

**Memorandum**Date **APR 15 1994**From June Gibbs Brown
Inspector General *June G. Brown*Subject Follow-up Review of the Pennsylvania Department of Public Welfare's Compliance
with the Federal Aggregate Upper Payment Limit Requirements for Prescription
To Drugs (A-03-92-00602)Bruce C. Vladeck
Administrator
Health Care Financing Administration

This memorandum alerts you to the issuance on April 18, 1994, of our final audit report. A copy is attached.

The report summarizes the results of our follow-up review of the Pennsylvania Department of Public Welfare's (State agency) compliance with the Federal aggregate upper payment limit requirements for prescription drugs for the period October 29, 1988 through October 28, 1989. The report also provides the Health Care Financing Administration (HCFA) with information necessary to monitor the State agency's progress in implementing corrective actions.

Under Federal regulations, States have the flexibility to pay more for some upper limit drugs and less for others. However, the States' claims for Federal financial participation (FFP) in payments for all upper limit drugs cannot exceed the aggregate of the drugs' individual upper payment limit established by HCFA plus a reasonable dispensing fee established by the State.

Our prior audit found that the State agency was not in compliance with HCFA's aggregate upper payment limit for the period October 29, 1987 through October 28, 1988 and, as a result, received FFP of over \$3.1 million in excess payments.

Our follow-up audit indicated that the State agency remained in a noncompliance status during the period October 29, 1988 through October 28, 1989. As a result, the State agency received between \$2,402,813 and \$6,757,991 of FFP in payments in excess of HCFA's aggregate upper payment limit. The actual amount of excess payments depends on whether the dispensing fee used in the upper payment limit calculation is the State agency's imputed dispensing fee of \$4.50 (\$2,402,813 of excess payments) or the State agency's actual dispensing fee paid to providers of \$2.75 (\$6,757,991 of excess payments).

Similar to our prior review, the causes for the noncompliance were (1) most upper limit drugs identified by HCFA were not included in the State agency's maximum allowable cost (MAC) program, (2) many MAC program prices were higher than HCFA's upper limit prices, and (3) widespread noncompliance by pharmacies and physicians with Federal and State regulations for transactions coded "brand medically necessary." We also found that the State agency's assurance of compliance for the year ended October 28, 1989 was incorrect.

In this report, we are recommending procedural improvements. We are also recommending that the State agency make a financial adjustment of \$2,402,813, the amount of FFP reimbursed that was in excess of HCFA's aggregate upper payment limit using the State agency's imputed \$4.50 as the "reasonable dispensing fee." We further recommend that the State agency either provide documentation to support its imputed dispensing fee of \$4.50 or take appropriate action to return the additional excess payments of up to \$4,355,178 FFP (\$6,757,991 less \$2,402,813).

In its August 9, 1993 response to a draft of this report, the State agency did not concur with our findings and recommendations because it believes it complied with Federal regulations concerning HCFA's aggregate upper payment limit. The State agency responded that the U.S. District Court recently ruled that the State was in compliance with the Federal reimbursement regulations and, therefore, was precluded by law from reducing its reimbursement rates to pharmacy providers for multiple source drugs.

The HCFA responded to a draft of this report on May 20, 1993. Despite the Federal court ruling, HCFA stated that it had advised the State agency that it must continue to make reimbursement for multiple source drugs in accordance with its approved State plan amendment effective January 11, 1991, or risk a disallowance action.

