REPORT OF THE
JOINT SUBCOMMITTEE STUDYING

THE FINANCIAL IMPACT OF THIRD PARTY REIMBURSEMENT ON THE COMMONWEALTH'S PHARMACIES

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

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REPORT OF THE
JOINT SUBCOMMITTEE STUDYING
THE FINANCIAL IMPACT OF THIRD PARTY REIMBURSEMENT
ON THE COMMONWEALTH'S PHARMACIES
PURSUANT TO HJRs 528 AND 556 OF 1993
AND
HJR 101 OF 1994

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I. STUDY BACKGROUND AND AUTHORITY

The issues surrounding pharmacy reimbursement and service delivery resulted in the introduction during the 1992 Session of HJR 240, requesting a legislative study to evaluate the use of mail-order pharmacies by third party payors. Although HJR 240 was not approved, a special subcommittee of the House Committee on Health, Welfare, and Institutions (HWI) was authorized to examine the HJR 240 concerns. The HWI special subcommittee recommended that a joint subcommittee be established to address the complex issues identified in its study (see HJR 528 attached).

During the 1993 Session, four resolutions calling for pharmacy-related reimbursement studies were approved--HJR 528 (joint subcommittee to study mail-order pharmacies; chief patron--Delegate Kenneth R. Melvin); HJR 556 (joint subcommittee to study impact of third party reimbursements on pharmacies; chief patron--Delegate Jerry M. Wood); HJR 658 (Secretary of Administration to study KeyAdvantage's mail-order pharmacy program; chief patron--Delegate Alson H. Smith, Jr.); and HJR 714 (Joint Commission on Health Care to study third party reimbursement programs; chief patron--Delegate Harvey B. Morgan).

House Joint Resolutions 528 and 556 were the original enabling resolutions for this study. House Joint Resolution 556 was designated as the joint subcommittee's "vehicle"; however, the current study represents a collaborative approach, encompassing the issues included in HJR 528 and HJR 556 as well as any issues covered in HJR 714 which were not noted in either of the enabling resolutions.

Establishing a nine-member joint subcommittee of six House and three Senate members, HJR 556 called for an examination of the following issues in relation to impact on pharmacies, the quality of pharmacy services, and the best interests of the consumer:

- Insurance law and regulations
- Agreements between self-funded employers and insurance companies serving as third party administrators

- Insurers' policies and reimbursement levels vis-à-vis the use of networks and mail-order pharmacies
- Competitive fairness, including drug-pricing differentials
- Quality-of-care issues related to the use of mail-order pharmacies, such as the loss of the physician-patient-pharmacist relationship and loss of personal counseling concerning drug effects and interactions
- The potential for abuse or improper use of controlled substances as a result of mail-order receipt of drugs and obtaining excess supplies of drugs
- The error rates, insofar as data is available, of mail-order versus store pharmacies
- Insofar as data can be obtained, the rates of hospitalization among patients with similar diagnoses who use mail-order and store pharmacies
- The feasibility of using possible administrative efficiencies to cut costs rather than limiting services, such as streamlining claims processing, simplifying claims forms, automating some claims reviews, and developing a single claims form for all payors in the Commonwealth
- Medicaid pharmacy policies to ascertain whether Medicaid reimbursement policies discriminate against certain pharmacies and whether Medicaid pharmacy reimbursement policies and restrictions on certain drugs are appropriate, promote quality health care, and effectively contain costs for the Commonwealth

The study plan was also structured to subsume the following issues described in HJR 528 and HJR 714:

- The effects of the increase in the required use of mail-order pharmacies by third party payors (HJR 528)
- The effects of third party reimbursement programs on the quality of health care services (HJR 714)
- Whether third party reimbursement programs jeopardize or unfairly take advantage of health care providers (HJR 714)
- The value of special pharmacy services, including, but not limited to, compounding drugs and medicines, furnishing special containers or applicators, or utilizing special equipment in preparing or dispensing drugs, applicators, or medicines (HJR 714)

II. HISTORY OF THE ISSUES

Drug treatment has been said to be the cornerstone of modern medicine. While this concept demonstrates the importance of drug therapy in the twentieth century, a cursory look at the past leads one to believe that

drug treatment has always been a most important, (perhaps the most important) tool of healers over the ages. During the early days of this country, the local apothecary served as a major source of health care and health education. Although the remedies of the seventeenth, eighteenth, and nineteenth centuries may seem simple when compared to presently available drugs, pharmacy had already started to evolve into the sophisticated practice it is today. In the middle 1800s, William Procter, known as the "Father of American Pharmacy," was one of the early researchers and academicians who identified drug formulas, developed pharmacopoeia, and established standards for preparation/adulteration of drugs.

Until recently, the pharmacist was responsible for "compounding" many, if not most, prescriptions. With the advent of modern medicine, pharmacy has been radically changed, e.g., compounding responsibilities have largely been shifted to drug companies; drug manufacturing has become very profitable; drug research has become highly competitive as well as productive; thousands of new medicines have been developed; and the possibilities for interaction and adverse effects have multiplied. Among the other important factors impacting pharmacy is the evolution of health insurance. That health insurance has become one of the most important of employee benefits is generally accepted. In recent years, health benefit plans have moved dramatically toward increased use of managed care, primarily as a result of efforts to contain the ever escalating costs of health care. Among the more recent managed care options are mail-order drug services, pharmaceutical benefits managers, and networks of providers.

According to experts, mail-order drug service is not a new phenomenon, having been available in the United States for at least 100 years. The pharmacy needs of rural patients have, in the past, been met through mail-order services provided by community and institutional pharmacies. Formal mail-order service is said to have been initiated by the Veterans Administration in 1946. In the 1950s, the American Association of Retired Persons started its mail-order service. With the increase in the older population and, consequently, larger membership in AARP, this service has grown exponentially.

Some authorities have stated that prescription drug prices increased by twice the inflation rate in the 1980s. Since older people usually take more prescription drugs because they experience more chronic conditions than the general population, the dramatic increases in prescription costs and the aging population have coincidentally operated, in concert with other factors, to increase pharmacy costs and to create the need to contain pharmacy costs. Companies and programs have responded by developing service delivery options, such as mail-order services and networks. Mail-order services focus on the distribution of maintenance drugs, thereby serving significant numbers of elderly. Since the early 1980s, mail-order services have experienced tremendous growth. According to various reports, mail-order

service revenues increased "from $100 million in 1981 to $1.5 billion in 1989" (*The Feasibility of Mail Order Pharmacy and Other Cost Containment Strategies in the Low Cost Drugs for the Elderly Program*, Staff Report to the Joint Standing Committee on Human Resources, State of Maine, 1991).

Many studies have focused on obtaining comparative data on the costs of drug distribution through mail-order services versus local pharmacies. The results of these studies are contradictory. A study ordered by Congress pursuant to the Medicare Catastrophic Coverage Act was not completed after the Act was repealed. The first phase of this study (Horgan and Knapp, 1989) did not substantiate large cost savings through the use of mail-order services. Only a two-cent difference was found. Another study focused on waste and cost, examining the question of waste of medication when 90-day supplies are dispensed. This study found that 90-day supplies can be cost-effectively distributed. Valid, impartial empirical data is scarce; however, the incredible growth in the mail-order market appears to support the existence of cost savings. For example, New York's optional Medicaid mail-order program was negotiated for average wholesale price less 13.5 percent and a reduction of 10 cents in the dispensing fee.

Cost containment efforts have resulted in the formation of many provider networks willing to negotiate special prices/discounts. These networks can be in the context of a preferred provider organization or health maintenance organization or, if a third party administrator is hired, then the network may be rented by self-funded employers. The result may well be that those who do not participate (either because they do not want to or because they were not accepted as participating providers) will suffer reduced revenues. The influence of networks on provider behavior, including prices, is already significant and will probably increase.

