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INDEPENDENT REGULATORY REVIEW COMMISSION

333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

December 5, 2002

Honorable Feather O. Houstoun, Secretary
Department of Public Welfare
333 Health and Welfare Building
Harrisburg, PA 17105

Re: Regulation #14-479 (IRRC #2297)
Department of Public Welfare
Pharmaceutical Services

Dear Secretary Houstoun:

Enclosed are the Commission's Comments which list objections and suggestions for consideration when you prepare the final version of this regulation. These Comments are not a formal approval or disapproval; however, they specify the regulatory criteria which have not been met.

The Comments will soon be available on our website at www.irrc.state.pa.us. If you would like to discuss them, please contact my office at 783-5417.

Sincerely,

Robert E. Nyce
Executive Director
cae
Enclosure
cc: Honorable George T. Kenney, Jr., Majority Chairman, House Health and Human Services Committee
Honorable Frank L. Oliver, Democratic Chairman, House Health and Human Services Committee
Honorable Harold F. Mowery, Jr., Chairman, Senate Public Health and Welfare Committee
Honorable Vincent J. Hughes, Minority Chairman, Senate Public Health and Welfare Committee
Nia Wilson, Legal Counsel, House Health and Human Services Committee
Stanley Mitchell, Chief Counsel, House Health and Human Services Committee

Comments of the Independent Regulatory Review Commission

on

Department of Public Welfare Regulation No. 14-479

Pharmaceutical Services

December 5, 2002

We submit for your consideration the following objections and recommendations regarding this regulation. Each objection or recommendation includes a reference to the criteria in the Regulatory Review Act (71 P.S. § 745.5a(h) and (i)) which have not been met. The Department of Public Welfare (DPW) must respond to these Comments when it submits the final-form regulation. If the final-form regulation is not delivered within two years of the close of the public comment period, the regulation will be deemed withdrawn.

1. **General. - Disapproval by a Standing Committee; Policy Decision Requiring Legislative Review; Protection of the Public Health, Safety and Welfare; Economic and Fiscal Impact; Feasibility; Reasonableness.**

Disapproval by the House Health and Human Services Committee; Policy decision requiring legislative review

The House Health and Human Services Committee (House Committee) disapproved the proposed amendments. In their letter dated October 9, 2002, the House Committee stated that a unanimous vote had been taken to "...express in the strongest possible terms our opposition to this regulation at the proposed stage."

The Senate Public Health and Welfare Committee (Senate Committee) Minority Chairman Vincent Hughes submitted a letter opposing this rulemaking. In his letter dated November 21, 2002, the Minority Chairman stated that he was "...not convinced that the Department has adequately explored alternatives to reducing reimbursement."

We agree with both the House and Senate concerns and herein state our objections to the proposed amendments.

2. **Determination of Dispensing Fee and Estimated Acquisition Cost (EAC) of Drugs – Economic Impact; Reasonableness.**

The proposed regulation sets the dispensing fee for legend and nonlegend drugs at $4.25, a 25-cent increase over the current dispensing fee. The regulation establishes the EAC for drugs at the average wholesale price (AWP) of the drug minus 15%. This represents a reduction in drug cost reimbursement compared to the current level of AWP minus 10%. Commentators have questioned the reasonableness of the proposed dispensing fee and EAC.

In 2001, the average reimbursement to pharmacies was $51.24 per claim using AWP minus 10% and a $4 dispensing fee. Under the proposed regulation at AWP minus 15% and a $4.25 dispensing fee, the average reimbursement to pharmacies would be $48.91. This represents an average decrease in reimbursement per prescription of $2.33. In 2001, DPW approved approximately 14.4 million claims. Therefore, the estimated annual decrease in pharmacy drug acquisition cost reimbursement resulting from the proposed regulation is $33,552,000.

Act 53 of 1996 directed DPW and the Department of Aging (Aging) to conduct a study to determine the cost of filling a prescription and providing pharmacy services in Pennsylvania. To fulfill this mandate, DPW and Aging contracted with Pricewaterhouse Coopers (PwC) to conduct a study to estimate pharmacy drug acquisition costs and profitability for the Medical Assistance (MA) Fee-for-Service and the Pharmaceutical Assistance Contract for the Elderly programs.

To determine the EAC, the PwC report examined data from a 1996 study on the acquisition cost of brand name drugs conducted by the Office of Inspector General for the United States Department of Health and Human Services (OIG study). The OIG study examined pharmacy costs for 10 randomly selected states and the District of Columbia. Pennsylvania was not included in the OIG study. The results of the OIG study estimated that the national average for pharmacies' acquisition cost for brand name prescription drugs was AWP minus 18.3%.

The PwC study estimated that the average dispensing costs in Pennsylvania in 1997 were $6.22, compared to the national average of $6.06. In determining the estimated dispensing costs in Pennsylvania, the PwC study relied on a 1998 study by the National Association of Chain Drug Stores (NACDS). The PwC study also determined that dispensing fees paid by state Medicaid programs fell within a range of $4.01 to $4.50.

