REPORT OF THE
JOINT COMMISSION ON HEALTH CARE

THERAPEUTIC INTERCHANGE OF CHEMICALLY DISSIMILAR DRUGS STUDY PURSUANT TO HJR 734

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

HOUSE DOCUMENT NO. 88

COMMONWEALTH OF VIRGINIA
RICHMOND
2000

JOINT COMMISSION ON HEALTH CARE

Chairman
The Honorable Kenneth R. Melvin

Vice Chairman
The Honorable Jane H. Woods

The Honorable William T. Bolling
The Honorable Joseph V. Gartlan, Jr.
The Honorable Benjamin J. Lambert, III
The Honorable Stephen H. Martin
The Honorable Edward L. Schrock
The Honorable Stanley C. Walker
The Honorable Thomas G. Baker, Jr.
The Honorable Robert H. Brink
The Honorable John J. Davies, III
The Honorable Jay W. DeBoer
The Honorable Alan A. Diamonstein
The Honorable Franklin P. Hall
The Honorable Phillip A. Hamilton
The Honorable Harvey B. Morgan

Secretary of Health and Human Resources
The Honorable Claude A. Allen

Executive Director
Patrick W. Finnerty

Preface

House Joint Resolution (HJR) 734 of the 1999 Session of the General Assembly directed the Joint Commission on Health Care to study issues relating to therapeutic interchange of chemically dissimilar drugs. In conducting its study, the Joint Commission was directed to:

(i) collect data on chemically dissimilar drugs which may be interchanged therapeutically to assess the efficacy of this practice;
(ii) solicit input from experts in pharmacy and chemical composition of drugs and the mechanisms by which drugs work in the human body to treat disease;
(iii) conduct a literature search for studies on the use of chemically dissimilar drugs for the same or similar therapies;
(iv) receive input from all stakeholders, including, but not limited to, physicians, pharmacists, insurance companies, health maintenance organizations, third-party benefit managers, managed care pharmacy organizations, patients and manufacturers;
(v) examine other states' laws and regulations to identify possible mechanisms for regulating the practice of therapeutic interchange of chemically dissimilar drugs;
(vi) conduct a comprehensive review of the related issues at the national level;
(vii) take such other actions as appear necessary and appropriate to collect sufficient data and analysis of the issues; and
(viii) make recommendations concerning whether the practice of therapeutic interchange of chemically dissimilar drugs should be regulated; the components of any such regulations, if recommended; definitions of relevant terms; and the appropriate body for such regulation, if recommended.

A copy of HJR 734 is attached at Appendix A.

Based on our research and analysis during this review, we concluded the following:

- National health expenditures on prescription drugs have doubled since 1990 increasing from $37.7 billion in 1990 to $79 billion in 1997. Prescription drugs is the fastest growing segment of national health expenditures.

- As more and more of the nation's health care dollars are spent on prescription drugs, employers and health plans are seeking ways to control these costs. Among the strategies being used are drug formularies and therapeutic interchange programs.

- Therapeutic interchange is defined as: "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."

- Therapeutic interchange is conducted for clinical reasons (e.g., drug interaction or the patient responds more favorably to another drug) or financial reasons (e.g., drug is not on the formulary, lower patient copayment, lower cost to plan sponsor or manufacturer discounts/rebates).

- Independent pharmacists and some physicians have expressed concern that therapeutic interchange that is done for the primary purpose of financial incentives such as rebates or discounts paid to the pharmacy benefit manager (PBM), pharmacist or health plan is wrong and unnecessarily puts patients at risk for possible harm. Pharmacy benefit managers (PBMs), chain drug stores, health plans, hospitals and business representatives argue there is little or no evidence that the practice of therapeutic interchange is harmful and that the associated savings are important in holding down the cost of prescription drugs.

- The Department of Medical Assistance Services (DMAS) contracted with two research organizations to conduct a study of therapeutic interchange. The DMAS study found the incidence of therapeutic interchange is low (3% of total prescriptions written in Virginia). DMAS also found that physicians and pharmacists reported very few patient complaints. Patients' satisfaction with prescription drug benefits is high. Fifty-nine percent of physicians and 38% of pharmacists believe therapeutic interchange worsens patient outcomes. Physicians and pharmacists have mixed views on the cost savings of therapeutic interchange.

- The U.S. Food and Drug Administration (FDA) administers the "MedWatch" program which receives reports from providers on adverse medical events associated with various health care treatments or practices. MedWatch has received few reports of adverse events associated with therapeutic interchange (108 of 10,000 reports in 1997; 61 of 16,000 reports in 1998). The MedWatch data suggest that therapeutic interchange was "associated" with certain adverse events; FDA officials state that its data do not suggest that therapeutic interchange "caused" the adverse events.

- The U.S. Attorney's Office is investigating certain PBM practices to determine: (i) if therapeutic interchanges are conducted deceptively, (ii)

- The U.S. Attorney's Office is investigating certain PBM practices to determine: (i) if therapeutic interchanges are conducted deceptively, (ii) whether there is full disclosure to the patients and physicians, and (iii) whether there are any fraudulent practices.

- While several states have passed laws regarding formularies, no state has passed a law prohibiting therapeutic interchange. There is federal legislation pending that also would require certain procedures be followed when developing drug formularies.

A number of policy options were offered for consideration by the Joint Commission on Health Care regarding the issues discussed in this report. These policy options are listed on pages 47-48.

In view of the complexity of the issues related to therapeutic interchange of chemically dissimilar drugs, a Subcommittee of the Joint Commission on Health Care was established to address the specific tasks outlined in HJR 734. The Subcommittee was chaired by Senator Benjamin J. Lambert, III; the other Subcommittee members were: Senator Edward L. Schrock, Delegate John J. Davies, III, Delegate Franklin P. Hall, and Delegate Harvey B. Morgan. The HJR 734 Subcommittee met four times. The initial meeting included a public hearing. The staff briefing on this issue comprises the body of this report. Following a presentation of the briefing to the Joint Commission, public comments were solicited. A summary of the public comments is attached at Appendix B.

On behalf of the Joint Commission on Health Care and its staff, I would like to thank the National Conference of State Legislatures, the U.S. Food and Drug Administration, the Department of Medical Assistance Services, the Virginia Commonwealth University School of Pharmacy, and the many organizations and health care associations who provided input and information during this study.

Patrick W. Finnerty
Executive Director

December, 1999

TABLE OF CONTENTS

I.
Authority for Study/Organization of Report

House Joint Resolution (HJR) 734 of the 1999 Session of the General Assembly directs the Joint Commission on Health Care to study issues relating to therapeutic interchange of chemically dissimilar drugs. In conducting its study, the Joint Commission is directed to:

(i) collect data on chemically dissimilar drugs which may be interchanged therapeutically to assess the efficacy of this practice;
(ii) solicit input from experts in pharmacy and chemical composition of drugs and the mechanisms by which drugs work in the human body to treat disease;
(iii) conduct a literature search for studies on the use of chemically dissimilar drugs for the same or similar therapies;
(iv) receive input from all stakeholders, including, but not limited to, physicians, pharmacists, insurance companies, health maintenance organizations, third-party benefit managers, managed care pharmacy organizations, patients and manufacturers;
(v) examine other states' laws and regulations to identify possible mechanisms for regulating the practice of therapeutic interchange of chemically dissimilar drugs;
(vi) conduct a comprehensive review of the related issues at the national level;
(vii) take such other actions as appear necessary and appropriate to collect sufficient data and analysis of the issues; and
(viii) make recommendations concerning whether the practice of therapeutic interchange of chemically dissimilar drugs should be regulated; the components of any such regulations, if recommended; definitions of relevant terms; and the appropriate body for such regulation, if recommended.

A copy of HJR 734 is attached at Appendix A.

A Joint Commission on Health Care Subcommittee Was Formed To Review The Issue of Therapeutic Interchange of Chemically Dissimilar Drugs

In view of the complexity of the issues related to therapeutic interchange of chemically dissimilar drugs, a Subcommittee of the Joint Commission on Health Care was established to address many of the specific tasks outlined in HJR 734. The Subcommittee is chaired by Senator Benjamin J. Lambert, III; the

other Subcommittee members are: Senator Edward L. Schrock, Delegate John J. Davies, III, Delegate Franklin P. Hall, and Delegate Harvey B. Morgan.

The HJR 734 Subcommittee met three times prior to this draft report being written. Figure 1 briefly summarizes the activities of the Subcommittee and the testimony presented at the three meetings. The Subcommittee will meet again on November 23rd to develop its recommendations regarding what action, if any, the Joint Commission on Health Care should take in response to the issue of therapeutic interchange of chemically dissimilar drugs.

Figure 1

Summary of HJR 734 Subcommittee Meetings: Activities and Testimony

July 14, 1999 Meeting

- Background on therapeutic interchange and the rising costs of prescription drugs (JCHC staff analysis)
- Legislative history in Virginia regarding therapeutic interchange (JCHC staff analysis)
- Overview of Virginia's Drug Control Act (Virginia Board of Pharmacy)
- Perspective and position of interested parties (physicians, insurers, pharmacists, consumers, manufacturers, health maintenance organizations, third-party benefit managers, managed care pharmacists, hospitals, and business)

August 12, 1999 Meeting

- Department of Personnel and Training's perspective on therapeutic interchange as it relates to the state employee health benefits program
- Department of Medical Assistance Services' (DMAS) study on pharmacy benefit managers and therapeutic interchange; and perspective of a major purchaser of prescription drugs
- Department of Health: a public health perspective on therapeutic interchange
- Perspective of the Deans of Virginia's Schools of Pharmacy

September 29, 1999 Meeting

- Therapeutic interchange laws in other states (National Conference of State Legislatures)
- Drug manufacturers' perspective on therapeutic interchange (Pharmaceutical Research & Manufacturers of America)
- The clinical impact of therapeutic interchange; results of the U.S. Food & Drug Administration's "MedWatch" Adverse Event Reporting System (FDA Division of Drug Marketing, Advertising & Communication)

Source: Joint Commission on Health Care staff summary

JCHC Staff Conducted Additional Research And Analysis Regarding Therapeutic Interchange

In addition to the information presented to the HJR 734 Subcommittee, JCHC staff conducted further research activities, including:

- A site visit to a pharmacy benefit manager (PBM) facility;
- Site visits to four different types of pharmacies (local independent pharmacy, local retail pharmacy, a health system pharmacy and a pharmacy operated by a health maintenance organization);
- A review of federal legislative activity regarding therapeutic interchange;
- Interviews with persons representing various organizations and positions regarding therapeutic interchange; and
- A review of the current literature regarding therapeutic interchange.

This Report, Which Is Presented In Six Major Sections, Summarizes The Information Presented During The Three Subcommittee Meetings As Well As The Additional Research And Analysis Conducted By JCHC Staff

The report is organized into six major sections. This first section identified the authority for the study, discussed the activities of the HJR 734 Subcommittee, and outlined the organization of the report. Section II presents information on the rising cost of prescription drugs and actions being taken by employers and health plans to better manage these costs. Section III describes the practice of therapeutic interchange of chemically dissimilar drugs, provides an overview of Virginia's Drug Control Act, and summarizes the legislative history of proposed actions to regulate and/or restrict this practice in Virginia. Section IV examines the prevalence, impact and controversy of therapeutic interchange. Section V includes an overview of other states' laws affecting therapeutic interchange and recent federal legislative activity in this area. Lastly, Section VI presents a series of policy options the Joint Commission may wish to consider in addressing the issue of therapeutic interchange.

II.
The Rising Costs Of Prescription Drugs

National Expenditures For Prescription Drugs Have Increased Markedly In Recent Years; Health Plans, Health Systems, Hospitals, And Employers Indicate That Formularies And Therapeutic Interchange Of Chemically Dissimilar Drugs Are Among The Strategies Used To Help Control These Expenditures

According to statistics developed by the U.S. Health Care Financing Administration (HCFA), national health care expenditures for prescription drugs have increased markedly in recent years. As these costs increase, health plans, health systems, hospitals, and employers continue to look for ways to control these costs. Prescription drug formularies and therapeutic interchange of chemically dissimilar drugs are among the principal strategies identified by these entities to help manage prescription drug costs. Third-party payers and employers indicate that these strategies are necessary in order to be able to continue offering/providing affordable health insurance benefits.

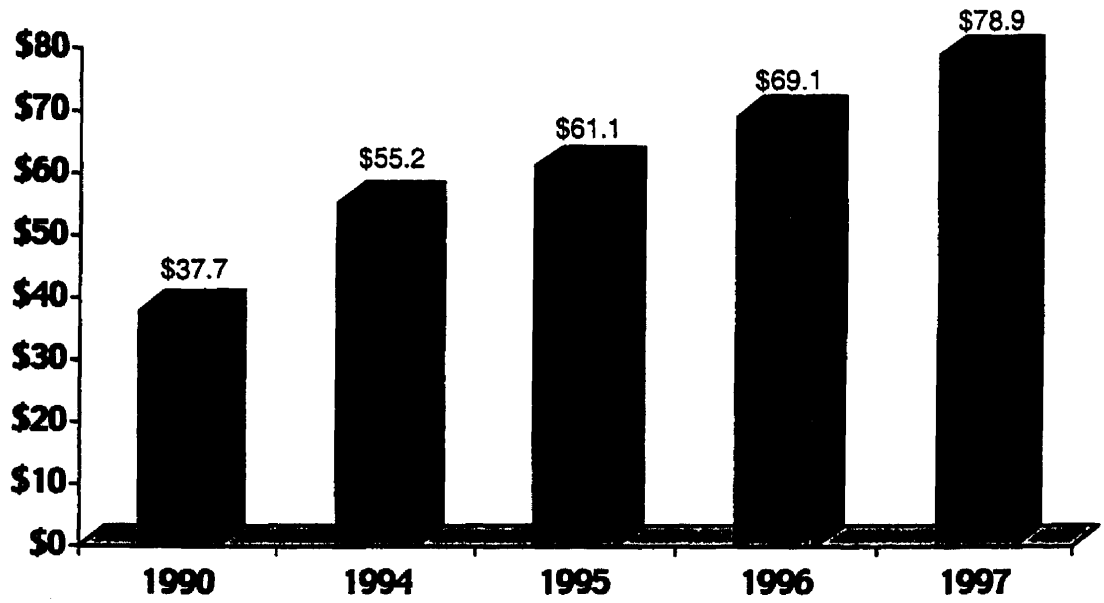
The following paragraphs summarize the most recent national health care expenditure data to illustrate the rising cost of prescription drugs and the need to control these expenditures.

The Total Amount Of Health Care Dollars Spent On Prescription Drugs Has More Than Doubled Since 1990

The most recent data on national health care expenditures (1997) published by HCFA indicate that the annual amount spent on prescription drugs has more than doubled since 1990, rising from $37.7 billion to $78.9 billion, an increase of $41.1 billion a year. Figure 2 illustrates these increases.