In any health care setting, cost issues must always be examined in the context of treatment efficiency and effectiveness. Pharmacy service issues include, therefore, many complex business, quality-of-care, patient satisfaction, and utilization concerns, such as waste/improper utilization of drugs, loss of state and local revenues, the implementation of adverse cost incentives to promote mail-order services, the integrity of the statutorially required physician-pharmacist-patient relationship, quality control, and safety.

III. VIRGINIA DATA

As of June 30, 1993, in Virginia, 1557 pharmacies were licensed by the Board of Pharmacy. In addition, 67 nonresident pharmacies are registered to do business in Virginia. Tentative data indicates that, in 1992, the Board issued 100 new pharmacy licenses as follows: 38 existing stores with change in ownership (due to sales or reorganizations), 37 chain store pharmacies, 7 institutional pharmacies (i.e., hospitals, health maintenance organizations,

etc.), 6 specialty pharmacies (nuclear, home infusion, or chemotherapy), 4 independent pharmacies, 3 physician-owned pharmacies, 3 free clinic pharmacies, 1 mail-order pharmacy, and 1 methadone clinic pharmacy. In the first six months of 1993, the Board issued 35 licenses as follows: 21 chain store pharmacies, 4 independent pharmacies, 4 specialty pharmacies, 3 institutional pharmacies, and 3 free clinic pharmacies. Over the last four years, the Board's data documents 44 community/independent pharmacy closings. Because the Board of Pharmacy does not distinguish between community pharmacies and other types of pharmacy practice and does not maintain data on closed pharmacies, these figures were manually obtained from existing data and may not be complete.

The Virginia Pharmacists Association notes that its membership is at its all-time high. However, VPhA estimates that significant modifications in membership characteristics have taken place over the last 10 years, with independent pharmacies declining from approximately 1050 to approximately 465. Over the years, VPhA's membership has shifted from 80 percent independent pharmacists/owners to today's membership of approximately 80 percent employee pharmacists and 20 percent independent pharmacists/owners.

Although it is impossible to draw conclusions from the available data, the numbers may indicate a decline in traditional community/independent pharmacy practice.

IV. VIRGINIA LAW

Chapter 34 (§ 38.2-3400 et seq.), Chapter 35 (§ 38.2-3500 et seq.), Chapter 42 (§ 38.2-4200 et seq.), and Chapter 43 (§ 38.2-4300) of Title 38.2 are relevant health insurance provisions. Particularly relevant to this study are the provisions related to preferred provider organizations (§ 38.2- 3407, pertaining to commercial health insurance companies, and § 38.2-4209, governing nonstock corporations offering health services plans) and health maintenance organizations (§ 38.2-4300 et seq.). Preferred provider organizations (PPOs), although prohibited from unreasonably discriminating against health care providers, are authorized to establish terms and conditions that must be met by preferred providers and to restrict the "numbers and types of providers of health care services eligible for payment as preferred providers." Health maintenance organizations (HMOs) are service delivery mechanisms, may be federally qualified or state licensed, and always strictly control provider participation and subscriber utilization of services. Federally qualified HMOs may not include deductibles or copayments; state-licensed HMOs may include deductibles and copayments. PPOs may be referred to as "networks" and may utilize managed care components, such as primary care providers and pre-authorization for certain services; HMOs may contract with networks or may employ providers and always utilize managed care components.

Chapter 33 (§ 54.1-3300 et seq.) and Chapter 34 (§ 54.1-3400) of Title 54.1 contain most law relevant to this study. Chapter 33, Pharmacy, provides the regulatory structure through establishing the Board of Pharmacy and defining its authority. The Board is charged with regulating the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs, cosmetics and devices; controlling the character and standard of all drugs, cosmetics and devices; investigating complaints; disciplining infractions of the law; and conducting inspections. Chapter 33 also requires minimum continuing education for pharmacists and authorizes refusal, revocation, suspension, and denial of pharmacists' licenses, including summary suspension without a hearing if there "is an imminent danger to the public health or safety" (§ 54.1-3317). Every pharmacist is required to "conduct a prospective drug review" prior to dispensing new prescriptions and to "offer to counsel any person who presents a new prescription for filling."

"Practice of pharmacy" is defined as "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" (§ 54.1-3300).

Chapter 34 ((§ 54.1-3400) of Title 54.1, known as the "Drug Control Act," sets forth a comprehensive regulatory scheme including relevant definitions (e.g., "compound," "dispense," "drug, "etc.) and requirements for record-keeping, prescribing and dispensing; licensure of wholesale distributors; permitting of pharmacies, medical equipment suppliers, warehouses, and manufacturers; nonresident pharmacy registration; drug standards and schedules (in conformance with federal law and regulations); misbranded and adulterated drugs and cosmetics; and controlled paraphernalia.

Section 54.1-3303, important to this study's issues, authorizes issuance of prescriptions by various practitioners (i.e., physicians, podiatrists, dentists, veterinarians, and, for Schedule VI drugs only, authorized nurse practitioners and physician's assistants) "in good faith" to a patient for a "medicinal or therapeutic purpose" and requires that the prescription be "issued only to persons or animals with whom the practitioner has a bona fide physician-patient relationship." This section also defines "a bona fide physician-patient-pharmacist relationship" as "one in which a physician 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." Issuance of prescriptions not intended for medicinal or therapeutic purposes is a violation of criminal law. Subsection B of § 54.1-3300 prohibits the filling of prescriptions not resulting from bona fide physician-patient-pharmacist relationship. Pharmacists are required to verify questionable prescriptions and are subject to criminal penalties for filling invalid prescriptions. Section 54.1-3408 mirrors the requirement of § 54.1-3300 that controlled substances be prescribed, dispensed, or administered in "good faith for medicinal or therapeutic purposes."

V. SYNOPSIS OF THE ISSUES

Some experts have noted that prescription drug costs represent approximately 6.7 percent of total health care costs. Although this percentage appears small and prices have recently stabilized, the costs are enormous, an estimated $50 billion annually. In addition, drug prices have increased by three times the inflation rate. Since senior citizens commonly have more prescription drug needs than the general population and the aging population continues to increase, these costs are a major concern in health care reform.

Pharmaceutical manufacturers have traditionally negotiated prices according to "classes of trade," based on control of the market share. Although the various classes of trade do not appear to have changed significantly, other health care industry pressures seem to have exacerbated the concerns of community pharmacies, both independent and chain, motivating litigation and legislation designed to mitigate the effects of "classes of trade" pricing.

In recent years, the drug manufacturer's position, heretofore a seller's market with fragmented purchasing power, has changed. A buyer's market has been created by the development of numerous medicines addressing the same medical condition; the increase in specific formularies, i.e., lists of drugs approved for reimbursement from particular programs; changes in policy makers' attitudes towards containing pharmacy costs; and the subsequent growth of managed care techniques for pharmacy, which centralize drug decisions. Decisions based on costs have become the norm--companies are required by most third party payors to discount the costs of their drugs in exchange for inclusion in the various formularies. Pharmaceutical company representatives, who traditionally approached doctors with new medications, must frequently convince benefits managers (who are not health care providers) to place their companies' drugs on program formularies.

