REPORT OF THE
JOINT SUBCOMMITTEE STUDYING

Pharmaceutical Costs In The Virginia Medical Assistance Program Pursuant to HJR 403

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

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pursuant to HJR 403

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Executive Summary

AUTHORITY AND STUDY OBJECTIVES

House Joint Resolution No. 403 established a joint subcommittee to study rising pharmaceutical costs in the Virginia Medical Assistance Program. The committee was charged with the responsibility of identifying and developing cost-containment measures to effectively manage these escalating expenditures. The resolution states that cost-control measures must be not only fiscally prudent but also equitable to Medicaid recipients, pharmacy providers, and pharmaceutical manufacturers. The committee's study necessarily focused on the complex pricing structures and opposing interests of the retail and manufacturing sectors of the pharmaceutical industry, as well as the purposes, goals, and procedures of the Virginia Medicaid program, inflationary influences in the pharmaceutical industry, and state and federal government directives regarding cost-containment measures.

PHARMACEUTICAL COSTS IN THE VIRGINIA MEDICAL ASSISTANCE PROGRAM

Background

In 1965, Congress enacted Medicaid, originally designed as a federal and state cooperative venture to reimburse health care providers for medical services rendered to specific categories of needy persons. Under the Medicaid program, the federal government is authorized to appropriate matching funds to those states which have submitted and received approval for their medical assistance plans. While state participation in the program is voluntary, each participating state must offer certain required medical services. Federal law permits the states to provide coverage for other optional services, such as dental care and prescription drugs. Federal funding of the approved state program is calculated according to a statutory per capita formula.

The Virginia Medicaid Program and Pharmacy Participation

In Virginia, the state Medicaid plan is developed and amended by the Board of Medical Assistance Services, and administered by the Director of the Department of Medical Assistance Services (**DMAS**). The Director and the Board are assisted by the state Advisory Board on Medicare and Medicaid in developing the plan and method of program administration.

Pharmacies choosing to participate in the Virginia Medicaid program must comply with a number of licensing and service requirements and must accept as full payment the reimbursement established by DMAS as the reasonable cost or maximum allowable charge. The present participation rate by Virginia pharmacies is over 90 percent.

Prescription drugs are one of the most widely covered of state Medicaid optional services, accounting for approximately seven percent of the Medicaid budget, or $67 million. Coverage is provided for most prescribed legend drugs and for certain over-the-counter drugs. Reimbursement of prescription drugs is based on the ingredient cost and

the pharmacy dispensing fee. While the dispensing fee in Virginia is set at $3.40, the ingredient cost is less easily determined. The drug ingredient cost is based on the lowest of several different cost determinations, which include "upper limits" set by the federal government, "maximum allowable costs" established by DMAS, estimated acquisition costs, and the pharmacy's "usually and customary charge."

Escalating Costs and State Government Response

Pharmacy expenditures in the Virginia Medicaid program increased by 71 percent between 1984 and 1988, although the number of Medicaid recipients remained relatively stable. Increased reimbursements to pharmacy providers have been attributed to a number of factors, including the escalating costs of sole-source drugs, increased home health care, and greater use of specialty drugs. The Commonwealth has been repeatedly challenged to reduce these spiraling costs without lowering the quality of care.

In the last decade, the General Assembly has created a number of study committees to review indigent health care issues and has charged DMAS to implement cost-containment measures and a drug utilization review program. Perhaps the most significant legislative action appeared in the 1988 Appropriations Act, which directed DMAS to implement cost-containment initiatives to reduce pharmacy expenditures by $5.5 million by fiscal year 1990. With the cooperation of the pharmaceutical industry, DMAS was to consider drug reimbursement methods which better reflect the pharmacy's actual acquisition cost. The agency cited the costs of sole-source drugs as a major contributor to increasing pharmaceutical expenditures and developed several options targeting this source, with recommendations for implementation.

DEVELOPING EQUITABLE COST-CONTAINMENT MEASURES

The development of equitable and effective cost-containment measures requires consideration of industry pricing issues, state budgetary concerns, agency recommendations, and broader changes affecting the overall health-care environment. Soaring health-care costs and increasing health insurance premiums, together with shifting payment sources, have been cited as major influences within the health-care environment. The impact of these changes on the provision of pharmacy services must be weighed; the burdens imposed by these changes may be unevenly distributed among retail pharmacies, drug manufacturers, consumers, and the Commonwealth.

Rising Drug Prices And Industry Pricing Practices

Prescription drug prices are a major factor in the escalation of Medicaid pharmaceutical expenditures. Studies indicate that prescription drug prices more than tripled the rate of inflation from 1981 to 1988. While the dramatic increase in prescription drug prices has been attributed to a number of factors, sole-source drug patent protection is commonly cited as a continuing inflationary influence. Although clinical trials and Food and Drug Administration (**FDA**) approval may consume seven to ten years of a new product's potential 17-year patent protection, manufacturers nonetheless may maintain a fair amount of market control through these products.

While the Committee received a great deal of information regarding industry profit margins and other financial data, the actual pricing of prescription drugs remains somewhat of a mystery. Pharmaceutical manufacturers, citing antitrust concerns, have

traditionally declined to discuss their pricing structures, but cite increased investments in research and development as the largest single factor in their costs. There are indications, however, that manufacturers are relying on price increases, rather than on "breakthrough" products, to generate revenues. Data compiled for the United States Senate Special Committee on Aging indicate that most of the "new" products introduced between 1981 and 1988 were classified by the FDA as level "C" drugs, offering little or no contribution to existing therapies. Interestingly, some of these "me-too" drugs were priced higher than the original innovator product.

In contrast to the pharmaceutical manufacturer is the retail pharmacy, which may have little control over the prices of prescription drugs. Increased product costs, heavy competition, and restricted third party payments have placed many pharmacies in a "cost-price squeeze." Losses resulting from delayed or reduced third party payments and other administrative costs were traditionally passed on to the private pay consumer, now a shrinking portion of the pharmacy payment base. Retail pharmacy gross profit margins have also declined steadily, although the average prescription price has increased. Pharmacies participating in the Medicaid program may carry additional burdens because they are paid less for Medicaid prescriptions, which typically cost more to dispense.

Agency Reimbursement Practices

The alarming increase in drug product costs suggests that how the Commonwealth computes reimbursement must be carefully scrutinized. Although federally mandated pharmacy reimbursement standards are broad, testimony before the Committee indicated that many states, including the Commonwealth, may be basing drug reimbursements on a published average wholesale price (**AWP**) which may not be representative of the amount a pharmacy actually pays for a product. Because pharmacies may earn discounts on the AWP based on timely payments and good business practices, computing drug reimbursements based on the AWP, rather than upon consideration of the product's actual acquisition cost, may result in unnecessary Medicaid expenditures.

COST-CONTAINMENT OPTIONS

Having received testimony from DMAS, the pharmaceutical industry, the medical community, and other professionals, the Committee weighed a number of cost-containment options and considered the impact of each option on the pharmaceutical industry, recipients, and the Commonwealth. Full funding for the pharmacy component of the Medicaid program was supported by manufacturer representatives to ensure the continuation of the "most cost effective Medicaid service." Under such a proposal, an open drug formulary would permit Medicaid patients to receive the most appropriate medication as determined by a physician. Expenditures for pharmaceutical products would likely increase, while ideally reducing expenditures in other components of the Medicaid program.

Also considered was the use of a restrictive formulary to reduce expenditures for products which have less expensive therapeutic alternatives. Inclusion in the formulary would be based on consideration of efficacy, safety, and cost, with exceptions made for nonformulary products upon prior authorization or in emergency situations. Manufacturer rebates and discounts were reviewed as well; establishing a contractual relationship with drug manufacturers would directly address the high costs of pharmaceutical products and would allow the Commonwealth to obtain pricing arrangements similar to

those already offered to health maintenance organizations, hospitals, and other large-volume purchasers. Agency regulations could outline requirements for rebate terms and computation.

Adjustment of the current reimbursement formula to reflect inflation and the actual acquisition costs of specific products would conform with recent federal directives. Savings to the Commonwealth would likely result as the revised formula would more closely reflect the discounts pharmacies may receive on certain products. Monitoring the use of prescription drugs in the Commonwealth through a Medicaid drug utilization review program is another cost-containment measure considered by the Committee. This option ideally would ensure necessary and appropriate care while curbing aberrant use and prescribing practices.

