

# **Pennsylvania Statutes Annotated**

## **Title 72. Taxation and Fiscal Affairs**

### **Chapter 3. State Fiscal Affairs in General State Lottery**

### **Chapter 5. Pharmaceutical Assistance for the Elderly**

#### **Sections 3761-501 through Sections 3761-806**

#### **§ 3761-501. Legislative Findings**

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

#### **§ 3761-502. 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:

"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." The Centers for Medicare and Medicaid Services of the United States.

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

"DESI." The Drug Efficacy Study Implementation List.

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

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

"HEALTH MAINTENANCE ORGANIZATION." An organized system which combines the delivery and financing of health care and which provides basic health services to voluntarily enrolled subscribers for a fixed prepaid fee.

"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 \$ 10,000 of the total of death benefits payments, and gifts of cash or property, other than transfers by gift between members of a household, in excess of a total value of \$ 300, but shall not include surplus food or other relief in kind supplied by a government agency or property tax rebate.

"LESS EXPENSIVE." The lowest net cost to the program. The net cost shall include the amount paid by the Commonwealth to a pharmacy for a drug under a current retail pharmacy reimbursement formula less any discount or rebates, including those paid during the previous calendar quarter and inclusive of all dispensing fees.

"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. 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 50 is eliminated.

"PACE." The Pharmaceutical Assistance Contract for the Elderly program provided for in this chapter.

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

"PHARMACY." A pharmacy licensed by the Commonwealth.

"PREFERRED PROVIDER ORGANIZATION." An entity organized and operating under 40 Pa.C.S. Ch. 63 (relating to professional health services plan corporations).

"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 who enters into a contract with the Commonwealth to provide services under the provisions of this chapter.

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

"PROVIDER." A pharmacy, dispensing physician or certified registered nurse practitioner enrolled as a provider in the program.

### **§ 3761-503. Determination of eligibility**

The department shall adopt regulations relating to the determination of eligibility of prospective claimants and providers, including dispensing physicians and certified registered nurse practitioners when acting in accordance with rules and regulations promulgated by the State Board of Nursing as required by the act of May 22, 1951 (P.L. 317, No. 69), known as The Professional Nursing Law, and the State Board of Pharmacy minimum standards of practice, 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.

### **§ 3761-504. 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.

### **§ 3761-505. 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.

### **§ 3761-506. Reduced assistance**

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

### **§ 3761-507. Rebates for expenses prohibited**

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

### **§ 3761-508. Request for proposal**

(a) GENERAL RULE.-- The department shall prepare a request for proposal for the purpose of providing pharmaceutical assistance for the elderly within this Commonwealth. Upon the adoption of the General Fund budget, the Department of Revenue shall be authorized to transmit the appropriated funds in the State Lottery Fund to the State Treasurer to be deposited in the Pharmaceutical Assistance Contract for the Elderly Fund. This fund shall consist of appropriations and interest and shall be created by the State Treasurer to fund the operations of the program by the department and the private contractor. Funds not expended in the fiscal year in which they were appropriated shall not lapse and be available for use in the next fiscal year.

(b) ADDITIONAL REQUESTS FOR PROPOSALS.-- To provide for the continued operation of the program, the department shall prepare, as needed, requests for proposals, in addition to that set forth in subsection (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.

### **§ 3761-509. 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 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 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.

### **§ 3761-510. 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 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.

## **§ 3761-511. Supply**

Prescription benefits for any single prescription shall be limited to a 30-day supply of the prescription drug or 100 units, whichever is less, except that, in the case of diagnosis for acute conditions, the limitation shall be a 15-day supply. This limitation shall not apply to topical ointments or gels that are not available in containers which meet the size and supply restrictions set forth in this section.

## **§ 3761-512. 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 (NOON) for the purpose of withdrawing the New Drug Application approved for that drug, reimbursement coverage shall be discontinued under the provisions of this chapter.

