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**HOUSE BILL NO. 104**

Offered January 9, 2002

Prefiled December 19, 2001

*A BILL to amend the Code of Virginia by adding in Title 32.1 a chapter numbered 15, consisting of sections numbered 32.1-366 through 32.1-372, relating to the Virginia Prescription Drug Payment Assistance Program; funding from proceeds of the Master Tobacco Settlement Agreement.*

Patrons—Morgan, Athey, Hamilton and McQuigg; Senator: Rerras

Referred to Committee on Health, Welfare and Institutions

**Be it enacted by the General Assembly of Virginia:**

**1. That the Code of Virginia is amended by adding in Title 32.1 a chapter numbered 15, consisting of sections numbered 32.1-366 through 32.1-372, as follows:**

**CHAPTER 15.****VIRGINIA PRESCRIPTION DRUG PAYMENT ASSISTANCE PROGRAM.****§ 32.1-366. Definitions.**

"Board" means the Board of Medical Assistance Services.

"Department" means the Department of Medical Assistance Services.

"Eligible person" means a person eligible for the Virginia Prescription Drug Payment Assistance Program pursuant to § 32.1-367.

"Fund" means the Prescription Assistance Fund established pursuant to § 32.1-371.

"Master Settlement Agreement" means the settlement agreement and related documents between the Commonwealth and leading United States tobacco product manufacturers dated November 23, 1998, and including the Consent Decree and Final Judgment entered in the Circuit Court of the City of Richmond on February 23, 1999, Chancery Number HJ-2241-4.

"Prescription drugs" means drugs and supplies that have been approved as safe and effective by the Federal Food and Drug Administration or are otherwise legally marketed in the United States, including items related to diabetes management, if not covered by Medicare, that a physician has deemed medically necessary for the diagnosis and treatment of the patient. For the purposes of this chapter, prescription drugs may include cost-effective over-the-counter pharmaceutical products if prescribed by a health care provider authorized to prescribe prescription drugs as an alternative to more costly drugs. Prescription drugs covered under this chapter shall be limited and subject to the provisions of § 32.1-368 and the rules and regulations adopted pursuant thereto.

"Program" means the Prescription Drug Payment Assistance Program established by this chapter.

**§ 32.1-367. Eligibility.**

To be eligible for payment assistance for prescription drugs a person shall:

1. Be a U.S. citizen or a lawfully admitted alien;
2. As set forth in the appropriation act, have income at or below 150 percent of the federal poverty level or have prescription drug expenses that exceed forty percent of his annual income;
3. Be a resident of the Commonwealth;
4. Be ineligible for Medicaid prescription benefits; however, nothing shall prohibit the enrollment of a person in the Program during the period in which their Medicaid eligibility is determined;
5. Not be receiving a prescription drug benefit through a Medicare supplemental policy or any other third party payor prescription benefit as of July 1, 2002; and
6. Be (i) aged sixty-five or over or (ii) be between the ages of nineteen and sixty-four and be otherwise eligible for benefits under Title II of the Social Security Act (Federal Old Age, Survivors, and Disability Insurance Benefits).

§ 32.1-368. Program established; administration; limitations; manufacturer rebate requirement.

A. There is hereby established the Prescription Drug Payment Assistance Program. The Program shall be administered by the Department, with such moneys as may be available therefor in the Fund. The Department may contract with third-party administrators to provide administrative services for the Program. Duties of the third-party administrators may include, but shall not be limited to, enrollment, outreach, eligibility determination, data collection, premium payment and collection, financial oversight and reporting and such other services necessary for the administration of the Program.

B. Payment assistance shall not exceed \$2,500 per fiscal year to assist each eligible person in the purchase of prescription drugs.

