PRINTER'S NO. 854

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 762 Session of 2001

INTRODUCED BY O'PAKE, LAVALLE, STOUT, COSTA, MELLOW, BODACK, HUGHES, WOZNIAK, KUKOVICH, LOGAN, EARLL, KASUNIC AND MUSTO, APRIL 3, 2001

REFERRED TO PUBLIC HEALTH AND WELFARE, APRIL 3, 2001

AN ACT

Establishing a prescription drug program; conferring powers and duties on the Department of Public Welfare and the State Board of Pharmacy; establishing the Dedicated Pharmacy Fund; providing for reduction of prescription drug prices; establishing the Prescription Drug Advisory Commission; and imposing penalties.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

CHAPTER 1

PRELIMINARY PROVISIONS

Section 101. Short title.

This act shall be known and may be cited as the Pharmaceutical Reform Act.

Section 102. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Board." The State Board of Pharmacy of the Commonwealth.

"Commission." The Prescription Drug Advisory Commission

established in section 502.

"Department." The Department of Public Welfare of the Commonwealth.

"Labeler." A person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the Food and Drug Administration under 21 CFR 207.20 (relating to who must register and submit a drug list).

"Secretary." The Secretary of Public Welfare of the Commonwealth.

CHAPTER 3

PRESCRIPTION PROGRAM

Section 301. Definitions.

The following words and phrases when used in this chapter shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Average wholesale price." The wholesale price charged on a specific commodity which is assigned by the drug manufacturer and is listed in a nationally recognized drug pricing file.

"Fund." The Dedicated Pharmacy Fund established in section 309.

"Initial discounted price." A price which is less than or equal to the average wholesale price minus 6% of that price, plus the dispensing fee provided under Article IV(f) of the act of June 13, 1967 (P.L.31, No.21), known as the Public Welfare Code.

"Manufacturer." A manufacturer of prescription drugs. The term includes a subsidiary or affiliate of a manufacturer.

"Participating retail pharmacy." A retail pharmacy located in this Commonwealth or another business licensed to dispense

prescription drugs in this Commonwealth, that participates in the program and that provides discounted prices to residents under section 305.

"Pharmacy benefit manager." An entity that procures prescription drugs at a negotiated rate under a contract.

"Program." The Prescription Drug Program established in section 302.

"Qualified resident." A resident of this Commonwealth who is enrolled in the program.

"Secondary discounted price." A price which is equal to or less than the initial discounted price minus the amount of any rebate paid by the Commonwealth to the participating retail pharmacy.

Section 302. Program.

(a) Establishment.--The Prescription Drug Pharmacy Program is established to reduce prescription drug prices for residents of this Commonwealth. The program is designed to utilize manufacturer rebates and pharmacy discounts to reduce prescription drug prices. In implementing the program, the Commonwealth shall serve as a pharmacy benefit manager.

(b) Goals.--The General Assembly finds that affordability is critical in providing access to prescription drugs for Pennsylvania residents. This chapter is enacted to enable the Commonwealth to act as a pharmacy benefit manager in order to make prescription drugs more affordable for qualified residents, thereby increasing the overall health of Pennsylvania residents, promoting healthy communities and protecting the public health and welfare. It is not the intention of the General Assembly to discourage employers from providing prescription drug benefits for their employees.

Section 303. Rebate agreement.

A drug manufacturer or labeler that sells prescription drugs in this Commonwealth through any publicly supported pharmaceutical assistance program shall enter into a rebate agreement with the department for this program. The rebate agreement must require the manufacturer or labeler to make rebate payments to the department each calendar quarter or according to a schedule established by the department.

Section 304. Rebate amount.

The department shall negotiate the amount of the rebate required from a manufacturer or labeler in accordance with the following:

(1) The department shall take into consideration the rebate calculated under the Medicaid rebate program under section 1927 of the Social Security Act (49 Stat. 620, 42 U.S.C. § 1396r-8), the average wholesale price of prescription drugs and any other information on prescription drug prices and price discounts.

(2) The department shall use its best efforts to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid rebate program under section 1927 of the Social Security Act.

(3) With respect to the rebate taking effect by October 1, 2002, the department shall use its best efforts to obtain an amount equal to or greater than the amount of any discount, rebate or price reduction for prescription drugs provided to the Federal Government.

Section 305. Discounted prices for qualified residents.

(a) Requirement.--A participating retail pharmacy that sells prescription drugs covered by a rebate agreement under section

303 shall discount the retail price of such drugs sold to qualified residents.

(b) Department.--The department shall establish discounted prices for drugs covered by a rebate agreement and shall promote the use of efficacious and reduced-cost drugs, taking into consideration reduced prices for federally and State capped drug programs, differential dispensing fees, administrative overhead and incentive payments. In determining the amount of discounted prices, the department shall consider an average of all rebates provided pursuant to section 304, weighted by sales of drugs subject to these rebates over the most recent 12-month period for which the information is available.

(c) Date.--

(1) Beginning January 1, 2002, a participating retail pharmacy shall offer the initial discounted price.

