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THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 1188 Session of 2006

INTRODUCED BY VANCE, BROWNE, ORIE, ARMSTRONG, BOSCOLA, CONTI, CORMAN, COSTA, EARLL, ERICKSON, FONTANA, GORDNER, GREENLEAF, JUBELIRER, KITCHEN, LAVALLE, LOGAN, MADIGAN, MELLOW, MUSTO, O'PAKE, PILEGGI, PIPPY, RAFFERTY, REGOLA, RHOADES, SCARNATI, STACK, WAUGH, WENGER, D. WHITE, M. WHITE, C. WILLIAMS, WONDERLING AND WOZNIAK, APRIL 17, 2006

REFERRED TO AGING AND YOUTH, APRIL 17, 2006

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 definitions, for physician, certified registered nurse practitioner and pharmacy participation, for reduced assistance, for program generally, for restricted formulary, for reimbursement, for income verification, for contracts and for the pharmaceutical assistance contract for the elderly needs enhancement tier, for pharmacy best practices and cost controls review; further providing for penalties; establishing the coordination of Federal and State benefits; and making editorial changes.

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

Section 1. Chapter 5 of the act of August 26, 1971 (P.L.351, No.91), known as the State Lottery Law, is amended by adding a subchapter heading to read:

SUBCHAPTER A

PRELIMINARY PROVISIONS

Section 1.1. The definitions of "eligible claimant," "maximum annual income" and "program" in section 502 of the act, amended or added November 21, 1996 (P.L.741, No.134) and November 26, 2003 (P.L.212, No.37), are amended and the section is amended by adding definitions to read:

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:

* * *

"Claimant." An eligible person who is enrolled in the program.

* * *

"Eligible [claimant] person." A resident of the Commonwealth for no less than 90 days, who is 65 years of age [and over] or older, 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.

* * *

"Maximum annual income." For PACE eligibility, the term shall mean annual income which shall not exceed $14,500 in the case of single persons nor $17,700 in the case of the combined annual income of persons married to each other. For PACENET eligibility, the term shall mean the annual income limits established under section 519. Persons may, in reporting income to the Department of Aging, round the amount of each source of income and the income total to the nearest whole dollar, whereby any amount which is less than 50ç is eliminated.

"Medicare advantage." A plan of health benefits coverage

offered under a policy, contract or plan by an organization certified under 42 U.S.C. § 1395w-26 (relating to establishment of standards) and formerly referred to as Medicare+Choice.

* * *

"Part D." A Federal program to offer voluntary prescription drug benefits to Medicare enrollees, as set forth in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173, 117 Stat. 2066).

"Part D plan" or "PDP." A prescription drug plan approved under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173, 117 Stat. 2066) in the PDP region that includes this Commonwealth, and approved by the Department of Aging of the Commonwealth and the Centers for Medicare and Medicaid Services of the United States for coordination of benefits with the programs established under this chapter.

* * *

"Program." The Pharmaceutical Assistance Contract for the Elderly (PACE) and the Pharmaceutical Assistance Contract for the Elderly Needs Enhancement Tier (PACENET) as established by this chapter[, unless otherwise specified].

* * *

"Regional benchmark premium." The average Part D premium calculated annually by the Centers for Medicare and Medicaid Services of the United States for PDPs in the PDP region that includes this Commonwealth.

Section 1.2. Chapter 5 of the act is amended by adding a subchapter heading to read:

SUBCHAPTER B

PROGRAMS

Section 2. Section 504 of the act, amended November 26, 2003 (P.L.212, No.37), is amended to read:

Section 504. Physician, certified registered nurse practitioner and pharmacy participation.

Any physician, certified registered nurse practitioner, pharmacist, pharmacy or corporation owned in whole or in part by a physician, certified registered nurse practitioner 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 or certified registered nurse practitioner precluded or excluded from the Department of Public Welfare's Medical Assistance Program shall have claims resulting from prescriptions paid for by the program.

Section 3. Section 506 of the act, added November 21, 1996 (P.L.741, No.134), is amended to read:

Section 506. Reduced assistance.

Any [eligible] claimant whose prescription drug costs are covered in part by any other plan of assistance or insurance, including Part D, may be required to receive reduced assistance under the provisions of this [chapter] subchapter or be subject to coordination of benefits under this chapter.

Section 4. Section 509 of the act, amended November 26, 2003 (P.L.212, No.37), is amended to read:

Section 509. Program generally.

