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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 888 Session of 2003

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AS REPORTED FROM COMMITTEE ON HEALTH AND HUMAN SERVICES, HOUSE OF REPRESENTATIVES, AS AMENDED, JUNE 2, 2003

AN ACT

Providing for pharmaceutical assistance for the elderly, for pharmaceutical purchasing, for limited prescription drug redistribution within certain health care facilities~~, for pharmaceutical practices and cost control program~~ and for the Pharmaceutical Assistance Clearinghouse; imposing additional powers and duties on the Department of Aging, the Department of Health, the Department of Public Welfare and the Secretary of Administration; and making repeals. <—

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

CHAPTER 1

PRELIMINARY PROVISIONS

Section 101. Short title.

This act shall be known and may be cited as the Pharmaceutical Reform Act.

CHAPTER 3

PHARMACEUTICAL MATTERS

SUBCHAPTER A

PHARMACEUTICAL ASSISTANCE FOR THE ELDERLY

Section 301. Legislative findings.

Finding that an increasing number of this Commonwealth's elderly citizens who are living on fixed incomes are experiencing difficulties in meeting the costs of life-sustaining prescription drugs, the General Assembly, in its responsibilities to provide for the health, welfare and safety of the residents of this Commonwealth, hereby continues a limited State pharmaceutical assistance program for the elderly.

Section 302. 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:

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

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

"Average wholesale price." Average wholesale cost.

"Board." The Pharmaceutical Assistance Review Board.

"CMS." Center for Medicare and Medicaid Services.

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

"Eligible claimant." A resident of this Commonwealth for no less than 90 days, who is 65 years of age and 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.

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

"Income." All income from whatever source derived, including, but not limited to, salaries, wages, bonuses, commissions, income from self-employment, alimony, support money, cash public assistance and relief, the gross amount of any pensions or annuities, including railroad retirement

benefits, all benefits received under the Social Security Act (49 Stat. 620, 42 U.S.C. § 301 et seq.) except Medicare benefits, all benefits received under State unemployment insurance laws and veterans' disability payments, all interest received from the Federal Government or any state government or any instrumentality or political subdivision thereof, realized capital gains, rentals, workmen's compensation and the gross amount of loss of time insurance benefits, life insurance benefits and proceeds, except the first $5,000 of the total of death benefits payments, and gifts of cash or property, other than transfers by gift between members of a household, in excess of a total value of $300, but does not include surplus food or other relief in kind supplied by a government agency or property tax rebate.

"Mail service program." A program set forth in section ~~312~~ 313 to dispense prescription drugs by postal delivery service designated and administered by the department and any entity with which it contracts, upon an enrollee's submission of a prescription and the applicable copayment. <—

"Maintenance drug." A prescription drug prescribed to an individual for a chronic condition the use of which is medically necessary for a consecutive period of at least 60 days.

"Maximum annual income." For PACE eligibility, annual income which shall not exceed ~~$14,000~~ $14,500 in the case of single persons nor ~~$17,200~~ $17,700 in the case of the combined annual income of persons married to each other. 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. <— <—

"PACE." The Pharmaceutical Assistance Contract for the

Elderly program provided for in this subchapter.

"PACENET." The Pharmaceutical Assistance Contract for the Elderly Needs Enhancement Tier provided for in this subchapter.

"Pharmacy." A pharmacy licensed by the Commonwealth.

"Prescription drug." All drugs requiring a prescription in this Commonwealth, insulin, insulin syringes and insulin needles. Experimental drugs or drugs prescribed for wrinkle removal or hair growth are prohibited.

"Private contractor." A person, partnership or corporate entity that enters into a contract with the Commonwealth to provide services under the provisions of this subchapter.

"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 subchapter, unless otherwise specified.

"Provider." A pharmacy or dispensing physician enrolled as a provider in the program.

Section 303. Determination of eligibility.

The department shall adopt regulations relating to the determination of eligibility of prospective claimants and providers, including dispensing physicians, and the determination and elimination of program abuse. To this end, the department shall establish a compliance unit staffed sufficiently to fulfill this responsibility. The department shall have the power to declare ineligible any claimant or provider who abuses or misuses the established prescription plan. The department shall have the power to investigate cases of suspected provider or recipient fraud.

Section 304. Physician and pharmacy participation.

