No. 1992-128

AN ACT

HB 2442

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 prescription drug education, for pharmaceutical purchasing and for applicability.

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

Section 1. Section 302 of the act of August 14, 1991 (P.L.342, No.36), known as the Lottery Fund Preservation Act, is amended by adding a definition 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:

"A-rated generic therapeutically equivalent drug." A drug product that the Commissioner of Food and Drugs of the United States Food and Drug Administration has approved as safe and effective and has determined to be therapeutically equivalent, as listed in "The Approved Drug Products with Therapeutic Equivalence Evaluations" (Food and Drug Administration "Orange Book"), with a specific "A" code designation only.

* * *

Section 2. Section 303(h)(5), (9), (10), (11), (12), (13), (14), (15), (16), (17) and (18) of the 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 25¢ 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 differentiat-**

ing 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 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.

(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.]** *The department shall verify the income of eligible claimants by requiring income documentation from the claimants. An application for benefits under this chapter shall constitute a waiver to the department of all relevant confidentiality requirements relating to the claimant's Pennsylvania State income tax information in the possession of the Department of Revenue. The Department of Revenue shall provide the department with the necessary income information shown on the claimant's Pennsylvania State income tax return solely for income verification purposes. It shall be unlawful for any officer, agent or employee of the department to divulge or make known in any manner whatsoever any information gained through access to the Department of Revenue information except for official income verification purposes under this chapter. A person who violates this act commits a misdemeanor and shall, upon conviction, be sentenced to pay a fine of not more than $1,000 or to*

imprisonment for not more than one year, or both, together with the cost of prosecution, and if the offender is an officer or employee of the Commonwealth, he shall be dismissed from office or discharged from employment. To the extent possible, the department and the Department of Public Welfare shall coordinate efforts to facilitate the application and enrollment of eligible older people in the Medicaid Healthy Horizons Program by processing these applications at senior citizens centers and other appropriate facilities providing services to the elderly.

(20) The retail price of the prescription shall be indicated on the label of the prescription container or furnished by separate receipt.

* * *

Section 3. Sections 305 and 307 of the act are amended to read:

Section 305. Board.

(a) Establishment.—A Pharmaceutical Assistance Review Board shall be established to ensure that the program is providing and continues to provide the assistance intended in a fiscally responsible manner without excessively hampering the pharmaceutical industry.

(b) Composition.—The board shall be comprised of the following **[seven]** *eight* persons:

(1) The Secretary of Aging, who shall serve as its chairman.

(2) The Secretary of Revenue.

(3) The Secretary of Health.

(4) **[Four]** *Five* public members, one appointed by the President pro tempore of the Senate, one appointed by the Minority Leader of the Senate, one appointed by the Speaker of the House of Representatives **[and]**, one appointed by the Minority Leader of the House of Representatives *and one appointed by the Governor*. Those appointed *by the legislative officers* shall include two senior citizens, who have not been a part of the pharmaceutical industry, to serve as consumer advocates and two representatives of the pharmaceutical industry, at least one of whom is a practicing Pennsylvania pharmacist. *The individual appointed by the Governor must be a physician.* A public member who misses two consecutive meetings without good cause acceptable to the chairman shall be replaced by the appointing authority.

(c) Review.—Using the semiannual reports submitted by the department pursuant to section 303(i) and other appropriate data sources, the board shall conduct a semiannual review. The board shall develop recommendations concerning any changes in the level of copayment or in the level of fees paid to participating pharmacists. *The board shall review the department's therapeutic drug utilization review program on an ongoing basis.* The board may also recommend other changes in the structure of the program and direct the department to enter into discussions with the private contractor concerning amendments to the contract. The copayment schedule shall only be adjusted on a semiannual basis.

(d) Quarterly meetings.—The board shall meet at least four times per year.

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 4. Chapter 5 of the act is repealed.

Section 5. The act is amended by adding a chapter to read:

CHAPTER 6
PRUDENT PHARMACEUTICAL PURCHASING

Section 601. Declaration of policy.

The General Assembly finds and declares as follows:

(1) The Commonwealth, through assistance programs enacted for the benefit of its citizens, is the largest single payor of prescription medications in Pennsylvania.

(2) In order to ensure that the Commonwealth, in expending money on behalf of its citizens, is not unduly harmed by being required to pay a price for pharmaceutical products purchased from manufacturers in excess of that established for other purchasers and reimbursers of these products and to ensure that the Commonwealth can efficiently and prudently expend its money and maximize its ability to provide for the health and welfare of as many of its needy citizens as possible, it is reasonable, necessary and in the public interest to require that pharmaceutical manufacturers offer a discount to the Commonwealth for pharmaceutical products purchased or reimbursed through State agencies.

