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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 444 Session of 2001

INTRODUCED BY WALKO, SOLOBAY, SHANER, LESCOVITZ, WOJNAROSKI, LAUGHLIN, DeWEESE, COSTA, CALTAGIRONE, STABACK, YOUNGBLOOD, TRELLO, PISTELLA, YUDICHAK, PETRARCA, STURLA, BELARDI, MANDERINO, MELIO, VEON, STEELMAN AND FREEMAN, FEBRUARY 8, 2001

REFERRED TO COMMITTEE ON HEALTH AND HUMAN SERVICES, FEBRUARY 8, 2001

AN ACT

Providing for programs for prescription drug price reduction in this Commonwealth; and providing for a penalty.

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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 Prescription Drug Price Reduction Act.

Section 102. Legislative findings.

The General Assembly hereby finds that:

(1) Pharmaceutical companies are charging the citizens of Pennsylvania excessive prices for prescription drugs, denying them access to medically necessary health care and threatening their health and safety. Many Pennsylvania citizens are admitted to or treated at hospitals each year because they cannot afford the drugs prescribed for them that could have prevented the need for hospitalization. Many others must enter expensive institutional care settings because they cannot afford the necessary prescription drugs that could have supported them outside of an institution. All Pennsylvania citizens are threatened by the possibility that, when they need medically necessary prescription drugs most, they may be unable to afford their doctor's recommended treatment.

(2) Citizens of Pennsylvania and other Americans pay the highest prices in the world for prescription drugs, prices that result in extremely high profits for pharmaceutical companies.

(3) Prescription drug costs represent the fastest growing item in health care and are a driving force in rapidly increasing hospital costs and insurance rates.

(4) Excessive pricing for prescription drugs threatens Pennsylvania's ability to assist with the health care costs of its citizens, undermines the financial capacity of Pennsylvania communities to meet the educational needs of its children, hurts the ability of the business community to provide health insurance coverage to Pennsylvania's work force and has a negative effect on its economy. The General Assembly finds that affordability is critical in providing

access to prescription drugs for Pennsylvania residents.

Section 103. Legislative intent.

The General Assembly finds and declares as follows:

It is the intent of the General Assembly to provide access for all Pennsylvania citizens to medically necessary prescription drugs at the lowest possible prices.

Section 104. 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:

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

"Commission." The Pennsylvania Prescription Drug Advisory Commission.

"Department." The Department of Health of the Commonwealth.

"Director." The director of the Pennsylvania Prescription Drug Advisory Commission.

"Federal supply schedule." The price catalog containing goods available for purchase by Federal agencies. Drug prices on the Federal supply schedule are negotiated by the Department of Veterans Affairs and are the best publicly available indicator of the prices drug companies charge favored customers.

"Fund." The Pennsylvania Rx Fund.

"Initial discounted price." A price that is less than or equal to the average wholesale price, minus 6%, plus any dispensing fee provided under the Medicaid program.

"Labeler." A entity or 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

Federal Food and Drug Administration under 21 CFR § 207.20 (relating to who must register and submit a drug list).

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

"Medicaid program." The medical assistance program established and operated by the Department of Public Welfare pursuant to Subarticle (f) of Article IV of the act of June 13, 1967 (P.L.31, No.21), known as the Public Welfare Code.

"PACE program." The Pharmaceutical Assistance Contract for the Elderly program provided for in Chapter 5 of the act of August 26, 1971 (P.L.351, No.91), known as the State Lottery Law.

"PACENET program." The Pharmaceutical Assistance Contract for the Elderly Needs Enhancement Tier program provided for in Chapter 5 of the act of August 26, 1971 (P.L.351, No.91), known as the State Lottery Law.

"Participating retail pharmacy" or "retail pharmacy." A retail pharmacy located in this Commonwealth, or another business licensed to dispense prescription drugs in this Commonwealth, that participates in the Pennsylvania Rx Program and that provides discounted prices to residents as provided in section 504.

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

"Prescription drug." A legend drug, insulin, an insulin syringe or an insulin needle eligible for which a prescription is required.

"Program." The Pennsylvania Rx Program.

"Qualified resident." A resident of this Commonwealth who has obtained from the Department of Health a Pennsylvania Rx

enrollment card.

"Secondary discounted price." A price that 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.

"Secretary." The Secretary of Health of the Commonwealth.

"State-sponsored program." The PACE and PACENET program, the medical assistance program, the Pennsylvania Employee Benefit Trust Fund, the State Employees' Retirement System, the Public School Employees' Retirement System or any other State agency or designated pharmaceutical program that purchases or arranges for the purchase of prescription medications.

