## THE GENERAL ASSEMBLY OF PENNSYLVANIA

## HOUSE BILL

No. 888

Session of 2003

INTRODUCED BY VANCE, EACHUS, KENNEY, WALKO, E. Z. TAYLOR, GRUCELA, ADOLPH, BARD, BALDWIN, BARRAR, BASTIAN, BROWNE, BUTKOVITZ, BUXTON, CAPPELLI, CASORIO, CORNELL, CORRIGAN, COSTA, DAILEY, DALLY, J. EVANS, FEESE, FLICK, FREEMAN, GABIG, GERGELY, GILLESPIE, GINGRICH, HARHAI, HARPER, HASAY, HENNESSEY, HERMAN, HERSHEY, HORSEY, JAMES, KELLER, KIRKLAND, LAUGHLIN, LEH, LEWIS, MACKERETH, MAHER, MARSICO, McCALL, McGILL, McNAUGHTON, MELIO, MICOZZIE, R. MILLER, S. MILLER, MUNDY, NAILOR, NICKOL, O'NEILL, PALLONE, PETRARCA, PETRI, PICKETT, PISTELLA, RAYMOND, READSHAW, ROSS, RUBLEY, SAINATO, SAYLOR, SCAVELLO, SCHRODER, SEMMEL, SHANER, SOLOBAY, STEIL, R. STEVENSON, T. STEVENSON, J. TAYLOR, THOMAS, TIGUE, TRAVAGLIO, TURZAI, WANSACZ, WATSON, WEBER, WILT, WRIGHT, YOUNGBLOOD, YUDICHAK, ZUG, FABRIZIO, REED, SAMUELSON, OLIVER, COY, TANGRETTI, HABAY, GEORGE, GORDNER AND DALEY, MARCH 13, 2003

AMENDMENTS TO SENATE AMENDMENTS, HOUSE OF REPRESENTATIVES, NOVEMBER 18, 2003

## AN ACT

Amending the act of August 26, 1971 (P.L.351, No.91), entitled "An act providing for a State Lottery and administration 2 3 thereof; authorizing the creation of a State Lottery 4 Commission; prescribing its powers and duties; disposition of 5 funds; violations and penalties therefor; exemption of prizes 6 from State and local taxation and making an appropriation," 7 further providing for definitions, for program generally, for 8 generic drugs, for restricted formulary, for reimbursement, 9 for nonliability, for the Pharmaceutical Assistance Contract for the Elderly Needs Enhancement Tier, for the 10 11 Pharmaceutical Assistance Review Board; providing for 12 pharmacy best practices and cost controls; further providing 13 for penalties, for the Prescription Drug Education Program, 14 for rebate agreement, for terms of rebate agreement and for 15 amount of rebate; providing for a Pharmaceutical Assistance Clearinghouse; further providing for annual report to General 16 Assembly; and providing for construction with Federal 17 programs and for continued use of Tobacco Settlement Fund. 18

- 1 The General Assembly of the Commonwealth of Pennsylvania
- 2 hereby enacts as follows:
- 3 Section 1. The definitions of "HCFA," "income," "maximum
- 4 annual income" and "provider" in section 502 of the act of
- 5 August 26, 1971 (P.L.351, No.91), known as the State Lottery
- 6 Law, added November 21, 1996 (P.L.741, No.134), are amended and
- 7 the section is amended by adding definitions to read:
- 8 Section 502. Definitions.
- 9 The following words and phrases when used in this chapter
- 10 shall have the meanings given to them in this section unless the
- 11 context clearly indicates otherwise:
- 12 \* \* \*
- 13 "CMS." The Centers for Medicare and Medicaid Services of the
- 14 United States.
- 15 \* \* \* \*
- 16 <u>"DESI." The Drug Efficacy Study Implementation List.</u>
- 17 \* \* \*
- 18 ["HCFA." The Health Care Financing Administration of the
- 19 United States.]
- 20 <u>"Health Maintenance Organization." An organized system which</u>
- 21 combines the delivery and financing of health care and which
- 22 provides basic health services to voluntarily enrolled
- 23 <u>subscribers for a fixed prepaid fee.</u>
- "Income." All income from whatever source derived,
- 25 including, but not limited to, salaries, wages, bonuses,
- 26 commissions, income from self-employment, alimony, support
- 27 money, cash public assistance and relief, the gross amount of
- 28 any pensions or annuities, including railroad retirement
- 29 benefits, all benefits received under the Social Security Act
- 30 (49 Stat. 620, 42 U.S.C. § 301 et. seq.) (except Medicare

