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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2442 Session of 1992

INTRODUCED BY STUBAN, TIGUE, DeWEESE, EVANS, ITKIN, KUKOVICH, JOSEPHS, STABACK, STEELMAN, WAMBACH, MUNDY, CAPPABIANCA, HERMAN, PESCI, VAN HORNE, MARKOSEK, DALEY, KOSINSKI, BATTISTO, LLOYD, TRELLO, STURLA, FAIRCHILD, HANNA, HAYDEN, HARPER, LaGROTTA, RUDY, BOWLEY, SCRIMENTI, WILLIAMS, VEON, GIGLIOTTI, STETLER, McNALLY, TRICH, OLASZ, BISHOP, MELIO, STISH, RITTER, PETRONE, HALUSKA AND BELARDI, MARCH 9, 1992

AS AMENDED ON THIRD CONSIDERATION, HOUSE OF REPRESENTATIVES, MARCH 11, 1992

AN ACT

Amending the act of August 14, 1991 (P.L.342, No.36), entitled "An act providing for the preservation of the State Lottery Fund; further providing for pharmaceutical assistance for the elderly; further providing for transportation assistance to the elderly; providing for pharmaceutical purchasing; conferring powers and duties upon the Department of Aging, the Department of Revenue and the Department of Transportation; imposing penalties; and making repeals," further providing for responsibilities of the Department of Aging, for pharmaceutical purchasing, for legislative intent, for definitions and for rebate agreements; providing for pharmaceutical purchasing discounts and for new best prices; and further providing for prudent pharmaceutical purchasing contracts and expiration.

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

Section 1. Section 303(h)(5), (9), (10), (11), (12), (13), (14), (15), (16), (17) and (18) of the act of August 14, 1991 (P.L.342, No.36), known as the Lottery Fund Preservation Act, are amended and the subsection is amended by adding paragraphs to read:

Section 303. Responsibilities of department.

* * *

(h) Program criteria.--The program shall include the following criteria:

* * *

(5) The system established shall include a participant copayment schedule of $4 for each prescription. The copayment shall increase or decrease on the annual basis by the average percent change of ingredient costs for all prescription drugs plus a differential to raise the copayment to the next highest 25ç increment. In addition, the department may approve a request for increase or decrease in the level of copayment based upon the financial experience and projections of the program and after consultation with the board. The department is prohibited from approving adjustments to the copayment on more than a semiannual basis. [The department shall evaluate the feasibility of instituting a bifurcated copayment differentiating between noninnovator multiple-source drugs and single-source or innovator multiple-source drugs. The department shall report its findings to the Aging and Youth Committee of the Senate and the Aging and Youth Committee of the House of Representatives by July 1, 1992. The department shall, by July 1, 1992, institute a bifurcated copayment unless the findings demonstrate that a bifurcated copayment is not cost effective. As used in this paragraph, the terms "innovator multiple-source drugs," "noninnovator multiple-source drugs" and "single-source drugs" shall have the meanings given to them in section 502.]

* * *

[(9) For purposes of this chapter, the eligible claimant

shall be liable to pay a fixed differential whenever a more expensive brand name drug is requested by the claimant when the physician permitted substitution of a less expensive generically equivalent drug approved under the provisions of the act of November 24, 1976 (P.L.1163, No.259), referred to as the Generic Equivalent Drug Law.

(10) The differential will be charged regardless of the availability of a less expensive generic equivalent in the providing pharmacy. In no case will the claimant bear the cost of the differential when the generic equivalent is not available.

(11) The department shall establish a pharmacist consultation reimbursement program for a period of not less than six months, following which the department may continue or discontinue the program. This program shall provide an additional $1 supplemental dispensing fee whenever a pharmacy's documented intervention resulted in a physician changing a prescription for a more expensive brand name product to a prescription allowing substitution of a less expensive generically equivalent drug. This supplemental dispensing fee shall provide the only exception to paragraph (8).