CHAPTER 3

PRESCRIPTION DRUG PRICE REDUCTION

Section 301. Pennsylvania Prescription Drug Advisory Commission.

(a) Establishment.--The Pennsylvania Prescription Drug Advisory Commission is hereby established. The commission shall consist of the following 12 members:

(1) Three members of the public, appointed by the President pro tempore of the Senate, one of whom must represent the interests of senior citizens.

(2) Three members of the public, appointed by the Speaker of the House of Representatives, one of whom must represent the interests of senior citizens.

(3) Two members of the health care community who are authorized by the laws of this Commonwealth to prescribe drugs, appointed by the Governor.

(4) Two pharmacists, appointed by the Governor. To be appointed to and remain on the commission, each pharmacist

must:

(i) Be licensed to practice pharmacy and be engaged in the practice of retail pharmacy in this Commonwealth.

(ii) Have at least five years of experience in this Commonwealth as a licensed pharmacist.

(iii) Be a resident of this Commonwealth.

(5) The secretary and the Secretary of the Commonwealth or their designees, both of whom shall serve as ex officio, nonvoting members.

(b) Terms.--Members of the board serve for terms of three years and may be reappointed for a second term. Members shall serve until their successor is qualified.

(c) Meetings.--The board shall meet at lease once per month. All meetings shall be subject to 65 Pa.C.S. Ch. 7 (relating to open meetings).

(d) Duties.--The duties of the commission shall include, but not be limited to, the following:

(1) To review access to prescription drugs for residents of this Commonwealth including, but not limited to, pricing and affordability information.

(2) To advise the secretary on access to prescription drugs and prescription drug prices, including, but not limited to:

(i) Insurance and third-party payments for prescription drugs.

(ii) The need for maximum retail prices.

(iii) If maximum retail prices are established, the procedures for adoption and periodic review of maximum retail prices.

(iv) The procedures for establishing maximum retail

prices for new prescription drugs and for reviewing maximum retail prices of selected drugs.

(v) The procedures for phasing out or terminating maximum retail prices.

(3) To advise the secretary on the adoption of rules necessary to implement this chapter.

(4) To report to the secretary, the General Assembly and the Governor by April 1, 2002, and annually thereafter by the second week in January, any recommendations for action regarding access to and the pricing of the prescription drugs.

(e) Director; staffing.--The secretary shall appoint a director who shall perform the duties delegated by the commission, including the administration of staff assigned to the commission. The department shall provide appropriate levels of staffing to assist the commission.

(f) Cooperation.--In performing its duties, the commission shall cooperate and work with the department, the Department of Aging, the Department of Revenue, the Department of State and the Department of Public Welfare, the Secretary of Administration, the State Employees' Retirement Board, the Public School Employees' Retirement Board, the State Board of Pharmacy and the Bureau of Professional and Occupational Affairs.

Section 302. Emergency drug pricing.

(a) Emergency drug pricing procedures.--The following provisions apply to determinations regarding maximum retail prices for prescription drugs and to the procedures for establishing those prices.

(1) By July 1, 2003, the department shall adopt rules

and regulations establishing the procedures for adoption and periodic review of maximum retail prices, the procedures for establishing maximum retail prices for new prescription drugs and for reviewing maximum retail prices of selected drugs and the procedures for phasing out or terminating maximum retail prices. The secretary shall consult with and consider the recommendations of the commission regarding the rules prior to adopting rules pursuant to this subsection.

(2) By January 5, 2004, the secretary shall determine whether the cost of prescription drugs provided to qualified residents under the Pennsylvania Rx 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 shall apply:

(i) The secretary shall review prescription drug use in the Medicaid program using data from the most recent six-month period for which data is available.

(ii) 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, using the data reviewed in subparagraph (i).

(iii) The secretary shall determine the cost of each prescription drug listed in subparagraph (ii) for qualified residents provided those drugs under the Pennsylvania Rx Program on a certain date. The average cost for each such drug must be calculated.

(iv) The secretary shall determine the lowest cost of each prescription drug listed in subparagraph (ii) paid by any purchaser on the date that is used for subparagraph (iii) delivered or dispensed in this

Commonwealth, taking into consideration the Federal supply schedule and prices paid by pharmaceutical benefits managers and by large purchasers and excluding drugs purchased through the Pennsylvania Rx Program. The average cost for each such drug must be calculated.