RECOMMENDATIONS

The development of cost-containment measures involves careful review of diverse interests: the recipient's interest in quality care, the industry's concern over equitable sharing of financial burdens, and the Commonwealth's commitment to maintaining fiscal integrity as well as fairness in its Medicaid program. After reviewing these interests and conferring with appropriate state agencies, representatives of the medical community and the pharmaceutical industry, and other professionals, the Committee concluded that the most effective and equitable measures would directly address the pricing of prescription drugs and the calculation of reimbursement. The Committee developed the following recommendations:

- *That a Virginia Medicaid drug formulary be established and that the Board of Medical Assistance Services promulgate regulations establishing an advisory committee to review product applications and to make recommendations to the Board regarding inclusion in the Formulary.*

- *That the Director of the Department of Medical Assistance Services be authorized to negotiate and enter into agreements directly with pharmaceutical manufacturers to obtain rebates for a negotiated percentage of the total product cost to the Department of a specific product to be included in the Virginia Medicaid Formulary and that those products for which a rebate is successfully negotiated or renewed be included automatically in the Virginia Medicaid Formulary.*

- *That upon failure to negotiate or renew a rebate agreement for a specific product, the pharmaceutical manufacturer be required to disclose to the Department information regarding its most favorable pricing arrangements made available to non-state government purchasers of the specific product, and that the Director shall establish a rebate for such product, regardless of whether the product is included in the Virginia Medicaid Formulary, based on such price information.*

- *That the Department of Medical Assistance Services develop and implement a drug utilization review program.*

- *That the Department of Medical Assistance Services amend its state plan to change the reimbursement formula to better reflect the pharmacy's actual acquisition cost of drug products and the cost to dispense such products, consistent with federal law and regulation.*

Final Report

I. Authority for Study

Adopted by the 1989 Session of the General Assembly, House Joint Resolution No. 403 established a joint subcommittee to study pharmaceutical costs within the Virginia Medical Assistance Program. The Committee was also charged with the responsibility of identifying appropriate cost-containment measures which would "equitably fall upon the entire pharmaceutical industry." The Committee was comprised of eight members, including two members of the House Appropriations Committee, one member of the House Committee on Health, Welfare, and Institutions, one member of the House Corporations, Insurance and Banking Committee, two members of the Senate Finance Committee, one member of the Senate Committee on Education and Health, and one *ex officio* member. The resolution required the Committee to submit its findings and recommendations to the Governor and the 1990 Session of the General Assembly.

II. Objectives and Study Design

Expressing the General Assembly's concerns regarding spiraling pharmaceutical expenditures in the Virginia Medicaid Program, HJR 403 called for the development of lasting cost-containment measures to manage these escalating costs. Citing the complex and diverse pricing structures of retail pharmacies and pharmaceutical manufacturers, the resolution stated that cost-containment measures must be not only "fiscally prudent" but also "equitable to recipients, pharmacy providers, and pharmaceutical manufacturers." The Committee's study has necessarily focused on the pricing structures and practices of the pharmaceutical industry, as well as the purposes, goals, and procedures of the state Medicaid program. The Committee has also examined the various influences prompting cost escalation in the pharmaceutical industry and the Medicaid program, and state and federal actions regarding cost-containment measures.

Throughout its study, the Committee received testimony from representatives of the retail and manufacturing sectors of the pharmaceutical industry and considered the perspectives of the medical profession, pharmaceutical economics research specialists, and other state Medicaid agencies. In addition, the work of the United States Senate Special Committee on Aging, chaired by Senator David Pryor of Arkansas (the **Pryor Committee**), provided valuable information about industry practices and efforts by the federal government, the states, and private entities to reduce pharmaceutical expenditures.

III. Pharmaceutical Costs within the Virginia Medical Assistance Program

Introduction

In 1965, Congress enacted Title XIX of the Social Security Act, creating Medicaid.[1] Originally conceived as a federal and state cooperative mission to reimburse health care providers for medical services rendered to specific categories of needy persons,[2] the Medicaid program evolved "somewhat unexpectedly" from the political debates surrounding the enactment of Medicare.[3] The program represented an outgrowth of the various state and federal social welfare programs generated by New Deal philosophies and the "Great Society" of the Johnson administration.[4] The Medicaid program has been described as a "creature of peculiar origins,"[5] an example of "cooperative federalism,"[6] and a "morass of service coverage and exceptions."[7]

To enable each state to furnish medical and rehabilitative services, the federal government is authorized to appropriate funds to those states which have submitted and received approval for state plans for medical assistance.[8] State participation in the Medicaid program is voluntary, and begins with the development and submission of the state plan to the United States Department of Health and Human Services.[9] Federal law requires participating states to provide seven basic services and permits the additional coverage of certain optional services, such as dental care and prescription drugs.[10]

Upon approval by the Secretary of the U.S. Department of Health and Human Services, the state program is eligible to receive federal funding, calculated pursuant to a per capita statutory formula.[11] In practice, the federal government generally provides

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1. Title XIX of the Social Security Act, Pub. L. No. 89-97, 79 Stat. 343-423 (codified as amended at 42 U.S.C.A. § 1396 et seq.), (1983 and 1989 Supp.).

2. See J. Perkins, "Increasing Provider Participation in the Medicaid Program: Is There a Doctor in the House?" 26 Hous. L. Rev. 77 (1989) [hereinafter referred to as Perkins]. Medicaid should provide "federal financial assistance to States that choose to reimburse certain costs of medical treatment for needy persons." Harris v. McRae, 448 U.S. 292, 301 (1980).

3. K. Wing, "The Impact of Reagan-Era Economics on the Federal Medicaid Program," 33 Cath. U.L. Rev. 1 at 3, 4 [hereinafter referred to as Wing]. Professor Wing notes that because Congress' primary attention was on Medicare legislation, Medicaid was actually a "sleeper"—legislation which was "hastily considered and not fully understood at the time it was passed." Id. at 3 n.2.

4. Wing, supra note 3, at 4.

5. Wing, supra note 3, at 3.

6. A. Sarro, "Determining Medical Necessity Within Medicaid: A Proposal for Statutory Reform," 63 Neb. L. Rev. 835 at 836 (1984) [hereinafter referred to as Sarro].

7. Wing, supra note 3, at 7

8. 42 U.S.C.A. § 1396 (1989).

9. Id. See also, Perkins, supra note 2, at 77

10. 42 U.S.C.A. § 1396d(a) (1989). Participating states must provide (i) inpatient hospital services, (ii) outpatient hospital services, (iii) laboratory and X-ray services, (iv) skilled nursing facility services, (v) services from state-licensed nurse midwives, (vi) certain home health services, and (vii) physician services. See also, Perkins, supra note 2, at 77 n.2.

11. 42 U.S. C.A. §§ 1396a(b), 1396b(a), (d) (1989). See also, J. Kennedy, "The Medicaid Program: Vague Standards Breed Litigation," 28 St. Louis U.L. Rev. 351, 352 (1984) [hereinafter referred to as Kennedy].

matching funds for state medical assistance services.[12] The state programs must comply with federal statutes and regulations, and must include procedures and safeguards to ensure proper utilization of services as well as "efficiency, economy, and quality of care."[13] The state plans cannot arbitrarily limit coverage based on diagnosis, illness, or condition,[14] and must ensure that each offered service, whether mandatory or optional, is "sufficient in amount, scope, and duration to reasonably achieve its purpose."[15] Finally, the state plan must include provisions ensuring that services are rendered in a manner "consistent with simplicity of administration and the best interests of the recipients."[16] Any amendment to a state plan must be approved by the U.S. Department of Health and Human Services.[17]

The Virginia Medicaid Program

The General Assembly authorized Medicaid for Virginia in 1966,[18] and subsequently created the Board of Medical Assistance Services, charged with the responsibility of preparing and amending the Virginia plan.[19] In preparing the plan, the Board is to "work cooperatively with the State Board of Health to ensure that quality patient care is provided."[20] The Board is also required to initiate cost-containment measures as set forth in the Appropriations Act, and may adopt and enforce any regulations necessary to carry out its duties.[21] The Director of the Department of Medical Assistance Services (**DMAS**) is authorized to administer the state plan and to expend federal funds in accordance with state and federal laws and regulations.[22] The Director and the Board are also aided by the State Advisory Board on Medicare and Medicaid in developing the plan and method of program administration.[23]

• *Pharmacy Participation*

The Virginia Medical Assistance Plan offers Medicaid coverage for a range of optional services in addition to the basic services required by federal law. Pharmacy providers wishing to participate in the Medicaid program must comply with a number of requirements. The pharmacy must be licensed by the State Board of Pharmacy and have a

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12. Kennedy, supra note 11, at 352. See also, Report of the Governor's Task Force on Indigent Health Care, Senate Document No. 11, at 61 (1988) [hereinafter referred to as Senate Document No. 11]. For fiscal year 1986, the Commonwealth obtained a 53 percent match from the federal government.

13. 42 U.S.C.A. § 1396a(a)(30) (1989). See also, Kennedy, supra note 11, at 352; Perkins, supra note 2, at 78.

14. Sarro, supra note 6, at 841, citing 42 C.F.R. § 440.230(b) (1988).

15. Sarro, supra note 6, at 840, citing 42 C.F.R § 440.230(b) (1988).

16. 42 U.S.C.A. § 1396a(a)(19) (1989).

17. 42 C.F.R. § 430.12 (1988). The state plan must be submitted to the Governor for approval before being submitted to the U.S. Department of Health and Human Services. Va. Code § 32.1-325 (1989 Supp.).

18. Department of Medical Assistance Services, Pharmacy Manual, ch. I, p.3 (1988 and 1989 Supp.) [hereinafter referred to as Pharmacy Manual].

19. Va. Code § 32.1-325 (1989 Supp.). The Department of Medical Assistance Services, created in 1984, operates under the guidance of the Commonwealth's Secretary of Human Resources and the agency Director. Va Code § 32.1-323 (1985). Development of the Commonwealth's Medicaid plan was previously the responsibility of the State Board of Health. 1984 Acts of Assembly, ch. 781.

20. Va. Code § 32.1-325 A (5) (1989 Supp.).

21. Id.

22. Va. Code § 32.1-325 B (1989 Supp.). The Director of Medical Assistance Services is appointed by the Governor, subject to confirmation by the General Assembly. Va. Code § 32.1-323 (1985).

