No. 1991-36

AN ACT

HB 1470

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.

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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 Lottery Fund Preservation Act.

Section 102. Declaration of policy.

The General Assembly finds and declares as follows:

- (1) The State Lottery Fund is the major source of providing assistance and programs to the elderly in this Commonwealth.
- (2) The State Lottery Fund's revenues are leveling off while the population served by the fund has increased by over 500,000 older adults since the fund was created.
- (3) The State Lottery Fund is experiencing serious financial strain because of increased demand and escalating prices of products and services. Prescription prices have risen an average of 15% annually while transportation costs have increased an average of 10% annually.
- (4) The following specific programs lack appropriate spending limits and are the major cause of strain on the State Lottery Fund:
 - (i) Pharmaceutical assistance for the elderly.
 - (ii) Shared transportation services for the elderly.
 - (iii) Fixed route transit subsidies for the elderly.
- (5) The best solution to the problem of ensuring the financial solvency of the State Lottery Fund is the consolidation and regulation of the programs listed in paragraph (4).

Section 103. 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:

"Department." The Department of Aging of the Commonwealth.

"Fund." The State Lottery Fund.

CHAPTER 3

PHARMACEUTICAL ASSISTANCE FOR ELDERLY

Section 301. Legislative findings.

Finding that an increasing number of the Commonwealth's elderly citizens who are living on fixed incomes are experiencing difficulties in meeting the costs of life-sustaining prescription drugs, the General Assembly, in its

responsibilities to provide for the health, welfare and safety of its residents, hereby establishes a limited State pharmaceutical assistance program for the elderly.

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:

"Average wholesale cost." The cost of a dispensed drug based upon the price published in a national drug pricing system in current use by the Department of Aging as the average wholesale price of a prescription drug in the most common package size.

"Average wholesale price." Average wholesale cost.

"Board." The Pharmaceutical Assistance Review Board.

"Eligible claimant." A resident of the Commonwealth for no less than 90 days, who is 65 years of age and over, whose annual income is less than the maximum annual income and who is not otherwise qualified for public assistance under the act of June 13, 1967 (P.L.31, No.21), known as the Public Welfare Code.

"Income." All income from whatever source derived, including, but not limited to, salaries, wages, bonuses, commissions, income from self-employment, alimony, support money, cash public assistance and relief, the gross amount of any pensions or annuities, including railroad retirement benefits, all benefits received under the Federal Social Security Act (except Medicare benefits), all benefits received under State unemployment insurance laws and veterans' disability payments, all interest received from the Federal Government or any state government, or any instrumentality or political subdivision thereof, realized capital gains, rentals, workmen's compensation and the gross amount of loss of time insurance benefits, life insurance benefits and proceeds, except the first \$5,000 of the total of death benefits payments, and gifts of cash or property, other than transfers by gift between members of a household, in excess of a total value of \$300, but shall not include surplus food or other relief in kind supplied by a government agency or property tax rebate.

"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 exceed \$13,000 in the case of single persons nor \$16,200 in the case of the combined annual income of married persons.

- "Pharmacy." A pharmacy licensed by the Commonwealth.
- "Prescription drug." All drugs requiring a prescription in this Commonwealth, insulin, insulin syringes and insulin needles. Experimental drugs are prohibited.
 - (1) Except as provided in paragraph (2), the term excludes drugs which are prescribed for wrinkles or hair growth.
 - (2) If this chapter takes effect before July 1, 1991, then, beginning July 1, 1991, the term excludes drugs which are prescribed for wrinkles or hair growth.
- "Private contractor." A person, partnership or corporate entity who enters into a contract with the Commonwealth to provide services under the provisions of this chapter.
- "Program." The pharmaceutical assistance contract for the elderly as established by this chapter.
- Section 303. Responsibilities of department.
- (a) Determination of eligibility.—The department shall adopt regulations relating to the determination of eligibility of prospective claimants and providers, including dispensing physicians, and the determination and elimination of program abuse. To this end, the department shall establish a compliance unit staffed sufficiently to fulfill this responsibility. The department shall have the power to declare ineligible any claimant or provider who abuses or misuses the established prescription plan. The department shall have the power to investigate cases of suspected provider or recipient fraud.
- (b) Physician and pharmacy participation.—Any physician, pharmacist, pharmacy or corporation owned in whole or in part by a physician or pharmacist enrolled as a provider in the program, or who has prescribed medication for a claimant in the program, who is precluded or excluded for cause from the Department of Public Welfare's Medical Assistance Program shall be precluded or excluded from participation in the program. No physician precluded or excluded from the Department of Public Welfare's Medical Assistance Program shall have claims resulting from prescriptions paid for by the program.
- (c) Drug utilization review system.—The department shall ensure that a state-of-the-art therapeutic drug utilization review system is established to monitor and correct misutilization of drug therapies.
- (d) Reduced assistance.—Any eligible claimant whose prescription drug costs are covered in part by any other plan of assistance or insurance may be required to receive reduced assistance under the provisions of this chapter at the discretion of the department.
- (e) Rebates for expenses prohibited.—A system of rebates or reimbursements to the claimant for prescription drugs shall be prohibited.
- (f) Request for proposal.—The department shall prepare a request for proposal for the purpose of providing pharmaceutical assistance for the elderly within this Commonwealth. Upon the adoption of the General Fund budget, the Department of Revenue shall be authorized to transmit the appropriated funds in the State Lottery Fund to the State Treasurer to be deposited in the Pharmaceutical Assistance Contract for the Elderly Fund.