Figure 2

National Prescription Drug Expenditures
1990-1997
(In Billions)

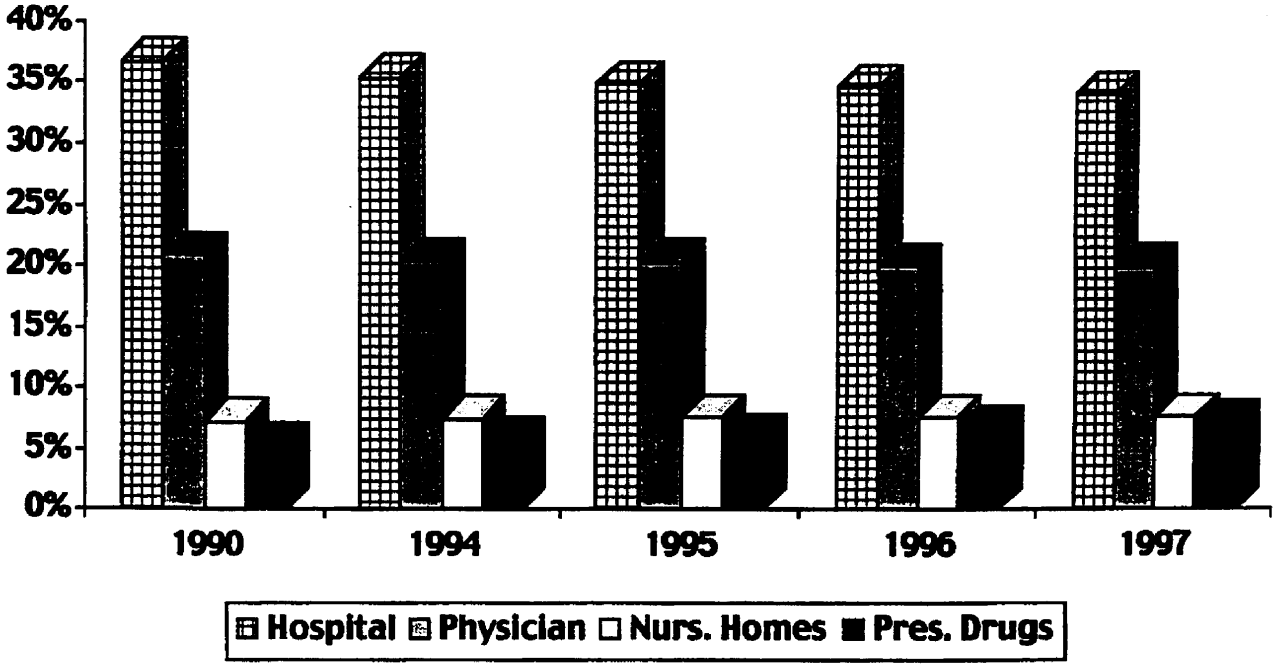


Source: National Health Care Expenditures, 1997, HCFA

While expenditures for prescription drugs comprise only a small percentage of total health care costs (Figure 3), they represent the fastest growing segment of national health care spending (Figure 4). Of the $1.7 trillion spent on health care in 1997, prescription drugs made up only about 7%, whereas expenditures for hospital services accounted for nearly 34%. Expenditures for physician services represented 20% of the total; nursing home expenditures made up 8% of total expenditures.

Figure 3

Percentage Of National Health Care Expenditures By Category of Expense 1990-1997

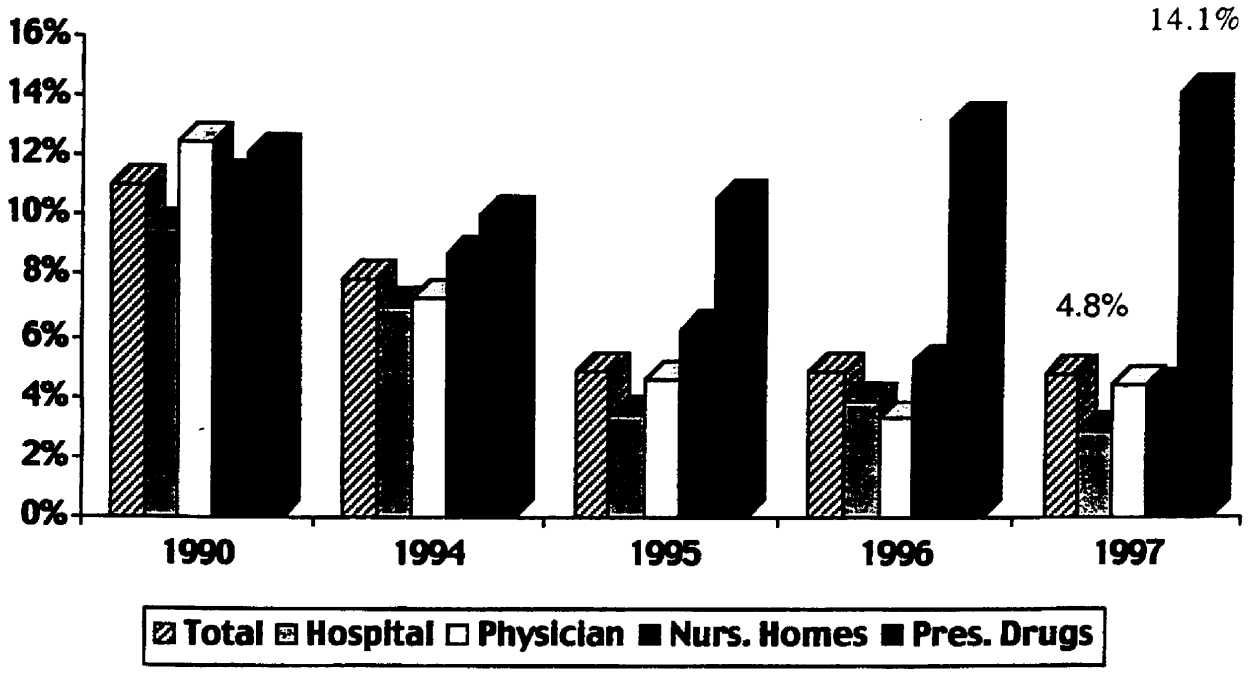


Source: National Health Care Expenditures, 1997, HCFA

Even though prescription drugs continue to represent a small percentage of total health care expenditures, as seen in Figure 4, the annual percentage growth of prescription drug expenditures was 14.1% in 1997, nearly three times the percentage growth in total expenditures (4.8%) for the same year.

Figure 4

Annual Percentage Growth In National Health Expenditures By Category of Expense 1990-1997



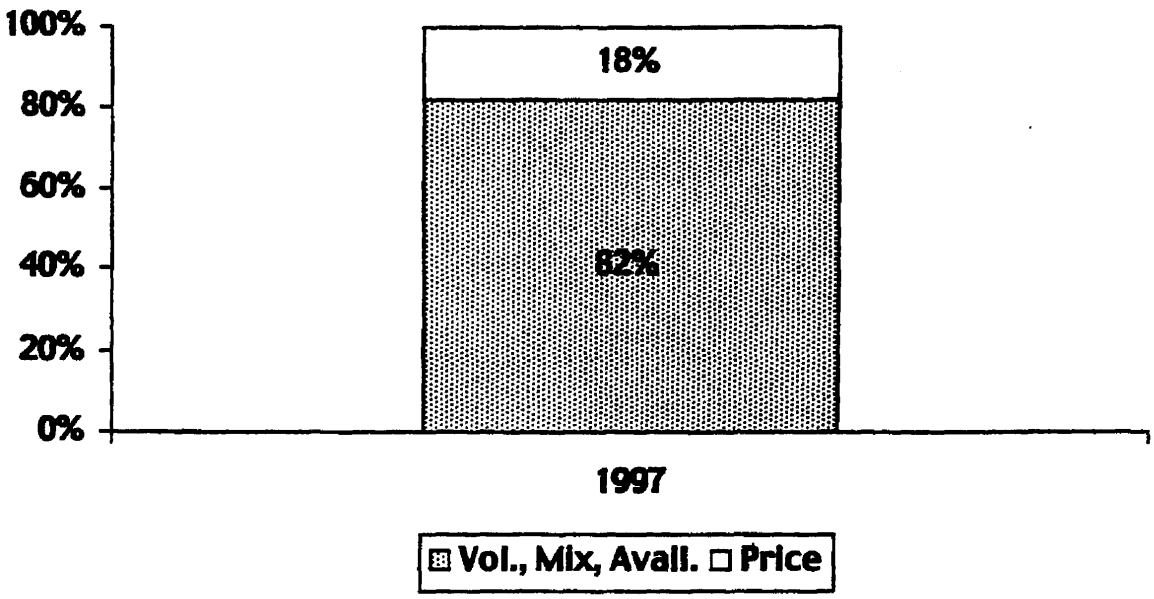
Source: National Health Care Expenditures, 1997, HCFA

Increased Volume, Mix And Availability Of Drugs Drives Cost Increases

According to HCFA, the recent increases in prescription drug expenditures are due in large part to the volume, mix and availability of drugs, whereas price increases for older drugs have played a considerably lesser role (see Figure 5). The sheer volume of prescriptions has increased by almost 600 million per year, growing from 1.9 billion in 1993 to 2.5 billion in 1998. The newer, higher-priced drugs (average price per prescription has increased from $26.21 in 1993 to $37.38 in 1998) are reflected in the "mix" of drugs being purchased. The increased number of persons who have a prescription drug benefit clearly has increased the "availability" of prescription drugs.

Figure 5

Factors That Drive Prescription Drug Expenditure Increases



Source: National Health Care Expenditures, 1997, HCFA

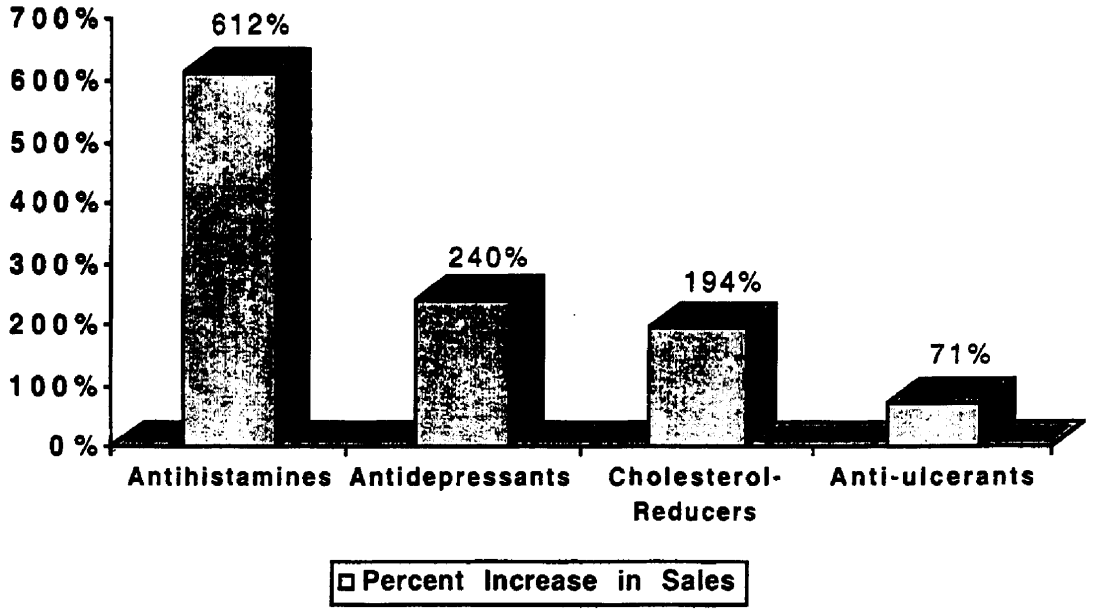
A Significant Portion Of Increased Prescription Drug Expenditures Is Concentrated In A Few Therapeutic Categories Which Tend To Include Heavily Advertised Drugs

According to a recent study published by the National Institute for Health Care Management (NIHCM), increases in total drug spending have been concentrated in a relatively small number of therapeutic categories: (i) oral antihistamines such as Claritin, Zyrtec, and Allegra; (ii) antidepressants such as Prozac, Zoloft, and Paxil; (iii) cholesterol-reducers such as Lipitor, Zocor, and Pravachol; and (iv) anti-ulcerants such as Prilosec, Prevacid, and Pepcid. Figure 6 illustrates the percentage increase in sales of each category of drug since 1993.

Figure 6

Percentage Increase in Sales for Four Top Therapeutic Categories

1993-1998



Source: NIHCM Foundation, July, 1999

The NIHCM study also found that these four categories of drugs accounted for 30.8% of the total increase in prescription drug expenses between 1993 and 1998. Figure 7 illustrates the dollar increase and the percent of the total increase in prescription drug expenditures that these four categories of drugs accounted for during the period 1993-1998.

Figure 7

Percentage Increase In Total Prescription Drug Costs Attributed To The Four Top Therapeutic Categories

1993-1998

	Antihist-amines	Anti-depres-sants	Cholesterol Reducers	Anti-Ulcerants	TOTAL
Dollar Increase*	$1.9	$5.0	$3.4	$2.7	$13.1
% Total Increase	4.5%	11.8%	8.0%	6.4%	30.8%

* Dollar increase in billions
• Totals do not add due to rounding

Source: NIHCM Foundation, July, 1999

Direct-To-Consumer Advertising Also Is Driving The Increase In Prescription Drug Expenditures

The NIHCM study found that the 10 drugs most heavily advertised directly to consumers in 1998 accounted for $9.2 billion or about 22% of the total increase in drug spending between 1993 and 1998. Seven of the 10 most heavily advertised drugs are among those previously listed as experiencing the greatest growth; these seven drugs are Claritin, Zyrtec, Allegra, Prozac, Zocor, Pravachol, and Prilosec. The other three most heavily advertised drugs were Propecia (a hair-loss treatment), Evista (an osteoporosis drug) and Zyban (a smoking deterrent).

The Increase In Prescription Drug Expenditures May Offset Other Cost Increases

The dramatic increases in prescription drug expenditures is not all necessarily bad news. More and more, drugs are used as a substitute for other

forms of health care services and often alleviate the need for more expensive treatments. Several studies have projected various levels of savings from more widespread use of certain prescription drugs.

Employers And Health Plans Have Absorbed Much Of The Increased Cost Of Prescription Drugs

HCFA's analysis of national health care expenditures from 1993 to 1998 indicate that much of the increase in the cost of prescription drugs has been shouldered by health plans and private employers. Third-party payments for prescription drugs have increased from 34.4% of total drug expenditures in 1990 to 50.6% in 1997, while at the same time, the percent of total drug expenditures paid through consumers' out-of-pocket payments actually decreased from 48.3% in 1990 to 29.2% in 1997. This is primarily due to the availability of prescription drug card benefits which typically require a small co-pay on the part of the patient.

Another indication that much of the increase in prescription drug costs is being borne by employers and health plans is evidenced by the NIHCM analysis of the HCFA data which indicated that prescription drugs accounted for more than one-third of the total 1993-1998 increase in medical benefits paid by private employers and health plans. This finding is illustrated in Figure 8.