23. Va. Code § 32.1-328 (1985).

current, signed participation agreement with DMAS.[24] The participating pharmacy must provide services and supplies to recipients in the same quantity and manner as provided to the general public, and must accept as payment in full the reimbursement amount established by DMAS as the reasonable cost or maximum allowable charge, plus any applicable copayment.[25] Presently, the participation rate by Virginia pharmacies is over 90 percent.[26]

• *Eligibility*

Recipient eligibility is determined by local social service departments pursuant to interagency agreements with the Virginia Department of Social Services.[27] Coverage is available to persons classified as "categorically" and "medically" needy. The "categorically needy" classification includes the aged, the blind, and certain disabled persons, as well as certain children and pregnant women.[28] "Medically needy" persons must meet similar criteria, although their income and resources may surpass those established for the categorically needy.[29]

• *Covered Services and Payment Methodology*

Prescription drugs are one of the most widely covered of Virginia Medicaid's optional services, accounting for approximately seven percent of the Virginia Medicaid budget, or about $67 million.[30] Coverage is extended to prescribed legend drugs, with certain exclusions, as well as to a limited number of over-the-counter drugs.[31] In all states, reimbursement for prescription drugs under Medicaid is based on two components: the drug cost and the pharmacist's dispensing fee.[32] The dispensing fee ostensibly covers costs related to the professional pharmacy service, such as overhead and professional

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24. Pharmacy Manual, supra note 18, at ch. II., p. 1. See also, Va. Code § 54.1-3307 (1988), regarding the specific powers of the Board of Pharmacy. The dispensing pharmacist must be authorized to practice pharmacy under the laws of the state in which the applicant pharmacy is licensed and practicing. Pharmacy Manual, supra note 18, at ch. II., p. 4.

25. Pharmacy Manual, supra note 18, at ch. II, p. 3., ch. IV, p. 3. See also, 42 C.F.R. § 447.15 (1988), which requires participating providers to accept the state agency's reimbursement as payment in full. Effective July 1, 1989, applicable copayments were increased from $.50 to $1.00 per prescription. Pharmacy Manual, supra note 18, at ch. IV, p. 7

26. Department of Medical Assistance Services, Legislative Report/Plan to Reduce Pharmacy Expenditures for FY 1990 (1988) at Appendix B, p. 1 [hereinafter referred to as DMAS Report].

27. Pharmacy Manual, supra note 18, at ch. I, p. 3.

28. Pharmacy Manual, supra note 18, at ch. III, p. 1. See also, 42 U.S.C.A. § 1396 (1989).

29. Pharmacy Manual, supra note 18, at ch. III, p. 2.

30. DMAS Report, supra note 26, at Appendix B, p. 1.

31. Pharmacy Manual, supra note 18, at ch. I, p. 5; ch. IV, pp. 1, 2. "Legend drugs" are defined as those drugs bearing the federal caution label prohibiting dispensing without a prescription. Id. at Appendix A, p. 5. Virginia Medicaid does not cover certain legend drugs, such as transdermal delivery systems, anorexiant drugs prescribed for weight loss, DESI (Drug Efficacy Study Implementation) drugs considered "less than effective" by the Food and Drug Administration, recalled drugs, and vaccines for routine immunizations. Id. at ch. IV, pp. 1, 2. "Non-legend" (or over-the-counter) drugs, even if prescribed, are generally not covered by Medicaid. Coverage is permitted, however, for certain supplies such as insulin, syringes and needles (except for recipients in nursing homes), and family planning drugs and supplies. Id. at ch. I, p. 7

32. Lederle Laboratories, "The Dilemma of Pharmacy Provider Compensation," Medicaid Pharmacy Bulletin (March-April 1988) [hereinafter referred to as Medicaid Pharmacy Bulletin].

time; federal regulations require state Medicaid agencies to establish a "reasonable" dispensing fee.[33] Although this standard is not defined by federal regulation, the U.S. Health Care Financing Administration (**HCFA**) has described a "reasonable dispensing fee" as one which adequately meets provider costs, ensures access to pharmaceuticals for recipients, and assures that Medicaid funds are not spent unnecessarily.[34] In Virginia, the established pharmacy dispensing fee is $3.40 per prescription.[35]

The "drug cost" component is less easily determined. Although the participating pharmacy simply bills DMAS for its "usual and customary" charges for all prescriptions dispensed, the DMAS claims processing system calculates provider reimbursement based on the lowest of five different cost determinations:[36]

- ❒ the "upper limit" established by HCFA for multiple-source drugs;[37]
- ❒ the Virginia Maximum Allowable Cost for multiple-source drugs listed on the Virginia Voluntary Formulary (**VVF**);[38]
- ❒ the estimated acquisition cost plus a dispensing fee;
- ❒ a mark-up allowance for covered non-legend drugs and legend oral contraceptives; or
- ❒ the pharmacy's usual and customary charge, as indicated by the claim.[39]

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33. Id. See also, 42 C.F.R. § 446.331 (1988).

34. Medicaid Pharmacy Bulletin, supra note 32. HCFA has indicated that because prescription drug coverage is an optional service, states are granted "considerable latitude" in administration.

35. Pharmacy Manual, supra note 18, at ch. IV, p. 7

36. Id. at ch. V, p. 1.

37. Id. at ch. IV, p. 4. Pursuant to 42 C.F.R. § 447.332, HCFA has established a specific upper limit for multiple-source drugs if the drug is listed by three suppliers and if all formulations of the drug approved by the FDA have been evaluated as therapeutically equivalent. Section 32.1-87 of the Code of Virginia allows pharmacists to substitute a generic equivalent for a brand name drug if the drug is listed in the Virginia Voluntary Formulary. Because the HCFA upper limits may apply to certain multiple source drugs not listed in the Virginia Voluntary Formulary, this reimbursement formula is not always applicable. Pharmacy Manual, supra note 18, at ch. IV, p. 5, and at Appendix C, p. 1.

38. Pharmacy Manual, supra note 18, at ch. IV, p. 4. DMAS may establish maximum allowable costs for specific multiple source drugs listed in the VVF, based on the lowest of certain cost formulas, including HCFA upper limits, estimated acquisition cost, and the pharmacist's usual and customary charge. Id. at ch. IV, p. 5. A physician may require the dispensing of a more expensive brand name drug by specifying "Brand Necessary" on the prescription. Although § 32.1-87 of the Code of Virginia states that use of the VVF is voluntary, the General Assembly has required that all prescriptions for Medicaid recipients be filled with generic products listed in the VVF 1983 Acts of Assembly, ch. 622.

39. Pharmacy Manual, supra note 18, at ch. IV, p. 4. Payments for pharmacy services rendered to recipients in skilled or intermediate care facilities are determined on a similar "lowest cost" basis, with only one dispensing fee permitted per month for each legend drug. If a prescription is refilled within the month, only the drug cost is reimbursed. Id. at ch. IV, p. 6.

Escalating Costs and State Government Response

Increasing health care costs and indigent health care have been cited as "the most critical issues facing the Commonwealth."[40] Pharmacy expenditures in the Virginia Medicaid program increased by 71 percent between fiscal years 1984 and 1988, although the number of Medicaid recipients remained relatively stable.[41] Increased reimbursements to Virginia pharmacy providers have been attributed to a number of factors, including the escalating costs of sole-source drugs, increased home health care, and greater usage of specialty drugs.[42]

The federal government and the states have thus been challenged to reduce these increased health-care costs by "using effective cost-containment strategies without lowering the quality of care."[43] Prior to 1981, cost-control measures for Medicaid primarily focused on freezing eligibility standards, lowering reimbursement rates, or reducing covered services.[44] In 1981, Congress amended the Medicaid statute to allow states greater flexibility to develop payment methods and rates;[45] in 1982, the law was again amended to permit states to impose nominal copayments on most Medicaid services.[46] Virginia first imposed copayments for pharmaceutical products in 1975.[47]

The Commonwealth has repeatedly expressed legislative concern over spiraling health-care costs.[48] In 1984, the General Assembly included in the Appropriations Act various requirements for cost-containment measures for medical assistance services and directed the Governor, in conjunction with the State Board of Health, to implement a drug utilization review program.[49] In 1986, SJR 32 created a Governor's Task Force on Indigent Health Care to study "all aspects of the indigent health care issue ...."[50] The 1988 General Assembly created a joint legislative subcommittee to study health care for all Virginians.[51]

Direct cost-containment measures for pharmaceutical expenditures appeared in the 1989 Appropriations Act, which required DMAS to increase the Medicaid client copayment to $1.00 per prescription, to limit pharmacist dispensing fees to one per legend drug per

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40. Senate Document No. 11, supra note 12, Letter of Transmittal from the Secretary of Human Resources.

41. DMAS Report, supra note 26, at 17 The number of Virginia Medicaid recipients increased from 221,394 in 1984 to 232,173 in 1987

42. Id.

43. Senate Document No. 11, supra note 12, at 28.

44. Id. at 68.

45. Kennedy, supra note 11, at 354. Apparently the Medicaid reimbursement standards were revised because Congress believed the original "reasonable cost" standard contributed to health care inflation. Id. at 356.