This fund shall consist of appropriations and interest and shall be created by the State Treasurer to fund the operations of the program by the department and the private contractor. Funds not expended in the fiscal year in which they were appropriated shall not lapse and be available for use in the next fiscal year.

- (g) Additional requests for proposals.—To provide for the continued operation of the program, the department shall prepare, as needed, requests for proposals, in addition to that set forth in subsection (f), for the purpose of providing pharmaceutical assistance for the elderly within this Commonwealth. A request for proposal shall require potential private contractors to submit a proposal for a period of time and with monetary limitations as determined by the department. Upon the enactment of an appropriation from the State Lottery Fund, the Department of Revenue shall be authorized to transmit the appropriated amount to the State Treasurer to be deposited in the Pharmaceutical Assistance Contract for the Elderly Fund. Funds not expended in the fiscal year in which they were appropriated shall not lapse and shall be available for use in the next fiscal year.
 - (h) Program criteria.—The program shall include the following criteria:
 - (1) Participating pharmacies are to be paid within 21 days of the contracting firm receiving the appropriate substantiation of the transaction. Pharmacies shall be entitled to interest for payment not made within the 21-day period at a rate approved by the board.
 - (2) Collection of the copayment by pharmacies shall be mandatory.
 - (3) Senior citizens participating in the program are not required to maintain records of each transaction.
 - (4) A system of rebates or reimbursements to eligible claimants for pharmaceutical expenses shall be prohibited.
 - (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 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.

(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 or the dispensing fee established by the department by regulation, whichever is greater.

- (7) The average wholesale cost shall be based on a list of package sizes to be established by the department. The list shall reflect the average wholesale cost of drugs based on the package size listed in the February 1984 "Yellow Book" distributed by the Health Care Financing Administration for the drugs contained on that list. The department shall have the authority to change the package size of drugs on that list and to add drugs and package sizes to that list with the review and approval of the board. Changes to the list shall take effect upon publication in the Pennsylvania Bulletin. The department shall have the authority to reimburse based upon the package sizes established in this paragraph.
- (8) In no case shall the Commonwealth be charged more than the price of the drug at the particular pharmacy on the date of the sale.
- (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) 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) 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) 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) The program must be in place and operational within 90 days of the effective date of the contract.
- (16) 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) Any health care professional 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) The department shall annually verify the income of eligible claimants. Verification shall be accomplished by a targeted sampling of 5% of the eligible claimants.
- (i) Reports by department.—The department shall maintain monthly statistical records on the program to effectively determine the cost of the program, level of participation and any patterns of unusual drug usage. Based on this information, the department shall submit a report every six months to the Aging and Youth Committee in the Senate, the Aging and Youth Committee in the House of Representatives and the board. The semi-annual report shall contain, but is not limited to, all information relating to the number of persons served by the program, their counties of residence, a breakdown of the numbers and kinds of pharmaceuticals used, the cost of

prescriptions and an estimate of actual expenses incurred by pharmacists participating in the program.

(j) Adjustments to program.—The department is authorized to enter into discussions with the private contractor pursuant to section 305(c). Section 304. Contract.

The department is authorized to enter into a contract providing for prescription drugs to eligible persons pursuant to this chapter. The department shall select a proposal that includes, but is not limited to, the criteria set forth in section 303.

