse. Since pharmacies may contract with as many as 10 third party plans, a significant amount of pharmacist time can be spent dealing with the different requirements of each plan.

Patients may choose to receive their medications from a mail-order prescription service in some plans to reduce their out-of-pocket expenses. Patients often are charged lower co-payments (i.e., small out-of-pocket fees incurred at the time of dispensing) if they will have their prescriptions filled by mail order. Many mail order prescriptions are filled out-of-state.

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[1] Asserting drugs as equally effective for all patients is controversial.

Most prescription plan networks are currently built around a chain of retail pharmacies, supplemented by independent pharmacies, with a mail-order pharmacy option. This combination of options permits broad coverage of acute and chronic pharmacy needs. It also gives prescription plans an advantage when negotiating purchasing contracts with pharmaceutical manufacturers. Prescription plans can threaten to restrict patient access to the drugs of a pharmaceutical company if a favorable price is not agreed to. These lowered drug prices often take the form of rebates (i.e., payments made to insurance companies or HMOs by drug manufacturers).

Rising Health Care Costs

The health care industry is under escalating pressure to control rising costs. In 1995, $988.5 billion was spent on health care in the United States.(1) This equates to $3621 for every individual man, woman, and child. Health care costs represent approximately 13.6% of the nation's economy as measured by the Gross National Product (GNP) increasing from only 5.3% in 1960.(1) This burden has caused purchasers of health care, including state and federal governments, employers, health insurance companies, and individual consumers, to look for ways to reduce these costs.

Although pharmaceutical costs are currently increasing at a faster rate than most other components of health care, pharmaceutical products and services are still a small component of overall health care costs. Over $55 billion is spent every year on prescription medications in the United States (i.e., approximately 6.3 cents of each dollar spent on health care services).(1) Figure 1 illustrates the distribution of the various components of overall health care costs. Although drug costs are a small portion of overall health care costs, they draw the attention of consumers and medical plan administrators because they are very visible. Prescription drugs are frequently used and consumers pay either a portion or all of their costs. Patients do not have to share nearly as much of the costs of physician services, hospitalization, and other components of the health care budget.

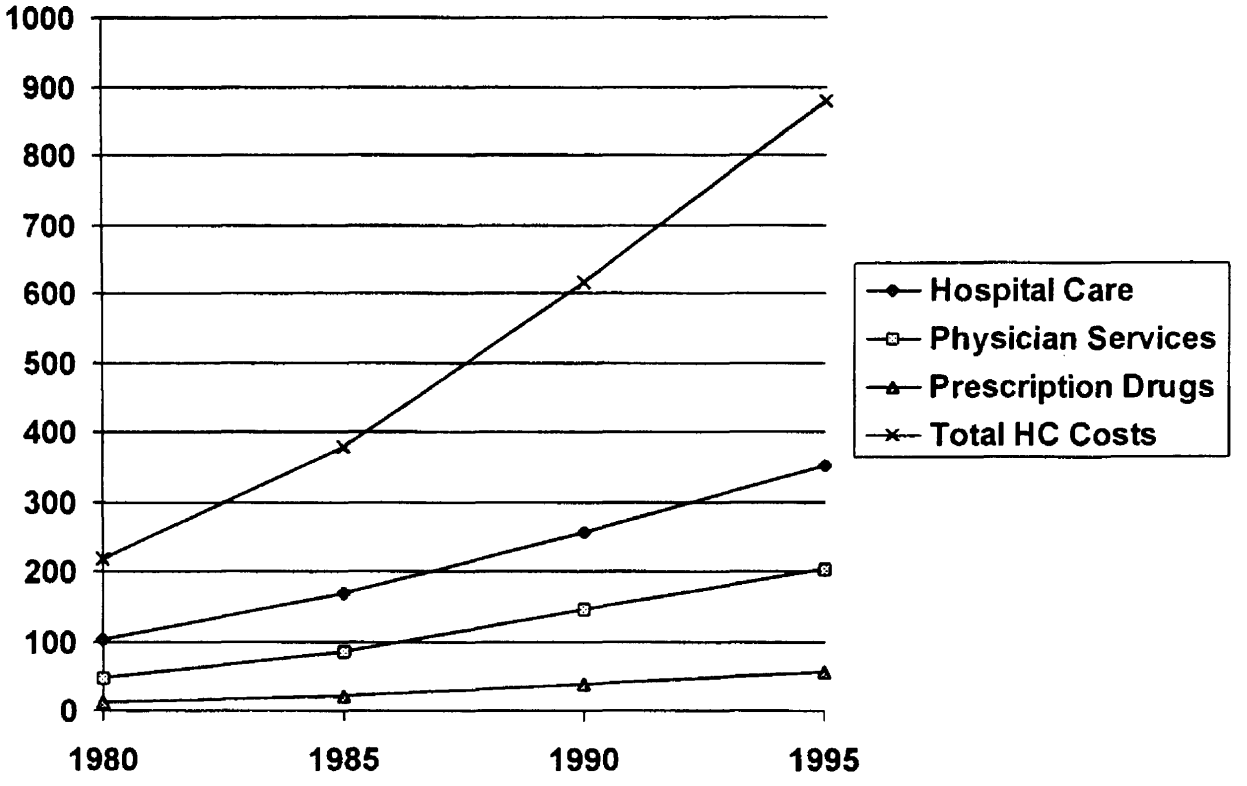

Figure 1: Health Care Spending in the United States (in billions of dollars)

Source:(1)

The Growth of Managed Care

Rising health care costs have encouraged payers of health care to embrace the concept of managed care. Managed care is a system of health care that attempts to manage cost, quality, and access to health care. Approximately 2 out of every three Americans (more than 165 million people) receive health care through a managed care plan.(2)

Managed care systems use a number of strategies to control the provision of health care, many of which can put financial pressures on health care providers. Managed care systems commonly provide insurance subscribers with medical insurance and services, using volume and long-term contracts to negotiate price discounts with health care providers.(3) Long-term contracts also help make cost increases predictable for payers, and often contain clauses for providers to share the risk of costs with payers. In addition, managed care attempts to gain sufficient numbers of subscribers to influence market demand and therefore increase their relative power in price negotiations with providers. Sometimes, providers are under sufficient competitive pressure to accept unfavorable managed care contracts in order to maintain a presence in a market.

Another managed care strategy is to control the utilization of health care resources. Controlling utilization can help further influence demand and hopefully promote higher quality

care at lower costs for those in greatest need. Drug formularies, clinical guidelines and pathways, and utilization reviews are used to control the use of health care by patients and providers.

The Evolution of Pharmacy Benefit Management Companies

Prescription benefit management is one of managed care's responses to rising drug costs. Pharmacy Benefit Managers (PBMs) are organizations whose primary purpose is to manage the pharmacy benefit. PBMs may form networks of community pharmacies that are willing to provide services at a contracted cost, negotiate discounts with pharmaceutical companies for the prescription drugs, help manage the utilization of pharmaceuticals, administer the prescription claims of patients and pharmacies, and a wide variety of other management functions.

The power of managed care and its effect on provider profitability has forced providers such as pharmaceutical firms, hospitals, pharmaceutical benefits managers (PBM's), and drugstore chains to merge or ally themselves with other providers. Pharmaceutical company purchases of PBM's (e.g., Merck & Medco, Smith Kline Beecham & Diversified Pharmaceutical Services, Eli Lilly & Pharmaceutical Card Systems), the growth of hospital networks (Columbia HCA), and a variety of strategic alliances between other health care providers have been, in part, a result of managed care.(3) These mergers are designed to permit managed care providers to offer better services at lower costs through the integration of health care.

The integration of health care through mergers and alliances has caused some concern in government and among some consumer groups. There is a concern that these alliances may reduce competition in the marketplace. For example, the Federal Trade Commission is examining the impact of drug company ownership of the three largest PBMs in the United States. Diversified Pharmaceutical Services, Merck-Medco Managed Care, and PCS Health Systems [2] are all owned by pharmaceutical companies.

The Promise of Pharmaceutical Benefit Management Companies

Pharmaceutical products and services are an essential component of the health care system and one of the most cost-effective therapies available in health care. However, there is not an unlimited budget for drugs. The promise of PBMs is that they can help manage the rising costs of drugs.

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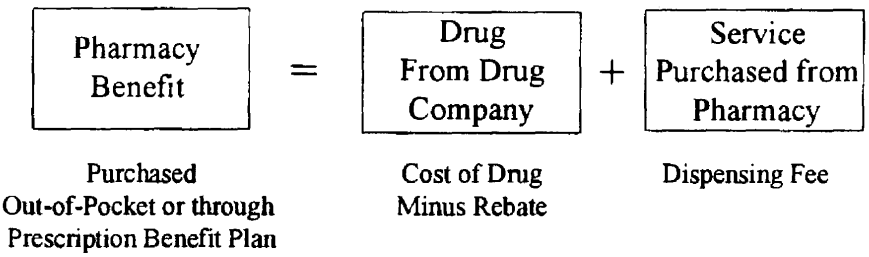
[2]The purchase of PCS by the pharmacy chain Rite Aid Corp. was announced on November 16, 1998. The deal has not been finalized at of November 18, 1998.

COVERAGE OF PHARMACEUTICAL BENEFITS

Pharmaceutical benefits consist of a drug product and a service component (Figure 2). Pharmaceutical benefits can be purchased out-of-pocket by individual customers or through individual or group prescription benefit plans. Prescription benefits plans are often purchased by individuals, employers, or governmental organizations as a part of a general health plan (i.e., covers all costs of health care). Because of the rising costs of prescription drugs, fewer individuals can afford to pay for pharmaceutical benefits out-of-pocket than in the past.

The drug product component of the pharmacy benefit is usually purchased by a pharmacy from a pharmaceutical manufacturer while pharmaceutical services are provided primarily by pharmacies. The cost of the drug product portion of the pharmaceutical benefit paid by prescription plans consists of the price charged to pharmacies minus a rebate negotiated with the manufacturer. The cost of the service portion of the benefit comprises a negotiated dispensing fee which is usually much less than the pharmacy's usual and customary dispensing fees to cash paying patients.

Figure 2: Components of the Pharmaceutical Benefit.



MANAGING THE PHARMACEUTICAL BENEFIT

Pharmaceutical benefits within health plans are primarily provided by PBMs and HMOs. HMOs may contract with the PBM or administer the benefit themselves. PBMs may contract with employers or employer groups or with HMOs. Table 1 lists some of the strategies used PBMs and HMOs to control overall drug costs. Many of these strategies will be discussed later in the paper.

Table 1: Strategies PBMs Use to Control Pharmaceutical Benefit Costs

Administrative Controls
- claims processing and analysis
- benefit structure and design
  - patient cost sharing requirements
  - coverage of drugs
  - coverage exclusions
  - limits on coverage
  - incentives for switching from retail to mail order
  - prescription size limits
- managing pharmacy networks
  - negotiating service discounts
  - auditing pharmacy services

Drug Use Controls
- managing formularies
  - prior approval programs
  - negotiating manufacturer contracts
  - therapeutic interchange
  - generic substitution
- drug utilization reviews (DURs)

Adopted from (47)

Pharmaceutical benefit management attempts to reduce the total prescription benefit cost by reducing the cost of drugs, the cost of services, and/or the number of prescriptions paid for. The total cost of prescription benefits can be represented by the following equation.

$$\textbf{Total Rx Benefit Costs} = (\textbf{Drug Cost} + \textbf{Service Cost}) \times (\#\ \textbf{Rx's paid})$$

Total benefit costs are controlled through the application of one or more management strategies. PBMs work under the direction of employers, insurers, and plan sponsors who choose which PBM programs they are willing to pay for and how much control over prescription drug costs is desired. PBMs control drug costs by negotiating manufacturer discounts, by getting patients to

use cheaper drugs through generic or therapeutic substitution, or by having the patient share part of the cost of the drug. Pharmacy service costs are controlled by negotiating service discounts with retail and mail order pharmacies, by restricting the size of the pharmacy network, and by increasing the prescription size limits so pharmacy customers will not have to visit the pharmacy as often. PBMs can control the total number of prescriptions by excluding certain drugs from coverage (e.g., non-prescription and birth control medicines), through patient cost sharing (i.e., some patients do not fill prescriptions if they have to pay), or by restricting access to medications with prior approval programs.

In most cases, a combination of approaches are used. For example, the maintenance of a formulary (i.e., a list of recommended drugs) is conducted with physician education programs or some type of reward system.

The effects of prescription benefit management are not independent of overall health care management. In other words, many activities designed to affect prescription costs and quality often alter overall health care costs and quality. For example, the state of New Hampshire tried to reduce state Medicaid drug costs by placing a cap on prescription drug coverage. The state implemented a 3 prescription per month maximum for Medicaid patients. The state found that it did decrease prescription drug costs as expected. However, they also found that restricting access to prescription drugs for community based schizophrenics cost the state 17 times the amount of drug savings due to increased utilization of acute mental health services and emergency room visits.(70) In addition, elderly and disabled patients were twice as likely to be admitted to nursing homes after implementation of the cap. As the state of New Hampshire found, addressing the high costs of drugs in isolation of total health care costs can result in unintended and undesirable consequences.

The following equation illustrates how drug costs are just one element of total health care costs. All components must be considered when evaluating total health care costs. Focusing on a single one element of total health care costs can lead to unintended effects on the other interrelated elements as the state of New Hampshire discovered.

Total Health Care Costs =

(Total Pharmaceutical Benefit Cost + Total Physician Benefit Cost + Total Hospitalization Benefit Cost + Total Nursing Home Benefit Cost + Total Laboratory Benefit Cost + Etc.)

WHAT ARE PHARMACEUTICAL BENEFITS MANAGERS (PBM'S)?

PBMs are organizations whose primary function is to administer and manage pharmaceutical benefits for customers. The primary customers of PBM companies are HMOs, employers, and governmental agencies. HMOs frequently use PBMs for all or a portion of their pharmacy benefit management because they find PBMs are able to control benefits more efficiently than they can themselves. PBMs manage benefits for 48.4% of HMO enrollees.(4) Employers who provide health benefits also contract with PBMs. Some indirectly contract with PBMs through their HMOs or health insurance plans. Many other employers separate or "carve out" the pharmacy benefit from their health plan and contract directly with a PBM company. One nationwide study found that 70.6% of employers separately contract with PBMs.(4) PBMs manage a much smaller number of governmental beneficiaries but substantial PBM management of Medicare and Medicaid benefits is expected in the future.(4) Virginia's Medicaid recipients in the Tidewater receive prescription benefits through PBMs.

PBM's are not the only organizations that administer and manage pharmaceutical benefits. Over 50% of HMOs manage pharmaceutical benefits within their own organization. Some large HMOs have their own PBM subsidiaries. Even when HMOs contract with PBMs, their contracts may only cover a portion of pharmacy benefit management (e.g., claims management) with the remainder conducted within the HMO. Therefore, HMOs are responsible for pharmacy benefit design for millions of health care beneficiaries.

Who Owns PBM's?

The largest five PBM firms in the United States account for over 80% of beneficiaries covered by PBMs.(5) The three biggest PBM's are owned by drug manufacturers. However, PBMs are owned by an assortment of other business entities (Table 2). Some PBMs are independently owned. Others are owned by managed care organizations and chain drugstores. Most major chains Rite Aid, Walgreens, CVS, Wal-Mart, Safeway, and Target own PBMs.(6)

Table 2: Examples of PBM Ownership

Drug Manufacturer Owned	
Diversified Pharmaceutical Services	Smith Kline Beecham
Merck-Medco Managed Care	Merck & Co.
PCS Health Systems [3]	Eli Lilly & Co.
Independent PBMs	
Caremark	Independently Owned

[3]The purchase of PCS by the pharmacy chain Rite Aid Corp. was announced on November 16, 1998. The deal has not been finalized as of November 18, 1998.

Express Scripts	Independently Owned
National Prescription Administrators	Independently Owned
Owned by MCOs	
Prescription Solutions	Pacificare
Aetna Pharmacy Management	Aetna
Pharmacy Gold	Blue Cross & Blue Shield Minnesota
RxPrime	Cigna
Owned by Drug Chains	
RxAmerica	American Stores
Eagle Managed Care	Rite Aid
PharmaCare Management Services	CVS
WHP Health Initiatives Inc.	Walgreens

Sources: (7)(8)

Many businesses that do not describe themselves as "PBMs" engage in PBM practices either directly or through their subsidiaries or partners. Health maintenance organizations, drugstore chains, and traditional health insurance companies manage pharmaceutical benefits. If traditional PBM's disappeared tomorrow, their functions and practices would still be conducted by HMO's, employer groups, pharmacy chains, etc. Since many of the "practices" of interest in this report are not restricted to PBMs and are common among most managed prescription benefit plans, it is important to define a PBM for the purpose of this study.