- 1 benefits), all benefits received under State unemployment
- 2 insurance laws and veterans' disability payments, all interest
- 3 received from the Federal Government or any state government or
- 4 any instrumentality or political subdivision thereof, realized
- 5 capital gains, rentals, workmen's compensation and the gross
- 6 amount of loss of time insurance benefits, life insurance
- 7 benefits and proceeds, except the first [\$5,000] \$10,000 of the
- 8 total of death benefits payments, and gifts of cash or property,
- 9 other than transfers by gift between members of a household, in
- 10 excess of a total value of \$300, but shall not include surplus
- 11 food or other relief in kind supplied by a government agency or
- 12 property tax rebate.
- 13 "Maximum annual income." For PACE eligibility, the term
- 14 shall mean annual income which shall not exceed [\$14,000]
- 15 \$14,500 in the case of single persons nor [\$17,200] \$17,700 in
- 16 the case of the combined annual income of persons married to
- 17 each other. Persons may, in reporting income to the Department
- 18 of Aging, round the amount of each source of income and the
- 19 income total to the nearest whole dollar, whereby any amount
- 20 which is less than 50ç is eliminated.
- 21 \* \* \*
- 22 "Preferred Provider Organization." An entity organized and
- 23 operating under 40 Pa.C.S. Ch. 63 (relating to professional
- 24 <u>health services plan corporations</u>).
- 25 \* \* \*
- 26 "Provider." A pharmacy [or], dispensing physician or
- 27 certified registered nurse practitioner enrolled as a provider
- 28 in the program.
- Section 2. Sections 503, 504 and 509 of the act, added
- 30 November 21, 1996 (P.L.741, No.134), are amended to read:

- 1 Section 503. Determination of eligibility.
- 2 The department shall adopt regulations relating to the
- 3 determination of eligibility of prospective claimants and
- 4 providers, including dispensing physicians and certified
- 5 registered nurse practitioners when acting in accordance with
- 6 rules and regulations promulgated by the State Board of Nursing
- 7 as required by the act of May 22, 1951 (P.L.317, No.69), known
- 8 as The Professional Nursing Law, and the State Board of Pharmacy
- 9 <u>minimum standards of practice</u>, and the determination and
- 10 elimination of program abuse. To this end, the department shall
- 11 establish a compliance unit staffed sufficiently to fulfill this
- 12 responsibility. The department shall have the power to declare
- 13 ineligible any claimant or provider who abuses or misuses the
- 14 established prescription plan. The department shall have the
- 15 power to investigate cases of suspected provider or recipient
- 16 fraud.
- 17 Section 504. Physician, certified registered nurse practitioner
- and pharmacy participation.
- 19 Any physician, certified registered nurse practitioner,
- 20 pharmacist, pharmacy or corporation owned in whole or in part by
- 21 a physician, certified registered nurse practitioner or
- 22 pharmacist enrolled as a provider in the program or who has
- 23 prescribed medication for a claimant in the program who is
- 24 precluded or excluded for cause from the Department of Public
- 25 Welfare's Medical Assistance Program shall be precluded or
- 26 excluded from participation in the program. No physician or
- 27 certified registered nurse practitioner precluded or excluded
- 28 from the Department of Public Welfare's Medical Assistance
- 29 Program shall have claims resulting from prescriptions paid for
- 30 by the program.

- 1 Section 509. Program generally.
- 2 The program shall include the following:
- 3 (1) Participating pharmacies shall be paid within 21
- 4 days of the contracting firm receiving the appropriate
- 5 substantiation of the transaction. Pharmacies shall be
- 6 entitled to interest for payment not made within the 21-day
- 7 period at a rate approved by the board.
- 8 (2) Collection of the copayment by pharmacies shall be
- 9 mandatory.
- 10 (3) Senior citizens participating in the program are not
- 11 required to maintain records of each transaction.
- 12 (4) A system of rebates or reimbursements to eligible
- claimants for pharmaceutical expenses shall be prohibited.
- 14 (5) PACE shall include [a] participant copayment
- 15 [schedule] <u>schedules</u> for each prescription, <u>including a</u>
- 16 copayment for generic or multiple-source drugs that is less
- 17 than the copayment for single-source drugs. [The copayment
- may increase or decrease on an annual basis by the average
- 19 percent change of ingredient costs for all prescription
- drugs, plus a differential to raise the copayment to the next
- 21 highest 25ç increment. In addition, the department may
- 22 approve a request for increase or decrease in the level of
- 23 copayment based upon the financial experience and projections
- of PACE and after consultation with the board. The department
- is prohibited from approving adjustments to the copayment on
- more than an annual basis.] The department shall annually
- 27 calculate the copayment schedules based on the Prescription
- 28 <u>Drugs and Medical Supplies Consumer Price Index. When the</u>
- 29 <u>aggregate impact of the Prescription Drugs and Medical</u>
- 30 Supplies Consumer Price Index equals or exceeds \$1, the