Any physician, pharmacist, pharmacy or corporation owned in

whole or in part by a physician or pharmacist enrolled as a provider in the program or that has prescribed medication for a claimant in the program who is precluded or excluded for cause from the Department of Public Welfare's medical assistance program shall be precluded or excluded from participation in the program. No physician precluded or excluded from the Department of Public Welfare's medical assistance program shall have claims resulting from prescriptions paid for by the program.

Section 305. Drug utilization review system.

The department shall ensure that a state-of-the-art therapeutic drug utilization review system is established to monitor and correct misutilization of drug therapies.

Section 306. Reduced assistance.

Any eligible claimant whose prescription drug costs are covered in part by any other plan of assistance or insurance may be required to receive reduced assistance under the provisions of this subchapter.

Section 307. Rebates for expenses prohibited.

A system of rebates or reimbursements to the claimant for prescription drugs shall be prohibited.

Section 308. Request for proposal.

(a) General.--The department shall prepare a request for proposal for the purpose of providing pharmaceutical assistance for the elderly within this Commonwealth. Upon the adoption of the General Fund budget, the Department of Revenue shall be authorized to transmit the appropriated funds in the State Lottery Fund to the State Treasurer to be deposited in the Pharmaceutical Assistance Contract for the Elderly Fund. This fund shall consist of appropriations and interest and shall be created by the State Treasurer to fund the operations of the

program by the department and the private contractor. Funds not expended in the fiscal year in which they were appropriated shall not lapse and shall be available for use in the next fiscal year.

(b) Additional requests.--To provide for the continued operation of the program, the department shall prepare, as needed, requests for proposals, in addition to that set forth in subsection (a), for the purpose of providing pharmaceutical assistance for the elderly within this Commonwealth. A request for proposal shall require potential private contractors to submit a proposal for a period of time and with monetary limitations as determined by the department. Upon the enactment of an appropriation from the State Lottery Fund, the Department of Revenue shall be authorized to transmit the appropriated amount to the State Treasurer to be deposited in the Pharmaceutical Assistance Contract for the Elderly Fund. Funds not expended in the fiscal year in which they were appropriated shall not lapse and shall be available for use in the next fiscal year.

SECTION 309. DRUG UTILIZATION REVIEW AND THERAPEUTIC INTERCHANGE. <—

(A) DRUG UTILIZATION REVIEW.--THE DEPARTMENT SHALL ENSURE THAT A STATE-OF-THE-ART THERAPEUTIC DRUG UTILIZATION REVIEW SYSTEM IS ESTABLISHED TO MONITOR AND CORRECT MISUTILIZATION OF DRUG THERAPIES.

(B) THERAPEUTIC INTERCHANGE.--THE DEPARTMENT MAY DEVELOP A THERAPEUTIC INTERCHANGE PROGRAM BASED ON NATIONAL MEDICAL STANDARDS THAT ESTABLISH THERAPEUTICALLY EQUIVALENT DRUGS WHICH PRODUCE IDENTICAL LEVELS OF CLINICAL EFFECTIVENESS AND OUTCOMES. THE PROGRAM SHALL AUTHORIZE PHARMACY BENEFIT COVERAGE WHEN A

PATIENT'S HEALTH CARE PROVIDER PRESCRIBES A PRESCRIPTION DRUG NOT IN THE PROGRAM IF ANY OF THE FOLLOWING APPLY:

(1) THE PROGRAM DRUG:

(I) HAS NOT BEEN EFFECTIVE IN TREATING THE PATIENT'S CONDITION; OR

(II) IS NOT EXPECTED WITH REASONABLE CERTAINTY TO BE EFFECTIVE IN TREATING THE PATIENT'S CONDITION.

(2) THE PROGRAM DRUG CAUSES OR IS REASONABLY EXPECTED TO CAUSE ADVERSE OR HARMFUL REACTIONS IN THE PATIENT.

(3) OTHER CLINICAL CRITERIA APPROVED BY THE DEPARTMENT ARE COMPLIED WITH.