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 persons:
 - (1) The Secretary of Aging, who shall serve as its chairman.
 - (2) The Secretary of Revenue.
 - (3) The Secretary of Health.
 - (4) Four 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. Those appointed 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. 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 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.

Section 306. Penalties.

(a) Prohibited acts and criminal penalties.—It shall be unlawful for any person to submit a false or fraudulent claim or application under this chapter; to aid or abet another in the submission of a false or fraudulent claim or application; to receive benefits or reimbursement under a private, Federal or State program for prescription assistance and claim or receive duplicative benefits hereunder; to solicit, receive, offer or pay any kickback, bribe or rebate, in cash or in-kind, from or to any person in connection with the furnishing of services under this chapter; or to otherwise violate any pro-

vision of this chapter. Any person who commits a prohibited act shall be charged with a criminal offense pursuant to the provisions of 18 Pa.C.S. (relating to crimes and offenses).

- (b) Suspension of license.—Any provider who has been found guilty under this chapter shall be subject to a suspension of his license to practice for a period of one year.
- (c) Repayment of gain.—Any provider or recipient who is found guilty under this chapter is subject to repay three times the value of the material gain he received.

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.
- (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.

CHAPTER 5 PRUDENT PHARMACEUTICAL PURCHASING

Section 501. 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, forprofit or nonprofit organizations, other manufacturers or wholesalers doing business in this Commonwealth in order to ensure that the Commonwealth 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.

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.

"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.

"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 503. 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.—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 504. 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 505 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 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 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.
 - (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 applicable percentage for calendar quarters beginning after January 1, 1991, is 10%.
- (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 506. Exemption.

Section 306(a) shall not apply to rebates under this chapter. Section 507. 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 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.

CHAPTER 7 TRANSPORTATION SERVICES

Section 701. 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:

"Shared-ride public transportation services." Demand-responsive transportation that is available to the general public, operates on a nonfixed route basis and charges a fare to all riders. For transportation to be included in this definition, the first fare paying passengers to enter the public transportation vehicle must not refuse to share the vehicle with other passengers during a given trip. The term excludes exclusive ride taxi service, charter and sight-seeing services, nonpublic transportation, school bus and limousine services. Section 702. Department of Transportation.

The Department of Transportation has the power and duty to make grants from the fund to transportation companies, county transportation systems and local transportation organizations to pay estimated transit losses resulting from providing free service or local common carrier mass transportation systems to persons 65 years of age or older when passage is on fixed route public transportation services during nonpeak riding hours and on holidays and weekends. Reimbursement shall be as follows:

- (1) The losses resulting from granting service on mass transportation systems shall be reimbursable at 100% of the system's average or base fare, whichever is less, multiplied by the number of trips made by senior citizens participating in the free transit program.
- (2) Notwithstanding paragraph (1), the department shall, with the approval of the Governor's Office of the Budget, reimburse transportation companies or local transportation organizations for 100% of the losses resulting from senior citizen transfer trips incurred under the conditions of this subsection.
- (3) Money appropriated from the General Fund to the Department of Transportation to augment fixed route public transportation services under this section shall be granted to transportation providers at the discretion of the Department of Transportation.

Section 703. Commuter rail fare.

With regard to passage on fixed-route commuter rail lines, the fare for adults 65 years of age or older who do not qualify as eligible claimants under the pharmaceutical assistance contract for the elderly program shall be limited to \$1 per trip but only when utilizing such transportation services during nonpeak riding hours and on holidays and weekends.

Section 704. Human service shared-ride transportation services for older adults.

(a) Program grants.—The Department of Transportation has the power and duty to administer, utilizing a fixed amount of money from the fund as appropriated by the General Assembly, a program providing shared-ride public transportation services for adults 65 years of age or older. Individuals

utilizing shared-ride public transportation services for older adults shall contribute 15% of the individual fare and 85% of the individual fare shall be reimbursed by the fund.