As drug costs have soared, insurance companies and public programs have sought ways to contain or cut pharmacy costs. Efforts to contain costs have resulted in various pharmacy service trends, e.g., managed care in the form of formularies, closed networks or mail-order services; sophisticated computer programs to conduct utilization review and search for drug

interactions; the growth of chain stores with substantial buying power; and the decrease in independent community pharmacies that may not be able to compete in today's industry. These developments cause two categories of pharmacy issues--financial issues and quality-of-care issues--all of which interact to create stress in the pharmacy market. Some of the major concerns involve:

- Benefit plan cost containment
- Classes of trade pricing
- Consumer choice in pharmacy providers
- Economies of scale
- Purchasing power and discounts
- Shifting or declining local and state revenues
- Immediacy of the services
- Personal contact, communication, and counseling
- Drug compliance and utilization

VI. THE JOINT SUBCOMMITTEE'S WORK

In August of 1993, the joint subcommittee began its examination of the financial impact of third party reimbursement on pharmacy services, including such issues as health care plan coverage and reimbursement levels, competitive fairness, quality of care, the statutorially required physician-patient-pharmacist relationship and the effectiveness of personal counseling on drug effects and interactions. Upon receiving information on the KeyAdvantage, Trigon Blue Cross Blue Shield, and Medicaid pharmacy programs and analyses of pharmacists' concerns, the joint subcommittee recognized the changing nature of pharmacy practice, for example, the increasing use of restricted networks and mail-order pharmacy services, the growth of managed care and specifically tailored "formularies," and the shift of pharmaceutical decision making from health care providers to reimbursement program managers.

A primary example of evolving pharmacy practice can be found in Virginia's employee benefit program. The Commonwealth's Outpatient Prescription Drug Program (part of KeyAdvantage) provides broad coverage for prescription drugs through participating PCS RECAP pharmacies, a mail-service pharmacy, and participating walk-in maintenance pharmacies. Financial incentives are provided for the use of mail service or walk-in maintenance drug pharmacies for 90-day supplies. This program encourages the use of generic drugs. Two hundred community pharmacies (1993 statistics) participate in Key Advantage as walk-in maintenance drug pharmacies. Data provided to the joint subcommittee indicated that 3.1 percent of claims are for prescriptions filled through mail order, 9.5 percent for prescriptions filled by walk-in maintenance drug pharmacies, and 87.4 percent for prescriptions filled by community pharmacies. In 1993, the mail-order pharmacy was paid $2,875,605 (7.5 percent), walk-in maintenance drug

pharmacies were paid $8,454,121 (22 percent), and community pharmacies were paid $27, 082,797 (70.5 percent).

In its testimony, Trigon Blue Cross Blue Shield stated that pharmacy benefits and mental health and substance abuse benefits are the fastest growing components of the health care cost equation. In fiscal year 1993, Trigon reimbursed at least 7 million pharmacy claims, totaling approximately $162 million. Approximately 850,000 of Trigon's 1.8 million insured Virginians had pharmacy benefits, with varying copayments, deductibles, and annual maximums. Trigon's preferred provider network--RX Alternative--served approximately 730,000 of these insureds; certain subsets of this group also had access to mail-service or retail maintenance-drug pharmacies. Trigon estimated that an additional cost of $12-15 million would have been incurred without the benefit management activities initiated in January 1991, including an electronic claims processing system to confirm coverage, copayments, and deductibles and to transmit acceptances and payment amounts to pharmacists' accounts. This system also detects fraud and abuse, such as over-utilization (multiple purchases in a short period) and alerts pharmacists to quality-of-care concerns such as interactions (the system includes prescriptions filled by other providers).

Although not currently utilizing managed pharmacy services other than pre-authorization of certain drugs, the Virginia Medicaid program is described as a prudent purchaser; however, Medicaid pharmacy costs have increased from $41 million in 1985 to $160 million in 1993. Product costs demonstrated the greatest increase, with drug manufacturers logging 17 percent annual rates of return. Medicaid has the highest Virginia dispensing fee at $4.40. No mail-order services are available through Virginia Medicaid at this time; however, costs are being contained through the federal rebate program. Virginia Medicaid has a fast turnaround time for claims--approximately six-and-a-half days.

After holding two informational meetings in 1993, receiving staff briefings, and hearing presentations on the Commonwealth's employee health benefits plan, Medicaid, and insurance, the joint subcommittee continued its study to 1994, holding six meetings during this second study year. The meetings included site visits, two public hearings, additional presentations on Medicaid, and much discussion of HB 842 of 1994, a carry-over bill which related to the joint subcommittee's study. Particular attention was paid to drug pricing differentials.

The first 1994 interim meeting on June 9 began with a short organizational meeting to receive the draft interim study report and to review the study objectives and the revised study schedule. Upon adjournment of this formal meeting, the joint subcommittee boarded a minibus for four community pharmacy site visits designed to demonstrate the operations of retail pharmacies.

Mr. Leonard Edloe owns and operates Edloe's Professional Pharmacy in the Church Hill area of Richmond. With a diverse patient population consisting of 50 percent or more Medicaid recipients, Mr. Edloe's concerns include the price inequities experienced by patients without insurance or with insurance not providing prescription drug coverage, particularly among the elderly poor or near poor who may have more pharmaceutical needs than younger populations. Some other problems noted were confusing formularies which differ from plan to plan, decreasing dispensing fees, and the competitive disadvantages of manufacturers' "classes of trade" pricing. Discriminatory pricing was explained using nitroglycerin heart patches as an example--health maintenance organizations, mail-order pharmacies and others may obtain these patches for as little as $5.00 per box while Edloe's cost is $38.00, resulting in a $43.47 consumer purchase price. Having a long, rich tradition in the community, Mr. Edloe wants to continue to provide extra services such as home delivery. Volume of trade, he noted, generates profit, rather than the percentage of kinds of trade.

Mr. Dan Herbert, proprietor of the Bremo-Westhampton Pharmacy in Henrico County, has initiated several creative clinical programs focused on counseling patients with certain chronic diseases. At this time, the counseling modules are being developed and are concentrated on hypertension, diabetes, high cholesterol, and asthma. Grant funded for three years, the program, which has just completed one year, is intended to demonstrate that better informed patients have fewer acute episodes and hospitalizations and that patient education and counseling are cost effective as covered services. The patient makes an appointment to receive services; however, no fee is currently charged. The services include a disease-state monitoring, a theme-type newsletter, videos, and informative pamphlets as well as the one-on-one counseling, education, and training. The patient is taught to improve his health, through such considerations as proper nutrition and drug protocol compliance. The Bremo-Westhampton Pharmacy also provides unusual dispensing services, i.e., sterile compounding services for chemotherapy patients and traditional compounding services for patients with unique dosage and therapy needs. A subissue of compounding services is the high costs of special containers--costs not reimbursed by third party payors. An atypical but essential practice, the compounding service does not attempt to duplicate commercially available products and is estimated to be needed by less than one percent of all patients. Patients are referred from physicians and other pharmacies.

The Mechanicsville Drugstore, a traditional independent community pharmacy, is owned and operated by Mr. Tommy Thomson. A neighborhood institution since Mr. Thomson's father operated it, the Mechanicsville Drugstore has long-term employees, a solid reputation, and an old-fashioned drugstore lunch counter with many daily patrons. Although he views the problems of independent and chain pharmacies as identical, Mr. Thomson noted the changing relationship between the independent retail pharmacies

and the drug manufacturing companies, explaining that the relationship had gone from friendly and cooperative to adversarial. The suffering of the retail business could also, he said, be attributed to restrictive health care plans which often lock out the small independent pharmacies. Noting that changes in insurance plans as well as differential pricing were impacting their business, Mr. Thomson explained that some patients had been with them for 40 years. Therefore, many patients who have been his customers for years have been forced to go elsewhere for pharmacy services because their health care plan will not reimburse Thomson's. For these and other reasons, the profit margins have decreased significantly in recent years. Mr. Thomson expressed hope for change with the passage of HB 840 relating to consumer freedom of choice.