The program shall include the following:

(1) Participating pharmacies shall 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] Claimants 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) PACE shall include participant copayment schedules for each prescription, including a copayment for generic or multiple-source drugs that is less than the copayment for single-source drugs. The department shall annually calculate the copayment schedules based on the Prescription Drugs and Medical Supplies Consumer Price Index. When the aggregate impact of the Prescription Drugs and Medical Supplies Consumer Price Index equals or exceeds $1, the department shall adjust the copayment schedules. Each copayment schedule shall not be increased by more than $1 in a calendar year.

(6) The program payment shall be the lower of the following amounts determined as follows:

(i) 90% of the average wholesale cost of the prescription drug dispensed:

(A) with the addition of a dispensing fee of the greater of:

(I) $4; or

(II) the amount set by the department by regulation;

(B) the subtraction of the copayment; and

(C) if required, the subtraction of the generic differential; or

(ii) the pharmacy's usual charge for the drug dispensed with the subtraction of the copayment and, if required, the subtraction of the generic differential; or

(iii) if a generic drug, the most current Federal upper payment limits established in the Medicaid Program under 42 CFR § 447.332 (relating to upper limits for multiple source drugs), plus a dispensing fee of $4 or the amount set by the department by regulation, whichever is greater minus the copayment. The department shall update the average wholesale costs and the Federal upper payment limits at least every 30 days.

(7) In no case shall the Commonwealth or any [person enrolled in the program] claimant be charged more than the price of the drug at the particular pharmacy on the date of the sale.

(8) The Governor may, based upon certified State Lottery Fund revenue that is provided to both the chairman and minority chairman of the Appropriations Committee of the Senate and the chairman and minority chairman of the Appropriations Committee of the House of Representatives, and after consultation with the board, decrease the eligibility limits established in this [chapter] subchapter.

Section 5. Section 510 of the act, amended or added November 21, 1996 (P.L.741, No.134) and November 30, 2004 (P.L.1722, No.219), is amended to read:

Section 510. Generic drugs.

(a) In general.--Notwithstanding any other statute or regulation, a brand name product shall be dispensed and not

substituted with an A-rated generic therapeutically equivalent drug if it is less expensive to the program. If a less expensive A-rated generic therapeutically equivalent drug is available for dispensing to a claimant, the provider shall dispense the A-rated generic therapeutically equivalent drug to the claimant. The department shall reimburse providers based upon the most current listing of Federal upper payment limits established in the Medicaid Program under 42 CFR § 447.332 (relating to upper limits for multiple source drugs), plus a dispensing fee as set forth in section 509(6). The department shall update the average wholesale costs and the Federal upper payment limits on a regular basis, at least every 30 days. The department shall not reimburse providers for brand name products except in the following circumstances:

(1) There is no A-rated generic therapeutically equivalent drug available on the market. This paragraph does not apply to the lack of availability of an A-rated generic therapeutically equivalent drug in the providing pharmacy unless it can be shown to the department that the provider made reasonable attempts to obtain the A-rated generic therapeutically equivalent drug or that there was an unforeseeable demand and depletion of the supply of the A-rated generic therapeutically equivalent drug. In either case, the department shall reimburse the provider for 90% of the average wholesale cost plus a dispensing fee based on the least expensive A-rated generic therapeutically equivalent drug for the brand drug dispensed.

(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.

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

(5) The brand name drug is less expensive to the program.

(b) Generic not accepted.--If a claimant chooses not to accept the A-rated generic therapeutically equivalent drug required by subsection (a), the claimant shall be liable for the copayment and 70% of the average wholesale cost of the brand name drug.

(c) Generic drugs not deemed incorrect substitution.--The dispensing of an A-rated generic therapeutically equivalent drug in accordance with this [chapter] <u>subchapter</u> shall not be deemed incorrect substitution under section 6(a) of the Generic Equivalent Drug Law.

(d) Medical exception.--A medical exception process shall be

established by the department, which shall be published as a notice in the Pennsylvania Bulletin and distributed to providers and recipients in the program.

Section 6. Sections 512 and 515 of the act, amended November 26, 2003 (P.L.212, No.37), are amended to read:

Section 512. Restricted formulary.

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 CMS. 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 or certified registered nurse practitioner, 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] subchapter.

Section 515. Reimbursement.