1	department shall adjust the copayment schedules. Each
2	copayment schedule shall not be increased by more than \$1 in
3	a calendar year.
4	(6) [The program shall consist of payments to pharmacies
5	on behalf of eligible claimants for 90% of the average
6	wholesale costs of prescription drugs which exceed the
7	copayment, plus a dispensing fee of at least \$3.50 or the
8	dispensing fee established by the department by regulation,
9	whichever is greater.] The program payment shall be the lower
10	of the following amounts determined as follows:
11	(i) 90% of the average wholesale cost of the
12	prescription drug dispensed:
13	(A) with the addition of a dispensing fee of the
14	<pre>greater of:</pre>
15	<u>(I) \$4; or</u>
16	(II) the amount set by the department by
17	regulation;
18	(B) the subtraction of the copayment; and
19	(C) if required the subtraction of the generic
20	<u>differential; or</u>
21	(ii) the pharmacy's usual charge for the drug
22	dispensed with the subtraction of the copayment and if
23	required the subtraction of the generic differential; or
24	(iii) if a generic drug, the most current Federal
25	upper payments limits established in the Medicaid Program
26	under 42 CFR § 447.332 (relating to upper limits for
27	multiple source drugs), plus a dispensing fee of \$4 or
28	the amount set by the department by regulation, whichever
29	is greater minus the copayment. The department shall
30	update the average wholesale costs and the Federal upper

- 1 payment limits at least every 30 days.
- 2 (7) In no case shall the Commonwealth or any person
- 3 enrolled in the program be charged more than the price of the
- 4 drug at the particular pharmacy on the date of the sale.
- 5 (8) The Governor may, based upon certified State Lottery
- 6 Fund revenue that is provided to both the chairman and
- 7 <u>minority chairman of the Appropriations Committee of the</u>
- 8 Senate and the chairman and minority chairman of the
- 9 Appropriations Committee of the House of Representatives, and
- 10 <u>after consultation with the board, decrease the eliqibility</u>
- limits established in this chapter.
- 12 Section 3. Section 510(a) of the act, added November 21,
- 13 1996 (P.L.741, No.134), is amended to read:
- 14 Section 510. Generic drugs.
- 15 (a) In general.--Notwithstanding any other statute or
- 16 regulation, if an A-rated generic therapeutically equivalent
- 17 drug is available for dispensing to a claimant, the provider
- 18 shall dispense the A-rated generic therapeutically equivalent
- 19 drug to the claimant. The department shall reimburse providers
- 20 <u>based upon the most current listing of Federal upper payments</u>
- 21 limits established in the Medicaid Program under 42 CFR §
- 22 447.332 (relating to upper limits for multiple source drugs),
- 23 plus a dispensing fee as set forth in section 509(6). The
- 24 <u>department shall update the average wholesale costs and the</u>
- 25 Federal upper payments limits on a regular basis, at least every
- 26 30 days. The department shall not reimburse providers for brand
- 27 name products except in the following circumstances:
- 28 (1) There is no A-rated generic therapeutically
- 29 equivalent drug available on the market. This paragraph does
- 30 not apply to the lack of availability of an A-rated generic

1 therapeutically equivalent drug in the providing pharmacy

2 unless it can be shown to the department that the provider

3 made reasonable attempts to obtain the A-rated generic

4 therapeutically equivalent drug or that there was an

5 unforeseeable demand and depletion of the supply of the A-

6 rated generic therapeutically equivalent drug. In either

7 case, the department shall reimburse the provider for 90% of

the average wholesale cost plus a dispensing fee based on the

least expensive A-rated generic therapeutically equivalent

10 drug for the brand drug dispensed.

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- (2) 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 paragraph on a regular basis.
- (3) 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.
- 24 (4) At the time of dispensing, the provider has a
  25 prescription on which the brand name drug dispensed is billed
  26 to the program by the provider at a usual and customary
  27 charge which is equal to or less than the least expensive
  28 usual and customary charge of any A-rated generic
  29 therapeutically equivalent drug reasonably available on the
  30 market to the provider.