The Pharmacy Care Center in the Peoples/CVS store on Lakeside Avenue was the final site-visit location. Mr. Michael Soiland, the counseling pharmacist, clarified that the center is operated through a lease arrangement by MonRoe Partners. Hoping to prove that consultation services are cost effective and, thereby promote such services for capitated reimbursement, the center's purpose is to reduce the overall costs of health care, increase patient satisfaction, and improve the quality of the patient's life. Currently funded as a study by Trigon Blue Cross Blue Shield, this program provides services to any BC/BS patient without charge and offers, for a fee, pharmacy care consultation services to all others, regardless of where the drugs are purchased. As part of this innovative service, the pharmacist provides written and verbal instruction on proper medication use through a monthly appointment. During the monthly appointment, the pharmacist instructs the patient; conducts disease-state monitoring for asthma, diabetes, hypertension and high cholesterol patients; assists with medication compliance; and answers medication-related questions and concerns. Written reports are made and medical profiles are maintained. Records are transmitted to physicians when the patient has an appointment. The typical patient, generally referred through the prescription procedure by the dispensing pharmacist, is over 50 years old, has asthma, diabetes, hypertension, or high cholesterol, and is taking five or six medications.

Continuing the pace set during its June meeting, the joint subcommittee's second meeting included substantive presentations and a site visit to observe the operations of a mail-order pharmacy. The findings from the Medicaid Drug Utilization Review (DUR) Annual Report, specifically related to the prospective DUR intervention program, were presented. In 1993, the cost-savings portion of the DUR program prospective component concentrated on antiulcer medications. Known as H_2-receptor antagonists, these costly medications are highly effective and have relatively few side effects. Frequently, patients in acute episodes are started on full dose therapy and, because of the lack of side effects, the patients may be continued on high dosages of these drugs for much longer than necessary or even for indefinite periods.

Reasoning that decreases in utilization would result in reduced costs, the Department of Medical Assistance Services (DMAS) initiated the antiulcer drug utilization study at the suggestion of the Virginia Pharmacists' Association (VPhA). Named *Check for Health*, this program required significant VPhA efforts to promote effective cooperation between its members and DMAS. On strictly a voluntary basis, pharmacists were asked to check the prescription records of patients on these antiulcer drugs for duration and intensity of therapy and to call the patients' physicians when the diagnosis and duration or intensity of the therapy appeared incompatible. Pharmacists were also asked to file intervention reports with the Department. Specifically, the pharmacist determined the duration of treatment, the diagnosis, and the patient's status. As deemed appropriate, the pharmacist then suggested to the physician and the patient that the treatment could either be discontinued or the dosage could be significantly reduced. This effort resulted in approximately $1.4 million in Medicaid pharmacy budget savings and dramatically demonstrated the cost effectiveness of pharmacy counseling and intervention services. Further, no increase in inpatient or physician services for ulcers and related diagnoses could be detected as a result of decreased antiulcer drug dosages.

The generosity of pharmacists' participation in these time-consuming intervention activities was noted. Although the antiulcer drug intervention efforts benefited the Commonwealth and possibly the patients, the participating pharmacies received no reimbursement or other benefit and may actually have experienced lower revenues through decreases in antiulcer drug sales. Further, the voluntary intervention activities added to the participating pharmacists' work loads. During the joint subcommittee's discussions, support was expressed for continuing this kind of intervention and the possibility of this kind of prospective onsite review of prescriptions being used to facilitate savings in other third party reimbursement programs. Upon adjournment of the formal meeting, the members boarded a van to proceed to Ashland for a tour of Caremark.

Caremark, a health services company with both a strong managed care emphasis and a multifaceted patient care focus, is an international organization providing many services, including home care such as infusion therapy, AIDS treatment, cancer treatment, and physical therapy; practice management; renal dialysis; mail-order pharmacy; and other prescription drug benefit services. Mail-order pharmacy services are delivered from four state sites in Illinois, Texas, Florida, and Virginia. The Ashland facility, which operates five days a week for 10 hours a day, processed only a couple of hundred prescriptions during its opening day in January 1991 and now processes an average of 6,100 prescriptions per day. Ninety-five percent of the orders which are received through the mail or over the telephone are completed within 48 hours. Twenty-four-hour patient counseling is available every day through a 1-800 telephone number.

The Caremark mail-order pharmacy, a highly computerized and automated operation, currently employs 200 people and brings in over $120 million in revenue--17 percent of which is Virginia-based business. Each order form requires the patient to note allergies and health conditions, etc., with a new form accompanying the filled order. Upon entry of the order and confirmation of eligibility, drug utilization review (DUR) is conducted by a pharmacist. Therapy duplication and early refills, fraud and abuse, and drug and allergy reactions are reviewed and such items as dosage and age consistency, appropriateness of the drug for the disease, dosage and recommended therapy compatibility, drug to drug interactions, drug to gender appropriateness, and specific formulary management are considered. Identified problems are transmitted to a clinical pharmacy station where another pharmacist evaluates the flagged concerns and either confirms the order as submitted or seeks revision of the prescription from the patient's physician.

Every prescription is sealed in a plastic bag and bar coded to match the proper drug and dosage at the beginning of the dispensing process. As the prescription proceeds through this process, computerized quality control mechanisms as well as a final three-pronged verification by a pharmacist, a technician, and a packer kicks out any detected glitches, such as mismatched prescriptions, bar codes, etc. The mailing label, as required by federal law, does not identify the company or the product. Drugs that must be maintained at cold temperatures or used within short periods are specially packaged and delivered.

A secured area is used for the dispensing of Schedules II, III, IV, and V controlled substances and for a limited amount of compounding. Many prescriptions are prepackaged to match commonly used dosages, etc., and other pills and capsules are counted automatically by machines known as Baker Cells and Kirby-Lester counters. Narcotics are counted by hand and machine. Although company executives were unable to cite an error rate, they noted that Caremark has never been disciplined by a state licensure board and has never been the subject of a lawsuit alleging a dispensing error.

With the conclusion of the Caremark tour, the joint subcommittee finished its scheduled site visits. The next two meetings were combination work sessions and public hearings, with the August focus being on the concerns of community pharmacies and managed care pharmacies and the September focus concentrating on manufacturers' pricing methods, insurance concerns, and other issues.

A revealing presentation on the Medicaid rebate program noted several current problems. With certain limited exceptions, state Medicaid programs are required to reimburse for drugs manufactured by pharmaceutical companies entering into agreements with the federal government to provide certain information and to return rebates to the

states. Although Virginia had a fledgling Medicaid formulary at the time of this federal legislation's passage in 1990, the original law did not allow for state drug restrictions; however, this law has since been modified to allow states to apply restrictions. Some of the problems with the rebate program are:

- Incorrectly coded prescriptions for multiple source drugs, e. g., generics of well-known brand name drugs that have gone off patent;
- Incomplete pricing information, i.e., the only pricing information received by state Medicaid programs is the Health Care Finance Administration's calculations of the unit rebate amounts because manufacturers are not required to release drug pricing information to states;
- Frequent disputes over the unit rebate amounts and sparse federal guidance, with only proposed regulations in place and only newsletters on which to rely;
- Differences between state and federal units of measure;
- Lack of adequate software, necessitating manual management of this complex program (this problem will be resolved as the Department of Medical Assistance implements a new contract);
- Potential for large billing errors to occur from very small patient mistakes; and
- Insufficient federal guidance in resolving rebate amount disputes and challenges, including reasonable options for settlements;
- No final regulations.

The public hearings conducted as part of two of these meetings demonstrated that many pharmacists decry managed care trends, citing quality-of-care and prevention concerns. Pharmacists, by training and by law, counsel patients and monitor prescription integrity as required by the statutory physician-pharmacist-patient relationship. Pharmacy plays a major role in prevention and avoidance of costs (e.g., costly hospitalization caused by failure to adhere to treatment protocols). Pharmacists also note that the costs of medications continue to increase; however, dispensing fees do not. Further, in the opinion of many pharmacists, cost shifting to the private sector is no longer a viable alternative, with cost-conscious pharmacy programs being implemented by the private and public insurance sectors. Community pharmacists, particularly owners of independent pharmacies, see the new managed care trends as eroding their market and pushing them out of business while not providing quality, personal care.