## **§ 3761-513. Mail order system**

The department may not enter into a contract with a private contractor for an exclusive mail-order system for the delivery of prescription drugs under this program. Only mail-order pharmacy services provided by pharmacies which are licensed by the Commonwealth and which have their principal place of business within this Commonwealth may participate as providers under the program. The department shall develop and promulgate specific regulations governing the practice of mail-order pharmacy and other enrolled providers to include the following minimum standards of practice to ensure the health, safety and welfare of program participants:

- (1) The appropriate method or methods by which such pharmacies shall verify the identity of the program recipient and the authenticity of prescriptions received.
- (2) The appropriate method or methods by which such pharmacies shall mail or deliver prescription drugs to program recipients ensuring, to the maximum extent possible, that the intended program recipient is the actual ultimate recipient of any prescription dispensed by such pharmacies.
- (3) The appropriate method or methods by which such pharmacies shall communicate with program participants in emergency situations.

## **§ 3761-514. Indication of price**

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

## **§ 3761-515. Reimbursement**

For-profit third-party insurers, health maintenance organizations, preferred provider organizations 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. Final determination as to the existence of third-party coverage shall be the responsibility of the department.

## **§ 3761-516. Nonliability**

(a) GENERAL RULE.-- 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.

## **§ 3761-517. 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 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.

(c) PENALTY.-- A person who violates this act 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.

## **§ 3761-518. Contract**

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

### **§ 3761-519. 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 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 50s 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.

(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.

## **§ 3761-520. Board**

(a) ESTABLISHMENT.-- 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 pharmaceutical industry.

(b) COMPOSITION.-- 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 pharmaceutical industry to serve as consumer advocates, one representative of the pharmaceutical 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) REVIEW.-- Using the annual report submitted by the department pursuant to section 2102 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.

### **§ 3761-520.1. 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.

## **§ 3761-521. Penalties**

(a) PROHIBITED ACTS.-- It shall be unlawful for any person to submit a false or fraudulent claim or application under this chapter, 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;

(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.

(b) CIVIL PENALTY.-- In addition to any appropriate criminal penalty for prohibited acts under this chapter 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 shall be suspended for a period of one year. The license of any provider who has committed three or more violations of this chapter 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 chapter 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.

### **§ 3761-522. Prescription drug education program**

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

- (1) The hazards of prescription drug overdose.
- (2) The potential dangers of mixing prescription drugs.
- (3) The danger of retaining unused prescription drugs after the need to take them no longer exists.
- (4) The necessity to carefully question physicians, certified registered nurse practitioners and pharmacists concerning the effects of taking prescription drugs, including the differences between brand-name drugs and generically equivalent 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, certified registered nurse practitioner or pharmacist concerning the time period a prescription drug should be taken.

### **§ 3761-701. Declaration of policy**

The General Assembly finds and declares as follows:

- (1) The Commonwealth, through assistance programs enacted for the benefit of its citizens, is the largest single payor of prescription medications in Pennsylvania.

(2) In order to ensure that the Commonwealth, in expending money on behalf of its citizens, is not unduly harmed by being required to pay a price for pharmaceutical products purchased from manufacturers in excess of that established for other purchasers and reimbursers of these products and to ensure that the Commonwealth can efficiently and prudently expend its money and maximize its ability to provide for the health and welfare of as many of its needy citizens as possible, it is reasonable, necessary and in the public interest to require that pharmaceutical manufacturers offer a discount to the Commonwealth for pharmaceutical products purchased or reimbursed through State agencies.

(3) It is in the public interest for pharmaceutical manufacturers to provide the Commonwealth with data relating to the price of pharmaceutical products sold by the manufacturer to public bodies, hospitals, for-profit or nonprofit organizations, other manufacturers or wholesalers doing business in this Commonwealth in order to ensure that the Commonwealth can determine that it is being provided with the best prices offered by the manufacturer.

(4) On a national level, there has been a recognition that the need for discounts to State Medicaid agencies, which reimburse for a high volume of pharmaceutical products, exists.