The Increasing Cost Of Prescription Drugs Is Having A Serious Impact On The State Employee Health Benefits Program

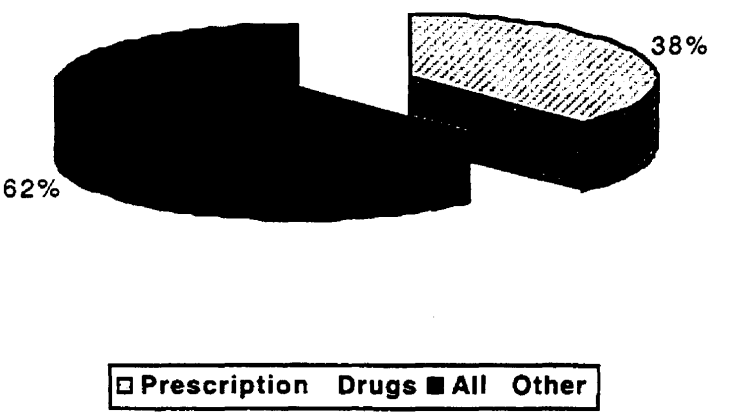
As noted above, employers and health plans have borne the greatest amount of the increasing cost of prescription drugs. The Commonwealth, as an employer, is among those being affected by these increases. This is evidenced by the fact that the prescription drug component of the total cost per employee has risen from $527 in fiscal year (FY) 1997 to $721 in FY 1999, an increase of 37%. Another indication of the increasing cost of the state employee prescription drug benefit is the increase in the total amount spent by the program on prescription drugs. As seen in Figure 9, this amount has increased from $42.6 million in FY 1997 to $56.3 million in FY 1999, a 32% increase in just two years.

In response to the rising cost of prescription drugs, the Department of Personnel and Training (DPT) projects that prescription drug costs will increase 24.6% per capita (for each employee and dependent) for FY 2001.

Figure 8

Prescription Drugs Accounted For 38% Of The Total Increase In The Cost Of Medical Benefits Paid By Private Employers And Health Plans

1993-1998



Source: HCFA, National Health Care Expenditure Projections, NIHCM Foundation, July, 1999

Three-Tiered Copayment Being Considered: One option being considered by DPT to help control plan costs is a three-tiered co-payment. Under this arrangement, three different levels of co-payment would be charged employees based on the cost of the prescription drug being purchased. The highest cost drugs would require the highest level of co-payment; employees would pay a lower co-payment for lower-priced drugs, and would pay the lowest co-pay for the lowest priced drugs. This process allows the employee to determine what drugs he/she wants to buy, but it also requires the employee to pay a higher co-pay when the selected drug is more expensive than other alternatives that are available.

The State Medicaid Program Also Has Seen The Cost Of Prescription Drug Benefits Increase

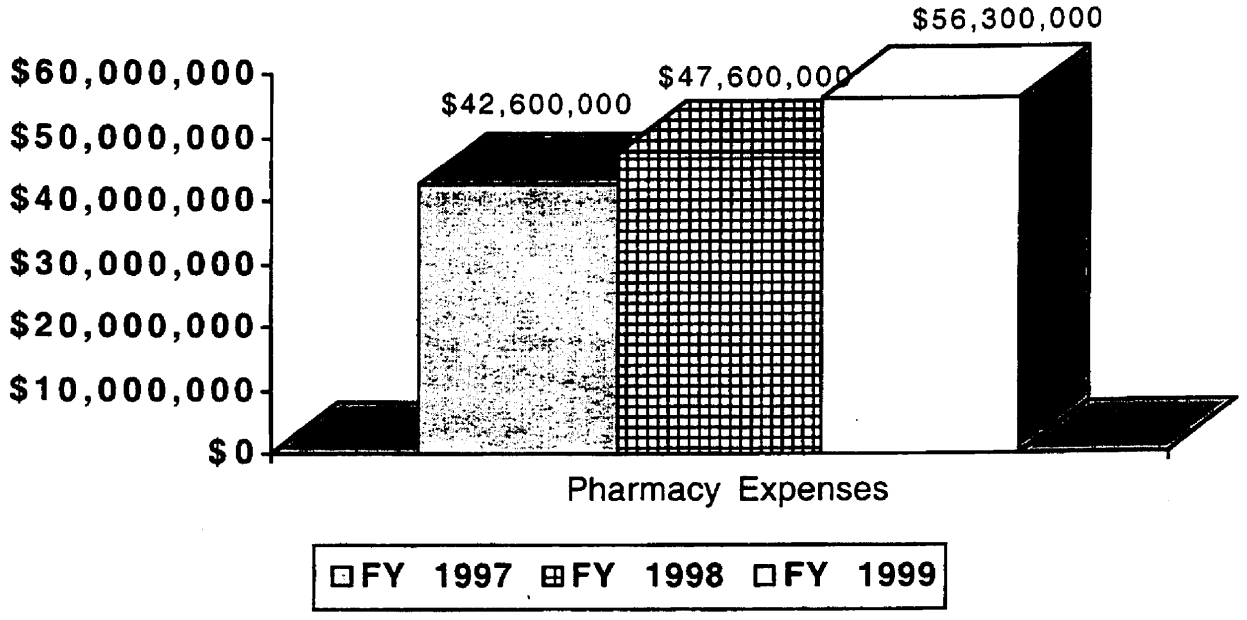
In addition to the increases seen in the state employee health benefits program, the state Medicaid program also has seen sharp increases in the cost of prescription drug benefits. Since 1993, annual Medicaid net expenditures (after

manufacturer rebates) for prescription drugs in fee-for-service programs have increased from $143.2 million in 1993 to $263 million in 1999, an 84% increase. (Medicaid receives a "unit rebate amount" for each drug that is paid for Medicaid recipients in fee-for-service programs. The rebate amounts are agreed to by HCFA and the drug manufacturers. The individual rebate amounts are proprietary information. DMAS reports that it received approximately $60 million in rebates in FY 1999.) Figure 10 illustrates the increases in net Medicaid prescription drug expenditures.

Figure 9

State Employees' Health Benefits Program:
Total Pharmacy Expense

1997-1999

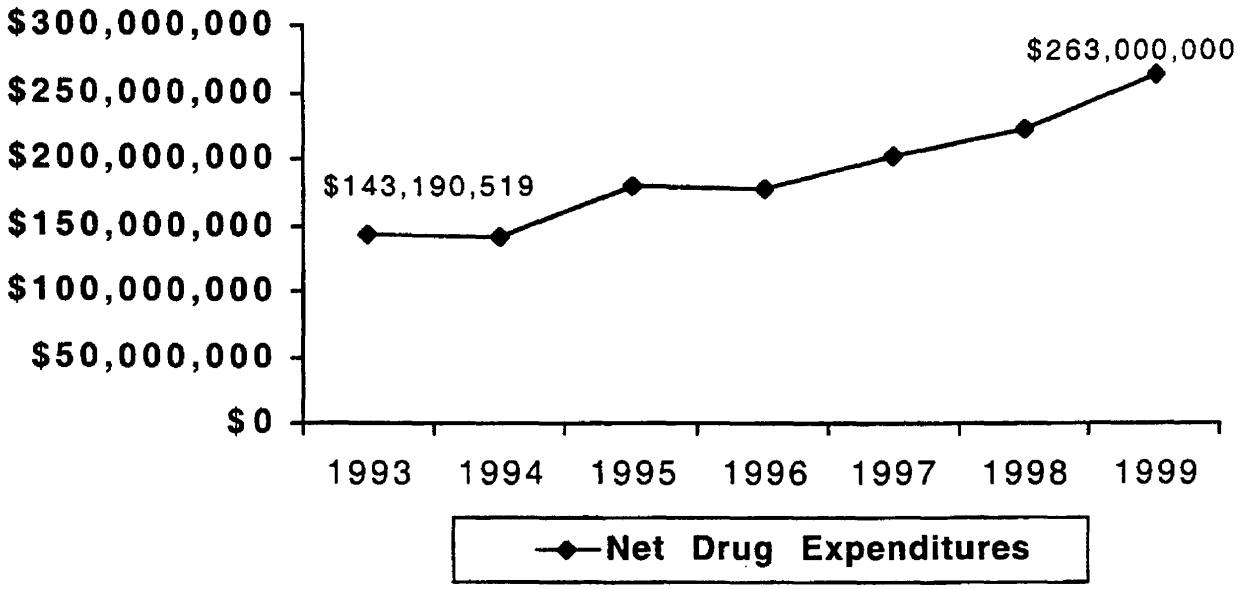


Source: Department of Personnel and Training

Figure 10

Medicaid Net Prescription Drug Expenditures

1993-1999



Source: Department of Medical Assistance Services, Statistical Record of the Virginia Medicaid Program

HCFA Projects That The Trend Of Increasing Prescription Drug Costs Will Continue Into The Foreseeable Future

According to HCFA, the recent increases in prescription drug expenditures are expected to continue at least through 2008. HCFA projects that the average annual percent change in expenditures for prescription drugs will continue at double-digit rates through 2005, and that the total amount spent on drugs will increase from the $78.9 billion level in 1997 to $243.4 billion in 2008, an increase of approximately 208%.

Health Plans And Employers Will Need To Find Ways To Manage Prescription Drug Costs In Order To Continue Offering Drug Benefits

As the cost of prescription drugs continues to increase, health plans and employers which sponsor employee health benefit programs will need to find ways to manage these costs in order to continue offering drug coverage as part of their overall health insurance benefits. The three-tiered copayment structure being considered by the state employee health benefits program has been implemented by a number of health plans and employers and is being considered by many others. Another strategy that has been used is to place a cap on the prescription drug benefit which establishes a dollar limit on the amount of prescription drug benefits that will be provided to a covered person.

A number of health plans and employers also have begun to mandate generic substitution of brand name drugs when a generic is available. This is a particularly effective strategy given the sizable difference in the average generic price and the average brand name price of drugs. Formularies and other practices such as disease management programs, utilization review programs, and therapeutic interchange of chemically dissimilar drugs also are being employed to help control costs.

III.
The Practice Of Therapeutic Interchange, Virginia's Drug Control Act And Recent Legislative Actions

There Are Varying Definitions Of Therapeutic Interchange Of Chemically Dissimilar Drugs; Therapeutic Interchange Occurs In Different Ways For Different Reasons

The practice of therapeutic interchange of chemically dissimilar drugs has been defined in various ways. A definition of therapeutic interchange was adopted by a Special Task Force formed to study this issue pursuant to HJR 630 of the 1997 Session of the General Assembly. This task force unanimously adopted the following definition of the practice 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."*

Pharmacy Benefit Managers: Another term that is often associated with therapeutic interchange is "pharmacy benefit managers" or PBMs. Like "therapeutic interchange," there are varying definitions and descriptions of PBMs. However, in general, PBMs are organizations whose primary function is to administer and manage pharmaceutical benefits for customers (e.g., HMOs and other health insurers, employers, and governmental benefit programs). PBM practices may include processing, adjudicating and analyzing prescription drug claims, managing pharmacy networks, and managing prescription drug formularies.

Formulary: A drug formulary is a list of approved, recommended, or preferred drugs used by a PBM, managed care organization, hospital, or other entity. Drugs are evaluated for inclusion on a given formulary based on safety, efficacy, and cost. A pharmacy and therapeutics (P&T) committee composed of pharmacists and physicians decides which drugs will be included on the formulary.

Formularies generally fall into one of three categories. An "open" formulary is the least restrictive and lists all drugs. While there may be a ranking of "preferred" drugs, the health benefits plan sponsor provides reimbursement for both formulary and non-formulary drugs. An "incentive-based" or "preferred" formulary includes only preferred drugs. Plan sponsors typically will cover non-formulary drugs; however, incentives (e.g., lower copays) are used to encourage selection of a formulary drug. A "closed" formulary generally is one in which the plan sponsor will provide reimbursement only when the prescribed drug is on the formulary unless a physician determines the non-formulary drug is medically necessary.

Therapeutic Interchange Is Different From Generic Substitution: It is important to differentiate between *therapeutic interchange*, which involves chemically dissimilar drugs, and *generic substitution*, which involves substituting a chemically identical generic drug for a brand name drug. The issues discussed herein are applicable only to therapeutic interchange and not generic substitution.

Setting of Therapeutic Interchange: Therapeutic interchange began in hospital settings and has been in practice in the inpatient setting for many years. Only in recent years has the practice become prevalent in outpatient settings. The issues discussed in this report focus on therapeutic interchange that occurs in outpatient settings in retail and mail-order pharmacies.

Clinical vs. Financial Reasons: The practice of therapeutic interchange can be described from a number of different perspectives and can be classified in various categories. Perhaps the most fundamental way to distinguish among the different reasons for seeking to switch an initial prescription to a chemically dissimilar drug is whether the interchange is done for clinical reasons or for financial/cost reasons. A common "clinical" reason for a therapeutic interchange is when the patient is taking other prescription medications and the interaction of the newly prescribed drug and the other medications could be harmful to the patient. Obviously, for clinical reasons, a therapeutic interchange is warranted to ensure the safety and health of the patient.

Other "clinical" reasons could include: (i) the patient has had prior experience with the originally prescribed drug that was unsatisfactory and requests a different drug; (ii) a newer, more clinically effective drug is identified by the pharmacist, health plan, or pharmacy benefit manager (PBM); and (iii) the originally prescribed drug may have a less favorable side effect profile than another chemically dissimilar, but therapeutically equivalent drug. There is almost universal agreement among all parties that in situations where there are

"clinical" indications that a drug other than the one originally prescribed would produce better clinical results, therapeutic interchange is appropriate.

While there is little or no debate over the appropriateness of therapeutic interchange when clinically indicated, there is considerable debate and strongly-held opposing views over the appropriateness of some instances of therapeutic interchange when performed for financial/cost reasons.

Therapeutic Interchange For Financial/Cost Reasons Involves Lower Copayments, Greater Discounts Or Rebates, Or Other Forms Of Financial Incentives To Use A Drug Other Than That Originally Prescribed For The Patient

Therapeutic interchange that occurs for reasons other than clinical indications is performed for financial or cost reasons. In these instances, the switch is pursued because of lower copayments, greater discounts or rebates, or other forms of financial incentives that the patient or some entity(ies) receives as a result of the switch. For the most part, there is little opposition or concern regarding therapeutic interchange when it is pursued as a means of providing the patient with a lower cost drug that directly saves money for the patient in the form of a lower copayment. (This assumes there is no indication that the lower cost drug would be clinically inappropriate or less effective for the patient.) However, as the financial incentive or economic reason for the switch becomes more and more removed from directly lowering the cost of the prescription for the patient, there are significant differences of opinion as to the appropriateness of this practice. (These differing opinions will be discussed in Section IV of this report.)

Discounts/Rebates/Other Financial Incentives: Therapeutic interchange that occurs for financial reasons other than a lower copayment for the patient generally is driven by discounts, rebates or other types of financial incentives. Drug manufacturers provide rebates to the PBM, health plan, or health system that is managing/ administering the prescription drug benefit for the patient. In these instances, the discounts or rebates are provided in order to increase the sales of certain drugs. The amount of the financial incentive often is tied to the volume of drug sales; therefore, an incentive often exists for the PBM, health plan or health system to encourage as many switches to the particular drug(s) as possible. Proponents of therapeutic interchange argue that these types of switches save money and are pursued only when clinically appropriate. Those who oppose therapeutic interchange that involves only financial incentives would argue that, in these instances, concern for the patient is not always as paramount as it should be.

A Study Of Therapeutic Interchange Commissioned By The Department Of Medical Assistance Services Identified Five Types Of Therapeutic Interchange

In response to HJR 574 of the 1997 Session of the General Assembly, the Department of Medical Assistance Services (DMAS) commissioned a study of therapeutic interchange of chemically dissimilar drugs. As part of its overall study, DMAS contracted with the Mercatus Center at George Mason University to determine the incidence of therapeutic interchange, the reasons that therapeutic interchange is initiated, the annual incidence of patient complaints, the perceptions of physicians and pharmacists on whether therapeutic interchange improves or worsens clinical outcomes, and other related issues. (The DMAS study also included a VCU School of Pharmacy survey of citizens which is discussed later.)

