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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2254 Session of 2000

INTRODUCED BY MELIO, PESCI, SOLOBAY, BARRAR, CALTAGIRONE, OLIVER, PETRARCA, JOSEPHS, MANN, HORSEY, HALUSKA, MYERS, SHANER, BISHOP, HARHAI, DeWEESE, READSHAW, CLARK, BELARDI, STEELMAN, GEORGE, BROWNE, M. COHEN, TANGRETTI, DeLUCA, YUDICHAK, HENNESSEY, LAUGHLIN, YOUNGBLOOD, WILLIAMS, PLATTS, PISTELLA, THOMAS, TRELLO, TRICH, VEON, BELFANTI, CASORIO, CURRY, GIGLIOTTI, FRANKEL, COSTA, CORRIGAN, WOJNAROSKI, BATTISTO, SANTONI, McGEEHAN, LEDERER, CARN, WATERS, VITALI, BLAUM, LESCOVITZ, GRUCELA, SURRA, MANDERINO, EACHUS, COLAFELLA AND McCALL, FEBRUARY 10, 2000

REFERRED TO COMMITTEE ON AGING AND YOUTH, FEBRUARY 10, 2000

AN ACT

Amending the act of August 26, 1971 (P.L.351, No.91), entitled "An act providing for a State Lottery and administration thereof; authorizing the creation of a State Lottery Commission; prescribing its powers and duties; disposition of funds; violations and penalties therefor; exemption of prizes from State and local taxation and making an appropriation," further providing for the prudent purchase of pharmaceuticals.

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

Section 1. Sections 701, 702, 703, 704, 705 and 709 of the act of August 26, 1971 (P.L.351, No.91), known as the State Lottery Law, added November 21, 1996 (P.L.741, No.134), are amended to read:

Section 701. Declaration of policy.

The General Assembly finds and declares as follows:

(1) The Commonwealth, through assistance programs

enacted for the benefit of its citizens, and as one of the largest employers in this Commonwealth, 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 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.

(6) Drug price inflation has caused an increase in the amount of public funds expended by PACE [and General Assistance.]<u>, State employee benefits and retirement programs, State-run facilities and the Medical Assistance Program.</u>

Section 702. 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 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 (49 Stat. 620, 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.

"Consumer Price Index-Urban" or "CPI-U." A price index compiled by the Bureau of Labor Statistics of the United States Department of Labor for measuring the average change in the prices paid by urban consumers for a fixed market basket of services.

"Covered prescription drug." A legend drug, insulin, an insulin syringe or an insulin needle eligible for payment by the Commonwealth under PACE, PACENET or designated pharmaceutical programs.

"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.

"Designated pharmaceutical programs." The General Assistance Program, the Medical Assistance Program and the Special Pharmaceutical Benefit Program in the Department of Public Welfare and the End Stage Renal Dialysis Program in the Department of Health.

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

"Dispensing fee." A fee of up to three dollars fifty cents ($3.50) which may be added by the dispensing pharmacist to the cost of a prescription medication to cover the cost of filling a

prescription.

"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.

"Fair and reasonable price." The price of a medication or drug as listed on the most recent Federal Supply Schedule plus the addition of a dispensing fee. The fair and reasonable price shall include the cost of any co-payment required from the consumer of that prescription medication.

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

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

"General Assistance." The General Assistance program of the Department of Public Welfare of the Commonwealth.

"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.

"Manufacturer's rebate." A rebate or refund provided by the manufacturer for a portion of the cost of a prescription medication. Such a rebate or refund may be paid to the prescribing physician, the dispensing pharmacist, or both.

"Medical Assistance Program." The program established pursuant to Article IV, subarticle (f) of the act of act of June

13, 1967 (P.L.31, No.21), known as the "Public Welfare Code."

"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." The program under Chapter 5.

"PACENET." The program established under section 519.

"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 licensed pharmacy or dispensing physician enrolled as a provider in PACE, PACENET or designated pharmaceutical programs.

"Public program." The PACE and PACENET program, the Medical Assistance Program, the State Employees' Benefit Trust Fund, the State Employees' Retirement System, the Public School Employees'

Retirement System and any other State agency or designated pharmaceutical program that purchases or arranges for the purchase of prescription medications.