(5) On a State level, the General Assembly recognizes that it is in the best interest of its citizens to provide pharmaceutical assistance in a reasonable and cost-efficient manner.

(6) Drug price inflation has caused an increase in the amount of public funds expended by PACE and General Assistance.

## **§ 3761-702. Definitions**

The following words and phrases when used in this chapter shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"AVERAGE MANUFACTURER PRICE (AMP)." With respect to a covered prescription drug of the manufacturer for a calendar quarter, the average unit price paid to the manufacturer for the drug by wholesalers for drugs distributed to the retail pharmacy class of trade, except for direct sales to hospitals, health maintenance organizations and wholesalers where the drug is relabeled under that distributor's national drug code number. Federal Supply Schedule prices shall not be included in the calculation of AMP. The term includes cash discounts and all other price reductions, other than rebates under this act and section 1927 of Title XIX of the Social Security Act (49 Stat. 620, 42 U.S.C., § 301 et seq.), added November 5, 1990 (Public Law 101-508, Title IV, § 4401(a)(3), 104 Stat. 1388-143), which reduce the actual price paid. For bundled or capitated sales, the allocation of the discount shall be made proportionately to the dollar value of the units of each covered prescription drug sold under the bundled or capitated arrangement. The AMP for a quarter shall be adjusted by the manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

"BEST PRICE." The lowest price available from the manufacturer during the rebate

period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity or any governmental entity subject to the exclusions and special rules set forth in sections 1902 and 1927(c)(1)(C) of the Social Security Act (49 Stat. 620, 42 U.S.C. § 1396c, 1396r-8(c)(1)(C)).

"BUNDLED OR CAPITATED SALES." The packaging of drugs of different types where:

- (1) the condition of rebate or discount is that more than one drug type is purchased; or
- (2) the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately.

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

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

"DEPOT PRICE." The price available to any depot of the Federal Government for purchase of drugs from the manufacturer through the depot system of procurement.

"DESIGNATED PHARMACEUTICAL PROGRAMS." The General Assistance Program and the Special Pharmaceutical Benefit Program in the Department of Public Welfare and the End Stage Renal Dialysis Program in the Department of Health.

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

"DISTRIBUTOR." A private entity under contract with the original labeler or holder of the national drug code number to manufacture, package or market the covered prescription drug

"DOING BUSINESS IN THIS COMMONWEALTH." The direct or indirect selling or the making of covered prescription drugs available for sale in a continuous and systematic manner with the reasonable expectation that these products will be sold to consumers in this Commonwealth.

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

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

"INNOVATOR MULTIPLE-SOURCE DRUGS." A multiple-source drug that was originally marketed under a new drug application approved by the FDA. The term includes:

- (1) covered prescription drugs approved under Product License Approval (PLA), Establishment License Approval (ELA) or Antibiotic Drug Approval (ADA); and

(2) a covered prescription drug marketed by a cross-licensed producer or distributor under the approved Abbreviated New Drug Application (ANDA) when the drug product meets this definition.

"MANUFACTURER."

(1) An entity which is engaged in any of the following:

(i) The production, preparation, propagation, compounding, conversion or processing of prescription drug products:

(A) directly or indirectly by extraction from substances of natural origin;

(B) independently by means of chemical synthesis; or

(C) by a combination of extraction and chemical synthesis.

(ii) The packaging, repackaging, labeling or relabeling, or distribution of prescription drug products.

**(2)** The entity holding legal title to or possession of the national drug code number for the covered prescription drug.

**(3)** The term does not include a wholesale distributor of drugs, drugstore chain organization or retail pharmacy licensed by the Commonwealth.

"NATIONAL DRUG CODE NUMBER." The identifying drug number maintained by the FDA. The complete 11-digit number must include the labeler code, product code and package size code.

"NEW DRUG." A covered prescription drug approved as a new drug under section 201(p) of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, 21 U.S.C. § 321(p)).