In the DMAS report, published in August, 1999, five types of therapeutic interchange were identified based on the broad definition adopted by the Task Force Studying the Practice of Therapeutic Interchange (see page 17). As previously noted, there are many different ways to define or categorize the types of therapeutic interchange. The five types of therapeutic interchange identified in the DMAS report are:

- *Formulary exclusion*, which describes interchanges that are made because the original prescribed drug is not covered on the pharmacy plan formulary;
- *Formulary inclusion*, which describes interchanges made because the originally prescribed drug is not a preferred drug on the pharmacy plan formulary;
- *Patient initiated*, which are instances wherein the patient requests the drug be changed (these can also be formulary exclusion or formulary inclusion types of interchanges as well);
- *PBM financial incentive*, which describes interchanges the pharmacy initiates as a result of financial incentives the PBM gives the pharmacy; and
- *Manufacturer financial incentive*, which describes interchanges that are initiated as a result of financial incentives the pharmaceutical manufacturer has agreed to pay.

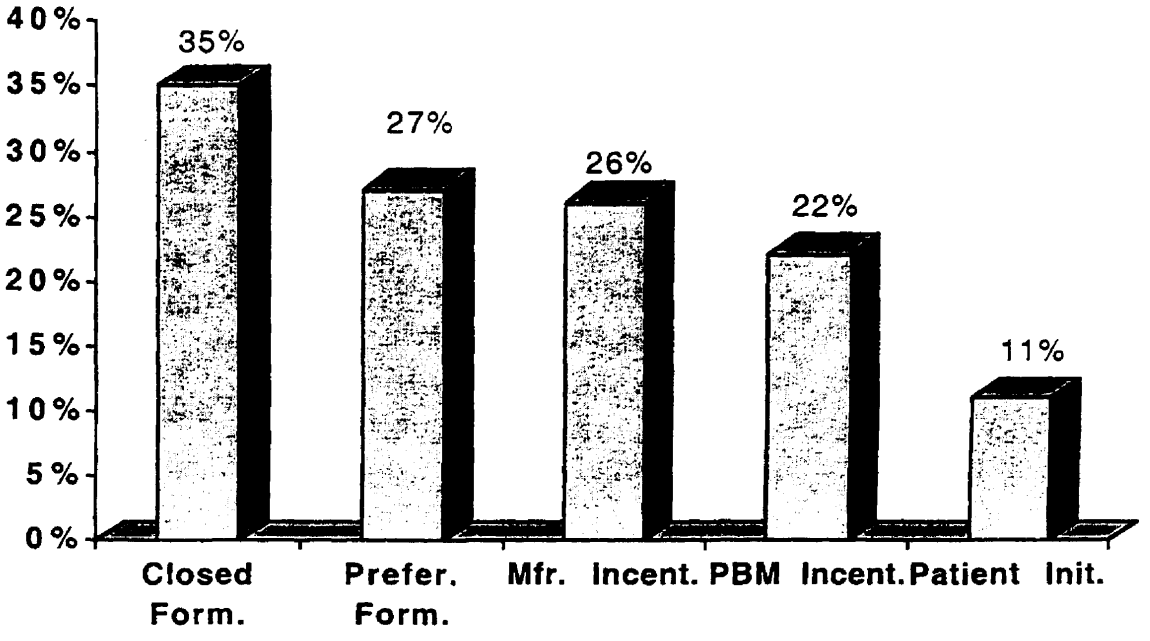
The DMAS study reported that interchanges due to closed formularies are reported by pharmacists as the most frequent reason for initiating a therapeutic interchange. Figure 11 illustrates the percentage of therapeutic interchanges initiated for each of the five types identified above. While therapeutic interchanges due to closed formularies (35%) and preferred formularies (27%) are cited as the most frequent reasons for initiating a switch, it is important to remember that the cost of drugs, often driven by financial incentives, is part of the consideration in determining which drugs are on a particular formulary. (As previously noted, drugs are selected for inclusion in formularies generally on the

basis of safety, efficacy and then cost.) Therefore, financial incentives are at least indirectly involved in most, if not all, interchanges initiated for reasons other than clinical indications.

Figure 11

Therapeutic Interchanges By Reason Of Initiation

1998



Note: Total exceeds 100% due to more than one reason could apply to some interchanges
Source: Department of Medical Assistance Services, HJR 574 Final Report

Virginia's Drug Control Act Prohibits A Pharmacist From Dispensing A Drug Other Than That Prescribed Unless The Prescriber Has Authorized The Change

Section 54.1-3457 of the *Code of Virginia* identifies a number of prohibited acts regarding the practice of pharmacy. Among the prohibited acts listed in this section is: "dispensing or causing to be dispensed, except as provided in §32.1-87 relating to the Virginia Voluntary Formulary, a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without the permission of the person ordering or prescribing." This law clearly states that any therapeutic interchange must first be approved by the prescriber.

Therapeutic Interchange Has Been The Focus Of Several Legislative Proposals And Studies

The issue of therapeutic interchange has been debated in the Virginia General Assembly on several occasions in the past few years. Bills were introduced in the 1997 and 1998 Sessions that dealt directly with therapeutic interchange. Other bills that relate to some of the issues around therapeutic interchange were passed in the 1999 Session. There also have been several studies conducted on therapeutic interchange and the practices of PBMs. The following paragraphs summarize these legislative proposals and studies according to the year in which they were introduced.

1997 Legislation

HB 2714/SB 1114 (1997) Anti-Drug Switching Patient Protection Act: As introduced, these bills would have prohibited the practice of soliciting or encouraging, after a physician with a bona fide physician/patient relationship issues a prescription for a drug, the substitution of that drug with a chemically dissimilar drug for the purpose of rebate, kick-back, or other such remuneration. The bills would have established civil penalties ranging from $10 per violation to $25,000. No action was taken by the House Committee on Health, Welfare, and Institutions (HWI) on HB 2714. SB 1114 passed the Senate with a substitute, but was passed by indefinitely in HWI.

House Joint Resolution 630 (1997): This resolution established a task force to study the practice of therapeutic interchange; a report was issued in 1998 (HD 57). It should be noted that several members of the task force submitted a minority report citing a dissenting opinion regarding the recommendations and proceedings of the task force.

House Joint Resolution 574 (1997): This resolution requested the Department of Medical Assistance Services (DMAS) to examine the impact of the practices of PBMs on the Commonwealth's citizens and upon the health care market. An interim report was published in January, 1999 (HD 32). A final report was issued in August, 1999. The findings of this report are discussed in detail in Section IV of this report.

1998 Legislation

HB 1127/SB 710 (1998) Ethics In Prescription Drug Choice Act: These bills were very similar to HB 2714/SB 1114 of the 1997 Session. As introduced, the 1998 bills would have prohibited the practice of soliciting or encouraging,

after a prescribing practitioner issues a prescription for a drug, the substitution of that drug with a chemically dissimilar drug for the purposes of rebate, kick-back, or other such remuneration. The bill would have established civil penalties ranging from $10 to $1,000, and would have provided for recovery of damages, if any. HB 1127 passed the House with amendments and was continued to 1999 in the Senate; no action was taken in the Senate Education and Health Committee. SB 710 was continued to 1999 in the Senate; no action was taken in the Senate Education and Health Committee.

HJR 140/SJR 106 (1998): These resolutions were approved by the 1998 General Assembly and continued the Special Task Force Studying the Practice of Therapeutic Interchange of Chemically Dissimilar Drugs. The reason for continuing the Task Force was to enable the members to review the findings of the HJR 574 study from the previous year. However, as noted above, the interim report from the HJR 574 study was not published until January, 1999. As such, the HJR 140/SJR 106 Task Force did not meet.

1999 Legislation

SB 1235/HB 871 (1999): These bills were passed by the 1999 General Assembly and signed by the Governor. The legislation became effective July 1, 1999. This legislation includes various provisions regarding managed care health insurance plans. Among the provisions are several that relate to prescription drug benefits.

- The state employee health plan and other private health insurance plans are allowed to utilize drug formularies so long as the formulary is developed, reviewed at least annually, and updated as necessary in consultation with and with the approval of a pharmacy and therapeutics committee, a majority of whose members are actively practicing physicians and pharmacists.

- The state employee health plan and private plans must establish a process to allow a person to obtain without additional cost-sharing, a specific, medically necessary non-formulary drug, if after reasonable investigation and consultation with the prescribing practitioner, the formulary drug is determined to be inappropriate therapy.

- Private plans must disseminate to providers and pharmacists the complete, current drug formulary(ies) including a list of drugs on the formulary by major therapeutic category that specifies whether a particular drug is preferred over other drugs.

SB 1154/HB 2428 (1999): These bills were passed by the 1999 General Assembly and signed by the Governor. The legislation became effective July 1, 1999. This legislation enables pharmacists and physicians to enter into "collaborative agreements" which authorize cooperative procedures related to treatment using drug therapy, laboratory tests or medical devices, under defined conditions and/or limitations, for the purpose of improving patient outcomes. The legislation includes a "sunset" provision indicating that the act will expire on July 1, 2004.

Discussions Were Held Regarding Whether The Virginia Voluntary Formulary Board Should Regulate Therapeutic Interchange; The Board Strongly Opposes Being Charged With The Responsibility For This Function

In attempting to reach a workable framework of monitoring and regulating therapeutic interchange, there were discussions in the recent past regarding this function being the responsibility of the Virginia Voluntary Formulary Board. This Board is established in §32.1-79 et. seq. of the *Code of Virginia* to recommend to the State Health Commissioner a formulary of generic equivalents of brand name drugs. Given the expertise of the Board members, consideration was given to having the Board assume some responsibility for regulating the practice of therapeutic interchange. However, the Board indicated that determining generic equivalents is entirely different from determining "therapeutically equivalent" drugs. The Board strongly opposes having to assume this responsibility.

IV.
The Incidence, Impact And Controversy Of Therapeutic Interchange

Literature reviews and interviews of various interested parties indicate that there is only minimal information available regarding the incidence of therapeutic interchange. However, the study of therapeutic interchange commissioned by the Department of Medical Assistance Services (DMAS) in response to HJR 574 included an analysis of how often therapeutic interchange occurs in Virginia. DMAS presented the results of its study to the HJR 734 Subcommittee at its August 12th meeting. The following paragraphs summarize the findings of the DMAS study.

The DMAS Analysis Of Therapeutic Interchange Is Based On Surveys Of Physicians, Pharmacists, And Citizens

DMAS contracted with Virginia Commonwealth University's School of Pharmacy to conduct a survey of citizens to determine the impact of PBM practices. The primary focus of the survey was on the PBM practice of therapeutic interchange. DMAS also contracted with the Mercatus Center at George Mason University to survey pharmacists and physicians to determine the incidence of therapeutic interchange, the reasons that therapeutic interchange is initiated, the annual incidence of patient complaints and the perceptions of physicians and pharmacists on whether therapeutic interchange improves or worsens clinical outcomes.

The DMAS Report Concluded That The Incidence Of Therapeutic Interchange Represents A Small Percentage Of Total Prescriptions Written

The findings of the Mercatus Center survey of physicians indicate that therapeutic interchange represents approximately 3% of total prescriptions written by physicians in Virginia. Specifically, the report states that of the approximately 65 million prescriptions written by physicians in 1998, 1.8 million involved a therapeutic interchange. This finding is corroborated by the findings of the VCU School of Pharmacy survey of Virginia citizens which estimated that 3.8% of persons with insurance coverage, or 3.1% of all Virginians, reported a therapeutic interchange during the 12-month period preceding the survey. Persons who had experienced a therapeutic interchange averaged between 2-3 interchanges during the 12-month period.

The authors of the study caution that the estimates of citizens experiencing therapeutic interchange are based on the perspective of the patient/consumer, and that the respondent may not always completely understand the practice of therapeutic interchange. The authors also note that these findings have a low statistical reliability because of the low number of cases having involved a therapeutic interchange.

The Impact Of Therapeutic Interchange Generally Is Evaluated In Terms Of Its Impact On Clinical/Patient Outcomes And On Costs; The Limited Amount Of Data In The Area Of Clinical/Patient Outcomes Has Produced Somewhat Mixed Results; The U.S. Food & Drug Administration (FDA) Reports Relatively Few Adverse Events

With respect to the impact of therapeutic interchange on clinical or patient outcomes, different authors/researchers have reached different conclusions regarding whether therapeutic interchange affects clinical/patient outcomes. In addition to the more formal research on the matter, several individual cases have been written about in newspaper and magazine articles wherein patients have experienced adverse effects following a therapeutic interchange. It is difficult to generalize the circumstances of these cases to the general population. The following paragraphs summarize some of the more frequently cited research efforts and articles on this topic as well as findings of the DMAS study on PBMs and therapeutic interchange that deal with clinical/patient outcomes.

The "Horn" Study Found That Therapeutic Interchange Leads To More Health Care Utilization; However, The Study Has Been Criticized For Methodological Flaws

This study is one of the most often-cited research efforts on the impact of therapeutic interchange. Susan Horn, a Ph.D. researcher from the Institute for Clinical Outcomes Research, was the lead investigator in a 1996 study on the intended and unintended consequences of managed care cost-containment strategies. The study examined the relationship of various managed care cost-containment strategies with the utilization of ambulatory care visits, hospital admissions, and prescription drugs. The study compared the ambulatory services provided to patients who had at least one of these five diseases (arthritis, asthma, epigastric pain/ulcer, hypertension, and otitis media (inflammation of the ear).

The Horn study concluded that, for all conditions except otitis media, formulary limitations on drug availability were significantly and positively related to higher rates of emergency department visits and hospital admissions, and positively, but not always significantly, related to drug cost, drug counts and

office visits. Horn concluded that greater formulary limitations were associated with greater health care utilization.

It must be noted that several articles were published after the Horn study criticizing it for various methodological flaws. Among the criticisms are that the study: (i) used an inappropriate study design; (ii) did not assess the proper data to show conclusively that a drug formulary results in denied access to certain prescription drugs and subsequently results in high total costs; and (iii) used an artificial measure of "formulary restrictiveness" which invalidates the research findings. Horn responded to these criticisms and defended her research. In sum, as with many aspects of the issue of therapeutic interchange, there are differing opinions regarding the validity and import of the Horn study.

The DMAS Study of Therapeutic Interchange Included An Analysis Of Physicians And Pharmacists' Perceptions On The Clinical Impact Of Therapeutic Interchange, And Patients' Satisfaction With Therapeutic Interchange

The DMAS study on therapeutic interchange included data on physicians, pharmacists, and patients' views on the impact of therapeutic interchange on clinical/patient outcomes. It is important to bear in mind that the findings of the DMAS study are based only on the opinions of pharmacists, physicians and patients, and not on empirical evidence of the impact of therapeutic interchange on clinical outcomes. The DMAS data also include information on the number of patient complaints and the level of patients' satisfaction with their prescription drug coverage.

