PRINTER'S NO. 3493

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2598 Session of 1996

INTRODUCED BY READSHAW, BLAUM, DeWEESE, ITKIN, COY, BELARDI, EVANS, MUNDY, TRICH, STURLA, BEBKO-JONES, GEORGE, McCALL, LAUGHLIN, GORDNER, GAMBLE, RIEGER, CURRY, TIGUE, KUKOVICH, CALTAGIRONE, JAROLIN, WALKO, MELIO, STABACK, SEMMEL, ROBINSON, LEH, DONATUCCI, CAPPABIANCA, HALUSKA, CORRIGAN, COWELL, HERMAN, MICOZZIE, BELFANTI, LEVDANSKY, FAJT, SURRA, TRAVAGLIO, SANTONI, BUXTON, VEON, B. SMITH, JOSEPHS, PETRARCA, STEELMAN, GIGLIOTTI, FARMER, SCRIMENTI, PISTELLA, McGEEHAN, ROBERTS, BARD, LUCYK, YOUNGBLOOD, ARGALL, BOSCOLA, ROONEY, MERRY, REBER, TANGRETTI, CAWLEY, DALEY, KREBS, TRELLO, DERMODY, M. COHEN AND RUBLEY, MAY 7, 1996

REFERRED TO COMMITTEE ON AGING AND YOUTH, MAY 7, 1996

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 defining "maximum annual income"; adding definitions; and providing for the use of brand name drugs and for rebates.

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

Section 1. The definition of "maximum annual income" in section 302 of the act of August 14, 1991 (P.L.342, No.36), known as the Lottery Fund Preservation Act, is amended and the section is amended by adding definitions to read:

Section 302. 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:

* * *

"Area Agency on Aging." An agency designated by the Department of Aging to administer and develop an area plan for a comprehensive and coordinated system of services for older people within the boundaries of a defined planning and service area.

* * *

"Maximum annual income." Annual income as determined by the department.

(1) Except as provided in paragraph (2), such amount shall not exceed $13,000 in the case of single persons nor $16,200 in the case of the combined annual income of married persons.

(2) If this chapter takes effect before September 1, 1991, the following shall apply:

(i) Before September 1, 1991, such amount shall not exceed $12,000 in the case of single persons nor $15,000 in the case of the combined annual income of married persons.

(ii) After August 31, 1991, such amount [shall] not to exceed [$13,000] $15,000 in the case of single persons nor [$16,200] $18,200 in the case of the combined annual income of married persons.

* * *

"PACE pharmacist." A pharmacist employed by a pharmacy that is enrolled as a provider in the PACE Program or the General Assistance Program.

"Prescription Evaluation Program (PEP)." Program operated by the Area Agency on Aging in cooperation with PACE pharmacists through grants administered by the Department of Aging designed to educate seniors on their prescription drug regimens.

* * *

Section 2. Sections 303(h)(6), (9) and (10) and 307 of the act, amended December 9, 1992, (P.L.792, No.128), are amended to read:

Section 303. Responsibilities of department.

* * *

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

* * *

(6) The program shall consist of payments to pharmacies on behalf of eligible claimants for the average wholesale cost of drugs, insulin, insulin syringes and insulin needles which exceed the copayment plus a dispensing fee of at least [$2.75] $3.25 or the dispensing fee established by the department by regulation, whichever is greater. In addition to current dispensing responsibilities, pharmacists shall be available to evaluate the prescription regiment of seniors upon request as well as in cooperation with any Area Agency on Aging as prescribed in the Prescription Evaluation Program (PEP) under section 307(b). This evaluation shall include the following:

(i) A pharmacist shall conduct a prospective drug review of the patient profile, maintained in the pharmacist's pharmacy in accordance with subparagraph (iii) before filing or delivering a new prescription to an individual in order to attempt to identify any

potential drug therapy problems due to therapeutic duplication, drug-interactions, incorrect drug dosage or duration of drug treatment, drug allergy interactions and clinical misuse.