Definition of a PBM:

A pharmacy benefit manager (PBM) is any organizational entity that engages in one or more of the following practices: prescription claims processing and analysis, managing pharmacy networks, and managing formularies.

The term pharmacy benefit management in the definition above includes activities designed to influence the utilization of drugs and the cost of pharmaceutical benefit.

CHARACTERISTICS OF PBM'S

PBMs and MCOs that administer pharmacy benefits have three primary weapons in controlling pharmacy benefit costs--pharmacy networks, claims administration, and drug formularies. Pharmacy benefit plans may use any or all of these weapons.

PBMs are paid administrative fees to manage all or part of the benefit. In addition, pharmaceutical manufacturers may pay rebates to the PBM for using their drugs. The PBM typically keeps a portion of the rebate and passes on a percentage to the managed care plans or employers contracting with them. The PBM often is responsible for establishing a pharmacy network, and is able to provide customers with reports such as members' use of pharmacy benefits, drug utilization/evaluation, formulary use, and copayment information.

According to the Department of Health and Human Services, table 3 table lists the proportions of HMOs using PBM services, by type of service. The remaining PBM services are managed internally by the HMO.(9)

Table 3: Proportion of HMOs using PBM services, by type of service

94%	claims processing
74%	pharmacy networks
46%	mail order
71%	formulary management
56%	patient and/or provider education
35%	Disease state management
28%	Outcomes research

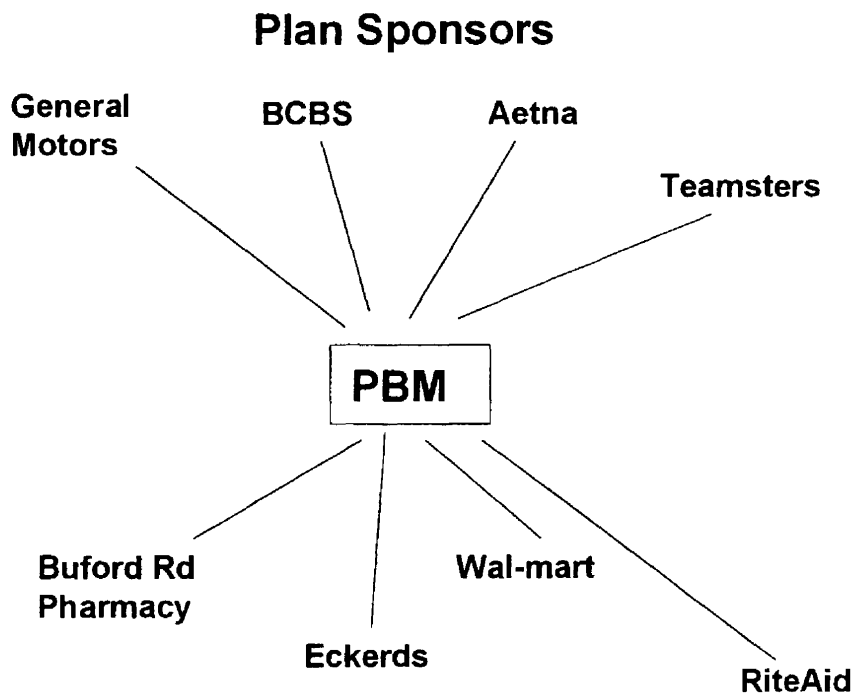
Source: (9)

BASIC PBM SERVICES

Claims processing

The original purpose of PBMs was to process prescription claims for pharmacists. The difficulty of handling prescription benefit claims from numerous insurers opened up a market for PBMs. PBMs act as intermediaries between pharmacies and third party payers of prescription drugs to coordinate the process of claims submission, reimbursements, and report generation (Figure 3).

Figure 3: PBM Claims Processing



PBMs reduce the cost to pharmacists of verifying prescription claims and processing the payments for dispensing services rendered. This is accomplished through the use of computers that permit on-line claims processing in contrast to the mail-in claims systems of the past. Over 90% of all prescription claims are adjudicated on-line.(10) PBMs also provide patients with membership cards with magnetic strips that can be used to confirm prescription plan membership.

PBMs provide employers and MCOs with reports that analyze and evaluate drug usage and costs. Either standard reports as a part of the PBM contract or reports individualized to the needs of the employer or MCO can be generated. Other services associated with claims processing may include the administration of cost sharing arrangements with patients (e.g., copayments, deductibles, co-insurance).

Establishing and Managing a Pharmacy Network

PBMs contract with multiple pharmacies to make services accessible to plan members over a wide geographic area. An open plan permits any pharmacy to contract with the PBM. A closed plan limits pharmacy participation to a restricted number. The incentive for pharmacies to contract with a closed network is *access to customers*. Pharmacies are usually offered a certain volume of prescriptions and a level of exclusivity not available in open plans. Pharmacies who do not participate in a closed network plan can be excluded from a significant portion of their customer base. In addition, the ability of PBMs to exclude pharmacies from networks permits them to aggressively negotiate pricing and service contracts with pharmacies.

Since some pharmacists argue that closed networks are unfair because they restrain free trade, Any-Willing-Provider (AWP) laws have been enacted in some states including Virginia. Any-Willing-Provider laws require managed care organizations (MCOs) to allow any provider that accepts the terms of a managed care contract the ability to participate in the network. The National Community Pharmacists Association (an independent community pharmacy association) supports AWP laws because of concern that its independent pharmacy members are being denied access to their customers.(11) Managed care associations and individual MCOs argue that AWP laws prevent MCOs from some of their most useful tools in controlling health care costs. They argue that AWP laws reduce the incentives for providers to offer discounts in exchange for increased patient volume and undercut the administrative efficiencies of managed care delivery systems.(11)

Even with AWP laws, pharmacists may choose not to contract with PBMs if they judge that service reimbursements are below their costs of providing them. Pharmacists state that they often agree to provide prescription drug dispensing services at prices below cost in order to increase customer traffic in non-prescription merchandise. In other words, the prescription department becomes a loss-leader that brings customers into a pharmacy. Those pharmacies whose business is primarily prescription related often are disadvantaged. Those who cannot make up their losses in departments other than the prescription department may be forced out of business. And if pharmacies do not accept the contract terms, they must rely on customers who pay for their medicines out-of-pocket, a shrinking portion of the pharmacy customer base.

In addition to accepting lower reimbursements, pharmacies that participate in a network typically agree to provide services established in the contract such as the promotion of generic and/or therapeutic substitution and the acceptance of maximum allowable cost reimbursements for generic drugs provided to patients.

Point-of-Service (POS) Technology

Pharmacies are connected to the PBMs with which they have contracts through computer modems and phone lines. As soon as a prescription has been entered into the pharmacy's computer, the pharmacist can submit it to the PBM for approval. The PBM will respond with a message that the prescription is approved (or not) for reimbursement. In addition, the PBM can send a variety of other types of messages. They are known as POS notifications.

PBMs often assist pharmacies with POS notifications. The purpose of POS notifications is to catch common problems at the point of prescription dispensing. For example, POS technology can monitor for patient eligibility for prescription coverage, identify non-formulary or restricted drugs, determine the co-payments to be charged to patients. In addition, it can enable immediate adjudication of pharmacy claims. POS can also be used to notify pharmacists of clinical problems such as drug allergies or drug interactions.

Formulary management

A formulary is a list of pharmaceutical products which have been approved by a PBM or MCO. Criteria for including drugs on a formulary include safety, efficacy, and cost. Drugs on the list constantly change based upon how they compare with other available drugs in terms of clinical effectiveness and the cost of purchasing them. The employers or HMOs that contract with PBMs determine how restrictive or lenient a formulary will be.

There are several types of formularies. Open formularies are simply lists of recommended drugs. Prescriptions for drugs not on the list are reimbursed but promotional efforts are made by the PBMs to voluntarily adhere to the open formulary. Prescribing compliance with open formularies frequently is poor. Closed formularies only permit reimbursement for drugs on the formulary. Reimbursement for non-formulary drugs may occur when medically appropriateness can be demonstrated. Partial or selectively closed formulary are hybrids between open and closed formularies. They are essentially an open formulary that excludes selected classes of drugs and/or some drugs that are overused or expensive. Typically, preferred formularies encourage the use of recommended formulary drugs by offering lower copayments to patients who choose the PBM's recommended drugs. Some preferred formularies levy such a high copayment for nonformulary drugs that for all intents and purposes, they are closed. The type of formulary used by the PBM is selected by employers, insurers, and plan sponsors.

Formularies that work in collaboration with other PBM controls are called formulary systems. Formulary systems are systems of controls that attempt to control the procurement, prescribing, and dispensing of pharmaceuticals. Formularies systems have been used for years in hospitals and have been demonstrated to reduce drug and overall health care costs. Formulary systems in the community have not been studied extensively. Table 4 lists a number of controls associated either directly or indirectly with formulary systems.

Table 4: Controls associated with formulary systems

Patient Copayments
Reimbursement Caps
Incentives for generic drug substitution
Incentives for therapeutic drug substitution
Prior authorization programs
Benefit exclusions (e.g., birth control pills and nonprescription medications)
Length of therapy limits (e.g., 90 day supply, restrictions on sleeping pills)

Source: (12)

Formularies are one of the PBM's most powerful tools.(13) Closed formularies can move market share for pharmaceutical companies. Most formularies are currently "open" due to concerns by employers about complaints associated with restricted access to drugs.(10) Employers and MCOs often are unwilling to upset employees or customers by limiting their drug choices but this may change..

Until recently, employers have been able to receive rebates without closing formularies because PBM's use the threat of closing the formulary as a bargaining chip with manufacturers.(13) However, pharmaceutical manufacturers are less willing to pay rebates without getting increases in market share or utilization of their drugs.(4)(14)

In the future, PBM's may try to reduce their use of open formularies in order to move market share and earn rebates from manufacturers.(4) Only those providers with significant control over formularies will be able to receive a rebate. This requires a level of control that can not be achieved by open formularies. The closing of formularies will only be possible if employers cooperate. Employers may be willing to inconvenience their employees if they receive a larger share of the rebate income.

Disease management

Disease management consists of a variety of strategies that target patients with diseases that utilize significant resources within the health care system. Disease management analyzes the medical needs and resources consumed by a disease population and then develops a strategy to control the delivery of care for this population. Often, diseases in disease management are chronic in nature because the cumulative costs of chronic diseases over a patient's lifetime can be significant. Since drug therapies are an integral part of managing many chronic diseases, PBMs offer programs in disease management.

Disease management strategies include the application of clinical practice guidelines, patient compliance programs, and provider education programs. Clinical practice guidelines are recommended series of actions that providers should take in treating a specific clinical condition. These recommendations are based on a comprehensive study of the research literature that

indicates what works and does not work under various clinical situations. One advantage of disease management protocols is that they standardize the care of patients so that every patient receives the most advanced, proven treatments.

Educational interventions

Pharmacists and physicians who do not follow formulary guidelines or do not follow other practices recommended by PBMs are often targeted for educational interventions. Initially, these consist of notification letters and educational newsletters. When written notifications are ineffective in changing behavior, providers may receive more personal contact such as group presentations, telephone calls, or personal face-to-face meetings by PBM representatives (often a physician or pharmacist).(13)

Risk sharing.

Under a risk sharing contract, the PBM and employer agree on a target drug cost per employee per month.(14) If the cost is greater than the target cost, the PBM provides a refund to the employer or HMO. If the cost is below the target, the PBM shares in the savings. Physician groups also participate in risk sharing contracts.

Provision of mail order services

Nearly all drug benefit plans offer a mail-service option.(10) PBMs promote mail-order service as a convenient way of receiving prescription drugs, since the prescription is delivered directly to the patient's door. PBMs usually receive larger discounts from mail order than from retail community pharmacies.

Many plans strongly encourage members to use mail-service pharmacies through the use of lower copays or larger quantities for the same copay.(15) Patients who fill and refill prescriptions for longer time limits (e.g., three months) than normal, do not have to visit pharmacies as often and pay a relatively smaller service fee. This reduces the number of service fees that PBM's need to pay their network pharmacists. It also reduces the number of claims that they need to process. For PBM's with their own mail order subsidiaries, promoting mail order gives them a new source of revenues.

In addition to customer convenience, the PBM and the employer both benefit by targeting chronic care drugs and decreasing distribution costs. Mail order dispensing uses automation and efficient system design to permit thousands of prescriptions to be filled per hour. This permits efficiencies that significantly decreases dispensing costs. Some patients feel that mail-order is more convenient than a neighborhood pharmacy. Mail-order dispensing also encourages generic substitution (unless prohibited by the prescriber) and aggressive promotion of therapeutic substitution of preferred products from a health plan's drug list. Successful switching to generics and therapeutic substitutes results in significant discounts from pharmaceutical companies whose products are promoted. (In spite of these potential savings, it has not been conclusively demonstrated that mail order pharmacies save money for employers or HMOs. Mail order

pharmacies typically have higher rates of drug wastage, since they dispense 2 to 3 month supplies, postage costs, and significant investments in automated equipment.)(66)(67)

Generic substitution

Pharmacists in networks are encouraged to use generic substitutes whenever possible. Multi source, generic substitutes are usually much cheaper than single source brand name drugs. Participation in pharmacy networks is often contingent on meeting generic substitution goals.

Therapeutic Interchange

Therapeutic interchange is the *authorized* exchange of different drugs that are therapeutically similar (result in the same therapeutic outcome) Therapeutic interchange differs from therapeutic substitution which is conducted without prior authorization of the prescriber.(16) Therapeutic interchange is more controversial than other cost savings methods because the decision of equivalence is not as clear as with generic substitutions. This controversy is complicated by the fact that many drug company owned PBMs have a financial stake in substituting their parent company's drugs for their competitor's. HMOs, PBMs and employers all predict that therapeutic interchange is a practice that will occur with increasing frequency.(10)

Drug Utilization Review (DUR)/Drug Utilization Evaluation (DUE)

DUR, also known as DUEs, are broadly defined as the review of physician prescribing, pharmacist dispensing, and patient use of drugs.(17) PBMs use DURs to identify problems in the drug use process. DUR screening may be initiated for specific expensive or frequently prescribed drugs, for drugs that have potential for inappropriate prescribing, for patients that utilize more drugs, for pharmacists that do not dispense as expected, and for physicians that prescribe differently from established norms. DURs target drug/disease conflicts, drug-drug interactions, chronic over utilization, underutilization, non-compliance, drug/sex and drug/ age conflicts, and drug/pregnancy contraindications. Once problems are identified, physician, pharmacist, and patient interventions are enacted. Interventions can be educational or some method of punishment or reward.

Prior Authorization.

Prior authorization requires physicians to obtain permission to prescribe certain drugs. Prior authorization is used for drugs that may be over-prescribed or are very expensive. The impotence drug Viagra might be a good candidate for a prior authorization because it is expensive ($7 to $10 per tablet) and may be easily prescribed for patients who do not need it. PBMs typically establish protocols which require physicians to receive prior authorization over the telephone using a automated system. The physician often will be prompted through a series of interactive menus requesting specific data about the patient and the condition being treated. At the end of the interactive menu, the physician is either given or denied authorization or may be connected with a pharmacist for further discussion. Seventy-seven percent of HMOs, PBMs and employers expect to increase their use of prior authorization. (10)

Treatment Guidelines and Step Protocols

Treatment guidelines are used to establish conditions for the use of certain drugs. For example, some drugs may only be appropriate for small segments of the overall patient population. Misoprostol (brand name Cytotec) is a unique drug for ulcers that are caused by nonsteroidal anti-inflammatory drugs (NSAIDs). Although there are no ready alternatives for Misoprotol, it should only be prescribed for patients who are at high risk of NSAID induced ulcers. Therefore, PBMs might restrict its use by requiring the physician to receive prior authorization for it, or the PBM might simply monitor its utilization and implement educational programs if inappropriate use occurs.

PBMs use step protocols to encourage physicians to prescribe certain drugs in a therapeutic category first before they try any other drugs. These step protocols typically recommend proven, older, cheaper drugs as first-line therapies before newer, more expensive drugs are prescribed. Most treatment protocols follow recommendations of national commissions, governmental agencies, and leading medical associations. National consensus guidelines have been found to exert a strong influence on PBM formulary decision processes. (18)

Physician profiling

Physician profiling monitors physician prescribing and compares physicians to expected prescribing patterns. Expectations are based on prescribing norms within the physician population and/or adherence to prescribing protocols recommended by experts such as those in national consensus guidelines. Peer comparison is generally within physician specialties and within defined geographic regions. Physicians whose prescribing differs from the norm are targeted for educational and other types of interventions. Educational interventions may range from a letter reminding the physician that he/she is prescribing outside of the norm to telephone calls and face-to-face visits.