The majority of physicians (59%) reported that they believe therapeutic interchange worsens outcomes; 38% of pharmacists shared that view. Figure 12 illustrates the opinions of pharmacists and physicians on the issue of whether therapeutic interchange improves outcomes, makes no difference, or worsens outcomes.

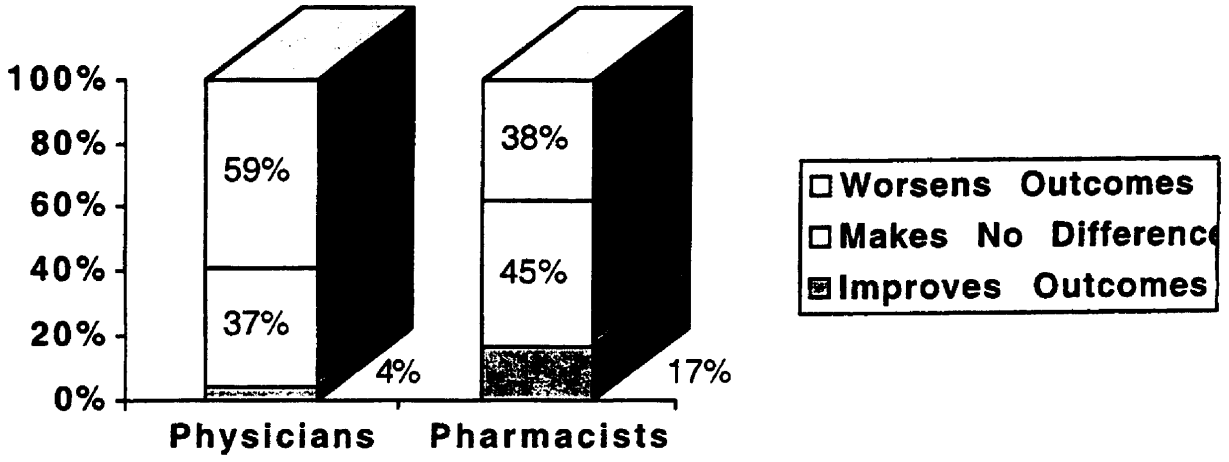
Physicians And Pharmacists Report Very Few Patient Complaints: Physicians reported that they receive complaints from about 4% of the patients who experience a therapeutic interchange, whereas pharmacists indicated that about 2% of patients complain.

Patient Satisfaction With Prescription Drug Coverage Is High, But Somewhat Lower For Persons Who Experience A Therapeutic Interchange; About Twenty-Nine Percent Of Persons Who Experienced A Therapeutic Interchange Reported They Were Not Satisfied With The New Drug They Were Switched To

The VCU survey of citizens found that while patient satisfaction with prescription drug benefits is high among those who had experience a therapeutic interchange, the level of satisfaction is lower than that of persons who had not experienced a therapeutic interchange. Figure 13 illustrates this finding.

Figure 12

Physicians and Pharmacists' Views On The Impact of Therapeutic Interchange on Patient Outcomes

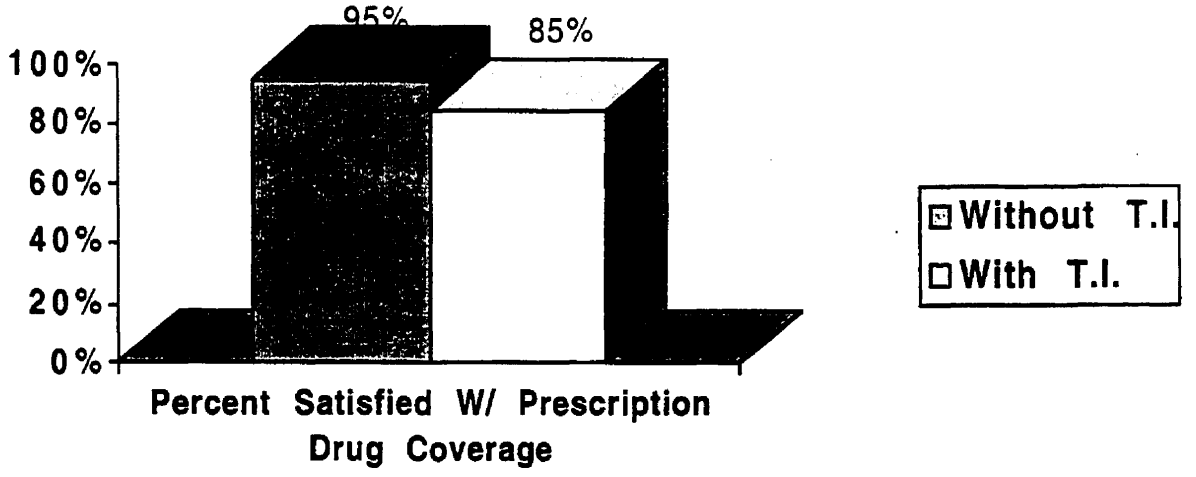


Source: Department of Medical Assistance Services, HJR 574 Final Report

Seventy-one percent of the survey respondents who had experienced a therapeutic interchange reported they were satisfied with the new drug; however, 29% reported they were not satisfied. For those persons who reported they had already been taking a drug for some time when the therapeutic interchange to a new drug occurred, 65% reported that the new drug worked better or about the same as the original drug; 35% stated the new drug did not work as well as the original drug. (It is important to remember that because the number of persons experiencing a therapeutic interchange is small [3% of total respondents], the percentages noted above are based on a very small number of respondents [N].)

Figure 13

Patients' Satisfaction With Prescription Drug Coverage



Source: Department of Medical Assistance Services, HJR 574 Final Report

The U.S. Food & Drug Administration's "MedWatch" Program Has Received Reports Of Adverse Events Associated With Therapeutic Interchange

The U.S. Food & Drug Administration (FDA) administers a program called "MedWatch." MedWatch is a voluntary program for health care professionals to report adverse medical events. The program serves as a signaling system to identify potential problems. In March, 1997, the FDA requested that health care professionals submit reports of any adverse consequences associated with therapeutic interchange. The request was made through a memorandum to health care professionals. FDA's activities in this area also were reported through articles in the FDA Medical Bulletin and the Journal of the American Medical Association. Staff from FDA's Division of Drug Marketing, Advertising and Communications presented the results of the MedWatch reports for 1997 and 1998 at the September 29th meeting of the HJR 734 Subcommittee. The following paragraphs summarize the FDA presentation.

Relatively Few MedWatch Reports Relate to Therapeutic Interchange: Based on the FDA MedWatch reports from 1997 and 1998, adverse events related

to therapeutic interchange comprise a small number of the total incidents reported. Figure 14 summarizes the number and types of reports received in 1997 and 1998.

Figure 14

Results Of "MedWatch" Reports Related To Therapeutic Interchange

	1997 MedWatch Reports (Mar.-Dec.)	1998 MedWatch Reports (Calendar Year)
Total Number of Voluntary Reports	10,000	16,000
Reports Related To Therapeutic Interchange	108	61
Percentage of Adverse Events Related to Lack of Effect of New Drug	30%	10%
Percentage of Adverse Events Related to "Side Effect" of New Drug	70%	90%
Reports of Death	None	None
Percent of Cases That Led To Hospitalization or Intervention To Prevent Permanent Morbidity	10%	5%
Percent Of Reports Related To Proton Pump Inhibitor Side Effects	50%	30%

Source: FDA Presentation to HJR 734 Subcommittee, September 29, 1999

As seen in Figure 14, adverse events associated with therapeutic interchange represent a very small percentage of the total number reported to FDA. It must be noted, however, that there are limitations to the FDA data. First, because the MedWatch program is voluntary, these results do not represent the entire number of potential adverse events associated with therapeutic

interchange. The results reported in Figure 14 represent only those reported to FDA. FDA also cautions that the results of MedWatch indicate that therapeutic interchange is associated with the adverse consequences. Without further investigation and appropriately designed experimental trials, the data should not be used to say that therapeutic interchange caused the adverse consequence. Proponents of therapeutic interchange also would argue that these types of adverse consequences also can occur as a result of the originally prescribed medication.

The FDA representative provided some additional information regarding 10 of the hospitalizations associated with therapeutic interchange that occurred in 1997 and 1998. Two of these examples from each year are presented in Figure 15.

The FDA official who addressed the HJR 734 Subcommittee indicated that, with the limited information they have been able to collect, it is difficult to determine the degree to which a problem with therapeutic interchange exists. FDA plans to continue collecting and analyzing information regarding adverse events associated with therapeutic interchange.

In Instances Where Therapeutic Interchange Lowers The Patient's Copayment, This Practice Decreases The Cost To The Patient

The impact of therapeutic interchange on the cost of prescription drugs varies depending on the manner in which it is performed. In instances where the patient's copayment to purchase the drug is lowered, therapeutic interchange does decrease the cost of that particular transaction for the patient. This type of cost-savings for the patient occurs when the drug originally prescribed is not on the formulary and the new drug is, or when the original drug is not a "preferred" drug on the formulary and the new drug is preferred. In either instance, when the copayment is lower as a result of being switched to the new drug, the patient saves money on that transaction.

Determining The Impact Of Therapeutic Interchange On The Cost Of Prescription Drugs And Overall Health Costs Is Difficult To Measure; HMOs And Employers Believe Cost Savings Are Achieved, Physicians And Pharmacists Question The Level Of Savings

While one of the key goals of therapeutic interchange is to control the cost of prescription drugs, it is difficult to determine exactly what the impact is both on prescription drug costs and on overall health care costs. In the 1998 DMAS study (HD 32) on the practices of PBMs, the VCU School of Pharmacy reported that most studies found that drug costs decreased, and that there was minimal effect on other services. However, the authors cautioned that "these studies are

characterized by weak research designs and small samples of both patients and products. 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."

Figure 15

Examples of Hospitalizations Associated With Therapeutic Interchange Adverse Events Reported To FDA's MedWatch Program

1998 Hospitalizations

- *A 45 year old male was switched from Lescol to Zocor. Nine days later, the patient complained of acute retrosternal chest pain and was admitted to the hospital. Patient was found to have a CP (muscle enzyme level) of 92,000 and myoglobin in his urine. Emergency treatment of acute rhabdomyolysis (muscle cell damage).*

- *A 66 year old male presented with acute renal failure. Patient began experiencing watery bowel movements about 4 days after being switched from Prilosec to Prevacid. Patient received aggressive hydration; diarrhea resolved. Patient was restarted an Prevacid and diarrhea returned. After changing back to Prilosec, diarrhea stopped.*

1997 Hospitalizations

- *A 55 year old male took Feldene for years, and then was switched to Voltaren due to restricted formulary list. Patient took 3 Voltaren tablets, later collapsed, and was brought to the hospital with symptoms of septic shock (systolic blood pressure=60, tachycardia, serious problems with blood clotting system (DIC), and increased hepatic enzymes). Patient was treated and returned home. Patient took 1 Voltatern tablet, had same reaction, and was hospitalized.*

- *A 55 year old male with longstanding ulcer disease was stable on Zantac. HMO mandated switch to Axid and peptic ulcer symptoms increased. HMO approved one month of Zantac, then resumed Axid. Patient was hospitalized with gastrointestinal bleed. (Definite association with rechallenge.)*

Note: The above examples were among 10 cases presented to the HJR 734 Subcommittee

Source: FDA Presentation to HJR 734 Subcommittee, September 29, 1999

The literature contains various reports and articles on this issue, but most are general discussions of the topic or opinions offered by various interested parties. There is little in the way of rigorous research or analysis that provides a definitive answer to the question of cost savings. There are reports which conclude therapeutic interchange actually increases costs, and others which conclude costs decrease as a result of this practice. However, as the VCU School of Pharmacy noted in its 1998 report, many of these have been challenged on methodological weaknesses.

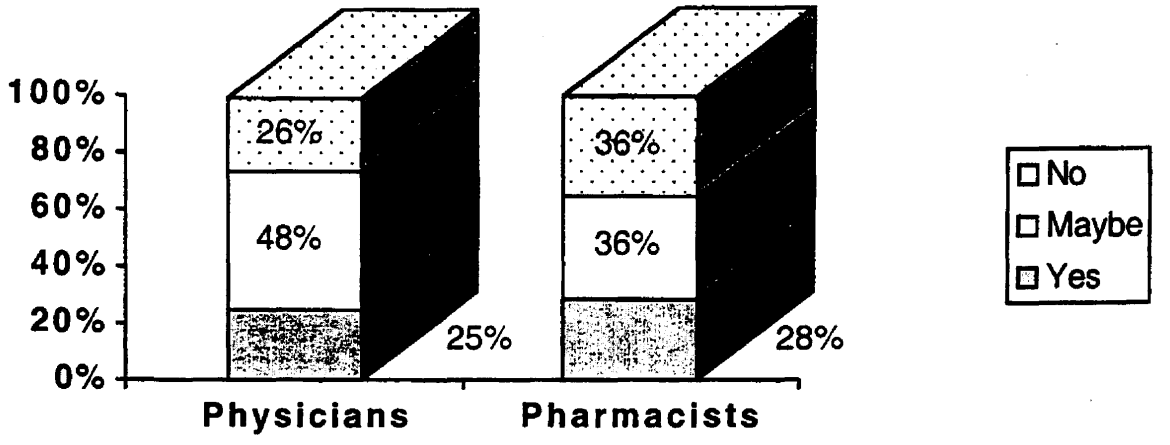
Health Plans' Views of Cost Savings: Health insurers and employers insist that therapeutic interchange and other PBM practices produce substantial savings in prescription drug costs. A 1997 study of HMO experiences with PBMs conducted by the Inspector General of the U.S. Department of Health and Human Services indicated that HMOs believe the biggest benefit of using PBMs is their ability to control prescription drug costs. Nearly 80% think PBMs help contain prescription costs to either a great extent (35%) or a moderate extent (44%). Slightly more than half (55%) of HMOs think PBMs help either to a great or moderate degree in containing overall health care costs. (It should be noted here that this study also reported HMOs' biggest concern with PBMs to be the potential for bias resulting from the PBMs' alliances with drug manufacturers.)

Physicians & Pharmacists' Views on Cost Savings: While insurers and employers are convinced of the savings attributable to therapeutic interchange and PBM practices, physicians and pharmacists are not convinced of the savings. In the DMAS study mentioned earlier, the Mercatus Center survey of physicians and pharmacists asked whether therapeutic interchange helped to control prescription drug costs and overall health costs. As seen in Figure 16, physicians and pharmacists have mixed views on whether therapeutic interchange produces savings in prescription drug costs.

Physicians and pharmacists have less favorable views on whether therapeutic interchange can reduce overall health care costs. Figure 17 illustrates the opinions of physicians and pharmacists in this regard.

Figure 16

Physicians And Pharmacists' Views On Whether Therapeutic Interchange Controls Prescription Drug Costs



Source: Department of Medical Assistance Services, HJR 574 Final Report

Drug Manufacturers' Views on Cost Savings: A representative of Pharmaceutical Research & Manufacturers of America (PhRMA) testified before the HJR 734 Subcommittee that restrictive formularies and therapeutic interchange may not be cost-effective in the long-run. The PhRMA representative cited the "Horn" study and a study of the Louisiana Medicaid program conducted in 1989 as evidence that restricted drug formularies and therapeutic interchange can result in higher overall health care costs. PhRMA also mentioned "a recent study in Virginia has come to the same conclusion – that the increased money spent on the *most appropriate* drug to treat schizophrenia results in benefits for both the payer and the patient, and an overall decrease in costs."