46. Wing, supra note 3, at 68. Among those services excluded from copayment requirements were medical emergency services, family planning services, and services to pregnant women. The original Medicaid statute had permitted the imposition of copayments for most services with restrictions regarding certain recipients. Wing, supra note 3, at 10 n.35.

47. DMAS Report, supra note 26, at 29. The original copayment amount was $0.50.

48. Senate Document No. 11, supra note 12, at 28.

49. 1984 Acts of Assembly, ch. 755, item 395.

50. Senate Joint Resolution No. 32 (1986). See also, Senate Joint Resolution No. 151 (1987), which extended the work of the Task Force for another year.

51. Senate Joint Resolution No. 99 (1988); House Joint Resolution No. 78 (1988). The subcommittee was continued by Senate Joint Resolution No. 214.

month, to discontinue Medicaid coverage for transdermal drug delivery systems, and to implement a plan to limit coverage of new drug products which have less expensive therapeutic equivalents.[52] Perhaps the most significant legislative action to contain pharmaceutical costs in the Virginia Medicaid program, however, was expressed in the 1988 Appropriations Act. The General Assembly specified that DMAS implement cost-containment initiatives by fiscal year 1990 to yield a savings on pharmacy costs of $2.7 million in general funds and $2.8 million in nongeneral funds, for a total of $5.5 million. The Director of DMAS was directed to develop an "implementation strategy" in cooperation with the pharmaceutical industry and to consider drug reimbursement methods "that better reflect the pharmacy's actual acquisition cost."[53]

In response to the directives of the 1988 Appropriations Act, DMAS developed and evaluated options and strategies to reduce pharmaceutical expenditures within the Virginia Medical Assistance Program. In its 1988 report, DMAS combined various options to offer "the most appropriate and equitable approach" to meet the $5.5 million cost-reduction mandate.[54] Noting the 71 percent increase in pharmacy expenditures in the last four years, the DMAS report cited the costs of sole-source drugs as a major contributing factor, accounting for 87 percent of 1987 Medicaid drug costs.[55] Payments for certain sole-source drugs increased from 46 percent to 57 percent, while the average reimbursement per prescription increased 41 percent.[56]

To develop cost-containment measures which would "control escalating drug costs in the long term,"[57] DMAS encouraged input from the pharmaceutical industry The agency study developed fifteen specific options, of which eight were considered "viable." These options were reviewed individually and in combinations; options were judged on the basis of projected savings, administrative impact of implementation, and distribution of the financial burden among recipients, the agency, and the pharmaceutical industry.[58] Four "viable" options, cited by the 1989 Appropriations Act, have already been addressed in proposed agency regulations. These included permitting one dispensing fee per month per legend drug dispensed to noninstitutionalized clients,[59] increasing the recipient copayment to $1.00,[60] and discontinuing coverage of transdermal delivery systems. These

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52. 1989 Acts of Assembly, ch. 668, item 389.

53. 1988 Acts of Assembly, ch. 800, item 389. DMAS was also to consider limiting the number of prescriptions for non-nursing home recipients to six per month.

54. DMAS Report, supra note 26, at 57

55. Id. at 3. Sole-source drugs accounted for 55.4 percent of pharmacy claims. While multiple source drugs accounted for the remaining 44.6 percent of all pharmacy claims, these drugs represented only 13 percent of Medicaid drug expenditures.

56. Id. at 3. Interestingly, the medical component of the Consumer Price Index percentage increase for the last four years is 28.37 percent.

57. Id. at 4. Due to revision of the HCFA upper cost limits established for specific multiple source drugs, DMAS estimated a $1,779,808 reduction in expenditures; however, an additional reduction of $3,720,192 would be required to meet the $5.5 million directive.

58. Id. at 5. Among the options not recommended as viable strategies was limiting the number of prescriptions per recipient to six per month, as suggested in the 1988 Appropriations Act, supra note 53.

59. DMAS Report, supra note 26, at 8, 28. Estimated savings for this option were $1,000,000. Should a prescription be refilled in the same calendar month, only the ingredient cost would be reimbursed.

60. Id. at 29. This option has been recommended by pharmacies to simplify collection. The copayment is not collected by the pharmacy in addition to the $3.40 dispensing fee, but is deducted from the total approved payment. Prior to the 1989 revisions, a $.50 copayment was charged for agency payments of $10.00 or less; $1.00 was charged for calculated payments exceeding $10.00.

three options were addressed in DMAS regulations effective July 1, 1989, pending federal approval.[61] Subject to public comment and federal approval, a fourth option, limiting coverage of new drug products, would be effective February 1, 1990.[62]

The Department's preferred plan for implementation of the Appropriations Act directive ostensibly had the least adverse impact on the interested parties and focused on sole-source drugs as the primary cause for increased pharmacy expenditures.[63] The plan was comprised of the copayment increase option, the dispensing fee limitation addressed in proposed regulations, the use of manufacturer rebates to permit the Commonwealth to benefit from the various rebates, discounts, and charge-backs presently used to market pharmaceutical products to hospitals and pharmacies,[64] and the elimination of coverage for add-on unit dose fees.[65]

Other options recommended by the DMAS plan as viable included the institution of a Medicaid drug formulary and the application of percentage discounts to pharmacy payments.[66] Options explored but not considered "viable" included reducing the pharmacy dispensing fee, limiting prescriptions to noninstitutionalized clients to six per month, discontinuing the "brand necessary" override, and instituting a provider incentive fee to increase generic use. Also reviewed were the options of redefining "usual and customary" charges, covering certain non-legend drugs for noninstitutionalized clients, and including non-legend drugs in the per diem coverage for nursing home care.[67]

IV. Developing Equitable Cost-Containment Measures

The development of appropriate and equitable pharmaceutical cost-containment measures required the Committee to consider not only state budgetary concerns and the recent recommendations and initiatives of DMAS, but also industry pricing issues and

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61. See generally, DMAS Report, supra note 26, at 28-30, 33-35; see also, Department of Medical Assistance Services, Regulation Review Summary, April 18, 1989, at 2, 3, and June 15, 1989, at 2. Because medication transferred by "patches" is available in other forms, both DMAS and the Virginia Pharmaceutical Association supported this option.

62. Department of Medical Assistance Services, Regulation Review Summary, June 15, 1989, at 2. See also, DMAS Report, supra note 26, at 34. Because new drugs are generally more expensive, the DMAS plan recommended restricting coverage for new products when there are less expensive alternatives on the market. A New Drug Review Committee would evaluate new pharmaceutical products; the Board of Medical Assistance Services would then determine coverage. Products not approved for coverage would qualify for reimbursement only if the prescribing physician obtains prior approval.

63. DMAS Report, supra note 26, at 23.

64. Id. at 26, 27 The estimated savings for a rebate program were $2,052,296, based on a five percent rebate applied to sole-source drugs alone.

65. Id. at 40, 41. Estimated savings under this option were $530,878. Currently, pharmacies may charge an additional $.01 dispensing fee per metric quantity for unit-dose packages dispensed to clients in skilled and intermediate care facilities. Pharmacy providers opposed to this option cited the risk of reverting to 30-day supply systems, which could result in Medicaid reimbursement for unused medications. An alternative option was also developed which merely reduces the unit-dose fee for oral liquids, resulting in estimated savings of $241,705 per year.

66. Id. at 31, 37 A specific percentage discount, based on total DMAS payments to the pharmacy, would be applied to each pharmacy. The discount would be applied to the estimated acquisition cost which may reflect the average wholesale price of the pharmaceutical product.

67. Id. at 42, 44, 47, 48, 50, 51, 53. The option to limit prescriptions to six per month was also proposed in the 1988 Appropriations Act, supra note 53.

broader changes affecting the current health-care environment. Soaring health-care costs and increasing health insurance premiums, together with shifting payment sources and increased corporate purchasing and delivery of health-care services, have been cited as major influences within the overall health-care environment.[68] Specifically, the impact of these changes on the provision of pharmacy services must be weighed; the burdens imposed by these changes may be unevenly distributed among retail pharmacies, drug manufacturers, consumers, and the Commonwealth. Developing effective cost-containment strategies necessitates identification and analysis of sources contributing to increased expenditures as well as consideration of the effects of cost containment on other Medicaid services. In meeting the charge of HJR 403, this Committee has reviewed these issues and the roles of pharmacies, manufacturers, and the Commonwealth in order to develop equitable solutions.

The Rising Costs of Prescription Drugs

Perhaps the greatest influence on the escalation of Medicaid pharmacy expenditures is the dramatic increase in prescription drug prices. Although prescription drug manufacturers were "a model of pricing restraint" in the 1960's and 1970's, studies indicate that prescription drug prices in the 1980's, "even after the deflationary effect of generics, have gone up more than twice as fast as consumer prices in general."[69] Other studies indicate that prescription drug prices more than tripled the rate of inflation from 1981 to 1988 and that "only half" of the increase in prescription drug prices from 1980 to 1987 was attributable to general inflation.[70] A 65 percent increase in drug prices in the last six years represents the greatest increase for any component of medical care.[71] Testimony before the Pryor Committee confirmed that U.S. average drug prices are 54 percent higher than the average paid by European Economic Community nations.[72]

As DMAS had found in its recommended plan for cost containment, sole-source drugs appear to play a major role in the escalation of Medicaid pharmaceutical expenditures. While the dramatic increase in prescription drug prices has been attributed to a number of factors, sole-source drug patent protection is commonly cited as a continuing inflationary influence. Although clinical trials and Food and Drug Administration (**FDA**) approval may consume seven to ten years of a new product's potential 17-year patent protection, manufacturers nonetheless may maintain a fair amount of market control

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68. Minutes, August 8, 1989 meeting. According to the testimony of Dr. Stephen Schondelmeyer, faculty member at the Purdue University School of Pharmacy and Pharmaceutical Economic Research Center, Medicaid pays for approximately 22 percent of prescriptions filled by independent pharmacies and 10 to 12 percent of prescriptions filled by chain drug stores. Dr. Schondelmeyer attributes this discrepancy, in part, to the accessibility of specific drug stores to the Medicaid population.