(v) The secretary shall establish maximum retail prices for any or all prescription drugs sold in this Commonwealth if the average cost for one or more prescription drugs under the Pennsylvania Rx 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). Maximum prescription drug prices established under this subparagraph must take effect July 1, 2004.

(3) In establishing maximum retail prices under this paragraph, the secretary shall consider the advice of the commission and shall follow procedures set forth by rules and regulations adopted by the department.

(b) Select prescription drugs.--In making a determination under this section, 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 that the secretary determines necessary if there is a severe limitation or shortage of or lack of access to prescription drugs in this Commonwealth that could threaten or endanger the public health or welfare.

Section 303. Appeals by retailer.

(a) Appeals.--A retailer of prescription drugs may appeal the maximum retail price of a prescription drug established pursuant to this section to the secretary.

(b) Commonwealth court.--Rulings on appeals by the commission may be appealed to the Commonwealth Court.

(c) Effect of appeal.--The filing of an appeal shall not delay the implementation of the maximum price imposed by the commission.

(d) Enforcement.--A violation of the maximum retail prices established under this section shall be deemed a violation of the act of December 17, 1968 (P.L.1224, No.387), known as the Unfair Trade Practices and Consumer Protection Law.

CHAPTER 5

PENNSYLVANIA RX PROGRAM

Section 501. Pennsylvania Rx Program.

(a) Establishment.--The Pennsylvania Rx Program is established to reduce prescription drug prices for residents of this Commonwealth. The program is designed for the Commonwealth 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 in establishing rebates and discounts on behalf of qualified residents.

(b) Goals.--The General Assembly finds that affordability is critical in providing access to prescription drugs for Commonwealth residents. This chapter is enacted by the General Assembly to enable the Commonwealth to act as a pharmacy benefit manager in order to make prescription drugs more affordable for qualified Commonwealth residents, thereby increasing the overall health of Commonwealth residents, promoting healthy communities

and protecting the public health and welfare. It is not the intention of the Commonwealth to discourage employers from offering or paying for prescription drug benefits for their employees or to replace employer-sponsored prescription drug benefit plans that provide benefits comparable to those made available to qualified Commonwealth residents under this chapter.

Section 502. Rebate agreement.

A drug manufacturer or labeler that sells prescription drugs in this Commonwealth through a State-sponsored 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 Commonwealth each calendar quarter or according to a schedule established by the department.

Section 503. Rebate amount.

The secretary shall negotiate the amount of the rebate required from a manufacturer or labeler in accordance with this section, taking into consideration:

(1) The rebate calculated under the Medicaid Rebate Program pursuant to 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) Obtaining an initial rebate amount equal to or greater than the rebate calculated under the Medicaid Rebate Program pursuant to 42 U.S.C. § 1396r-8.

(3) Obtaining an amount equal to or greater than the amount of any discount, rebate or price reduction for prescription drugs provided to the Federal Government with respect to the rebate taking effect no later than October 1,

2001.

Section 504. Discounted prices for qualified residents.

(a) Discount.--Any participating retail pharmacy that sells prescription drugs covered by a rebate agreement pursuant to section 502 shall discount the retail price of those drugs sold to qualified residents.

(b) Establishment.--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 Commonwealth and federally capped drug programs, differential dispensing fees, administrative overhead and incentive payments.

(c) Initial discounted price.--A participating retail pharmacy shall offer the initial discounted price beginning January 1, 2002.

(d) Secondary discounted price.--A participating retail pharmacy shall offer the secondary discounted price no later than October 1, 2002.

(e) Amount of discounted prices.--The department shall consider an average of all rebates provided pursuant to section 503, weighted by sales of drugs subject to these rebates over the most recent 12-month period for which the information is available in determining the amount of discounted prices.

Section 505. Operation of program.

(a) Requirements.--The requirements of this section shall apply to participating retail pharmacies.

(b) Disclosure.--The State Board of Pharmacy shall adopt rules and regulations requiring disclosure by participating retail pharmacies to qualified residents of the amount of savings provided as a result of the program. The rules must

consider and protect information that is proprietary in nature.

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

(d) Verification.--A participating retail pharmacy shall submit claims to the department to verify the amount charged to qualified residents under section 504.

(e) Reimbursement.--The department must reimburse a participating retail pharmacy for discounted prices provided to qualified residents under section 504 and professional fees on a weekly or biweekly basis, which must be set by the secretary. The amount of the initial professional fee must be set at $3 per prescription.

(f) Confidentiality.--The department shall collect utilization data from the participating retail pharmacies submitting claims necessary to calculate the amount of the rebate from the manufacturer or labeler. The department shall protect the confidentiality of all information subject to confidentiality protection under Federal or State law.

