REPORT OF THE
JOINT SUBCOMMITTEE STUDYING

INDEPENDENT PHARMACIES

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

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TABLE OF CONTENTS

I. EXECUTIVE SUMMARY 1

II. AUTHORITY FOR STUDY 2

III. BACKGROUND 2
- A. Decline of Independent Pharmacies 3
- B. Competing Sources 4

IV. COGNITIVE SERVICES 6
- A. Pharmaceutical Care and Patient Outcome 6
- B. Other state activities 8
- C. Recommendations 8

V. RESTRICTIVE FORMULARIES AND DRUG SWITCHING 9
- A. Guidelines for Medication Incentive Programs 9
- B. Restrictive Formularies 10
- C. Recommendations 12

VI. PREFERENTIAL PRICING 12

VII. THIRD-PARTY PAYER ISSUES 14
- A. MCV/VCU School of Pharmacy Study 14
- B. Pharmacy Freedom of Choice 16
- C. Medicaid 17
- D. Recommendations 18

VIII. OTHER LEGISLATIVE STUDIES 18

IX. APPENDICES 21

JOINT SUBCOMMITTEE STUDYING INDEPENDENT PHARMACIES
HOUSE JOINT RESOLUTION NO. 158, 1996

I. EXECUTIVE SUMMARY

Pharmaceutical services have become an integral component in the delivery of adequate, appropriate health care as more and more people are served in out-of-facility settings which are controlled to a great extent by health maintenance organizations and other types of health care programs. As a result, pharmacists are playing an even greater role in the health care setting as they provide invaluable information on such things as drug interactions, personal care, and counseling. But, as a result of changing pricing and reimbursement structures and increasing responsibilities, many of which are nonreimburseable, many small pharmacies are being forced to close or to join large chain operations to remain open. As a result of a year-long study of these issues, the Joint Subcommittee to Study the Demise of Independent Pharmacies (HJR 158, 1996) made a number of recommendations: (Appendix A)

- Direct, by resolution, the Department of Medical Assistance Services and the Department of Personnel and Training to initiate pilot programs to examine the effect of paying pharmacists for delivering cognitive services to their patients. The Departments are requested to cooperatively work with various professional groups to identify the range of services which would be eligible for reimbursement, the payment levels, and the filing procedures, and to develop an evaluation to determine the potential overall savings in health care expenditures for Medicaid and state employee recipients.

- Adopt statutory language which would recognize pharmacists as "health care practitioners" and "health care providers" to allow pharmacists to bill and receive compensation from HMOs, insurance companies, and other third-party payers for counseling and other cognitive services.

- Introduce legislation to prohibit the practice of drug switching of chemically dissimilar drugs in the Commonwealth.

- Require the Department of Personnel and Training and the Department of Medical Assistance Services to take steps to ensure that programs under their purview comply with the Pharmacy Freedom of Choice statute in the Code of Virginia and to require compensation to pharmacies which allows them a reasonable profit as participating providers.

II. AUTHORITY FOR STUDY

Citing the historical contributions to the health of community citizens and the recent decline in the number of independent pharmacies owned and operated by private individuals, the 1996 General Assembly adopted House Joint Resolution No. 158 to evaluate the impact of this phenomenon and make recommendations to the 1997 General Assembly. The joint subcommittee met on three occasions, twice in Richmond, and once, a public hearing, in Charlottesville.

III. BACKGROUND

Health professionals are seeing a massive shift away from acute care toward ambulatory care. The shift is being made to reduce the growing health care burden that, by some estimate, will reach 20 percent of the Gross National Product (GNP) by the year 2000. Another notable trend is the aging of the population which naturally will place additional burdens on the health care system, all in a context of a limited number of primary care providers.[1] It has been conservatively estimated that 28 percent of the hospitalized elderly in this country were placed there through inappropriate utilization of medications, including over-and under-utilization, wrong drug, toxicity, and abuse. A recent *Archives of Internal Medicine* article estimated the cost of inappropriate drug use in this country at $76.6 billion.[2]

The role of pharmacy and drug treatment has been crucial in the development of preventive and remedial health care over the ages. Treating illnesses with natural drugs, compounded by a person who studied the effects of naturally occurring substances, has evolved over hundreds of years, and, coincidentally, is enjoying a resurgence in interest. Throughout all of this, the local apothecary or pharmacy has been a source of education and health care. Until the advent of computerized medicine, the responsibility for compounding the drugs and educating the recipient about possible hazards or interactions of mixing certain drugs, as well as providing person-to-person interaction, counseling, and observation of the health status of the patient, remained with the pharmacist who dispensed the drugs. All of the personal services provided by the pharmacist would come under the description of "pharmacist care" as opposed to "pharmaceutical care," as

[1] Alan McKay, Ph.D., Professor and Dean, Shenandoah University School of Pharmacy, testimony submitted to the Joint Subcommittee, November 1996.
[2] *Archives of Internal Medicine*, 155:1949-1956 (Oct. 1995).

resolved by the National Community Pharmacists Association, emphasizing the individualized, personal services provided by pharmacists.[3]

A. Decline of Independent Pharmacies

Independent pharmacies numbered about 35,000 in the U.S. in 1994, but that number has steadily declined. In 1996, it was estimated that the number of independent pharmacies in Virginia alone was decreasing by one per week. In a period of ten short years, (1989-1997), independent pharmacies will number approximately 465, a decrease of over 600 businesses. According to the Virginia Pharmacists Association, membership has shifted from 80 percent independent pharmacists/owners to approximately 80 percent employee pharmacists and 20 percent independent pharmacists/owners.[4] In addition, after 45 years of steady growth, total sales in the average independent pharmacy dropped 7.7 percent to just over $1 billion in 1994.[5] This decline is attributed to a decrease in the nonprescription sales, which represented about 17 percent of total sales for independents, down from about 24 percent. In 1991, nonprescription sales made up about 31 percent of sales. According to the *1995 NARD/Lilly Digest*, this trend translates into an increasing reliance on prescription drug sales. Independent pharmacies previously required a 30 percent gross margin (the cost of goods sold as a percentage of sales), but 1993 total expenses were reduced to 26.3 percent gross margin, an accomplishment which points to increasing operating efficiencies by the independent pharmacies in their attempt to remain profitable in the competition with other business forces.[6]

Total Dollar Growth by Market Channel*

Market	`1994	% Change from 1993
Total	$71,301,449	+7%
Chains	29,622,037	+10
Independents	16,574,927	+1
Nonfederal hospitals	10,031,553	+1
Supermarkets	6,455,802	+13
Clinics	3,369,594	+25
Long-term care	1,988,095	+19
Closed-wall HMOs	1,727,619	+2
Federal facilities	1,531,822	+30

[3] Michael F. Conlan, "Independents Put Emphasis on 'Pharmacist Care,'" *Drug Topics*, November 6, 1995, p. 78.

[4] *The Financial Impact of Third Party Reimbursement on the Commonwealth's Pharmacies*, House Document No. 67, 1995, p. 5.

[5] Michael F. Conlan, "Volume Off at Independents For First Time in 46 Years," *Drug Topics*, November 6, 1995, p. 82.

[6] Ibid.

B. Competing Sources

As demonstrated in the table above, chain drug stores, one of the most serious competitors for the retail pharmacy business, gained in its dominance of the prescription business. Chain drugstores filled one of every two retail prescriptions in 1994 and sales rose approximately 10 percent with a 38 percent share of the total pharmaceutical market of $71.3 billion. Independent pharmacies were second, but experienced a three percent loss in filled prescriptions with total sales up only one percent. Supermarket pharmacies showed a thirteen percent increase.[7]

Independent pharmacies face a variety of threats to their continuing livelihood-lack of payments from customers or third-party payers for cognitive services, inadequate reimbursement from third-party payers and managed care systems, and lack of competitiveness as a result of preferential pricing afforded to certain hospitals and managed care systems. Today, 55 percent of all prescriptions are for customers enrolled in various managed care or drug benefit plans, up from 26 percent in 1990. That number is anticipated to reach 80 percent by the year 2000. Because of declining profits, about 1,000 drug stores have ceased doing business since 1992. About 3,500 drugstores have been sold, many to the large chain operations who then hire the pharmacist as an employee. Many of these large chains and other mass merchandisers, such as supermarkets or discount chains, often lose money on prescriptions because they can sell a multitude of other items, in "one-stop shopping," which have a potential for higher mark-up and profit. By employing various economies in other areas, these large retailers can offer many conveniences, including computerized prescription filling, telephone refills, drive-through service, and other amenities besides low cost.[8] In addition, retail pharmacies have been forced to deal with a mountain of paperwork, since most of the newer health plans do not involve the payment by the client, but instead rely on the health care card offered by the consumer and for which the pharmacy must submit forms for reimbursement. In the U.S., these small third-party receivables amount to about $700 million each week from about 4,500 different health plans. Many independents complain that payments are, in many cases, slow or nonexistent. It is estimated that pharmacies lose about $1.2 billion a year in uncollected receivables, three percent of the $40 billion spent on prescription drugs through health care plans.[9]

Besides losing access to pharmaceutical care when pharmacies close, the loss to the community and the state in terms of financial contributions is substantial. For example, each pharmacy contributes payroll, state sales tax, local sales tax, personal property tax, merchants' capital tax, business license tax, and matching withholding amounts contributed by the employer. The table below looks at those figures for five pharmacies which closed in the Commonwealth in different areas of the state.

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[7] Carol Ukens, "Chain Gain," *Drug Topics*, May 8, 1995.

[8] Toddi Gutner Block, "We Need You, You Need Us," *Forbes*, Vol., 155, No. 10, May 8, 1995.

[9] Schifrin, Matthew Rudnitsky, Howard, "Rx for Receivables," *Forbes*, Monday, May 6, 1996, Vol. 157, No. 9.

Closed Virginia Pharmacies

	Pharmacy A	Pharmacy B	Pharmacy C	Pharmacy D	Pharmacy E
Year Closed	1995	1996	1996	1996	1996
Gross Sales	$810,371	$694,575	$973,965	$1,050,278	$1,052,841
Total payroll (Non-RPh)	$43,379	$38,979	$21,879	$79,412	$57,250
Total	$853,750	$733,554	$995,844	$1,129,690	$1,110,091
State Sales Tax	$753	$1,906	$2,298	$1,987	$6,000
Local Sales Tax	$215	$564	$656	$568	$0
Personal Property Tax	$270	$1,212	$2,260	$302	$930
City/County Merchants's Capital Tax	None	$1,465	$570	None	Integrated with personal property tax
Business License Tax	$1,971	$50	$250	$2,109	$1,579
Total	$3,209	$5,197	$6,034	$4,966	$8,509
Federal, State Withholding & Matched Amounts by Employer	$15,681	$10,204	$61,308	$20,739	$38,281

IV. COGNITIVE SERVICES

Cognitive services are those functions performed by pharmacists, such as education about drug interaction, evaluation of the interaction with other drugs, evaluation of the appropriateness of the drug regimen as well as the prescribed dose, and visual evaluation of the patient's reaction to any drug regimen.

The role of community pharmacists has been described as an integral part of a truly managed system of health care, due mainly to their accessibility to the patient and their training and skills in appropriate medication therapy. Pharmacists have a face-to-face relationship with their clients; and by providing education and other cognitive services to the patient, they have the ability to provide services that extend the effectiveness of the physician, cut health care costs, and improve the quality of care.

A 1995 study estimates that for every dollar spent to purchase prescription drugs, Americans spend another dollar to fix the problems caused by underuse and misuse of those drugs. Proper administration of medications or evaluation of drug interactions can also prevent many "drug misadventures" when side effects occur, conditions worsen, and hospital emergency room visits are required.