69. J. Novack, "Drug price bust," Forbes at 39, 40 (October 30, 1989) [hereinafter referred to as Forbes].

70. Staff Memorandum, October 2, 1989 [hereinafter referred to as Staff Memorandum], summarizing the United States Senate Special Committee on Aging, Staff Briefing Paper, "Prescription Drug Prices: Are We Getting Our Money's Worth?" (July 18, 1989).

71. Forbes, supra note 69, at 40. Nationwide, Medicaid paid $3.3 billion for drugs in 1988 and covered 18 percent of all prescriptions.

72. Staff Memorandum, December 12, 1989, regarding the United States Senate Special Committee on Aging, Staff Information Paper, "Skyrocketing Prescription Drug Prices: Turning a Bad Deal into a Fair Deal" (November 16, 1989) and the Pryor Committee's November 16, 1989 hearing [hereinafter referred to as Hearing Memorandum]. It was noted that, in addition to its high drug prices, the United States also has a high prescription drug consumption rate.

through these products.[73] Sole-source drugs account for approximately 87 percent of Virginia Medicaid pharmacy expenditures, but comprise only about 55 percent of Medicaid pharmacy reimbursement claims.[74]

Another commonly cited influence on prescription drug prices is the cost of pharmaceutical research and development. Representatives of the Pharmaceutical Manufacturers Association (**PMA**) testifying before this Committee indicated that its member companies devote a greater percentage of their sales profits to research and development than any other high-technology industry. These companies expected to invest about $7.5 billion in the research and development of new drug therapies in 1989; in 1988, the manufacturing industry invested 16.5 percent of its sales in research and development, and increase from 10.2 percent in 1965.[75] Manufacturers cite their increased expenditures for research and development as the largest single factor in their costs and contend that the period of time in which a pharmaceutical company may recover its research costs has been compressed by competition from generic products, delays in the FDA approval process, intense competition within the research-based industry, increasing foreign competition, and patent piracy. The PMA estimates that the average cost of bringing a new medicine "from discovery to the pharmacy" exceeds $125 million.[76]

Although the research efforts of the pharmaceutical industry have yielded many "miracle medicines," there are indications that pharmaceutical manufacturers are relying on price increases, rather than "breakthrough" drug products, to generate revenues.[77] A marked increase in manufacturer profits has far surpassed research and development expenditures; marketing expenditures also have reportedly increased. The estimated $125 million drug development cost may actually apply to only about 25 percent of new drug products; many new drug products are "streamlined versions of old drugs."[78] According to data compiled for the Pryor Committee, 84 percent of pharmaceutical products introduced between 1981 and 1988 were classified by the FDA as level "C" drugs, offering "little or no" contribution to existing therapies. These "me-too" drugs may not supply new markets and, in some cases, may simply substitute for older products.[79]

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73. Minutes, August 8, 1989 meeting and October 3, 1989 meeting. The initial issue period is afforded patent protection ostensibly to encourage the research and development of new products.

74. Minutes, August 8, 1989 meeting.

75. Minutes, October 3, 1989 meeting. The PMA represents more than 100 research-based pharmaceutical companies which discover, develop, and produce most of the prescription drugs used in the United States.

76. Staff Memorandum, supra note 72, summarizing materials and statements presented to the U.S. Senate Special Committee on Aging in July, 1989. Gerald J. Mossinghoff, President, Pharmaceutical Manufacturers Association, quoted an estimate made by Professor Steven N. Wiggins of Texas A & M regarding the costs of bringing new drugs to the market.

77. Id.

78. Minutes, August 8, 1989 meeting; see also, Staff Memorandum, supra note 70, referring to Senator Pryor's opening statements regarding research and development costs.

79. Minutes, August 8, 1989 meeting; see also, Staff Memorandum, supra note 70. PMA testimony before this Committee indicated that the FDA ratings system was developed as an administrative, internal categorization for product approval applications. According to the PMA, because only the first drug in a class of therapeutically similar new products will receive and "A" rating, the FDA rating may reflect timing rather than product quality or value.

Of the 781 new drug products approved by the FDA between 1981 and 1988, only 182 were new molecular entities, accounting for 84 percent of the pharmaceutical industry's research and development expenditures. The remaining research and development costs funded the improvement of existing therapies. The PMA indicated that the Pryor Committee's findings regarding new products had been prepared without PMA input. Minutes, October 3, 1989 meeting.

Industry Pricing Practices

Analysis of price increases for specific pharmaceutical products, the relationship between product price and market share, and the subsequent development of appropriate cost-containment measures have traditionally been hampered by a lack of information concerning pharmaceutical industry pricing structures. Throughout its study, the Committee encouraged participation by the retail and manufacturing sectors of the pharmacy industry in gathering the pricing information necessary to develop appropriate cost-containment initiatives. The Committee learned that retail pharmacies have little control over the prices of prescription drugs because increased product costs, heavy competition, and restricted third party reimbursements have placed many pharmacies in a "cost-price squeeze."[80] By 1995, it is expected that only 25 percent of all prescriptions will be paid for directly by the consumer; third party coverage, public or private, pay for nearly 75 percent of all prescriptions in retail pharmacies. Retail pharmacies compensating for low reimbursement rates for the bulk of its prescription sales may increase drug prices, control personnel efficiency, and adjust other product costs.[81]

Experts have noted a steady decline in retail pharmacy gross profit margins, although the average prescription price has increased. About 28 percent of the retail pharmacy dollar goes to the pharmacy itself, primarily as payment for operating costs. An estimated 5 percent of the retail dollar goes to the drug wholesaler, while the drug manufacturer receives 67 percent. Delayed third party payments, which may diminish a pharmacy's ability to obtain certain discounts, and other administrative costs further erode the retail pharmacy's profit. These costs were traditionally shifted to private pay customers, a shrinking portion of the pharmacy payment base.[82]

Pharmacies participating in the Medicaid program may carry additional burdens. Somewhat ironically, the retail pharmacy is paid less for Medicaid prescriptions, which typically cost more to dispense. Although the average Medicaid pharmacy dispensing fee has increased slightly in recent years, in "real dollar" terms, it has decreased.[83] Testimony before this Committee indicated that while prescription drugs may have a low dollar value per claim, they comprise a disproportionately large number of total Medicaid claims submitted. Pharmacies may thus bear a large portion of the administrative costs of processing Medicaid claims.[84]

While the Committee received a great deal of information regarding industry profit margins and other financial data, the actual pricing of prescription drug products remains somewhat of a mystery. Throughout the course of this study, and to some extent, throughout the Pryor Committee study, pharmaceutical manufacturers have declined to discuss their pricing practices, citing potential antitrust concerns.[85] Although these

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80. Staff Memorandum, supra note 76, summarizing the statement of Joseph Thomas III, Ph.D., Associate Director, Pharmaceutical Economics Research Center, School of Pharmacy, Purdue University.

81. Minutes, August 8, 1989 meeting.

82. Minutes, August 8, 1989 and December 13, 1989 meetings. Independent and chain pharmacies have a before-tax profit margin of three percent and 4.5 percent, respectively.

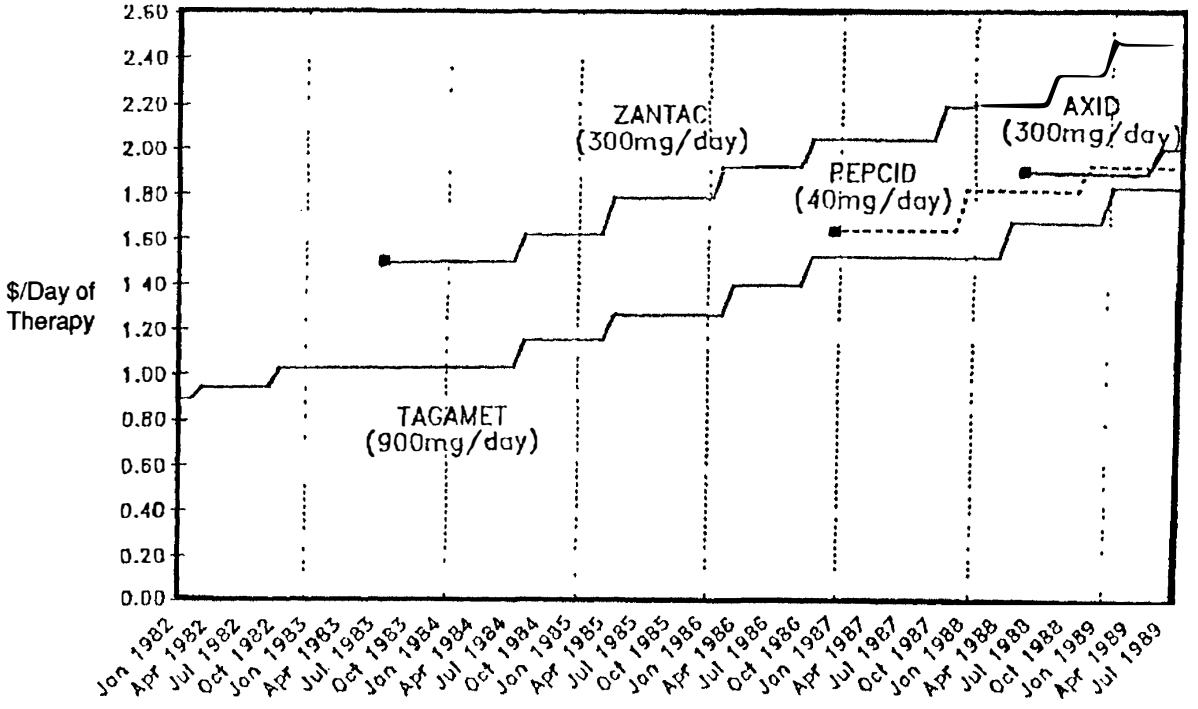
83. Minutes, August 8,1989 meeting. Dr. Schondelmeyer stated that independent pharmacies are more severely affected by these reimbursement discrepancies, as prescriptions may account for 70 percent of the independent pharmacy's business. Chain drugs are also affected, although prescription drugs comprise only 20 percent of their business.