- 1 \* \* \*
- 2 Section 4. Sections 512, 515, 516, 519 and 520(b) of the
- 3 act, added November 21, 1996 (P.L.741, No.134), are amended to
- 4 read:
- 5 Section 512. Restricted formulary.
- 6 The department may establish a restricted formulary of the
- 7 drugs which will not be reimbursed by the program. This
- 8 formulary shall include only experimental drugs and drugs on the
- 9 Drug Efficacy Study Implementation List prepared by [the Health
- 10 Care Finance Administration] CMS. A medical exception may be
- 11 permitted by the department for reimbursement of a drug on the
- 12 Drug Efficacy Study Implementation List upon declaration of its
- 13 necessity on the prescription by the treating physician or
- 14 <u>certified registered nurse practitioner</u>, except that, for DESI
- 15 drugs for which the FDA has issued a Notice for Opportunity
- 16 Hearing (NOOH) for the purpose of withdrawing the New Drug
- 17 Application approved for that drug, reimbursement coverage shall
- 18 be discontinued under the provisions of this chapter.
- 19 Section 515. Reimbursement.
- 20 For-profit third-party insurers, health maintenance
- 21 organizations, preferred provider organizations and not-for-
- 22 profit prescription plans shall be responsible for any payments
- 23 made to a providing pharmacy on behalf of a claimant covered by
- 24 such a third party. Final determination as to the existence of
- 25 third-party coverage shall be the responsibility of the
- 26 <u>department</u>.
- 27 Section 516. Nonliability.
- 28 (a) [Persons rendering service] <u>General rule</u>.--Any person
- 29 rendering service as a member of a utilization review committee
- 30 for this program shall not be liable for any civil damages as a

- 1 result of any acts or omissions in rendering the service as a
- 2 member of any such committee except any acts or omissions
- 3 intentionally designed to harm or any grossly negligent acts or
- 4 omissions which result in harm to the person receiving such
- 5 service.
- 6 (b) [Officer and employees of department] <u>Department</u>
- 7 personnel. -- Any officer or employee of the department rendering
- 8 service as a member of a utilization review committee for this
- 9 program shall not be liable for any civil damages as a result of
- 10 any acts or omissions in rendering the service as a member of
- 11 any such committee or as a result of any decision or action in
- 12 connection with the program except any acts or omissions
- 13 intentionally designed to harm or any grossly negligent acts or
- 14 omissions which result in harm to the person receiving such
- 15 service.
- 16 Section 519. The Pharmaceutical Assistance Contract for the
- 17 Elderly Needs Enhancement Tier.
- 18 (a) Establishment.--There is hereby established within the
- 19 department a program to be known as the Pharmaceutical
- 20 Assistance Contract for the Elderly Needs Enhancement Tier
- 21 (PACENET).
- 22 (b) PACENET eligibility. -- A claimant with an annual income
- 23 of not less than [\$14,000] <u>\$14,500</u> and not more than [\$16,000]
- 24 \$23,500 in the case of a single person and of not less than
- 25 [\$17,200] \$17,700 and not more than [\$19,200] \$31,500 in the
- 26 case of the combined income of persons married to each other
- 27 shall be eliqible for enhanced pharmaceutical assistance under
- 28 this section. A person may, in reporting income to the
- 29 department, round the amount of each source of income and the
- 30 income total to the nearest whole dollar, whereby any amount

- 1 which is less than 50¢ is eliminated.
- 2 (c) Deductible.--Upon enrollment in PACENET, eligible
- 3 claimants in the income ranges set forth in subsection (b) shall
- 4 be required to meet [an annual] <u>a</u> deductible in unreimbursed
- 5 prescription drug expenses of [\$500] \$40 per person[.] per
- 6 month. The \$40 monthly deductible shall be cumulative and shall
- 7 <u>be applied to subsequent months to determine eliqibility. The</u>
- 8 <u>cumulative deductible shall be determined on an enrollment year</u>
- 9 basis for an annual total deductible not to exceed \$480 in a
- 10 year. To qualify for the deductible set forth in this subsection
- 11 the prescription drug must be purchased for the use of the
- 12 eligible claimant from a provider as defined in this chapter.
- 13 The department, after consultation with the board, may approve
- 14 an adjustment in the deductible on an annual basis.
- 15 (d) Copayment.--
- 16 <u>(1)</u> For eligible claimants under this section, the
- 17 copayment schedule[, which may be adjusted by the department
- on an annual basis after consultation with the board,] shall
- 19 be:
- 20 (i) eight dollars for noninnovator multiple source
- 21 drugs as defined in section 702; or
- 22 (ii) fifteen dollars for single-source drugs and
- 23 innovator multiple-source drugs as defined in section
- 24 702.
- 25 (2) The department shall annually calculate the
- 26 <u>copayment schedules based on the Prescription Drugs and</u>
- 27 Medical Supplies Consumer Price Index. When the aggregate
- 28 <u>impact of the Prescription Drugs and Medical Supplies</u>
- 29 <u>Consumer Price Index equals or exceeds \$1, the department</u>
- 30 shall adjust the copayment schedules. Each copayment schedule