Pharmacists characterize their work as being not only a help to the patient but to the health care system as well because of that intimate relationship with their clientele. As one pharmacist describes it, " . . . we are saving our customers, their insurance companies, or the Medicaid programs an average of $400 or more per day. As a profession, we are saving millions in physician office visits, unnecessary prescriptions, and unneeded lab tests. Often, we pick up situations that have slipped through the cracks but need attention. These interventions contribute considerably to the reduction of medical problems and costs."[10]

While acknowledging that certain economies and creative merchandising to meet the needs of the consumer all contribute to healthy competition, independents also feel that it is impossible to place a monetary value on the personalized services they offer to clients. Traditionally, except for specially authorized "trials," pharmacists are not allowed to charge for educational or cognitive services.

A. Pharmaceutical Care and Patient Outcomes

Numerous studies on pharmaceutical care have demonstrated that pharmaceutical care improves patient care and patient outcomes. The following is a sample of outcomes:

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[10] Truman Lastinger, "Commentary," *Drug Topics*, October 11, 1993.

- Asthma patients who are high users of hospital emergency departments for acute asthma attacks experienced over an 80 percent decline in the frequency of emergency visits as a result of ongoing pharmacist consultation.[11]
- Geriatric consumers, who account for about 30 percent of drug use in the U.S., were able to reduce the number of drugs taken and achieve significantly better compliance with their drug regimen after counseling by pharmacists, with no increased costs.[12]
- Ambulatory patients used significantly fewer health services, saving over $640 per year in health costs per individual as a result of comprehensive pharmacist counseling.[13]
- Community pharmacists counseling patients identified and resolved problematic prescription drug therapy in about two percent of new prescription orders, with about 28 percent of these judged capable of causing "patient harm" if the pharmacists had not intervened. The direct cost of medical care that was avoided was estimated to be $112.98 per problematic prescription, or $2.32 for each new prescription order that was screened during the study.[14]
- Physicians accepted about 83 percent of pharmacists' recommendations for drug therapy changes in an ambulatory care clinic. For 80 percent of these recommendations, "improvement or resolution of a patient's disease state" occurred. Cost reduction was also noted.[15]
- Clinical pharmacists practicing independently in community pharmacy settings demonstrated improved health outcomes in hypertensive patients. Pharmacists provided comprehensive education, blood pressure monitoring and assessment, compliance and adverse drug reaction monitoring, while a control group received traditional prescription services. Statistical differences in blood pressure control and compliance were documented between the two groups.[16]
- Relative to a control group, diabetic patients who received pharmaceutical care were more compliant in keeping appointments, made fewer medication errors, and had a lowered incidence of hospital admissions and "medical contacts." In addition, their symptoms improved in five of the eight variables measured.[17]
- A project was conducted to demonstrate the feasibility of a pharmacist-managed anticoagulation clinic in a private community hospital. The preliminary results indicate a high level of physician satisfaction, reduction in the number of admissions to treat warfarin-related bleeding, and financial stability through reimbursement from third-party payers and patients.[18]

(Additional anecdotal information about savings is contained in Appendix B.)

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[11] M. T. Rupp., *Ann Pharmacotherapy* 1992;26:1580-1584.
[12] H. L. Lipton, and Bird, L.A., *Gerontologist*, 1994.
[13] L. R. Borgsdorf, *American Journal of Hospital Pharmacy*, 1994.
[14] M. T. Rupp, *Ann Pharmacotherapy* 1992;26:1580.
[15] N. H. Lobas, et al. *American Journal of Hospital Pharmacy* 1992.
[16] J. M. McKenney., et al, *Circulation* 1973;48:1104-11.
[17] Sczupak, C.A. and Conrad, W.F., *American Journal of Hospital Pharmacy* 1977.
[18] J. L. Wilson, et al, *American Journal of Hospital Pharmacy* 1996;53:1151.

B. Other State Activities

Several states, including Mississippi, New Jersey, Oklahoma, Washington, West Virginia and Wisconsin, are leading efforts to alter the way pharmacists are paid for their services. Pharmacists have traditionally been compensated solely for dispensing medications. The states noted have developed programs which expand the services offered by pharmacists, providing incentives for patient monitoring, education and drug therapy management.

Mississippi: This state has also approved changes in payments to pharmacists for providing nondispensing services to Medicaid recipients, although the range of services has not yet been determined. Payments are limited to twice the current dispensing fee and the program must yield overall savings to be continued.

New Jersey: The New Jersey State Legislature adopted a provision for covering diabetes education as a mandated benefit in all state health insurance programs. Like certified diabetes educators (CDEs), pharmacists certified by New Jersey Board of Pharmacy as having completed adequate training in diabetes are eligible to bill for and collect compensation for diabetes education activities.

Oklahoma and West Virginia: Both of these states have passed statutes similar to the New Jersey legislation on diabetes education. In Oklahoma, the law applies to all insurance programs, while in West Virginia the program is limited to the state Medicaid population.

Washington: The Health Care Financing Administration (HCFA) awarded Washington State a grant to conduct a demonstration project examining the effect of paying pharmacists for delivering cognitive services to Medicaid recipients. The multi-year project is just completed, and preliminary analysis reveals that payment changes did provide adequate incentives for pharmacists to change the types of services provided to patients and yielded overall savings in total health expenditures for Medicaid recipients in the demonstration. The state decided to extend the program following the conclusion of the demonstration project.

Wisconsin: Effective July 1, 1996, pharmacists began billing the Wisconsin Medicaid program for cognitive services provided to recipients. The state agency worked with the state pharmaceutical and medical associations and with the pharmaceutical industry to identify the range of services eligible for reimbursement and payment levels for those activities. An evaluation must reveal overall costs savings in the Medicaid program to continue the reimbursement system.

C. Recommendations

The joint subcommittee endorsed the following recommendations, by resolution or budget language:

- That the Department of Medical Assistance Services and the Department of Personnel and Training initiate pilot programs to examine the costs and benefits of paying pharmacists for delivering cognitive services to recipients. The Departments are requested to work cooperatively with the various professional groups to identify the range of services which would be eligible for reimbursement, the payment levels, and the filing procedures, and to develop an evaluation to determine the potential overall savings in health care expenditures for Medicaid recipients and state employee. (Appendix A)

- That the General Assembly adopt statutory language which would recognize pharmacists as "health care practitioners" and as "health care providers" to allow pharmacists to bill and receive compensation from HMOs, insurance companies, and other third-party payers for counseling and other cognitive services (Appendix A)

V. RESTRICTIVE FORMULARIES AND DRUG SWITCHING

A. Guidelines for Medication Incentive Programs

Prescription retail drug costs have climbed progressively over the last ten years, and employers and insurance companies have searched for methods to control costs in order to continue to offer health insurance while providing appropriate health services. Some of these efforts have succeeded while others have had marginal or adverse effects. Both health care professionals, the doctor and the pharmacist, are entrusted, however, with making decisions which are in the patient's best interest. The American Pharmacy Association has developed "Guidelines for Medication Incentive Programs," a document intended to assist health professionals in judging the ethical merits and professional integrity of medication incentive programs. Medication incentive programs by definition include "coupon programs, academic detailing, tele-marketing, compliance, and therapeutic switches, that attempt to influence the use of particular medications over alternative medications or therapies."[19]

These guidelines for acceptable medication incentive programs incorporate the following principles:

- The patient's health and safety should take precedence. Positive patient outcomes are the cornerstone of any medication incentive program in that it must have a therapeutic and/or economic benefit without harming the patient. The

[19] "Guidelines for Medication Incentive Programs," American Pharmaceutical Association, May 1995.

therapeutic benefit should never be compromised, and programs should be economically neutral or beneficial in defraying other health care costs.

- Patients are entitled to pharmaceutical care services. Pharmacists must be able to provide pharmaceutical care which is the "responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. By definition, "pharmaceutical care" requires cooperation between the pharmacist and with other health care professionals in designing, implementing and monitoring a therapeutic plan.

- Patients and their health care professionals are entitled to full disclosure concerning medication incentive programs within the health care system for the use or omission of pharmaceuticals. "Full disclosure" includes the provision of material facts (including any remuneration received by the pharmacist from the program sponsor) that would affect a person's conduct or decision on the purchase or selection of goods or services.

- Patients' privacy rights must be protected. This includes the disclosure of patient-specific information to non-health care providers only with explicit patient approval.

- It is appropriate to provide fair remuneration to pharmacists for providing pharmaceutical care and cognitive services to patients. Traditionally, reimbursement to pharmacists has been tied to the cost of the medication or device and not to the value of cognitive services provided to patients.

B. Restrictive Formularies

A formulary, or restrictive drug formulary, is a list of prescription medications that a health care organization, such as a hospital, HMO, (or even the state as a healthcare provider), recommends be used for its patients. Medicines not listed are excluded, unless the treating physician secures special permission for a particular patient.

Formularies are used in an effort to keep costs down. Recent studies of cost containment practices, sponsored by the National Pharmaceutical Council concluded, however, that "greater formulary restrictions are associated with greater use of health care services and thus with greater costs."[20] Research found that restrictive medication formularies were associated with increased use of health care services, longer duration of illness, more visits to doctors and emergency rooms, and higher overall drug use. Use of multi-source drugs, older drugs whose patents have expired, was also associated with higher total treatment costs. Additionally, some patients respond to particular medicines but not to others that are different chemically, even though they are in the same therapeutic class or category. Availability of a broad choice of medicines in a category is

[20] "Bull's-Eye Report," National Pharmaceutical Council, No. 2.

viewed as giving physicians and patients more opportunity to arrive at effective therapy.[21] Therefore, although pharmacy costs decreased, there were demonstrated increases in other health care costs.

Prescription drug benefits for many insurance plans are administered by health maintenance organizations (HMOs), pharmacy benefits managers (PBM), or the insurance companies themselves. Using restrictive drug formularies to limit the number of drugs which are approved for use within a particular therapeutic category is viewed as being driven by volume discounts, or preferential pricing, set up by agreements between the manager and the insurance plan to lower prescription drug costs. In many cases, prescription drug-switching programs are utilized, sometimes without the doctor's knowledge since the PBM manager may speak only to a secretary or aide, to advise a pharmacist to dispense a drug different than the one prescribed by the doctor and for one which is heavily discounted or for which there are rebates available. As discussed earlier in this report, there are many drugs in each therapeutic classification, but each individual patient may react better or worse to a given one. They are not generic. Such switching programs are viewed as being disruptive to the doctor-patient relationship and, in many cases, more costly because of unintended results. Personnel, who work for PBMs and others and are usually responsible for the calls made to switch the drugs, are not professionals and do not have access to the patient's health records. Additionally, it has been alleged that PBMs, HMOs, and health insurance companies routinely capture and resell patient information to drug manufacturers for advertising purposes.

Current Virginia statute might seem to prohibit such interference in the health care provided to patients in that § 54.1-3303 clearly states that "a bona fide practitioner-patient-pharmacist relationship is one in which a practitioner prescribes, and a pharmacist dispenses, controlled substances in good faith to his patient for a medicinal or therapeutic purpose within the course of his professional practice." Subsection B also goes further to require that "No prescription shall be filled which does not result from a bone fide practitioner-patient-pharmacist relationship."

The State of Texas has addressed this issue in such a manner as to include those persons who perform acts which would affect the diagnosis or treatment of a patient in Texas within the definition of a practitioner. Any person who practices medicine in the state without a license would be subject to prosecution for a third degree felony.[22]

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[21] Ibid., citing from "Intended and Unintended Consequences of HMO Cost-Containment Strategies: Results from the Managed Care Outcomes Project," Horn, Susan D., et al, *The American Journal of Managed Care*, Vol.II.No.3:253-264.