(3) It is in the public interest for pharmaceutical manufacturers to provide the Commonwealth with data relating to the price of pharmaceutical products sold by the manufacturer to public bodies, hospitals, for-profit or nonprofit organizations, other manufacturers or wholesalers doing business in this Commonwealth in order to ensure that the Com-

monwealth can determine that it is being provided with the best prices offered by the manufacturer.

(4) On a national level, there has been a recognition that the need for discounts to State Medicaid agencies, which reimburse for a high volume of pharmaceutical products, exists.

(5) On a State level, the General Assembly recognizes that it is in the best interest of its citizens to provide pharmaceutical assistance in a reasonable and cost-efficient manner.

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

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:

"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 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.

"Bundled or capitated sales." The packaging of drugs of different types where:

(1) the condition of rebate or discount is that more than one drug type is purchased; or

(2) the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately.

"Covered prescription drug." A legend drug, insulin, an insulin syringe or an insulin needle eligible for payment by the Commonwealth under the PACE Program or under the General Assistance Program.

"Depot price." The price available to any depot of the Federal Government for purchase of drugs from the manufacturer through the depot system of procurement.

"Direct seller." Any person, partnership, corporation, institution or entity engaged in the selling of pharmaceutical products directly to consumers in this Commonwealth.

"Distributor." A private entity under contract with the original labeler or holder of the national drug code number to manufacture, package or market the covered prescription drug.

"Doing business in this Commonwealth." The direct or indirect selling or the making of covered prescription drugs available for sale in a continuous and systematic manner with the reasonable expectation that these products will be sold to consumers in this Commonwealth.

"FDA." The Food and Drug Administration of the Public Health Service of the Department of Health and Human Services.

"General Assistance Program." The General Assistance Program of the Department of Public Welfare.

"Innovator multiple-source drugs." A multiple-source drug that was originally marketed under a new drug application approved by the FDA. The term includes:

(1) covered prescription drugs approved under Product License Approval (PLA), Establishment License Approval (ELA) or Antibiotic Drug Approval (ADA); and

(2) a covered prescription drug marketed by a cross-licensed producer or distributor under the approved Abbreviated New Drug Application (ANDA) when the drug product meets this definition.

"Manufacturer."

(1) An entity which is engaged in any of the following:

(i) The production, preparation, propagation, compounding, conversion or processing of prescription drug products:

(A) directly or indirectly by extraction from substances of natural origin;

(B) independently by means of chemical synthesis; or

(C) by a combination of extraction and chemical synthesis.

(ii) The packaging, repackaging, labeling or relabeling, or distribution of prescription drug products.

(2) The entity holding legal title to or possession of the national drug code number for the covered prescription drug.

(3) The term does not include a wholesale distributor of drugs, drugstore chain organization or retail pharmacy licensed by the Commonwealth.

"National drug code number." The identifying drug number maintained by the FDA. The complete eleven digit number must include the labeler code, product code and package size code.

"New drug." A covered prescription drug approved as a new drug under section 201(p) of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, 21 U.S.C. § 321(p)).

"Noninnovator multiple-source drug." Any of the following:

(1) A covered prescription drug which is not an innovator multiple-source drug approved under an Abbreviated New Drug Application (ANDA) or an Amended Antibiotic Drug Approval (AADA).

(2) A drug that has been approved for substitution under the act of November 24, 1976 (P.L.1163, No.259), referred to as the Generic Equivalent Drug Law.

"PACE Program." The program under Chapter 3.

"Private entity." Includes a for-profit entity and a nonprofit entity.

"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.

"Provider." A pharmacy or dispensing physician enrolled as a provider in the PACE Program or the General Assistance Program or a pharmacy licensed by the Commonwealth.

"Secretary." The Secretary of Aging of the Commonwealth.

"Single-source drugs." Legend drug products for which the FDA has not approved an Abbreviated New Drug Application (ANDA).

"Unit." A drug unit in the lowest identifiable amount, such as tablet or capsule for solid dosage forms, milliliter for liquid forms and gram for ointments or creams. The manufacturer shall specify the unit for each dosage form and strength of each covered prescription drug in accordance with the instructions developed by the Health Care Financing Administration for purposes of the Federal Medicaid Rebate Program under section 1927 of Title XIX of the Social Security Act (Public Law 74-271, 42 U.S.C. § 301 et seq.).

"Wholesaler." Any person, partnership, corporation, institution or entity to which the manufacturer sells the covered prescription drug, including a pharmacy or chain of pharmacies, but that does not relabel or repackage the covered prescription drug.