- shall not be increased by more than \$1 in a calendar year.
- 2 Section 520. Board.
- 3 \* \* \*
- 4 (b) Composition.--The board shall be comprised of the
- 5 following eight persons:
- 6 (1) The Secretary of Aging, who shall serve as its
- 7 chairman.
- 8 (2) The Secretary of Revenue.
- 9 (3) The Secretary of Health.
- 10 (4) Five public members, one appointed by the President
- 11 pro tempore of the Senate, one appointed by the Minority
- 12 Leader of the Senate, one appointed by the Speaker of the
- House of Representatives, one appointed by the Minority
- 14 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
- 17 the pharmaceutical industry to serve as consumer advocates
- [and two representatives], one representative of the
- 19 pharmaceutical industry[, at least one of whom is a] and one
- 20 practicing Pennsylvania pharmacist. The individual appointed
- 21 by the Governor must be a physician. A public member who
- 22 misses two consecutive meetings without good cause acceptable
- 23 to the chairman shall be replaced by the appointing
- 24 authority.
- 25 \* \* \*
- 26 Section 5. The act is amended by adding a section to read:
- 27 Section 520.1. Pharmacy best practices and cost controls
- 28 <u>review.</u>
- 29 <u>(a) Review process.--The secretary shall review and</u>
- 30 recommend pharmacy best practices and cost control mechanisms

- 1 that maintain high quality in prescription drug therapies but
- 2 are designed to reduce the cost of providing prescription drugs
- 3 for PACE and PACENET enrollees including:
- 4 (1) A list of covered prescription drugs with
- 5 <u>recommended copayment schedules. In developing the schedules,</u>
- 6 the department shall take into account the standards
- 7 published in the United States Pharmacopeia-Drug Information.
- 8 (2) A drug utilization review procedure, incorporating a
- 9 prescription review process for copayment schedules.
- 10 (3) A step therapy program that safely and effectively
- 11 <u>utilizes in a sequential manner the least costly</u>
- 12 <u>pharmacological therapy to treat the symptoms of or effect a</u>
- cure for the medical condition or illness for which the
- therapy is prescribed.
- 15 (4) Education programs designed to provide information
- and education on the therapeutic and cost-effective
- 17 utilization of prescription drugs to physicians, pharmacists,
- 18 certified registered nurse practitioners and other health
- 19 care professionals authorized to prescribe and dispense
- 20 <u>prescription drugs.</u>
- 21 (b) Report and recommendations. -- No later than two years
- 22 from the effective date of this section, the department shall
- 23 submit a report with recommendations to the Aging and Youth
- 24 Committee, the Appropriations Committee and the Public Health
- 25 and Welfare Committee of the Senate and the Aging and Older
- 26 Adult Services Committee, the Appropriations Committee and the
- 27 Health and Human Services Committee of the House of
- 28 Representatives. The report shall include information regarding
- 29 the efficacy of the pharmacy best practices and control
- 30 mechanisms set forth in subsection (a) including recommended

- 1 copayment schedules with impacted classes of drugs, exceptions,
- 2 cost effectiveness, improved drug utilization and therapies,
- 3 movement of market share and increased utilization of generic
- 4 drugs.
- 5 Section 6. Sections 521(d) and 522 of the act, added
- 6 November 21, 1996 (P.L.741, No.134), are amended to read:
- 7 Section 521. Penalties.
- 8 \* \* \*
- 9 (d) [Repayment of gain] Reparation. -- Any provider, recipient
- 10 or other person who is found guilty of a crime for violating
- 11 this chapter shall repay three times the value of the material
- 12 gain received. In addition to the civil penalty authorized
- 13 pursuant to subsection (b), the department may require the
- 14 provider, recipient or other person to repay up to three times
- 15 the value of any material gain to PACE or PACENET.
- 16 Section 522. Prescription drug education program.
- 17 The department, in cooperation with the Department of Health,
- 18 shall develop and implement a Statewide prescription drug
- 19 education program designed to inform older adults of the dangers
- 20 of prescription drug abuse and misuse. The prescription drug
- 21 education program shall include, but not be limited to,
- 22 information concerning the following:
- 23 (1) The hazards of prescription drug overdose.
- 24 (2) The potential dangers of mixing prescription drugs.
- 25 (3) The danger of retaining unused prescription drugs
- after the need to take them no longer exists.
- 27 (4) The necessity to carefully question physicians,
- 28 certified registered nurse practitioners and pharmacists
- 29 concerning the effects of taking prescription drugs,
- including the differences between brand-name drugs and