(12)] (9) Notwithstanding any other statute or regulation, if an approved United States Food and Drug Administration "A"-rated generic therapeutically equivalent drug is available for dispensing to a claimant, the provider shall dispense the generic therapeutically equivalent drug to the claimant. The department shall not reimburse providers for brand name drugs except in the following circumstances:

(i) There is no "A"-rated generic therapeutically

equivalent drug available on the market. This subparagraph does not apply to the lack of availability of an "A"-rated generic therapeutically equivalent drug in the providing pharmacy.

(ii) An "A"-rated generic therapeutically equivalent drug is deemed by the department, in consultation with a utilization review committee, to have a narrow therapeutic index for safe and effective dispensing in the community setting. The department shall notify providing pharmacies of prescription drugs under this subparagraph on a regular basis.

(iii) The Department of Health has determined that a drug shall not be recognized as a generic therapeutically equivalent drug for purpose of substitution under section 5(b) of the act of November 24, 1976 (P.L.1163, No.259), referred to as the Generic Equivalent Drug Law.

(10) If a claimant chooses not to accept the generic therapeutically equivalent drug required by paragraph (9), the claimant shall be liable for the entire cost of the brand name drug and the copayment less the average wholesale cost of the least expensive generic therapeutically equivalent drug present at the providing pharmacy. The average wholesale cost of the least expensive generic therapeutically equivalent drug present at the providing pharmacy shall be reimbursed by the program. If no generic therapeutically equivalent drug is present in the providing pharmacy, no reimbursement shall be provided by the program. THIS <—
PARAGRAPH SHALL NOT APPLY IF A PRESCRIBER CAN DEMONSTRATE TO THE DEPARTMENT THAT:

(I) THE CLAIMANT IS IN DANGER OF AN ADVERSE REACTION

FROM USE OF THE GENERIC THERAPEUTICALLY EQUIVALENT DRUG REQUIRED BY PARAGRAPH (9).

(II) USE OF THE PRESCRIBED BRAND NAME DRUG WOULD ELIMINATE THE DANGER OF THE ADVERSE REACTION.

(11) Prescription benefits for any single prescription shall be limited to a 30-day supply of the prescription drug or 100 units, whichever is less, except that, in the case of diagnosis for acute conditions, the limitation shall be a 15-day supply.

[(13)] (12) The department may establish a restricted formulary of the drugs which will not be reimbursed by the program. This formulary shall include only experimental drugs and drugs on the Drug Efficacy Study Implementation List prepared by the Health Care Finance Administration. A medical exception may be permitted by the department for reimbursement of a drug on the Drug Efficacy Study Implementation List upon declaration of its necessity on the prescription by the treating physician; except that, for DESI drugs for which the FDA has issued a Notice for Opportunity Hearing (NOOH) for the purpose of withdrawing the New Drug Application approved for that drug, reimbursement coverage shall be discontinued under the provisions of this chapter.

[(14)] (13) The department may not enter into a contract with a private contractor for an exclusive mail-order system for the delivery of prescription drugs under this program. Only mail-order pharmacy services provided by pharmacies which are licensed by the Commonwealth and which have their principal place of business within this Commonwealth may participate as providers under the program. The department shall develop and promulgate specific regulations governing

the practice of mail-order pharmacy and other enrolled providers to include the following minimum standards of practice to ensure the health, safety and welfare of program participants:

(i) The appropriate method or methods by which such pharmacies shall verify the identity of the program recipient and the authenticity of prescriptions received.

(ii) The appropriate method or methods by which such pharmacies shall mail or deliver prescription drugs to program recipients ensuring, to the maximum extent possible, that the intended program recipient is the actual ultimate recipient of any prescription dispensed by such pharmacies.

(iii) The appropriate method or methods by which such pharmacies shall communicate with program participants in emergency situations.