"NONINNOVATOR MULTIPLE-SOURCE DRUG." Any of the following:

1. A covered prescription drug which is not an innovator multiple-source drug approved under an Abbreviated New Drug Application (ANDA) or an Amended Antibiotic Drug Approval (AADA).
2. A drug that has been approved for substitution under the act of November 24, 1976 (P.L. 1163, No. 259), referred to as the Generic Equivalent Drug Law.

"PACE." The program under Chapter 5.

"PACENET." The program established under section 519

"PRIVATE ENTITY." Includes a for-profit entity and a nonprofit entity.

"PRODUCER PRICE INDEX FOR PHARMACEUTICALS." The prescription drug producer price index compiled by the Bureau of Labor Statistics of the United States Department of Labor for measuring average changes in selling prices received by domestic drug manufacturers.

"PROVIDER." A licensed pharmacy, dispensing physician or certified registered nurse practitioner enrolled as a provider in PACE, PACENET or designated pharmaceutical programs.

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

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

"SINGLE-SOURCE DRUGS." Legend drug products for which the FDA has not approved an Abbreviated New Drug Application (ANDA).

"UNIT." A drug unit in the lowest identifiable amount, such as tablet or capsule for solid dosage forms, milliliter for liquid forms and gram for ointments or creams. The manufacturer shall specify the unit for each dosage form and strength of each covered prescription drug in accordance with the instructions developed by the Health Care Financing Administration for purposes of the Federal Medicaid Rebate Program under section 1927 of Title XIX of the Social Security Act (49 Stat. 620, 42 U.S.C. §301 et seq.).

"WHOLESALE." Any person, partnership, corporation, institution or entity to which the manufacturer sells the covered prescription drug, including a pharmacy or chain of pharmacies, but that does not relabel or repackage the covered prescription drug.

### **§ 3761-703. Rebate agreement**

(a) REQUIREMENT.-- PACE, PACENET and designated pharmaceutical programs shall not reimburse for any covered prescription drug without a rebate agreement between the department and the manufacturer of the covered prescription drug.

(b) EXCEPTION.-- Subsection (a) shall not apply if the availability of the drug is essential to the health of eligible claimants as determined by the department.

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

(d) NOTICE.-- The department shall notify enrolled providers of PACE, PACENET and designated pharmaceutical programs on an annual basis and, as appropriate, of all manufacturers who have entered into a rebate agreement.

(e) DRUG FORMULARY.-- Except as provided in section 512, there shall be no drug formulary, prior or retroactive approval system or any similar restriction imposed on the coverage of outpatient drugs made by manufacturers who have agreements in effect with the Commonwealth to pay rebates for drugs utilized in PACE and PACENET, provided that such outpatient drugs were approved for marketing by the Food and Drug Administration. This

subsection shall not apply to any act taken by the department pursuant to its therapeutic drug utilization review program under section 505

### **§ 3761-704. Terms of rebate agreement**

(a) QUARTERLY BASIS.-- A rebate agreement shall require any manufacturer of covered prescription drugs to provide to the department a rebate each calendar quarter in an amount specified in section 705 for covered prescription drugs of the manufacturer reimbursed during the quarter. The rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in subsection (b) for the period involved.

(b) INFORMATION.--

(1) The department shall report to each manufacturer, not later than 60 days after the end of each calendar quarter, information by zip code of provider on the total number of dosage units of each covered prescription drug reimbursed under PACE, PACENET and designated pharmaceutical programs during the quarter.

(2) A manufacturer may review the information provided under paragraph (1) and verify information. Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.

(3) In the event that in any quarter a material discrepancy in the department's information is certified by the manufacturer prior to the due date of the rebate, the department and the manufacturer shall, in good faith, attempt to resolve the discrepancy. If resolution is not reached within 30 days of receipt of the manufacturer's certification by the department, the manufacturer may appeal the department's decision under the department's formal fair hearings and appeals process. The manufacturer shall pay the department that portion of the rebate amount which is not disputed within the required time frame under this chapter. Any balance due, plus statutory interest, shall be paid or credited by the manufacturer or the department by the due date of the next quarterly payment after resolution of the dispute.