C. The Department shall restrict prescription drugs covered under the Program to those manufactured by pharmaceutical companies that agree to provide manufacturer rebates. The Department

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59 shall establish a rebate program to collect rebates from pharmaceutical manufacturers. Under such  
60 rebate program, the manufacturer rebate amount for a rebate period with respect to each dosage form  
61 and strength of a single source drug or innovator multiple source drug shall equal the product of the  
62 total number of units of each dosage form and strength paid for under the Program in the rebate period  
63 and the greater of (i) the difference between the average manufacturer price and the best price (as  
64 reported for the most recent quarter to the United States Secretary of Health and Human Services  
65 pursuant to section 1927(b) of the Social Security Act [42 U.S.C. 1396r-8(b)]) for such prescription  
66 drug or (ii) 15.1 percent of the reported average manufacturer price for such prescription drug. For all  
67 other prescription drugs, the rebate amount shall equal the product of the total number of units of each  
68 dosage form and strength paid for under the Program and eleven percent of the reported average  
69 manufacturer price for such prescription drug.

70 D. Eligible persons shall be required to make a co-payment, which shall not exceed twenty-five  
71 percent of the acquisition cost but shall be no lower than five dollars, subject to the regulations  
72 promulgated pursuant to subdivision 3 of § 32.1-369.

73 E. The Director of the Department or third-party administrator shall provide to eligible persons in  
74 the Program a clear, written explanation defining the scope of the Program's coverage, the amount of  
75 the cost-sharing requirements and any limitations on access to covered prescription drugs. The  
76 Department or third-party administrator shall provide notice when seventy-five percent of the enrollee's  
77 \$2,500 per fiscal year cap has been expended. The Department or third-party administrator shall also  
78 notify persons of the process to appeal a decision denying reimbursement for prescription drugs or  
79 denying a person's eligibility for the Program.

80 F. Services shall begin on the first day of the month, following the month that eligibility is  
81 determined. Eligible individuals will receive an identification card certifying their enrollment in the  
82 Program. The card shall conform to administrative standards developed and published by the National  
83 Council for Prescription Drug Programs.

84 G. The Department shall establish guidelines for maximum dosing units or supply of prescription  
85 drugs.

86 H. No system of administration shall make a direct cash payment to any eligible person.

87 I. The Department shall require a mandatory point-of-sale claims submission within fourteen days  
88 unless extenuating circumstances, as defined by the Department, exist.

89 J. The Program shall allow any licensed pharmacist in the Commonwealth to participate in the  
90 Program so long as the pharmacist is willing to abide by the terms and conditions the Board establishes  
91 to participate.

92 K. Payment amounts to pharmacists for providing prescription drugs shall be reasonable to cover the  
93 costs of items, including the cost of the product and all costs of dispensing the product.

94 L. The Program shall not vary pharmacist payment amounts based on the size of the entity  
95 dispensing the prescription, and shall not vary beneficiary cost sharing amounts based on the source of  
96 dispensing or method of distribution of the prescription.

97 M. The Program shall require the use of approved generic prescription drugs. If eligible persons  
98 elect to take a brand-named prescription drug for which an approved generic prescription drug is  
99 available, the eligible person shall pay the price difference between the brand-named prescription drug  
100 and the approved generic prescription drug, in addition to the co-payment.

101 § 32.1-369. Regulations of the Board.

102 The Board shall promulgate such regulations as are necessary to implement the Program in a  
103 cost-effective manner and to ensure that the Program is the payor of last resort for prescription drugs.  
104 The regulations shall:

105 1. Limit application to the Program to a specific open-enrollment period, with coverage effective as  
106 of the date the application is approved;

107 2. Establish an annual enrollment fee in an amount not to exceed twenty dollars to be paid by all  
108 eligible persons in the Program to defray administrative expenses. Payment of any such fee shall be  
109 credited to the Fund;

110 3. Establish guidelines providing that (i) required co-payment amounts may vary when a generic  
111 drug is purchased by eligible persons in the Program and (ii) the co-payment may be waived in cases of  
112 severe hardship;

113 4. Establish terms and conditions for licensed pharmacist participation;

114 5. Establish reasonable procedures and criteria for determining the eligibility of applicants.  
115 However, nothing shall prohibit the enrollment of a person in the Program during the period in which  
116 his Medicaid eligibility is determined;

117 6. Establish the Virginia Prescription Drug Payment Assistance Program Advisory Committee, which  
118 shall consist of no more than twenty citizens who represent the following organizations, Community  
119 Pharmacy, Long-Term Care/Consultant Pharmacy, the Virginia Pharmacists Association, the Virginia  
120 Association of Chain Drug Stores, and the Pharmaceutical Research and Manufacturers of America, or

who have experience with the issues related to prescription drug coverage and senior citizens. The Advisory Committee shall work with the Department to implement the Program and report on their progress annually to the Board and to the Chairmen of the House Appropriations and Senate Finance Committees; and

7. Develop a comprehensive, statewide, community-based outreach plan to enroll eligible persons in the Program and, if so eligible, in Medicaid.