Section ~~309~~ 310. Program generally. <—

(a) Parameters of program.--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 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) There shall be the following copayments:~~ <—

~~(i) For generic drugs - $5.~~

~~(ii) For preferred drug list drugs - $10.~~

~~(iii) For drugs which are not on the preferred drug list - $15.~~

(5) THE COPAYMENT AMOUNT FOR GENERIC OR MULTI-SOURCE DRUGS SHALL BE LESS THAN THE COPAYMENT AMOUNT FOR SINGLE-SOURCE DRUGS. <—

(6) Payments as follows:

(i) Except as provided in subparagraph (ii), to pharmacies on behalf of eligible claimants for costs of the prescription drug in excess of the copayment as provided in subsections (b) and (c), plus a dispensing fee of $3.50 or the dispensing fee established by the department by regulation, whichever is greater.

(ii) For A-rated generic therapeutically equivalent drugs, to pharmacies on behalf of eligible claimants for the upper limits established under 42 CFR § 447.332 (relating to upper limits for multiple source drugs), plus a dispensing fee of $4 or the dispensing fee established by the department by regulations, whichever is greater.

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

(b) Multiple-source drugs.--Except for brand name drugs that are certified in accordance with subsection (d), the department payment for multiple-source drugs must not exceed the amount that would result from the application of the specific limits established in accordance with subsection (e). If a specific limit has not been established under subsection (e), then the rule for "other drugs" set forth in subsection (c) applies.

(c) Other drugs.--The department payments for brand name drugs certified in accordance with subsection (d) and drugs other than multiple-source drugs for which a specific limit has

been established under subsection (e) must not exceed in the aggregate payment levels that the department has determined by applying the lower of the:

(1) Estimated acquisition costs plus reasonable dispensing fees established by the department.

(2) Providers' usual and customary charges to the general public.

(d) Certification of brand-name drugs.--

(1) The upper limit for payments for multiple-source drugs for which a specific limit has been established under subsection (e) does not apply if a physician certifies in his or her own handwriting that a specific brand is medically necessary for a particular recipient.

(2) The department must decide what certification form and procedure are used.

(3) A checkoff box on a form is not acceptable but a notation like "brand necessary" is allowable.

(4) The department may allow providers to keep the certification forms if the forms will be available for inspection by the department.

(e) Establishment and issuance of a listing of multiple-source drugs.--

(1) The department will use the CMS listings that identify and set upper limits for multiple-source drugs that meet the following requirements:

(i) All of the formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically equivalent in the most current edition of their publication, Approved Drug Products with Therapeutic Equivalence Evaluations,

including supplements or in successor publications.

(ii) At least three suppliers list the drug, which has been classified by the FDA as category "A" in its publication, Approved Drug Products with Therapeutic Equivalence Evaluations, including supplements or in successor publications, based on all listings contained in current editions, or updates, of published compendia of cost information for drugs available for sale in this Commonwealth.

(2) The department publishes the list of multiple-source drugs for which upper limits have been established and any revisions to the list in Medicaid program instructions.

(3) The department will identify the sources used in compiling these lists.

Section ~~310~~ 311. Generic drugs. <—

(a) General.--Notwithstanding any other statute or regulation, if an A-rated generic therapeutically equivalent drug is available for dispensing to a claimant, the provider shall dispense the A-rated generic therapeutically equivalent drug to the claimant. The department shall not reimburse providers for brand name products except in the following circumstances:

(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) 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.

(3) 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.

(b) Copayment.--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) Substitution or construction.--The dispensing of an A-rated generic therapeutically equivalent drug in accordance with this subchapter 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 ~~311~~ 312. Supply. <—

(a) Requirement.--Except as set forth in subsection (b), prescription benefits for any single prescription shall be limited to a 30-day supply of the prescription drug or 100 units, whichever is less for acute conditions.

(b) Exceptions.--

(1) In the case of diagnosis for acute conditions, prescription benefits for any single prescription shall be limited to a 15-day supply.

(2) Subsection (a) shall not apply to topical ointments or gels which are not available in containers which meet the size and supply restrictions set forth in subsection (a).

(c) Subsection (a) does not apply to contracts under section ~~312(c)~~ 313(C). <—

Section ~~312~~ 313. Mail service program. <—

(a) General rule.--The department shall encourage the use of a mail service program for maintenance drugs for eligible claimants. Only mail order pharmacy services provided by pharmacies which are licensed by the Commonwealth and which have their principal place of business within this Commonwealth may participate as providers under the program.

(b) Minimum standards of practice.--The department shall develop and promulgate specific regulations governing the practice of mail order pharmacy and other enrolled providers to include the following minimum standards of practice to ensure the health, safety and welfare of program participants:

(1) The appropriate method by which pharmacies verify the identity of the eligible claimant and the authenticity of prescriptions received.