(2) No later than October 1, 2002, a participating retail pharmacy shall offer the secondary discounted price.

Section 306. Operation of program.

The following apply to participating retail pharmacies:

(1) The board shall promulgate regulations requiring participating retail pharmacies to disclose to qualified residents the discount provided as a result of the program. The regulations shall consider and protect information that is proprietary in nature.

(2) The department may not impose transaction charges under this program on retail pharmacies that submit claims or receive payments under the program.

(3) A participating retail pharmacy shall submit claims to the department to verify the amount charged to qualified residents under section 305.

(4) On a semimonthly basis, the department shall reimburse a participating retail pharmacy for discounted prices provided to qualified residents under section 303.

(5) The department shall collect data from participating pharmacies submitting claims to calculate the rebate from the manufacturer or labeler. Data under this paragraph shall not be considered to be of public record.

Section 307. Action with regard to nonparticipating manufacturers and labelers.

The names of manufacturers and labelers that do not enter into rebate agreements pursuant to this chapter are public information. The department shall impose prior authorization requirements in medical assistance under Article IV(f) of the act of June 13, 1967 (P.L.31, No.21), known as the Public Welfare Code, for the dispensing of prescription drugs provided by those manufacturers and labelers.

Section 308. Discrepancies in rebate amounts.

Discrepancies in rebate amounts shall be resolved as follows:

(1) If there is a discrepancy in the manufacturer's or labeler's favor between the amount claimed by a pharmacy and the amount rebated by the manufacturer or labeler, the department, at the department's expense, may hire a mutually agreed-upon independent auditor. If a discrepancy still exists following the audit, the manufacturer or labeler shall justify the reason for the discrepancy or make payment to the department for any additional amount due.

(2) If there is a discrepancy against the interest of the manufacturer or labeler in the information provided by the department to the manufacturer or labeler regarding the manufacturer's or labeler's rebate, the manufacturer or

labeler, at the manufacturer's or labeler's expense, may hire a mutually agreed-upon independent auditor to verify the accuracy of the data supplied to the department. If a discrepancy still exists following the audit, the department shall justify the reason for the discrepancy or refund to the manufacturer any excess payment made by the manufacturer or labeler.

Section 309. Fund.

The Dedicated Pharmacy Fund is established to receive revenue from manufacturers and labelers who pay rebates as provided in section 304 and any appropriations or allocations designated to the fund. The purposes of the fund are as follows:

(1) Reimburse retail pharmacies for discounted prices provided to qualified residents pursuant to section 305.

(2) Reimburse the department for contracted services, administrative and associated computer costs, professional fees paid to participating retail pharmacies and other reasonable program costs.

Section 310. Annual summary report.

The department shall annually report the enrollment and financial status of the program to the General Assembly by the second week in January.

Section 311. Obligations of department.

(a) General rule.--The department shall establish simplified procedures for determining eligibility and issuing enrollment cards to qualified residents, and shall undertake outreach efforts to build public awareness of the program and maximize enrollment. The department may adjust the requirements and terms of the program to accommodate any new federally funded prescription drug programs.

(b) Waivers.--The department may seek any waivers of Federal law necessary to implement the provisions of this chapter.

CHAPTER 5

PRESCRIPTION DRUG PRICE REDUCTION ACT

Section 501. Purpose.

The General Assembly finds that affordability is critical in providing access to prescription drugs. This chapter is enacted as a positive measure to make prescription drugs more affordable for qualified residents, thereby increasing the overall health of residents, promoting healthy communities and protecting the public health and welfare of residents.

Section 502. Commission.

(a) Establishment.--The Prescription Drug Advisory Commission is established to do all of the following:

(1) Review access to and the pricing of prescription drugs for residents of this Commonwealth.

(2) Advise the commissioner on prescription drug pricing and to provide periodic reports to the Governor, the General Assembly and the commissioner.

(b) Membership.--The commission shall consist of the following 11 members:

(1) Four legislative appointees, who must be residents of this Commonwealth:

(i) One appointed by the President pro tempore of the Senate.

(ii) One appointed by the Minority Leader of the Senate.

(iii) One appointed by the Speaker of the House of Representatives.

(iv) One appointed by the Minority Leader of the

House of Representatives.

(2) Six gubernatorial appointees:

(i) Two practitioners of the healing art licensed to prescribe medication.

(ii) Two pharmacists.

(iii) One individual who is over 55 years of age and who resides in this Commonwealth.

(iv) One individual who resides in and works in this Commonwealth.

(3) The secretary or a designee.

(c) Terms.--

(1) A member under subsection (a)(1) shall serve a term of two years.

(2) A member under subsection (a)(2) shall serve a term of four years.

(3) The secretary shall serve ex officio.

(d) Meetings; chair.--

(1) The commission shall meet at least four times per year.

(2) The members shall select a chair from among the members.

(3) Additional meetings may be called by the chair.

(e) Powers and duties.--The commission has the following powers and duties:

(1) To review access to prescription drugs for residents of this Commonwealth, including pricing and affordability information.

(2) To review access to prescription drugs and prescription drug prices, including:

(i) Insurance and third-party payments for

prescription drugs.