[(15)] (14) The program must be in place and operational within 90 days of the effective date of the contract.

[(16)] (15) For-profit third party insurers and not-for-profit prescription plans shall reimburse the department for any payments made to a providing pharmacy on behalf of a claimant covered by such a third party.

[(17)] (16) Any [health care professional] person rendering service as a member of a utilization review committee for this program shall not be liable for any civil damages as a result of any acts or omissions in rendering the service as a member of any such committee except any acts or omissions intentionally designed to harm or any grossly negligent acts or omissions which result in harm to the person receiving such service.

[(18)] (17) Any officer or employee of the department rendering service as a member of a utilization review committee for this program shall not be liable for any civil damages as a result of any acts or omissions in rendering the service as a member of any such committee or as a result of any decision or action in connection with the program except any acts or omissions intentionally designed to harm or any grossly negligent acts or omissions which result in harm to the person receiving such service.

(18) The dispensing of an "A"-rated generic therapeutically equivalent drug in accordance with this chapter shall not be deemed incorrect substitution under section 6(a) of the Generic Equivalent Drug Law.

(19) The department shall annually verify the income of eligible claimants. Verification shall be accomplished by a targeted sampling of 5% of the eligible claimants.

(20) THE RETAIL PRICE OF THE PRESCRIPTION SHALL BE INDICATED ON THE LABEL OF THE PRESCRIPTION CONTAINER. <—

* * *

SECTION 2. SECTION 307 OF THE ACT IS AMENDED TO READ: <—

SECTION 307. PRESCRIPTION DRUG EDUCATION PROGRAM.

THE DEPARTMENT, IN COOPERATION WITH THE DEPARTMENT OF HEALTH, SHALL DEVELOP AND IMPLEMENT A STATEWIDE PRESCRIPTION DRUG EDUCATION PROGRAM DESIGNED TO INFORM OLDER ADULTS OF THE DANGERS OF PRESCRIPTION DRUG ABUSE AND MISUSE. THE PRESCRIPTION DRUG EDUCATION PROGRAM SHALL INCLUDE, BUT NOT BE LIMITED TO, INFORMATION CONCERNING THE FOLLOWING:

(1) THE HAZARDS OF PRESCRIPTION DRUG OVERDOSE.

(2) THE POTENTIAL DANGERS OF MIXING PRESCRIPTION DRUGS.

(3) THE DANGER OF RETAINING UNUSED PRESCRIPTION DRUGS

AFTER THE NEED TO TAKE THEM NO LONGER EXISTS.

(4) THE NECESSITY TO CAREFULLY QUESTION PHYSICIANS AND PHARMACISTS CONCERNING THE EFFECTS OF TAKING PRESCRIPTION DRUGS, INCLUDING THE DIFFERENCES BETWEEN BRAND NAME DRUGS AND GENERICALLY EQUIVALENT DRUGS.

(5) THE ADVISABILITY OF MAINTAINING A PRESCRIPTION DRUG PROFILE OR OTHER RECORD OF PRESCRIPTION DRUG DOSAGE AND FREQUENCY OF DOSAGE.

(6) THE DESIRABILITY OF ADVISING FAMILY MEMBERS OF THE TYPES AND PROPER DOSAGE OF PRESCRIPTION DRUGS WHICH ARE BEING TAKEN.

(7) THE DANGERS OF TAKING PRESCRIPTION DRUGS IN EXCESS OF PRESCRIBED DOSAGES.

(8) THE NEED TO OBTAIN COMPLETE, DETAILED DIRECTIONS FROM THE PHYSICIAN OR PHARMACIST CONCERNING THE TIME PERIOD A PRESCRIPTION DRUG SHOULD BE TAKEN.

Section ~~2~~ 3. Section 501 of the act is amended by adding a paragraph to read: <——

Section 501. Declaration of policy.

The General Assembly finds and declares as follows:

* * *

(6) Drug price inflation has caused a dramatic increase in the amount of public funds expended by the PACE Program and the General Assistance Program.