Patient Cost Sharing

Patient cost-sharing is the practice of charging patients for a portion of the cost of a dispensed drug (through a deductible, coinsurance charge, or copayment). Cost sharing is a common insurance practice designed to discourage patients from seeking unnecessary care for minor health problems and to recoup some of the drug cost directly from the patient. Cost sharing has increased significantly in recent years.(10) Patients that wish to receive a product other than the generic or therapeutic equivalent recommended by the PBM frequently have higher cost sharing expenses.

Pharmaceutical Company Rebates

Pharmaceutical companies frequently pay MCOs and PBMs to encourage the use of their prescription drugs. MCOs and PBMs encourage the use of specific drugs by listing them on their formularies, by charging lower copays for them, and through therapeutic interchange. Most of the PBM's profits come from rebates because the 35 to 50 cents charged per prescription for

administering pharmaceutical benefits are so low that they are loss leaders (do not generate net income). (19) Therefore, rebates are a critical source of income for prescription drug plans. One estimate places the total amount of money rebated by pharmaceutical companies at approximately $2 billion annually.(20)

The importance of rebates prompts PBMs to drive hard bargains with pharmaceutical companies. The PBMs attempt to get the best deal with drug companies and offer to share a portion of the rebate with employers and MCOs as an incentive to participate in their plans. The negotiating power of PBM's is based on their ability to increase the market share of the manufacturer's drugs. If the PBM can get physicians to prescribe for drugs contracted with the manufacturer, the PBM can negotiate a better deal.

However, the future of rebates is becoming uncertain. MCOs are cutting back on the use of PBMs. Approximately one third do not use them and another third are planning on reducing their use of PBMs.(19) In addition, many manufacturers feel that most MCOs and PBMs are unable to sufficiently move their drug market share sufficiently to justify rebates. Some manufacturers may have rebate contracts with more than 100 PBMs, MCOs, and employers, and the ability of each of these groups to move significant market share is questionable.(20) Manufacturers have cut back rebates to PBMs by 50% or more.(19)

PRESCRIPTION BENEFIT MANAGEMENT IN VIRGINIA

Prescription benefit management is conducted primarily by national firms. Therefore, most national trends and practices probably affect Virginia. However, little information has been published about the operation of PBMs in the Commonwealth.

IMPACT OF PBM'S ON PHYSICIANS

Physicians complain that PBM practices intrude on their ability to practice medicine, and that they do so with little oversight. Representatives of the American Medical Association protest that PBM representatives frequently call to request that prescriptions be altered.(19) PBMs reply that these substitutions are voluntary and that physicians are free to refuse these requests. [Virginia state laws do not permit substitution of therapeutically equivalent drugs (for example, the ulcer medicine Tagamet for the ulcer medicine Zantac) without a physician's permission.]

However, there are risks to physicians for refusing to honor PBM requests to change prescriptions. Physicians who prescribe outside of established formularies are subject to "educational" notification through letter or visit from PBM representatives. Although these educational notices are not meant to be punitive, (80% of HMOs currently allow physicians to override the formulary and prescribe drugs they believe to be therapeutically necessary (19)) there may be the perception of a potential future reprimand by the PBM. That potential reprimand may include being dropped from a health plan contract. Furthermore, nonformulary prescribing is documented by PBMs and many physicians are aware of this documentation. Eighty percent of prescription benefit plans use physician report cards and 58% use peer review for physician prescribing.(10)

Choosing nonformulary drugs may also generate administrative inconveniences. Physicians may have to justify their selections through phone calls, letters, or electronic notifications. They may also have unhappy patients to deal with because some PBMs charge patients extra for nonformulary drugs. Whether these inconveniences are real or simply perceived has not been empirically documented.

Even when physicians wish to comply with managed care formularies, physicians may be required to stay current with as many as 10 to 15 formularies; each with different approved drugs.(19) It is not uncommon for a physician to switch from a nonformulary drug A to a formulary drug B for one patient, and find that the next patient's PBM has drug A on the formulary and not drug B.

However, PBMs state that physicians need more guidance in their prescribing. A study by one of the largest managed-care companies, United HealthCare Corp., found that many doctors often do not follow standard, widely recommended guidelines for medical practice and prescribing.(21) They found that physicians routinely fail to prescribe essential drugs for conditions ranging from diabetes and heart disease.

Prescribing guidelines are written recommendations of the best practices for managing disease based upon detailed summaries of recent literature and expert opinion. They are meant to provide the most consistent application of current methods for preventing, diagnosing, and treating diseases. Treatment guidelines and protocols for many diseases are readily available from governmental and professional organizations and in the published literature. PBM guidelines often are based on these published recommendations.

Physicians respond that the use of formularies and guidelines can lead to "cook-book medicine" in which patients are not treated as individuals. Instead, every patient is treated the same and receives the same drug regardless of individual need. In addition, some physicians argue that formularies often are not based on medical evidence but on the business objectives of the PBM's parent pharmaceutical company.(19)

IMPACT OF PBM'S ON PHARMACISTS

PBM practices significantly affect pharmacist practice. Overall, most community pharmacists do not believe this effect to be positive. One study found the word "frustration" most frequently used to describe the impact of PBM practices on their everyday duties.(22) Much of the complaints from pharmacists originate in the low reimbursements provided to pharmacists. The *average dispensing fee paid* to managed care network pharmacies was $2.23 in 1997.(4) This contrasts significantly with the *average cost of dispensing* a prescription ranges from $5.55 to $6.77.(23) That means that PBMs have been able to set dispensing fees at less than one half of pharmacies' cost.

Less service and more prescriptions

How can pharmacists continue to fill prescriptions at a loss? The primary strategies used by pharmacies are to provide less service, fill more prescriptions per hour, and use the pharmacy as a "loss-leader."(28)(69) Reducing the level of service and filling more prescriptions are ways to reduce the cost of dispensing to a level commensurate with the dispensing fee paid by prescription benefit plans. Pharmacies provide less service by having pharmacists spend less time with customers or by utilizing nonprofessional personnel in place of pharmacists. Dispensing costs are also reduced by increasing the number of prescriptions filled by each pharmacist. The increasing workload required by pharmacists has brought about calls from pharmacist associations to mandate restrictions on the number of prescriptions that a pharmacist can be required to fill in an hour.

A survey found that pharmacists must use creative strategies to reduce the amount of time spent on addressing problems with PBMs.(24) Some pharmacists have telephones installed in their patient waiting area and ask patients to handle difficulties with third party payers. This is used both as time saver for the pharmacist and as an educational tool for the patients. Other pharmacists ask the patient to pay cash and submit their claims for later reimbursement when too much time is being spent on a claim. Some pharmacists spend extra money and time to train technicians to handle prescription claims. These technicians often command premium salaries.

Pharmacies often contract at dispensing fees below cost in order to increase customer traffic in non-prescription merchandise.(69) The use of the prescription department as a loss-leader forces pharmacies to make up losses outside of the pharmacy department or to rely on customers who pay for their prescriptions out-of-pocket.(28)

What is the impact of low dispensing fees?

Although no cause and effect relationship has not been established between PBM practices and the structure of the pharmacy market, a number of trends suggest that there may have been at least a partial impact. The total number of retail pharmacies in the United States has declined from 58,756 in 1990 to 51,579 in 1996,(25) despite retail sales of precription products increasing from $37.7 billion to $62.2 billion during the same period.(1) The failure rate of independent retail pharmacies has been high. Over this time period, the number of independently owned retail

pharmacies has declined from 32,079 to 21,975.(25) Increases in the number of supermarket pharmacies, mass merchising stores, and mail order pharmacies have offset the losses of independent pharmacies. One empirical study demonstrated the instant impact of PBMs on pharmacy profitability. Immediately after the implementation of a pharmacy benefit plan, the average gross margin of two study pharmacies fell 27%.(26)

Why don't pharmacists just refuse to contract at unreasonable rates?

Many pharmacists feel that they must accept PBM contracts with low dispensing fees in order to maintain their customer base. Negotiation is not possible because negotiating power remains primarily in the hands of the PBM's. In many situations, the PBM represents a significant portion of the pharmacy's customer base. Refusal of a PBM contract results in a loss to the pharmacy of this group of customers, but for the PBM it has little impact because there are usually other pharmacies available to accept the terms of the contract.

Many pharmacists feel that the power of PBM's has allowed them to have a "take it or leave it" approach to pharmacies, particularly small pharmacies. One PBM forced an independent pharmacy in New York to charge the much lower drug prices from a Michigan drug wholesaler.(27) Another promised 30 day reimbursement but averaged 52 days for payment.(27) How widespread are these types of practices has not been studied.

The response of small pharmacies to their lack of market dominance has been to consolidate. Large pharmacy chains have been purchasing smaller chains and independent pharmacies. This has led to the top 4 chains operating 12,647 pharmacies in 1997 up from 7,379 in 1989.(28) As pharmacy chains become larger, they are better able to refuse low dispensing fees and force PBMs/MCOs to pay higher fees. For example, a number of large pharmacy chains in Maryland refused to participate in Merck-Medco's network for state employees due to low reimbursements.(28) As a result, Merck-Medco was unable to meet the terms of their contract and lost the contract to PCS.

What is the impact of PBM preference for mail order on community pharmacies?

PBM promotion of mail-service pharmacies has helped sales rise 22% from 1996 to 1997 making them the fastest growing prescription pharmacy outlet.(29) PBMs often encourage prescription plan participants to switch to mail-service by charging lower copays(in comparison to community retail pharmacies). This promotion of mail-service (many of which are located out of state) has been one of the reasons that 1,118 independent pharmacies closed in 1997.(29)

Mail order services offer a number of advantages to PBMs. They can purchase drugs at significantly lower prices due to preferential pricing contracts, although these preferential pricing contracts are currently being litigated against.(28) The volume of prescriptions passing through mail order pharmacies also permits dispensing to be conducted in highly efficient settings that often use robotics and computer technology. As a result, dispensing costs are much lower because pharmacists and technicians are not interrupted by telephone calls or patients, and they have greater control over their dispensing environment.(28)

What are pharmacy desk audits?

PBMs may audit pharmacies to determine whether the pharmacy has, through fraud or negligence, improperly billed it for prescriptions. The typical audit involves an auditor visiting the pharmacy and reviewing pharmacy records to determine if there has been improper billing. If there has, the pharmacy is required to repay the PBM for the amount of improper billings.

Desk audits are different.(30) To conduct a desk audit, the PBM analyzes its database of computerized prescription claims to determine the average values for some parameter such as the number of prescriptions which have been submitted as "Dispense as written".

The PBM then analyzes its claims data to determine the number of pharmacies which have exceeded the average by some amount. The PBM then bills those pharmacies for an amount related to the extent to which their dispensing of dispense as written prescriptions exceeds the average. The procedure is based on the assumption that the greater than average number of these prescriptions dispensed is due to fraudulent or improper billing. Pharmacists object to desk audits because they overlook the obvious fact that some pharmacies will legitimately have higher than average numbers of prescriptions for which the physician has specified "dispense as written". The desk audit assumes that any pharmacy with higher than average values is either fraudulent or negligent.

Extrapolation is a common tactic in pharmacy audits that occurs when auditors dispute the claims pharmacies charge.(31) For disputed claims, pharmacists are asked to reimburse not only the amount found but an amount extrapolated to all prescriptions filled for that plan. A minor discrepancy of $100 for 30 prescriptions may be extrapolated to the 3000 prescriptions filled for the plan resulting in the plan asking for $10,000 from the pharmacy. Disputes of these charges can take up significant time and money on the part of the pharmacist even when the pharmacist wins the dispute.

Prescription plan administrators argue that the sampling of prescriptions is scientifically sound and are meant as a way of ensuring that pharmacists maintain appropriate records. And in many cases, pharmacists are only charged for discrepancies that exceed a certain percentage of the total claims filed (e.g., 5%). (31)

However, auditors are often highly motivated because they may receive part of the recovered penalties. These financial rewards give auditors an incentive to be aggressive in how they interpret pharmacy discrepancies. Pharmacists say that some auditors, as a result, have a "witch hunt" mentality. (32) Pharmacists say that they have a right to due process but some auditors are perceived to approach a suspect pharmacy as guilty before proven innocent.(32) In many cases the procedure of due process can be too time consuming and expensive than the pharmacist is willing to pay. In these cases, the pharmacist just gives up.

Do PBMs discourage pharmacists' responsibilities?

The current PBM reimbursement system for pharmacists provide few rewards for pharmacists who want to provide innovative cognitive services such as smoking cessation programs and diabetes education although there is a significant need. Many drug related problems in health care can be prevented with the use of pharmacist services. Preventable adverse drug events (ADEs) are the result of improper drug selection, inadequate monitoring of therapy, and errors by health care professionals. Classen et al.(33) found that 2.43 of every 100 patient hospital admissions were caused by ADEs and resulted in increased hospital stays, costs, and patient deaths. Einarson (34) found more than twice Classen's reported rate (i.e., 5.1 per 100 admissions). Bates et al.(35) estimated that the cost of preventable ADEs at just two hospitals was $2.8 million annually.

Medication non-compliance is also a common problem that leads to poor patient health and increased health care costs. Sullivan et al.(36) estimated that 5.1% of all hospitalizations in the United States were due to patients not taking their medications correctly. Colt et al.(37) determined that 11.4% of hospital admissions were due to noncompliance.

The cost of drug-related morbidity and mortality in the United States has been estimated to be $76.6 billion annually.(38) This sum indicates that for every dollar spent each year on prescription medications in the United States, another dollar and one-half is spent to correct drug-related problems associated with these medications. Annual drug-related costs exceed the annual health care costs for obesity ($45.8 billion) and diabetes ($45.2 billion).

In a follow-up study, Johnson and Bootman assessed the economic impact if all pharmacists in ambulatory settings were to provide pharmaceutical care (38). They estimated that $45.6 billion in direct costs could be saved and 120,000 deaths could be avoided. Johnson and Bootman conceded that pharmacists currently do not provide the levels of services that could achieve these savings. They suggested that extensive changes in reimbursement methods would be necessary for this to happen.

In sum, preventable drug-related problems in ambulatory patient populations cost billions of dollars annually in the United States. Since pharmacists are the most accessible health professional and best trained to deal with drug issues, they should be better utilized to assist with this problem. The current rates of reimbursement paid by PBMs do not allow pharmacists adequate time to address these problems.(23)

IMPACT OF PBM'S ON PATIENTS

How do employers choose PBM services for their employees?

Employers use relatively unsophisticated methods for selecting HMOs and their pharmacy benefits plans.(39) Access and geographic coverage are the most important criteria and cost is the second most important. Quality of care, as measured by the use of HEDIS quality data, was of importance to only 25% of respondents.(39) Employee satisfaction was the most important quality indicator used by HMOs although satisfaction is a relatively poor measure of the technical quality of pharmacy services.(40)

Are PBM programs directed toward helping patients or PBMs?

There is little research literature which assesses the number of patients affected by PBM practices or the impact of PBM practices on patient health.

In an article in U.S. News & World Report, Virginia pharmacist John Ferraro complained that PBMs routinely instruct him to replace perfectly adequate, generic drugs with brand-name equivalents that may be five times more expensive.(41) His argument was that PBMs often make decisions for business reasons than for the good of the patient. Because of rebates paid by manufacturers of brand name drugs, PBMs can frequently make more money from reimbursing expensive brand-name products than from generics.

The health impact of PBM promotions have not been studied but anecdotal reports have appeared in the news. One patient claimed that she was successfully taking the ulcer medicine Prilosec for a number of weeks without incident.(41) When her HMO switched to a generic equivalent of the ulcer drug Tagamet against her doctor's objections, she and her doctor claimed that the ulcer worsened to the point of needing surgery. Recovering from the operation, she suffered a paralyzing stroke. Her HMO sympathized with her but did not believe her complications were caused by the switch.

Many changes are made on drugs that patients have used successfully for years. A professor of pharmacy at the University of Florida, learned that a mail-order pharmacy run by PBM switched his asthmatic niece from the inhaler Aerobid, which she had used for years, to Azmacort.(41) If his niece had followed the pharmacy's instructions instead of calling him, he said that she would have received 60 percent less medication. "She could have been hospitalized." A spokesman for PBM disclaimed responsibility stating that dosage instructions were the responsibility of the doctor. Doctors complain particularly about PBM pressures to change heart medications, because they must often tinker for weeks before coming up with the right combination.(41) These examples do not necessarily indicate a problem with PBM practices on patient health but no one knows, because the issue has not been empirically studied.