84. Id.

85. See generally, Minutes, August 8, 1989 meeting.

pricing mechanisms remain a secret, comparative information regarding the pricing patterns of certain drugs indicates that high prices are sometimes established for "new drug therapies that duplicate existing, and generally less expensive, drug therapies."[86] In reviewing this issue, the Pryor Committee examined the pricing patterns for four anti-ulcer drugs produced in the 1980's. While each product was based on new patented molecules, all work similarly. The three newer products received FDA "C" ratings, but, interestingly, were priced higher than the original product.[87] **(See Table).**

Comparative Cost Per Day of Anti-Ulcer Therapy: Prices for Innovative Drug Tagamet vs. "C"-Rated Patented Competitors



SOURCE: U.S. Senate Special Committee on Aging, Staff Briefing Paper, "Prescription Drug Prices: Are We Getting Our Money's Worth?" (July 18, 1989)

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86. Staff Memorandum, supra note 71, quoting a finding cited in Pryor Committee Staff Briefing Paper, July 18, 1989.

87. Id.

Agency Reimbursement Practices

While prescription drugs are an extremely cost-effective therapy and may well reduce expenditures for other Medicaid services, such as surgery and hospitalization, it is nonetheless clear that manufacturer pricing practices have contributed greatly to the escalation in Medicaid pharmaceutical expenditures. The Committee's study of cost-containment strategies would be incomplete, however, without an examination of agency reimbursement practices. Experts have suggested that such an examination be based on consideration of the eligible population, intensity or frequency of need, drug unit costs, and agency administrative costs. As testimony before the Committee indicated, Virginia's Medicaid population increased only seven percent between 1983 and 1988. Drug product costs, however, increased by 81 percent, while the pharmacy dispensing fee increased by less than one percent. The intensity or measure of need factor also increased; the number of Medicaid prescriptions increased 26.5 percent, and the number of prescriptions per recipient increased 19.4 percent. No specific data were available regarding any increase in DMAS administrative costs.[88] These statistics, specifically, the alarming increase in drug product costs, suggest that how the Commonwealth computes drug product reimbursement must also be carefully scrutinized.

Although federally mandated pharmacy reimbursement standards are broad and feature varied cost determinations for multiple and sole-source drugs, testimony before the Committee indicated that many states, including the Commonwealth, may be basing drug reimbursements on a published average wholesale price (**AWP**) which may not be representative of the amount a pharmacy actually paid for a product. Formerly reflecting an average price wholesalers received for a product, the AWP is now more often indicative of a suggested wholesale price set by the manufacturer. Because pharmacies may earn discounts on the AWP based on timely payments and good business practices, the Commonwealth's practice of computing drug reimbursements based on the AWP, rather than upon consideration of the product's actual acquisition cost, may result in unnecessary Medicaid expenditures.[89] The AWP has been criticized as an artificial figure, one which might be distorted or inflated. In response to these concerns, HCFA has mandated that states revise pharmacy reimbursement formulas based on AWP computations.[90]

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88. Minutes, August 8, 1989 meeting. See also, note 41, supra. Dr. Schondelmeyer noted that the Virginia prescription-per-recipient number exceeds the national norm.

89. Minutes, August 8, 1989 and December 13, 1989 meetings. See also, notes 32-39, supra, regarding reimbursement formulas.

90. Minutes, December 13, 1989 meeting. DMAS had not previously revised its use of AWP in order to allow pharmacists to keep some mark-up on drug products in consideration of a relatively low dispensing fee.

Testimony before the Pryor Committee in July, 1989 indicated that the AWP is a "standard reference price" which does not recognize discounts for quantity purchased, bid or contract prices, or other trade discounts. Pricing patterns for AWP may be unique for specific companies or particular drug therapies. Companies, in some cases, may continue to price an off-patent product, which competes with lower-priced generics, in the same manner as if the product were still a sole-source drug. Staff Memorandum, supra note 70.

V. Cost-Containment Options

Having reviewed recent agency initiatives and the testimony of industry representatives and other professionals, the Committee weighed a variety of cost-containment options. Balancing the Commonwealth's interest in decreased Medicaid pharmacy expenditures with the goals of simplicity, flexibility, and preservation of patient access to quality care, the Committee considered the impact of each option on the pharmaceutical industry, Medicaid recipients, and the agency.

Full Funding

Representatives of the PMA supported full funding for the pharmacy component of the Virginia Medicaid Program to ensure the continuation of "the most cost-effective Medicaid service."[91] Under such a proposal, an open drug formulary would arguably permit Medicaid patients to receive the most appropriate medication as determined by a physician. The South Carolina Medicaid program instituted an open formulary system in 1984; while this new plan did not materially affect the state's total Medicaid expenditures, pharmaceutical expenditures did increase by $5 million. Overall expenditures for hospital services, however, decreased significantly after the institution of the open formulary.[92]

Restrictive Formulary

Limiting Medicaid coverage to specific drug products through the institution of a restrictive formulary may reduce pharmaceutical expenditures for products which have less expensive therapeutic alternatives. This proposal, previously recommended by DMAS as a "viable" option, contemplates coverage for drug products based upon consideration of "efficacy, safety, and cost." Excluded products would, ideally, offer only "marginal therapeutic advantages" over formulary products.[93] Coverage for nonformulary products could be provided upon prior authorization or in emergency situations, thus preserving patient access to quality care as well as the prescriber's authority.[94] While restrictive formularies are not typically favored by the medical profession, broad-based formularies, similar to those already used by many hospitals and nursing homes, would not impose an undue burden on most physicians.[95] Twenty-two states already maintain

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91. Minutes, October 3, 1989 meeting.

92. Id.

93. DMAS Report, supra note 26, at 31, 37

94. Minutes, December 13, 1990 and January 8, 1990 meetings. Pursuant to the 1983 Acts of Assembly, Chapter 622, prescriptions for Medicaid recipients must be filled with generic products. Physicians may require another product if it is "brand necessary." See note 38, supra.

95. Minutes, December 13, 1989 meeting. The Committee received testimony from the Medical Society of Virginia citing potential disadvantages of drug formularies, such as limited patient access to quality care and possible adverse effects of substituting drug products. While noting recent national concerns regarding the use of generic drugs, the Medical Society offered no objection to a "minimally restrictive" formulary.

The PMA offered data compiled by a University of Tennessee study questioning the value of restrictive formularies. It has noted that the Council of State Governments, as part of its legislative package, had passed a resolution calling for the use of open formularies.

Medicaid drug formularies; these programs vary greatly, covering from 1,200 to 45,000 products.[96]

Manufacturer Rebates or Discounts

Authorizing the Director of DMAS to negotiate with pharmaceutical manufacturers to obtain periodic rebates or discounts for drug products would bring drug manufacturers into the Medicaid cost-savings equation. The contractual relationship between the state Medicaid program and the retail pharmacy already facilitates the development of certain cost-containment initiatives; establishing a contractual arrangement with manufacturers would directly address the high costs of pharmaceutical products and would allow the Commonwealth the benefits of differential pricing arrangements presently used by some manufacturers.[97] This option is strongly opposed by most manufacturers, although similar discounts and rebates have been made available to health maintenance organizations, hospitals, the Department of Veterans Affairs, and other large-volume purchasers.[98] Price negotiation programs have been adopted in Kansas and Alabama; however, these programs have been hampered by pharmaceutical manufacturers' refusal to bid on state requests.[99]

Rebate or discount programs may operate in a number of ways. Under one model reviewed by the Committee, DMAS would periodically compute the expenditures for a particular product and then recover a negotiated percentage of the Medicaid payment through a rebate or discount. (**See chart, page 16**). Manufacturer participation in a rebate program might be encouraged by offering automatic inclusion in a Medicaid drug formulary upon successful negotiation of a rebate or discount.[100] Agency regulations could outline requirements for rebate computation, terms, renewal, and renegotiation.