(2) The appropriate method by which pharmacies mail or deliver prescription drugs ensuring, to the maximum extent

possible, that the intended eligible claimant is the actual ultimate recipient of any prescription dispensed.

(3) The appropriate method by which pharmacies communicate with eligible claimants in emergency situations.

(c) Ninety-day supply.--The department shall negotiate mail order contracts to provide a 90-day supply of drugs to eligible claimants at a single copayment rate equal to a 30-day supply for each order.

~~(d) Requirement.--Except as set forth in subsection (e), an~~ <—

(D) OPTION.--AN eligible claimant ~~shall~~ MAY use the mail <— service program if the eligible claimant:

(1) utilizes a ~~maintenance drug~~ DRUG DEEMED BY THE <— DEPARTMENT TO BE APPROPRIATE FOR MAIL ORDER SERVICE;

(2) has filled a prescription; and

(3) has refilled the prescription under paragraph (2) at least once.

~~(e) Exception.--Subsection (d) shall not apply to an~~ <— ~~eligible claimant who submits to the department, in a form acceptable to the department, a written statement asserting the eligible claimant's right to fill prescriptions at the pharmacy chosen by the eligible claimant.~~

~~(f)~~ (E) Rebates.--A mail order contract must include a <— rebate from the prescription drug manufacturer. The rebate must be at least as much as follows:

(1) For a brand-name drug, the sum of subparagraphs (i) and (ii):

(i) A dispensing fee of at least $6.

(ii) The difference between:

(A) the average wholesale price; and

(B) 20% of that price.

(2) For a generic drug, the sum of subparagraphs (i) and (ii):

(i) A dispensing fee of at least $6.

(ii) The difference between:

(A) the average wholesale price; and

(B) 50% of that price.

~~(g)~~ (F) Negotiated payments.--The department shall not discriminate against a pharmacy that agrees to accept negotiated payment levels with the same terms and conditions and to adhere to quality standards established by the PACE and PACENET programs. <—

Section ~~313~~ 314. Indication of price. <—

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

Section ~~314~~ 315. Reimbursement. <—

(a) Indication.--The department shall indicate third-party coverage for each eligible claimant.

(b) Result.--For-profit third-party insurers and not-for-profit prescription plans shall be responsible for any payments made to a providing pharmacy on behalf of a claimant covered by such a third party.

Section ~~315~~ 316. Nonliability. <—

(a) General.--Any person rendering service as a member of a utilization review committee for this program shall not be liable for any civil damages as a result of any acts or omissions in rendering the service as a member of any such committee except any acts or omissions intentionally designed to harm or any grossly negligent acts or omissions which result in harm to the person receiving such service.

(b) Department personnel.--Any officer or employee of the department rendering service as a member of a utilization review committee for this program shall not be liable for any civil damages as a result of any acts or omissions in rendering the service as a member of any such committee or as a result of any decision or action in connection with the program except any acts or omissions intentionally designed to harm or any grossly negligent acts or omissions which result in harm to the person receiving such service.

Section ~~316~~ 317. Income verification. <—

(a) General.--The department shall annually verify the income of eligible claimants by requiring income documentation from the claimants. An application for benefits under this 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) Unlawful act.--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 subchapter.

(c) Penalty.--A person who violates this chapter 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 of effort.--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 ~~317~~ 318. Contract. <—

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

Section ~~318~~ 319. 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) Eligibility.--A claimant with an annual income of not less than ~~$17,000~~ $14,500 and not more than ~~$20,000~~ $22,450 in the case of a single person and of not less than ~~$20,001~~ $17,770 and not more than ~~$23,200~~ $30,300 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) Requirements.--Upon enrollment in PACENET, eligible

claimants in the income ranges set forth in subsection (b) shall be required to meet a monthly deductible in unreimbursed prescription drug expenses of $40 per person per month. 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 subchapter. The department, after consultation with the board, ~~may~~ SHALL approve an adjustment in the deductible on an annual basis. <—

~~(d) Copayments.--The following are the copayments:~~ <—

~~(1) For generic drugs - $6.~~

~~(2) For preferred drug list drugs - $12.~~

~~(3) For drugs which are not on the preferred drug list - $18.~~

(D) COPAYMENT.--THE COPAYMENT AMOUNT FOR GENERIC OR MULTI-SOURCE DRUGS SHALL BE LESS THAN THE COPAYMENT AMOUNT FOR SINGLE-SOURCE DRUGS. <—

Section ~~319~~ 320. Board. <—

(a) General.--The Pharmaceutical Assistance Review Board is continued to ensure that the program is providing and continues to provide the assistance intended in a fiscally responsible manner without excessively hampering the pharmacy industry.