For-profit third-party insurers, health maintenance organizations, preferred provider organizations [and], not-for-profit prescription plans, Medicare advantage plans and PDPs shall be responsible for any payments made to a providing pharmacy on behalf of a claimant covered by such a third party. Final determination as to the existence of third-party coverage shall be the responsibility of the department.

Section 7. Sections 517 and 518 of the act, added November 21, 1996 (P.L.741, No.134), are amended to read:

Section 517. Income verification.

(a) Procedure.--The department shall annually verify the income of [eligible] claimants. The department shall verify the income of [eligible] claimants by requiring income documentation from the claimants. An application for benefits under this [chapter] subchapter shall constitute a waiver to the department of all relevant confidentiality requirements relating to the claimant's Pennsylvania State income tax information in the possession of the Department of Revenue. The Department of Revenue shall provide the department with the necessary income information shown on the claimant's Pennsylvania State income tax return solely for income verification purposes.

(b) Information confidential.--It shall be unlawful for any officer, agent or employee of the department to divulge or make known in any manner whatsoever any information gained through access to the Department of Revenue information except for official income verification purposes under this [chapter] subchapter or as authorized under section 534.

(c) Penalty.--A person who violates this [act] section commits a misdemeanor and shall, upon conviction, be sentenced to pay a fine of not more than $1,000 or to imprisonment for not more than one year, or both, together with the cost of prosecution, and, if the offender is an officer or employee of the Commonwealth, he shall be dismissed from office or discharged from employment.

(d) Coordination with Department of Public Welfare.--To the extent possible, the department and the Department of Public Welfare shall coordinate efforts to facilitate the application and enrollment of eligible older people in the Medicaid Healthy Horizons Program by processing these applications at senior citizens centers and other appropriate facilities providing

services to the elderly.

Section 518. Contract.

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

Section 8. Section 519 of the act, amended November 26, 2003 (P.L.212, No.37), is amended to read:

Section 519. The Pharmaceutical Assistance Contract for the Elderly Needs Enhancement Tier.

(a) Establishment.--There is hereby established within the department a program to be known as the Pharmaceutical Assistance Contract for the Elderly Needs Enhancement Tier [(PACENET)].

(b) PACENET eligibility.--A [claimant] person with an annual income of not less than $14,500 and not more than $23,500 in the case of a single person and of not less than $17,700 and not more than $31,500 in the case of the combined income of persons married to each other shall be eligible for enhanced pharmaceutical assistance under this section. A person may, in reporting income to the department, round the amount of each source of income and the income total to the nearest whole dollar, whereby any amount which is less than 50ç is eliminated.

[(c) Deductible.--Upon enrollment in PACENET, eligible claimants in the income ranges set forth in subsection (b) shall be required to meet a deductible in unreimbursed prescription drug expenses of $40 per person per month. The $40 monthly deductible shall be cumulative and shall be applied to subsequent months to determine eligibility. The cumulative

deductible shall be determined on an enrollment year basis for an annual total deductible not to exceed $480 in a year. To qualify for the deductible set forth in this subsection the prescription drug must be purchased for the use of the eligible claimant from a provider as defined in this chapter. The department, after consultation with the board, may approve an adjustment in the deductible on an annual basis.]

(c.1) Premium.--In those instances in which a PACENET claimant does not enroll in Part D, the claimant shall be required to pay a monthly premium equivalent to the regional benchmark premium.

(d) Copayment.--

(1) For [eligible] claimants under this section, the copayment schedule shall be:

(i) eight dollars for noninnovator multiple source drugs as defined in section 702; or

(ii) fifteen dollars for single-source drugs and innovator multiple-source drugs as defined in section 702.

(2) The department shall annually calculate the copayment schedules based on the Prescription Drugs and Medical Supplies Consumer Price Index. When the aggregate impact of the Prescription Drugs and Medical Supplies Consumer Price Index equals or exceeds $1, the department shall adjust the copayment schedules. Each copayment schedule shall not be increased by more than $1 in a calendar year.

Section 9. Section 520.1 of the act, added November 26, 2003 (P.L.212, No.37), is amended to read:

[Section 520.1. Pharmacy best practices and cost controls review.

(a) Review process.--The secretary shall review and recommend pharmacy best practices and cost control mechanisms that maintain high quality in prescription drug therapies but are designed to reduce the cost of providing prescription drugs for PACE and PACENET enrollees, including:

(1) A list of covered prescription drugs with recommended copayment schedules. In developing the schedules, the department shall take into account the standards published in the United States Pharmacopeia Drug Information.