Many community pharmacists also view the practice of "classes of trade" pricing as discriminatory. Speaking as supporters of HB 842, many community pharmacists considered this practice as unfair, if not actually illegal. Noting that attempts to garner the advantages of high volume through forming buying cooperatives have not helped in obtaining lower prices from the manufacturers, etc., the independent pharmacies believe "classes of trade" pricing to be one of the major factors in reducing their

numbers, revenues, etc. The community pharmacists, except for "closed shop pharmacies" providing services to nursing homes, aver the differences in price differentials to be significant--more than 50 percent--with substantial effect on patients' pharmacy service choices.

The proponents of HB 842 claim that the long-term effects of nondiscriminatory pricing would be to reduce prices overall, thereby increasing competition among the various providers and improving access to prescription drugs for the uninsured working poor or near poor and the elderly, near-poor Medicare beneficiaries. Among the bill's proponents, few or no unexpected consequences of the price regulation are anticipated.

Proponents note that Wisconsin adopted a law similar to HB 842 in the 1970s and that in the 1992 case brought under this statute against American Home Products Corporation (*K-S Pharmacies, Inc. v. American Home Product*s, 962 F2d 728 (7th Circuit 1992)), the Circuit Court found that, since state law applies only within the relevant state, the Wisconsin law did not violate the Commerce Clause and that price discrimination laws are constitutional. Therefore, proponents view this legislation as appropriate and timely for state consideration.

Opponents of the HB 842 concept included nonprofit organizations such as Planned Parenthood, Inc., health maintenance organizations such as Kaiser Permanente, closed shop pharmacies, drug manufacturers, and wholesalers of various types. The opponents presented evidence related to price increases because of legislative "tinkering" with market forces, including the Medicaid rebate program. The opponents noted that "classes of trade" practices have not been found by the Federal Trade Commission to present sufficient evidence for charges of violations of the Robinson-Patman Act and that such practices are justified in the free enterprise system by competitive factors such as volume, turn-around time, and influence on market share, i.e., controlling prescribing practices.

Opponents of HB 842 state the differences in price differentials to be within what they consider to be competitive ranges--such as 15 percent. Many organizations in opposition to HB 842 claim that the long-term effects of pricing regulation would be to increase drug costs across the board, because discounts would be eliminated by the companies. In the opinion of some opponents, the canceling of contracts providing discounts could cause an increase in health care costs, thereby decreasing access to prescription drugs for the uninsured working poor or near poor and the elderly, near-poor Medicare beneficiaries.

Opponents believe there will be many unexpected consequences of state price regulation and argue that these laws are vague because of lack of time lines, thus creating a static business environment in which prices must remain stationary. Opponents also aver that such laws do violate the

Commerce Clause, which vests only Congress with the authority to regulate interstate commerce. Therefore, they state, such laws may not be within state purview, notwithstanding the 7th Circuit decision, which is not controlling in Virginia.

Opponents further note ongoing litigation on these issues presently being pursued in state and federal courts. Currently, there are also three state cases in California. In addition, at least, four federal pharmacy cases have been filed and are seeking certification as class actions, i.e., California, New York, Pennsylvania and, as of August 31, 1994, Virginia. Plaintiffs in these cases allege violations of the Clayton Act (private antitrust action for federal law violations), the Robinson-Patman Act (price discrimination which limits ability to compete; higher prices for consumers because of limitations on discounts for providing conversion services; knowingly inducing or receiving prohibited discriminatory prices), or the Sherman Act (charge-back agreements, etc., constitute unlawful group boycotts, unlawful price-fixing agreements, etc.).

VII. THE JOINT SUBCOMMITTEE'S RECOMMENDATIONS

The joint subcommittee believes that open competition, good faith dealings, and agreeable relationships are possible between the various components of the pharmacy market; however, industry practices which have been in existence for years are converging with new market influences to create a difficult environment, rife with accusations and litigation. Many of the problems brought to the joint subcommittee's attention are beyond its reach to remedy and others are so complex and ambiguous that quick solutions are impossible. Therefore, after considering all of the presentations, data, and opinions received during the two years of this study, the joint subcommittee submits the following recommendations:

1. That the Joint Commission on Health Care continue to monitor the implementation of the "Freedom of Choice" law in the coming year to assess its effects on competition and health care costs.

2. That the term "ancillary provider" as defined in the "Freedom of Choice" law be clarified.

3. 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.

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

5. That all third party payors, 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.

6. 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.

The joint subcommittee wishes to thank the many pharmacists, manufacturers' representatives, associations, experts, agencies, insurance companies, and health care professionals who have contributed so generously of their time in assisting with this study.

Respectfully submitted,

Delegate Kenneth R. Melvin, Chairman

Delegate Alan E. Mayer, Vice Chairman

Delegate Julia A. Connally

Delegate Joyce K. Crouch

Delegate John J. Davies III

Delegate Harvey B. Morgan

Senator Frank W. Nolen

Senator Elliot S. Schewel

Senator Jane H. Woods

APPENDICES

Statement of Delegate John J. "Butch" Davies

Statement of Delegate Alan E. Mayer

Enabling Resolutions
HJR 528 of 1993
HJR 556 of 1993

1994 Legislation
HJR 101 - Continuing Resolution

Other Relevant Legislation
HJR 714 of 1993
HB 842 of 1994 (as introduced)
HB 842 of 1994 (as carried over)

COMMONWEALTH OF VIRGINIA

HOUSE OF DELEGATES

RICHMOND

JOHN J. "BUTCH" DAVIES
122 WEST CAMERON STREET
CULPEPER, VIRGINIA 22701

THIRTIETH DISTRICT

COMMITTEE ASSIGNMENTS:
COURTS OF JUSTICE
HEALTH, WELFARE AND INSTITUTIONS
AGRICULTURE
NOMINATIONS AND CONFIRMATION

TO: Norma E. Szakal, Senior Attorney
Education and Health
Division of Legislative Services
Second Floor - GAB

CC: Ken Melvin

FROM: John J. "Butch" Davies

DATE: January 10, 1995

RE: Comments on the Report of the Joint Subcommittee Setting the Impact of Third Party Reimbursement on the Commonwealth's Pharmacies

The primary focus of the attention of the pharmaceutical companies and pharmicists during our hearings was on the ability to drive market share. The pharmaceutical companies want to make sure that price preference is provided on the ability to drive market share while the pharmacists do not believe this is fair or reasonable.

During the hearings it became evident that in rural areas the additional concern of access to health care was being overlooked. Community pharmacies are an essential part of the health care system in rural areas. Structuring a delivery system for pharmaceuticals which results in the closure of community pharmacies will isolate those in rural areas.

Transportation is also an issue. Individuals need access to pharmacies as well as other health care facilities.

The trend to managed health care is evident, but it has the potential of having a negative impact on those who live in areas of lower population density.

It is essential that the pharmaceutical companies work closely with the pharmacists to develop a pilot project to determine if market share can be driven by the community pharmacies. Obviously, the community pharmacies participate in coop buying. This allows them to buy in large quantities. They can generate some discount from the pharmaceutical companies on volume purchasing but are unable to benefit from the ability to drive market share. It is incumbent on the pharmaceutical companies to find a method to allow the pharmacists to participate in the effort to drive market share and to provide reasonable discounts.

A level playing field is essential to ensure that access to quality health care and community pharmacies remains available to those in rural areas.

Butch Davies

COMMONWEALTH OF VIRGINIA
HOUSE OF DELEGATES
RICHMOND

ALAN E. MAYER
6423 FAIRLAND STREET
LINCOLNIA, VIRGINIA 22312

THIRTY-NINTH DISTRICT

COMMITTEE ASSIGNMENTS:
COURTS OF JUSTICE
GENERAL LAWS
HEALTH, WELFARE AND INSTITUTIONS
MILITIA AND POLICE
INTERSTATE COOPERATION

ADDENDUM TO HJR 101 REPORT

Although I concur with this report, I am disappointed with the results of the study. After two years of extensive study, the Committee was unable to achieve its primary purpose: to find ways to preserve the community-based pharmacies which are fast disappearing from our urban and rural neighborhoods.. For many years they have provided an important niche service to the communities they serve.