(c) MANUFACTURER PROVISION OF PRICE INFORMATION.--

(1) Each manufacturer with an agreement in effect under this chapter shall report the average manufacturer price and the best price for all covered prescription drugs produced by that manufacturer to the department not later than 30 days after the last day of each quarter.

(2) The department shall retain the services of an independent contractor to survey wholesalers, direct sellers and manufacturers that directly distribute their covered prescription drugs, when necessary, to verify manufacturer prices reported under paragraph (1). Any survey conducted shall not reveal to the department nor to any other person or entity other than the independent contractor the name, identity, location, actual acquisition invoice, other proprietary information or any information from which the department might be enabled to ascertain the name, identity or location of any wholesaler, direct seller or provider so surveyed unless the contractor shall have gathered sufficient evidence to enable the department to bring charges against any

wholesaler, direct seller or provider in violation of subsection (d)(3).

(d) PENALTIES.-- The department shall administer penalties as follows:

(1) A manufacturer who fails to supply information required under subsection (c)(1) shall be liable for a civil penalty in the amount of 2% of the rebate next required to be paid, plus \$ 1,000 for each day that the information is late. If the information is not reported within 30 days of the due date, the agreement shall be suspended for services furnished after the end of the 30-day period until the date the information is reported or the expiration of 45 days, whichever is later.

(2) A manufacturer who knowingly supplies false information that is required under subsection (c)(1) shall be liable for a civil penalty in the amount of \$ 50,000 for each item of false information.

(3) A direct seller, manufacturer or wholesaler who refuses a request for information or knowingly provides false information that is required under subsection (c)(2) shall be liable for a civil penalty in the amount of \$ 50,000.

(4) Penalties collected under this subsection shall be deposited into the fund.

(5) All civil monetary penalties imposed under this chapter are in addition to other civil or criminal penalties.

(e) CONFIDENTIALITY OF INFORMATION.-- Information disclosed by manufacturers, wholesalers or direct sellers under this chapter is confidential and shall not be disclosed by the department in a form which discloses the identity of a specific manufacturer, wholesaler or direct seller or the prices charged for drugs by the manufacturer or wholesaler, except as the department determines to be necessary to carry out this chapter and to permit the

Department of the Auditor General and the Office of State Inspector General to review the information provided.

(f) LENGTH OF AGREEMENT.-- A rebate agreement shall remain in effect for an initial period of not less than one year and shall be automatically renewed for a period of not less than one year unless terminated under subsection (g).

(g) TERMINATION.--

(1) The department may provide for termination of a rebate agreement for any reason. Termination shall not be effective earlier than 60 days after the date of receipt of notice of termination by the manufacturers.

(2) A manufacturer may terminate a rebate agreement for any reason. Termination shall not be effective earlier than 60 days after the date of receipt of notice of termination by the department.

(3) Termination of the rebate agreement shall not affect rebates due under the agreement before the effective date of termination.

(4) Commonwealth Court shall have original jurisdiction over cases of termination of agreements under this subsection. Commencement of an action under this paragraph shall not delay the effective date of termination.

(5) If a rebate agreement is terminated for cause, another agreement with the same manufacturer or a successor manufacturer may not be entered into until a period of one year has elapsed from the date of the termination unless the department finds good cause for an earlier agreement.

### **§ 3761-705. Amount of rebate**

(a) SINGLE-SOURCE DRUGS AND INNOVATOR MULTIPLE-SOURCE DRUGS.-- With respect to single-source drugs and innovator multiple-source drugs, each manufacturer shall remit a rebate to the Commonwealth. Except as otherwise provided in this section, the amount of the rebate to the Commonwealth per calendar quarter with respect to each dosage form and strength of single-source drugs and innovator multiple-source drugs shall be as follows:

(1) For quarters beginning after September 30, 1992, and ending before January 1, 1997, the product of the total number of units of each dosage form and strength reimbursed by PACE and General Assistance in the quarter and the difference between the average manufacturer price and 85% of that price, after deducting customary prompt payment discounts, for the quarter.