§ 32.1-370. Pharmacist duty to collect co-payment.

A pharmacist shall not dispense or provide a covered prescription drug to an eligible person until the eligible person makes the required co-payment.

§ 32.1-371. Prescription Assistance Fund established.

A. Money received by the Commonwealth pursuant to the Master Settlement Agreement shall be deposited in the state treasury subject to the special nonreverting funds established by subsection B of § 9-385 and § 32.1-360, and shall be included in general revenue calculations for purposes of subsection C of § 58.1-3524 and subsection B of § 58.1-3536.

B. There is hereby created in the state treasury a special nonreverting fund to be known as the Prescription Assistance Fund. The Fund shall be established on the books of the Comptroller. Ten percent of the annual amount received by the Commonwealth from the Master Settlement Agreement shall be paid into the state treasury and credited to the Fund. In addition, manufacturer rebates and co-payments collected pursuant to § 32.1-368 and enrollment fees collected pursuant to § 32.1-369 shall be deposited into the Fund. The Fund shall also consist of such moneys as shall be appropriated by the General Assembly and any federal funds available for this purpose. Interest earned on moneys in the Fund shall remain in the Fund and be credited to it. Any moneys remaining in the Fund, including interest thereon, at the end of each fiscal year shall not revert to the general fund but shall remain in the Fund.

C. Moneys in the Fund shall be used solely for the purposes set forth in this chapter; however, overhead and administrative costs incurred by the Department in its implementation of this Program pursuant to this chapter shall, to the extent such moneys are available in the Fund, be paid from manufacturer rebates collected pursuant to subsection C of § 32.1-368. Expenditures and disbursements from the Fund shall be made by the State Treasurer on warrants issued by the Comptroller upon written request signed by the Director of the Department or his designee.

D. This chapter shall not be construed as creating any legally enforceable right or entitlement to prescription drug coverage on the part of any eligible person or any right or entitlement to participation. The Program created in this chapter shall only be available to the extent that funds are appropriated therefor.

§ 32.1-372. Annual report.

The Department or third-party administrator shall maintain data to evaluate the cost and effectiveness of the Program, and shall submit a report annually by November 1 to the Governor and the General Assembly regarding the implementation and effectiveness of the Program established pursuant to this chapter. The report shall review the financial impact that the enactment of this chapter will have on the cost of prescription drugs and the availability of prescription drugs for eligible persons in the Commonwealth.

**2. That there is hereby appropriated to the Prescription Assistance Fund ten percent of all amounts received by the Commonwealth from the Master Settlement Agreement between the effective date of this act and June 30, 2003. All remaining funds received by the Commonwealth from the Master Settlement Agreement between the effective date of this act and June 30, 2003, shall be deposited in the general fund.**

**3. That the amounts appropriated by this act shall be subject to reduction in the event that the federal government takes as recovery of the federal share of Medicaid expenditures money from the amounts received by the Commonwealth from the Master Settlement Agreement. Should such recovery by the federal government occur, the appropriations provided by this act to the Prescription Assistance Fund shall be five percent of the net amounts received from the Master Settlement Agreement, after any amounts recovered by the federal government are subtracted from all amounts received from the Master Settlement Agreement.**

**4. That the Board of Medical Assistance Services shall adopt the first set of regulations to implement the provisions of Chapter 15 (§ 32.1-366 et seq.) of Title 32.1 to be effective within 280 days of the enactment of this provision.**

**5. That this act shall take effect on July 1, 2002; however, the Program created by this act shall not be implemented until the earlier of (i) ninety days following the promulgation of regulations by the Board of Medical Assistance Services as set forth in § 32.1-369 or (ii) July 1, 2003.**