For further information, contact:

Thomas J. Robertson
Regional Inspector General
for Audit Services, Region III
(215) 596-6744

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**FOLLOW-UP REVIEW OF THE
PENNSYLVANIA DEPARTMENT OF
PUBLIC WELFARE'S COMPLIANCE WITH
THE FEDERAL AGGREGATE UPPER
PAYMENT LIMIT REQUIREMENTS FOR
PRESCRIPTION DRUGS**



**JUNE GIBBS BROWN
Inspector General**

**APRIL 1994
A-03-92-00602**



DEPARTMENT OF HEALTH & HUMAN SERVICES

REGION III
3535 MARKET STREET
PHILADELPHIA, PENNSYLVANIA 19104

TELEPHONE:
AREA CODE 215
596-6743-6744

OIG OFFICE OF AUDIT SERVICES

MAILING ADDRESS:
P.O. BOX 13716, MAIL STOP 9
PHILADELPHIA,
PENNSYLVANIA 19101

Our Reference: Common Identification Number A-03-92-00602

Ms. Karen F. Snider, Secretary
Department of Public Welfare
Commonwealth of Pennsylvania
Room 333, Health and Welfare Building
7th and Forester Streets
Harrisburg, Pennsylvania 17120

Dear Ms. Snider:

Enclosed for your information and use are two copies of a final HHS/OIG Office of Audit Services report titled FOLLOW-UP REVIEW OF THE PENNSYLVANIA DEPARTMENT OF PUBLIC WELFARE'S COMPLIANCE WITH THE FEDERAL AGGREGATE UPPER PAYMENT LIMIT REQUIREMENTS FOR PRESCRIPTION DRUGS. Your attention is invited to the audit finding and recommendations contained in the report.

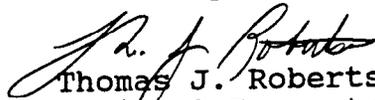
Final determination as to actions to be taken on all matters will be made by the HHS official named below. The HHS action official will contact you to resolve the issues in this audit report. Any additional comments or information that you believe may have a bearing on the resolution of this audit may be presented at that time.

In accordance with the principles of the Freedom of Information Act (Public Law 90-23), the HHS/OIG Office of Audit Services reports issued to the Department's grantees and contractors are made available, if requested, to members of the press and general public to the extent information contained therein is not subject to exemptions in the Act, which the Department chooses to exercise. (See Section 5.71 of the Department's Public Information Regulation, dated August 1974, as revised.)

Page 2 - Karen F. Snider

To facilitate identification, please refer to the referenced common identification number in all correspondence relating to this report.

Sincerely yours,



Thomas J. Robertson
Regional Inspector General
for Audit Services

Enclosures

Direct Reply to:

Associate Regional Administrator
Division of Medicaid
Health Care Financing Administration
Region III

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**FOLLOW-UP REVIEW OF THE
PENNSYLVANIA DEPARTMENT OF
PUBLIC WELFARE'S COMPLIANCE WITH
THE FEDERAL AGGREGATE UPPER
PAYMENT LIMIT REQUIREMENTS FOR
PRESCRIPTION DRUGS**



JUNE GIBBS BROWN
Inspector General

APRIL 1994
CIN: A-03-92-00602

SUMMARY

We conducted a follow-up review of an Office of Audit Services (OAS) report entitled, "REVIEW OF THE PENNSYLVANIA DEPARTMENT OF PUBLIC WELFARE'S COMPLIANCE WITH THE FEDERAL AGGREGATE UPPER PAYMENT LIMIT REQUIREMENTS FOR PRESCRIPTION DRUGS" (CIN: A-03-89-00233), which was issued on October 4, 1990.

Our prior audit found that the Department of Public Welfare (State agency) was not in compliance with the Health Care Financing Administration (HCFA) aggregate upper payment limit for the period October 29, 1987 to October 28, 1988 and, as a result, received Federal financial participation (FFP) of over \$3.1 million in excess payments. We found that most upper limit drugs identified by HCFA were not included in the State agency's Maximum Allowable Cost (MAC) program. Moreover, many MAC program prices were higher than upper limit prices established by HCFA. We also found widespread non-compliance by pharmacies and physicians with Federal and State regulations for transactions coded "brand medically necessary."

In our prior report, we made several recommendations to the State agency regarding needed procedural improvements. We also recommended that the State agency: (1) make a financial adjustment of over \$3.1 million, the amount in excess of HCFA's aggregate upper payment limit for the period October 29, 1987 to October 28, 1988; and (2) perform a review of its compliance with HCFA's aggregate upper payment limit for the period October 29, 1988 to October 28, 1989, and make the appropriate financial adjustment.