(2) For quarters beginning after December 31, 1996, and ending before January 1, 2003, the product of the total number of units of each dosage form and strength reimbursed by PACE, PACENET and designated pharmaceutical programs in the quarter and the difference between the average manufacturer price and 83% of that price, after deducting

customary prompt payment discounts.

(3) For quarters beginning after December 31, 2002, each manufacturer shall remit a rebate to the Commonwealth for the total number of units of each dosage form and strength reimbursed by PACE, PACENET and designated pharmaceutical 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)).

(b) REBATE FOR OTHER DRUGS.--

(1) The amount of the rebate to the Commonwealth for a calendar quarter with respect to covered prescription drugs which are noninnovator multiple-source drugs shall be equal to the product of:

(i) the applicable percentage of the average manufacturer price, after deducting customary prompt payment discounts, for each dosage form and strength of such drugs for the quarter; and

(ii) the number of units of such form and dosage reimbursed by PACE and General Assistance in the quarter.

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

(c) REVISED REBATE FOR OTHER DRUGS.-- Beginning after December 31, 1996, and ending before January 1, 2004, all of the following shall apply:

(1) The amount of the rebate to the Commonwealth for a calendar quarter with respect to covered prescription drugs which are noninnovator multiple-source drugs shall be the greater of the product of:

(i) The applicable percentage of the average manufacturer price, after deducting customary prompt payment discounts, for each dosage form and strength of such drugs for the quarter; and

(ii) the number of units of such form and dosage reimbursed by PACE, PACENET and designated pharmaceutical programs in the quarter.

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

(C.1) REBATES FOR OTHER DRUGS.-- For quarters beginning after December 31, 2003, each manufacturer shall remit a rebate to the Commonwealth for the total number of units of each dosage form and strength reimbursed by PACE, PACENET and designated pharmaceutical programs in the quarter pursuant to the determination established by section 1927(c)(3) of the Social Security Act (49 Stat. 620, 42 U.S.C. § 1396r-8(c)(3)).

(d) DRUGS APPROVED AFTER ACT TAKES EFFECT.-- In the case of a covered outpatient drug approved for marketing after the effective date of the act of August 14, 1991 (P.L. 342, No. 36), known as the Lottery Fund Preservation Act, any reference to January 1, 1991, shall be a reference to the first day of the first month during which the drug was marketed.

## **§ 3761-706. Excessive pharmaceutical price inflation discount**

(a) GENERAL RULE.-- A discount shall be provided to the department for all covered

prescription drugs. The discount shall be calculated as follows:

(1) For each quarter for which a rebate under section 705(a) and (b) is to be paid after December 31, 1991, and before January 1, 1997, the average manufacturer price for each dosage form and strength of a covered prescription drug shall be compared to the average manufacturer price for the same form and strength in the previous calendar year, and a percentage increase shall be calculated.

(2) For each quarter under paragraph (1), the average percentage increase in the Producer Price Index for Pharmaceuticals over the same quarter in the previous calendar year shall be calculated.

(3) If the calculation under paragraph (1) is greater than the calculation under paragraph (2), the discount amount for each quarter shall be equal to the product of:

(i) the difference between the calculations under paragraphs (1) and (2); and

(ii) the total number of units of each dosage form and strength reimbursed by PACE and General Assistance and the average manufacturer price reported by the manufacturer under section 704(c)(1).

(b) REVISED GENERAL RULE.-- A discount shall be provided to the department for all covered prescription drugs. The discount shall be calculated as follows:

(1) For each quarter for which a rebate under section 705(a) and (c) is to be paid after December 31, 1996, the average manufacturer price for each dosage form and strength of a covered prescription drug shall be compared to the average manufacturer price for the same form and strength in the previous calendar year and a percentage increase shall be calculated.