Section 603. Rebate agreement.

(a) Requirement.—The PACE Program and the General Assistance Program shall not reimburse for any covered prescription drug without a rebate agreement between the department and the manufacturer of the covered prescription drug.

(b) Exception.—Subsection (a) shall not apply if the availability of the drug is essential to the health of eligible claimants as determined by the department.

(c) Agreements.—Manufacturers of prescription drugs reimbursed under the PACE Program and the General Assistance Program must enter into a rebate agreement with the department within 120 days of the effective date of this chapter. If a manufacturer has not entered into an agreement within the 120-day period, an agreement subsequently entered into shall not be effective until the first day of the calendar quarter that begins 120 days after the date the agreement is entered into.

(d) Notice.—The department shall notify enrolled providers of the PACE Program on an annual basis and as appropriate of all manufacturers who have entered into a rebate agreement.

(e) Drug formulary.—Except as provided in section 303(h)(12), 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 agreements in effect 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 Adminis-

tration. This subsection shall not apply to any act taken by the department pursuant to its therapeutic drug utilization review program under section 303(c).

Section 604. Terms of rebate agreement.

(a) Quarterly basis.—A rebate agreement shall require any manufacturer of covered prescription drugs to provide to the department a rebate each calendar quarter in an amount specified in section 605 for covered prescription drugs of the manufacturer reimbursed during the quarter. The rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in subsection (b) for the period involved.

(b) Information.—

(1) The department shall report to each manufacturer, not later than 60 days after the end of each calendar quarter, information by ZIP Code of provider on the total number of dosage units of each covered prescription drug reimbursed under the PACE Program and under the General Assistance Program during the quarter.

(2) A manufacturer may review the information provided under paragraph (1) and verify information. Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.

(3) In the event that, in any quarter, a material discrepancy in the department's information is certified by the manufacturer prior to the due date of the rebate, the department and the manufacturer shall, in good faith, attempt to resolve the discrepancy. If resolution is not reached within 30 days of receipt of the manufacturer's certification by the department, the manufacturer may appeal the department's decision under the department's formal fair hearings and appeals process. The manufacturer shall pay the department that portion of the rebate amount which is not disputed within the required time frame under this chapter. Any balance due, plus statutory interest, shall be paid or credited by the manufacturer or the department by the due date of the next quarterly payment after resolution of the dispute.

(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.

(2) The department shall retain the services of an independent contractor to survey wholesalers, direct sellers and manufacturers that directly distribute their covered prescription drugs, when necessary, to verify manufacturer prices reported under paragraph (1). Any survey conducted shall not reveal to the department nor to any other person or entity other than the independent contractor the name, identity, location, actual acquisition invoice, other proprietary information or any information from which the department might be enabled to ascertain the name, identity or location of any wholesaler, direct seller or provider so surveyed unless the contractor shall have gathered sufficient evidence to enable the department to bring

charges against any wholesaler, direct seller or provider in violation of subsection (d)(3).

(d) Penalties.—The department shall administer penalties as follows:

(1) A manufacturer who fails to supply information required under subsection (c)(1) shall be liable for a civil penalty in the amount of 2% of the rebate next required to be paid, plus $1,000 for each day that the information is late. If the information is not reported within 30 days of the due date, the agreement shall be suspended for services furnished after the end of the 30-day period until the date the information is reported or the expiration of 45 days, whichever is later.

(2) A manufacturer who knowingly supplies false information that is required under subsection (c)(1) shall be liable for a civil penalty in the amount of $50,000 for each item of false information.

(3) A direct seller, manufacturer or wholesaler who refuses a request for information or knowingly provides false information that is required under subsection (c)(2) shall be liable for a civil penalty in the amount of $50,000.

(4) Penalties collected under this subsection shall be deposited into the fund.

(5) All civil monetary penalties imposed under this chapter are in addition to other civil or criminal penalties.

(e) Confidentiality of information.—Information disclosed by manufacturers, wholesalers or direct sellers under this chapter is confidential and shall not be disclosed by the department in a form which discloses the identity of a specific manufacturer, wholesaler or direct seller or the prices charged for drugs by the manufacturer or wholesaler, except as the department determines to be necessary to carry out this chapter and to permit the Department of the Auditor General and the Office of State Inspector General to review the information provided.

(f) Length of agreement.—A rebate agreement shall remain in effect for an initial period of not less than one year and shall be automatically renewed for a period of not less than one year unless terminated under subsection (g).

(g) Termination.—

(1) The department may provide for termination of a rebate agreement for any reason. Termination shall not be effective earlier than 60 days after the date of receipt of notice of termination by the manufacturers.