The State agency did not concur with our recommended financial adjustment because it believed that we did not fully consider dispensing fees as a reimbursement component when determining HCFA's aggregate upper payment limit. The State agency pointed out that the \$2.75 dispensing fee it actually paid was artificially low and regulations specify that a reasonable dispensing fee was to be included in the computation of the aggregate upper payment limit.

The State agency appealed the financial disallowance to the U.S. Department of Health and Human Services, Departmental Appeals Board (DAB). The DAB concluded that the regulations permit a State to calculate the aggregate upper payment limit using an amount other than the dispensing fee which it actually paid. However, unless the State provides documentation or analysis that the "reasonable dispensing fee" which it established is based on actual dispensing costs, HCFA reasonably may presume that the amount actually paid represents a reasonable dispensing fee. Accordingly, the DAB upheld the financial disallowance, subject to reduction by HCFA if the State furnishes documentation to HCFA which establishes the reasonableness of the \$3.50 fee (or some lesser amount which exceeds the \$2.75 fee actually paid).

Our follow-up audit indicated that the State agency has made progress in implementing corrective actions but that it remained in a non-compliance status during the period October 29, 1988 to October 28, 1989.

Effective January 11, 1991, the State agency amended its State plan to incorporate HCFA's upper limit drugs and prices. Second, the State agency reemphasized to providers the need to comply with Federal and State regulations. Third, the State agency increased its monitoring of providers and took action against the pharmacy chain that miscoded most of the generic drug claims in our prior review.

OAS review determines that the State agency implemented several procedural improvements aimed at ensuring future compliance with HCFA's aggregate upper payment limit. During the period of our review, however, the State agency remained out of compliance with Federal regulations.

These actions, while aimed at ensuring that the State agency complied with HCFA's aggregate upper payment limit, had no impact during the year under review. Our follow-up review found that the State agency was not in compliance with HCFA's aggregate upper payment limit for the period October 29, 1988 to October 28, 1989. As a result, the State agency received between \$2,402,813 and \$6,757,991 of FFP in payments in excess of HCFA's aggregate upper payment limit. The actual amount of excess payments depends on whether the dispensing fee used in the upper payment limit calculation is the State agency's imputed dispensing fee of \$4.50 (\$2,402,813 of excess payments) or the State agency's actual dispensing fee paid to providers of \$2.75 (\$6,757,991 of excess payments).

Similar to our prior review, the causes for the non-compliance were: (1) most upper limit drugs identified by HCFA were not included in the State agency's MAC program; (2) many MAC program prices were higher than HCFA's upper limit prices; and (3) widespread non-compliance by pharmacies and physicians with Federal and State regulations for transactions coded "brand medically necessary." Regarding this widespread non-compliance, we noted continued emphasis on this by the State agency, and an increase in the violations detected. We also found that the State agency's assurance of compliance for the year ended October 28, 1989 was incorrect.

In this report, we are recommending two procedural improvements. We are also recommending that the State agency make a financial adjustment of \$2,402,813, the amount of FFP reimbursed that was in excess of HCFA's aggregate upper payment limit using the State agency's imputed \$4.50 as the "reasonable dispensing fee." We further recommend that the State agency

provide documentation to support its imputed dispensing fee of \$4.50 or some lesser amount which exceeds the \$2.75 fee actually paid. If the State agency is unable to provide sufficient documentation to support its imputed dispensing fee, it should take appropriate action to return the additional excess payments of up to \$4,355,178 FFP (\$6,757,991 less \$2,402,813).

By letter dated August 9, 1993, the State agency provided comments to a draft of this report. The State agency did not concur with our findings and recommendations because it believes it complied with Federal regulations concerning HCFA's aggregate upper payment limit. The State agency responded that the U.S. District Court recently ruled that the State was in compliance with the Federal reimbursement regulations and, therefore, was precluded by law from reducing its reimbursement rates to pharmacy providers for multi-source drugs.