- (b) Future options.—
- (1) The department, in cooperation with the Department of Transportation, shall conduct a study addressing options for future administration of the shared-ride program. 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 March 1, 1992.
- (2) The department and the Department of Transportation shall conduct a study of the existing shared-ride programs for cities of the first class. The study shall include information on ridership levels, complaints per 1,000 rides, telephone service, public information efforts, no-show analysis, contract enforcement and other concerns identified by the departments. The completed study, with appropriate recommendations for the operation of the shared-ride programs in cities of the first class. shall be submitted to the Aging and Youth Committee, the Appropriations Committee and the Transportation Committee of the Senate and to the Aging and Youth Committee, the Appropriations Committee and the Transportation Committee of the House of Representatives by February 7, 1992. After review of the study, the General Assembly may, by resolution, direct the Department of Transportation to consider, by May 1, 1992, alternate approaches to the provision of shared-ride services in cities of the first class. After submission of the study under this paragraph and before June 30, 1992, the Department of Transportation and contracted providers of shared-ride services in cities of the first class may incorporate recommendations from the study into existing contracts.
- (3) By November 15, 1991, the Department of Transportation shall compare the average shared-ride public transportation ridership levels in cities of the first class for the months of August, September and October in 1990 and 1991. If the average ridership in August, September and October 1991 is not at least 85% of the ridership in the same months of 1990, the Department of Transportation shall deem all contracts relating to shared-ride public transportation in cities of the first class in default and shall cancel all such contracts consistent with the terms of the contract.
- (c) Regulations.—The Department of Transportation shall promulgate regulations necessary to carry out the purposes of this section, including regulations that permit limited reimbursement for shared-ride public transportation services providing access to and from public airports. The Department of Transportation, in consultation with the Pennsylvania Public Utility Commission and the department, shall establish reasonable per mile or trip fare limits for purposes of subsection (a). In accordance with section 2203-A(a)(27) of the act of April 9, 1929 (P.L.177, No.175), known as The Administrative Code of 1929, no regulation shall take effect until submitted to the department for comment.
- (d) Coordinated transportation plans.—The Department of Transportation shall require that each transportation provider or designated coordi-

nator, whichever is appropriate, annually develop a coordinated transportation plan which shall include, but not be limited to, any current fixed-route system and shared-ride programs. All plans must be submitted to and approved by the department no later than June 1 of each fiscal year.

- (e) Other forms of assistance.—Any eligible claimant whose transportation services are covered in part by any other plan of assistance may be required to receive reduced transportation assistance under the provisions of this chapter.
- (f) Entitlement not created.—Nothing in this chapter creates or provides any individual with an entitlement to services. It is the intent of the General Assembly that services under this chapter shall be made available only to the extent of the availability and level of appropriations made by the General Assembly.

CHAPTER 9 MISCELLANEOUS PROVISIONS

Section 901. Savings.

- (a) General rule.—This act does not affect any act done, regulation promulgated, liability incurred or right accrued or vested or affect any civil or criminal proceeding pending or to be commenced to enforce any right or penalty or punish any offense under any statute or part of a statute repealed by this act.
- (b) References.—The reference to the act of January 22, 1968 (P.L.42, No.8), known as the Pennsylvania Urban Mass Transportation Assistance Law of 1967, in section 12 of the act of August 26, 1971 (P.L.351, No.91), known as the State Lottery Law, shall be deemed a reference to Chapter 7. Section 902. Severability.

The provisions of this act are severable. If any provision of this act or its application to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of this act which can be given effect without the invalid provision or application.

Section 903. Repeals.

- (a) Inflation dividends.—The act of March 11, 1971 (P.L.104, No.3), known as the Senior Citizens Rebate and Assistance Act, reenacted and amended December 21, 1979 (P.L.570, No.131), is repealed insofar as it relates to inflation dividends.
 - (b) Specific repeals.—The following acts and parts of acts are repealed:
 - (1) The following provisions of the act of January 22, 1968 (P.L.42, No.8), known as the Pennsylvania Urban Mass Transportation Law:
 - (i) The definition of "shared ride public transportation services" in section 202.
 - (ii) Section 203(5).
 - (2) The act of November 4, 1983 (P.L.217, No.63), known as the Pharmaceutical Assistance Contract for the Elderly Act.
 - (3) The last three sentences of section 1901(c)(16) of Title 75 of the Pennsylvania Consolidated Statutes.

(c) Inconsistent repeals.—All acts and parts of acts are repealed insofar as they are inconsistent with this act.

Section 904. Applicability.

The rebate provisions of Chapter 5 and section 903(a) shall be retroactive to January 1, 1991.

Section 905. Effective date.

This act shall take effect immediately.

APPROVED—The 14th day of August, A. D. 1991.

ROBERT P. CASEY