I had hoped that the study committee could provide the vehicle for reaching agreement among the pharmacists, the insurance companies, and the producers of pharmaceuticals starting with the recognition of the importance of preserving community-based pharmacies. For a variety of reason beyond the control of the committee, this was not to be the case.

Market forces and changes in the delivery of health care services may spell the demise of all but the healthiest pharmacies. However regrettable, I do not believe that it is the responsibility of the General Assembly to attempt to dictate economic outcomes by legislation. If there is a solution, it should be national in scope and addressed by the Federal Government. Problems such as this transcend state borders and are beyond the reach of one state legislature.

The work of this committee now passes to the Joint Commission on Health Care. That is appropriate and necessary. I would hope that the participating interests get beyond their legal entanglements and get on with finding solutions to the continuing problems addressed by the Study Committee.

Alan E. Mayer
Delegate, 39th District

GENERAL ASSEMBLY OF VIRGINIA--1993 SESSION

HOUSE JOINT RESOLUTION NO. 528

Establishing a Select Committee of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health to study the effects of the increase in the required use of mail-order pharmacies by third-party payers.

Agreed to by the House of Delegates, February 25, 1993
Agreed to by the Senate, February 23, 1993

WHEREAS, national health care spending totaled over $600 billion in 1990, of which eight percent, or $55 billion, was for drugs or nondurables; and

WHEREAS, some health insurers have sought to contain the escalating cost of health care by limiting patient choice of providers, including the required use of mail-order pharmacies; and

WHEREAS, while it is generally agreed that health care costs must be controlled in order to maintain or increase access for all our citizens, it is recognized that the working relationship between the doctor, patient and other health professionals, including pharmacists, is crucial to the maintenance of good health; and

WHEREAS, there is some concern that the use of mail-order pharmacies interrupts the longstanding relationship between the doctor, patient, and pharmacist and eliminates one aspect of personal care which may be crucial to patient care; and

WHEREAS, pursuant to direction by the Speaker, a select subcommittee of the House Committee on Health, Welfare and Institutions met during the interim to discuss the background and merits of such concerns; and

WHEREAS, this subcommittee determined that there was adequate concern about the possible interruption in patient care under the managed care system and that the issue deserved greater study in detail to resolve and address such concerns; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That a Select Committee of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health study the effects of the increase in the required use of mail-order pharmacies by third-party payers. The Select Committee shall consist of seven members as follows: four members to be appointed by the Speaker of the House and three members to be appointed by the Senate Committee on Privileges and Elections.

The Select Committee shall complete its work in time to submit its findings and recommendations to the Governor and the 1994 General Assembly as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents.

Implementation of this resolution is subject to subsequent approval and certification by the Joint Rules Committee. The Committee may withhold expenditures or delay the period for the conduct of the study.

GENERAL ASSEMBLY OF VIRGINIA--1993 SESSION

HOUSE JOINT RESOLUTION NO. 556

Establishing a joint subcommittee to study the financial impact of third party reimbursement on the Commonwealth's pharmacies.

Agreed to by the House of Delegates, February 9, 1993
Agreed to by the Senate, February 16, 1993

WHEREAS, from the 19th century and the time of William Procter, the father of American pharmacy, Americans have depended on local pharmacists to provide guidance in health matters; and

WHEREAS, this tradition has been endorsed by federal policy requiring counseling to Medicaid patients on drug interactions, contraindications, allergies, and other matters, and by the Commonwealth's policy, pursuant to § 54.1-3319, of requiring counseling of all patients on these matters; and

WHEREAS, in Virginia, pursuant to § 54.1-3303, a prescription can only be filled if it has resulted from a bona fide physician-patient-pharmacist relationship, in good faith and for a therapeutic or medicinal purpose; and

WHEREAS, the unique relationship between pharmacists, physicians, and patients has been used by Virginia as a deterrent for drug diversion and misuse; and

WHEREAS, health care costs have been escalating over the past fifty years and have become one of the primary concerns of policy makers, businessmen, and consumers; and

WHEREAS, the configurations of the health care industry are undergoing a dramatic evolution, which is often confusing and frustrating to consumers; and

WHEREAS, some of the new configurations in the health care industry can be attributed to efforts to reduce costs by third party payors, such as the use of mail-order pharmacies and the development of networks for preferred provider organizations and health maintenance organizations; and

WHEREAS, although the authorization to purchase, at very low cost, ninety-day supplies of maintenance drugs from mail-order pharmacies may reduce costs, this practice can result in the abuse of controlled substances and devices, purchases of excess quantities, and improper consumption; and

WHEREAS, the loss of one-on-one contact with pharmacists and personal counseling services may reduce the quality of care being delivered to the patient; and

WHEREAS, medications are frequently, when prescribed, dispensed, and properly used, a cost effective means of avoiding more costly care such as hospitalization; and

WHEREAS, large interstate and intrastate chain pharmacies are able to bargain for and to purchase large quantities of controlled substances at reduced prices from drug manufacturers; and

WHEREAS, the bargaining position of independent pharmacies is not as efficacious; and

WHEREAS, as networks of pharmacies are developed, the small, independent pharmacy may find it difficult to compete against chain stores and mail-order pharmacies; and

WHEREAS, yet, independent pharmacies often provide services that are not delivered by chain drug stores, such as compounding of drugs that are not produced commercially; and

WHEREAS, the Commonwealth of Virginia has enjoyed and must continue to enjoy safe and effective services delivered by highly trained, licensed personnel working in permitted pharmacies; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That there is hereby established a joint subcommittee to study the financial impact of third party reimbursement on the Commonwealth's pharmacies. The joint subcommittee shall consist of nine members to be appointed as follows: six members of the House of Delegates to be appointed by the Speaker of the House and three members of the Senate to be appointed by the Senate Committee on Privileges and Elections.

In its deliberations, the joint subcommittee is directed to examine, in relationship to impact on pharmacies, the quality of pharmacy services, and the best interests of the consumer, the following: insurance law and regulations; agreements between self-funded employers and insurance companies serving as third party administrators; insurers' policies and reimbursement levels vis-a-vis the use of networks and mail-order pharmacies; competitive fairness, including drug-pricing differentials; quality of care issues related to the use of mail-order pharmacies, such as the loss of the physician-patient-pharmacist relationship and loss of personal counseling concerning drug effects and interactions; the potential for abuse of or improper use of controlled substances as a result of mail-order receipts of drugs and obtaining excess supplies of drugs; the error rates, in so far as data is available, of mail-order versus store pharmacies; a comparison of, in so far as data can

be obtained, the rates of hospitalization among patients with similar diagnoses who use mail-order and store pharmacies; and the feasibility of using possible administrative efficiencies to cut costs rather than limiting services, such as streamlining claims processing, simplifying claims forms, automating some claims review, and developing a single claims form for all payors in the Commonwealth. The joint subcommittee will also examine Medicaid pharmacy policies to ascertain whether Medicaid reimbursement policies discriminate against certain pharmacies and whether Medicaid pharmacy reimbursement policies and restrictions on certain drugs are appropriate, promote quality health care, and do effectively contain costs for the Commonwealth. The joint subcommittee may consider study proposals for Medicaid and insurance pharmacy program flexibility.

All agencies of the Commonwealth shall assist the joint subcommittee as deemed necessary.

The joint subcommittee shall complete its work in time to report its findings and recommendations to the Governor and the 1994 General Assembly in accordance with the procedures of the Division of Legislative Automated Systems for the processing of legislative documents.