The HCFA responded to a draft of this report on May 20, 1993. Despite the Federal court ruling, HCFA stated that it had advised the State agency that it must continue to make reimbursement for multi-source drugs in accordance with its approved State plan amendment effective January 11, 1991, or risk a disallowance action.

The State agency and HCFA responses to our recommendations are summarized after the Conclusions and Recommendations section of this report. The State agency's and HCFA's comments are included in their entirety as Appendix C and Appendix D.

CONTENTS

SUMMARY	i
INTRODUCTION	1
BACKGROUND	1
SCOPE OF AUDIT	2
FINDINGS AND RECOMMENDATIONS	5
COMPLIANCE WITH HCFA'S AGGREGATE UPPER PAYMENT LIMIT	5
RESULTS OF PRIOR OAS AUDIT	5
State Agency Position	6
State Agency Appeal	6
RESULTS OF FOLLOW-UP AUDIT	8
Improvements Made by the State Agency	8
Continued Non-Compliance With HCFA's Upper Payment Limit	11
State Agency Assurance of Compliance	12
Claims Not Coded "Brand Medically Necessary"	12
Claims Coded "Brand Medically Necessary"	14
CONCLUSIONS AND RECOMMENDATIONS	16
State Agency Response	18
HCFA Response	19
OIG Comments	20
Appendix A - Sample Plan - Aggregate Upper Limit Drugs	
Appendix B - Sample Plan - "Brand Medically Necessary" Drugs	
Appendix C - State Agency Response	
Appendix D - HCFA Response	

INTRODUCTION

BACKGROUND

The Medicaid program, authorized under Title XIX of the Social Security Act, was established to pay for the cost of medical services for eligible persons whose income and resources were insufficient to pay for their health care. The HCFA administers Medicaid at the Federal level.

Although payment for prescription drugs is an optional service covered by Medicaid, Pennsylvania has availed itself of this option. However, because of the cost of this option, the Department of Health and Human Services established a task force to determine ways to ensure the Federal Government was a prudent buyer of drugs. Federal regulations were revised (42 CFR 447) effective October 29, 1987 to require HCFA to identify multiple source drugs and to establish a specific upper payment limit for each of them.

The HCFA designated a multiple source drug as an upper limit drug when:

- All formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically equivalent in the current edition of the publication, Approved Drug Products with Therapeutic Equivalence Evaluations; and
- At least three suppliers list the drug in a current edition of a published national drug compendium of cost information for drugs available nationally.

For multiple source drugs that meet these conditions, HCFA establishes an upper payment limit for that drug based on:

- 150 percent of the published price for the commonly listed package size in any of the above drug compendia for the least costly therapeutically equivalent drug that can be purchased by pharmacists; and
- a reasonable dispensing fee established by the State agency.

Under Federal regulations, States have the flexibility to pay more for some upper limit drugs and less for others. However, the States' claims for FFP in payments for all upper limit drugs cannot exceed the aggregate of the drugs' individual upper payment limit.

Section 6305 of the State Medicaid Manual makes one major exception to the upper payment limit methodology. This occurs

when a physician certifies, in his or her handwriting, on the prescription form, that a specific brand name drug is medically necessary. In such a case, the Federal government shares in the cost of the brand name drug and the upper payment limit does not apply.

Section 6305.2 of the State Medicaid Manual requires the State agency to submit a written assurance to HCFA that, in the aggregate, its Medicaid expenditures for upper limit drugs are in accordance with upper payment limit requirements. Furthermore, the State agency must maintain and make available to HCFA pertinent records to support its assurances.

In Pennsylvania, the Department of Public Welfare is the State agency responsible for administering the Medicaid program. As such, the State agency is responsible for providing the required compliance assurance to HCFA and establishing the necessary internal controls to ensure that claims for FFP in upper limit drugs do not exceed HCFA's aggregate upper payment limit.