- 1 generically equivalent drugs.
- 2 (5) The advisability of maintaining a prescription drug
- 3 profile or other record of prescription drug dosage and
- 4 frequency of dosage.
- 5 (6) The desirability of advising family members of the
- 6 types and proper dosage of prescription drugs which are being
- 7 taken.
- 8 (7) The dangers of taking prescription drugs in excess
- 9 of prescribed dosages.
- 10 (8) The need to obtain complete, detailed directions
- from the physician, certified registered nurse practitioner
- or pharmacist concerning the time period a prescription drug
- 13 should be taken.
- 14 Section 7. The definition of "provider" in section 702 of
- 15 the act, added November 21, 1996 (P.L.741, No.134), is amended
- 16 and the section is amended by adding a definition to read:
- 17 Section 702. Definitions.
- 18 The following words and phrases when used in this chapter
- 19 shall have the meanings given to them in this section unless the
- 20 context clearly indicates otherwise:
- 21 \* \* \*
- 22 "Best price." The lowest price available from the
- 23 manufacturer during the rebate period to any wholesaler,
- 24 retailer, provider, health maintenance organization, nonprofit
- 25 entity or any governmental entity subject to the exclusions and
- 26 special rules set forth in sections 1902 and 1927(c)(1)(C) of
- 27 the Social Security Act (49 Stat. 620, 42 U.S.C. §§1396c, 1396r-
- 28 8(c)(1)(C).
- 29 \* \* \*
- 30 "Provider." A licensed pharmacy [or], dispensing physician

- 1 or certified registered nurse practitioner enrolled as a
- 2 provider in PACE, PACENET or designated pharmaceutical programs.
- 3 \* \* \*
- 4 Section 8. Sections 703(e) and 704(c)(1) of the act, added <-
- 5 November 21, 1996 (P.L.741, No.134), are amended to read:
- 6 Section 703. Rebate agreement.
- 7 \* \* \*
- 8 (e) Drug formulary. Except as provided in section 512,
- 9 there shall be no drug formulary[, prior or retroactive approval
- 10 system or any similar restriction] imposed on the coverage of
- 11 outpatient drugs made by manufacturers who have agreements in
- 12 effect with the Commonwealth to pay rebates for drugs utilized
- 13 in PACE and PACENET, provided that such outpatient drugs were
- 14 approved for marketing by the Food and Drug Administration. This
- 15 subsection shall not apply to any act taken by the department
- 16 pursuant to its therapeutic drug utilization review program
- 17 under section 505.
- 18 SECTION 8. SECTION 704(C)(1) OF THE ACT, ADDED NOVEMBER 21, <---
- 19 1996 (P.L.741, NO.134), IS AMENDED TO READ:
- 20 Section 704. Terms of rebate agreement.
- 21 \* \* \*
- 22 (c) Manufacturer provision of price information. --
- 23 (1) Each manufacturer with an agreement in effect under
- 24 this chapter shall report the average manufacturer price and
- 25 <u>the best price</u> for all covered prescription drugs produced by
- that manufacturer to the department not later than 30 days
- after the last day of each quarter.
- 28 \* \* \*
- 29 Section 9. Section 705(a) and (c) of the act, added November
- 30 21, 1996, (P.L.741, No.134), are amended and the section is