The indirect costs of this study are estimated to be $ 13,045; the direct costs of this study shall not exceed $ 8,100.

Implementation of this resolution is subject to subsequent approval and certification by the Joint Rules Committee. The Committee may withhold expenditures or delay the period for the conduct of the study.

GENERAL ASSEMBLY OF VIRGINIA -- 1994 SESSION

HOUSE JOINT RESOLUTION NO. 101

Continuing the Joint Subcommittee Studying the Financial Impact of Third Party Reimbursement on the Commonwealth's Pharmacies.

Agreed to by the House of Delegates, February 8, 1994

Agreed to by the Senate, February 28, 1994

WHEREAS, drug treatment has been said to be the cornerstone of modern medicine, thereby demonstrating the importance of drug therapy in the twentieth century and beyond; and

WHEREAS, the value of pharmacy services cannot be overestimated in avoiding more costly care such as hospitalization and long-term care, and in preventing health deterioration; and

WHEREAS, until recently, the community pharmacist was responsible for "compounding" many, if not most, prescriptions; but with the development of large drug manufacturing companies, the role of the pharmacist has changed; and

WHEREAS, health insurance has evolved from its early days to become today a pervasive force in the health care industry, and health benefits have rapidly metamorphosed in recent years, primarily as a result of efforts to contain the ever-escalating costs of health care; and

WHEREAS, pharmacists allude to the proliferation of third-party payment systems as the cornerstone of change in pharmacy practice, with managed care approaches locking certain providers out of specific markets and bargaining positions being eroded by the advent of the large chain pharmacies and mail-order services; and

WHEREAS, the ordinary citizen, by all reports, does not understand the importance of adhering to a drug protocol, particularly a maintenance drug protocol such as blood pressure medications; and

WHEREAS, the community pharmacy and pharmacists are able to provide personal counseling and observation to the patient, thereby teaching the individual about the risks and benefits of prescription and over-the-counter drugs; and

WHEREAS, the pharmacy issues of the 1990s are complex and significant, requiring detailed and careful study, as can be seen in every jurisdiction of the Commonwealth, with independent and chain community pharmacies changing hands or going out of business; and

WHEREAS, during the 1993 Session, unprecedented interest in these pharmacy issues was evinced, as demonstrated by the passage of HJR 528 and HJR 556; and

WHEREAS, the joint subcommittee appointed to address these issues has met, considered the issues, and developed a solid study plan and a preliminary report; and

WHEREAS, the joint subcommittee's adopted study schedule could not be completed in 1993; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Joint Subcommittee Studying the Financial Impact of Third Party Reimbursement on the Commonwealth's Pharmacies is hereby continued. The members appointed to serve by the appropriate appointing bodies shall continue to serve, except that any vacancies shall be filled as provided in the original enabling resolutions.

The joint subcommittee shall continue to examine the issues set forth in its enabling resolutions, in relationship to the impact on the quality of pharmacy services and the best interests of the consumer, including insurance law and regulations; agreements between self-funded employers and insurance companies serving as third party administrators; the growing use of formularies, networks, and mail-order pharmacies; competitive fairness, such as drug-pricing differentials, and drug-purchasing arrangements; and the fair reimbursement of pharmacy services.

All agencies of the Commonwealth shall assist the joint subcommittee as deemed necessary.

The direct costs of this study shall not exceed $ 5,400.

The Division of Legislative Services shall provide staff support for the study.

The joint subcommittee shall complete its work in time to submit its findings and recommendations to the Governor and the 1995 Session of the General Assembly in accordance with the procedures of the Division of Legislative Automated Systems for the processing of legislative documents.

Implementation of this resolution is subject to subsequent approval and certification by the Joint Rules Committee. The Committee may withhold expenditures or delay the period for the conduct of the study.

GENERAL ASSEMBLY OF VIRGINIA--1993 SESSION

HOUSE JOINT RESOLUTION NO. 714

REPRINT

Requesting the Joint Commission on Health Care to study the reimbursement of health care providers by third party reimbursement programs.

Agreed to by the House of Delegates, February 25, 1993
Agreed to by the Senate, February 23, 1993

WHEREAS, soaring health care costs, increasing insurance premiums, greater corporate purchasing and delivery of health care, and shifting power structures in the managerial and provider sectors of the health care industry have profoundly influenced the overall health care environment in the Commonwealth; and

WHEREAS, changing payment sources have also severely affected the provision of health care goods and services; and

WHEREAS, the reimbursement of health care providers, including physicians, pharmacists, hospitals, and other sources of health care services and goods, by third party payers has increased dramatically in recent years; and

WHEREAS, it has been estimated that by 1995, in the retail pharmacy sector alone, public or private third party reimbursement will pay for nearly 75 percent of all prescriptions; and

WHEREAS, the value of special pharmacy services, including, but not limited to, compounding drugs and medicines, furnishing special containers or applicators, or utilizing special equipment in preparing or dispensing drugs or medicines cannot be underestimated; and

WHEREAS, medications are frequently a cost-effective means of avoiding more costly care, such as hospitalization, when they are prescribed, dispensed and properly used; and

WHEREAS, third party reimbursements may not adequately cover the provider's actual costs of delivering health care goods and services; and

WHEREAS, the advent of such third party reimbursement for health care services and goods has also contributed to an adversarial relationship between patrons and providers; and

WHEREAS, third party reimbursement programs often either specify particular providers that insureds or enrollees must use or encourage or discourage use of particular providers; and

WHEREAS, third party reimbursement may increase the administrative costs of health care providers; and

WHEREAS, the increase in third party reimbursements may force providers to raise prices charged to the diminished direct-pay population; and

WHEREAS, many of these third party payers are not insurance companies and are therefore not subject to regulation by the State Corporation Commission; and

WHEREAS, health care providers may not have the ability to negotiate effectively with third party reimbursement programs; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Joint Commission on Health Care be requested to study the reimbursement of health care providers by third party reimbursement programs. In its deliberations, the Commission shall consider (i) the effect of such programs upon the quality of health care services in the Commonwealth, (ii) whether such programs jeopardize or unfairly take advantage of health care providers in the Commonwealth, and (iii) the value of special pharmacy services, including, but not limited to, compounding drugs and medicines, furnishing special containers or applicators, or utilizing special equipment in preparing or dispensing drugs, applicators, or medicines. In order to ensure the delivery of quality and cost-effective health care services, the Commission shall recommend any legislation deemed necessary to ensure reasonable participation by all sectors of the provider community in third party reimbursement programs and provider networks.

The Commission shall complete its work in time to submit its findings and recommendations to the Governor and the 1994 Session of the General Assembly as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents.

1994 SESSION

LD2925364

HOUSE BILL NO. 842

Offered January 25, 1994

A BILL to amend the Code of Virginia by adding in Title 59.1 a chapter numbered 38, consisting of sections numbered 59.1-460 through 59.1-464, relating to drugs; prohibition of discriminatory wholesale pricing; penalty.

Patrons—Morgan, Bennett, Cox, Cranwell, DeBoer, Forbes, Hall, Hargrove, Parrish, Plum, Putney, Shuler, Tata and Thomas; Senators: Calhoun, Trumbo and Woods

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Referred to Committee on General Laws

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Title 59.1 a chapter numbered 38, consisting of sections numbered 59.1-460 through 59.1-464 as follows:

CHAPTER 38.

VIRGINIA DISCRIMINATORY DRUG PRICING ACT.

§ 59.1-460. Definitions.

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

"Drug" means any substance subject to section 201(g) of the Federal Food, Drug and Cosmetic Act.

"Manufacturer" means any person who sells drugs to sellers or purchasers.

"Purchaser" means any person who engages in selling or dispensing drugs directly to consumers.

"Seller" means any person who sells drugs to purchasers.