How do patients feel about PBMs?

Most patients are generally satisfied by their pharmacy benefit plans although the more experience one has with the plans the less satisfied they are.(42)(4) Only 22% are aware of any restrictions on

physician prescribing. As for freedom to choose pharmacies, one study found that 49% of all consumers are free to patronize the pharmacy of their choice, 42% are restricted to a network pharmacy and 9% do not know. (43) A survey of people with mail-order benefits found that 75% had never used the service before but of the 25% who had used the service, 22% expressed dissatisfaction with their experience.(10)

An exploratory study of Virginia Medicaid recipients in several HMOs found that few patients had serious problems getting their medicines as a result of restricted formularies. Most respondents indicated that they were satisfied with managed care prescription coverage. On the other hand, a small number of patients experienced significant problems getting their prescriptions. Of the 150 patients in the sample, 8% did not get their medicines and 9% had to pay for their medicines out of pocket. Whether this had any effect on the patients' health outcomes is not clear, but some respondents seemed to think so. One patient reported having to visit the emergency room to obtain her medicines. Another said her son missed school for several days as a result of not having his medicine.(44)

Only 15% of respondents in a national study reported that one of their drugs had been switched (therapeutic substitution) during the past year. Of the respondents who had more than 30 prescriptions filled per year, 28% had drugs switched.(43) No information about the impact of these switches on patient health (either positive or negative) or satisfaction was reported.

WHAT IS THE EMPIRICAL EVIDENCE OF THE VALUE OF PBM'S?

There have been a number of reports publicizing the value provided by PBMs.

A 1997 GAO report cited that 3 federal health plans reduced their pharmacy benefit costs by more than $600 million as a result of contracting with PBMs without negatively affecting patient satisfaction.(45) The majority of the savings (52.3%) came from the pharmacy service fee (i.e., retail and mail order discounts). The next largest component came from drug company discounts (21.2%). Retail pharmacists complained that governmental savings disproportionately came out of pharmacist service fees and that the plans encouraged patients to use mail service rather than their community pharmacist.

Another study estimated pharmacy benefit management savings to be from 14% to 31% when compared to plans in which the benefit is not managed.(18) A listing of the savings according to PBM practice is listed in table 5.

Table 5: Estimated annual cost savings in the drug budget for the five largest U.S. PBMs

PBM drug product selection activities	
Generic substitution	6-10 %
Formularies (including compliance measures)	5-15 %
Concurrent drug utilization review	2- 4 %
Prior authorization	14-31 %
Total range	14-31%

Source: (18)
Note: Does not include estimated savings for basic PBM activities like claims processing, pharmacy and mail order services, and benefit design. When these are included savings can range from 25-45%.

However, the majority of the sums stated in table 5 and in the GAO report have not been substantiated through empirical research. The savings estimates are based on interviews of PBM executives and promotional material from the PBMs. Therefore, the size of the savings should be taken with a degree of skepticism. In fact, a number of researchers have questioned the ability of PBMs to substantiate their cost savings.(46)(47)

Researchers have agreed that PBMs have potential to deliver costs savings to patients, employers, and MCOs but they currently are unable to track the long-term outcomes and costs of their practices.(46)(47) The impact of many practices designed to manage the pharmacy benefit is largely untested for several reasons. First, health and pharmaceutical information databases rarely are of sufficient detail and quality to conduct appropriate assess of the impact of programs.(47) Since medical databases are frequently not integrated pharmaceutical databases, the impact of pharmaceutical benefit management on medical outcomes and costs is usually not examined. Second, research that examines the impact of PBM practices is an expensive task that does not contribute to the bottom line of PBM's. Therefore, since good methodologically sound research has not been demanded by payers, little has been conducted. Third, sharing findings with others

may give competitors an advantage.(48) Much of the data is proprietary and publication of findings may tip off competitors to new services being offered.

Finally, the idea of pharmacy benefit management makes intuitive sense. One would expect that if physicians are restricted to a limited list of approved drugs, then prescribing will be easier and better. As long as managed care can convince purchasers of health care that "formularies save money" it will be unnecessary to conduct unbiased studies that might show a different result. PBM effectiveness claims seem plausible on the face of it, but have been neither confirmed or refuted by empirical evidence.

Empirical Evidence for Factors Influencing Pharmaceutical Utilization and Expenditure

Some PBM claims of cost savings are readily apparent. For example, the claims handling capabilities of PBMs result in millions of dollars administration cost savings to pharmacies and MCOs. Drug discounts off of the average wholesale price (AWP) also reduce overall pharmaceutical costs to payers (at least in the short term). These practices clearly save money. In contrast, the impact of some of these interventions on overall costs and quality of health care is not as clear.

Impact of Drug Formularies. Formularies (i.e., drug lists) attempt to control drug costs by restricting the drugs available in a pharmacy benefit. They usually are employed with educational programs or other programs that encourage adherence to formularies. The restrictiveness of the formulary can be limited (e.g., open formulary) in which all drugs are available regardless of formulary status or strict (e.g., closed formulary) in which many drugs are not available.

Although it seems reasonable to expect closed formularies to decrease drug costs, the literature does not clearly support this conclusion.(49) Moreover, the influence of formularies on overall medical costs e.g., hospitalization, emergency room visits, physician costs), has not been established. Although some studies have investigated the impact of Medicaid formularies on overall costs, the results are not conclusive because of study-design limitations.(49)(50) In addition, most formulary studies examined the unique characteristics of Medicaid populations which differ significantly from most managed care populations.

One recent study refutes the claim that formularies reduce overall health care costs.(51) This study concluded that formularies result in lower quality of care and increased health care costs.

Due to the limitations of research conducted so far, it is difficult to conclude that PBM formulary restrictions actually reduce overall health care costs. Additionally, the effect of formularies combined with other PBM controls have not been examined.

Impact of Prior Authorization/Step Care. A prior-authorization (PA) program sets rules governing the circumstances under which a patient may receive a particular medication. Thus, prior authorization is often mandated for medications that have defined clinical advantages but are commonly prescribed for cosmetic purposes. The major advantage of prior authorization is that it allows for monitoring of the use of certain medications without denying patients access to other

medications. Potentially negative effects of PA programs include long processing times for PA requests (i.e., the patient and pharmacist must wait for a reply from the PBM) and frequent denials of PA requests.(52)

Step-care protocols are variants of prior authorization in which the use of more expensive drugs is not allowed until the patient has been treated with less expensive alternatives. Although the use of protocols/guidelines is relatively common on an inpatient basis, the use of protocols on an outpatient basis, particularly those specific to pharmaceutical therapies, is less common because administrative costs are high.(47)

A recent study found that a Medicaid prior-authorization/step-care program for nonsteroidal anti-inflammatory drugs (NSAIDs) decreased average annualized expenditures for NSAIDs by 53% over 2 years.(52) There was no increase in Medicaid expenditures for other medical care. Another study of a NSAID-prescribing protocol found that use of NSAIDs fell from 34% to 21%, resulting in a 30% decrease in costs.(52) Physicians had few objections to the program.

Finally, a recent study examined a Medicaid PA program for antiarthritic drugs, benzodiazepines (sedatives), antiulcer drugs, and antihistamines.(52) Gross savings were set at 2.5 to 3.8 million dollars. However, the average response time for each PA was 52 minutes, meaning that a patient would either have to wait for almost an hour for their medication or make an extra trip to pick it up later.

It seems that PA programs can save drug costs although no published studies for PBMs were found. All studies have been conducted on Medicaid PA programs and findings may be different for PBM populations. The negative side of PA programs is that they inconvenience both pharmacists and patients.

Therapeutic interchange. Therapeutic switch programs utilize various patient, physician, and pharmacy incentives as well as education and/or feedback to encourage the voluntary switch from one medication to another for the same condition. Over the last few years there have been a number of studies that looked specifically at therapeutic interchange. Most found that drug costs decreased, there was minimal effect on use of other services, and that there was no adverse effect on patient health. However, these studies are characterized by weak research designs and small samples of both patients and products.(53) (54)(55)(56)(57) Further work is needed to determine the extent to which various forms of incentives, education, and/or feedback affect therapeutic switch rates and, subsequently, costs.

Drug utilization review. A recent review of the DUR literature concluded that "methodological flaws, liberal assumptions, and conflicting results of previous studies" limit any conclusions as to the influence of retrospective DUR.(58) Other researchers agree with this conclusion.(59)

Zimmerman and colleagues (58) provided limited evidence that a DUR intervention letter for H2 blockers resulted in overall cost savings without an increase in hospitalization rates for ulcer recurrence or gastrointestinal bleeding. However, the investigators brought out several points that warrant repeating. First, the cost-effectiveness of a retrospective DUR program is dependent on

the "experience, automation, and economies of scale" within the particular institution. Second, the marginal savings from a DUR program may decrease over time, as the providers learn from messages received after program implementation. Third, a DUR program is likely to be cost-effective only for therapeutic categories that are amenable to claims review and prescriber intervention. Each of these factors must be considered when studying the cost-effectiveness of a particular retrospective DUR program.

Summary

Most research on PBM practices has been conducted in Medicaid populations and the ability to compare these results with commercial insurance or managed care populations is limited. Methodological limitations of research have not resulted in conclusive results about the effect of traditional cost-containment methods (i.e., formularies, cost sharing, generic incentives, DUR, and prior authorization) on pharmaceutical and overall medical expenditures.(47) In addition, there is very little published research on the impact of newer tools (e.g., therapeutic interchange, step-care protocols, and disease state management) on pharmaceutical and overall medical expenditures. Given the lack of conclusive evidence, further empirical assessment is needed.

There are some conclusions that can be drawn from the literature. Pharmacy benefit design is a complex process. Therefore, interventions to reduce costs should be carefully considered. Overly simplistic approaches, can have unforeseen negative consequences. Many PBM practices when appropriately applied, can result in reduced overall health care costs and higher quality. However, poor administration of these programs can result in false savings and can result in unintended and undesirable consequences.

DIFFICULTIES FACED IN MANAGING THE DRUG BENEFIT

Managing the prescription benefit is a difficult and complex task that requires PBMs to customize a variety of benefit plans to the needs of numerous customers. The effect of each program on the cost and quality of drug utilization or on the cost and quality of the overall health care budget is complicated and rarely known. For example, requirement of a copayment for each prescription drug is intended to reduce inappropriate over utilization of drugs. However, patients may not make rational decisions on which drugs to use or not use resulting in underutilization of important therapies.(50) In the short run, the drug budget shows savings, but underutilization of some drugs can lead to increased long term utilization of drugs. Additionally, underutilization of drugs may lead to avoidable and costly emergency room visits and hospitalizations.

The Art of Pharmacy Benefit Management

Many of the tactics used in pharmacy benefit management of managed care populations have not been shown to actually result in an overall positive effect on costs and quality of overall health care.(50)(49) (47) Methods such as formularies have been demonstrated to be effective in hospitals but there have been no conclusive studies conducted in ambulatory populations. The impact of other methods such as coverage exclusions and patient cost sharing requirements have only been observed on Medicaid populations and/or only their impact on drug costs has been scrutinized. In addition, the effect of these programs used in combination (e.g., formularies and copayments) has not been studied. Therefore, pharmacy benefit management is an art more than a science.

That does not mean that PBM practices do not positively impact drug costs and overall health care costs. Rebates reduce the overall cost of drugs without having negatively altering health care quality. Additionally, one can reasonably state the programs that review physician prescribing and pharmacist dispensing (e.g., DUR's) can result in better patient health outcomes. Nevertheless, most practices by PBMs have not been demonstrated to be either effective or ineffective.

Difficulty in researching impact

The lack of evidence of the effectiveness of PBM practices is partly the result of the fragmentation of the health care system. PBMs have extensive claims databases of all prescriptions filled by network and mail service pharmacists. However, they rarely have access to medical claims data which may list hospitalizations, emergency room visits, physician office visits, laboratory values, and other non-drug claim data. Even when they have this data, information systems often are not compatible, making it difficult to link drug utilization with other health care utilization.

Law of Unintended Consequences

In addition to the problem of insufficient cost effectiveness information of PBM practices, one finds that there are long term consequences of PBM practices that may be unintended. For

example, the increasing use of generic drugs and therapeutic substitution has caused changes in the way the pharmaceutical industry does business.

Pharmaceutical companies have changed their research focus, purchased PBMs, and increased direct-to-consumer advertising.(3) Pharmaceutical companies have increased spending in order to bring new, therapeutically unique drugs onto the market. This is a wonderful development for patients and society but pharmaceutical companies have charged high prices to cover their research and marketing costs of these new drugs.(60)

New drug products cost more. The impotence pill Viagra costs from $7 to $10, the diabetes drug Rezulin $4 per tablet, $11 to $15 for the migraine drugs Imitrex and Maxalt, and $500 to $1000 for a toenail fungus treatment.(60) The cost of new prescription drugs was a major reason why the average cost of a prescription in 1997 rose to $32.87, an 11.1% increase from 1996.(61) Despite the fact that new drugs may improve the overall health of patients and reduce overall morbidity and mortality, some PBM administrators see their drug budgets increase by as much as 15% annually. For example, Trigon Blue Cross Blue Shield received 6,500 claims in the first 40 days Viagra was on the market. At 10 dollars per tablet, Viagra had a significant effect on the prescription drug budget.(62)

Pharmaceutical companies also responded to PBM practices by buying their own PBMs. Patient advocates, physicians, and pharmacists have expressed concern that ownership of PBMs by pharmaceutical manufacturers raises questions about the independence and integrity of the drug formulary decisions and other PBM practices. Both the Food and Drug Administration and the Federal Trade Commission are currently examining potential problems associated with drug company ownership of PBMs.

Another response of pharmaceutical companies has been to promote prescription drugs directly to consumers. This has resulted in a significant increase in managed care drug budgets.(63) Direct-to-consumer advertising for drugs such as Prozac, Claritin, Fosamax, Pravachol, and Allegra encourages patients to ask their physicians for advertised drugs. Physicians are under tremendous pressure from patients to prescribe these drugs, and PBMs are under equal pressure to reimburse for them.

Drug companies spent $700 million on direct-to-consumer prescription advertising in 1996, $1 billion in 1997, and are projected to spend $1.6 billion in 1998.(64) Although physicians state that they are not effected by prescription advertising, prescription audits indicate that 90% of physicians prescribe drugs that patients ask for.(61)

Do PBMs Actually Work as Promoted?

Do PBM practices actually control costs? If so, why have drug prices have been increasing so quickly? Drug benefit costs to employers are expected to increase from 15 to 22 percent due to mergers of insurers, greater bargaining leverage of health care providers, expensive new drugs, and increasing profits of prescription drug plan managers.(68) These causes of higher drug benefit costs may be a partial result of PBM practices.(3) Expansion of prescription drug

coverage has also been an important reason for increased utilization.(65) Of the $88 billion paid by consumers for prescription drugs in 1997, only 2.4% was due to price increases, 4.3% from new drugs on the market, and 5.4% was from higher utilization of drugs.(29) Would drug costs be so much higher if PBMs were not around? Would the quality of health care be less? These questions still remain to be answered.

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APPENDIX A
ANNOTATED BIBLIOGRAPHY

Annotated Bibliography of Research Related to Pharmacy Benefit Managers

American Medical Association, Report 9 of the Board of Trustees (I-97) - Pharmaceutical Benefits Management Companies, American Medical Associaton, 1997.

This report discusses the AMA's concerns with drug formulary management practices in PBMs. The report includes nine concerns that PBM practices are inconsistent with official AMA policies and ethical opinions. The report also includes background information on PBMs, relevant AMA policies, and recommendations. The AMA's concerns focus around lack of physician oversight of PBM formularies, ethical problems arising from financial incentives. lack of public scrutiny of PBM formulary practices, and PBMs lack of legal liability for formulary decisions.

Carroll NV. Formularies and therapeutic interchange: the health care setting makes a difference. American Journal of Health-System Pharmacy; in press.

This commentary presents the case that formularies and therapeutic interchange do not work as well in outpatient settings as in hospitals. The factors which led to the success of formularies in hospitals - such as a monitored patient care environment, local control of the formulary, decreased costs for the pharmacy, and lack of financial incentives for providers - are absent in outpatient settings. The article provides definitions of terms, discusses legislative initiatives to regulate formularies, and makes recommendations as to steps managed care organizations should take to improve the operation of outpatient formularies.

Carroll NV. The effects of managed care on the retail distribution of pharmaceuticals. Managed Care Interface; in press.