(ii) In performing a prospective drug review, an offer to counsel or discuss matters which the pharmacist, in the exercise of the pharmacist's professional judgment, deems significant shall be made to each person or caregiver who presents a prescription. The offer to counsel may be made by the pharmacist in person, by a designee or by toll-free telephone. If personal contact is not made between the pharmacist or a designee and the patient or caregiver, a written offer to counsel accompanying the prescription shall be made. If a person indicates that he wants counseling on his entire drug regimen, the pharmacist shall counsel the person, in person, upon request or according to a scheduled appointment within a reasonable time period. The following are examples of matters which a pharmacist, in the exercise of his professional judgment, might deem significant:

(A) The name and description of the medications.

(B) The route, dosage form, dosage route of administration and duration of drug therapy.

(C) Special directions and precautions for preparation, administration and use by the patient.

(D) Common severe side effects or adverse side effects or interactions and therapeutic contradictions that may be encountered, including their avoidance and the action required if they

occur.

(E) Techniques for self-monitoring drug therapy.

(F) Proper storage.

(G) Prescription refill information.

(H) Action to be taken in the event of a missed dose.

(iii) The pharmacist shall make a reasonable effort to obtain, record and maintain the following information about each patient:

(A) The name, address, telephone number, date of birth and gender.

(B) Individual history if significant, including known drug allergies and drug reactions, and a comprehensive list of their medications and relevant devices.

(C) Pharmacist comments relative to the individual's drug therapy.

(D) The patient profile may be maintained electronically or manually.

(E) The pharmacist is not required to provided consultation in regard to significant matters under subparagraph (ii) or obtain information about the patient for the patient profile under this subsection when a patient or caregiver of the patient refuses the offer to consult or refuses to divulge information for the patient profile.

* * *

(9) Notwithstanding any other statute or regulation, if an A-rated generic therapeutically equivalent drug is available for dispensing to a claimant, the provider shall

dispense the A-rated generic therapeutically equivalent drug to the claimant. The department shall not reimburse providers for brand name products 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, unless it can be shown to the department that the provider made reasonable attempts to obtain the A-rated generic therapeutically equivalent drug or that there was an unforeseeable demand and depletion of the supply of the A-rated generic therapeutically equivalent drug. In either case, the department shall reimburse the provider for the average wholesale cost plus a dispensing fee based on the least expensive A-rated generic therapeutically equivalent drug for the brand drug dispensed.

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

(iii) The Department of Health has determined that a drug shall not be recognized as an A-rated 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.

(iv) At the time of dispensing, the provider has a prescription on which the brand name drug dispensed is billed to the program by the provider at a usual and customary charge which is equal to or less than the least expensive usual and customary charge of any A-rated generic therapeutically equivalent drug reasonably available on the market to the provider.

[(v) At the time of dispensing, the provider has a prescription on which the prescriber has handwritten "brand necessary" or "brand medically necessary" on the prescription.]

(10) If a claimant chooses not to accept the A-rated generic therapeutically equivalent drug required by paragraph (9), the claimant shall be liable for the copayment and 70% of the average wholesale cost of the brand name drug. This paragraph shall not apply if the prescriber can demonstrate in writing on a form provided by the department that:

(i) The claimant is in danger of an adverse reaction from use of the generic therapeutically equivalent drug required under paragraph (9).

(ii) Use of the prescribed brand name drug would eliminate the danger of the adverse reaction.

* * *

Section 307. [Prescription drug education program.] Consumer education.

(a) 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.

(b) Prescription Evaluation Program (PEP) grants.--In order to further the education efforts specified in subsection (a), the department shall administer a grant program for the development and implementation of any Prescription Evaluation Program (PEP) to be operated in cooperation with PACE pharmacists. Upon the request of an Area Agency on Aging, PACE pharmacists will participate in programs to counsel seniors

about the prescription drugs they are currently taking. The evaluations made at Prescription Evaluation Program (PEP) events shall include a review of the patient's drug regiment in an attempt to identify potential drug therapy problems due to therapeutic duplication, drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, incorrect drug dosage and clinical abuse or misuse. PACE pharmacists shall maintain patient profiles, electronically or manually as described in section 303(h)(6)(iii) as records of their participation in any evaluation program. Under Prescription Evaluation Program (PEP), each senior citizen shall be guaranteed at least one review of their prescriptions per year. Grant funds will be managed and administered in accordance with subsection (c).

(c) Grants.--

(1) Grant application forms shall be developed by the department and distributed to all Area Agencies on Aging. Applications shall include information on proposed Prescription Evaluation Program (PEP) events, event locations and cost estimates.