The OAS conducts follow-up reviews to determine whether recommended actions have been implemented or are in process, and such actions have led to or will lead to resolution of problems noted. Our follow-up work was conducted pursuant to the OAS' responsibilities under the Office of Management and Budget's Circular A-50 to review and report on management responses to OAS findings.

SCOPE OF AUDIT

Our review was conducted in accordance with generally accepted government auditing standards. The objectives of our review were to: (1) determine whether the State agency had implemented our recommendations contained in the prior report; and (2) to quantify the FFP reimbursed to the State agency for the period October 29, 1988 to October 28, 1989 in excess of HCFA's aggregate upper payment limit.

We visited the HCFA regional office and reviewed all documentation related to the settlement of our prior audit report. At the State agency, we reviewed all actions taken as a result of our prior audit findings. Our review included an examination of the State agency's paid claim history file for the period October 29, 1988 through October 28, 1989, using the OAS computer program developed as part of the prior audit. We revised the original computer program to incorporate the upper payment limit for each drug using limits in effect during our current audit period.

We validated the reliability of the data included in the paid claim history file through the following test. We randomly

selected 100 transactions for upper limit drugs (Appendix A). For each transaction selected, we obtained a copy of the invoice submitted for payment (if available) and the remittance advice. We compared information on the invoices and remittance advices to information retrieved from the paid claim history file by the OAS computer program. The data was identical and the State agency's paid claim history file was, therefore, accurate.

To determine whether the State agency complied with the HCFA aggregate upper limit, we made two calculations. The first assumed that the State agency's \$4.50 imputed dispensing fee used in making its upper limit assurance to HCFA was the "reasonable dispensing fee." The second calculation assumed that the State agency's \$2.75 actual dispensing fee paid to providers was the "reasonable dispensing fee." For each dispensing fee processed against the State agency's validated paid claim history file, the OAS computer program:

1. Determined the total amount paid by the State agency for all upper limit drugs identified by HCFA. The total amount included prices of drugs and dispensing fees paid to pharmacies.
2. Determined the total amount that should have been paid by the State agency based on HCFA's upper payment limit. This total amount also included prices of drugs and dispensing fees.
3. Compared both amounts to determine if the State agency exceeded HCFA's aggregate upper payment limit.
4. Determined the total amount that the State agency claimed for claims coded "brand medically necessary."

To evaluate the adequacy of the internal controls in place to ensure claims coded "brand medically necessary" were in compliance with Federal regulations and, therefore, exempt from the upper payment limit methodology, we randomly sampled 100 transactions (Appendix B), visited dispensing pharmacies and reviewed prescriptions to determine compliance with Federal regulations.

For those items tested, we found no instances of noncompliance except for those matters discussed in the FINDINGS AND RECOMMENDATIONS section of this report. With respect to those items not tested, nothing came to our attention to cause us to believe that the untested items would have shown results which varied from the results of the tested items.

Our review was conducted at the State agency in Harrisburg, Pennsylvania, at selected pharmacies located throughout

Pennsylvania, and the HCFA regional office, during May through September 1992.

FINDINGS AND RECOMMENDATIONS

COMPLIANCE WITH HCFA'S AGGREGATE UPPER PAYMENT LIMIT

Our follow-up review showed that the State agency implemented many of the procedural recommendations included in our previous audit report. The State agency, however, did not implement our recommendations pertaining to a financial adjustment and a self-review to determine its compliance with HCFA's aggregate upper payment limit for the period October 29, 1988 to October 28, 1989. We, therefore, made this determination during our follow-up audit. We concluded that the State agency was not in compliance with HCFA's aggregate upper payment limit and that, as a result, it was reimbursed excess FFP of between \$2,402,813 and \$6,757,991. The excess FFP varies depending on whether the dispensing fee used in the aggregate upper limit calculation is the State agency's imputed fee of \$4.50 (\$2,402,813 of excess payments) or the State agency's actual dispensing fee paid to providers of \$2.75 (\$6,757,991 of excess payments).