(2) For each quarter under paragraph (1), the average percentage increase in the Consumer Price Index-Urban over the same quarter in the previous calendar year shall be calculated.

(3) If the calculation under paragraph (1) is greater than the calculation under paragraph (2), the discount amount for each quarter shall be equal to the product of:

(i) the difference between the calculations under paragraphs (1) and (2); and

(ii) the total number of units of each dosage form and strength reimbursed by PACE, PACENET and designated pharmaceutical programs and the average manufacturer price reported by the manufacturer under section 704(c)(1).

(c) NEW BIMARKETED DRUGS.-- For covered prescription drugs that have not been marketed for a full calendar year, subsection (a) shall apply after the covered prescription drug has been on the market for four consecutive quarters. The drug's initial average manufacturer price shall be based on the first day of the first quarter that the drug was marketed.

### **§ 3761-707. Lowered best price**

(a) GENERAL RULE.-- If the rebate under section 705 and the discount under section 706 would establish a lowered Federal best price, as defined in section 1927(c)(1)(C) of the Social Security Act (49 Stat. 620, 42 U.S.C. § 1396r-8(c)(1)(C)), the manufacturer shall be liable for a total rebate and discount in an amount that does not reduce the Federal best price for that covered prescription drug.

(b) PROCEDURE.-- Any claim by a manufacturer that a rebate would establish a lower Federal best price under subsection (a) shall be verified in writing by a department-approved independent public accounting firm within 45 days of the end of the quarter for which the claim is asserted. The information provided to the public accounting firm shall remain confidential.

(c) CIVIL PENALTY.-- A manufacturer which provides false information under this section shall be liable for a civil penalty in an amount not to exceed \$ 50,000. Each item of false information constitutes a separate violation.

### **§ 3761-708. Exemption**

Section 521(a) shall not apply to rebates under this chapter.

NOTICE: This section is repealed in part insofar as it is inconsistent with Section 2 of Act 1999, June 25, P.L. 226.

### **§ 3761-709. Disposition of funds**

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

(b) DESIGNATED PHARMACEUTICAL PROGRAMS.-- Money received under this chapter in connection with designated pharmaceutical programs shall be treated as a refund of expenditures to the appropriation which originally provided the funding for the pharmaceutical purchase.

### **§ 3761-801. 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:

"Clearinghouse." The Pharmaceutical Assistance Clearinghouse established in section 802

"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.

"Voluntary health organization." An organization whose main purpose is to educate the public on the symptoms, treatments and research of a disease and that may provide support for persons who have the disease.

### **§ 3761-802. Pharmaceutical Assistance Clearinghouse**

(a) ESTABLISHMENT.-- Within 120 days of the effective date of this chapter, 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 a patient assistance program.

(b) INFORMATION.-- The clearinghouse shall maintain the information submitted by pharmaceutical manufacturers and any appropriate voluntary health organization that would like to participate and make it available to the public.

(c) STAFF.-- The department shall ensure that the clearinghouse is staffed at least during normal business hours.

### **§ 3761-803. Toll-free telephone number**

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

### **§ 3761-804. Assistance available**

(a) DIRECT.--

- (1) The clearinghouse shall assist without charge an 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 without charge 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 or certified registered nurse practitioner 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 an appropriate voluntary health organization or any publicly funded program for which it deems a patient eligible.

### **§ 3761-805. 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 under section 804(a)(1) and the number of such individuals under section 804(a)(2).

(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 804(b). Programs under this paragraph include, but are not limited to, 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.

NOTICE: As to repeal of this section where inconsistent with act 1999, June 25, P.L. 226, § 2, see said act.

### **§ 3761-806. Internet availability of information**

The department shall maintain and provide to the public the information under this chapter on its World Wide Web site. The department shall also provide to appropriate organizations the information necessary for the organizations to establish a link to the location of clearinghouse information on the department's World Wide Web site.

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