CDL-1

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Copy below is hereby approved as to form and legality. Attorney General

Cristina L. Rapone

(Deputy Attorney General)

SEP 23 2002

Date of Approval

Check if applicable
Copy not approved. Objections attached.

Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:

DEPARTMENT OF PUBLIC WELFARE
(Agency)

LEGAL COUNSEL:

DOCUMENT/FISCAL NOTE NO. 14-479

DATE OF ADOPTION:

BY: Heather Houston

TITLE: SECRETARY
(Executive Officer, Chairman or Secretary)

Copy below is hereby approved as to form and legality. Executive or Independent Agencies.

BY:

SEP 20 2002

Date of Approval

(Deputy General Counsel)
~~(Chief Counsel, Independent Agency)~~
~~(Strike inapplicable title)~~

☐ Check if applicable. No Attorney General approval or objection within 30 days after submission.

Notice of Proposed Rulemaking
Department of Public Welfare
Office of Medical Assistance Programs
[55 Pa. Code Chapter 1121]
Pharmaceutical Services
Revisions to Reimbursement

STATUTORY AUTHORITY

Notice is hereby given that the Department of Public Welfare, under the Authority of the Public Welfare Code, Act of June 13, 1967, P.L. 13, (No. 21), 62 P.S. § 201 (2), intends to amend the regulation set forth in Annex A to this notice.

PURPOSE

The purpose of this regulation is to revise the rates paid by the Department of Public Welfare to pharmacy providers governing payment for and dispensing of brand-name prescription drugs under the fee-for-service component of the Medical Assistance Program.

NEED FOR THE REGULATION

The Medical Assistance Program ("The Program") assures the availability of a wide array of medically-necessary healthcare services, supplies and equipment to approximately 1.5 million indigent persons. Prescription drugs are among the healthcare services covered by the Program. Drugs available from multiple manufacturers are often referred to as generic or multi-source drugs. Drugs available from only one manufacturer that hold the patent for the drug product are referred to as single-source or brand-name drugs.

Under federal law, the payment for prescription drugs reflects the state Medicaid agency's best estimate of the price generally and currently paid by pharmacy providers for a drug marketed or sold by a particular manufacturer in the package size of the drug most frequently purchased by providers (i.e., the "estimated acquisition cost" or "EAC") plus a reasonable dispensing fee. (42 C.F.R. 447.331(b)). Prior to October 1995, the Department's regulations defined the estimated acquisition cost as "the average wholesale price" ("AWP") for a drug. The AWP is the price assigned to the drug by its manufacturer as listed in publications universally

used in the pharmaceutical industry. The listed AWP does not reflect discounts or rebates offered to pharmacy providers by manufacturers.

Until October 1995, the Department, unlike 40 other state Medicaid agencies and most other private sector third-party payors throughout the Commonwealth, paid for brand-name prescription drugs with no percentage discount off the AWP price. After determining that the payment rates of most of these other public and commercial payors reflected discounts equal to or greater than AWP minus 10%, and having determined as well that clients covered by those other payors enjoyed access to quality pharmacy services, the Department, consistent with its responsibility to assure clients' access to quality healthcare services at efficient and economical rates (42 U.S.C. 1396a(a)(30)(A)), adopted AWP minus 10%, plus a $4.00 dispensing fee as its fee-for-service payment policy for brand-name prescription drugs.

When the Department adopted the changes to its prescription payment policy in October 1995, it was aware that other payors reimbursed at discounts in excess of 10% and that the Office of Inspector General ("OIG") for the U.S. Department of Health and Human Services had issued reports in 1984 and 1989 of nationwide studies it had conducted evidencing that pharmacies were purchasing brand-name drugs at discounts of AWP minus 15.5%. (In November 1990, the Omnibus Budget Reconciliation Act of 1990, Pub.L. No. 101-508, 104 Stat. 1388, was passed which placed a four-year moratorium on changes to states' reimbursement policies for prescription drugs.) The Department, in adopting AWP minus 10% plus a $4.00 dispensing fee, determined that although a greater discount off AWP could be justified (in addition to a lower dispensing fee), under the then-existing circumstances, the proposed rate represented an appropriate initial change to its payment policy.