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96. Hearing Memorandum, supra note 72. The U.S. Senate Staff Information paper prepared for this hearing stated that "Medicaid programs include more drug products on their formularies than either hospitals of HMOs, and pay much higher prices for the prescription drugs they purchase." The Information Paper also noted that the HMOs and hospitals apparently spend more funds than states on the education of physicians to avoid unnecessary prescribing practices. The paper also indicated that the "most successful formularies: (1) are founded on sound clinical judgment of physicians and pharmacists regarding therapeutic interchange ability; (2) ensure the availability of at least one (and sometimes several) high class of drugs; and (3) physicians can readily and easily obtain an off-formulary drug for a patient with unusual needs such as allergies to the listed product or improved response from an off-formulary agent."

97. The Code of Virginia presently authorizes the Director of DMAS to enter into agreements and contracts with "medical care facilities, physicians, dentists and other health care providers where necessary to carry out the provisions of such state plan." Va. Code § 32.1-325 C (1989 Supp.).

98. Staff Memorandum, supra note 70.

99. Hearing Memorandum, supra note 72. See also, Staff Memorandum, supra note 70. The Kansas Medicaid Program offers a bidding procedure whereby a manufacturer may become the sole provider of a Medicaid-covered product for a specified contract term. Materials submitted to the Pryor Committee indicate that while the Kansas bid program may save only a few hundred thousand dollars in 1989 due to lack of manufacturer participation, potential annual savings may range from $2 million to $4 million.

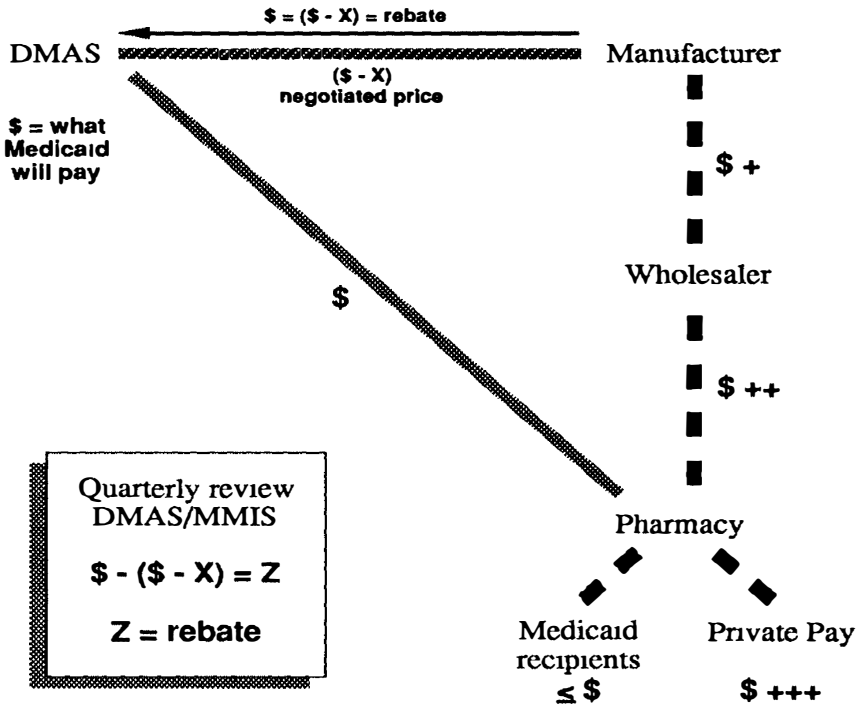
Frustrated by a lack of manufacturer participation in the bid program Kansas Medicaid officials have proposed a multistate Medicaid buying group; two dozen states have expressed interest. Efforts to adopt a similar rebate or discount program were defeated in California. Forbes, supra note 69, at 40.

DMAS had proposed a voluntary five percent rebate program to the 1988 Session of the General Assembly; the measure was defeated. Minutes, December 13, 1989 meeting.

100. Minutes, December 13, 1989 meeting. According to testimony from James M. Assey, pharmacist and Medical Director of the South Carolina Health and Human Services Finance Commission, South Carolina is exploring the use of manufacturer rebates to increase the state's purchasing power for its Medicaid program. Minutes, October 3, 1989 meeting.

The use of a manufacturer rebate was included in the DMAS "preferred plan" for meeting the cost-containment directives of the 1988 Appropriations Act. The proposal contemplated setting rebates at a specific percentage or limiting rebates to specific drugs. A rebate program places no additional burdens on recipients or retail pharmacies, who already subsidize the Medicaid program through copayments and the assumption of administrative costs; however, increased agency staff may be required to administer this option.[101]

Rebate Model



Adjustment of Reimbursement Formula

Revising the Medicaid pharmaceutical product reimbursement formula to reflect inflation and the actual acquisition costs of specific products would conform with recent HCFA directives regarding the reliance on AWP to compute product reimbursement. Because a pharmacy's actual acquisition cost may be as much as 10 percent less than AWP, reimbursement computations based solely on AWP may result in overpayments. A revised formula might rely on the medical component of the Consumer Price Index, adjusting a base product cost to reflect inflation. An adjusted formula might also reflect consideration of "most favored nation" status; Medicaid reimbursements might be based on the most favorable pricing made available to non-state government purchasers, such as hospitals and HMOs. Successful implementation of this option would require not only manufacturer disclosure of these arrangements but also protection for manufacturer trade secret information.[102]

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101. DMAS Report, supra note 26, at 26, 27

102. Minutes, December 13, 1989 meeting. DMAS had not previously revised its use of the AWP to compensate pharmacists for a relatively low dispensing fee.

Drug Utilization Review

A Medicaid drug utilization review program, a concept supported by manufacturers and pharmacies, would identify aberrant users and prescribers, over- and under-utilization practices, adverse reactions, and undesirable prescription combinations. "Doctor shopping" patients who obtain prescriptions unnecessarily or inappropriately would be temporarily restricted to one physician for primary care. While such a program may contemplate additional agency administrative costs, long-term costs savings would likely result as recipients receive necessary and appropriate pharmaceutical therapies. A drug utilization review program is supported by both the retail and manufacturing sectors of the pharmacy industry and may result in substantial savings to the Commonwealth.[103]

VI. Recommendations

Medicaid reform is "a task both technically and administratively complex, as well as politically sensitive."[104] Throughout this study, the Committee has examined many complicated and, in some instances, fiercely debated issues in order to develop appropriate cost-containment measures. While the implementation of General Assembly directives and the revision of DMAS regulations may meet short-term budgetary goals, continuing debate exists over long-term solutions to the Medicaid pharmaceutical expenditures issue. Within the pharmaceutical industry, controversy persists over the appropriateness and fairness of various cost-containment measures. In meeting the challenge of HJR 403, the Committee has carefully reviewed diverse interests: the recipients' interest in quality care, the pharmacy industry's concern for equitable sharing of financial burdens and benefits, and the Commonwealth's interest in maintaining fiscal integrity as well as effectiveness and fairness in its Medicaid program.[105] After reviewing these concerns, the Committee has concluded that the most effective and equitable measures would directly address the pricing of prescription drugs and the calculation of reimbursement. The Committee makes the following recommendations:

- *That a Virginia Medicaid drug formulary be established and that the Board of Medical Assistance Services promulgate regulations establishing an advisory committee to review product applications and to make recommendations the Board regarding inclusion in the Formulary.*

- *That the Director of the Department of Medical Assistance Services be authorized to negotiate and enter into agreements directly with pharmaceutical manufacturers to obtain rebates for a negotiated percentage of the total product cost to the Department of a specific product to be included in the Virginia Medicaid Formulary and that those products for which a rebate is successfully negotiated or renewed be included automatically in the Virginia Medicaid Formulary.*

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103. Minutes, October 3, 1989 meeting and January 8, 1990 meeting. The 1984 Appropriations Act directed the Governor, in conjunction with the State Board of Health, to implement such a program.

104. Wing, supra note 3, at 76.

105. Sarro, supra note 6, at 838.

- *That upon failure to negotiate or renew a rebate agreement for a specific product, the pharmaceutical manufacturer be required to disclose to the Department information regarding its most favorable pricing arrangements made available to non-state government purchasers of the specific product, and that the Director shall establish a rebate for such products, regardless of whether the product is included in the Virginia Medicaid Formulary, based on such price information.*

- *That the Department of Medical Assistance Services develop and implement a drug utilization review program.*

- *That the Department of Medical Assistance Services amend its state plan to change the reimbursement formula to better reflect the pharmacy's actual acquisition cost of drug products and the cost to dispense such products, consistent with federal law and regulation.*

The Committee wishes to extend its appreciation to representatives of the pharmaceutical industry and the Department of Medical Assistance Services for their assistance and cooperation during the course of this study.

Respectfully submitted,

William T. Wilson, *Chairman*
John C. Buchanan, *Vice Chairman*
Robert S. Bloxom
Jean W. Cunningham
Elmon T. Gray
George H. Heilig, Jr.
William A. Truban
Harvey B. Morgan, *ex officio*

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HOUSE JOINT RESOLUTION NO. 403

Establishing a joint subcommittee to study pharmaceutical costs in the Virginia Medical Assistance Program.