Retail pharmacies have been subject to substantial changes over the last decade. These include lack of growth in number of retail outlets, loss of volume to mail order pharmacies, increasing control by PBMs, and lower profit margins. This article argues that these changes have been a direct result of the growth of managed care. The article provides evidence to support this argument, discusses retail pharmacies' responses to the growth of managed care, and argues that the future success of PBMs, managed care organizations and retail pharmacies will depend on closer cooperation.

Carroll, N. V., Wright, S. S, and Holdford, D. A. Medicaid patients' experiences with restrictive formularies in a managed care program. 1997. Working paper, Division of Pharmacy Administration, School of Pharmacy, Virginia Commonwealth University.

Presents the results of a project that examined Medicaid patients experiences with drug formularies in a managed care program in Virginia. A total of 39% of the 150 respondents reported some type of problem getting their medicines in the managed care program. Most problems were formulary related. The majority of problems involved inconveniences to patients; however, 8% failed to get the prescribed medicine and 9% had to pay for their medicines out of pocket.

Gibaldi, M. Vertical integration: the drug industry and prescription benefit managers. Pharmacotherapy 1995; 15(3):265-271.

Describes the mergers of major pharmaceutical manufacturers and PBMs. The article discusses the reasons for the mergers and early criticism of them.

Grabowski HG, Mullins D. Pharmacy benefit management, cost-effectiveness analysis and drug formulary decisions. Social Science and Medicine. 1997;45:535-44.

An analysis of the use of cost-effectiveness analysis in the formulary decision making process of PBMs. The analysis is based on interviews and materials provided by the five largest PBMs which, at the time of the study, accounted for over 80% of beneficiaries covered by formularies. The results include an estimate of the drug savings resulting from PBM's activities in generic substitution, formulary management, DUR, and prior authorization. The article concludes that the use of cost-effectiveness analysis in formulary decision-making is limited but will probably increase in the future.

Green M, Vasisht R, Martin J. Compromising Your Drug of Choice: How HMOs are Dictating Your Next Prescription. New York, NY: Office of the Public Advocate, 1996.

This report was produced by the Public Advocate for the City of New York. The report indicates that managed care organizations' efforts to control drug costs through closed formularies and therapeutic interchange frequently result in patients not receiving the most appropriate drugs for their medical problems. The report is based on analysis of the formularies of 15 HMOs operating in New York, interviews with pharmacists and physicians, examination of PBM-HMO contracts, and a review of the literature.

Green M, Vasisht R, Martin J, Bachrach A. Pharmaceutical payola: How secret commercial deals are dictating your next prescription and harming your health. New York, NY: Office of the Public Advocate, 1997.

A follow-up to *Compromising Your Drug of Choice* which presents more evidence of problems resulting from therapeutic interchange and provides an update on federal oversight activities. The report includes the results of surveys of pharmacists and physicians in New York State. The physician survey indicates that 83% of responding physicians had been contacted by health plans or pharmacists and urged to change prescriptions and that over half reported that patients had problems after drugs were switched. The majority of pharmacist respondents indicated that they believed drug switches diminished the quality of medical care (74%) and that they were uncomfortable making substitutions (79%). The report also includes a description of formulary decisions by PCS, a major PBM, which favored the parent company's product over products recommended by independent consultants.

Horn SD, Sharkey PD, Tracy DM, Horn CE, James B, Goodwin F. Intended and Unintended Consequences of HMO Cost-Containment Strategies: Results from the Managed Care Outcomes Project. The American Journal of Managed Care. 1996;2:253-64.

This study examined the relationship between the restrictiveness of an HMO's formulary and the health care use of its patients. Data were gathered from a nation-wide sample of 6 HMOs and 13,000 patients suffering from 5 selected diseases. The results indicated that patients in HMOs which had more restrictive formularies experienced

higher rates of hospitalizations and emergency room visits, drug cost, number of prescriptions, and number of physician office visits. The study has been widely criticized because of deficiencies in research design. There are, however, no studies of similar size and scope that contradict its findings.

Kozma CM, Schulz RM, Dickson WM, et al. Economic impact of cost-containment strategies in third party programmes in the US (Part II). PharmacoEconomics. 1993;4:187-202.

Reviews the research literature regarding the economic impact of formularies, capitation, drug utilization review (DUR), prior approval (PA), and drug product selection. (Drug product selection was used to describe pharmacists' practice of dispensing a comparable generic product for prescriptions written for brand name products.) Formularies were found to decrease drug costs, but possibly to result in increased use of other health care services. Capitation appeared to decrease costs through increasing use of generic and over the counter drugs. DUR was found to save costs. PA and drug product selection were found to result in savings when viewed independently of other health care services. However, the extent of cost shifting, the size of administrative costs, and increased costs from decreased patient access resulting from these practices have not been reliably estimated.

Kreling,D.H.; Lipton,H.L.; Collins,T.; Hertz,K.C. Assessment of the Impact of Pharmacy Benefit Managers, HCFA Master Contract, HCFA-95-023/PK, September 30, 1996, Center for Health Systems Research and Analysis, Madison, Wisconsin.

A large, scale investigation of PBMs funded by HCFA. The purpose of the study was to examine the "organization, scope of services, types of clients, and impact of PBMs on cost, quality, and the larger pharmaceutical market." The study provides a wealth of background information on PBMs and the functions and activities that they pursue. One of the more important conclusions of the study is that "data and/or evidence on the cost and quality of PBM activities are not always available, clear, or conclusive." The authors identify significant barriers to answering these questions. These include the proprietary nature of much PBM data, difficulties in establishing baselines against which cost and quality changes can be measured, research design difficulties in controlling for the many factors which can affect outcomes in real world systems like PBMs, and difficulties in linking pharmacy and medical information. The authors also conclude that "the PBM industry has not given states a compelling reasons (sic) to establish direct contracts for managing their Medicaid drug programs."

Lyles A, Luce BR, Rentz AM. Managed care pharmacy, socioeconomic assessments and drug adoption decisions. Social Science and Medicine. 1997;45(4):511-521.

Reviews a telephone survey of pharmacy directors at 51 managed care plans. The surveys found a wide variety of criteria used in assessing drugs for formulary inclusion. Some plans left the decision up to the PBMs managing their prescription benefits. Others relied (in order of importance) on PBM recommendations, advice from other managed care plans, peer reviewed literature, evaluations performed by industry, articles in non-peer reviewed publications, and governmental reports.

McGahan AM. Industry structure and competitive advantage. Harvard Business Review. 1994;72:115-24.

Discusses changes in the pharmaceutical marketplace that led to the growth and increased importance of PBMs. It provides an overview of the pharmaceutical industry prior to 1993, describes how the structure of the industry has changed since then, discusses competitive advantages a pharmaceutical firm gains by owning a PBM, and presents concerns about pharmaceutical firm-PBM mergers.

Motheral BR, Fairman KA, Teitelbaum F, Schafermeyer KW, Parker AR, Barrow SM. Factors influencing utilizaton and costs in a pharmacy benefit program. Drug Benefit Trends. 1996;8:10-34.

This paper provides a conceptual model for analyzing factors that affect pharmaceutical benefits and use and summarizes research evidence for the impact of these factors. The evidence for most factors is inconclusive because of the quality of the research.

Office of the Inspector General. Experiences of Health Maintenance Organizations with Pharmacy Benefit Management Companies. Washington, D.C.: Department of Health and Human Services, 1997:1-19.

A report from the federal Office of the Inspector General based on a mail survey of HMOs. The report found that three-fourths of responding HMOs used PBMs. HMOs' primary reason for using PBMs was control of drug costs. Other important reasons were to improve the quality of prescribing and increase patients' access to pharmacy services. HMOs' biggest concern was that the ownership of PBMs by drug manufacturers would affect PBMs'

abilities to make unbiased decisions with regard to which products to include on their formularies. The report also found that PBMs were subject to little oversight or regulation by outside entities. HCFA and state Medicaid agencies provided only minimal oversight, there was no private accreditation for PBMs, and the HMOs depended primarily on data from the PBMs to evaluate PBM performance.

Phillips,C.R.; Larson,L.N. Evaluating the operational performance and financial effects of a drug prior authorization program. Journal of Managed Care Pharmacy 3:699-706, 1997.

This article evaluates the operational and economic performance of the state prior authorizations program in Iowa. Operational indicators include volume of PA requests, average response time, and approval rates by therapeutic category. Economic performance was evaluated based on increases in the percentage of generic products used in each therapeutic category.

Reeder CE, Lingle EW, Schulz RM, et al. Economic impact of cost-containment strategies in third party programmes in the US (PartI). PharmacoEconomics. 1993;4:92-103.

Reviews the research literature regarding the economic impact of cost sharing, prescription limits, drug product rebates in the Medicaid program, and the maximum allowable cost (MAC) and estimated acquisition cost (EAC) programs in the Medicaid program. The review indicates that cost sharing and prescription limits decrease drug use and expenditures. The effect on other health care services is unknown although there is some evidence that both practices may increase use. The effects of the rebate program on Medicaid expenditures have not been conclusively demonstrated and questions remain about the extent of cost shifting to other purchasers. The MAC program led to direct drug cost savings but the administrative costs of the program have not been reliably estimated. The EAC program was not found to have generated savings.

The Regulation of Pharmaceutical Benefit Managers (PBMs): Current Trends, Future Options. California Legislature. Senate Committee on Insurance, Senator Herschel Rosenthal, Chair and the Conference Committee on Assembly Bill 1136 (Valerie Brown), February 7, 1996, Sacramento, California.

Assembly Bill 1136 increases the regulation of PBMs. It contains language which would make formularies subject to review by the health plans' "quality assurance program", require PBMs to disclose to consumers whether financial incentives were offered to pharmacists in drug switch programs, and ensure that enrollees have access to grievance processes when pharmacy benefits are denied. This document presents a brief background of PBMs and drug formularies, current California regulation of PBMs, and testimony on the issues from PBMs, pharmacists, physicians, and a drug manufacturer.

Rosoff, AJ. The Changing Face of Pharmacy Benefits Management: Information Technology Pursues a Grand Mission. Saint Louis University Law Journal 1998; 42(1):1-53.

This article provides a broad overview of the evolution of PBMs, the economic and legal issues associated with them, and their impact on patients and the health care system. The author appears to not fully understand some issues - such as the extent to which cost-effectiveness analysis is used by PBMs and the differences between generic and therapeutic interchange. On the other hand, he presents a much broader discussion of patient privacy issues and potential anti-kickback regulations than do most other sources.

Schulman KA, Rubinstein E, Abernathy DR, Seils DM, Sulmasy DP. The effect of pharmaceutical benefits managers: is it being evaluated? Annals of Internal Medicine. 1996;124:906-13.

This article reviews the development of PBMs, their current role in the pharmaceutical distribution channel, and their relationship to pharmaceutical manufacturers. A major focus of the article is on the use of formularies in PBMs. The article presents a number of recommendations including making the formulary development process more open to review, maintaining formulary stability so physicians become more accustomed to formulary drugs, monitoring the effects of therapeutic interchange programs, and requiring pharmacists to ask about patients' health status when prescriptions are refilled.

Soumerai SB, Ross-Degnan D. Experience of state drug benefit programs. Health Affairs. 1990;9:36-54.

This review of the literature discusses the intended and unintended consequences of state efforts to control cost and improve the quality of prescribing in state Medicaid programs. The study notes that commonly used efforts to decrease costs - such as prescription limits (i.e. the state pays for a maximum of 3 prescriptions per patient per month), patient copays, and formularies which deny payment for non-essential drugs (those believed to be of marginal effectiveness) - have unintended effects. While they may lead to decreases in drug expenditures, they are also associated with decreased use of essential drugs, increased use of other health care services, physical harm to those most dependent on drug therapy (the elderly, disabled, and / or females). Efforts to improve prescribing that involve printed materials alone are usually ineffective. Effective interventions usually require face to face interactions with respected colleagues in small group or one to one meetings.

Soumerai SB, Ross-Degnan D, Fortess EE, Abelson J. A Critical Analysis of Studies of State Drug Reimbursement: Research in Need of Discipline. The Milbank Quarterly. 1993;71:217-52

An analysis of research on the effects of drug coverage restrictions in state Medicaid plans on expenditures and patient health. The report examines two types of restrictions: patient-level restrictions on access, such as cost sharing and prescription drug limits, and administrative restrictions, such as formularies and prior authorization. The research shows that patient-level restrictions decrease drug use and, consequently, state drug program expenditures The effect on patient health is less certain. Some studies have shown adverse effects on health from prescription limits. The research on administrative restrictions is not conclusive due to the low quality of most investigations.

Taniguchi R. Pharmacy benefit management companies. American Journal of Health-System Pharmacy. 1995;52:1915-7.

Presents a basic review of the services PBMs provide, how they evolved, and how they operate.

U.S.Government Accounting Office. Pharmacy benefit managers: FEHBP plans satisfied with savings and services, but retail pharmacies have concerns. Washington, D.C.: U.S. General Accounting Office, 1997:1-24.

Provides an evaluation of the performance of PBMs in helping the Federal Employees Health Benefits Program (FEHBP) in reducing prescription drug costs. The GAO evaluated the experiences of three FEHBP plans that used PBMs. The plans estimated that use of a PBM resulted in savings of 20 to 27% over what would have been paid without the PBM. Savings estimates were based on data or analyses supplied by the PBMs. Surveys indicated high enrollee satisfaction with prescription benefits. The report noted that FEHBP plans' use of PBMs shifted a substantial amount of business to mail order pharmacies and away from retail pharmacies. The report also states

that future efforts to control prescription costs in FEHBP plans may require more restrictive cost control efforts that could decrease employees access to drugs and pharmacies and decrease their satisfaction.

U.S.General Accounting Office. Pharmacy benefit managers: early results on ventures with drug manufacturers. Washington, DC: U.S. Government Accounting Office, 1996:

Provides a basic review of services that PBMs provide and focuses on formulary changes at two of the largest PBMs - Medco and DPS - after their mergers with major pharmaceutical manufacturers. Medco's formulary changed substantially in the months immediately before and during the first year following its merger with Merck. The changes involved adding seven of Merck's eight best selling products and eliminating products that competed with Merck products. By comparison, there were few changes in the DPS formulary after it merged with Smith Kline Beecham, another major pharmaceutical firm. The report concludes that the changes in Medco's formulary were sufficient to justify the FTC's actions in continuing to monitor Merck/Medco and other drug company - PBM mergers.

Worthington, M. and Sisler, J. Literature Review: Therapeutic substitution and therapeutic interchange of drugs, prepared for HJR 630 Task Force. July 16, 1997.

This literature review was developed for the use of the HJR 630 Task Force. It provides a review of the literature on drug formularies, including their use in hospitals, outpatient settings, and Medicaid programs. It also includes definitions of terms.

APPENDIX B
INTERVIEWS

Interview Methodology

To aid in defining the issues surrounding PBMs and to ensure that no emerging issues were overlooked, representatives from five groups that are affected by PBMs were interviewed. The five groups included employers who used PBMs, pharmacists, patients, physicians, and management and employees of PBMs.

Representatives from each group were selected, whenever possible, for their ability to represent the views of the group. With this in mind, the pharmacy representatives included the executive directors of the Virginia Pharmacists Association (VPhA), the Pharmaceutical Care Management Association (PCMA), and an employee of a PBM based in Virginia. The VPhA represents community pharmacy, and primarily independent community pharmacy, in Virginia. The PCMA is a trade association of PBMs and mail order pharmacy. The executive directors of both groups are pharmacists. A representative from the Virginia Association of Chain Drug Stores was contacted but has not yet replied. One of the physician representatives, Dr. Sheldon Retchin, serves as Executive Director of MCV Associated Physicians. One of the patients was Legislative Director of the Consumer Federation of America. The employer representatives were selected from organizations with large numbers of employees in Virginia. The employer groups included the Commonwealth's Department of Personnel and Training, Ukrops, Ethyl Corporation, and Virginia Power.

In general, the number of interviews conducted was related to the amount of new information they provided. Since most issues related to PBMs have been widely disseminated in the literature, interviews quickly reached a point of diminishing returns. Further interviews would have provided little extra benefit in further defining the issues related to PBMs.

A standard set of questions was developed and asked of each group. These questions focused on what the researchers believed to be the most salient issues regarding PBMs. The questions were modified for each group so that the wording was appropriate. Some questions were not asked of all groups because of applicability. Because of time limitations and varying levels of interest and knowledge from the interviewees, not all questions were asked to all interviewees. Because the purpose of the interviews was to define and identify issues, no formal statistical analysis of the data was done.

Interviews were conducted by telephone by one of the researchers.