§ 59.1-461. Price discrimination prohibited.

A. Every manufacturer shall offer drugs to every seller with all rights and privileges offered or accorded by the manufacturer to the most favored seller, including purchase prices for similar volume purchases. Every manufacturer shall offer rebates, free merchandise, samples and similar trade concessions on proportionally equal terms to every seller. Nothing in this subsection prohibits the giving of a discount for volume purchases, so long as such discount is justified by the economies or efficiencies resulting from such volume purchases and such discount is made available to all sellers on proportionally equal terms.

B. Every manufacturer or seller shall offer drugs to every purchaser, with all rights and privileges offered or accorded by the manufacturer or seller to the most favored purchaser, including purchase prices for similar volume purchases. A manufacturer or seller shall offer rebates, free merchandise, samples or similar trade concessions on proportionally equal terms to every purchaser. Nothing in this subsection prohibits the giving of a discount for volume purchases, so long as such discount is justified by the economies or efficiencies resulting from such volume purchases and such discount is made available to all purchases on proportionally equal terms.

C. This section shall apply to any purchase of drugs which shall be delivered to a purchaser or purchaser's facility located in this Commonwealth.

§ 59.1-462. Purchases by Commonwealth prohibited in certain instances.

No agency of the Commonwealth shall purchase any drugs from any manufacturer or seller that engages in any price discrimination prohibited by this chapter.

§ 59.1-463. Civil action; treble damages.

Any purchaser damaged by a violation of this chapter may bring an action against the seller to recover treble damages sustained by reason of such violation. Proof of price discrimination shall constitute prima facie evidence of damage to a disfavored purchaser.

§ 59.1-464. Injunctions; civil penalties.

A. The Attorney General, an attorney for the Commonwealth, or an attorney for any city, county or town may cause an action to be brought in the appropriate circuit court in the name of the Commonwealth, or of a county, city or town to enjoin any violation of

this chapter.

B. If any person violates any injunction to cease and desist from any violation of this chapter, the Attorney General, an attorney for the Commonwealth, or an attorney for any city, county or town may, upon petition to the court, recover for the literary fund a civil penalty of not less than $1,000 and not more than $100,000.

C. The circuit court may make such additional orders or decrees as may be necessary to enforce the provisions of this chapter.

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

HOUSE BILL NO. 842

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on General Laws

on _____)

(Patron Prior to Substitute--Morgan)

A BILL to amend the Code of Virginia by adding in Title 59.1 a chapter numbered 38, consisting of sections numbered 59.1-460 through 59.1-465, relating to drugs; prohibition of discriminatory wholesale pricing; penalty.

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Title 59.1 a chapter numbered 38, consisting of sections numbered 59.1-460 through 59.1-465 as follows:

CHAPTER 38.

EQUALITY IN DRUG PURCHASING INCENTIVES ACT.

§ 59.1-460. Definitions.

As used in this chapter:

"Drug" means any substance subject to section 201(g) of the Federal Food, Drug and Cosmetic Act.

"Manufacturer" means any person engaged in the manufacture or processing of a drug or drugs as defined in § 510(a)(1) of the Federal Food, Drug and Cosmetic Act.

"Purchaser" means any person who engages in selling or dispensing drugs directly to consumers within this Commonwealth.

"Seller" means any person, other than a manufacturer, who sells or distributes drugs to purchasers or other sellers within this Commonwealth.

§ 59.1-461. Price discrimination prohibited.

A. Every manufacturer shall sell drugs to every seller to which it sells or distributes with all rights and privileges contemporaneously accorded by the manufacturer to the most favored seller. Blended product volume discounts, rebates, free merchandise, payment terms, samples and related trade concessions made available by a manufacturer to any seller to which it sells or distributes must be contemporaneously available to every seller to which it sells or distributes. Nothing in this subsection prohibits (i) the giving of a discount for volume purchases, so long as such discount is justified by the economies or efficiencies resulting from such volume purchases and such discount is contemporaneously made available by a manufacturer to all sellers to which it sells or distributes; (ii) reasonable reimbursement for the value to the manufacturer of a seller's actual marketing functions, provided that such functional discounts are contemporaneously made available on proportionally equal terms to every seller to which it sells or distributes; or (iii) meeting in good faith the equally low prices or terms of a competitor.

B. Every manufacturer or seller shall sell drugs to every purchaser or consumer to which it sells or distributes with all rights and privileges contemporaneously accorded by the manufacturer or seller to the most favored purchaser. Blended product volume discounts, rebates, payment terms, free merchandise, samples or related trade concessions made available by a manufacturer to any purchaser or consumer to which it sells or distributes must be contemporaneously available to every purchaser or consumer to which it sells or distributes. Nothing in this subsection prohibits (i) the giving of a discount for volume purchases, so long as such discount is justified by the economies or efficiencies resulting from such volume purchaser and such discount is contemporaneously made available by a manufacturer to all purchasers or consumers to which it sells or distributes; (ii) reasonable reimbursement for the value to the manufacturer of a purchaser's actual marketing functions, provided that such functional discounts are contemporaneously made available on proportionally equal terms to all purchasers and sellers to which it sells or distributes, or (iii) meeting in good faith the equally low prices or terms of a competitor.

C. Every seller shall sell drugs to every purchaser to which it sells or distributes with all rights and privileges contemporaneously accorded by the seller to the most favored purchaser. Blended product volume discounts, rebates, payment terms, free merchandise, samples, and related trade concessions made available by a seller to any purchaser to which it sells or distributes must be contemporaneously available to every purchaser to which it sells or distributes. Nothing in this subsection prohibits (i) the giving of a discount for volume purchases, so long as such discount is justified by the economies or efficiencies resulting from such volume purchases and such discount is contemporaneously made available by a seller to all purchasers to which it sells or distributes; (ii) reasonable reimbursement for the value to a seller of a purchaser's actual marketing functions, provided that such functional discounts are contemporaneously made available on proportionally equal terms to every purchaser to which it sells or distributes, or (iii) meeting in good faith the equally low prices or terms of a competitor.

D. This section shall apply to any purchase of drugs which shall be delivered to a seller, purchaser, purchaser's facility, or a consumer located in this Commonwealth.

E. Agencies of government and political subdivisions, charitable organizations, nonprofit hospitals or nursing homes when purchasing for their own use, and other nonprofit institutions are not sellers or purchasers under this section, and manufacturers and sellers of drugs are not prohibited from according to them pricing or related arrangements which are not made available to other sellers or purchasers in this state.

§ 59.1-462. Purchases by Commonwealth prohibited in certain instances.

No agency of the Commonwealth shall purchase, or reimburse for the purchase of, any product line from a manufacturer, seller, or purchaser that engages in any price discrimination prohibited by this chapter.

§ 59.1-463. Civil action; treble damages.

Any seller or purchaser damaged by a price discrimination in violation of this chapter may bring an action against the manufacturer or seller to recover treble damages sustained by

reason of such violation. Proof of price discrimination shall constitute prima facie evidence of damage to a disfavored purchaser.

§ 59.1-464. Injunctions; civil penalties.

A. The Attorney General, an attorney for the Commonwealth, or an attorney for any city, county or town may cause an action to be brought in the appropriate circuit court in the name of the Commonwealth, or of a county, city or town to enjoin any violation of this chapter.

B. If any person violates any injunction to cease and desist from any violation of this chapter, the Attorney General, an attorney for the Commonwealth, or an attorney for any city, county or town may, upon petition to the court, recover for the literary fund a civil penalty of not less than $1,000 and not more than $50,000.

C. Any person who violates any provision of this chapter or any order or injunction to cease and desist from such violations shall for the purposes of the state Medicaid program have all of their drug entities declared ineligible for sale under the state Medicaid program.

§ 59.1-465. Statute of limitations.

An action under this section is barred if it is not commenced within two years after the cause of action accrues.

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