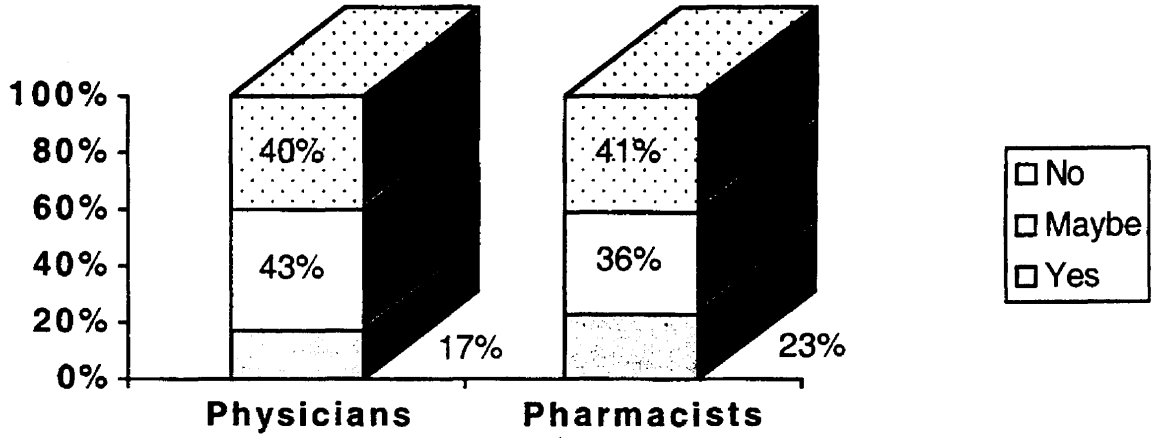
A 1997 GAO Study Reported That PBMs Generated Significant Savings In Prescription Drug Costs For The Federal Employees' Health Benefits Plan

The General Accounting Office (GAO) conducted a study in 1997 on PBMs. The study looked at three health plans that provided prescription drug benefits to the Federal Employees Health Benefits Program (FEHBP). The GAO report indicates that the health plans estimated "that PBMs saved them [FEHBP

program] more than $600 million in 1995 by obtaining manufacturer and pharmacy discounts and managing drug utilization. These savings reduced the pharmacy benefit costs each plan believes it would have paid without using a PBM by between 20 and 27 percent." (It must be noted that GAO stated in the report that the savings are based on the plans' estimates of what they would have paid for prescription drugs and related services without a PBM. The estimates were prepared by plan or PBM officials using PBM savings data. Savings estimates were not examined by independent auditors.)

Figure 17

Physicians And Pharmacists' Views On Whether Therapeutic Interchange Controls Overall Health Care Costs



Source: Department of Medical Assistance Services, HJR 574 Final Report

There Is A Considerable Amount Of Controversy Over Therapeutic Interchange Of Chemically Dissimilar Drugs; Many Pharmacists And Physicians Have Serious Concerns About Certain Aspects Of Therapeutic Interchange

As evidenced by the number of legislative proposals and studies regarding therapeutic interchange, there is a considerable amount of controversy over this practice. While health plans, PBMs, many employers, and some pharmacists

(primarily those associated with managed care plans or health systems) endorse the practice, physicians and a number of pharmacists have serious concerns.

Pharmacists: The pharmacists that have raised the most concerns about therapeutic interchange are independent pharmacists. A group of approximately 100-200 independent pharmacists was instrumental in getting the anti-drug switching legislation introduced in the 1997 and 1998 Sessions of the General Assembly.

In general, the concern of these pharmacists is that the practice of therapeutic interchange often is guided by reasons other than good patient care and in the economic interests of the PBM and drug manufacturers rather than the patient. The specific concerns identified by these pharmacists include:

- Therapeutic interchange sometimes involves a switch to a more expensive product rather than a less expensive product or from a generic to a brand name drug, which raises questions about why the switch is being made; these pharmacists believe that in a number of instances the switch is made simply because the manufacturer's rebate or discount is greater for the more expensive drug than the less expensive drug;
- The financial relationships between PBMs and the manufacturers and the impact that these relationships have on patient care, particularly when the manufacturer is the PBM's parent company;
- The degree to which discounts, rebates, and other forms of remuneration that manufacturers give to PBMs and managed care firms are factored into the decisions as to which drugs are included in a formulary;
- A substantial portion of the discounts and rebates received by PBMs are not passed on to the plan sponsor thus minimizing any potential reduction in health care costs;
- The frequency with which PBMs and other managed care plans' formularies change requiring patients to change from the drug they have been taking with good results to another drug that they know nothing about; in these instances, the patient often must be re-titrated on the new drug which can be difficult;
- Having to call the physician to obtain permission to switch the drug is time-consuming and often is an inconvenience for the patient, pharmacist and physician;
- Some pharmacists feel pressured to initiate drug switches that they believe are unwarranted; and
- Switching a drug because of financial incentives realized by PBMs, managed care organizations and manufacturers is viewed as somewhat

undermining their professionalism and expertise in knowing what is best for the patients who come to their pharmacies.

In summary, the pharmacists who oppose the practice of therapeutic interchange believe that while there may be few documented instances of actual patient harm that result from therapeutic interchange of chemically dissimilar drugs, switching a drug only because of the financial arrangements between the PBM or managed care entity and the drug manufacturer simply is not worth the risk.

Other Concerns of Independent Pharmacists: In addition to independent pharmacists' concerns specifically related to therapeutic interchange, these pharmacists also have concerns regarding other related issues. These concerns include matters such as: (i) the manner in which some manufacturers bring new drugs into the market in ways that protect their market share and shift patients to the new drug, (ii) the manner in which prescription drugs are sold to various entities and the different pricing structures used for different purchasers; and (iii) the administrative and operational requirements that PBMs place on pharmacists when processing and adjudicating claims. While these concerns are related to the issue of therapeutic interchange, they would require an additional level and type of analysis that was beyond the scope of this study.

Physicians: Much of the concerns about therapeutic interchange that have been voiced by physicians are similar to those of the independent pharmacists outlined above. The principal concerns of physicians include the following.

- Physicians' primary concern is with efforts to encourage therapeutic interchange after a prescription has been written, after the decision regarding proper medication has been made by the physician, and when the attempt to switch the drug is motivated by financial incentives and not patient care.
- Being contacted by pharmacists, PBMs or managed care organizations to switch drugs because of financial incentives is time-consuming and requires the physician to take time away from other patients. This is particularly bothersome to physicians when the attempt to switch the drug is for reasons other than clinical factors or the drug not being on the plan's formulary.
- Physicians typically prescribe certain drugs that they know and are comfortable with in terms of the drug's efficacy and potential side effects; telephone calls requesting they switch to drugs that they are not knowledgeable about causes concern that the drug may not be in the best interest of the patient.
- There generally is not sufficient time to research a drug suggested during a therapeutic interchange, and the physician is put in the

position of relying on someone else's suggestions regarding a drug treatment for the patient. Often, the person calling the physician is completely unknown to the physician.

- There also is some level of feeling that the physician's medical training and knowledge is being "second-guessed" by persons attempting to initiate a therapeutic interchange.

One possible action suggested by some to relieve the amount of telephone calls received by physicians is to include an additional box on the prescription blank format labeled "therapeutic interchange allowed" or some other similar language that would authorize a different drug when it is considered to be therapeutically appropriate for the patient. Currently, the prescription blank format has two boxes; one which says "dispense as written;" and the other which says "Voluntary Formulary Permitted." Adding a third box authorizing therapeutic interchange may help to reduce the number of calls received by physicians requesting a drug switch. Physicians have cautioned, however, that this may be problematic in keeping up with exactly what prescription the patient actually received.

Health Plans, Hospitals, Chain Drug Stores, PBMs, And Many Employers Believe That There Has Not Been Sufficient Evidence Presented To Indicate There Is A Problem With Therapeutic Interchange

Based on JCHC staff interviews with representatives of health plans, hospitals, chain drug stores, and PBMs, the "bottom line" position of these organizations is that there has not been sufficient evidence presented to indicate that there is a problem with therapeutic interchange. This position also was stated in testimony before the HJR 734 Subcommittee by representatives of these entities, including the Virginia Chamber of Commerce.

These groups point to the following as support for their position: (i) the available research suggests that therapeutic interchange occurs infrequently; (ii) the limited data that has been collected on patient outcomes indicate there has been a relatively small number of cases in which therapeutic interchange has been associated with adverse clinical outcomes; and (iii) therapeutic interchange reduces prescription drug costs for plan sponsors, employers and consumers.

The PBMs' response to some pharmacists' concerns about a less expensive drug being switched to a more expensive drug is that the more expensive drug may result in fewer treatment failures, better patient adherence to the treatment plan, or fewer side effects. PBM representatives also indicated that if there are concerns about the financial incentives often involved in therapeutic interchanges, there should be similar concerns about the practices of "drug

detailers" who visit physician offices and encourage physicians to prescribe their company's line of products.

PBMs, health plans, and others who support therapeutic interchange also stress that no therapeutic interchange occurs unless the prescribing physician authorizes it. Representatives interviewed by JCHC staff argue that if the prescriber has any doubts whatsoever about the appropriateness of the interchange, he/she should say "no," and the switch does not occur.

Proponents of therapeutic interchange also point out that recent managed care legislation addresses concerns regarding the quality of managed care plans. Specifically, these individuals note that the provisions of the 1999 managed care legislation (SB 1235/HB 871) which require formularies be developed, and disseminated to providers according to certain guidelines, and which provide patients access to non-formulary drugs when medically necessary sufficiently address the issues regarding appropriate access to prescription drugs. The 1998 legislation (SB 712) which requires the Virginia Department of Health (VDH) to examine the quality of managed care health insurance plans (MCHIPs) also is cited as further state regulation and oversight of managed care plans.

While the 1998 MCHIP legislation requires plans to receive a certificate of quality from VDH, neither the Code provisions nor VDH's proposed regulations include specific requirements that plans' therapeutic interchange programs must meet. The General Assembly may wish to consider adding a specific requirement that MCHIPs' therapeutic interchange programs must be examined and approved as part of VDH's review and issuance of a certificate of quality.

Concern Was Expressed By One Health System And One Staff Model HMO That Efforts To Restrict The Therapeutic Interchange Practices Of Some Firms That Worry Pharmacists And Physicians Would Also Affect Their Therapeutic Interchange Programs Which Operate Differently

As noted in Section II of this report, JCHC staff conducted site visits to four different pharmacies, including a health system (Sentara) and a staff model HMO (Kaiser). In interviews with representatives of these organizations, concerns were raised that legislative efforts to restrict the therapeutic interchange practices of some firms also would apply to their therapeutic interchange programs, which they contend are different from other programs.

Sentara, for example, stated that it uses its own formulary which is developed by a Sentara pharmacy and therapeutics (P&T) committee composed of Sentara physicians and pharmacists. The formulary is used for Sentara enrollees who, by and large, use Sentara hospitals and physicians. The

processing and adjudication of prescription claims is contracted out to a third-party administrator; however, the contractor simply administers the program as designed by Sentara physicians and pharmacists. In sum, Sentara officials indicate that their therapeutic interchange program is somewhat unique in that it: (i) is developed by Sentara health care professionals, (ii) is used by Sentara hospitals and contracting physicians; and (iii) applies only to Sentara enrollees/patients. While other providers outside of the Sentara network may be affected by its therapeutic interchange program, it is different from the therapeutic interchange programs of PBMs that are used by different health plans, and apply to many different physicians.

Kaiser's situation is very similar to Sentara's, in that the therapeutic interchange program it uses is developed by Kaiser health care professionals, affects primarily Kaiser physicians, and is used only for Kaiser subscribers. The formulary is developed by Kaiser physicians who are staffed by Kaiser pharmacists. Kaiser also manages their therapeutic interchange program in-house. Another distinguishing characteristic is that, as a staff model HMO, the vast majority of physicians who treat Kaiser patients are Kaiser employees. In sum, Kaiser officials argue that because all of the individual components of the system (i.e., health plan, pharmacy program, physicians) work for the same corporate entity, this mitigates many of the concerns that have been raised regarding other therapeutic interchange programs.

The Position Of Drug Manufacturers Is That The Prescribing Physician Must Authorize All Therapeutic Interchanges

In testimony before the HJR 734 Subcommittee, representatives of PhRMA indicated some concerns regarding therapeutic interchange. As previously discussed, PhRMA cited studies indicating that therapeutic interchange can increase overall health care costs. PhRMA noted that "substitution of a chemically dissimilar drug for the drug prescribed for the patient is far more than a simple 'switch' in therapy." PhRMA's testimony also included the statement that "by allowing practitioners who are not the patient's physician to second-guess or countermand the physician's orders, patients may be placed in danger." PhRMA also "believes that the therapeutic interchange of chemically dissimilar drugs without the authorization of the physician or primary health care provider increases the probability that patients will not benefit to the fullest extent from drug therapy." (In Virginia, as well as in all other states, the prescription cannot be changed without the authorization of the prescribing physician.)

There Has Been Limited "Consumer" Input Into The Issue Of Therapeutic Interchange; Surveys Indicate Few Patient Complaints And High Levels Of Satisfaction With Prescription Drug Benefits; However, Some Patient Advocates Have Expressed Concern About The Practice

Broad-based consumer input into the appropriateness of therapeutic interchange has been limited. In the surveys conducted as part of the DMAS study of therapeutic interchange and PBMs, physicians and pharmacists reported very few patient complaints. Moreover, the citizen survey conducted by the VCU School of Pharmacy found that patients who had experienced a therapeutic interchange had a high level of satisfaction with their prescription drug benefits, albeit somewhat lower than that of persons who had not experienced a therapeutic interchange.

AARP Policy: The AARP policy on therapeutic interchange is that "pharmacy benefit management should be accompanied by safeguards that prevent prescriptions from being inappropriately switched to lower-priced drugs that could endanger beneficiaries' health. In addition, its use should be monitored with respect to its impact on the overall costs and quality of health care." AARP also believes that "PBMs should disclose and make allowance for formulary exceptions when medical necessity dictates that a non-formulary alternative is needed, and ensure that plan members are aware of how such alternatives can be obtained."

Consumer Federation of America: The Consumer Federation of America (CFA) testified in favor of HB 1127/SB 710 (Virginia Ethics in Prescription Drug Choice Act) in 1998. CFA testified that it believes therapeutic interchange is largely unknown to the public and places its members at risk. The CFA testimony also noted that "it is simply unacceptable that a practice which puts people at risk and which clearly makes health care professionals so uncomfortable be driven by inducement payments." At the federal level (in 1998), CFA was pushing for certain formulary disclosure and development practices as part of a patients' bill of rights for enrollees of health plans.

CFA also noted in its testimony that it had been working with the Public Advocate for the City of New York, Mark Green, in researching the practices of PBMs. Mr. Green testified on behalf of the proponents of the anti-drug switching legislation introduced in 1997 (HB 2714/SB 1114). Mr. Green testified that he had conducted a 6-month investigation into PBM practices. Mr. Green identified several findings that he felt were detrimental to the public welfare, including: (i) conflicts of interest dictating drug choices; (ii) pharmacists and physicians being pressured to switch drugs; and (iii) patients experiencing therapeutic interchange potentially having adverse health consequences.