(b) Membership.--The board shall be comprised of the following eight persons:

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

(2) The Secretary of Revenue.

(3) The Secretary of Health.

(4) Five public members, one appointed by the President pro tempore of the Senate, one appointed by the Minority Leader of the Senate, one appointed by the Speaker of the

House of Representatives, one appointed by the Minority Leader of the House of Representatives and one appointed by the Governor. Those appointed by the legislative officers shall include two senior citizens who have not been a part of the pharmacy industry to serve as consumer advocates, one representative of the pharmacy industry and one practicing Pennsylvania pharmacist. The individual appointed by the Governor must be a physician. A public member who misses two consecutive meetings without good cause acceptable to the chairman shall be replaced by the appointing authority.

(c) Annual review.--Using the annual report submitted by the department pursuant to section 2102 of the act of August 26, 1971 (P.L.351, No.91), known as the State Lottery Law, and other appropriate data sources, the board shall conduct an annual review. The board shall develop recommendations concerning any changes in the level of copayment, deductible or in the level of fees paid to participating pharmacists. The board shall review the department's therapeutic drug utilization review program on an ongoing basis. The board may also recommend other changes in the structure of the program and direct the department to enter into discussions with the private contractor concerning amendments to the contract, or the department may enter into such discussion if it deems necessary. The copayment or deductible schedule shall only be adjusted on an annual basis.

(d) Meetings.--The board shall meet at least two times per year.

Section ~~320~~ 321. Penalties. <——

(a) General.--It shall be unlawful for any person to:

(1) Submit a false or fraudulent claim or application under this subchapter, including, but not limited to:

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

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

(iii) 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 subchapter;

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

(v) otherwise violating any provision of this subchapter.

(2) Charge a copay if the amount of the copay exceeds the actual cost of the drug purchased.

(b) Civil penalty.--In addition to any appropriate criminal penalty for prohibited acts under this 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, which shall be collected by the department, in an amount not less than $500 and not more than $10,000 for each violation of this chapter. 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.--The license of any provider who has been found guilty under this subchapter shall be suspended for a period of one year. The license of any provider who has committed three or more violations of this subchapter may be suspended for a period of one year.

(d) Reparation.--Any provider, recipient or other person who is found guilty of a crime for violating this 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 or other person to repay up to three times the value of any material gain to PACE or PACENET.

Section ~~321~~ 322. Prescription Drug Education Program. <—

The department, in cooperation with the Department of Health, shall develop and implement a Statewide prescription drug education program designed to inform older adults of the dangers of prescription drug abuse and misuse. The prescription dug education program shall include, but not be limited to, information concerning the following:

(1) The hazards of prescription drug overdose.

(2) The potential dangers of mixing prescription drugs.

(3) The danger of retaining unused prescription drugs after the need to take them no longer exists.

(4) The necessity to carefully question physicians and pharmacists concerning the effects of taking prescription drugs.

(5) The advisability of maintaining a prescription drug profile or other record of prescription drug dosage and

frequency of dosage.

(6) The desirability of advising family members of the types and proper dosage of prescription drugs which are being taken.

(7) The dangers of taking prescription drugs in excess of prescribed dosages.

(8) The need to obtain complete, detailed directions from the physician or pharmacist concerning the time period a prescription drug should be taken.

Section ~~322~~ 323. Outreach program. <—

The department, in consultation with appropriate Commonwealth agencies, shall coordinate the development of an outreach plan to inform potential contractors, providers and enrollees regarding eligibility and available benefits of the PACE and PACENET programs. The plan shall include provisions for reaching special populations, including nonwhite and non-English-speaking people; for reaching different geographic areas, including rural and inner-city areas; and for assuring that special efforts are coordinated within the overall outreach activities throughout this Commonwealth.