Standard questions for PBM interviews

1. What services does the PBM provide? (e.g., claims processing, formulary, reports, disease state management)

2. Does a PBM decrease prescription drug costs? How? By how much?

3. How are rebates divided between PBM and employer group? Has this changed much over the last few years? Has the amount of rebates changed? Are rebates called by any other names?

4. Does the PBM use a mail order pharmacy? Do they encourage this with lower copays or greater quantities? How do employees like the mail order plan?

5. Does the PBM have a restricted pharmacy network? How do employees like it? How are PBM relations with network pharmacies?

6. Does the PBM encourage therapeutic interchange or have a restricted formulary? How do employees like it?

7. Do you think the PBM has contributed to improving employees' health? How?

8. How are disputes between you or your employees and PBMs resolved?

9. What should an employer look for in a PBM?

10. How is your P&T committee composed?

Standard questions for patients interviewed

1. Have you ever used a mail order pharmacy? Why did you use it? Were you satisfied? Why?

2. Has your insurance company ever told you that you had to go to a pharmacy on its approved list. Did this require you to change pharmacies? Was this a problem for you?

3. Has your pharmacist ever told you that the insurance company would not pay for the medicine your physician prescribed, but that it would pay for another medicine which would have the same effect? Did the medicine work for you? If this has not ever happened to you, how do you think you would feel about it if it did happen? Would you be willing to try it to get the medicine for a lower price?

4. Have you ever had a dispute with your insurance company over payment for a particular medicine? How was it resolved?

Employer group

Ethyl Corporation Karen Shelton

Employees can select from United Health Care or several HMOs: Prudential, Southern Health, Cigna. Ethyl provides insurance carrier and carrier arranges for prescription benefits. Consumers with complaints deal directly with HMO - company has no leverage with the HMOs, they have no fear that company will move business. HMOs provide little flexibility - they have rules and enforce them. No great amount of complaining to company. Open enrollment every year so employees can change if dissatisfied.

Employer group

T.J Clayton
Department of Personnel and Training
Office of Health Benefits
James Monroe Building
13th Floor
101 N. 14th Street

Mr. Clayton negotiates contracts for health benefits for the state. The prescription program is separate from the medical and surgical insurance program. It is a coincidence that Trigon has both programs. (KeyAdvantage is a grouping together of separate programs for medical and surgical benefits, prescription drugs, and mental health benefits.) Eight companies bid on the prescription drug program. Interestingly, the incumbent - PCS - did not get its bid in on time and so was not considered. The 8 bids were scored on written criteria. The state negotiated with the 2 highest bidders, then rescored the criteria and awarded the contract. Contracts are rebid every 4 to 5 years.

Mr. Clayton noted that the state has experienced cost increases in double digits in the drug program over the last several years. This rate of increase is much higher than seen in the medical and surgical programs and something he said that cannot continue indefinitely.

1. do you use a PBM for prescription drug benefits? Why or why not? What services does the PBM provide for you? (claims processing, formulary, reports, DM)

The state uses PAID for the prescription drug program for the self-insured plan (Key Advantage). The HMOs in the state plan may use their own, separate PBMs. (We didn't talk much about them). Mr. Clayton was enthusiastic in saying that PBMs definitely, no question, reduce drug costs. He mentioned two important cost-saving PBM functions:

1. All PBMs use networks and networks give discounts on prescription prices. It is foolish to pay full retail price for rxs in todays market.

2. Software - At the time the original contract was awarded not all pharmacies and chains were computerized, so the availability of software to detect drug interactions at the point of sale was an important feature which PBMs provided.

3. He also mentioned the PBMs ability to administer a mandatory generic substitution program.

4. He mentioned that reports that PAID provided as being extremely useful to the state in managing the program. He said that the exploding increases in the cost of the drug program came about half from increased utilization and about half from price increases. He said you could not do anything about the price increases because nobody had enough clout to influence the manufacturers. The reports allow you to figure out how much of the cost increase is from increased price and how much from increased utilization. They also help you in deciding how to control the increases - through increased copays or two or three tiered pricing. The management group needs the report information to manage the program. The in-house people, along with actuaries and benefit consultants, decide what steps to take to control the program. These are forwarded to the actual decision makers in the state government. When people from DPT go to the state money committees, the reports provide the evidence they need to support their recommendations.

2. Does using a PBM decrease your prescription drug costs? By how much?

See above

3. Do you receive a substantial portion of rebates which the PBM gets? Has this changed much over the last few years?

I asked him about rebates. He said that the state receives most of the drug company rebate, but didn't know off hand what the specific percentage or amount was. He remarked that one of the disadvantages of a 4 or 5 year contract in the drug market was that the market changed so fast. The example was rebates. On the last contract awarded (the one before the current one), rebates were not part of the market so the contract did not mention them. When rebates became part of the market, the state could not take advantage of them because it already had a contract. In the most recent contract, rebates were included.

4. Does the PBM use a mail order pharmacy? Do they encourage this with lower copays or greater quantities? How do your employees like the mail order plan?

I asked if mail order was a big consideration. He indicated that it was an important feature, but one which was underutilized by state employees. He said that mail order should be use more for maintenance drugs because the state receives a larger discount on mail order prescriptions. He said for example that if the state paid "Redbook less 20%" for a prescription filled in the community, it might get an additional 20% discount from mail order. In addition, he liked mail order for the convenience. He stated that he usually requested his refills 2 weeks before he ran out.

5. Does the PBM have a restricted pharmacy network? How do employees like it?

See number 1 above

6. Does the PBM encourage therapeutic interchange or have a restricted formulary? How do employees like it?

The Key Advantage program uses the Virginia Voluntary Formulary and does not do a great deal of therapeutic interchange to the best of his knowledge. The HMOs are much more involved in interchange.

He did not have concerns about interchange in the state program, but did express some concerns about therapeutic interchange in general. He said that he hoped interchange decisions were based on need and not on manufacturer ties. He was concerned about the conflict of interest in a PBM which was owned by a drug manufacturer and was engaged in product interchange. He remarked that "the only people it (therapeutic interchange) serves well are the stockholders. I fail to see how it serves the users." His concerns were more that the entire drug industry "had run amuck" than that the Virginia program had problems.

7. Do you think using the PBM has contributed to improving your employees' health? How?

We did not address this issue. He did mention, several times, that decreasing costs in the prescription program served the employees of the state because the money saved translated into increased compensation for them.

Employer groups

Mona Powell, Health Benefits Manager Ukrops

Ukrops does not handle the details of its prescription drug program. The company has a contract with Southern Health and, in terms of working out the details of the prescription drug program, "that's what we pay them to do". Southern Health provides prescription benefits through Express Scripts.

Employer group

Jeff Hewitt
Health Benefits Manager
Virginia Power

1. do you use a PBM for prescription drug benefits? Why or why not? What services does the PBM provide for you? (claims processing, formulary, reports, DM)

Virginia Power uses Trigon as its primary insurer. Trigon uses PAID as a PBM. Virginia Power's drug program is integrated into its medical plan. Patients use the same card for medical and drug benefits. The drug benefit has a deductible (currently $67), a 20% coinsurance after the deductible is met, and a maximum out-of-pocket limit of 5 times the deductible. Payment is made to the pharmacy by the PBM so the patient does not have to pay in cash and then submit receipts to get repaid.

2. Does using a PBM decrease your prescription drug costs? By how much?

By being part of the PAID network, Virginia Power receives discounts off the pharmacy's normal price

3. Do you receive a substantial portion of rebates which the PBM gets? Has this changed much over the last few years?

Virginia Power receives all the rebate or "all it is supposed to get". Mr. Hewit was not sure how the amount of the rebate had changed over time.

4. Does the PBM use a mail order pharmacy? Do they encourage this with lower copays or greater quantities? How do your employees like the mail order plan?

VP does not use a mail order pharmacy. They felt that to get savings with mail order they would have to send most of their maintenance drugs through mail order and that this would require forcing employees to do so. They did not want to push mail order so they do not offer it.

5. Does the PBM have a restricted pharmacy network? How do employees like it?

See #1 above

6. Does the PBM encourage therapeutic interchange or have a restricted formulary? How do employees like it?

With certain exceptions, there is no formulary. There is no attempt to push therapeutic interchange. The program does push generics. If the physician approves a generic but the patient wants brand, the patient must pay the difference in price. If the physician does not approve generic, VP pays for the brand. Also, certain products, such as growth hormone and acne products for those over 18 are subject to prior approval. (Acne products are used by adults to reverse wrinkling.) The company also does not cover Viagra. Overall, the company does not want to interfere in the doctor patient relationship or to limit patients' choice of products.

6. Do you think using the PBM has contributed to improving your employees' health? How?

Did not ask

7. How are disputes between you or your employees and PBMs resolved?

There have been very few problems. If they occurred, they would be resolved at Virginia Power.

PBM Employees

Mike Deskin, Pharmacy Benefit Management Institute (PBMI)
(PBMI is an independent company that is not affiliated with any PBM, pharmaceutical manufacturer, community pharmacy organization, or other benefit management company. PBMI provides information, consulting services education about PBMs to employers and other potential PBM clients.)

*** Mr. Deskin pointed out that most of his experience involves *employers* who contract with PBMs. He has much less involvement with HMOs that use PBMs.

1. What services does the PBM provide? (claims processing, formulary, reports, DM)
administer benefits, contract for pharmacy networks, handle financial arrangements

2. Does a PBM decrease prescription drug costs? By how much?

PBMs have definitely reduced the amounts that pharmacies are paid for prescriptions but they may or may not have reduced total spending on drugs. They probably have..

The most important method that PBMs use to decrease drug costs is to encourage generic substitution. The second most important way is to negotiate discounts from pharmacies. Rebates from manufacturers have a relatively small impact on total savings. Mr. Deskin estimated that the average rebate is around $1 per prescription and the employer-sponsor receives about 2/3 of this. Given an average prescription charge of $30, the rebate only amounts to about 3% and the sponsor's savings amounts to 2% of total prescription charge.

3. How are rebates divided between PBM and employer group? Has this changed much over the last few years? Has the amount of rebates changed? What they are called?

As mentioned above, rebates average about $1 per prescription and the sponsor receives about two thirds of this. I asked why there is so much interest in rebates when the amounts are so minimal. Mr. Deskin listed several reasons. First, he said, the rebate amounts have historically been higher - in the range of 4 to 5% of prescription costs (versus 2-3% now). Second, rebates had no impact on beneficiaries so, from the employer's point of view, they were easy to implement. Third, while rebates represent a small percentage of total prescription payments, they represent a large part of PBM profits. The administrative fees which PBMs charge have been declining over time. They averaged $1 per claim in 1992 and are down to $0.20 to $0.50 per claim currently. Since PBMs can no longer make money on the administrative fee, the money from the rebate has become more important. Finally, many PBMs consider the formulary, which is rebate related, as the starting point of their drug utilization management activities.

Rebates have been declining over the past few years. Rebates are low enough now that many employers believe it is not worth closing a formulary or incentivizing patients in order to capture rebates. They have come down because manufacturers have become more discriminating in their contracting and because performance in moving market share has been so poor. PBMs find it hard to move market share when employers will not close formularies, incent patients, or implement therapeutic interchange.

Non-rebate revenue is becoming more common. An example was discussed in a recent **San Francisco Chronicle**. A letter to the paper discussed Bristol Myers Squibb offering a large HMO a non-rebate payment of $1 million a month in return for an exclusive contract for 5 of its products. The understanding was that this money would not be shared with the HMO's clients, it would go directly to the HMO's profits. This may be part of a natural progression in negotiations. As customers figure out one angle, another one is developed. An analogy might be to generic drugs. They were originally priced at a real cost of about 10% of AWP. This allowed retail pharmacies a bigger spread between their real costs and the amounts they were reimbursed.

I asked about the amount of savings that PBMs have realized through formulary management, prior authorization, and therapeutic interchange. Mr. Deskin said he had heard claims of savings, but he had not seen anything documented.

I asked about smaller PBMs and rebates. He said that they frequently did not have the resources to negotiate for rebates so they piggy-backed on larger PBMs' contracts. The larger PBM did this for an administrative fee.

4. Does the PBM use a mail order pharmacy? Do they encourage this with lower copays or greater quantities? How do employees like the mail order plan?

PBMs can realize savings through mail order because mail order pharmacies give bigger discounts off AWP. He estimated that larger plans may receive an additional 4-5% off AWP from mail order, while smaller ones get 2-3%. He also mentioned that many employers do not realize savings because they incent patients to use mail order at such a level that any savings realized from mail order discounts are eaten up by the added patient incentives.

He estimated that, industry wide, 10% of prescription dollar volume and 2-3% of prescription numbers go through mail order. The small number of plans who have mandatory mail order may see as much as 2/3 of dollar volume go through the mail.

5. Does the PBM have a restricted pharmacy network? How do employees like it? How are your relations with network pharmacies?

Did not ask

6. Does the PBM encourage therapeutic interchange or have a restricted formulary? How do employees like it?

Few employers have restricted formularies. However, therapeutic interchange and three tiered copays are increasing. I stated that I had heard numbers for 3 tiered copays in the range of $5 for a preferred formulary product, $10 for a nonpreferred formulary product, and $50 for a nonformulary product. He thought the $50 was too high. He said that United Health had just implemented a three tiered copay nationwide at $5/$10/$20. He thought that at $50 the patient received no benefit from the drug benefit. He also stated that PBMs were more favorable to these practices than were employers.

7. Do you think the PBM has contributed to improving employees' health? How?

PBMs probably have improved health. The first means of doing so was by making the prescription benefit more accessible. Before PBMs, most benefits involved a patient coinsurance of 20% in which the patient paid the full cost at the pharmacy and then submitted a paper claim to the insurer for reimbursement. By going to copay based systems in which the patient was not initially responsible for paying for the drug, the PBMs have made prescriptions more affordable and accessible for many people.

PBMs have also improved health through concurrent DUR. This has been primarily a function of increasing automation at the pharmacy. Whether or not this would have occurred without PBMs is debatable.

8. How are disputes between you or your employees and PBMs resolved?

Did not ask.

9. What should an employer look for in a PBM?

Employers should focus on results and not process. They should have the PBM measure and report on performance in many different areas. An example would be in customer service - how long does it take to answer a beneficiary's phone call; or in eligibility - how long does it take to provide drug cards to beneficiaries.

10. How are PBM P&T committees composed?

Mr. Deskin did not know how a great deal about how P&T committees operated.

PBM Employees

Joann C. Woods
Director of Client Services
International Pharmacy Management
(a small independent PBM)

1. What services does the PBM provide?

IPM provides the basic package of PBM services: claims processing, pharmacy network, rebates, utilization reports, mail order pharmacy. They offer some very basic disease management services but are not into it heavily because they are a small PBM. They also do not do much in the way of formulary management or therapeutic interchange. They may soon also offer a physician dispensing program.

They offer both fee-for-service card programs and capitated programs in which the PBM assumes risk.

2. Does a PBM decrease prescription drug costs? By how much?

IPM claims to save its members from 10 to 30% on prescription drug programs. The amount depends on the type of program they currently have. For the transition from an unmanaged cash program the savings are higher, for a well managed program they are lower. Ms. Woods could not estimate how much saving came from each service.

About half IPM's clients have a mandatory generic program in which the patient must get a generic or pay the difference in price between generic and brand out of pocket.

3. How are rebates divided between PBM and employer group? Has this changed much over the last few years? Has the amount of rebates changed? What they are called?

On average, IPM's clients receive from 50 to 70% of the rebate. The bigger clients are more likely to get 70%. Ms. Wood would not provide IPM's average rebate amount but said that industry wide rebates amounted to about $0.50 to $1.50 per claim. PBMs which were larger, and those with tighter formulary restrictions, tended to get larger rebates. IPM tries to operate as independently of manufacturers as possible. This allows it to select the best product for its clients rather than the product being pushed by a particular manufacturer.

IPM does not deal directly with manufacturers. It goes through a rebate company - IPS - which is a kind of middleman.. IPS has the negotiated contracts with drug manufacturers. IPM submits claims to IPS in proper form; IPS processes the claim and calculates the covered rebate amount. The manufacturer then pays IPS which pays IPM.

4. Does the PBM use a mail order pharmacy? Do they encourage this with lower copays or greater quantities? How do employees like the mail order plan?

IPM has its own mail order pharmacy. Most clients encourage mail order use through copays. An employee can pay one copay per month at the retail pharmacy or pay one copay for a 3 month supply through the mail. The mail order does some therapeutic interchange.

5. Does the PBM have a restricted pharmacy network? How do employees like it? How are your relations with network pharmacies?

IPM has both restricted and open networks. If the employees feel they have an adequate number of pharmacies, they like it. If they feel restricted they may be more resistant. Relations with network pharmacies are good. IPM encourages good relations by having an actual person (rather than a voice mail or automated system) answer calls from network pharmacies. The pharmacist talks with a customer service rep or with the contracts manager.