The U.S. Attorney's Office For The Eastern District Of Pennsylvania Is Investigating Certain PBM Practices

JCHC staff interviewed the Chief of the Civil Division within the U.S. Attorney's Office for the Eastern District of Pennsylvania which is conducting an investigation into certain PBM practices. The investigation, which began in late 1997, is looking into such issues as: (i) how therapeutic interchanges are conducted and whether any of these are done deceptively; (ii) whether there is full disclosure to patients and physicians; and (iii) whether there are any fraudulent activities associated with therapeutic interchange. At this time, there are no investigative findings that have been made available to the public. The investigation is expected to conclude by next summer.

V.
Laws Affecting Therapeutic Interchange In Other States

The National Conference of State Legislatures (NCSL) conducted a survey of other states' laws concerning therapeutic interchange, and presented its findings at the September 29th meeting of the HJR 734 Subcommittee. This section summarizes the findings of the NCSL analysis.

While Every State Prohibits Pharmacists From Switching A Prescription Without The Prescriber's Permission, There Has Been Little Legislative Activity Specifically Targeting Therapeutic Interchange

NCSL reported that every state has a law similar to Virginia's that makes it unlawful for a pharmacist to change a prescription without the permission of the prescribing practitioner. However, there has been little legislative activity that specifically targets the practice of therapeutic interchange. A few states (Missouri, Indiana, and Illinois) have passed laws aimed specifically at health plans to prohibit contracts, policies or procedures from allowing an entity or individual to dispense a different drug in place of the drug ordered or prescribed by the prescribing physician. NCSL indicated that the effect of these laws is really no different than Virginia's current statute.

No State Has Enacted Legislation To Prohibit Therapeutic Interchanges That Are Prompted By Financial Incentives; However, A Number Of States, Including Virginia, Have Enacted Legislation Regulating Drug Formularies

NCSL reported that no state has enacted legislation which prohibits the practice of therapeutic interchanges that are prompted by financial incentives such as rebates or discounts. Instead, a number of states have passed laws which regulate how drug formularies are developed and administered. NCSL indicated that these laws reflect an attempt to control and regulate prescription drug benefits and formularies without prohibiting the practice of therapeutic interchange. The following describes the types of laws that have been adopted in other states that deal with the kinds of drugs that must be covered.

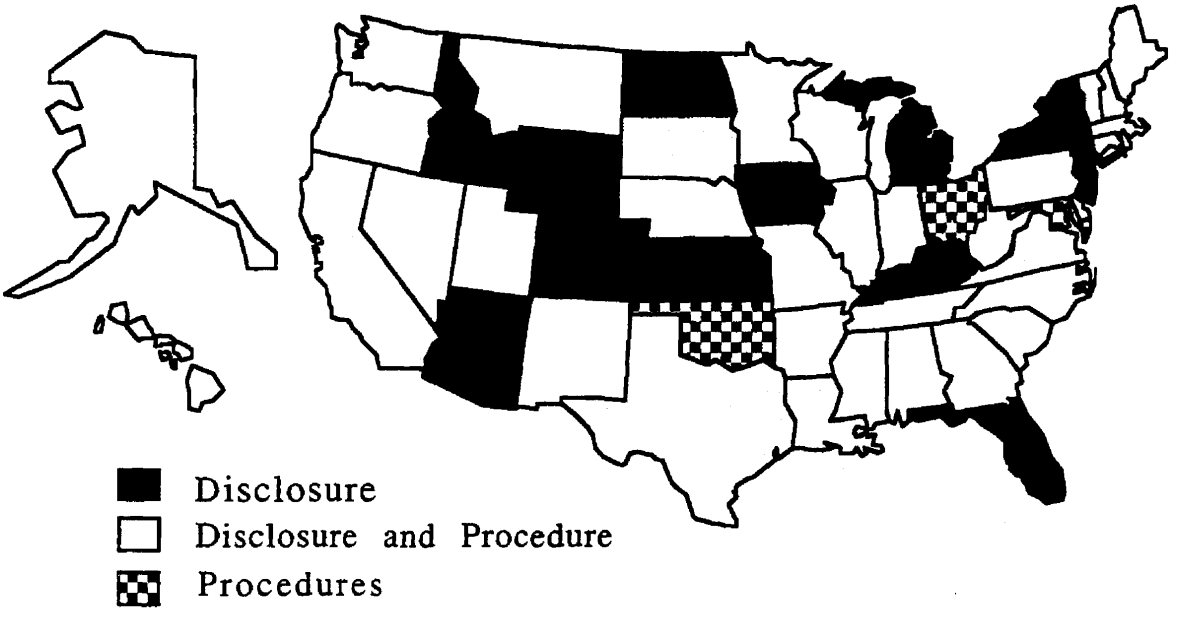
- 17 states either require insurers to cover or offer coverage for contraceptives;
- 38 states either require insurers to cover or offer coverage for some form of diabetes treatment;

- 33 states require insurers to cover off-label drugs either for cancer, AIDS or all life-threatening illnesses; and
- 21 states either require insurers to cover or offer coverage for inherited metabolic diseases such as PKU.

In addition to the above state actions regarding what drugs must be included in insurance coverage, 31 states, including Virginia, have enacted legislation regulating prescription drug formularies. These laws generally fall into three categories: (i) laws that require only the disclosure of the formulary; (ii) laws that require certain procedures be followed when developing a formulary; and (iii) laws that address both the disclosure of the formulary and procedural requirements. Figure 18 illustrates these states.

Figure 18

Laws Regulating Drug Formularies



Source: National Conference of State Legislatures, Presentation to HJR 734 Subcommittee

The North Carolina Board Of Pharmacy Has Adopted Regulations Requiring Pharmacists To Inform Physicians If They Are Receiving A Fee From A Manufacturing Company To Recommend The Use Of That Company's Products

In response to concerns over the practice of therapeutic interchange, the North Carolina Pharmacy Board adopted a rule in 1997 requiring pharmacists to inform physicians if they are receiving a fee from a manufacturing company to recommend the use of that company's line of products. If the evidence warrants, the board has the authority to restrict a pharmacy's operating permit or a pharmacist's professional license. The Pharmacy Board acknowledged the rule can be difficult to enforce.

Federal Legislation Being Debated In Congress Includes Provisions Regarding The Disclosure And Administration Of Drug Formularies

Legislation has been introduced in the 106th Congress that would provide certain consumer protections for persons enrolled in managed care plans and other health coverage. H.R. 2723, called the Bipartisan Consensus Managed Care Improvement Act of 1999, includes provisions which regulate prescription drug formularies. Section 118 of the bill states that if a group health plan or health insurance issuer offers health insurance coverage that provides benefits with respect to prescription drugs but the coverage limits such benefits to drugs included in a formulary, the plan or issuer shall:

- ensure participation of participating physicians and pharmacists in the development of the formulary;
- disclose to providers, and disclose upon request under section 121(c)(5) to participants, beneficiaries and enrollees, the nature of the formulary restrictions; and
- provide for exceptions from the formulary limitation when a non-formulary alternative is medically indicated.

H.R. 2723 passed the House last week, and is awaiting action in the U.S. Senate.

The provisions of H.R. 2723 are very similar to the requirements included in Virginia's 1999 legislation (SB 1235/HB 871) that addresses formularies and access to non-formulary drugs. However, while current *Code of Virginia* provisions require the formulary be sent to providers, there is no requirement that the information be sent to enrollees as required in H.R. 2723. The General Assembly may wish to consider requiring that formulary information be sent to enrollees upon request.

VI.
Policy Options

The following Policy Options are offered for consideration by the Joint Commission on Health Care. They do not represent the entire range of actions that the Joint Commission may wish to pursue.

It is recognized that some of the options listed below would require further analysis and legal expertise to develop the specific language needed to effect the objective of the respective policy decision(s). The wording that is used here is intended to provide a general statement of the different actions that could be taken rather than exact legislative language. Further, it is recognized that, for some options, there are substantial details that would need to be worked out.

Option I: **Take no action**

Option II: **Introduce legislation to define therapeutic interchange and amend §32.1-87 of the *Code of Virginia* by adding an additional box on the prescription blank format labeled "therapeutic interchange allowed" or similar language which would allow a prescriber to initially authorize a different drug when it is not considered a therapeutic problem for the patient; legislation also would require the pharmacist to inform the prescriber in writing if a different drug is dispensed.**

Option III: **Introduce legislation to require pharmacists contacting physicians to initiate a therapeutic interchange to disclose all drugs in a therapeutic class that are on the formulary and could be dispensed to the patient and not only those of a particular manufacturer**

Option IV: **Introduce legislation to require pharmacists contacting physicians to initiate a therapeutic interchange to disclose whether a fee or other financial incentive is being paid to the pharmacy or pharmacist to recommend use of a particular manufacturer's product line.**

Option V: **Introduce legislation amending §38.2-3407.9:01(B)(1) of the *Code of Virginia* to require insurers to provide the complete, current drug formulary(ies) and the formulary restrictions to enrollees upon request of the enrollee.**

Option VI: **Introduce legislation to require managed care health insurance plans (MCHIPs) which utilize therapeutic interchange programs to submit information as determined by the Commissioner of Health in order to have their respective programs reviewed and approved as part of the overall MCHIP certificate of quality process required by § 32.1-137.1 et seq. of the *Code of Virginia*. The legislation also would require the Virginia Department of Health to develop the appropriate regulations to implement this requirement.**

Option VII: **Introduce legislation to define and allow the practice of therapeutic interchange only when: (i) the interchange is indicated due to patient safety concerns or clinical reasons; (ii) the interchange is from a drug which is not on the health plan's formulary to a drug which is on the formulary; (iii) the interchange directly results in a lower co-payment to the patient; or (iv) the health plan sponsor realizes a minimum specified portion of any associated cost-savings that result from the interchange.**

APPENDIX A

HOUSE JOINT RESOLUTION NO. 734

Directing the Joint Commission on Health Care to study the issues relating to therapeutic interchange of chemically dissimilar drugs.

Agreed to by the House of Delegates, February 4, 1999
Agreed to by the Senate, February 18, 1999

WHEREAS, over the last decade issues relating to the pharmacy services have frequently been of prime importance to policy makers in Virginia; and

WHEREAS, chief among such issues has been the practice of therapeutic interchange of chemically dissimilar drugs, and

WHEREAS, the issues relating to therapeutic interchange of chemically dissimilar drugs are involved and difficult, including medical ethics, closed formularies, pharmacy company marketing, the practice of pharmacy, the operation of the business of pharmacy, patient rights, and appropriate medical treatment; and

WHEREAS, even the matter of defining "chemically dissimilar" presents many technical and highly charged discussions; and

WHEREAS, the significant and sometimes passionate reactions raised by the issues relating to the therapeutic interchange of chemically dissimilar drugs have resulted in many legislative initiatives; and

WHEREAS, several groups outside the legislature, both formal and informal, have examined these issues and have made some recommendations; and

WHEREAS, attempts to resolve the complex and intricate issues relating to therapeutic interchange of chemically dissimilar drugs have not, however, been completely successful; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Joint Commission on Health Care be directed to study the issues relating to therapeutic interchange of chemically dissimilar drugs. In conducting its study, the Joint Commission shall:

1. Collect data on therapeutically dissimilar drugs which may be interchanged therapeutically to assess the efficacy of this practice;

2. Solicit input from experts in pharmacy and chemical composition of drugs and the mechanisms by which drugs work in the human body to treat disease;

3. Conduct a literature search for studies of the use of therapeutically dissimilar drugs for the same or similar therapies;

4. Receive input from all stakeholders, including, but not limited to, physicians, pharmacists, insurance companies, health maintenance organizations, third-party

benefit managers, managed care pharmacy organizations, physicians, patients, and manufacturers;

5. Examine other states' laws and regulations to identify possible mechanisms for regulating the practice of therapeutic interchange of chemically dissimilar drugs;

6. Conduct a comprehensive review of the related issues at the national level;

7. Take such other actions as appear necessary and appropriate to collect sufficient data and analysis of the issues; and

8. Make recommendations concerning whether the practice of therapeutic interchange of chemically dissimilar drugs should be regulated; the components of any such regulation, if recommended; definitions of relevant terms; and the appropriate body for such regulation, if recommended.

All agencies of the Commonwealth shall provide assistance to the Joint Commission for this study, upon request.

The Joint Commission shall complete its work in time to submit its findings and recommendations to the Governor and the 2000 Session of the General Assembly as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents.

APPENDIX B

JOINT COMMISSION ON HEALTH CARE

SUMMARY OF PUBLIC COMMENTS: THERAPEUTIC INTERCHANGE OF CHEMICALLY DISSIMILAR DRUGS STUDY (HJR 734)

Individuals/Organizations Submitting Comments

A total of 15 organizations submitted comments in response to the therapeutic interchange report.

- AARP
- Academy of Managed Care Pharmacy
- Kaiser Permanente
- Merck-Medco Managed Care
- PCS Health Systems
- Pharmaceutical Care Management Association (PCMA)
- Pharmaceutical Research and Manufacturers of America
- Sentara Healthcare
- The Medical Society of Virginia
- Trigon Blue Cross Blue Shield
- Virginia Association of Health Plans
- Virginia Association of Independent Pharmacies
- Virginia Hospital and Healthcare Association
- Virginia Pharmacists Association
- Virginia Society of Health-System Pharmacists

Policy Options Included in the HJR 734 Issue Brief

Option I **Take no action.**

Option II **Introduce Legislation To Define Therapeutic Interchange And Amend §32.1-1-87 Of The *Code Of Virginia* By Adding An Additional Box On The**

Prescription Blank Format Labeled "Therapeutic Interchange Allowed" Or Similar Language Which Would Allow A Prescriber To Initially Authorize A Different Drug When It Is Not Considered A Therapeutic Problem For The Patient; Legislation Also Would Require The Pharmacist To Inform The Prescriber In Writing If A Different Drug Is Dispensed.

Option III Introduce Legislation To Require Pharmacists Contacting Physicians To Initiate A Therapeutic Interchange To Disclose All Drugs In A Therapeutic Class That Are On The Formulary And Could Be Dispensed To The Patient And Not Only Those Of A Particular Manufacturer.

Option IV Introduce Legislation To Require Pharmacists Contacting Physicians To Initiate A Therapeutic Interchange To Disclose Whether A Fee Or Other Financial Incentive Is Being Paid To The Pharmacy Or Pharmacist To Recommend Use Of A Particular Manufacturer's Product Line.

Option V Introduce Legislation Amending §38.2-3407.9:01(B)(1) Of The *Code Of Virginia* To Require Insurers To Provide The Complete, Current Drug Formulary(ies) And The Formulary Restrictions To Enrollees Upon Request Of The Enrollee.

Option VI Introduce Legislation To Require Managed Care Health Insurance Plans (MCHIPS) Which Utilize Therapeutic Interchange Programs To Submit Information As Determined By The Commissioner Of Health In Order To Have Their Respective Programs Reviewed And Approved As Part Of The Overall MCHIP Certificate Of Quality Process Required By §32.1-137.1 Et Seq. Of The *Code Of Virginia.* The Legislation Also Would Require The Virginia Department Of Health To Develop The Appropriate Regulations To Implement This Requirement.