[22] "It is the position of the Texas State Board of Medical Examiners, consistent with the provisions of section 3.06(i) of the Medical Practice Act, that the determination of medical necessity or appropriateness of proposed care so as to effect the diagnosis or treatment of a patient is the practice of medicine. To engage in the determination of medical necessity or appropriateness of an evaluation or care so as to effect the diagnosis or treatment of a patient in Texas requires a Texas medical license. Consistent with section 3.06(i) of the Medical Practice Act, the Texas State Board of Medical Examiners recognizes that a person physically located in another jurisdiction who, through any medium, performs an act that is part of a

C. Recommendations.

The joint subcommittee recommends the introduction of legislation to prohibit the practice of drug switching in the Commonwealth. (The Joint Subcommittee, citing the lateness of the introduction of this proposal and the complex issues involved, voted to advance this proposal for purposes of discussion.) (Appendices A and C)

VI. PREFERENTIAL PRICING

Preferential pricing, or discounting, is a recent development in the pharmaceutical industry. Traditionally, aside from some discounts offered to large-volume customers, everyone always paid the same price. In the 1980s, to contain costs, some hospitals and emerging HMO plans developed formularies, or preferred drugs, for use by doctors in their system. With the multitude of drugs which are pharmaceutically equivalent, costs can be cut by carrying only one brand. In order to gain access to these markets, manufacturers were required to discount certain drugs and these drugs might be the preferred drugs recommended to their participating physicians. Competition with other manufacturers discounted the prices even further and enabled HMOs and other similar plans to offer drug benefit plans at sharply reduced prices. Retail pharmacies have been left out of process and receive no discounts. Even the formation of types of consortiums by groups of pharmacies have failed to garner the substantial cuts enjoyed by the managed care programs. In addition, pharmacists must carry a full spectrum of drugs to comply with physicians' orders and, therefore, have limited bargaining power with the manufacturers.[23]

To counter this trend, considered life-threatening by independents, pharmacies across the country have joined in a number of lawsuits contesting the discounting practices of manufacturers which they say violate various antitrust laws. In addition, charges have been made that the manufacturers have engaged in illegal [24]collusion to collectively deny discounts.[25]

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patient service initiated in this state and that would effect the diagnosis or treatment of a patient is also engaged in the practice of medicine so as to require a Texas medical license

An individual or entity which makes a determination of medical necessity or appropriateness of any medical evaluation or care so as to effect the diagnosis or treatment of a patient in Texas, and who does not possess a Texas medical license or other authorization to practice medicine in this state, shall be subject to referral for further investigation, criminal prosecution, injunctive action, and the possible imposition of monetary penalties. A person who practices medicine in Texas without a license or permit so as to cause financial, physical, or psychological harm shall be subject to prosecution for a third degree felony as provided for in section 3.07 of the Medical Practice Act." Position Statement adopted by the Texas State Board of Medical Examiners, October 5, 1996.

[23] Laurie P. Cohen and Elyse Tanouye, "Bitter Pill: Drug Makers Set to Pay $600 Million to Settle Lawsuit by Pharmacies, The Wall Street Journal, Thursday, January 18, 1996.

[24] In re Brand Name Prescription Drugs Antitrust Litigation, 1996 WL 167350 (N.D. Ill.) April, 1996.

In re Brand Name Prescription Drugs Antitrust Litigation (No. 94 C 897)

This litigation is the result of a number of lawsuits filed by various retail pharmacies in a consolidated action heard before the United States District Court in Chicago. Retail pharmacies claim that numerous drug manufacturers have violated portions of the Sherman Antitrust Act and the Robinson-Patman Act. The suit alleges that the drug manufacturers established and maintained a dual pricing system which offers discounts to certain groups while maintaining high prices to retail pharmacies. Inherent in the suit are the charges that manufacturers engaged in collusion to deny these benefits to retail pharmacies and that these agreements date back to the early 1980s. The wholesale industry initially was included in the suit for its "chargeback" practices, that is, when a discounted contract price is negotiated by the manufacturer and the favored purchaser, the discounted drug is supplied out of the wholesaler's inventory, the wholesaler delivers the product to the favored purchaser at the discounted price, and then the wholesaler "charges back" the manufacturer for the difference between the price paid and the lower price at which delivered. However, wholesalers have been dismissed from the suit because the court found that the manufacturers ultimately controlled the discounts offered.

The court denied the manufacturer defendants motions for summary judgment and granted the wholesalers' motions.

Section 1 of the Sherman Antitrust Act prohibits the formation of any "contract, combination . . . or conspiracy in restraint of trade or commerce . . ."[26] A civil plaintiff seeking recovery under Section 1 must allege and ultimately prove: "(1) a contract, combination, or conspiracy; (2) a resultant unreasonable restraint of trade in the relevant market; and (3) an accompanying injury."[27] The court found that the drug manufacturers had (i) the opportunity to conspire, (ii) the mechanism through their association to access information from other manufacturers, and (iii) continued to deny any type of discounts to retail pharmacies.

A number of Virginia pharmacies have filed their own complaint in the United States District Court for the Eastern District, but the case has not yet been heard. The complaints are similar to the preceding case and invoke protection under the federal Clayton, Sherman Antitrust and Robinson-Patman Acts. At present, no date has been scheduled for hearing.

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[26] 15 U.S.C. s 1.

[27] *Denny's Marina, Inc. v. Renfro Productions*, Inc., 8 F. 3d 1217, 1220.

VII. THIRD-PARTY PAYER ISSUES

A. MCV/VCU School of Pharmacy Study

The growth of third-party reimbursement for pharmaceuticals has significantly affected community pharmacies. In 1972, third-party payers paid for only 18.5 percent of prescriptions dispensed in community pharmacies. By 1985, the figure had grown to 28.4 percent, and by 1994 third party payors were finally acknowledged as being responsible for the majority of prescriptions. At that time, state Medicaid programs paid for 13 percent of outpatient prescriptions and private third parties paid for 45 percent.[28] The study goes on to cite evidence that third-party reimbursement appears to have had an adverse impact on the profitability of community pharmacies, i.e., pharmacies with high percentages of third-party reimbursement have substantially lower gross and net profits than pharmacies with low percentages of third-party reimbursement. This results from the practice of third-party payers paying pharmacies lower prices than those paid by uninsured patients and pharmacies paying higher dispensing costs (computer programs, software, prescribed forms, on-line time, long distance phone costs, etc.) for reimbursement from third-party payers. This study found, and the results were corroborated by testimony to the joint subcommittee, that pharmacies continue to fill these prescriptions they find to be unprofitable in order to maintain their community clientele.

Pharmaceutical care, defined earlier, is a crucial part in effective medical therapy. Recent federal and state legislation mandates that counseling be provided to all patients, but most reimbursement levels do not take into account the extra time the pharmacists must spend with each client to meet those counseling mandates, and that the availability of this service depends upon the number and location of pharmacies. The study made the following observations and conclusions:[29]

- Data indicate that the gross and net profitability of independent pharmacies is steadily declining, averaging only three percent from 1990 to 1993.
- Declining reimbursement levels and profitability do not allow sufficient funds to provide for the increased professional staff needed to provide mandated counseling.
- As profitability declines, the hardest hit are the independent pharmacies, which are the pharmacies most likely to serve patients in rural and inner city locations.

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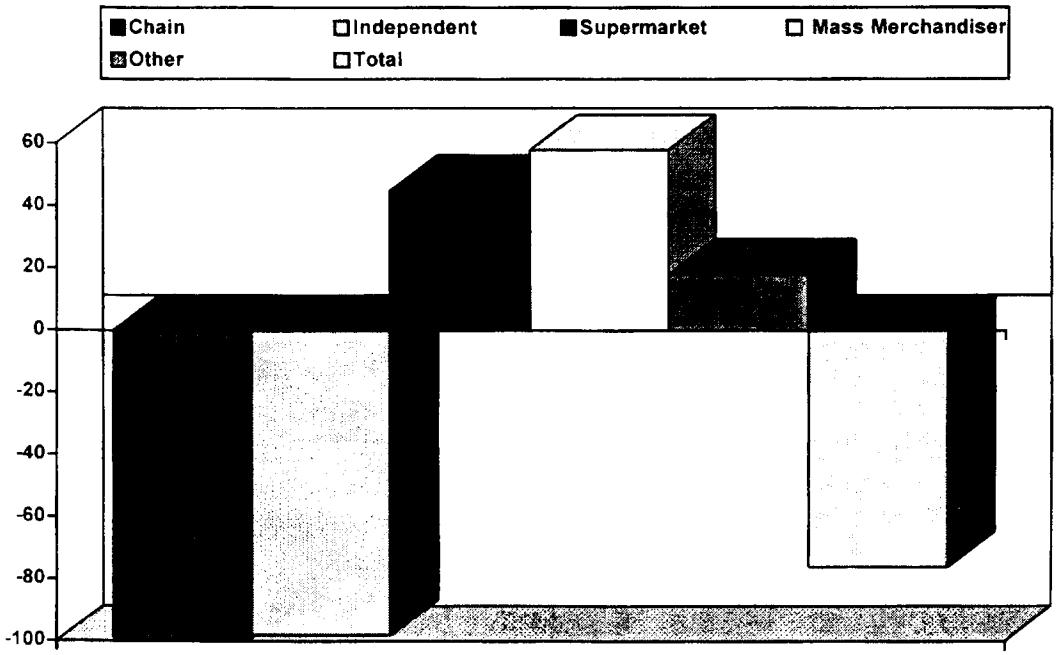
[28] Norman V. Carroll, R.Ph., Ph.D., Patrick A Miederhoff, R.Ph., Ph.D., and Lawrence W. Waters, B.S., M.B.A., "The Impact of Third-Party Reimbursement on the Economic Viability of Community Pharmacy Practice", August 21, 1995.
[29] Ibid.

- Pharmacy closings equal patients without access to pharmaceutical care. The report did note that mail order prescription services can provide services in these areas, but only for long-term chronic conditions and not short-term emergencies.

- From 1989 to 1994, there was a net loss of 84 outpatient pharmacies (258 opened and 342 closed). Chain and independent pharmacies decreased while supermarket and mass merchandising pharmacies increased.



- There was no change during that period in the total absence in eight localities of an outpatient pharmacy.areis eroding the profitability of community pharmacies.
- Data indicate that a 15 percent shift in reimbursement from private-pay to private third-party payment would be sufficient to reduce pharmacy net profit by three percent which would totally eliminate the net profit of the average independent pharmacy.
- Results show an early trend of pharmacies already moving away from areas populated by the poor and elderly.
- Managed care programs achieve savings by excluding some providers and by negotiating substantial discounts from others which will erode the profitability of pharmacies and decrease access by consumers.
- Although access by consumers is not yet a problem, this study did conclude that such problems are likely to emerge in the near future.

B. Pharmacy Freedom of Choice

Testimony received by the joint subcommittee frequently mentioned "pharmacy freedom of choice" issues, saying that many drug plans currently would not appear to meet the conditions of this statute. Virginia Code Section 38.2-3407.7 specifically states that "no insurer proposing to issue preferred provider policies or contracts shall prohibit any person receiving pharmacy benefits furnished thereunder from selecting, without limitation, the pharmacy of his choice to furnish such benefits. This right of selection extends to and includes pharmacies that are nonpreferred providers and that have previously notified the insurer, by facsimile or otherwise, of their agreement to accept reimbursement for their services at rates applicable to pharmacies that are preferred providers, including any copayment consistently imposed by the insurer, as payment in full." However, besides the apparent lack of compliance, evidence presented indicated that third-party contracts were frequently offered in a "take it or leave it" approach with reimbursement levels so low as to contain little, if any, profit. For example, one pharmacy detailed a random prescription sampling for a period of approximately five months. For those 268 prescriptions, insurance paid $21,480.74 for actual dollar acquisition costs of $21,205.13, leaving a total profit of $275.61. Out of this profit, the following overhead costs must be paid:

Profit per prescription	$1.03
Less average prescription vial cost	.28
Less average electronic transmission charge	.15
Less OSHA patient counseling aid	.05
Less Special Insurance Receipt	.01
Less Prescription Label	.02
Less Prescription Bag	.02
Adjusted gross	.50

Only then are standard overhead costs paid, such as rent, utilities, insurance, taxes, and salaries.