(2) A manufacturer may terminate a rebate agreement for any reason. Termination shall not be effective earlier than 60 days after the date of receipt of notice of termination by the department.

(3) Termination of the rebate agreement shall not affect rebates due under the agreement before the effective date of termination.

(4) Commonwealth Court shall have original jurisdiction over cases of termination of agreements under this subsection. Commencement of an action under this paragraph shall not delay the effective date of termination.

(5) If a rebate agreement is terminated for cause, another agreement with the same manufacturer or a successor manufacturer may not be entered into until a period of one year has elapsed from the date of the termination unless the department finds good cause for an earlier agreement.

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:

(1) For quarters beginning after December 31, 1990, and ending before October 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.

(2) For quarters beginning after September 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 October 1, 1992, is 10%.

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

(c) Drugs approved after act takes effect.—In the case of a covered outpatient drug approved for marketing after the effective date of this act, any reference to January 1, 1991, shall be a reference to the first day of the first month during which the drug was marketed.

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 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).

(b) New bi-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 605.2. Lowered best price.

(a) General rule.—If the rebate under section 605 and the discount under section 605.1 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.—Any claim by a manufacturer that a rebate would establish a lower Federal best price under subsection (a) shall be verified in writing by a department-approved independent public accounting firm within 45 days of the end of the quarter for which the claim is asserted. The information provided to the public accounting firm shall remain confidential.

(c) Civil penalty.—A manufacturer which provides false information under this section shall be liable for a civil penalty in an amount not to exceed $50,000. Each item of false information constitutes a separate violation.

Section 606. Exemption.

Section 306(a) shall not apply to rebates under this chapter.

Section 607. Disposition of funds.

(a) PACE Program.—Money received under this chapter in connection with the PACE Program shall be deposited in the Pharmaceutical Assistance Contract for the Elderly Fund.

(b) General Assistance Program.—Money received under this chapter in connection with the General Assistance Program shall augment the medical assistance outpatient appropriation to the Department of Public Welfare.

Section 6. The act is amended by adding a section to read:

Section 901.1. Statement of policy and report.

(a) Statement of policy.—The department shall publish in the Pennsylvania Bulletin a statement of policy describing the therapeutic drug utilization review system and the structure and responsibilities of the therapeutic drug utilization review committees. This publication shall be considered a statement of policy, as defined in section 102(13) of the act of July 31, 1968 (P.L.769, No.240), referred to as the Commonwealth Documents Law, and shall not be subject to the act of June 25, 1982 (P.L.633, No.181), known as the Regulatory Review Act.

(b) Report.—Annually, by March 1, the department shall submit to the Secretary of the Senate and to the Chief Clerk of the House of Representatives a report regarding the operation of the therapeutic drug utilization review system. The report shall cover the prior calendar year. The report shall, at a minimum, do all of the following:

(1) Detail the scope of physician and pharmacist participation in the system.

(2) Describe claimant response to the system.

(3) Provide data for each month of the covered period regarding the number of prescription revisions based on utilization review. Data under this paragraph includes drug information, cost savings and the policy used by the department that contributes to utilization review decisions.

Section 7. Section 904 of the act is amended to read:

Section 904. Applicability.

The rebate provisions of **[Chapter 5]** *sections 601 through 605, 606 and 607* and section 903(a) shall be retroactive to January 1, 1991.

Section 8. The General Assembly, 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 General Assembly no later than December 31, 1993.

Section 9. This act shall apply retroactively as follows:

(1) The addition of sections 605.1 and 605.2 of the act shall be retroactive to January 1, 1992.

(2) Except as provided in paragraph (1), the addition of Chapter 6 of the act shall apply retroactively to July 1, 1992, and any action taken under a provision of Chapter 5 of the act after June 30, 1992, and before the effective date of Chapter 6 of the act shall be deemed taken under the corresponding provision of Chapter 6 of the act as long as there is a corresponding provision. Notwithstanding the expiration set forth in section 509 of the act, the rebate system in place under section 505 of the act shall continue in operation until the rebate system under section 605 of the act takes effect, and the following shall apply from July 1, 1992, until the effective date of section 605 of the act:

(i) For drugs commonly known as brand name drugs, the rebate shall be 12.5% of the average manufacturer price, in accordance with section 505(a) and other applicable provisions of the act.

(ii) For drugs commonly known as generic drugs, the rebate shall be 10% of the average manufacturer price, in accordance with section 505(b) and other applicable provisions of the act.

Section 10. This act shall take effect immediately.

APPROVED—The 9th day of December, A. D. 1992.

ROBERT P. CASEY