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SENATE BILL NO. 377

Offered January 14, 2004

Prefiled January 14, 2004

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—Deeds; Delegate: Baskerville

Referred to Committee on Education and Health

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 40 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 his 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, 2004; and
6. Be (i) aged 65 or older or (ii) be between the ages of 19 and 64 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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SB377

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 11 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 25 percent of
71 the acquisition cost but shall be no lower than \$5, subject to the regulations promulgated pursuant to
72 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 75 percent of the enrollee's \$2,500
77 per fiscal year cap has been expended. The Department or third-party administrator shall also notify
78 persons of the process to appeal a decision denying reimbursement for prescription drugs or denying a
79 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 14 days unless
88 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-name prescription drug for which an approved generic prescription drug is
99 available, the eligible person shall pay the price difference between the brand-name 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 \$20 to be paid by all eligible
108 persons in the Program to defray administrative expenses. Payment of any such fee shall be credited to
109 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 20 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 provisions governing the special nonreverting funds established by subsection B of § 3.1-1111 and §§ 3.1-1109.1 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 10 percent of all amounts received by the Commonwealth from the Master Settlement Agreement.

3. 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 of the Code of Virginia to be effective within 280 days of the enactment of this provision.

4. That this act shall take effect on July 1, 2004; however, the Program created by this act shall not be implemented until the earlier of (i) 90 days following the promulgation of regulations by the Board of Medical Assistance Services as set forth in § 32.1-369 or (ii) July 1, 2005.