During the past seven years, additional studies, reports and data have been released relating to payment for and the dispensing of brand-name prescription drugs. The DHHS, Office of General Inspector released two new studies relating to pharmacy reimbursement. A study was released in November 1998 by Pricewaterhouse Coopers ("PwC") concerning the cost of filling a prescription and providing pharmacy services, including reasonable profits derived in the Pennsylvania Medicaid and PACE [Pennsylvania Pharmaceutical Assistance Contract for the Elderly] Programs. The Legislative Budget and Finance Committee also released a report ("Long Term Care Pharmacy Dispensing Costs"), in December 2000, concerning "the relative adequacy of Medical Assistance reimbursement for pharmacies dispensing medications to residents of long-term care nursing facilities compared to pharmacies dispensing to traditional retail customers."

The OIG report issued in April, 1997, was entitled "Medicaid Pharmacy – Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs" (Report #A-06-96-00030). The OIG randomly selected ten states and the District of Columbia (California, Delaware, Florida, Maryland, Missouri, Montana, Nebraska, New Jersey, North Carolina and Virginia) and reviewed their drug purchases. The OIG combined the results of four categories of pharmacies, including rural-chain pharmacies, rural-independent pharmacies, urban-chain and urban-independent pharmacies, and estimated that pharmacies' actual acquisition cost for brand-name prescription drugs was a national average of AWP minus 18.3%.

In August 2001, the OIG issued results of another study ("Medicaid Pharmacy – Actual Acquisition Costs of Brand Name Prescription Drug Products [A-06-00-00023]) involving an eight-state sample (Montana, Florida, Colorado, Indiana, Texas, Washington, West Virginia and Wisconsin) of the same types of pharmacies as in the prior study plus "non-traditional

pharmacies" (i.e., nursing home pharmacies and hospital pharmacies). The non-traditional pharmacies were sampled separately. The OIG estimated that nationally, the invoice price for brand-name drugs was an average of 21.84% below AWP for traditional pharmacies and 31.18% below AWP for non-traditional pharmacies.

The purpose of the pharmacy service study conducted by PwC for the Departments of Aging and Public Welfare, released in November 1998, was to determine the "full cost of filling a prescription and providing pharmacy services, including reasonable profits, in the Commonwealth's PACE/PACENET and Medical Assistance programs". The study was conducted at the direction of the General Assembly (Act 1996-53, 71 P.S. § 581-13). The authors of the study estimated that pharmacy net income for the dispensing of Medical Assistance fee-for-service claims in 1997 was minus $0.01 per claim or –0.0% of acquisition costs and concluded that independent pharmacies are not disadvantaged by the Medical Assistance payment relating to the cost of acquiring drugs. The estimate did not reflect additional income pharmacies receive from manufacturers in the form of rebates and discounts, as well as the sale of non-prescription items. The study noted that other third-party payors, unlike most state Medicaid agencies, paid pharmacies at AWP minus 12-14% for most brand-name drugs. It was also noted that the National Association of Chain Drug Stores issued a strong rebuttal to the findings contained in the HHS-OIG 1997 audit of actual acquisition costs.

The LBFC, in preparing its report, sent surveys to all long-term care providers in Pennsylvania. In its report, LBFD noted that 42% of the providers surveyed, serving 87% of the state's licensed nursing beds, responded to the survey. The LBFC concluded that there is "no reason to conclude that there are significant differences in drug acquisition costs for the retail pharmacies as a group and long-term care pharmacies." (See LBFC Report at p. 10).

The LBFC study recommended that the Department "should consider" adjusting the dispensing fee to long-term care pharmacies so as "to take into account the additional activities pharmacies are required to perform when dispensing to residents of long term-care facilities." (See LBFC Report at p. 10). Based on reported, non-verified cost information, the LBFC concluded that the "additional cost" (i.e., costs above what would be incurred in a retail pharmacy) for the long-term care dispensing amounted to $2.87 per prescription.

The PwC study, relying on a 1998 study by the National Association of Chain Drug Stores, estimated that the average dispensing costs in 1997 were $6.22 per claim in Pennsylvania, compared to a national average of $6.06 per claim and a $6.44 per claim average in the states contiguous to Pennsylvania. The PwC study also determined that the prevalent payment by state Medicaid program rates relating to dispensing fees fell within a range of between $4.01-$4.50.