Section ~~3~~ 4. The definition of "average manufacturer price" in section 502 of the act is amended and the section is amended by adding a definition to read: <——

Section 502. 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 manufacturer price (AMP)." With respect to a covered prescription drug of the manufacturer for a calendar quarter, the average unit price paid to the manufacturer for the drug [in this Commonwealth] by wholesalers for drugs distributed to the retail pharmacy class of trade, except for direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor's national drug code number. Federal Supply Schedule prices shall not be included in the calculation of AMP. The term includes cash discounts and all other price reductions, other than rebates under this act and section 1927 of Title XIX of the Social Security Act (Public Law 74-271, 42 U.S.C. § 301 et seq.), added November 5, 1990 (Public Law 101-508, Title IV, section 4401(a)(3), 104 Stat. 1388-143), which reduce the actual price paid. For bundled or capitated sales, the allocation of the discount shall be made proportionately to the dollar value of the units of each covered prescription drug sold under the bundled or capitated arrangement. The AMP for a quarter shall be adjusted by the manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

* * *

"Consumer Price Index-Urban." The Consumer Price Index for All Urban Consumers compiled by the Bureau of Labor Statistics of the United States Department of Labor.

* * *

Section ~~4~~ 5. Sections 503(e) and 505(a) and (b) of the act are amended to read: <——

Section 503. Rebate agreement.

* * *

[(e) Drug formulary.--There shall be no drug formulary, prior or retroactive approval system or any similar restriction imposed on the coverage of outpatient drugs made by manufacturers who have entered into agreements with the Commonwealth to pay rebates for drugs utilized in the PACE program, provided that such outpatient drugs were approved for marketing by the Food and Drug Administration prior to July 1, 1991.]

Section 505. Amount of rebate.

(a) Single-source drugs and innovator multiple-source drugs.--With respect to single-source drugs and innovator multiple-source drugs, each manufacturer shall remit a rebate to the Commonwealth. Except as otherwise provided in this section, the amount of the rebate to the Commonwealth per calendar quarter with respect to each dosage form and strength of single-source drugs and innovator multiple-source drugs shall be [equal to] as follows:

(1) For quarters beginning after December 31, 1990, and ending before July 1, 1992, the product of the total number of units of each dosage form and strength reimbursed by the PACE Program and the General Assistance Program in the quarter and the difference between the average manufacturer price and 87.5% of that price, after deducting customary prompt payment discounts, for the quarter[, which rebate shall be applicable for quarters beginning on and after January 1, 1991].

(2) For quarters beginning after June 30, 1992, the product of the total number of units of each dosage form and strength reimbursed by the PACE Program and the General Assistance Program in the quarter and the difference between

the average manufacturer price and 85% of that price, after deducting customary prompt payment discounts, for the quarter.

(b) Rebate for other drugs.--

(1) The amount of the rebate to the Commonwealth for a calendar quarter with respect to covered prescription drugs which are noninnovator multiple-source drugs shall be equal to the product of:

(i) the applicable percentage of the average manufacturer price, after deducting customary prompt payment discounts, for each dosage form and strength of such drugs for the quarter; and

(ii) the number of units of such form and dosage reimbursed by the PACE Program and the General Assistance Program in the quarter.

(2) For the purposes of paragraph (1), the following shall apply:

(i) The applicable percentage for calendar quarters beginning after January 1, 1991, and ending before July 1, 1992, is 10%.

(ii) The applicable percentage for calendar quarters beginning after June 30, 1992, is 11%.

* * *

Section ~~5~~ 6. The act is amended by adding sections to read: <—

Section 505.1. Excessive pharmaceutical price inflation discount.