Pharmacy contracts usually do not engage in negotiation about reimbursement and, more importantly, about the charge to a patient. Pharmacists are generally reimbursed based on a complex system of "average wholesale price," (AWP), "actual acquisition cost," "maximum allowable cost," (MAC), and other interrelated business considerations. Contributing factors to the actual acquisition cost include the arrangement that particular store has with its wholesaler. Arrangements usually take one of two forms:

1. Wholesaler cost + (plus) a percentage, or
2. Average wholesale price - (minus) a percentage

Maximum allowable cost, usually reserved for generic drug reimbursement, is one additional factor to be considered. MAC can vary from one insurance company to another and is based on an arbitrary calculation that fluctuates.

In the past, stores were reimbursed from the insurance company based on the average wholesale price plus a dispensing fee. The amount reimbursed covered not only the cost of the product, but the dispensing fee offset the expenses of providing the services associated with interactive patient care and drug therapy. Current reimbursement contracts are based on terms most often based on national cost averages of the product, not necessarily the actual acquisition cost. Reimbursement contracts range from:

Brand Name: AWP - 9% +$4.25 to AWP - 16% + $1.50
Generic: MAC + a fee to AWP - 30% + a fee

The state employee drug plan was discussed extensively in light of its reimbursement (AWP - 18% + no fee), the lack of freedom of choice in that only certain pharmacies have been enrolled as providers, and the fact that the plan has an incentive for pushing patients to use the mail order program by requiring higher copayments when prescriptions are filled at the local pharmacy. This plan functions with a mandatory generic usage and a closed formulary administrated through Trigon and the contracted pharmacy benefits manager (PBM).

C. Medicaid

Pharmacy services are an optional program in Medicaid, meaning that the state has the option to provide those services. Currently, in Virginia, Medicaid pharmacy services include:

- Drug coverage currently is limited in the outpatient population to legend (prescription only) drugs except for insulin; needles and syringes for diabetes; glucose test strips for children; and family planning drugs and supplies. Additionally, specific nonlegend therapeutic categories for nursing home patients are currently covered. Prescriptions for multiple source drugs are to be filled with generics from the Virginia Voluntary Formulary unless the prescriber certifies a particular brand is medically necessary.
- Co-payments of $1.00 per prescription are required of categorically needy and medically needy recipients, except for persons under 21 years of age; patients residing in nursing facilities; and those taking drugs for family planning or pregnancy-related conditions. This co-payment is paid directly to the dispensing pharmacy but is deducted from the reimbursement to the provider through the program.
- Pre-authorization is currently required in the Medicaid fee-for-service system for growth hormones; anorexiants, when used for attention deficit disorders (ADD) or narcolepsy; and total parenteral nutrition (TPN), intravenous feedings used when nutrients cannot be absorbed through the gastrointestinal route.

Medicaid reimbursement is currently AWP - 9% + $4.25, but private, for-profit HMOs contracting with DMAS (generally Medallion II) to provide pharmacy services to Medicaid recipients are allowed to reimburse Virginia chain or independent pharmacies at their regular commercial rates. DMAS generally does not use mail order pharmacies but contracted HMOs may do so. The Department has indicated an interest in exploring the concept of Disease State Management, which, for purposes of pharmacy, is the practice of monitoring the patient's drug therapy in relation to what is usually a long-term disease and intervening when necessary. The goal is helping patients maintain or improve their health as much as possible.

D. Recommendations

The joint subcommittee recommended that the State Department of Personnel and Training and the Department of Medical Assistance Services take steps to ensure that programs under their purview comply with the Pharmacy Freedom of Choice statute in the Code of Virginia and to require compensation to pharmacies which allows them a reasonable profit as participating providers. (Appendix A)

VIII. OTHER LEGISLATIVE STUDIES

Over the years from 1992 through 1995, a number of resolutions have been introduced into the General Assembly which deal with pharmacy costs, relationships between pharmacies and other health care programs, and the best interests of the consumer. Although the latest study, chaired by Delegate Kenneth R. Melvin, examined other issues such as quality of pharmacy services, the issue of drug discounting and its impact on independents constituted a major core of the study. In its 1995 *Report of the Joint Subcommittee Studying the Financial Impact of Third Party Reimbursements on the Commonwealth's Pharmacies* (House Document No. 67, 1995), the joint subcommittee made the following recommendations:

- That the Joint Commission on Health Care continue to monitor the implementation of the "Freedom of Choice" law in 1996 to assess its effects on competition and health care costs.
- That the term "ancillary provider" as defined in the "Freedom of Choice" law be clarified.
- That the Joint Commission on Health Care examine the effects of agreements between self-funded employers and insurance companies serving as third party administrators on health care costs, competition, access to care, and the quality of care.

  The Joint Commission on Health Care, while pursuing a number of health-related studies, has not yet undertaken a specific study of these issues at this time.

- That insurers recognize through reimbursement the inherent value (in terms of patient compliance and appropriate drug utilization) of pharmacists' counseling and cognitive services.

This proposal has not yet been implemented.

- That all third party payers, including the Department of Medical Assistance Services, strive to implement administrative efficiencies to constrain costs, such as streamlining claims processing, simplifying claims forms, automating claims review, and using a single claims form.
- That the United States Congress initiate revisions in the Medicaid Rebate Program to address the lack of federal guidance on unit rebate amount disputes and challenges; the differences between state and federal units of measure; prescription coding problems and the potential for large billing errors resulting from small mistakes; and the failure to promulgate final federal regulations.

According to testimony, DMAS has been active in many of the suggested areas, in cooperation with the Virginia Health Outcome Partnership (VHOP), and, more recently, the Medicaid Pharmacy Liaison Committee. Their initiatives focus on several of the areas addressed in the previous recommendations:

1. Cognitive services - At present, the only additional payment to pharmacists for these services is the Clozaril® counseling fee. The department is currently watching with interest the results of the pharmacists' part in disease state management and outcomes management programs being developed.
2. The Virginia Medicaid program has been instructed by the General Assembly to enhance the use of the pharmacy on-line claims submission (point-of-service or POS) system for improved patient care, and cost savings. In addition, a mandate has been issued to utilize a program of disease state management through the pharmacy component of the Medicaid program.
3. The DMAS Point-of-Service (POS) system was brought up in August 1994. In the most recent three months, paper submissions have averaged only about 9.5 percent of claims. On an average, approximately 14,480 paper documents are handled per month, generating about 76,000 total claims monthly by paper submission. Many of those claims are for: minimal effort on the part of the provider since there are no forms to fill 's ability to override denials if justified by medical judgment; expedited payment to the provider, with most payments being made within seven to ten days of service; and reduced staffing/bookkeeping requirements.
4. Medicaid rebates have been addressed. Virginia rebate collections have amounted to $168 million as of October 10, 1996. Portions are credited by to the state and federal programs according to Federal Funding Participation guidelines. Virginia's portion is returned to the general fund. In addition, in

July 1995, Virginia began collecting rebates on drug products billed on the HCFA 1500 claim form, used by all providers other than pharmacies. Within a year, claims exceeded $800,000 and other billings are outstanding. Additional rebates are expected through the use of a new form for compounded prescriptions which will identify rebate-bearing NDCs, and through a new mechanism for billing intravenous therapies.

Respectively submitted,

Delegate John J. "Butch" Davies, Chair
Delegate I. Vincent Behm
Delegate Joyce K. Crouch
Delegate Brian J. Moran
Senator Joseph S. Benedetti
Senator Emily Couric
Senator Charles R. Hawkins

IX. APPENDICES

APPENDIX A

970097198

HOUSE JOINT RESOLUTION NO. 614

Offered January 20, 1997

Requesting the Departments of Medical Assistance Services and Personnel and Training to initiate pilot programs to examine the costs and benefits of paying pharmacists for delivering cognitive service to patients.

Patrons—Behm, Baker, Bennett, Brickley, Callahan, Cox, Cranwell, Crouch, Davies, Dickinson, Guest, Hall, Heilig, Melvin, Moran, Morgan, Spruill and Woodrum; Senators: Benedetti, Couric, Earley, Gartlan, Hawkins, Holland, Lambert, Potts and Wampler

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Referred to Committee on Health, Welfare and Institutions

WHEREAS, cognitive services are those functions performed by pharmacists, such as evaluation of and education about drug interaction, evaluation of the appropriateness of the drug regimen as well as the prescribed dose, and visual evaluation of the patient's reactions to any drug regimen; and

WHEREAS, it is not uncommon for the pharmacist to have more frequent contact with the patient than does the physician in regards to all aspects of the patient's health; and

WHEREAS, in many cases, the pharmacist is the first line of much medical advice and care when answering questions of patients as they come through the pharmacy; and

WHEREAS, a 1995 study estimates that for every dollar spent to purchase prescription drugs, Americans spend another dollar to fix the problems caused by underuse and misuse of those drugs; and

WHEREAS, pharmacists are currently mandated by state and federal law to provide counseling to patients but are not allowed them to bill for such services; and

WHEREAS, numerous studies on pharmaceutical care have demonstrated that pharmaceutical care improves patient care and patient outcomes by, among other things, reducing the frequency of emergency visits, reducing the number of drugs being taken, eliminating problematic drug interactions which would have resulted in direct medical costs, helping keep patients informed about and compliant with drug therapies, and reducing the number of hospital admissions; and

WHEREAS, pharmacists have traditionally been compensated solely for dispensing drugs, but several states around the nation have been leading efforts to alter this payment schedule by developing programs which expand the paid services offered by pharmacists, and providing incentives for patient monitoring, education, and drug therapy management; and

WHEREAS, one of the more outstanding programs was developed in Wisconsin which, in July 1996, allowed pharmacists to begin billing the Wisconsin Medicaid program for cognitive services provided to recipients; and

WHEREAS, the strength of the Wisconsin program is attributed to the fact that it was developed in concert with the state pharmaceutical and medical associations and with the pharmaceutical industry to identify the range of services eligible for reimbursement and payment levels for those activities; and

WHEREAS, in the Wisconsin program, as in others, an evaluation must reveal overall costs savings in the Medicaid program to continue the reimbursement system; and

WHEREAS, the Virginia Department of Medical Assistance Services currently allows additional payment to pharmacists for medication management services for those patients who are taking Clozaril, a medication taken by some persons with a specific mental health diagnosis; and

WHEREAS, the Commonwealth now provides drug prescription services to a number of recipients, through Medical Assistance Services as well as to all full-time employees of the state; now, therefore, be it

RESOLVED, by the House of Delegates, the Senate concurring, That the Departments of Medical Assistance Services and Personnel and Training each initiate a pilot program to examine the costs and benefits of paying pharmacists for delivering cognitive services to recipients. Each department, in the design of the program, is requested to examine the programs already in effect in other states and to cooperatively work with the various professional groups to identify the range of services which would be eligible for reimbursement, the payment levels, and the filing procedures, and develop an

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1 evaluation to determine the potential overall savings in health care expenditures for Medicaid and
2 state employee recipients.
3 The Departments of Medical Assistance Services and Personnel and Training shall complete their
4 preliminary work and submit initial plans, prior to implementation, for such a program by October 1,
5 1997, for evaluation by the 1998 Session of the General Assembly as provided in the procedures of
6 the Division of Legislative Automated Systems for the processing of legislative documents. Such a
7 program, if approved by the General Assembly, shall be in place no later than July 1, 1998.

Official Use By Clerks

Passed By The House of Delegates		**Passed By The Senate**	
without amendment	☐	without amendment	☐
with amendment	☐	with amendment	☐
substitute	☐	substitute	☐
substitute w/amdt	☐	substitute w/amdt	☐
Date: _____		Date: _____	
_____		_____	
Clerk of the House of Delegates		Clerk of the Senate	

970098198

HOUSE JOINT RESOLUTION NO. 473

Offered January 15, 1997

Expressing the sense of the General Assembly regarding the invaluable services performed by pharmacists for the people of the Commonwealth and asking that third-party payers consider reimbursing pharmacists for the provision of counseling and other cognitive services.