~~Section 323. Accountability.~~ <—

~~(a) Audits.--The PACE and PACENET programs shall be subject to an audit by an independent entity at least once each fiscal year. This subsection shall include fiscal audits, provider claims audits, benefits manager administration audits and manufacturer's rebate audits.~~

~~(b) Conduct of audit.--The audit shall be conducted in accordance with generally accepted auditing standards as prescribed by the American Institute of Certified Public Accountants, the Governmental Accounting Standards Board, the~~

~~United States General Accounting Office or other professionally recognized entities that prescribe auditing standards.~~

~~(c) Access.--The auditor shall be entitled to have access to all of the books, accounts, confidential or nonconfidential reports, vouchers or other records of information in the department and its contractors including access to all electronic data. The auditor shall have access to copyrighted or restricted information obtained by the department and its contractors under subscription agreements and utilized in the preparation of economic estimates only for audit purposes.~~

~~(d) Purpose and report.--The audit shall determine the following:~~

~~(1) Whether the records, books and accounts of the department and its contractors accurately reflect the financial and fiscal operations.~~

~~(2) Whether effective accounting control over revenues, obligations, expenditures, assets and liabilities is maintained.~~

~~(3) Whether the department and its contractors have obligated, expended, received and used State funds in accordance with the purpose for which those funds have been appropriated.~~

~~(4) Whether the records, books and accounts of the department and its contractors fairly and accurately reflect the financial and fiscal operations relating to the obligation receipt, expenditure and use of State funds.~~

~~(5) Whether the department and its contractors are managing and utilizing resources, personnel, property, equipment and space in an economical and efficient manner including causes of inefficiencies or uneconomical practices,~~

~~inadequacies in management information systems, internal and administrative procedures, organizational structure, use of resources, allocation of personnel, purchasing policies and equipment.~~

~~(6) Whether financial, program and statistical reports of the department and its contractors contain useful data and are fairly presented.~~

~~(7) Whether the objectives and intended benefits are being achieved efficiently and effectively.~~

~~(8) Whether the programs are being performed and administered as authorized and required by law.~~

~~(9) Whether the benefits manager and pharmacy providers are accurately transmitting and billing PACE and PACENET prescription claims.~~

~~(e) Report.--The auditor shall submit an annual report of its findings, conclusions and recommendations to the department and its contractors and 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.~~

~~(f) Response.--The Department of Aging shall respond to the audit report within 30 days of its release.~~

~~(g) Contract.--The department shall contract for the audit as follows:~~

~~(1) The auditor shall earn a basic fee not to exceed $200,000. This fee shall be credited to the department if the auditor is compensated under paragraph (2) in the amount of at least $600,000.~~

~~(2) The auditor shall earn 30% of the funds collected by~~

~~the department as a result of the audit.~~

SUBCHAPTER B

PRUDENT PHARMACEUTICAL PURCHASING

Section 341. 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:

"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.

"Designated pharmaceutical programs." The general 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.

"PACE." The program under Subchapter A.

"PACENET." The program established under section ~~318~~ 319. <—

Section 342. Rebate agreement.

PACE, PACENET and designated pharmaceutical programs shall reimburse for any covered prescription drug with a rebate agreement drafted on the same basis as provided in section 1927 of Title XIX of the Social Security Act (49 Stat. 620, 42 U.S.C. § 1396 r-8).

Section 343. Disposition of funds.

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

(b) Pharmaceutical programs.--Money received under this subchapter 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.

~~SUBCHAPTER C~~ <—

~~PHARMACY BEST PRACTICES AND COST CONTROL PROGRAM~~

~~Section 361. 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:~~

~~"Committee." The Pharmacy Best Practices and Cost Control Advisory Committee established in section 362.~~

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

~~"Program." The Pharmacy Best Practices and Cost Control Program established in section 363.~~

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

~~§ 362. Advisory committee.~~

~~(a) Establishment.--The Pharmacy Best Practices and Cost Control Advisory Committee is established in the department.~~

~~(b) Members.--The committee is comprised of the following:~~

~~(1) The secretary or a designee, who shall serve as chairperson.~~

~~(2) Four members appointed by the Governor. Members under this paragraph must possess expertise in medicine or pharmacy.~~

~~(3) One member appointed by the President pro tempore of the Senate and one member appointed by the Minority Leader of the Senate.~~