Commentators, including the Pennsylvania Pharmacy Council, the Pennsylvania Association of Chain Drug Stores, the Pennsylvania Pharmacists Association and individual pharmacy operators, challenge the validity of the OIG study. They note that the OIG study was challenged, and as a result, the estimated acquisition cost for brand name drugs revised to AWP minus 17.2%. Commentators, however, still question the methodology used in the revised report. Commentators also object to the proposed dispensing fee, asserting that the actual dispensing costs are significantly higher. Some commentators suggest a dispensing fee of $7.35 would reflect the actual cost to dispense a prescription in Pennsylvania. Another commentator noted that a 2000 NACDS study found the cost of dispensing a Medicaid prescription at $7.14.

We have several concerns related to the EAC and dispensing fees in the proposed regulation.

First, Act 53 directed the Department to conduct a study of the dispensing costs and drug acquisition costs in Pennsylvania. However, the OIG study, on which the PwC relied, did not include Pennsylvania. Furthermore, PwC did not conduct an independent survey of drug acquisition costs or dispensing fees within Pennsylvania. Therefore, we question whether DPW has met the mandate of Act 53.

Second, the proposed $4.25 dispensing fee falls significantly short of the $6.22 average dispensing cost cited in the PwC study. DPW should explain why it accepts the EAC estimates in the PwC study, but rejects the dispensing cost estimate in the same study.

Finally, without Pennsylvania specific data, we cannot determine if the proposed EAC of AWP minus 15% is a reasonable representation of Pennsylvania pharmacists' drug acquisition costs. We are also unable to determine if the proposed 25-cent increase in the dispensing fee is

sufficient to adequately reimburse pharmacists for their actual dispensing costs. Consistent with the directive in Act 53, DPW should conduct a Pennsylvania-specific study of drug acquisition costs and dispensing costs to determine any necessary modification to the reimbursement levels in the existing regulations. DPW should also include an analysis of the economic impact of revisions to reimbursement levels on participating MA program pharmacies.

3. **Additional Reimbursement for Long-Term Care Pharmacies. – Economic Impact; Reasonableness.**

In current and proposed regulations, long-term care (LTC) pharmacies receive the same dispensing fee reimbursement rate that other pharmacies receive. In their comments, the LTC Pharmacy Alliance (LTCPA) and other LTC pharmacies listed specific services that LTC pharmacies provide that traditional retail pharmacies commonly do not provide. Examples of these services include 24-hour service, providing and maintaining emergency drug kits, and developing drug carts to be used on specific floors of specific LTC facilities. LTCPA estimates the cost for a LTC pharmacy to dispense a prescription is $11.37 based on a study by the accounting firm of BDO Seidman. LTCPA further estimates that this regulation will reduce the reimbursement to LTC pharmacies by approximately $22 million.

The 2000 Pennsylvania Legislative Budget and Finance Committee report estimates that it costs a LTC pharmacy an additional $2.87 to dispense a prescription. Other states such as Maryland, New Jersey, Florida, Virginia, and Michigan provide additional reimbursement to LTC pharmacies based on the cost to provide additional services.

Given the Pennsylvania Legislative Budget and Finance Committee 2000 report; the costs associated with additional services provided by LTC pharmacies; and supplemental reimbursement given by other states, DPW should provide additional reimbursement to LTC pharmacies or explain why additional reimbursement is not justified.

4. **Pharmacy Carve-Out. – Reasonableness; Economic Impact.**

Senator Hughes, Minority Chair of the Senate Public Health and Welfare Committee, submitted comments objecting to the proposed regulation due to concerns that DPW has not fully explored alternatives to reducing pharmacy reimbursement. Senator Hughes specifically addressed "carving-out" pharmaceutical services from managed care as an option to be explored as a cost cutting measure. He suggested that DPW complete a comprehensive analysis of pharmacy "carve-out" to determine if additional pharmacy rebates resulting from a "carve-out" would exceed the potential increase in administrative costs associated with operating pharmaceutical services on a fee-for-service basis.

Additionally, the Philadelphia Association of Retail Druggists (PARD) asserts that "carving-out" pharmacy services would generate substantial increases in drug manufacturer rebates. Specifically, PARD estimates that "carving out Pharmacy from the Health Choices program would generate an increase of $136 million/year in manufacturers rebates and control drug costs."

Has DPW evaluated the "carve-out" option? If so, what are the evaluation results, and why hasn't it been pursued as an option to reducing pharmacy reimbursement?

5. Effective Date of the Regulation. – Reasonableness; Economic Impact.

The Preamble to the proposed regulation sets the effective date as October 1, 2002. There is no statutory mandate for retroactive implementation of the proposed regulation. Absent such a mandate, we find it unreasonable for DPW to retroactively lower reimbursement to pharmacists participating in the MA program. Furthermore, the administrative costs of recalculating prior pharmacy reimbursements could be substantial, and could significantly reduce anticipated savings associated with retroactive implementation. The effective date of the regulation should be set as the date of final publication in the *Pennsylvania Bulletin*.