Patrons—Crouch, Behm, Davies and Moran; Senators: Benedetti, Couric and Hawkins

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Referred to Committee on Health, Welfare and Institutions

WHEREAS, community pharmacists have been described as an integral part of a managed system of health care due mainly to their accessibility to the patient and in their training and skills in appropriate medication therapy; and

WHEREAS, cognitive services are those functions performed by pharmacists, such as evaluation of and education about drug interactions, evaluation of the appropriateness of the drug regimen as well as the prescribed dose, and visual evaluation of the patient's reaction to any drug regimen; and

WHEREAS, pharmacists have a face-to-face relationship with their clients, and by providing education and other cognitive services to the patient, they have the ability to provide services that extend the effectiveness of the physician, cut health care costs, and improve the quality of care; and

WHEREAS, a 1995 study estimates that for every dollar spent to purchase prescription drugs, Americans spend another dollar to fix the problems caused by underuse and misuse of those drugs; and

WHEREAS, current state and federal law requires pharmacists to provide counseling to patients, when either directed by protocol or requested by the client, and most produce a computer counseling page to advise the client after leaving the pharmacy regarding certain directions and advice; and

WHEREAS, pharmacists describe their work as being not only a help to the patient but to the health care system as well because of that intimate relationship with their clientele; and

WHEREAS, pharmacists have documented that they are saving their customers, their insurance companies, or the Medicaid programs an average of $400 or more per day; and

WHEREAS, as a profession, pharmacists feel that they save millions in physician office visits, unnecessary prescriptions, and unneeded lab tests by noticing situations that have slipped through the cracks but need attention; and

WHEREAS, these interventions contribute considerably to the reduction of medical problems and costs; now, therefore, be it

RESOLVED, by the House of Delegates, the Senate concurring, That this General Assembly, being cognizant of the need to contain health care costs in an environment that provides the best outcome for the patient, recognizes the value of cognitive services provided by pharmacists to their clientele. While counseling services are now required by state and federal mandate, it has been an unfunded mandate except in certain specified circumstances under the Medicaid program. Provision of these educational and monitoring services has proven to be a great benefit, both in terms of financial savings to payers as well as in terms of alleviation of or avoidance of adverse health situations; and, be it

RESOLVED FURTHER, That the General Assembly does strongly encourage all insurance companies, health maintenance organizations, and other third-party payers doing business in the Commonwealth to appropriately recognize the value of and to adequately compensate pharmacists for the provision of these cognitive and educational services. Interventions such as these contribute considerably to the reduction of medical problems and, ultimately, of medical costs.

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GENERAL ASSEMBLY OF VIRGINIA -- 1997 SESSION

HOUSE JOINT RESOLUTION NO. 473

Expressing the sense of the General Assembly regarding the invaluable services performed by pharmacists for the people of the Commonwealth and encouraging third-party payers to adequately reimburse pharmacists for the provision of counseling and other cognitive services.

Agreed to by the House of Delegates, February 20, 1997
Agreed to by the Senate, February 19, 1997

WHEREAS, community pharmacists have been described as an integral part of a managed system of health care due mainly to their accessibility to the patient and their training and skills in appropriate medication therapy; and

WHEREAS, cognitive services are those functions performed by pharmacists, such as evaluation of and education about drug interactions, evaluation of the appropriateness of the drug regimen as well as the prescribed dose, and visual evaluation of the patient's reaction to any drug regimen; and

WHEREAS, pharmacists have a face-to-face relationship with their clients, and by providing education and other cognitive services to the patient, they have the ability to provide services that extend the effectiveness of the physician, cut health care costs, and improve the quality of care; and

WHEREAS, a 1995 study estimates that for every dollar spent to purchase prescription drugs, Americans spend another dollar to fix the problems caused by underuse and misuse of those drugs; and

WHEREAS, current state and federal laws require pharmacists to provide counseling to patients, when either directed by protocol or requested by the client, and most produce a computer counseling page to advise the client after leaving the pharmacy regarding certain directions and advice; and

WHEREAS, pharmacists describe their work as being not only a help to the patient but to the health care system as well because of that intimate relationship with their clientele; and

WHEREAS, pharmacists have documented that they are saving their customers, their insurance companies, or the Medicaid programs an average of $400 or more per day; and

WHEREAS, as a profession, pharmacists feel that they save millions in physician office visits, unnecessary prescriptions, and unneeded lab tests by noticing situations that have slipped through the cracks but need attention; and

WHEREAS, these interventions contribute considerably to the reduction of medical problems and costs; and

WHEREAS, the General Assembly is aware of the need to contain health care costs in an environment that provides the best outcome for the patient, and recognizes the value of the cognitive services provided by pharmacists to their clientele; and

WHEREAS, while counseling services are now required by state and federal mandate, it has been an unfunded mandate except in certain specified circumstances under the Medicaid program; and

WHEREAS, the provision of these services has proven to be a great benefit, both in terms of financial savings to payers as well as in terms of the alleviation or avoidance of adverse health situations; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the General Assembly strongly encourage all insurance companies, health maintenance organizations, and other third-party payers doing business in the Commonwealth to appropriately recognize the value of and adequately reimburse pharmacists for the provision of counseling services and other cognitive services.

970117198

HOUSE BILL NO. 2714

Offered January 20, 1997

A BILL to amend the Code of Virginia by adding in Title 54.1 a chapter numbered 34.1, consisting of sections numbered 54.1-3480 through 54.1-3487, relating to the Virginia Anti-Drug Switching Patient Protection Act; penalties.

Patrons—Davies, Baker, Bloxom, Cooper, Councill, Cranwell, Crouch, Dickinson, Hall, Hargrove, Jackson, Johnson, Keating, McEachin, Melvin, Moran, Morgan, Nelms, Orrock, Plum, Spruill, Stump, Tate, Van Yahres, Wagner and Woodrum; Senators: Couric, Edwards, Gartlan, Hawkins and Trumbo

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Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Title 54.1 a chapter numbered 34.1, consisting of sections numbered 54.1-3480 through 54.1-3487, as follows:

CHAPTER 34.1.

VIRGINIA ANTI-DRUG SWITCHING PATIENT PROTECTION ACT.

§ 54.1-3480. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Advertisement" means a representation disseminated in any manner or means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of a prescription drug. The term does not include any act prohibited by the chapter.

"Attorney" means the Attorney General of Virginia, and the attorney for any city, county or town.

"Caregiver" means (i) a parent or guardian of a minor patient, (ii) a relative, close friend or employee of a patient who provides in-person physical assistance to the patient, or (iii) a person employed by another to care for a patient who provides in-person physical assistance to the patient.

"Chemically dissimilar" means a prescription drug which possesses one or more active ingredients that are different from those of another prescription drug.

"Deliver" means the actual, constructive, or attempted transfer of any item regulated by this chapter, whether or not there exists an agency relationship.

"Dispense" or "dispensing" means to deliver a prescription drug to a patient by or pursuant to the lawful order of a prescribing practitioner.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in an individual; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of an individual; or (iv) articles or substances intended for use as a component of any article specified in (i), (ii), or (iii). "Drug" does not include devices or their components, parts or accessories.

"Employer" means a person who provides monetary or other compensation to another person for goods or services, whether the one receiving monetary or other compensation is an employee, agent, partner, independent contractor or other.

"Manufacture" means the production, preparation, propagation, conversion or processing of any item regulated by this chapter, either directly or indirectly by extraction from substances of natural origin, or independently by means or chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container.

"Manufacturer" means any person who manufactures and all agents of that person.

"Monetary incentive" means any rebate, discount, kick-back, fee, special charge or other financial incentive received directly or indirectly from a manufacturer.

"Patient" means an ultimate consumer of a prescription drug who obtains the prescription drug from a licensed pharmacist or practitioner who is authorized by law to prescribe or dispense prescription drugs.

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"Pharmacists" means a person duly licensed by the Virginia Board of Pharmacy to practice pharmacy or a person duly licensed by any other state or U.S. territory to practice pharmacy.

"Practitioner" means a person duly licensed by the Commonwealth or by any other state or U.S. territory as a physician, dentist, osteopath, podiatrist, nurse practitioner, TPA-certified optometrist, or physician's assistant.

"Prescribing practitioner" means a practitioner who (i) prescribes a prescription drug for a patient and (ii) is authorized by applicable law to prescribe or administer such drugs.

"Prescription drug" or "prescribed drug" means any drug required by federal law of regulation to be dispensed only pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503 (b) of the Federal Food, Drug, and Cosmetic Act.

"Sells" or "selling" includes barter, exchange, transfer, or gift, or offer therefor.

§ 54.1-3481. Exceptions to applicability of chapter; no exemption from other provisions of title.

A. The provisions of this chapter shall not apply to any prescription drug prescribed by a scientific investigator for purposes of research or prescribed by a veterinarian. Where the solicitation or encouragement prohibited herein is directed to a practitioner, this chapter shall only apply to a solicitation or encouragement where the practitioner has a bona fide practitioner-patient relationship with a specific patient for whom a specific drug has been prescribed from which a substitution is sought.

B. This chapter shall not be construed as exempting any person from the requirements of Chapter 33 (§ 54.1-3300 et seq.) or Chapter 34 (§ 54.1-3400 et seq.) of this title.

§ 54.1-3482. Unlawful actions.

A. No person shall solicit or encourage the prescribing practitioner of a patient residing in the Commonwealth, while that patient is physically located in the Commonwealth, to substitute a prescription drug which the prescribing practitioner originally prescribed for the patient with any chemically dissimilar prescription drug, unless the person is the patient, another practitioner, or a caregiver of the patient. The foregoing shall in no way limit the ability of any person to contact a patient's prescribing practitioner to warn of a contraindication, precaution or adverse reaction

B. No practitioner shall solicit or encourage the prescribing practitioner of a patient residing in the Commonwealth, while that patient is physically located in the Commonwealth, to substitute a prescription drug the prescribing practitioner originally prescribed for the patient with any chemically dissimilar prescription drug where a purpose of the substitution is to assist the practitioner, or an employer of the practitioner, in receiving a monetary incentive from the manufacturer of the chemically dissimilar prescription drug which is based upon the substitution of that prescription drug in the place of another prescription drug which is chemically dissimilar.

C. No pharmacist shall sell or dispense a prescription drug to a patient residing in the Commonwealth, while that patient is physically located in the Commonwealth, if the pharmacist possesses actual knowledge that (i) a person solicited or encouraged the patient's prescribing practitioner to substitute the originally prescribed drug with any chemically dissimilar prescription drug, and (ii) that a purpose of the substitution is to assist such person or any employer of that person in receiving a monetary incentive from the manufacturer of the chemically dissimilar prescription drug which is based upon the substitution of that prescription drug in the place of another prescription drug which is chemically dissimilar.

D. No person shall solicit or encourage (i) a patient residing in the Commonwealth, while that patient is physically located in the Commonwealth, (ii) a caregiver of the patient, or (iii) a practitioner of the patient to request the patient's prescribing practitioner to substitute a prescription drug the prescribing practitioner originally prescribed with a chemically dissimilar prescription drug where a purpose of the substitution is to assist such person or an employer of that person in receiving a monetary incentive from the manufacturer of the chemically dissimilar prescription drug which is based upon the substitution of that prescription drug in the place of another prescription drug which is chemically dissimilar.

§ 54.1-3483. Presumption of violation.

For purposes of this chapter, where a person or a person's employer receives a monetary incentive from a manufacturer of a prescription drug based upon the substitution of that prescription drug in the place of another prescription drug which is chemically dissimilar, it shall be presumed to

be a violation of this chapter.

§54.1-3484. Violators entitled to bring suit.

A. Any person entitled to bring an action pursuant to this chapter as set forth herein may do so regardless of whether that person has violated a provision of this chapter himself.

B. Any practitioner who violates any provision of this chapter shall pay for each violation a civil penalty of not more than ten dollars, plus attorney fees and costs. However, if a practitioner or his employer receives in violation of this chapter any monetary incentive from another person for his assistance in substituting a chemically dissimilar prescription drug for the prescription drug originally prescribed in violation of this chapter, each practitioner or employer shall pay a civil penalty of not more than $100, plus attorney fees and costs. Any person other than a practitioner who violates any provision of this chapter shall, for each violation, pay a civil penalty of not more than $5,000, plus attorney fees and costs. The civil penalty shall be in addition to any other causes of action or remedies that may exist against such person and shall be paid into the Literary Fund.