~~(4) One member appointed by the Speaker of the House of Representatives and one member appointed by the Minority Leader of the House of Representatives.~~

~~(c) Terms.--Terms are as follows:~~

~~(1) The secretary shall serve ex officio.~~

~~(2) A member under subsection (b)(2) shall serve a term of six years.~~

~~(3) A member under subsection (b)(3) shall serve a term of four years but may be removed at the pleasure of the appointing authority.~~

~~(4) A member under subsection (b)(4) shall serve a term of two years but may be removed at the pleasure of the appointing authority.~~

~~(5) An appointment to fill a vacancy shall be for the period of the unexpired term or until a successor is appointed and qualified.~~

~~(d) Quorum.--A majority of the members of the committee constitutes a quorum.~~

~~(e) Compensation.--Members shall receive no payment for their services. Members who are not employees of State government shall be reimbursed for necessary and reasonable expenses incurred in the course of their official duties.~~

~~Section 363. Program.~~

~~(a) Establishment.--The secretary shall establish a Pharmacy Best Practices and Cost Control Program for PACE and PACENET enrollees designed to reduce the cost of providing prescription drugs, while maintaining high quality in prescription drug therapies. The program shall be implemented consistent with section 1927 of the Social Security Act (49 Stat. 620, 42 U.S.C. § 1396r-8). The program shall include all of the following:~~

~~(1) A preferred list of covered prescription drugs which identifies preferred choices within selected therapeutic classes for particular diseases and conditions, including generic alternatives. Therapeutic classes and drugs to be~~

~~preferred in the classes shall be selected by the department upon recommendations by the committee.~~

~~(2) Utilization review procedures, including a prior authorization review process which meets the requirements of section 1927(d)(5) of the Social Security Act (42 U.S.C. § 1396r-8(d)(5)).~~

~~(3) A supplemental rebate program or any other strategy designed to negotiate with pharmaceutical manufacturers to lower the cost of prescription drugs for the department's Medicaid program.~~

~~(4) Education programs, including a counterdetailing program, designed to provide information and education on the therapeutic and cost-effective utilization of prescription drugs to physicians, pharmacists and other health care professionals authorized to prescribe and dispense prescription drugs.~~

~~(5) Any other cost containment activity adopted by the department which is designed to reduce the cost of providing prescription drugs while maintaining high quality in prescription drug therapies.~~

~~(b) Pooling.--The secretary shall evaluate the benefits of participating, but is not required to participate, in joint prescription drug purchasing agreements or pooling arrangements with other states. Such actions shall include:~~

~~(1) The execution of any lawful joint purchasing or pooling agreements with other participating states which the secretary determines will lower the Medicaid cost of prescription drugs while maintaining high quality in prescription drug therapies.~~

~~(2) Renegotiation and amendment of existing contracts to~~

~~which the department is a party if renegotiation and amendment will be of economic benefit to the department.~~

~~(c) Reports.--The secretary shall report quarterly to the committee on the department's progress in securing participation in joint purchasing or pooling agreements.~~

~~(d) Authorized coverage.--The program shall authorize pharmacy benefit coverage when a patient's health care provider prescribes a prescription drug not on the preferred drug list or a prescription drug which is not the list's preferred choice under the same terms as coverage for preferred choice drugs if any of the following apply:~~

~~(1) The preferred choice has not been effective or, with reasonable certainty, is not expected to be effective in treating the patient's condition.~~

~~(2) The preferred choice causes or is reasonably expected to cause adverse or harmful reactions in the patient.~~

~~(3) Other clinical criteria recommended by the committee and approved by the department is complied with.~~

~~(4) If the prescriber does not wish substitution to take place, the prescriber shall write "brand necessary" or "no substitution" in the prescriber's own handwriting on the prescription blank, together with a written statement that the generic or therapeutic equivalent has not been effective, or with reasonable certainty is not expected to be effective, in treating the patient's medical condition or causes or is reasonably expected to cause adverse or harmful reactions in the patient. In the case of an unwritten prescription, there shall be no substitution if the prescriber expressly indicates to the pharmacist that the brand name drug is~~

~~necessary and substitution is not allowed because the generic or therapeutic equivalent has not been effective, or with reasonable certainty is not expected to be effective, in treating the patient's medical condition or causes or is reasonably expected to cause adverse or harmful reactions in the patient.~~