- 1 amended by adding a subsection to read:
- 2 Section 705. Amount of rebate.
- 3 (a) Single-source drugs and innovator multiple-source
- 4 drugs. -- With respect to single-source drugs and innovator
- 5 multiple-source drugs, each manufacturer shall remit a rebate to
- 6 the Commonwealth. Except as otherwise provided in this section,
- 7 the amount of the rebate to the Commonwealth per calendar
- 8 quarter with respect to each dosage form and strength of single-
- 9 source drugs and innovator multiple-source drugs shall be as
- 10 follows:
- 11 (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
- 14 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.
- 18 (2) For quarters beginning after December 31, 1996, and
- 19 ending before January 1, 2003, the product of the total
- 20 number of units of each dosage form and strength reimbursed
- 21 by PACE, PACENET and designated pharmaceutical programs in
- 22 the quarter and the difference between the average
- 23 manufacturer price and 83% of that price, after deducting
- 24 customary prompt payment discounts.
- 25 (3) For quarters beginning after December 31, 2002, each
- 26 <u>manufacturer shall remit a rebate to the Commonwealth for the</u>
- 27 total number of units of each dosage form and strength
- reimbursed by PACE, PACENET and designated pharmaceutical
- 29 programs in the quarter pursuant to the determination
- established by section 1927(c)(1) of the Social Security Act

(49 Stat. 620, 42 U.S.C. § 1396r-8(c)(1)). 1 \* \* \* 2 3 (c) Revised rebate for other drugs. -- Beginning after 4 December 31, 1996, and ending before January 1, 2004, all of the 5 following shall apply: The amount of the rebate to the Commonwealth for a 6 (1)7 calendar quarter with respect to covered prescription drugs 8 which are noninnovator multiple-source drugs shall be the 9 greater of the product of: 10 (i) The applicable percentage of the average 11 manufacturer price, after deducting customary prompt payment discounts, for each dosage form and strength of 12 13 such drugs for the quarter; and (ii) the number of units of such form and dosage 14 15 reimbursed by PACE, PACENET and designated pharmaceutical 16 programs in the quarter. 17 (2) For purposes of paragraph (1), the applicable 18 percentage is 17%. (c.1) Rebates for other drugs for quarters beginning after 19 20 December 31, 2003.--For quarters beginning after December 31, 2003, all of the following shall apply: 21 22 (1) the amount of the rebate to the Commonwealth for a 23 calendar quarter with respect to covered prescription drugs 24 which are noninnovator multiple-source drugs shall be equal 25 to the product of: 26 (i) the applicable percentage of the average 27 manufacturer price, after deducting customary prompt 28 payment discounts, for each dosage form and strength of 29 such drugs for the quarter; and (ii) the number of units of such form and dosage 30

- reimbursed by PACE, PACENET and designated pharmaceutical
- 2 <u>programs in the quarter.</u>
- 3 (2) For purposes of paragraph (1), the applicable
- 4 percentage is 14%.
- 5 \* \* \* \*
- 6 Section 10. The act is amended by adding a chapter to read:
- 7 CHAPTER 8
- 8 PHARMACEUTICAL ASSISTANCE CLEARINGHOUSE
- 9 Section 801. Definitions.
- 10 The following words and phrases when used in this chapter
- 11 shall have the meanings given to them in this section unless the
- 12 <u>context clearly indicates otherwise:</u>
- 13 <u>"Clearinghouse." The Pharmaceutical Assistance Clearinghouse</u>
- 14 established in section 802.
- 15 "Department." The Department of Aging of the Commonwealth.
- 16 <u>"Patient assistance program." A program offered by a</u>
- 17 pharmaceutical manufacturer under which the manufacturer
- 18 provides prescription medications at no charge or at a
- 19 substantially reduced cost. The term does not include the
- 20 provision of a drug as part of a clinical trial.
- 21 <u>"Voluntary health organization." An organization whose main</u>
- 22 purpose is to educate the public on the symptoms, treatments and
- 23 research of a disease and that may provide support for persons
- 24 who have the disease.
- 25 Section 802. Pharmaceutical Assistance Clearinghouse.
- 26 (a) Establishment. -- Within 120 days of the effective date of
- 27 this chapter, the department shall establish the Pharmaceutical
- 28 Assistance Clearinghouse. Each pharmaceutical manufacturer that
- 29 <u>does business in this Commonwealth and offers a patient</u>
- 30 <u>assistance program shall inform the department of all of the</u>