We calculated two excess payment amounts because, according to the DAB, the regulations permit a State to calculate the aggregate upper payment limit using an amount other than the dispensing fee which it actually paid. However, the State must provide documentation or analysis that the "reasonable dispensing fee" it established is based on actual dispensing costs.

RESULTS OF PRIOR OAS AUDIT

Our prior audit found that the State agency was not in compliance with the HCFA aggregate upper payment limit for the period October 29, 1987 to October 28, 1988 and, as a result, received FFP of over \$3.1 million in excess payments. We found that most upper limit drugs identified by HCFA were not included in the State agency's MAC program. Moreover, many MAC program prices were higher than upper limit prices established by HCFA. We also found widespread non-compliance by pharmacies and physicians with Federal and State regulations for transactions coded "brand medically necessary."

We recommended that the State agency strengthen internal controls over expenditures for upper limit drugs; reemphasize to participating physicians and pharmacies the need to comply with Federal and State regulations and policies and monitor their compliance; and adequately document and support all future assurances to HCFA. We also recommended that the State

agency make a financial adjustment to the Federal account in the amount of \$3,152,092 which consisted of:

- \$2,780,538 of FFP in payments in excess of HCFA's aggregate upper payment limit for claims not coded as "brand medically necessary."
- \$362,455 of FFP in payments in excess of HCFA's aggregate upper payment limit for transactions erroneously coded as "brand medically necessary."
- \$9,099 of FFP in payments in excess of the State agency's MAC limits (this is net of the amount above).

Our final recommendation was that the State agency perform a review of its compliance with HCFA's aggregate upper payment limit for the period October 29, 1988 to October 28, 1989, and make the appropriate financial adjustment.

State Agency Position

In its March 16, 1990 response to our draft report, the State agency generally did not concur with our recommendations. The State agency did not concur with our recommended financial adjustment because it believed the OAS did not fully consider dispensing fees as a reimbursement component when determining the aggregate upper payment limit. The State agency pointed out that the \$2.75 dispensing fee it actually paid was artificially low and regulations specify that a reasonable dispensing fee was to be included in the computation of the aggregate upper payment limit. It argued that had the OAS used a reasonable dispensing fee, there would have been no financial adjustment recommended.

State Agency Appeal

The State agency disagreed with HCFA's \$3,152,092 disallowance based on our audit and filed an appeal with the DAB. During the appeals process, the State agency conceded that \$371,554 was properly disallowed. The issues with respect to the \$2,780,538 of FFP remaining in dispute were whether the regulations require that, in calculating the aggregate upper payment limit, the State agency use the \$2.75 dispensing fee which it actually paid to pharmacies, and, if not, whether the \$3.50 dispensing fee used by the State agency in making its assurances that it would not exceed the upper payment limit was a "reasonable dispensing fee" within the meaning of the regulations.

On March 18, 1992, the DAB (Decision No. 1315) concluded that the regulations permit a State to calculate the aggregate upper

payment limit using an amount other than the dispensing fee which it actually paid. However, unless the State provides documentation or analysis that the "reasonable dispensing fee" which it established is based on actual dispensing costs, HCFA reasonably may presume that the amount actually paid represents a reasonable dispensing fee. The DAB concluded that the State did not show that the \$3.50 dispensing fee used to make its assurances was a reasonable dispensing fee. Accordingly, the DAB upheld HCFA's disallowance, subject to reduction by HCFA if the State furnishes documentation to HCFA which establishes the reasonableness of the \$3.50 fee (or some lesser amount which exceeds the \$2.75 fee actually paid).

On May 13, 1992, in response to the DAB decision, the State agency submitted for HCFA's consideration certain documentation to support the imputed dispensing fee used in the State's assurance. The documentation included:

- 1) "An Assessment of Chain Pharmacies' Cost of Dispensing a Third Party Prescription" dated April 1990 and prepared by the Pharmaceutical Economics Research Center at the request of the National Association of Chain Drug Stores (Assessment).
- 2) A study by the State agency showing actual dispensing costs based upon the usual charges for prescription drugs.