As of September 1, 2002, the average dispensing fee paid by six contiguous state Medicaid programs for pharmacy services was approximately $3.91 per claim and the average payment by the largest 15 state Medicaid programs (excluding Pennsylvania) was approximately $4.30.

The Department, in setting payment rates for pharmacy services under the Medical Assistance Program, seeks to assure the availability to medical assistance clients of high quality pharmacy services, equal to that of the general population in the same geographic regions, at the best possible price. In proposing the changes in payment for and the dispensing of brand-name drugs, we have considered the concerns expressed by both retail and long-term care pharmacies that current payments for pharmacy services do not reflect the "costs" they incur in providing those services. We have taken into account the studies and reports noted above and their review

of the "profitability" of providing pharmacy services and consideration of accounting for rebates, discounts, manufacturer's promotions, and mix of prescriptions by payor, along with consideration of profitability from total pharmacy revenues (i.e., non-prescription sales).

When the Department modified its payment rate from AWP to AWP minus 10% in 1995, the pharmacy industry predicted that the reduction in payment would restrict recipient access to and the quality of pharmacy services. To date, there is no evidence that remotely suggests that the change in payment reduced access by Medical Assistance clients to high quality pharmacy services anywhere in the state let alone resulted in less access to service than that enjoyed by members of the general public.

Since 1995, payment rates both nationally and within the state for brand-name drugs and dispensing fees have continued to fall. Pharmacy providers generally contend that the decreases in payments by third-party payors are unfair to them and adversely impact their customers. As the payor of pharmacy coverage for 1.5 million Medical Assistance adults and children, the Department has a duty to act as a prudent purchaser while assuring access to service. In analyzing the data and reviewing the analyses of the data contained in the several reports and studies released during the past several years, a fair reading of that information supports a conclusion that private and public payors nationally, regionally, and within Pennsylvania obtain access to pharmacy services for their members/enrollees at payments for brand name drugs that range from AWP – 10% to AWP – 21% and at dispensing fees that range from $2.00 to over $6.00. These ranges are also consistent with payment information disclosed by pharmacies in the course of litigation with the Department. The information disclosed by pharmacies establishes that they routinely are paid at rates well below AWP – 10% plus $4.00. Indeed, the larger commercial insurers pay in the range of AWP minus 15-16% plus a $2.00 dispensing fee.

Given these payment ranges, and taking into account providers' claims relating to the costs of providing services, the Department believes that its proposal to pay for brand-name drugs at AWP minus 15% plus a dispensing fee of $4.25 per prescription, though higher than necessary to obtain access by client to quality pharmacy services, is consistent with its duty to assure access by Medical Assistance clients to pharmacy services at rates that compare most favorably with those of other major payors, both public and private, of pharmacy services.

SUMMARY OF REGULATION CHANGES

The Department proposes to amend Chapter 1121 as follows:

1. Section 1121.55 revises the Department's payment formula to include the dispensing fee increase to $4.25 for all MA prescriptions.
2. Section 1121.56 contains the Department's proposed amendment to EAC as the AWP minus 15 percent.

AFFECTED ORGANIZATIONS

Approximately 3,100 pharmacy providers enrolled in the MA Program and participating in the fee-for-service delivery system will be affected by the lower reimbursement rates.

ACCOMPLISHMENTS/BENEFITS

The Commonwealth will benefit by aligning its payment policies for brand-name prescription drugs with that of other third-party payors.

FISCAL IMPACT

THE COMMONWEALTH

The application of the proposed revision to the EAC determination and the proposed increase in the dispensing fee for the balance of Fiscal Year (FY) 2002-2003 should result in a

reduction of $22,538,000 in total expenditures. This reduction will represent a net savings of $10,381,000 for FY 2002-2003 in State funds.

POLITICAL SUBDIVISIONS

There will be no fiscal impact on the political subdivisions as a result of these proposed regulation changes.