(2) A drug utilization review procedure, incorporating a prescription review process for copayment schedules.

(3) A step therapy program that safely and effectively utilizes in a sequential manner the least costly pharmacological therapy to treat the symptoms of or effect a cure for the medical condition or illness for which the therapy is prescribed.

(4) Education programs designed to provide information and education on the therapeutic and cost-effective utilization of prescription drugs to physicians, pharmacists, certified registered nurse practitioners and other health care professionals authorized to prescribe and dispense prescription drugs.

(b) Report and recommendations.--No later than two years from the effective date of this section, the department shall submit a report with recommendations to the Aging and Youth Committee, the Appropriations Committee and the Public Health and Welfare Committee of the Senate and the Aging and Older Adult Services Committee, the Appropriations Committee and the Health and Human Services Committee of the House of Representatives. The report shall include information regarding

the efficacy of the pharmacy best practices and control mechanisms set forth in subsection (a), including recommended copayment schedules with impacted classes of drugs, exceptions, cost effectiveness, improved drug utilization and therapies, movement of market share and increased utilization of generic drugs.]

Section 10. Section 521 of the act, amended or added November 21, 1996 (P.L.741, No.134) and November 26, 2003 (P.L.212, No.37), is amended to read:

Section 521. Penalties.

(a) Prohibited acts.--It shall be unlawful for any person to submit a false or fraudulent claim or application under this [chapter] subchapter, including, but not limited to:

(1) aiding or abetting another in the submission of a false or fraudulent claim or application;

(2) receiving benefits or reimbursement under a private, Federal or State program for prescription assistance and claiming or receiving duplicative benefits hereunder;

(3) soliciting, receiving, offering or paying 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] subchapter;

(4) engaging in a pattern of submitting claims that repeatedly uses incorrect National Drug Code numbers [for the purpose of obtaining wrongful enhanced reimbursement]; or

(5) otherwise violating any provision of this [chapter] subchapter.

(b) Civil penalty.--In addition to any appropriate criminal penalty for prohibited acts under this [chapter] subchapter whether or not that act constitutes a crime under 18 Pa.C.S.

(relating to crimes and offenses), a provider who violates this section may be liable for a civil penalty in an amount not less than $500 and not more than $10,000 for each violation of this act which shall be collected by the department. Each violation constitutes a separate offense. If the department collects three or more civil penalties against the same provider, the provider shall be ineligible to participate in either PACE or PACENET for a period of one year. If more than three civil penalties are collected from any provider, the department may determine that the provider is permanently ineligible to participate in PACE or PACENET.

(c) Suspension of license.--The license of any provider who has been found guilty under this [chapter] subchapter shall be suspended for a period of one year. The license of any provider who has committed three or more violations of this [chapter] subchapter may be suspended for a period of one year.

(d) Reparation.--Any provider, [recipient] claimant or other person who is found guilty of a crime for violating this [chapter] subchapter shall repay three times the value of the material gain received. In addition to the civil penalty authorized pursuant to subsection (b), the department may require the provider, [recipient] claimant or other person to repay up to three times the value of any material gain to PACE or PACENET.

Section 11. Chapter 5 of the act is amended by adding a subchapter to read:

SUBCHAPTER C

COORDINATION OF FEDERAL AND STATE BENEFITS

Section 531. Definitions.

The following words and phrases when used in this subchapter

shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"LIS." Low-income subsidy assistance from Part D provided by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173, 117 Stat. 2066) to help pay for annual premiums, deductibles and copayments charged to individuals enrolled in Part D by prescription plans approved under that act.

"Noncoverage phase." The deductible phase or the difference between Part D initial coverage and catastrophic coverage for certain Part D enrollees, as set forth in section 1860D-2 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173, 117 Stat. 2066).

"Part D eligible individual." An eligible person who is entitled to benefits under Part A of Medicare, or enrolled in Part B of Medicare, as specified in section 1860D-1 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173, 117 Stat. 2066.).

"Part D enrollee." A claimant enrolled in a Part D plan.

"Part D provider." A pharmacy or other prescription drug dispenser authorized by a Part D enrollee's Part D plan.

Section 532. Purpose.