C. Notwithstanding any other provisions of law to the contrary, the attorney may cause an action to be brought in the appropriate circuit court in the name of the Commonwealth, the city, county, or town, the Virginia Board of Pharmacy, or the Virginia Board of Medicine, respectively, to enjoin any violation of this chapter, to impose civil penalties as prescribed herein and to recover reasonable attorney fees and costs. Any circuit court having jurisdiction is authorized to issue temporary and permanent injunctions to restrain ana prevent violations of this chapter notwithstanding the existence of an adequate remedy at law. In any action under this chapter, it shall not be necessary that damages be proven.

§ 54.1-3485. Investigative orders.

A. Whenever the attorney has reasonable cause to believe that any person has engaged in, or is engaging in, or is about to engage in any violation of this chapter, the attorney, if after making a good faith effort to obtain such information, is unable to obtain the data and information necessary to determine whether such violation has occurred, or believes that it is impractical for him to do so, he may apply to the circuit court within whose jurisdiction the person having the information resides, the person has a principal place of business in the Commonwealth, or where any part of the alleged violation occurred in the Commonwealth, which includes without limitation, the jurisdiction of the practitioner's place of business, the jurisdiction in which the patient resides, and the jurisdiction in which the patient's caregiver resides, for an investigative order requiring such person to furnish to the attorney such data and information as is relevant to the subject matter of the investigation.

B. The circuit courts are empowered to issue investigative orders, authorizing discovery by the same methods and procedures as set forth for civil actions in the Rules of the Supreme Court of Virginia, in connection with investigations of violations of this chapter by the attorney. An application for an investigative order shall identify:

1. The specific act or practice alleged to be in violation of this chapter;

2. The grounds which shall demonstrate reasonable cause to believe that a violation of this chapter may have occurred, may be occurring, or may be about to occur;

3. The category or class of data or information requested in the investigative order; and

4. The reasons why the attorney is unable to obtain such data and information, or the reason why it is impractical to do so, without a court order.

C. Within twenty-one days after the service upon a person of an investigative order, or at any time before the return date specified in such order, whichever is later, such person may file a motion to modify or set aside such investigative order or to seek a protective order as provided by the Rules of the Supreme Court of Virginia. Such motion shall specify the grounds for modifying or setting aside the order, and may be based upon the failure of the application or the order to comply with the requirements of this chapter, or upon any constitutional or other legal basis or privilege of such person.

D. Where the information requested by an investigative order may be derived or ascertained from the business records of the person upon whom the order is served, or from an examination, audit or inspection of such business records, or from a compilation, abstract or summary thereof, and the burden of deriving or ascertaining the information is substantially the same for the attorney as for the person from whom such information is requested, it shall be sufficient for that person to specify the

records from which the requested information may be derived or ascertained, and to afford the attorney reasonable opportunity to examine, audit or inspect such records and to make copies, compilations, abstracts or summaries thereof.

E. It shall be the duty of the attorney, his assistants, employees and agents, to maintain the secrecy of all evidence, documents, data and information obtained through the use of investigative orders or obtained as a result of the voluntary act of the person under investigations and it shall be unlawful for any person participating in such investigations to disclose to any other person not participating in such investigation any information so obtained. Any person violating this subsection shall be subject to a civil penalty not to exceed $25,000 and contempt of court. Notwithstanding the foregoing, this section shall not preclude the presentation and disclosure of any information obtained pursuant to this section in any suit or action in any court of this Commonwealth wherein it is alleged that a violation of this chapter has occurred, is occurring or may occur, nor shall this section prevent the disclosure of any such information by the attorney to any federal or state law-enforcement authority that has restrictions governing confidentiality and the use of such information similar to those contained in this subsection.

F. Upon the failure of a person without lawful excuse to obey an investigative order under this section, the attorney may initiate contempt proceedings in the circuit court that issued the order to hold such person in contempt.

G. No information, facts or data obtained through an investigative order shall be admissible in any civil or criminal proceedings other than for the enforcement of this chapter and the remedies provided herein.

§ 54.1-3486. Tolling of limitation.

When any of the authorized government agencies file suit under this chapter, the time during which such governmental suit and all appeals therefrom are pending shall not be counted as any part of the period within which a private cause of action under this chapter shall be brought.

§ 54.1-3487. Individual action for damages or penalty; statute of limitations.

A. If a person who is not a practitioner solicits or encourages a patient, a caregiver of the patient or a practitioner of the patient in violation of any provision of this chapter or if a person who is not a practitioner violates any other provision of this chapter, the patient shall be entitled to initiate an action against such person to recover actual damages, if any, or liquidated damages of $5,000 per violation, whichever is greater, to enjoin the person from continuing such activities in the Commonwealth, and to recover reasonable attorney fees and costs expended in pursuit of the matter.

B. If any practitioner solicits or encourages a patient in violation of any provision of this chapter or if any practitioner violates any other provision of this chapter, the patient shall be entitled to initiate an action against such practitioner to recover actual damages, if any, or liquidated damages of ten dollars per violation whichever is greater, to enjoin the person from continuing such activities in the Commonwealth, and to recover reasonable attorney fees and costs expended in pursuit of the matter; however, if the practitioner or his employer receives any monetary incentive from another person for his assistance in committing an act that is in violation of this chapter, the patient may recover actual damages or liquidated damages of $100 per violation, in lieu of the ten dollars liquidated damages provision, whichever is greater, in addition to injunctive relief, reasonable attorney fees and costs.

C. Any caregiver or practitioner who is solicited or encouraged in violation of any provision of this chapter by a person who is not a practitioner shall be entitled to initiate an action against such person to recover actual damages, if any, or liquidated damages of $5,000 per violation, whichever is greater, to enjoin the person from continuing such activities in the Commonwealth, and to recover reasonable attorney fees and costs.

D. Any caregiver or practitioner who is solicited or encouraged in violation of any provision of this chapter by a practitioner shall be entitled to initiate an action against such practitioner to recover actual damages, if any, or liquidated damages of ten dollars per violation, whichever is greater, to enjoin the person from continuing such activities in the Commonwealth, and to recover reasonable attorney fees and costs; however, if the practitioner or his employer receives any monetary incentive from another person for his assistance in committing an act that is in violation of this chapter, the caregiver or practitioner may recover actual damages or liquidated damages of $100

1 *per violation, in lieu of the ten dollars liquidated damages provision, whichever is greater, in*
2 *addition to injunctive relief, reasonable attorney fees and costs.*
3 *E. Except as provided in § 54.1-3486, any claim arising under this chapter shall be brought within*
4 *two years of the wrongful act or discovery of the act, whichever is later.*

Official Use By Clerks

Passed By The House of Delegates		**Passed By The Senate**	
without amendment	☐	without amendment	☐
with amendment	☐	with amendment	☐
substitute	☐	substitute	☐
substitute w/amdt	☐	substitute w/amdt	☐
Date:		Date:	
Clerk of the House of Delegates		Clerk of the Senate	

970096198

HOUSE JOINT RESOLUTION NO. 623

Offered January 20, 1997

Requesting the Department of Personnel and Training and the Department of Medical Assistance Services to take steps to ensure that programs under their purview comply with the Pharmacy Freedom of Choice statute and to review their levels of compensation to pharmacies who act as providers in their programs.

Patrons—Moran, Baker, Behm, Bennett, Brickley, Callahan, Cox, Cranwell, Crouch, Davies, Dickinson, Guest, Hall, Heilig, Jackson, McEachin, Melvin, Orrock, Puller, Spruill, Tate, Van Landingham and Woodrum; Senators: Benedetti, Couric, Earley, Gartlan, Hawkins, Holland, Lambert, Potts and Wampler

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Referred to Committee on Health, Welfare and Institutions

WHEREAS, the growth of third-party reimbursement for pharmaceuticals has had a significant impact on community pharmacies; and

WHEREAS, in 1972, third-party payers paid for only 18.5 percent of prescriptions dispensed in community pharmacies, they paid for 28.4 percent in 1985, and for the majority of prescriptions filled in 1994; and

WHEREAS, in 1994, state Medicaid programs paid for 13 percent of outpatient prescriptions and private third parties paid for 45 percent; and

WHEREAS, a recent study conducted at the Medical College of Virginia/Virginia Commonwealth University has shown that third-party reimbursement appears to have adversely affected the profitability of community pharmacies, and there are indications that pharmacies are tending to close or leave areas with high numbers of poor and elderly; and

WHEREAS, in addition to low reimbursement rates by third-party payers which do not provide adequate profit for pharmacies to stay solvent, many patients are required by their prescription plan to utilize only certain participating provider pharmacies or mail-order operations in order to cut costs; and

WHEREAS, many such plans penalize the patient for having the prescription filled at a non-participating pharmacy or for not using mail order by requiring the patient to pay higher rates for the filled prescription; and

WHEREAS, Virginia Code Section 38.2-3407.7 specifically states that "...no insurer proposing to issue preferred provider policies or contracts shall prohibit any person receiving pharmacy benefits furnished thereunder from selecting, without limitation, the pharmacy of his choice to furnish such benefits. This right of selection extends to and includes pharmacies that are nonpreferred providers and that have previously notified the insurer, by facsimile or otherwise, of their agreement to accept reimbursement for their services at rates applicable to pharmacies that are preferred providers, including any copayment consistently imposed by the insurer, as payment in full ..."; and

WHEREAS, testimony provided to the Joint Subcommittee Studying the Demise of Independent Pharmacies during the 1996 interim attributed the decline in the number of pharmacies and the precarious situation of many others, in part, to the apparent lack of compliance to the freedom-of-choice laws, inadequate reimbursement for services rendered, and a general lack of any type of negotiation with regard to contracts for services which recognize not only good patient care, but also the fluctuating market as well as the total overhead costs incurred by pharmacies in the delivery of their services to the public; now, therefore, be it

RESOLVED, by the House of Delegates, the Senate concurring, That the Departments of Medical Assistance Services and Personnel and Training evaluate their prescription drug programs to ensure that they comply with the Pharmacy Freedom of Choice statute in the Code of Virginia and evaluate the level of compensation to participating providers to provide a payment level which will allow them a reasonable profit.

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APPENDIX B

Virginia Pharmacists: Cognitive Skills Impact Patient Care and Cost of Care

The Commonwealth of Virginia has pharmacists who provide care for their patients which influences their outcome and their health related costs.

Specific examples of programs across the state include but are not limited to:

I. Improvement in the management of anticoagulation therapy by pharmacists. *Martha Jefferson Hospital, Charlottesville.*

a. length of patient stay: *4.2 vs 6 days*
b. average time to achieve anticoagulation: *10 vs 48 hours*
c. turn around time from test to required dose change: *2 vs 4 hours*
d. cost savings to hospital : *$370,000 per year*
e. cost savings by decreased lab monitoring: *$ 10,000 per year*

II. Reduced medication costs and improved care through patient care oriented clinical pharmacy services.
Shenandoah Shared Hospital Services, Inc.

a. annual cost savings range: *$ 202,436-350,428 per year*
b. reduced drug- dose related seizures
and kidney toxicity.