6. Does the PBM encourage therapeutic interchange or have a restricted formulary? How do employees like it?

Not at this time although we can provide some through our mail order pharmacy.

7. Do you think the PBM has contributed to improving employees' health? How?

Yes. A prescription program will monitor things such as over and under-utilization, drug utilization, and others. DUR will contribute positively to employees' health.

8. How are disputes between you or your employees and PBMs resolved?

There have been very few pharmacy disputes. Some problems have occurred with product price increases not getting loaded quickly enough. These are usually fixed after the contracts manager does some research.

Clients have an appeals process for disputes. The appeals board is composed of IPM employees and board members.

9. What should an employer look for in a PBM?

"PBMs are a dime a dozen". An employer should look for one that is flexible, one that can work with the clients needs. The PBM should be a partner with the client. IPM is a smaller PBM so it may be a better fit for smaller employers. These smaller employers frequently find that they do not get good service from large PBMs because they are an insignificant part of the PBMs business. They may get better service from a smaller PBM because they represent a larger share of their business.

I asked if IPM stressed its independence from manufacturers as an advantage. Ms. Woods said that was very important. It allowed them to put the client's interests first.

10. How is your P&T committee composed?

The P&T Committee consists of IPM employees and non-employees. The employees are pharmacists. The non-employees include faculty members from Sanford University's School of Pharmacy and the Univ. of Birmingham Medical School. There is a nurse on the committee and several people with "broad industry experience". These are people with experience in administering health benefits in an HMO or insurance company. Most come from HMOs.

PBM Employees

Delbert D. Konnor, Executive Vice President Pharmacist
Pharmaceutical Care Management Association
(the trade association for PBMs and mail order pharmacies)

1. What services does the PBM provide? (claims processing, formulary, reports, DM)

did not ask

2. Does a PBM decrease prescription drug costs? By how much?

PBMs serve clients who make decisions about whether or not to use PBMs in an open market. If PBMs were not successful in reducing drug costs then clients would no longer use them.

I asked Mr. Konnor about the statement made by PBM opponents that why did costs of prescriptions continue to increase if PBMs were successful in controlling costs. Mr. Konnor provided a number of reasons. First, the pharmaceutical industry introduces many new and expensive products each year. Of these, many are "better living" or "quality of life" drugs such as Viagra. Second, in the indemnity insurance programs, patients collected prescriptions receipts and submitted them for reimbursement at the end of the year. In this system, many claims were either lost or otherwise never submitted for reimbursement. In the pharmaceutical card plans now prevalent in the industry, reimbursement is provided directly to the pharmacy at the time the prescription is dispensed. Thus, there are no (or far fewer) lost or non-submitted claims. Finally, many PBMs monitor the compliance of patients with their drug therapy and make interventions to increase compliance. Increased compliance results in higher drug use and, consequently, higher drug costs. Mr. Konnor stated that employers should view expenditures on prescription drugs not as a cost, but as an investment in employee productivity. In this view, some types of increased drug costs - such as those from improved compliance - are good investments in that they result in more productive employees.

3. How are rebates divided between PBM and employer group? Has this changed much over the last few years? Has the amount of rebates changed? What they are called?

Mr. Konnor cautioned that he had never worked in the operations end of a PBM and, because of that, he did not have first-hand knowledge of how rebates were handled. He said that it was his impression that manufacturers began giving rebates to PBMs as a way of getting on the PBM's formulary. Manufacturers were afraid that if they did not give rebates then they would be left off of the PBM formulary. Over time manufacturers have changed in how they view rebates. Now, PBMs are more likely to be required to meet performance standards in order to get rebates.

Mr. Konnor felt that the term "rebate" was a poor choice of terminology which had, unfortunately, become institutionalized. He stated that a rebate was more like a trade discount or an incentive provided to the PBM based on its sales volume. In the latter sense, he said a rebate was like the "hold back" a new car dealer receives from the manufacturer at the end of the year. If the dealer has met his sales target it receives the "hold back" from the manufacturer. If it has not met the target, it does not get the "hold back".

I asked Mr. Konnor about the existence of non-rebate income. He remarked that this term reflected that "rebate" was a poor choice of term. The term non-rebate income now may refer to fees or monies that PBMs receive in return for services they provide - such as promotional activities.

4. Does the PBM use a mail order pharmacy? Do they encourage this with lower copays or greater quantities?

Not asked. It is well known that most PBMs do use mail order pharmacies. The extent to which their use is encouraged with lower copays of greater quantities varies by PBM.

5. Does the PBM have a restricted pharmacy network? How do employees like it? How are your relations with network pharmacies?

Not asked.

6. Does the PBM encourage therapeutic interchange or have a restricted formulary? How do employees like it?

7. Do you think the PBM has contributed to improving employees' health? How?

PBMs offer a number of programs which improve employees' health. An example is patient compliance programs.

PBMs have evolved from interest in simply dispensing drugs to adding formulary management systems. In the early 1980's, when drug prices were sky rocketing, unions pressed employers to offer prescription drug coverage. Employers began offering prescription drug insurance to their employees. What made the system work on a national or broad regional basis was the presence of technology. Computer technology gave PBMs and employers the ability to monitor patients at any pharmacy in the U.S. Technology also gave the patient the ability to have their prescriptions dispensed, and paid-for, at almost any pharmacy in the country.

Once they began offering drug coverage, employers wanted to buy prescription drugs the same way they purchased steel or other commodities. To learn how to do this, they brought in mail-order pharmacy representatives to educate them through sales presentations. Employers were told that they could not get discounts on patented prescription products regardless of the volume they purchased. Working with PBMs, the employers figured out how to get discounts on patented products. They did this through use of the formulary system.

Over time, PBMs evolved from interest in cost savings to interest in patient compliance and wellness. The retail pharmacy never did this. PBMs can monitor compliance because they have the patient's total prescription record. No matter where the patient gets his prescriptions, the PBM has a record of them (as long as they are reimbursed through the PBM). The retail pharmacy only has a record of those prescriptions purchased from that pharmacy.

The evolution led to disease state management programs. Employers asked how else they might save money on drugs. The answer was to focus on the 10% of patients who use 70% of drugs. Disease state management focuses on the high-use patients and on teaching or educating pharmacists and physicians about how best to treat these patients. PBMs are much better able than retail pharmacies to offer these programs because they have trained specialists for each disease state. It is highly unlikely that a community pharmacist could have the depth or breadth of knowledge of the staffs of specialists employed by PBMs. Disease state management, according to Mr. Konnor, is all about taking care of patients. An important feature of disease state management is that the patient has to learn how to take care of their own health care because they are ultimately responsible.

Later, Mr. Konnor remarked that retail pharmacies cannot thoroughly counsel patients without more information than they currently collect. PBMs are collecting the additional information. When asked, Mr. Konnor said that the additional information related to the patient's medical information. (Currently, most retail pharmacies and PBMs have only prescription-related information. A major emphasis of PBMs is the integration of patient prescription drug and medical information into a single database.)

PBMs offer programs targeted at prescribing for the elderly and disease state management for asthma, diabetes, hypertension, among others. More are being developed.

Merck Medco offers a program called "Prescriber's Choice". In this program, Medco monitors prescribing and dispensing practices in target cities. It identifies prescribers who are prescribing outside approved clinical guidelines and sends trained clinical pharmacists to their offices to educate them about appropriate drug therapy.

Mr. Konnor remarked that the "focus has to be on the patient. If you focus on yourself, you go out of business."

7. How are disputes between you or your employees and PBMs resolved?

   Not asked.

8. What should an employer look for in a PBM?

   Not asked.

9. How is your P&T committee composed?

Mr. Konnor cautioned that he was not involved in PBM operations, but offered some general comments. Most, if not all, PBMs have independent pharmacy and therapeutics committees. Typically, the names of P&T committee members are not made public. This is done to protect them from drug company promotional efforts. Formulary decisions are made scientifically. The purpose is to teach physicians proper prescribing habits.

Some PBMs are putting their formularies in the physicians' offices by posting them on the internet and providing physicians with the passwords. This allows the physician to deal with formulary issues at the point of prescribing. This allows the physician to override the formulary, if he wishes, in the office and before the patient gets to the pharmacy. It also allows the physician to discuss drug choices with the patient. This is especially useful as three tiered copays are becoming more popular. (A three tiered copay has one, relatively low, copay for preferred formulary products, a higher copay for non-preferred formulary products, and a higher still copay for nonformulary products.) The patient can decide on his choice of product with the physician and having knowledge of how much the product will cost.

Pharmacists 10-12-98

Rebecca Snead, Executive Director
Virginia Pharmacists Association
(A trade association representing Virginia pharmacists)

1. What services does the PBM provide to the pharmacy? (claims processing, formulary, reports, DM)

PBMs allow automated transmission of claims data and automated claims adjudication. This lets the pharmacist know, at the time the prescription is being dispensed, whether the person is covered, whether the drug is covered, the quantity that will be reimbursed, and the amount of the patient's copay. This is very valuable. Historically, pharmacies submitted paper claims. The pharmacy had to have a resident expert who would know the specifics of all the insurance plans with which it dealt. If it did not, or whenever the expert was wrong, the pharmacy could dispense a prescriptions for which it would not be paid as a result of patient or drug not being eligible under the terms of the plan.

Ms. Snead has been told that most PBM contracts include a clause that allow a PBM to positively adjudicate a claim (to give the pharmacist the OK to fill the prescription) and then, if they subsequently find out the patient was not eligible, to not pay the pharmacist. She believes this only happens rarely. It occurs when a patient drops or is dropped from an insurance plan but has a prescription filled before the PBM can upload the data showing he has been dropped. This situation may not occur often, but it unfairly places the burden on the pharmacy.

PBMs also provide another screen for drug interactions and duplicate therapy. If a drug interaction occurs between a drug being dispensed at pharmacy A and a drug the patient has obtained from pharmacy B, the PBM will not adjudicate the claim. It will not provide the pharmacists with the specific information to solve the problem, it just will not adjudicate. This provides some protection and allows the pharmacist to attempt to get the needed information from the patient.

2. Does a PBM decrease prescription drug costs? By how much? Where do the savings come from?

PBMs may, but probably do not, decrease prescription drug costs. They definitely do not reduce total health care costs. PBMs frequently will not pay for the drug of choice for the patient. The result may be the patient having to take two or three other drugs to accomplish the same therapeutic result. In addition, therapeutic interchange increases the amount of time both pharmacist and physician spend trying to get drug therapy covered for the patient. The result is increase in total health care costs.

This may occur because PBMs have no incentive to manage total costs. They are paid solely to manage prescription costs. If other costs increase, that is not their concern.

I asked her about the savings estimates from the GAO report on the FEHBP. She replied that if the PBMs had fully disclosed their financial information one would see much greater potential savings because the PBMs have not shared their rebates to the extent they say they have. They have to make more money on drug rebates because they are practically giving away the claims processing service. So, any profit they make must come from rebate money. Also, the savings from decreased reimbursement to providers is real savings to the plan sponsor.

I mentioned that the savings estimates in the PBM report come from the PBMs, not the plans. She replied that the figures are suspect because of the way PBMs count savings. For example, she says that if a PBM in the Medicaid program denies a claim because its an early refill the cost of the claim is counted as a savings. This ignores the fact that the claim will be filled a few days later. Similarly, prior authorization savings are counted as the dollar value of PA requests denied. This ignores the costs of therapy provided in lieu of the PA request and the administrative cost of the program. She stated that PBMs frequently count payment deferred as cost savings.

3. How are rebates divided between PBM and employer group? Has this changed much over the last few years? Has the amount of rebates changed? What they are called?

She did not have first hand knowledge of rebates. She hears from manufacturers that millions of rebate dollars are being paid to PBMs and from PBMs that rebates do not amount to much. She said that the uncertainty would be resolved if the PBMs would disclose their financial arrangements in terms of where there money came from and how much they received from each source. Her view was that if they are not doing anything suspect then full disclosure should not be an issue.

4. Does the PBM use a mail order pharmacy? Do they encourage this with lower copays or greater quantities? How does this effect pharmacies? Patients?

A tremendous number of prescriptions are going to mail order pharmacies. This represents lost revenues to retail pharmacies. It also inhibits the ability of retail pharmacies to provide continuity of care to their patients and may, therefore, harm patient health. PBMs argue that they provide a safety net because their computer system includes all drugs the patient is on regardless of which pharmacy he uses. Retail pharmacists response is that if the PBM did not encourage patients to use mail order they would get all their prescriptions at one pharmacy.

There is little evidence that patients prefer mail order pharmacies. They use them because PBMs offer substantial copay differences to encourage them to do so. Patients have not rebelled at having to use mail order because of the large copay differences involved.

Some patients do actually prefer mail order because they do not want to interact with a health care provider. These are frequently patients who use multiple physicians or are noncompliant. They do not want to interact with a pharmacist because he might confront them about using multiple physicians or being noncompliant. These are the patients who need to see a pharmacist face to face.

5. How have restricted pharmacy networks affected pharmacies? Patients?

Being closed out of a network is not as much of a problem as it used to be. The bigger problem is insurers directing patients to preferred pharmacies by not listing nonpreferred participating pharmacies in their directories. This gives new insureds the idea that the nonlisted pharmacies are not participating providers.

6. Have PBMs encouraged therapeutic interchange or have a restricted formulary? How has this affected pharmacies? Patients?

Therapeutic interchange is never in the patient's interest. There is never a benefit to changing a patient off of a medicine which he is stabilized and doing well on. And if he is not responding well, the physician would change the medicine anyway. There may be a benefit to changing a new prescription from one which the literature indicates does not work well to one that is more appropriate. But most pharmacists would probably attempt this change even without the PBMs intervention.

I asked about the argument that physicians do not know much about drugs and that what they know comes from drug reps. She replied that any physician who does not see a proper response from a drug will change it. Frequently physicians ask pharmacists for their suggestions if a given product does not work.. No physician will continue to use a drug just because a salesman suggested it.

PBMs frequently claim they need to intervene because they analyze claims data and see evidence of physicians continuing to use "antiquated therapy". Usually there is a good reason for this. It may involve the patients idiosyncracies or the fact that he is stabilized on and comfortable with that drug. "Do you think a physician would prescribe a drug which has bad side effects if there's no good reason to do so?"

Ms. Snead stated that PBMs do not have a license to practice medicine or pharmacy. When they limit the choices for a patient's therapy they are making decisions reserved for licensed practitioners. This is wrong. Further, she stated that one cannot make individual treatment decisions from statistically analyzing claims data. The results of these analyses could be used for educating pharmacists and physicians - for pointing out that their decisions are different from their colleagues' - but not for restricting the choices available to physicians. This is essentially practicing without a license.

7. Do you think PBMs have contributed to improving employees' health? How?

PBMs may not have harmed anyone's health, but they certainly have not improved it. Most prescriptions, probably 60 to 70% of all prescriptions, are processed through PBMs. This has been true for at least 5 years. If PBMs provide all the health-improving services that they claim to provide, then why do we still have the major problems with drug misadventuring that we have? PBMs are not well positioned to address these problems. The professions - pharmacists and physicians - need to address them.

8. How are disputes between pharmacies and PBMs resolved? Patients and PBMS?

Patients resolve problems through their health insurers, not through PBMs because they have a financial relationship with the insurer, not with the PBM. The insurer has a financial relationship with the PBM.

The entire PBM audit procedure is an area of dispute. PBM contracts state that the PBM can audit data from the past five years. Audits present a large time burden to pharmacies. The PBM may, for example, send a list of 100 prescriptions to be audited. Because of patient confidentiality concerns, the pharmacist must pull the prescriptions. He then must explain how the prescriptions were handled to the auditor. The auditor writes up a report to which the pharmacist can respond. Even if the pharmacist is not at fault, he has spent a great deal of time in the process.

Audits frequently focus on picky and pointless problems. An ointment may come in a 3.5 gm tube. The computer will not accept decimals so the pharmacy bills for 4 gms. The PBM knows about the problem with decimals so it pays for a 3.5 gram tube. But the auditor notes that the pharmacist charged for payment for a 4 gm tube when he only dispensed 3.5 gm. Or, a patient has a prescription written for 100 tablets. The PBM allows a 34 day supply. The pharmacy dispenses 34 with 2 refills. The auditor notes that the pharmacy dispensed 102 tablets when only 100 were prescribed. The pharmacy must then call the physician for approval for dispensing the 2 tablets. Ms. Snead wondered why the PBMs do not change their audit criteria because they are constantly charging, then forgiving, the same picky violations.