Section 506. Action with regard to nonparticipating manufacturers and labelers.

The names of manufacturers and labelers who do not enter into rebate agreements pursuant to this chapter are public information. The department shall release this information to health care providers and the public. The department shall impose prior authorization requirements in the Medicaid program, as permitted by law, for the dispensing of prescription drugs provided by those manufacturers and labelers.

Section 507. Discrepancies in rebate amounts.

Discrepancies in rebate amounts shall be resolved using the

process established in this section:

(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 508. Pennsylvania Rx Fund.

(a) Establishment.--The Pennsylvania Rx Fund is established to receive revenue from manufacturers and labelers who pay rebates as provided in section 502 and any appropriations or allocations designated for the fund.

(b) Purposes.--The purposes of the fund are to:

(1) Reimburse retail pharmacies for discounted prices provided to qualified residents pursuant to section 504.

(2) Reimburse the department for contracted services, administrative and associated computer costs, professional

fees paid to participating retail pharmacies and other reasonable program costs.

(3) Benefit the PACE and PACENET programs.

Section 509. Annual summary report.

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

Section 510. Obligations of department.

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

Section 511. Contracting.

The department may contract with a third party or third parties to administer any or all components of the program, including, but not limited to, outreach, eligibility, claims, administration and rebate recovery and redistribution.

Section 512. Medical assistance programs.

The department shall administer the program and other medical and pharmaceutical assistance programs in a manner that is advantageous to the programs and to the enrollees in those programs. In implementing this section, the department may coordinate the other programs and this program and may take actions to enhance efficiency, reduce the cost of prescription drugs and maximize the benefits to the programs and enrollees, including providing the benefits of this program to enrollees in other programs.

Section 513. Rules and regulations.

The department shall adopt rules and regulations to implement this section.

Section 514. Waivers.

The department may seek any waivers of Federal law, rule or regulation necessary to implement the provision of this chapter.

CHAPTER 7

PROFITEERING IN PRESCRIPTION DRUGS

Section 701. Profiteering in prescription drugs.

(a) Profiteering.--A manufacturer, distributor or labeler of prescription drugs engages in illegal profiteering if that manufacturer, distributor or labeler:

(1) exacts or demands an unconscionable price;

(2) exacts or demands prices or terms that lead to any unjust or unreasonable profit;

(3) discriminates unreasonably against any person in the sale, exchange, distribution or handling of prescription drugs dispensed or delivered in this Commonwealth; or

(4) intentionally prevents, limits, lessens or restricts the sale or distribution of prescription drugs in this Commonwealth in retaliation for the provisions of this chapter.

(b) Right of action and damages.--The Commonwealth may bring a civil action for a direct or indirect injury to any person, group of persons, the Commonwealth or a political subdivision of the Commonwealth caused by a violation of this chapter. If the Commonwealth prevails, the defendant shall pay treble damages and the costs of suit, including necessary and reasonable investigative costs, reasonable expert fees and reasonable attorney fees. Punitive damages may be awarded for a willful or

repeated violation of this section. The damages must be equitably distributed by the Commonwealth to all injured parties after deductions of the costs of distribution.

(c) Civil violation.--Each violation of this section is a civil violation for which the Attorney General may obtain, in addition to other remedies, injunctive relief and a civil penalty in an amount not to exceed $100,000, plus the costs of suit, including necessary and reasonable investigative costs, reasonable expert fees and reasonable attorney fees.

(d) Unfair trade practice.--A violation of this section shall be deemed a violation of the act of December 17, 1968 (P.L.1224, No.387), known as the Unfair Trade Practices and Consumer Protection Law.

Section 702. Investigation by Attorney General.

The Attorney General, upon the Attorney General's own initiative or upon petition of the secretary or of 50 or more residents of this Commonwealth, shall investigate suspected violations of this chapter.

Section 703. Agreements with governments of other jurisdictions and other entities.

The Commonwealth may negotiate and enter into purchasing alliances and regional strategies with the governments of other jurisdictions and with other public and private entities for the purpose of reducing prescription drug prices for residents of this Commonwealth.

CHAPTER 49

MISCELLANEOUS PROVISIONS

Section 4901. Appointments and first meeting of Pennsylvania Prescription Drug Advisory Commission.

All appointments must be completed no later than 30 days

following the effective date of this act. The director shall call the first meeting of the commission within 30 days after the appointments have been completed.

Section 4902. Effective date.

This act shall take effect in 60 days.