PRIVATE SECTOR

The proposed revision to the EAC determination with the proposed dispensing fee increase will result in an overall reduction in payments to all pharmacy providers enrolled in the MA Program who participate in the fee-for-service delivery system.

GENERAL PUBLIC

There will be no fiscal impact on the general public with these proposed regulation changes.

PAPERWORK REQUIREMENTS

There will be no additional reports or new forms needed to comply with the proposed regulation changes, nor will there be additional legal, accounting, or consulting assistance required to fulfill the requirements of these regulations.

EFFECTIVE DATE:

The effective date for the implementation of these proposed regulation changes is October 1, 2002.

SUNSET DATE:

The effectiveness of the proposed regulation revisions will be evaluated on an ongoing process. Necessary and appropriate changes will be made in response to letters and

recommendations from other offices, agencies, and individuals. Therefore, no sunset date has been set.

PUBLIC COMMENT PERIOD

Interested persons are invited to submit written comments, suggestions, or objections regarding the proposed regulation to the Department of Public Welfare, Office of Medical Assistance Programs, c/o Deputy Secretary's Office, Attention: Regulations Coordinator, Room 515, Health and Welfare Building, Harrisburg, PA 17120 within 30 days after the date of publication of this Notice in the Pennsylvania Bulletin. All comments received within 30 calendar days will be reviewed and considered in the preparation of the final regulation. Comments received after the 30 day comment period will be considered for any subsequent revisions of this regulation.

Persons with a disability may use the AT&T Relay Service by calling 1-800-654-5984 (TDD users) or 1-800-654-5988 (Voice users).

REGULATORY REVIEW ACT

Under section 5 (a) of the Regulatory Review Act, the Act of June 30, 1989 (P.L. 73, No. 19) (71 P.S. §§ 745.1-745.15), the Department submitted a copy of these proposed amendments on SEP 2 5 2002 to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Committee on Health and Human Services, and the Senate Committee on Public Health and Welfare. In addition to submitting the proposed amendments, the agency has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

If the Commission has any objections to any portion of the proposed regulation, it will notify the agency 30 days after the close of the public comment period. Such notification shall specify the regulatory review criteria which have not been met by that portion. The Act specifies detailed procedures for review, prior to final publication of the regulation of objections raised, by the agency, the General Assembly and the Governor.

ANNEX A

PART III. MEDICAL ASSISTANCE MANUAL

TITLE 55. PUBLIC WELFARE

CHAPTER 1121

PHARMACEUTICAL SERVICES

* * * * *

§ 1121.55. Method of payment.

(a) The Department will pay a pharmacy for a compensable legend and nonlegend drug (after deducting the applicable copayment amount, as described in § 1101.63(b) (relating to payment in full)), the lowest of the following amounts:

(1) The estimated acquisition cost (EAC) for the drug, multiplied by the number of units dispensed, plus a [$4] $4.25 dispensing fee.

(2) The State MAC for the drug, multiplied by the number of units dispensed, plus a [$4] $4.25 dispensing fee.

* * * * *

(b) The Department will pay a pharmacy for a compensable compounded prescription at the lower of the cost of all ingredients plus a [$5] $5.25 dispensing fee or the provider's usual and customary charge to the general public.

* * * * *

§ 1121.56. Drug cost determination.

(a) The Department will base its drug cost for compensable legend and nonlegend drugs on the lower of:

(1) The Estimated Acquisition Cost (EAC) established by the Department as the current AWP found in the Department's pricing service for the most common package size of that product minus [10%] 15%.

* * * * *

Independent Regulatory
Review Commission
14th Floor, Harristown II

TRANSMITTAL SHEET FOR REGULATIONS SUBJEC
REGULATORY REVIEW ACT

I.D. NUMBER:	14-479
SUBJECT:	Pharmaceutical Services - Revisions to Reimbursement
AGENCY:	DEPARTMENT OF PUBLIC WELFARE

TYPE OF REGULATION

X Proposed Regulation

Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
9/25	A. Reeker	HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
9/25	J. Chan	
9/25/02	Kristi Knelson	SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
9/25/02	L. Culver	
9/25/02	J. Pagán	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
9/25/02	Mayo Cauley	LEGISLATIVE REFERENCE BUREAU

September 24, 2002