OTHER INFORMATION

Retail pharmacies' main difficulty with PBMs is the amount of liberties that PBMs take in controlling access to products and their methods of controlling access. PBMs make it very difficult for pharmacies and physicians to get the products they want for their patients.

The Medicaid program is a good example of how PBMs could interact positively with pharmacies. The Medicaid on-line adjudication system provides pharmacies with educational messages about patients' drug therapy. For example, the message may tell the pharmacist that the drug should only be used for a maximum of 3 days and that the patient has been on the drug longer than that. But the pharmacist can easily override the message if he thinks its warranted. The patient may, for example, be a cancer patient on long term pain therapy. The Medicaid system provides pharmacists with information, but allows them to easily override the system if there is good reason to do so.

Most PBM systems require the pharmacists to jump through many more hoops to override the system. The result of erecting barriers may be that the patient does not get the therapy he needs. For example, the cancer patient is denied needed pain therapy while the pharmacist deals with the administrative bureaucracy necessary to get the

drug approved. This is another situation in which the PBM assumes the role of a health care provider. The PBM is not licensed to do this and does not bear legal liability that licensed providers do.

Patient Interview -- Patient #1 -- 10/28/98

Patient #1 was an elderly, retired female with chronic medical conditions. She and her husband were covered by the Commonwealth of Virginia's employee health plans before her husband's retirement a few years ago. Currently she has a drug discount card through her insurance plan (secondary to Medicare) which pays a small part of her prescription drug expenses.

Patient #1 has used mail-order pharmacy service in the past. It was not satisfactory, primarily because of the postal service. One prescription she received was shredded by the post office. After that happened, she found a local pharmacy which offered prices comparable to those offered by mail order. This pharmacy was not convenient. Currently she and her husband get their prescriptions from a local pharmacy even though it is more expensive than the mail order pharmacy.

I asked if she had ever had the experience of her pharmacist telling her that the insurance company would not pay for the drug her physician had prescribed, but they would pay for a different drug which would have the same effect. She asked if this was a generic drug. I said that it was not, that it was a different drug but one that was supposed to have the same effect. Patient #1 had never had this happen. I asked how she felt about the concept. She did not feel very good about it. She explained that her physician had been a pharmacist before becoming a physician and that this was one of the reasons she used him. She felt he knew about drugs. I explained that the change of drugs cannot occur without the physician's approval. I further explained that when this situation occurs the patient is usually told that the insurance company will pay for the alternate, physician-approved product, but not for the originally prescribed product. She said it sounded like an HMO trick to her. She and her husband had been members of an HMO some years ago. She said the HMO's emphasis was on keeping people healthy, but that they did not want to treat older people for things that go wrong with them. Her husband had had a problem with his back. The HMO physician refused to send him to a specialist and instead treated the pain with narcotic drugs. She felt that her husband was not appropriately cared for because doing so would be more expensive. She said that HMOs might be fine for younger people, but not for older people. She felt that the HMO's main concern was making money.

Patient interview -- Patient #2 -- 10/28/98

Patient #2 is a retiree who takes several prescription medicines including warfarin and pravastatin. He is retired from a major corporation which provides generous health benefits. He has never used a mail order pharmacy although he thinks he might be able to get larger quantities and reduced prices from mail order. He uses a local community pharmacy with which he is well pleased. His insurance company has never asked him to change pharmacies to maintain his drug coverage.

He had never been asked to accept a therapeutic alternate. When asked how he felt about the concept, he replied that he was not comfortable with it. He said that changing the kind of drugs he was taking was "fooling around with touchy stuff" and that he preferred to continue using what worked.

He had never had a dispute with the insurer over any of his medicines. His only complaint was that he could only get one month's supply at a time. But he remarked that this complaint was about as picky as one could get.

Patient #3 10/29/98

Patient #3 is a married, middle aged woman with four children. One of the children has substantial physical and mental disabilities.

Patient #3 has never used a mail order pharmacy and does not think her insurance provides her with economic incentives to do so. She buys the family's medicines at a local community pharmacy in the rural area where they live. She knows of no insurance-related restrictions on which pharmacy she may use.

Patient #3 had never been asked to accept a therapeutic alternate. When the concept was explained to her she said that she would be reluctant to accept an alternate for a medicine on which she was stabilized. She said that if the medicine were working and not causing side effects she would not want to change. She said she would probably try the alternate if insurance restrictions made it substantially less expensive to her. Patient #3 indicated that she would accept an alternate on a medicine she had never taken before. She would only do so if the physician approved the change after making sure it was not contraindicated and that it would not interact with other medicines she was taking.

Patient interview 11/3/98

Mary Rouleau
Legislative Director
Consumer Federation of America

1. What services does the PBM provide? (e.g., claims processing, formulary, reports, disease state management)

not asked

2. Does a PBM decrease prescription drug costs? How? By how much?

There is, perhaps, some truth to PBMs' assertion that they control drug costs. However, there are two serious problems with this assertion. First, no one has objectively examined the savings generated by PBMs. Usually this is because the information needed to do so is labeled as proprietary by the PBMs. Second, PBMs may have already extracted the "easy discounts" from the market. If this is the case, there is not a lot more they can do to hold costs down.

Prescription costs continue to rise. I asked Ms. Rouleau if by this statement she was implying that PBMs do not control costs. Her response was that because PBMs make the claim that they save money, the burden is on them to prove it, and they have not done so.

3. How are rebates divided between PBM and employer group? Has this changed much over the last few years? Has the amount of rebates changed? Are rebates called by any other names?

Ms. Rouleau did not know much about rebates.

4. Does the PBM use a mail order pharmacy? Do they encourage this with lower copays or greater quantities? How do employees like the mail order plan?

Ms. Rouleau only addressed mail order pharmacy from the point of view of its effects on drug switching. She said that drug switching was more complicated when done by a mail order pharmacy. It was more complicated because there was no face to face contact, or personal relationship, between pharmacist and patient. She was also concerned about the type of employees who made the drug switching calls. Her concern was that these employees might be more likely to be technicians, rather than pharmacists, when the calls were made by a mail order pharmacy. She also commented that mail order was a cheaper method of dispensing drugs.

5. Does the PBM have a restricted pharmacy network? How do employees like it? How are PBM relations with network pharmacies?

Her only concern with restricted networks was that in areas where pharmacies might be scare, such as in rural areas, a restricted network could be an extreme inconvenience for patients.

6. Does the PBM encourage therapeutic interchange or have a restricted formulary? How do employees like it?

She suggested that restrictive formularies are increasingly used in drug benefit programs. They represent problems for consumers in terms of timely access to drugs and price. Access is affected because consumers, through their physicians or pharmacists, must go through bureaucratic processes to have non-formulary drugs

approved. This may take several days, so consumers prescribed non-formulary drugs may have to go several days without their medicines. Price is a factor when drug plans require patients to pay higher copays or full price for non-formulary medicines.

Another problem with restrictive formularies is the issue of who put the formulary together and what considerations or incentives motivated their decisions. Ms. Rouleau was concerned that cost considerations might be more important than clinical ones. To her, this is an important and troublesome issue because three of the largest PBMs are owned by drug manufacturers and these three control the majority of prescriptions handled by PBMs. She noted that there was a strong incentive for PBMs to create restrictive formularies, price them to clients at lower prices than their open formularies, and use them to move market share for manufacturers. Because rebates are increasingly based on moving market share, this creates an incentive for PBMs to create restrictive formularies based on cost considerations. The extent to which this occurs is an open question. Ms. Rouleau felt that answers were needed. She was also concerned that there is little public scrutiny or oversight of PBM formulary decisions.

7. Do you think the PBM has contributed to improving employees' health? How?

Ms. Rouleau replied that "the jury was still out" on whether PBMs had improved patients' health. She felt that the burden was on PBMs to prove that they improved or had no negative effect on patients' health and that they had not done so. She mentioned that there is a body of literature which suggests that restrictive formularies are injurious to patients and increase health care costs. She felt that there were two reasons that PBMs had not demonstrated their positive (or neutral) effects on patient health. First, they may not be able to prove it because it is not true. Second, it is a very difficult thing to prove because of problems inherent in doing research in this area.

I asked her about PBMs' assertions that there is no evidence that therapeutic interchange or restrictive formularies harm consumers. Her emphatic response was that this is absolutely untrue. FDA has a voluntary reporting program for adverse drug reactions, including those caused by therapeutic interchanges. This system, called MedWatch, has recorded a number of significant health problems linked to therapeutic interchanges. Second, there have been a number of reports in the media of consumers harmed by a therapeutic interchange. While neither of these sources provides an accurate measure of the true number of consumers harmed, both indicate that some consumers are harmed by interchanges.

8. How are disputes between you or your employees and PBMs resolved?

Ms. Rouleau did not know. She suggested that physicians might be a better source for this information.

9. How is your P&T committee composed?

Ms. Rouleau commented that the "jury was still out" on whether P&T committees were independent or whether they made decisions in an unbiased way. She commented that the burden of proof was on PBMs to She felt there was a need to make the composition of P&T Committees public information and for the committees to keep minutes and make these minutes available to the public. She said that a certain amount of this information, primarily that dealing with prices, would have to be kept from the public because it was truly proprietary. She also commented that her experience with other industries had revealed that what companies label as "proprietary" is not always truly proprietary. Many times companies use the proprietary label to shield information which they do not wish to make public even though there is no compelling public reason to keep it private. She commented that most pricing information was truly proprietary. I asked why pricing information should be kept from the public. She replied that if it were made public it would lead to price collusion among competitors.

10. Other issues - consumer privacy

Ms. Rouleau was concerned that PBMs may violate patients' privacy. She referred to an article in the Washington Post which reported on a major PBM visiting an endocrinologist to educate him on proper drug treatment of his patients. The physician was extremely upset that the PBM knew who his patients were and what drugs they were taking and that the PBM was suggesting to him how he should treat these patients. He was also concerned that the PBM was making treatment decisions based without having a personal relation with the patient. Ms. Rouleau pointed this out as an example of PBMs overstepping their bounds in using confidential patient information and as an intrusion on the physician - patient relationship.

11. Much of Ms. Rouleau's comments can be summarized by her written statement to the Federal Trade Commission that "the most fundamental questions about PBMs remain unanswered in the public domain: What is the extent, if any, of cost savings provided by PBMs? What is the impact of PBM practices on the quality of pharmaceuticals supplied to consumers?" Ms. Rouleau repeated pointed out that the burden of proof for these questions is on PBMs and that they have done little to meet this burden.

Physician Interview 10/16/98

Sheldon Retchin, MD, Executive Director, MCV Associated Physicians

Interacting with PBMs consumes a lot of physician time. Their impact on physician practices is significant and negative. Although no specific number was given, on a daily basis physicians must deal with some issue related to PBM practices. According to this respondent, PBMs have not contributed to improved health for their patients.

Perhaps one of the most noteworthy negative aspects of PBM practices on physician practices is the lack of uniformity across PBMs. Physician may be faced with being asked to switch two patients on the SAME Rx to two different alternatives as a result of the particular formularies involved. It appears that most of the business of PBMs is about money and nothing else.

Disputes are resolved through lobbying, negotiation, and any other means necessary. Dispute resolution is time consuming and contributes to the significant, negative impact of PBM practices on physician practices in the Commonwealth.

Physician Interview November 3, 1998

Kenneth G. Tilghman, M.D., a local pediatrician

Regarding therapeutic interchange, the usual scenario is that a Pharmacist calls our office and advises us that the insurance company has denied a claim. In response, we usually try to find an equivalent substitute.

This practice affects our practice because it affects what prescriptions we can write for patients. In many instances we may have to try something not as effective or that we're not as familiar with. This significantly affects our clinical management of the patient. The practice makes practicing a lot more complicated. We can't keep up with what formulary contains what agents. Even Pharmacists don't know when we ask them. They advise us that they have to "punch in the agent" before they know whether or not a particular company covers that agent.

There is usually very little latitude and flexibility in these cases. We just have to change the agent. It's as simple as that. Since we are a pediatric practice, we are not as affected perhaps because of the narrow classes of agents we use regularly. It's not like an adult practice where you are trying to treat someone's hypertension or something like that.

I do believe that these companies help to keep health costs down. I believe they do this by making deals with the drug manufacturers. In doing so, they drive costs of the agents down and increase competition in the market; which also drives costs down.

No, I do not believe that the health of my patients is improved by this practice because the practice impairs my ability to practice autonomously. My ability to do my job is greatly impaired by the practice and I believe that ultimately affects my patients' health. In other words, I believe that the PBM practice of therapeutic interchange is detrimental to my patients' health care because it is limits my options and choices of agents. As I said earlier, we are often forced to resort to other agents than those we desire and that greatly complicates the clinical management of our patients.

Summary of Major Issues

The purpose of interviewing groups affected by PBMs was to identify and define the major issues. A summary of the issues follows. The focus of the summary is on identification of issues, not on drawing conclusions about them.

1. Do PBMs decrease costs?

PBMs lead to savings on drug costs primarily through discounts from network pharmacies, computerization which increases the efficiency of claims processing and serves as an additional check for drug interactions and contra-indications, and generic substitution programs.

The extent of savings that PBMs generate is an open question. There are several reasons for this. First, the extent of savings depends on the baseline. Savings are greater when the baseline is an unmanaged prescription drug program than when the baseline is some type of managed program. Second, most of the estimates of savings come from PBMs themselves. They are not unbiased sources and some of their methods of counting savings reflect this. For example, savings from prior authorization programs are based on number of claims denied. This ignores both the cost of operating the program and the cost of prescriptions that are dispensed as alternates to the denied products. Third, significant questions remain about whether other PBM activities -especially those involving limiting product choices through formularies and therapeutic interchange - result in savings. PBMs have already realized the easy savings. Future savings will require increased interventions. As Ralph Hemingway pointed out, there is a point at which the cost of interventions is greater than the savings realized from them. PBMs are getting closer to this point, but it is not know how close they are. Finally, there is a question of whether PBM activities lower total health care costs or just drug costs. As Rebecca Snead commented, PBMs have little incentive to be concerned with total health care costs because they are paid only to manage prescription costs. Given the fact that very few PBMs, employers, or HMOs can integrate medical and pharmacy data, it would not be easy to detect higher total health care costs caused by decreased prescription costs.

The views on PBM cost savings can be summarized in two questions. PBM proponents ask, "If PBMs did not save money, why would clients continue to use them?". PBM opponents ask, "If PBMs are so successful in controlling drug costs, then why are they increasing so rapidly?". Both sides can make valid cases but neither has supported the case with hard data. Mary Rouleau, of the Consumer Federation of America, has stated that if PBMs make the claim that they save money then the burden is on them to prove it.

2. Do PBMs improve patients' health?

PBMs may have improved patients' health by making prescription drug benefits more accessible to more consumers and by using automation to provide screens for drug interactions and contra-indications. PBMs argue that therapeutic interchange, restricted formularies, and prescriber education programs also improve health by improving the quality of prescribing and drug therapy. Opponents argue that these programs contribute to lower quality care because they limit patients' choice of prescription drugs and overlook differences in the way patients respond to medicines. As with cost savings claims, Mary Rouleau makes the point that if PBM claim that their activities improve health the burden is on them to prove it.

3. How does therapeutic interchange affect patients and plan sponsors?

Many of the comments on PBMs' effects on health apply here as well. There is also the question of the primary motivation for therapeutic interchange - is it done for clinical reasons and on clinical bases or is it driven by the desire of PBMs to earn larger rebates and discounts or due to their ownership by drug manufacturers.

Other questions with regard to therapeutic interchange include how frequently it occurs, whether and to what extent the frequency is increasing, and how frequently it occurs for patients who are stabilized on a drug versus patients who are newly diagnosed.

4. How independently do Pharmacy and Therapeutics Committees operate?

The extent to which P&T committees operate independently of PBMs or drug companies and the composition of P&T committees determine whether formulary decisions are made on clinical and medical bases rather than on cost and ownership bases. PBMs prefer to treat cost and pricing confidentially because of concerns about proprietary data. They prefer not to make names of P&T committee members public because doing so would allow drug manufacturers to target promotional efforts to these individuals. Consumer advocates argue that P&T committee composition and the basis on which individual formulary decisions are made should be open to public scrutiny.

5. Should PBMs be regulated?

PBMs strongly influence prescribing decisions through their formulary and reimbursement decisions. Some argue that this constitutes practicing medicine without a license and without legal liability for their decisions. They feel that PBMs should be held accountable for their actions by some regulatory body.

6. Do PBMs interfere with patients' privacy rights?

PBMs have substantial amounts of patient information. Do they violate patients' privacy rights when they use this information for targeted therapeutic interchange or physician education programs?