(a) General rule.--A discount shall be provided to the department for all covered prescription drugs. The discount shall be calculated as follows:

(1) For each quarter for which a rebate under section

505(a) and (b) is to be paid after December 31, 1991, the average manufacturer price for each dosage form and strength of a covered prescription drug shall be compared to the average manufacturer price for the same form and strength in the previous calendar year; and a percentage increase shall be calculated.

(2) For each quarter under paragraph (1), the average percentage increase in the Consumer Price Index-Urban over the same quarter in the previous calendar year shall be calculated.

(3) If the calculation under paragraph (1) is greater than the calculation under paragraph (2), the discount amount for each quarter shall be equal to the product of:

(i) the difference between the calculations under paragraphs (1) and (2); and

(ii) the total number of units of each dosage form and strength reimbursed by the PACE Program and General Assistance Program and the average manufacturer price reported by the manufacturer under section 504(c)(1).

(b) New by-marketed drugs.--For covered prescription drugs that have not been marketed for a full calendar year, subsection (a) shall apply after the covered prescription drug has been on the market for four consecutive quarters. The drug's initial average manufacturer price shall be based on the first day of the first quarter that the drug was marketed.

Section 505.2. Lowered best price.

(a) General rule.--If the rebate under section 505 and the discount under section 505.1 would establish a lowered Federal best price, as defined in section 1927(c)(1)(C) of the Social Security Act (Public Law 74-271, 42 U.S.C. § 1396r-8(c)(1)(C)),

the manufacturer shall be liable for a total rebate and discount in an amount that does not reduce the Federal best price for that covered prescription drug.

(b) Procedure.--If a manufacturer asserts a lowered Federal best price under subsection (a), it must provide substantial evidence of the existing best price within 30 days of the end of the quarter for which the price is asserted.

(c) Civil penalty.--A manufacturer which provides false information under this section shall be liable for a civil penalty in the amount of $50,000. Each item of false information constitutes a separate violation.

Section ~~6~~ 7. Sections 508 and 509 of the act are amended to read: <—

[Section 508. Existing agreements.

Any rebate agreement between the department and a manufacturer entered into prior to the effective date of this chapter shall remain in effect and be considered a rebate agreement in compliance with this chapter until the agreement expires or until either party terminates the agreement.

Section 509. Expiration of chapter.

This chapter shall expire July 1, 1992, unless reenacted by the General Assembly.]

SECTION 8. THE ACT IS AMENDED BY ADDING A SECTION TO READ: <—

SECTION 901.1. RULES AND REGULATIONS.

ALL RULES AND REGULATIONS PROMULGATED UNDER THIS ACT SHALL BE SUBJECT TO THE ACT OF JUNE 25, 1982 (P.L.633, NO.181), KNOWN AS THE REGULATORY REVIEW ACT, AND TO LEGISLATIVE REVIEW BY THE AGING AND YOUTH COMMITTEE OF THE SENATE AND THE AGING AND YOUTH COMMITTEE OF THE HOUSE OF REPRESENTATIVES.

SECTION 9. THE HOUSE OF REPRESENTATIVES, RECOGNIZING THE

OVERSIGHT ROLE THAT THE LEGISLATIVE BUDGET AND FINANCE COMMITTEE HAS WITH REGARD TO THE PROGRAMS AND SERVICES OF THE DEPARTMENT OF AGING, DIRECTS THE LEGISLATIVE BUDGET AND FINANCE COMMITTEE TO CONDUCT A STUDY OF THE STATE LOTTERY AS IT IMPACTS UPON THE FUTURE OF PROGRAMS AND SERVICES FOR OLDER PENNSYLVANIANS AND THE POSSIBLE NEED FOR LEGISLATIVE ACTION AND MAKE A REPORT TO THE HOUSE OF REPRESENTATIVES NO LATER THAN DECEMBER 31, 1992.

Section ~~7~~ 10. The addition of sections 505.1 and 505.2 of the act shall be retroactive to January 1, 1992. <—

Section ~~8~~ 11. This act shall take effect immediately. <—