III. Cost savings from psychiatric pharmacy services.
Western State Hospital, Staunton .

a. cost savings from drug class duplication: *$ 24,750 per year*
b. medication wastage by formulation change: *$ 22,152 per year*
c. eliminate inventory of drugs not used: *$12,600 per year*

IV. Cost savings through pharmacist interventions.

Johnston Memorial Hospital, Abington.

a. intravenous medication to oral form: *$18,000 per year*
b. decreased drug required lab costs: *$5,000 per year*
c. drug formulary issues: *$ 49,000 per year*

V. Pharmacist interventions prevent patient drug related misadventures.

Medical College of Virginia, Richmond.

a. interventions ranked for potential risk: moderate to high
   high: 5 - 10 times over or under dose
   moderate: 1- 4 times overdose
b. interventions related to safety issues 59 % time
c. interventions related to dose changes 40% time
   secondary to reduced kidney function , pediatric dose

VI. Pharmacists monitoring therapy in patient care areas reduce cost of health care.

Medical College of Virginia , Richmond.

a. patient length of hospital stay: *1.5 days shorter*
b. cost savings per patient admission: *$1293*
c. drug cost savings per patient admission: *$155*

VII. Virginia medicaid pharmacist drug utilization reviews prevent drug misadventures and lower drug costs.

a. pharmacists detect potential level 2 interventions
   level 2: major to moderate clinical impact on patient
b. prevent overutilization of antiulcer medication: *$ 1.4 million in 1993*

VIII. Progressive pharmacy services in community hospital improves patient care and drug budget.

Danville Regional Medical Center, Danville.

a. drug dosing service achieves therapeutic levels sooner
b. hospital medicine reimbursement for indigent patients via manufacturer reimbursement programs .

IX. Pharmacist managed anticoagulation clinics improve therapy and costs. *Kaiser Permanente Medical Center Springfield, Woodbridge, and Falls Church , VA.*

a .hospitalizations decreased: 49 %
b. emergency room visits decreased: 35 %
c. physician time saved on dose adjustment: 536 hrs
d. physician satisfaction survey with pharmacist: 100 %
e. patient satisfaction of clinic: very 88 % satisfied 12 %
f. cost savings : *$250,000*

X. Pharmacist managed diabetic patient care clinic.

Kaiser Permanente Medical Center: Fair Oaks, Reston, Springfield, VA.

a. patient diabetic education increased pre and post clinic: 27 vs 97%
b. patient nutrition education increased pre and post clinic: 40 vs 97 %
c. eye exams pre and post clinic: 68 vs 97 %
d. patient history and physical performed: 40 vs 95 %
e. laboratory information improved: by average 20 %

XI. Pharmacist impact in managed care home health care setting: *Kaiser Permanente Home IV Pharmacy, Reston, VA.*

a. estimated total savings: *$421,907*
b. net cost avoidance due to decreased length of patient stay: *$272,000*
c. avoided hospital days due to pharmacist interventions: 340 days

XII. Community pharmacists improve patient outcomes and health costs in disease management programs.

MEDOutcomes, Inc. Pharmaceutical Care Model. Richmond, Va.

a. pharmacists interventions improve hypertension and hypercholesterolemia.
b. patient health care costs decreased: *$ 290 per patient per month*

compiled by: Virginia Society of Health System Pharmacists Professional Practice Committee 1996

acknowledgment of submissions: hospitals, Kaiser, retail pharmacy, medicaid, MedOutcomes Inc.

The Virginia residents described below are specific examples whereby pharmacists, as a member of the health care team, have provided pharmaceutical care. The care is medication related, provided directly to the patient in order to produce a definite outcome which improves their quality of life.

A pediatric patient known to be on an anticoagulant medication was placed on an antibiotic which would interact to cause bleeding.. Recommendations by the pharmacist for dosage decrements of the anticoagulant at the time the antibiotic was started prevented potential signs of bleeding.

Critically ill pediatric patients who require sedative drugs to allow the ventilator to breathe for them were noted to experience significant drug withdrawal symptoms. An analysis of the drug dependent signs, their onset, and patient risk factors were determined by the pharmacist. Development and implementation of drug treatment regimens have been successful to ameliorate the patient withdrawal symptoms and allow for early discharge.

A patient with AIDS was prescribed a drug to increase gastric emptying by one physician and an antifungal medicine by the infectious disease physician. The pharmacists was able to prevent the potential cardiac arrhythmia by notifying the physician of the drug interaction.

A pharmacist reported that an elderly female complained of nausea, and asked her daughter to go to the pharmacy to get her some medicine for it. The pharmacist, upon investigation ,suspected digoxin toxicity and called the physician. The patients dose of digoxin was later decreased since it was too high and the cause of the nausea..

An 82 year old lady admitted to the hospital was found by the pharmacist to have stomach pain with her aspirin medication. A recommendation by the pharmacist to change to enteric coated aspirin and an agent to protect her stomach alleviated the pain.

An eleven year old hispanic male and family was counseled by the pharmacist in spanish to improve compliance and educate the family on the new diagnosis. Additionally, the pharmacist noted the patient was not started on vitamin supplements which the treatment medications deplete as well as the need for iron due to the patients anemia.

APPENDIX C

YES VIRGINIA, YOU CAN LEGISLATIVELY SAY "NO" TO PRESCRIPTION DRUG SWITCHING PROGRAMS

By Wyatt B. Durrette, Jr., Esquire
and
Kenneth D. McArthur, Jr., Esquire
Durrette, Irvin & Bradshaw, P.C.
Richmond, Virginia

(Messieurs Durrette and McArthur are registered lobbyists and attorneys specializing in commercial litigation and health care law. The law firm of Durrette, Irvin & Bradshaw, P.C. represents over 200 Virginia pharmacists and is part of a nationwide team of law firms which collectively represent over 4,000 pharmacists in 48 states and the District of Columbia.)

During the General Assembly's upcoming legislative session, a bill will be introduced which (if successfully passed) will outlaw prescription drug switching programs in Virginia. There are many very good reasons for consumers and businesses to support this bill. There are also many very good reasons for doctors and other health care practitioners to support this bill. The subject of this article, however, is limited to explaining a major reason why one group of health care practitioners in particular--pharmacists--should fight to support this bill. What is that reason? Put simply, how Virginia legislators vote on this bill may well determine whether the pharmacy profession will exist in Virginia into the next millennium.

To understand the tremendous importance of this bill to pharmacists, it is first necessary to understand the truth about "prescription drug switching programs," what they really are and how they came into being--not what those who promote these programs say they are.

DISCRIMINATORY PRICING AND THE GENESIS OF PRESCRIPTION DRUG SWITCHING PROGRAMS

By now, virtually every Virginia pharmacist knows the story of discriminatory pricing and the famous Chicago antitrust litigation. But, here it is again. Starting in 1993, a large number of chain and independent pharmacies (about 50,000 altogether) filed lawsuits against most of the major brand name prescription drug manufacturers for refusing to extend to them the discounts they have been giving to their competitors for years. The drug manufacturers at first denied giving these discounts at all, but later stated that they give these discounts only to those who do something "special" for them. That something "special," they have claimed, is "moving market share."

Make no mistake, ***there is no such thing as discounts (whether purchase price discounts or rebates) based upon actual movement of market share***. The drug manufacturers' so-called "class of trade" (i.e., you are either in a class that gets the discount or you aren't) basis for discounting is nothing more than an elaborate ruse designed to stop the spread of discounting from the relatively small group of "favored purchasers" (i.e., PBMs, HMOs, mail

order pharmacies, etc.) to the largest segment of their drug sales (chain and independently-owned pharmacies represent approximately 85% of all drug manufacturer sales).

So what does all of this have to do with prescription drug switching programs? Plenty. Because of the spotlight recently directed on the drug manufacturers' pricing practices (created by both the Chicago litigation and the Federal Trade Commission's recent investigation), those favored purchasers who have been receiving the special "just for being you" discounts are now coming under increasing pressure to actually do something that would legally justify the discounts.

This development has many favored purchasers scrambling because rebates and purchase price discounts from drug manufacturers represent a very substantial portion of their profits. A dip in these discounts, therefore, could be devastating to their bottom lines. So what have they come up with? In a desperate attempt to continue receiving drug manufacturer kickbacks, some have now resorted to "prescription drug switching programs."

FAILED ATTEMPTS AT CONTROLLING DOCTORS LEAD TO ATTEMPTS AT EXPLOITING VIRGINIA'S COMMUNITY PHARMACISTS

Before you can understand what prescription drug switching programs really are, you must first understand that they were born out of favored purchasers' failed attempts at controlling doctors.

With some exceptions, only doctors can choose which drug gets prescribed and, therefore, gets into the hands of the ultimate consumer (i.e., the patient). Because of these exceptions, however, doctors do not have complete control over drug product choice. Some other health care practitioners (e.g., nurse practitioners and TPA-certified optometrists) can also prescribe drugs. Also, under certain circumstances, pharmacists have the power to decide, from among different brand or generic versions of chemically ***similar*** drugs, which version they will dispense--even without consulting with the prescriber. However, to switch between chemically ***dissimilar*** drugs (i.e., drugs with different active ingredients) in Virginia requires the doctor (or other prescriber) to authorize a whole new prescription.

Understanding the important role doctors play in the drug selection process, many PBMs, HMOs, mail order pharmacies, and others took the hospital-originated concept of drug formularies (or a list of preferred drug products listed by therapeutic class) and set out to influence doctors to prescribe only the drugs on their formularies so that they could get kickbacks from drug companies. Not surprisingly, doctors largely ignored favored purchaser attempts at encouraging their compliance with their formularies. As a practical matter, doctors (many of whom see patients belonging to 50 or 100 different health care plans) couldn't keep track of all the different formularies (and revised versions of each) even if they wanted to. The drug manufacturers know this, and now that their pricing practices are being scrutinized, have to demand more than simply the empty promise of market share movement

from these favored purchasers. Faced, for the first time, with demands to produce actual hard evidence of market share movement in exchange for discounts, some PBMs, HMOs, mail order pharmacies, and others tried setting up phonebanks to call doctors' offices in an effort to pester them to switch prescriptions to those for which they could receive a kickback from a drug manufacturer.

Unfortunately for the PBMs, HMOs, mail order pharmacies, and others trying to convince drug manufacturers that they have the ability to control doctors' prescribing habits, doctors insisted on believing that their years of specialized education and training, together with their **personal** knowledge of their patients' lifestyles and medical histories, entitled them to make drug therapy decisions free from the influence of corporations (sometimes located thousands of miles away) who have no, and cannot ever have, comparable knowledge.

Although most doctors are resistant--if not outright hostile--to this kind of uninformed and greed-motivated, outside interference with their professional judgment, they are (not surprisingly) open to suggestions offered by chain and independent pharmacists who have personal knowledge of their patients which is similar to their own and whose advice is not motivated by kickbacks from drug companies.

Realizing their own shortcomings and the esteem doctors have for community pharmacists and fearing that the Chicago litigation or the FTC investigation might result in drug manufacturers making discounts available directly to chain and independent pharmacists, many PBMs and HMOs have something new cooked up to ensure that those kickbacks keep coming in. They are starting to precondition **chain and independent pharmacy** participation in their provider networks on a willingness to engage in PBM and HMO, rebate-driven, prescription drug switching programs. The major PBMs are particularly rabid about supporting these programs because ***nearly 100% of their net profits come directly from drug manufacturer rebate retention!***

There is an extremely well-funded, well-organized, and intensely-aggressive effort afoot in Virginia to legitimize and spread prescription drug switching programs. Unless prescription drug switching programs are stopped **NOW**, the pharmacy profession and patient health care will take serious turns for the worse.

PRESCRIPTION DRUG SWITCHING PROGRAMS ARE BAD FOR THE PHARMACY PROFESSION

If community pharmacies, fast going out of business, are now being offered a chance by PBMs and HMOs to share in drug manufacturer kickbacks for drug switches, how can this be bad for pharmacists? Consider the following.

First, pharmacists are licensed health care practitioners who consistently top the annual Gallup poll of America's most trusted professionals. Study after study has shown that

switching a patient's originally prescribed drug to a chemically dissimilar drug (i.e., one that possesses different active ingredients than the originally prescribed drug) often increases overall health care costs and creates unnecessary risks and, in some cases, actual harm to patient health. Patients and those who pay for health care insurance (on behalf of themselves and/or others) are clearly better off without these switch programs. Therefore, pharmacist support of such programs could harm the reputation and integrity of the pharmacy profession.