~~(e) Exclusions.--The department, with recommendations from the committee, shall determine diseases and therapeutic classes relating to treatment for diseases excluded from the program as to Medicaid enrollees already taking specified drugs at the time the program is implemented.~~

~~(f) Response.--The program's prescriber-indicated prior authorization process shall ensure that there will be a response to a request for prior authorization by telephone or other telecommunication device within 24 hours after receipt of the request for prior authorization and that a 72-hour supply of the drug prescribed will be provided in an emergency or when the program does not provide a response within 24 hours. The prior authorization process shall be designed to minimize administrative burdens on prescribers, pharmacists and consumers.~~

~~(g) Procedure.--The program shall establish procedures for the timely review of prescription drugs newly approved by the Food and Drug Administration, including procedures for the review of newly approved prescription drugs in emergency circumstances.~~

~~(h) Reports.--The department shall submit annual reports on the programs under subsection (a) and (b) 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 reports shall include classes of drugs, exceptions, cost effectiveness, movement of market share and increased utilization of generic drugs.~~

SUBCHAPTER ~~D~~ C <—

PHARMACEUTICAL ASSISTANCE CLEARINGHOUSE

Section ~~371~~ 361. 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:

"Clearinghouse." The Pharmaceutical Assistance Clearinghouse established in section ~~372~~ 362. <—

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

"Patient assistance program." A program offered by a pharmaceutical manufacturer under which the manufacturer provides prescription medications at no charge or at a substantially reduced cost. The term does not include the provision of a drug as part of a clinical trial.

Section ~~372~~ 362. Pharmaceutical Assistance Clearinghouse. <—

(a) Establishment.--Within 120 days of the effective date of this subchapter, the department shall establish the Pharmaceutical Assistance Clearinghouse. Each pharmaceutical manufacturer that does business in this Commonwealth and offers a patient assistance program shall inform the department of all of the following:

(1) The existence of the patient assistance program.

(2) The eligibility requirements for the patient assistance program.

(3) The drugs covered by the patient assistance program.

(4) Information, such as a telephone number, which may be used to apply for the patient assistance program.

(b) Information.--The clearinghouse shall maintain the information submitted by pharmaceutical manufacturers and make it available to the public.

(c) Staff.--The department shall ensure that the clearinghouse is staffed at least during normal business hours. The department shall contract for the services of a school of pharmacy to staff the clearinghouse.

Section ~~373~~ 363. Toll-free telephone number. <—

The department shall establish a toll-free telephone number through which the members of the public may obtain information from the clearinghouse about available patient assistance programs.

Section ~~374~~ 364. Assistance available. <—

(a) Direct.--

(1) The clearinghouse shall assist any individual in determining whether a patient assistance program is offered for a particular drug and whether the individual may be eligible to obtain the drug through a patient assistance program.

(2) The clearinghouse may assist an individual who wishes to apply for a patient assistance program by assisting with the preparation of an application and coordinating communications between the individual's physician and a pharmaceutical manufacturer on behalf of the individual for the purpose of obtaining approval to participate in the patient assistance program.

(b) Referrals.--The clearinghouse shall make referrals to any publicly funded program for which it deems a patient

eligible.

Section ~~375~~ 365. Reporting. <—

The department shall report annually to the Governor and the General Assembly on the activities of the clearinghouse. The report shall include:

(1) The number of individuals who have been assisted by the clearinghouse.

(2) The number and benefits of patient assistance programs listed with the clearinghouse.

(3) The number of patients referred to publicly funded programs under section ~~374(b)~~ 364(B). Programs under this <— paragraph include the Pharmaceutical Assistance Contract for the Elderly Program, medical assistance and programs of the Department of Veterans Affairs.

(4) Other information deemed relevant by the department.

CHAPTER 51

MISCELLANEOUS PROVISIONS

Section 5101. Federal programs.

If the Federal Government enacts programs similar to PACE or PACENET, the State programs shall be construed to only supplement the Federal programs and all persons qualified for coverage under the Federal program shall utilize that Federal program before utilizing any State program.

Section 5102. Repeals.

(a) Specific.--Chapters 5 and 7 of the act of August 26, 1971 (P.L.351, No.91), known as the State Lottery Law, are repealed.

(b) General.--All other acts and parts of acts are repealed insofar as they are inconsistent with this act.

Section 5103. Effective date.

This act shall take effect immediately.