The benefits available to a claimant enrolled in the program under Subchapter B shall be a supplement to the benefits available under Part D. The department may require claimants to utilize Part D benefits prior to utilizing benefits provided under either program and shall coordinate the benefits of the programs with those provided under Part D.

Section 533. Coordination of benefits.

(a) General coordination.--In addition to the specific

provisions of subsection (b), the department shall establish standards and minimum requirements it deems necessary to allow for the coordination of benefits between the program and Part D.

(b) Specific coordination provisions.--The following provisions shall apply to claimants who are also Part D enrollees:

(1) The primary payor shall be the PDP.

(2) Part D enrollees shall be required to utilize providers authorized by their PDPs.

(3) The program shall pay the premium assessed by a PACE enrollee's PDP in an amount not to exceed the regional benchmark premium and any copayments in excess of those set forth in section 509.

(4) Part D enrollees enrolled in PACENET shall pay the Part D premiums charged by their PDP and the program shall pay any copayments in excess of those set forth in section 519.

(5) For Part D enrollees enrolled in PACE who are not eligible for LIS, PACE shall reimburse Part D providers for prescription drugs in any noncoverage phase of Part D. For Part D enrollees enrolled in PACENET, PACENET shall reimburse Part D providers for prescription drugs in any noncoverage phase of Part D.

(6) The provisions of Chapter 7 shall apply to all payments made by the program in the noncoverage phase.

(7) The department shall advise a claimant on the various benefits and drugs provided by each PDP approved by the department as follows:

(i) Analyze the claimant's eligibility for and assist the claimant in applying for LIS.

(ii) Identify the claimant's prescription drug needs and preferred pharmacy.

(iii) Assist the claimant in enrolling in the PDP that best fits the claimant's prescription drug needs.

(iv) File and pursue appeals with the claimant's PDP to convert noncovered drugs to covered drugs or nonpreferred brand drugs to preferred drugs.

(c) Contracts.--The department is authorized to enter into contracts with Part D plans to provide for prescription drugs to Part D enrollees through Part D pursuant to this subchapter. In selecting Part D plans, the department shall consider all of the following:

(1) The extensiveness of the prescription drugs covered by the PDP.

(2) The adequacy of the PDP pharmacy network.

(3) The cost to claimants and the Commonwealth.

Section 534. Application for low-income subsidy.

(a) Procedure.--The department may obtain information on the financial resources of a Part D eligible individual for the purpose of determining the individual's potential eligibility for the LIS and assisting the individual in making an application to the Social Security Administration for qualification under the LIS. The authority granted under this subsection shall be exercised only with respect to a Part D eligible individual who has income which is below the applicable threshold established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173, 117 Stat. 2066) for qualification under the LIS.

(b) Waiver.--An application by a Part D eligible individual for enrollment in the program shall constitute a waiver to the

department of relevant confidentiality requirements relating to the prospective claimant's financial resources in the possession of any Commonwealth agency or third party when the information is required for the purposes listed under subsection (a). This waiver shall extend to the application phase and throughout the entire time the claimant is in the program.

(c) Information confidential.--

(1) It shall be unlawful for an officer, agent or employee of the department to divulge or make known information obtained from a Commonwealth agency or third party except for the purposes under subsection (a).

(2) A person that violates this subsection commits a misdemeanor of the third degree and shall, upon conviction, be sentenced to pay a fine of not more than $1,000 or to imprisonment for not more than one year, or both, and to pay the cost of prosecution. If the offender is an officer or employee of the Commonwealth, the offender shall be dismissed from office or discharged from employment.

Section 535. Reimbursement.

For-profit insurers, health maintenance organizations, preferred provider organizations, not-for-profit prescription plans, Medicare Advantage plans and PDPs shall be responsible for any payments made to a pharmacy on behalf of a Part D enrollee covered by any such third party. Final determination as to the existence of third-party coverage shall be the responsibility of the department.

Section 12. Section 2103 of the act, added November 26, 2003 (P.L.212, No.37), is amended to read:

Section 2103. Federal programs.

If the Federal Government enacts pharmacy programs similar to

PACE or PACENET, the State programs shall be construed to only supplement the Federal pharmacy programs.[, and all] All persons qualified for coverage under [the] a Federal pharmacy program [shall], including the prescription drug benefit program provided by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173, 117 Stat. 2066), may be required by the department to utilize [that] the Federal program before utilizing any State program.

Section 13. This act shall take effect immediately.