Option VII **Introduce Legislation To Define And Allow The Practice Of Therapeutic Interchange Only When: (i) The Interchange Is Indicated Due To Patient Safety Concerns Or Clinical Reasons; (ii) The Interchange Is From A Drug Which Is Not On The Health Plan's Formulary To A Drug Which Is On The Formulary; (iii) The Interchange Directly Results In A Lower Co-Payment To The Patient Or (iv) The Health Plan Sponsor Realizes A Minimum Specified Portion Of Any Associated Cost-Savings That Result From The Interchange.**

Option VIII **Introduce Legislation To Amend §2.1-20.1(H)(2) and §38.2-3407.9:01(B)(2) Of The *Code Of Virginia* Deleting The Requirement That, Before An Enrollee Can Obtain A Medically Necessary Non-Formulary Drug, A Reasonable Investigation Must Be Completed To Determine That The Formulary Drug Is An Inappropriate Therapy For The Medical Condition Of The Person. This Subsection Would Be Revised Such That The Enrollee Could Obtain The Non-Formulary Drug If The Prescribing Physician Deems It To Be Medically Necessary.**

Overall Summary of Comments

There was a great deal of diversity in the comments that were received. The table on the next page summarizes the comments that were received on each policy option. Only responses that specifically indicated a position on the various options were included in the Table.

As shown, none of the Options received broad support except Option I that was supported by eleven commenters. Option V was supported by two commenters while Options VI and VIII were each supported by one commenter. All of the options were opposed by at least two commenters except Option V which had no opposition. Option II received the highest number of opposing commenters with five.

Policy Option	Number of Comments in Support	Number of Comments in Opposition
I	11	2
II	0	5
III	0	3
IV	0	4
V	2	0
VI	1	3
VII	0	3
VIII	1	4

Summary of Individual Comments

Academy of Managed Care Pharmacy

Judith A. Cahill, as Executive Director of the Academy of Managed Care Pharmacy (AMCP), expressed support of Option I. Ms. Cahill noted that AMCP "supports the use of therapeutic interchange programs as part of a comprehensive approach to quality cost-effective patient care." Ms. Cahill also stated the following: (1) a small percentage of prescriptions in Virginia involve therapeutic interchange (about 3 percent according to the DMAS study on pharmacy benefit managers), (2) the FDA's MedWatch program reported that of 16,000 reports on adverse drug problems only 61 were determined to be possibly caused by the therapeutic interchange, (3) and prescribers should and do make the final decision on the appropriateness of an interchange. In closing, it was maintained that if therapeutic interchange legislation is enacted, "such legislation would deprive patients of a valuable means of improving their care and reducing their prescription costs."

AARP

William L. Lukhard, as the Vice Chairman of the AARP State Legislative Committee, commented in support of Options V, VI, and VIII. In supporting these options, Mr. Lukhard stated that AARP "has consistently viewed the issue from the perspective of the patient as to health impact and prescription drug costs." AARP also suggested that JCHC consider another option to enact the following language: "When a health plan initiates a therapeutic drug interchange for a specific patient (enrollee), the patient will be notified by the physician or pharmacist as to why the interchange is being recommended, its possible side effects and the cost savings or increase for the patient and for the plan."

Mr. Lukhard indicated opposition to Options I, II and VII and took no position on Options III and IV.

Kaiser Permanente

Gail M. Thompson, Director of Government Relations, commented in support of Option I stating that there does not appear to be a problem that requires legislative or regulatory intervention.

Merck-Medco Managed Care, LLC

Stephen D. Rosenthal of Mays & Valentine L.L.P. wrote on behalf of Merck-Medco Managed Care in support of Option I. In supporting Option I, the following factors were noted: (1) therapeutic interchange "as practiced today is safe and, moreover, is an important means of lowering the costs of pharmaceuticals in a way that ensures broader access to important medicines;" (2) therapeutic interchange "is an integral part of pharmacy practice and has been for decades;" and (3) pharmacists have continuously made recommendations to physicians about the availability of "equally effective but less expensive therapies."

In opposing Option II, Mr. Rosenthal stated that it was not a viable option because it deals with therapeutic interchange as simply an economic issue and not a clinical issue, and because there is too much variability in the various therapeutic interchange programs for

physicians to know about all of the alternatives. "More fundamentally, this option undermines the sacrosanct physician-patient relationship, and the laws and regulations that prohibit a person from dispensing a chemically different drug in place of the drug prescribed without the permission of the prescribing physician."

Option III was reported to be "unworkable" because formularies are not always involved in therapeutic interchanges. "A patient with indemnity insurance, or a cash-paying patient, for example, would not be bound by any formulary."

Option IV was considered to be impractical both for pharmacists employed by chain drug stores and for independent pharmacists. In the first instance, the pharmacist may be unfamiliar with any agreements the employer has with a manufacturer. In the second instance, there is often a "global fee that includes everything from dispensing the medication to counseling, with no breakdown of the many elements that comprise the total fee." In summary, Mr. Rosenthal noted that the option presumes that a particular drug would be recommended because of an economic benefit for the pharmacist. "There is no evidence before the Joint Commission that supports the unseemly notion that a pharmacist would recommend a particular drug for financial gain only, and in spite of the patient's welfare."

Mr. Rosenthal did not speak to Option V. Regarding Option VI, it was noted that the Option "assumes that therapeutic interchange is harmful, and needs to be regulated in managed care, but that somehow the identical practice is not harmful in hospitals, independent pharmacies and clinics.

Option VII was opposed noting that the Board of Pharmacy which is responsible for governing the "professional practice of pharmacy has not found it necessary or desirable to regulate in this area." The option was also considered to undermine last year's legislation which "requires that all health plans have Pharmacy and Therapeutics Committees to oversee the formation and implementation of formularies, which includes therapeutic interchange programs...."

Option VIII was seen as providing "a state-sanctioned license to health care providers to totally circumvent any formulary. All that a health care provider would have to do is deem every drug he/she prescribes as 'medically necessary.' This option would inevitably drive up the costs of pharmaceutical benefits because, as all the evidence before the Joint Commission shows, formularies are necessary and appropriate to help contain the costs of the pharmaceutical benefit – a cost that, without controls, will quickly spiral out of control, making the drug benefit unavailable to those who need it the most."

PCS Health Systems

Lisa Block, Director of State Government Affairs, stated that PCS relies on the American Medical Association's definitions of therapeutic interchange and therapeutic substitution and that this facilitates communication and enhances general understanding. Thus, they recommended that these definitions be used. Ms. Block stated that their primary concern with the proposed legislative options is that they would severely limit or eliminate the benefits derived from the practice of therapeutic interchange, without giving patients any additional protections. A second major concern of PCS was Option VIII. They commented that Option VIII, while giving the prescribing physician the authority to override formulary decisions, does not require the physician to evaluate all the criteria that PCS currently does to ensure the best drug is prescribed for the patient. PCS does not believe Option VIII, as drafted, is in the best interests of the patient.

Pharmaceutical Care Management Association (PCMA)

Patrick B. Donoho, Vice President of Government Affairs and Public Policy, commented in support of Option I. Specifically, he stated that "as health care evolves into the next century, we urge caution in enacting new laws that will inhibit innovation and not impart a positive benefit to the system."

Pharmaceutical Research and Manufacturers of America

Christopher Badgley, Vice President of State Government Affairs for the Pharmaceutical Research and Manufacturers of America (PhRMA) commented in support of "adopting the definition of 'therapeutic interchange' that requires the patient's prescriber to approve any change in the originally prescribed drug therapy in the report." This would address what Mr. Badgley noted was PhRMA's primary concern "that the patient's physician be aware of and authorize the drug being taken by the patient." PhRMA recommended that the proposed definition of "therapeutic interchange" be added to such statutory sections as the Pharmacy Practice Act, the Insurance Code, and the Medical Practice Act.

Mr. Badgley also noted PhRMA's support for Option VIII. "PhRMA believes that a determination of medical necessity by the patient's prescriber should guarantee that the patient can receive, at a cost that is not punitive or prohibitive, the drug therapy determined necessary by the prescriber.

Mr. Badgley indicated that PhRMA is opposed to Options II, and IV. Option II was seen as causing confusion and as making it quite difficult to track a patient's current drug therapies. This confusion was expected to be caused and exacerbated by such factors as a patient's use of more than one pharmacy or of more than one prescriber as well as any changes occurring in the insurance coverage and formularies. In opposing Option IV, Mr. Badgley stated that typically a pharmacist will not know about any financial incentives that may be involved in a therapeutic interchange. Option VII was considered to be a more acceptable means of ensuring that financial incentives involved in therapeutic interchanges are recognized.

Sentara Healthcare

Mark Szalwinski commented on behalf of Sentara Healthcare in support of Option I. In his support of Option I, Mr. Szalwinski cited that available data suggest the use of therapeutic interchange is low, patients are generally satisfied with their prescription drug benefits, and there "have been very few adverse events associated with

therapeutic interchange. We know that therapeutic interchange does generate significant savings for consumers and health plan sponsors. Therapeutic interchange allows some individuals who would not otherwise be able to afford much needed prescription drugs to afford them."

The Medical Society of Virginia

Michael Jurgensen, Director of Health Policy and Medical Economics for The Medical Society of Virginia, commented in support of Options I and V. Mr. Jurgensen noted that the Medical Society supports Option V as "an effective tool for both patient education and patient's rights" but continued by saying "we do not believe it affords much, if any, resolution or assistance to the problems inherent to the therapeutic switching issue." Mr. Jurgensen delineated four basic principles the Medical Society used in evaluating the study Options. In summary, these principles stated: (1) any contact of a physician regarding changing a prescription should be "motivated by a genuine safety concern for the patient or to inform the physician that a drug is not covered by the patient's insurance policy;" (2) no contact should be prompted by a desire to receive additional revenue by influencing a physician to change a prescription; (3) pharmacists should "be bound by a clear code of ethics forbidding any violations of these guidelines;" and (4) "employers of pharmacists should not impose guidelines or requirements that would force an individual pharmacist to violate these guidelines. These are patient focused, medically centered principles that place the responsibility squarely where it belongs – between the patient, the physician, and the pharmacist – relying extensively on the professional ethics of the health care providers involved."

Mr. Jurgensen opposed Options II, III, IV, VI, VII and VIII.

Trigon Blue Cross Blue Shield

Leonard L. Hopkins, Jr., Vice President, Public Policy Officer for Trigon Blue Cross Blue Shield, commented in support of Option I. In maintaining that no action should be taken, Mr. Hopkins stated the following: First and foremost, in Virginia (like every other state), state law prohibits a pharmacist from dispensing a drug other than

that prescribed unless the prescriber has authorized the change. Thus, if a physician has concerns about any request for therapeutic interchange, the physician can simply say 'No." Moreover, it appears that therapeutic interchange occurs very infrequently and that there is little evidence that there are any more problems with therapeutic interchange than with initial prescriptions....In the future, the real challenge will be to find an effective way to manage prescription drug costs so that plan sponsors and consumers can continue to afford prescription drug benefits."

Virginia Association of Health Plans

Mark C. Pratt, Executive Director of the Virginia Association of Health Plans, commented in support of Option I. In discussing the advantages of therapeutic interchange, Mr. Pratt stated, "Therapeutic interchange generates significant savings for health plan sponsors and consumers and, thereby, contributes to making prescription drug benefits available and affordable for Virginians. Additional regulation will only serve to increase cost pressures in the marketplace and jeopardize prescription benefits for Virginians."

Virginia Association of Independent Pharmacies

Irvin Durrette submitted comments on behalf of the Virginia Association of Independent Pharmacies. Mr. Durrette indicated that none of the Options were supported. Options I, III and IV were opposed while no position was taken on Options II, and V through VIII. Option I was noted as being "strongly opposed" because "the record is clear that there is a need for immediate legislative action to (1) protect Virginia patients from both the risks and actual harm associated with kickback-driven drug switching practices, and (2) protect Virginia patients and third party payors (both public and private) from fraud and increased health care expenditures."

In stating that the Association had no position on Issue VIII, the following remarks were made: "in actual practice, prescribers are currently under financial pressures to prescribe certain drugs, and not others, regardless of their individual opinions regarding medical necessity....What is needed in Virginia is a law that regulates the

entities attempting to influence prescribing and dispensing decisions not a law that regulates those making them under pressure."

Virginia Hospital and Healthcare Association

Katherine M. Webb, Senior Vice President of the Virginia Hospital and Healthcare Association, commented in support of Option I. In support of Option I, Ms. Webb stated: first, a review of the 1999 managed care legislation and the 1999 collaborative agreement legislation shows that much legislative attention has been directed already to the design and utilization of formularies. This legislation needs time to work. Second, the Department of Medical Assistance Services study has concluded that the incidents of therapeutic interchange is low in Virginia. Third, no other state has enacted laws regulating drug formularies.....Formulary changes as a result of managed care legislation in 1999 should result in greater patient access to prescription drugs that their physicians believe are therapeutically appropriate. Further action in this arena is unwarranted at the present time."

Virginia Pharmacists Association

Rebecca P. Snead, Executive Director of the Virginia Pharmacists Association, did not directly support any of the proposed options but proposed that JCHC consider addressing specific formulary and complaint system concerns. First, the Association would support the amending of Section 38.2-3407.9:01 "to require insurers to post their complete, current formularies on the internet and make it accessible to any participating provider or enrollee. Additionally, health plans should disclose their formulary determination process and revision timelines." Second, the Association suggests "there is a role for the Department of Health under Section 32.1-137 to set up an ongoing complaint system and appeals process. In the alternative, Section 32.2-5904 could be amended to give the Managed Care Ombudsman responsibility for receiving and responding to any complaints about alleged "drug switches.'"

Ms. Snead indicated that Options VII and VIII "have merit, but we do not feel that sufficient political support exists at this time."

Ms. Snead indicated opposition to Options II through VI.

Virginia Society of Health-System Pharmacists

Fred D. Chatelain, Chair of the Virginia Society of Health-System Pharmacists' Legislative and Regulatory Affairs Committee commented in support of Option I. Mr. Chatelain noted that their "membership of pharmacists participate in therapeutic interchange after the approval by medical staff committees have had the opportunity to review all the information and approved the interchange. Therefore, the interchange is performed with prior approval, and not accomplished at the time of the presentation of the prescription for dispensing. Because the issue is primarily directed to the retail section of Pharmacy; VSHP seeks an exemption for clinics, hospitals, and dispensaries that are engaged in formularies limited to their facilities, of any possible legislation.

JOINT COMMISSION ON HEALTH CARF

Executive Director

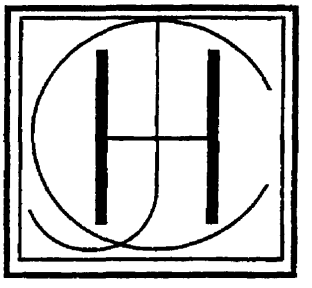
Patrick W. Finnerty

Senior Health Policy Analysts

Joseph J. Hilbert
William L. Murray, Ph.D.
E. Kim Snead

Office Manager

Mamie V. White



Joint Commission on Health Care
Old City Hall
1001 East Broad Street
Suite 115
Richmond, Virginia 23219
(804) 786-5445
(804) 786-5538 (FAX)

E-Mail: jchc@leg.state.va.us

Internet Address:

http://legis.state.va.us/jchc/jchchome.htm