- 1 following:
- 2 (1) The existence of the patient assistance program.
- 3 (2) The eligibility requirements for the patient
- 4 <u>assistance program.</u>
- 5 (3) The drugs covered by the patient assistance program.
- 6 (4) Information, such as a telephone number, which may
- 7 <u>be used to apply for a patient assistance program.</u>
- 8 (b) Information. -- The clearinghouse shall maintain the
- 9 <u>information submitted by pharmaceutical manufacturers and any</u>
- 10 appropriate voluntary health organization that would like to
- 11 participate and make it available to the public.
- 12 (c) Staff.--The department shall ensure that the
- 13 <u>clearinghouse is staffed at least during normal business hours.</u>
- 14 <u>Section 803. Toll-free telephone number.</u>
- The department shall establish a toll-free telephone number
- 16 through which members of the public may obtain information from
- 17 the clearinghouse about available patient assistance programs.
- 18 Section 804. Assistance available.
- 19 (a) Direct.--
- 20 (1) The clearinghouse shall assist without charge an
- 21 <u>individual in determining whether a patient assistance</u>
- 22 program is offered for a particular drug and whether the
- 23 individual may be eligible to obtain the drug through a
- 24 <u>patient assistance program.</u>
- 25 (2) The clearinghouse may assist without charge an
- 26 individual who wishes to apply for a patient assistance
- 27 program by assisting with the preparation of an application
- 28 and coordinating communications between the individual's
- 29 <u>physician or certified registered nurse practitioner and a</u>
- 30 pharmaceutical manufacturer on behalf of the individual for

- 1 the purpose of obtaining approval to participate in the
- patient assistance program.
- 3 (b) Referrals.--The clearinghouse shall make referrals to an
- 4 appropriate voluntary health organization or any publicly funded
- 5 program for which it deems a patient eligible.
- 6 <u>Section 805</u>. <u>Reporting</u>.
- 7 The department shall report annually to the Governor and the
- 8 General Assembly on the activities of the clearinghouse. The
- 9 <u>report shall include:</u>
- 10 (1) The number of individuals who have been assisted by
- the clearinghouse under section 804(a)(1) and the number of
- such individuals under section 804(a)(2).
- 13 (2) The number and benefits of patient assistance
- programs listed with the clearinghouse.
- 15 (3) The number of patients referred to publicly funded
- programs under section 804(b). Programs under this paragraph
- 17 include, but are not limited to, the Pharmaceutical
- 18 Assistance Contract for the Elderly Program, medical
- 19 assistance and programs of the Department of Veterans
- 20 Affairs.
- 21 (4) Other information deemed relevant by the department.
- 22 Section 806. Internet availability of information.
- 23 The department shall maintain and provide to the public the
- 24 <u>information under this chapter on its World Wide Web site. The</u>
- 25 <u>department shall also provide to appropriate organizations the</u>
- 26 <u>information necessary for the organizations to establish a link</u>
- 27 to the location of clearinghouse information on the department's
- 28 World Wide Web site.
- Section 11. Section 2102(a) of the act, added November 21,
- 30 1996 (P.L.741, No.134), is amended to read:

- 1 Section 2102. Annual report to General Assembly.
- 2 (a) Submission of report. -- The department shall submit a
- 3 report no later than April 1 of each year to the chairman and
- 4 minority chairman of the Aging and Youth Committee of the
- 5 Senate, the chairman and minority chairman of the Aging and
- 6 [Youth] Older Adult Services Committee of the House of
- 7 Representatives and the Pharmaceutical Assistance Review Board.
- 8 \* \* \*
- 9 Section 12. The act is amended by adding a section to read:
- 10 <u>Section 2103</u>. <u>Federal programs</u>.
- 11 If the Federal Government enacts programs similar to PACE or
- 12 PACENET, the State programs shall be construed to only
- 13 <u>supplement the Federal programs and all persons qualified for</u>
- 14 coverage under the Federal program shall utilize that Federal
- 15 program before utilizing any State program.
- 16 Section 13. Funding, to the extent authorized by section
- 17 306(b)(vii) of the act of June 26, 2001 (P.L.755, No.77), known
- 18 as the Tobacco Settlement Act, shall continue to be appropriated
- 19 from the Tobacco Settlement Fund to the Pharmaceutical
- 20 Assistance Contract for the Elderly Fund to support the program
- 21 expansions contained in this act.
- 22 Section 14. The Department of Aging may use a PACE or
- 23 PACENET program applicant's most recent annual income
- 24 information to determine program eligibility until April 1,
- 25 2004.
- 26 Section 15. The amendment of section 704(c)(1) of the act
- 27 shall apply retroactively to January 1, 2003.
- 28 Section 16. This act shall take effect as follows:
- 29 (1) The following provisions shall take effect January
- 30 1, 2004:

- 1 (i) The amendment or addition of the definitions of 2 "CMS," "HFCA" and "maximum annual income" in section 502 of the act. 3
- (ii) The amendment of section 519 of the act. 4
- 5 (2) The addition of section 509(8) of the act shall take effect January 1, 2005. 6
- 7 (3) The remainder of this act shall take effect 8 immediately.