Agreed to by the House of Delegates, February 24, 1989
Agreed to by the Senate, February 23, 1989

WHEREAS, the General Assembly is concerned about the escalating costs of pharmaceutical products in the Virginia Medical Assistance Program; and

WHEREAS, the General Assembly desires the Department of Medical Assistance Services to adopt lasting cost-containment measures; and

WHEREAS, the General Assembly intends any cost-containment measures to be not only fiscally prudent but also equitable to recipients, pharmacy providers, and pharmaceutical manufacturers; and

WHEREAS, the pricing structures in the pharmaceutical industry, including both pharmacies and pharmaceutical manufacturers, are complex and diverse; and

WHEREAS, appropriate cost-containment measures may require new legislation that takes into account the complexity and diversity within the pharmacy industry in order to achieve fiscally prudent and equitable cost-containment measures that better ensure a lasting resolution to uncontrolled pharmaceutical costs in the Virginia Medical Assistance Program; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That a joint subcommittee be established to conduct a study on pharmacy costs, their effect upon the cost of the Virginia Medical Assistance Program, and the identification of appropriate cost-containment measures that would equitably fall upon the entire pharmaceutical industry. The joint subcommittee shall be composed of seven members to be appointed as follows: two members of the House Committee on Appropriations, one member of the House Committee on Health, Welfare and Institutions and one member of the House Committee on Corporations, Insurance and Banking to be appointed by the Speaker of the House and two members of the Senate Committee on Finance and one member of the Senate Committee on Education and Health to be appointed by the Senate Committee on Privileges and Elections.

The joint subcommittee may recommend modifications to such laws as it may determine necessary.

All agencies of the Commonwealth shall provide assistance upon request as the joint subcommittee deems appropriate.

The joint subcommittee shall complete its work in time to submit its findings and recommendations to the Governor and the 1990 Session of the General Assembly as provided in the procedures of the Division of Legislative Automated Systems for processing legislative documents.

The indirect costs of this study are estimated to be $12,045; the direct costs of this study shall not exceed $6,300.

1990 SESSION

LD2317450

HOUSE BILL NO. 1046

Offered January 23, 1990

A BILL to amend the Code of Virginia by adding in Chapter 10 of Title 32.1 an article numbered 2, consisting of sections numbered 32.1-331.1, 32.1-331.2, and 32.1-331.3, relating to a drug formulary and the negotiation of rebates for pharmaceutical products.

Patrons–Cunningham, J.W., Heilig, DeBoer, Cooper, Byrne, Stambaugh, Keating, Cranwell, Van Yahres, Bloxom, Stosch, Jackson, Croshaw, Munford, Jones, J.C., Quillen, Thomas, Harris, E.R., Councill, Tata, Giesen, Agee, Guest, Jennings, Woods, Hamilton, Howell, Orrock, Finney, Crouch, Purkey, Hawkins, Stafford, Moss and Cohen: Senators: Fears, Buchanan, Gray, Cross, Miller, E.F., Holland, C.A. and Saslaw

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Referred to the Committee on Health, Welfare and Institutions

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Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Chapter 10 of Title 32.1 an article numbered 2, consisting of sections numbered 32.1-331.1, 32.1-331.2, and 32.1-331.3 as follows:

Article 2.

Virginia Medicaid Drug Formulary and Negotiation of Rebates.

§ 32.1-331.1. Definitions.–As used in this article:

"Board" means the Board of Medical Assistance Services.

"Department" means the Department of Medical Assistance Services.

"Director" means the Director of Medical Assistance Services.

"Formulary" or "Virginia Medicaid Drug Formulary" means the Virginia Medicaid Drug Formulary prepared in accordance with the provisions of this article.

"Pharmaceutical manufacturer" or "manufacturer" means any person, partnership, corporation, or other institution or entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or in the packaging, repackaging, labeling, or relabeling and distribution of prescription drug products.

§ 32.1-331.2. Virginia Medicaid Drug Formulary established; advisory committee; immunity.–A. The Board shall amend the state plan and adopt regulations to establish a Formulary consisting of prescription drug products which are eligible for payment under the state plan. The selection of prescription drug products to be included in the Formulary shall be based upon consideration of, among other things, (i) information from the federal Food and Drug Administration; (ii) scientific data; (iii) the professional judgments of pharmacists and prescribers; (iv) product efficacy, cost, and medical necessity; and (v) the availability and efficacy of less expensive therapeutic alternatives.

Coverage by the state plan may be provided for nonformulary products when the prescriber obtains prior authorization from the Department or upon written notification to the Department by the prescriber that a nonformulary product was prescribed or administered in an emergency when it was not reasonable to obtain prior authorization from the Department.

B. The Board shall also promulgate regulations establishing the Virginia Medicaid Drug Formulary and an advisory committee to review product applications and to make recommendations to the Board regarding the Formulary and any revisions or amendments to the Formulary The Board may accept or reject some or all of the recommendations of the advisory committee, but may not otherwise revise, amend, or add to such recommendations. The advisory committee shall meet on a regular basis and upon the request of the Director.

Members of the Board and advisory committee shall be immune individually and

jointly from civil liability for any act, decision, or omission done or made in performance of their duties pursuant to this section while serving as a member of the Board or such committee, provided that such act, decision, or omission is not done or made in bad faith or with malicious intent. The advisory committee shall not be required to consider subsequent applications for products for which inclusion in the Formulary has been previously denied for twelve months from the date of such denial.

C. In formulating its recommendations regarding the Formulary and revisions or amendments to the Formulary to the Board, the advisory committee shall not be deemed to be formulating regulations for the purposes of the Administrative Process Act (§ 9-6.14:1 et seq.). The advisory committee shall, however, conduct public hearings prior to making such recommendations to the Board. The advisory committee shall give thirty days' written notice by mail of the time and place of its hearings to any manufacturer or other supplier who, in the opinion of the advisory committee, would be aggrieved by the advisory committee's proposed recommendations and to those manufacturers and other suppliers who request the advisory committee in writing that they be informed of such hearings. In addition, the advisory committee shall give thirty days' notice of such public hearings to the public by publishing its intention to conduct hearings in the Calendar of Events of the Virginia Register of Regulations and a newspaper of general circulation located in Richmond. In acting on the advisory committee's recommendations, the Board need not conduct further proceedings under the Administrative Process Act.

§ 32.1-331.3. Negotiation of rebate for pharmaceutical products.—A. The Director is authorized to negotiate and enter into agreements directly with manufacturers whose prescription drug products are sold in the Commonwealth for all sole-source and multiple-source drugs to be paid for under the state plan for eligible recipients. Such agreements shall provide for a periodic rebate of a negotiated percentage of the total product cost to be paid by the Department for a specific product included within the Formulary established pursuant to § 32.1-331.2.

B. Products for which a rebate has been successfully negotiated, renegotiated, or renewed shall automatically be included in the Virginia Medicaid Drug Formulary for a period of time coterminous with the rebate. Products for which there is no established or renegotiated rebate shall be included in the Formulary only upon satisfaction and completion of the application and approval process established pursuant to § 32.1-331.2.

C. Upon the failure to negotiate, renegotiate, or renew a rebate agreement for a specific product, the pharmaceutical manufacturer shall disclose to the Department its most favorable pricing arrangements available to nonstate government purchasers of such product. The Director shall establish a reasonable rebate for such product, based upon such price information.

D. The Board shall amend the state plan and promulgate regulations as permitted under federal law and regulation to provide for the specific terms and conditions of rebates. Such amendments and regulations shall also provide guidelines for, among other things, rebate computation and the renegotiation or renewal of rebate agreements.

E. Trade secret information identified as such by a manufacturer or supplier in writing in advance and furnished to the formulary advisory committee, the Director, the Department, or the Board pursuant to this section and § 32.1-331.2 shall not be subject to the disclosure requirements of the Virginia Freedom of Information Act (§ 2.1-340 et seq.).

F The provisions of the Virginia Public Procurement Act (§ 11-35 et seq.) shall not apply to the activities of the Director authorized by this section.

REQUEST FOR BUDGET BILL AMENDMENT
TO HOUSE BILL 30 AS INTRODUCED

DATE: 1/25/90

ITEM: 466
AMEND. #: 2
PATRON: Robert S. Bloxom

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES(602)

MEDICAL ASSISTANCE SERVICES(456)

LANGUAGE:

Page 155, line 37 insert:
"Effective August 1, 1990, the Department shall amend the State Plan for Medical Assistance to change the reimbursement formula to better reflect a pharmacy's actual acquisition cost of drug products and the cost to dispense such products to be consistent with federal law and regulations."

JUSTIFICATION FOR REQUEST:

(This amendment is recommended by the Joint Subcommittee studying pharmaceutical costs in the Virginia Medical Assistance Program (HJR 403).)

REQUEST FOR BUDGET BILL AMENDMENT
TO HOUSE BILL 30 AS INTRODUCED

DATE: 1/25/90

ITEM: 466
AMEND. #: 3
PATRON: Robert S. Bloxom

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES(602)

MEDICAL ASSISTANCE SERVICES(456)

LANGUAGE:

Page 155, line 37 insert:
"Effective October 1, 1990, pursuant to regulations adopted by the State Board of Medical Assistance Services, the Department shall implement a drug utilization review program."

JUSTIFICATION FOR REQUEST:

(This amendment is recommended by the Joint Subcommittee studying pharmaceutical tests in the Virginia Medical Assistance Program (HJR 403).)