Second, PBMs and HMOs, notorious for amending the terms of pharmacy provider agreements, now have a brand new angle for cutting pharmacy reimbursement. Under prescription drug switching program contracts, already impossibly low (but guaranteed) pharmacy reimbursement rates are lowered even further as part of the total pharmacy reimbursement now becomes conditioned on the performance of a switch. Of course, the terms of that switch performance can now also be freely modified by the PBM or HMO. Plus, failure to meet switch performance standards can result in substantial chargebacks and/or network removal.

Third, if prescription drug switching programs take root in the community pharmacy setting, you can forget cognitive services and pharmaceutical care. Decisions regarding drug therapy will be made entirely by PBMs, HMOs, and their self-appointed P&T committees. They will define "cognitive services" as implementing switches to comply with their kickback-driven formularies.

Finally, prescription drug switching programs may lead to the ultimate elimination of practicing pharmacists altogether. If the pharmacist's professional, patient-by-patient, judgment as to best drug therapy is made "unnecessary" (in fact, undesirable) by substituting it with PBM and HMO corporate decision-making based upon drug manufacturer kickbacks, why keep pharmacists around? As PBMs and HMOs continue unchallenged in their corporate practice of medicine, slowly gaining false legitimacy and slowly substituting their own judgment for that of health care practitioners, pharmacists could easily be replaced by lower cost employees (or, better yet, mechanical devices) whose sole job is to comply with orders.

Undoubtedly, there are those (maybe even some licensed Virginia pharmacists) who will attempt to divide the pharmacy profession because of a lack of complete understanding of the issues or because of corporate interests in receiving drug manufacturer kickbacks. Nonetheless, Virginia pharmacists should just say "NO" to prescription drug switching programs by supporting legislation to outlaw them.

F:\KDM\PHARMACY\VAIP\VPHA.ART

REASONS TO OUTLAW DRUG SWITCHING PROGRAMS

This legislation prohibits drug switching programs that are driven by kick-backs, rebates and discounts from drug manufacturers.
This legislation is designed to protect the health, safety and welfare of Virginia citizens. It permits drug changes designed to increase therapeutic effectiveness, to prevent side effects and to prevent potentially dangerous drug interactions.

Currently, many out of state pharmacy benefit managers (PBMs) and many local and foreign health maintenance organizations (HMOs) try to switch the drug prescribed by a patient's physician in order that the PBM or HMO can receive a kick-back, rebate or discount from the manufacturer of the substituted drug - not in the interest of the patient, doctor, or pharmacist.
As stated below, these practices actually increase overall medical costs and patient suffering. Moreover, PBM's and HMO's frequently do not pass any or much of the kick-backs, rebates or discounts onto the patients or third party payors who must pay the additional health care bills.

Study after study has shown that switching a patient's originally prescribed drug with a chemically dissimilar drug (one that possesses different active ingredients from the originally prescribed drug) increases overall health care costs and causes unnecessary risks to the health of patients.
Patients sometimes require additional physician visits, hospital stays or drug therapy to compensate for the less appropriate drug they receive as a result of the switch.

This legislation permits generic substitution.
Generic substitution, the substitution of a brand name drug with a generic drug that possesses the same active ingredients, has been demonstrated to be very effective in reducing overall health care costs. Such substitution is not affected by this legislation.

This legislation enables a patient's pharmacist and physician to focus more time and effort on addressing patient needs, and eliminates the time currently spent on the bureaucratic red tape produced by the PBMs' and HMOs' procedures for drug switching programs.
The legislation gives the power to choose the best drug for patients back to the patient's personal physicians, pharmacists and other health care team members instead of corporate entities whose choice of prescription drug is motivated by kick-backs or rebates from drug manufacturers.

OUTLAWING INAPPROPRIATE DRUG SWITCHING IS PRO-PATIENT, PRO-PRACTITIONER, PRO-COMPETITION! IT ALSO HELPS TO LOWER OVERALL HEALTH CARE COSTS. THIS ISSUE IS SUPPORTED BY THE MAJORITY OF PRACTICING PHARMACISTS IN VIRGINIA.

THE FACTS AND MYTHS CONCERNING DRUG SWITCHING

MYTH: Kick-back based prescription drug switches reduce health care costs.
FACT: Kick-back or rebate based prescription drug switches often have a negative impact on overall health care costs and quality of care. Studies demonstrate that switching patients to chemically dissimilar drugs in order to receive kick-backs or rebates shift any direct drug budget savings to other areas of health care (emergency room visits, additional doctor office visits, etc.) thereby increasing the overall cost of health care. (See "Component Management Fails to Save Health Care System Costs"; R.A.Levy &D.Cocks;1996 NPC)

MYTH: Kick-back or rebate based drug switches improve patient outcomes.
FACT: In some cases, drug switches introduce patients to unnecessary increased health risks, additional doctor office visits, prolonged therapy and, occasionally, actual immediate harm.

MYTH: This legislation would eliminate the use of drug formularies.
FACT: Formularies based on clinical effectiveness and cost effectiveness are not affected.

MYTH: This legislation outlaws Brand to Generic or Generic to Brand substitutions.
FACT: This legislation only addresses chemically dissimilar products. It does not affect generic substitution.

MYTH: This legislation would prohibit advancement of Disease State Management and Pharmaceutical Care.
FACT: This legislation ONLY outlaws the practice of engaging in drug switching where the purpose is a kick-back or rebate.

MYTH: This legislation prohibits "therapeutic interchange".
FACT: This legislation <u>ONLY</u> prohibits kick-back or rebate-driven switching of chemically dissimilar drugs.

MYTH: Pharmacists and doctors will be investigated, harassed, and unfairly prosecuted because they cannot prove they changed a drug for proper reasons.
FACT: A patient's pharmacist and doctor are not the problem. Non-health care providers or corporate entities interfering in the directing of treatment and drug selections are the problem. Legitimate, medically-based decisions to change a prescription will be easily determinable.

MYTH: This legislation would prevent any contact to change prescriptions to help the patient, particularly if the change is to a lower priced drug.
FACT: Cost savings to the consumer are not affected nor are changes for the purpose of improving patient care. Only kick-back or rebate driven switches are unlawful.

APPENDIX D

DRUG CONTROL ACT
CLARIFICATION OF PRACTITIONER

BACKGROUND-As defined in the Virginia Pharmacy Practice Act (section 54.1-3300), the "practice of pharmacy" means the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging and dispensing of drugs, medicines and devices used in the diagnosis, treatment, or prevention of disease, whether compounded, or dispensed on a prescription or otherwise legally dispensed or distributed, and shall include the proper and safe storage and distribution of drugs, the maintenance of proper records and the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease.

- **This Bill will clarify and bring into continuity different sections of the Pharmacy Practice Act and the Drug Control Act..**
- **Pharmacists are already defined by virtue that they dispense.**
- **OBRA '90, current Federal legislation, requires that pharmacists provide services (counseling and educating) in addition to the dispensing of a product.**
- **Interaction between both the patient and other members of the health care team recognize pharmacists as practitioners, not just dispensers of medication.**

DRUG CONTROL ACT
CLARIFICATION FOR IMMUNIZATION

BACKGROUND-As defined in the Virginia Pharmacy Practice Act (section 54.1-3300), the "practice of pharmacy" means the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging and dispensing of drugs, medicines and devices used in the diagnosis, treatment, or prevention of disease, whether compounded, or dispensed on a prescription or otherwise legally dispensed or distributed, and shall include the proper and safe storage and distribution of drugs, the maintenance of proper records and the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease.

In the October 11, 1996 Morbidity and Mortality Weekly Report, **THE CENTER OF DISEASE CONTROL** states: "To achieve the year 2000 objective for influenza pneumococcal vaccination levels, additional efforts should be directed toward high-risk populations, including all persons aged > 65 yr. Measures for increasing coverage require:

1. Collaboration between public and private organizations to improve awareness about the need for these vaccines.
2. Changes in clinical practice to improve vaccine delivery.
3. Vaccine delivery mechanisms that limit cost and remove accessibility constraints."

- This Bill will clarify what is already defined as the practice of pharmacy.
- This Bill will increase the opportunity for more adult Virginians to be immunized.
- This Bill will develop procedural standards of care by requiring approved protocols.

"Administer wording"

Drug Control Act 54.1-3408, page 190

54.1-3408. Professional use be practitioners. --- A. ..... A practitioner may authorize the administration of vaccines to adults for immunization, when a practitioner with prescriptive authority is not physically present, by registered nurses or licensed practical nurses under the immediate and direct supervision of a registered nurse, *or a pharmacist* pursuant to a protocol approved by the Board of Nursing. A practitioner acting on behalf of and in accordance with established protocols of the Department of Health may authorize a the administration of vaccines to any person by a nurse *or a pharmacist* when the prescriber is not physically present.

APPENDIX E

VCU
MCV CAMPUS

Virginia Commonwealth University

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November 21, 1996

Gayle Vergara
c/o Legislative Services
General Assembly Building, Second Floor
910 Capitol Street
Richmond, Virginia 23219

Dear Ms. Vergara:

I am writing to express some of my opinions relating to the discussions arising from hearing of the Joint Subcommittee Studying the Demise of the Commonwealth's Independent Pharmacies on November 8, 1996.

By way of introduction, I am the newly appointed dean of the MCV/VCU School of Pharmacy, having assumed this position July 1, 1996. I have a long standing commitment to community-based pharmacy practice and believe it has the potential to offer our practitioners a challenging and professionally rewarding career. In order to reach this potential pharmacists must be recognized legally as health care providers and must be given the responsibility and authority to make decisions concerning the patient's drug therapy that result in positive cost effective outcomes. Clearly, reimbursement issues are paramount to the ultimate survival of the community-based pharmacist and must be looked at in unconventional terms. In the past, pharmacists were reimbursed largely through a fee for service system and were permitted to determine what to charge for the prescription and the accompanying services that were provided. Today, however, third party reimbursement and managed care has ratcheted down the price of the prescription to a point where it is virtually impossible for the community pharmacist to compete in the marketplace. What this painful experience has taught us is that pharmacists must provide a value added service to patient care that is recognized by the health care system as unique and cost effective. We in pharmacy education believe pharmacists must be able to function effectively in multi- health professional teams in order to contribute to quality patient care. To do this, pharmacists must be able to communicate verbally and in writing and must be able to apply medication use data in individual patient care decisions as well as decisions affecting patient subgroups. In recognition that pharmacists will be compensated based on documentation of the provision of services, pharmacists must document clearly the services they provide to their patients. Pharmacists are unique in that they bring to the health care team

the perspective, recommendations and conclusions based on the pharmaceutical sciences. All members of the health care team are expected to communicate, to think critically, and to solve problems. What makes pharmacists of value on the team is their background in the pharmaceutical sciences. This is a background that no other team member possesses. No nurse or physician can bring to the pharmacotherapy decision-making process an understanding of the role of chemical structure relationships or how the pH or protein binding of a drug influences drug effectiveness or toxicity. That is why I was particularly concerned during the hearing regarding the discussion of chemically dissimilar drugs and the lack of understanding the presenter had regarding this area. It does not have anything to do with the generic/brand name issues as suggested by the presenter. Chemically dissimilar drugs within the same class of agents *may or may not be* interchangeable. To substitute chemically dissimilar drugs based on rebate alone is dangerous at best and reflects a lack of understanding of appropriate drug therapy. It ignores the appreciation for the in-depth training and background that properly trained pharmacists can best provide.

We at the MCV/VCU School of Pharmacy have changed our curriculum extensively since 1994 and now provide doctoral level education to all of our students. We are about to launch a statewide program to give baccalaureate-trained pharmacists the opportunity to earn the doctor of pharmacy degree in their own community without the need to take a leave of absence from their practice to return to Richmond. We believe that this program will provide pharmacists with the proper background and clinical skills to make an effective contribution as a member of the health care team. A strong alliance between the School of Pharmacy and the practitioners of the Commonwealth of Virginia will allow the profession to meet the challenges of an ever evolving health care system.

I will be pleased to meet with you and the member of the subcommittee either collectively or individually. Thanks for your support of community pharmacy.

Sincerely,

Victor A. Yanchick, Ph.D.
Dean

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cc: Subcommittee Members