(2) Grants will be made to any Area Agency on Aging and are not to exceed $10,000 per agency. Any Area Agency on Aging shall, at least quarterly, hold Prescription Evaluation Programs (PEP) across the service area. Funds are to be used for costs incurred in development and implementation of Prescription Evaluation Programs (PEP) which may include, but are not limited to, the purchasing of necessary materials, outreach and advertising of the programs.

(3) Prescription Evaluation Program (PEP) grants shall be funded through an annual appropriation of $1,000,000 from

the fund. Unallocated funds shall be returned to the fund at the end of each fiscal year.

Section 3. The definition of "Producer Price Index for Pharmaceuticals" in section 602 of the act, added December 9, 1992 (P.L.792, No.128), is amended and the section is amended by adding definitions to read:

Section 602. 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:

* * *

"Best price."

(1) For current covered prescription drugs, the lesser of:

(i) the lowest price available for the drug in this Commonwealth from the manufacturer to any wholesaler, retailer, provider, private entity or governmental entity doing business in this Commonwealth during the quarter; or

(ii) the lowest price available for the drug, as of July 1, 1995, in this Commonwealth from the manufacturer to any wholesaler, retailer, provider, private entity or governmental entity doing business in this Commonwealth increased by the Consumer Price Index-Urban from July 1995 to the month before the beginning of the calendar quarter involved.

(2) For new drugs approved for marketing after July 1, 1995, the lesser of:

(i) the lowest price available for the drug in this Commonwealth from the manufacturer to any wholesaler,

retailer, provider, private entity or governmental entity doing business in this Commonwealth during the quarter; or

(ii) the lowest price available for the drug, during the first month in which the drug was marketed, in this Commonwealth from the manufacturer to any wholesaler, retailer, provider, private entity or governmental entity doing business in this Commonwealth, increased by the percentage increase in the Consumer Price Index-Urban from the first day of the first month of marketing to the beginning of the calendar quarter involved.

(3) The term excludes any price less than 8% of the average manufacturer price in the same quarter for which the average manufacturer price is computed.

(4) The term includes Federal supply schedule prices.

(5) Best price shall be determined on a unit basis and shall be adjusted by the manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized. For capitated sales, the allocation of the discount shall be made proportionally to the dollar value of the units of each drug sold under the capitated arrangement.

* * *

"Consumer Price Index-Urban." The index of consumer prices developed and updated by the Bureau of Labor Statistics of the United States Department of Labor.

* * *

["Producer Price Index for Pharmaceuticals." The prescription drug producer price index compiled by the Bureau of Labor Statistics of the United States Department of Labor for

measuring average changes in selling prices received by domestic drug manufacturers.]

* * *

Section 4. Sections 604(c), 605(a) and 605.1(a) of the act, added December 9, 1992 (P.L.792, No.128), are amended to read:

Section 604. Terms of rebate agreement.

* * *

(c) Manufacturer provision of price information.--

(1) Each manufacturer with an agreement in effect under this chapter shall report [the average manufacturer price for all covered prescription drugs produced by that manufacturer] to the department not later than 30 days after the last day of each quarter[.] all of the following:

(i) The average manufacturer price.

(ii) For single-source drugs and innovator multiple source drugs:

(A) the manufacturer's best price for covered prescription drugs for the quarter; and

(B) the best price in effect on July 1, 1995.

(iii) For new drugs, the best price in effect during the first month of marketing the new drug.

* * *

Section 605. 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 [as

follows:] equal to 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 following:

(1) For quarters beginning after [December 31, 1990, and ending before October 1, 1992,] April 1996 [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.] the greater of the following:

(i) The difference between the average manufacturer price and 85% of that price after deducting customary prompt payment discounts for the quarter.

(ii) The difference between the average manufacturer price for a drug and the best price. For calendar quarters beginning after April 1, 1996, and ending before January 1, 1997, the rebate under this subparagraph shall not exceed 25% of the average manufacturer price. For calendar quarters beginning after December 31, 1996, and ending before January 1, 1998, the rebate under this subparagraph shall not exceed 50% of the average manufacturer price.

* * *

Section 605.1. 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

605(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 [Producer Price Index for Pharmaceuticals] 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 604(c)(1).

* * *

Section 5. This act shall take effect in 60 days.