(ii) The need for maximum retail prices.

(3) If maximum retail prices are established, the procedures for:

(i) adoption and periodic review of maximum retail prices;

(ii) establishing maximum retail prices for new prescription drugs and reviewing maximum retail prices of selected drugs; and

(iii) phasing out or terminating maximum retail prices.

(4) To propose regulations of the department necessary to implement this chapter.

(5) To annually report to the Governor and the General Assembly by the second week in January, including in the report any recommendations for action regarding access to and the pricing of prescription drugs.

(f) Staffing.--The department shall provide staffing for the commission.

(g) Compensation.--Public members not otherwise compensated by their employers or other entities whom they represent are entitled to reimbursement of necessary expenses and a per diem equal to the legislative per diem for their attendance at authorized meetings of the commission.

Section 503. Emergency drug pricing.

(a) General rule.--In order to achieve the public health purposes listed in section 501, maximum retail prices for prescription drugs may be established as follows:

(1) By July 1, 2001, the department shall promulgate regulations establishing the procedures for all of the

following:

(i) Adoption and periodic review of maximum retail prices.

(ii) Establishing maximum retail prices for new prescription drugs and reviewing maximum retail prices of selected drugs.

(iii) Phasing out or terminating maximum retail prices.

(2) By January 5, 2002, the secretary shall determine whether the cost of prescription drugs provided to qualified residents under the program is reasonably comparable to the lowest cost paid for the same drugs delivered or dispensed in this Commonwealth. In making this determination the following provisions apply:

(i) The secretary shall review prescription drug use in medical assistance under Article IV(f) of the act of June 13, 1967 (P.L.31, No.21), known as the Public Welfare Code, using data from the most recent six-month period for which data is available.

(ii) Using the data reviewed in subparagraph (i), the secretary shall determine the 100 drugs for which the most units were provided and the 100 drugs for which the total cost was the highest.

(iii) For each prescription drug listed in subparagraph (ii), the secretary shall determine the cost for each drug for qualified residents needing those drugs under the program on a certain date. The average cost for each drug shall be calculated.

(iv) For each prescription drug listed in subparagraph (ii), the secretary shall determine the

lowest cost for each drug paid by a purchaser on the date which is used for subparagraph (iii), taking into consideration the Federal supply schedule and prices paid by pharmaceutical benefits managers and by large purchasers and excluding drugs purchased through the program. The average cost for each such drug shall be calculated.

(v) If the average cost for a prescription drug under the program, as determined in subparagraph (iii), is not reasonably comparable to the average lowest cost for the same drug or drugs as determined in subparagraph (iv), the secretary shall establish maximum retail prices for prescription drugs sold in this Commonwealth. Maximum prescription drug prices established under this subparagraph must take effect July 1, 2002.

(vi) In establishing maximum retail prices under this paragraph, the secretary shall consider the advice of the commission.

(b) Select prescription drugs.--In making a determination under subsection (a), the secretary may rely on pricing information on a selected number of prescription drugs if that list is representative of the prescription drug needs of the residents of this Commonwealth and is made public as part of the process of establishing maximum retail prices.

(c) Public health or welfare.--The secretary may take actions necessary if there is a severe limitation or shortage of or lack of access to prescription drugs in this Commonwealth which could threaten or endanger the public health or welfare.

Section 504. Penalty.

(a) Assessment.--The department may assess an administrative

penalty of up to $5,000 for a violation of maximum pricing under this chapter.

(b) Procedure.--A penalty under this section is subject to 2 Pa.C.S. Ch. 5 Subch. A (relating to practice and procedure of Commonwealth agencies) and Ch. 7 Subch. A (relating to judicial review of Commonwealth agency action).

CHAPTER 7

PROFITEERING

Section 701. Prohibition.

(a) Scope.--This section applies to all of the following:

(1) Manufacturers.

(2) Distributers.

(3) Labelers.

(b) Conduct.--A person listed in subsection (a) may not do any of the following:

(1) Charge an unconscionable price.

(2) Utilize contract terms which lead to an unreasonable profit.

(3) Restrict sale or distribution of prescription drugs in this Commonwealth.

Section 702. Remedy.

(a) Law.--For a violation of section 701, the following apply:

(1) The Commonwealth may bring an action in a court of competent jurisdiction to recover:

(i) a civil penalty of up to $100,000; or

(ii) three times the amount of actual damages resulting from the violation.

(2) A person may bring an action in a court of competent jurisdiction to recover three times the amount of actual

damages resulting from the violation.

(b) Equity.--For a violation of section 701, the Commonwealth or a person may bring an action in a court of competent jurisdiction to enjoin the violation.

(c) Combination.--Remedies under subsections (a) and (b) are not exclusive of each other.

CHAPTER 50

MISCELLANEOUS PROVISIONS

Section 5001. Effective date.

This act shall take effect as follows:

(1) The following provisions shall take effect immediately:

(i) Section 305(b).

(ii) This section.

(2) Chapter 7 shall take effect in one year.

(3) The remainder of this act shall take effect in 60 days.