"Public School Employees' Retirement System." The retirement system established by 24 Pa.C.S. Part IV (relating to retirement for school employees).

"Rebate period." A calendar quarter or other period specified by the Secretary of Aging with respect to the payment of rebates under an agreement as provided in section 703.

"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).

"State agency." Any agency under the jurisdiction of the Governor, the General Assembly or the Unified Court System that purchases or provides coverage for prescription medications.

"State Employees' Benefit Trust Fund." The trust fund established to purchase health insurance coverage, including coverage for prescription medications, for State employees.

"State Employees' Retirement System." The retirement system established under 71 Pa.C.S. Part XXV (relating to retirement for school employees and officers).

"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 (49 Stat. 620, 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 703. Rebate agreement.

(a) Requirement.--[PACE, PACENET and designated pharmaceutical programs]Public programs 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 PACE, PACENET and designated pharmaceutical programs] by public programs must enter into a rebate agreement with the department under this chapter to obtain such reimbursement. Nothing in this chapter shall be deemed to affect or impair any agreement made under the former provisions of Chapter 6 of the act of August 14, 1991 (P.L.342, No.36), known as the Lottery Fund Preservation Act.

(d) Notice.--The department shall notify enrolled providers of PACE, PACENET [and], designated pharmaceutical programs and other State agencies 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 512, 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 PACE and PACENET, provided that such outpatient drugs were approved for marketing by the Food and Drug Administration. This subsection shall not apply to any act taken by the department pursuant to its therapeutic drug utilization review program under section 505.

Section 704. 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 705 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 PACE, PACENET and designated pharmaceutical programs during the quarter. Other State agencies shall report the same information in the same format and according to the same schedule to each manufacturer.

(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 or State agency's information is certified by the manufacturer prior to the due date of the rebate, the department or State agency 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 or State agency, the manufacturer may appeal the department's or State agency's decision under the department's or State agency's formal fair hearings and appeals process. The manufacturer shall pay the department or State agency 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 or State agency 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). The department shall share the results of said survey with each State agency.

(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 705. 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 September 30, 1992, and ending before January 1, 1997, the product of the total number of units of each dosage form and strength reimbursed by PACE and General Assistance 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.

(2) For quarters beginning after December 31, 1996, and ending before July 1, 2000, the product of the total number of units of each dosage form and strength reimbursed by PACE, PACENET and designated pharmaceutical programs in the quarter and the difference between the average manufacturer price and 83% of that price, after deducting customary prompt payment discounts.

(3) For quarters beginning after July 1, 2000, the product of the total number of units of each dosage form and

strength reimbursed by each public program in the quarter and the difference between the average manufacturer price and 80% of that price, after deducting customary prompt payment discounts.

(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 PACE and General Assistance in the quarter.

(2) For the purposes of paragraph (1), the applicable percentage for calendar quarters beginning after September 30, 1992, and ending before January 1, 1997, is 11%.

(c) Revised rebate for other drugs.--Beginning after December 31, 1996:

(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 the greater of 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 PACE, PACENET and designated pharmaceutical

programs in the quarter.

(2) For purposes of paragraph (1), the applicable percentage is 17%.

(c.1) Revised rebate for other drugs.--Beginning after July 1, 2000:

(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 the greater of 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 each public program in the quarter.

(2) For purposes of paragraph (1), the applicable percentage is 20%.

(d) Drugs approved after act takes effect.--In the case of a covered outpatient drug approved for marketing after the effective date of the act of August 14, 1991 (P.L.342, No.36), known as the Lottery Fund Preservation 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 709. Disposition of funds.

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

(b) Designated pharmaceutical programs.--Money received under this chapter in connection with designated pharmaceutical programs shall be treated as a refund of expenditures to the

appropriation which originally provided the funding for the pharmaceutical purchase.

(c) Other State agencies.--Money received under this chapter in connection with State agencies other than PACE, PACENET or designated pharmaceutical programs shall be treated as a refund of expenditures to those agencies which provided the funding for the pharmaceutical purchase.

Section 2. The act is amended by adding a section to read:

Section 710. Fair and reasonable price.

Notwithstanding any other provision of this section to the contrary, each State agency shall pay a fair and reasonable price for each prescription medication covered by or paid for by that agency.

Section 3. This act shall take effect July 1, 2000, or immediately, whichever is later.