On October 19, 1992, the State agency was notified that HCFA had concluded that the State agency's documentation did not establish that the \$3.50 dispensing fee used by the State agency in calculating the upper limit for multiple source drugs reasonably reflected actual dispensing costs in Pennsylvania. The HCFA found that the Assessment was seriously flawed and therefore unreliable. The HCFA also determined that the State agency study did not contain sufficient information to allow an evaluation of the computer printouts and handwritten computations.

The HCFA took several actions to recover the \$3,152,092 disallowance. On June 11, 1992, HCFA issued a negative grant award to recover the \$371,554 conceded by the State agency during the appeals process. In April 1993, HCFA recovered \$1,509,498 representing the excess FFP in payments received by the State agency if the upper payment limit was established using the State agency's imputed dispensing fee of \$3.50. On July 27, 1993, because the State agency was unable to provide sufficient documentation to support the reasonableness of its imputed dispensing fee of \$3.50 (or some lesser amount which exceeds the \$2.75 actual dispensing fee), HCFA issued a negative grant award to recover the remaining \$1,271,040 plus accrued interest amounting to \$100,911.

On August 30, 1993, HCFA notified the State agency that it should respond to HCFA's October 19, 1992 letter that rejected the State agency's documentation provided initially to support the reasonableness of the \$3.50 dispensing fee. The HCFA indicated that it was willing to review any new information the State may submit to support the \$3.50 fee, and, if the imputed fee is supportable, it would reduce the disallowance to \$1,509,498.

RESULTS OF FOLLOW-UP AUDIT

Our follow-up review disclosed that despite its nonconurrence with our prior procedural recommendations, the State agency has taken action to implement several of them. We believe these actions will improve compliance in the future. The State agency, however, remained out of compliance with HCFA's aggregate upper payment limit during the period October 29, 1988 to October 28, 1989, regardless of whether the State agency's imputed dispensing fee of \$4.50 or its actual dispensing fee of \$2.75 was used in the upper limit calculation. As a result, the State agency received between \$2,402,813 and \$6,757,991 of excess FFP. Therefore, the State agency's assurance that it would have been in compliance using \$4.50 as a "reasonable dispensing fee" rather than the actual dispensing fee of \$2.75 was in error.

Improvements Made by the State Agency

We found that the State agency took action to implement several of our recommendations for procedural improvements. For example:

- On May 22, 1989 the State agency issued a medical assistance bulletin to all pharmacies and physicians to reemphasize the need to comply with Federal and State regulations and policies. The bulletin also notified providers that the submission of a pharmacy claim that misrepresents the actual service provided is a serious violation of program regulations and may violate the Medicaid Fraud Control Act.
- On December 11, 1990 the State agency issued a medical assistance bulletin notifying pharmacies and physicians of a revised payment system for multiple source drugs that was to take effect the following month.
- Effective January 11, 1991, the State agency amended its State plan to include any HCFA multiple source

drug as a MAC drug with the upper limit price established by HCFA as the State agency's MAC price.

The State agency also improved its system to monitor use of the "brand medically necessary" indicator. The State agency system now identifies pharmacies that demonstrate excessive use of the "brand medically necessary" indicator in relation to their total claims. The State agency evaluates exceptions to determine if further action is warranted.

The State agency referred those claims submitted by the major pharmacy chain addressed in our prior report to its Bureau of Quality Assurance for immediate and appropriate action. Based on its evaluation, the State agency has proposed sanctions against the pharmacy chain and is presently negotiating a settlement.

In our follow-up review, we tested the effectiveness of the State agency's actions. For the most part, we found them to be effective. For example, we compared the drug products on HCFA's upper limit drug listing as of September 1, 1990 to the State agency's MAC drug listing effective January 11, 1991. We found that the State agency's MAC program included 98 percent (384 of 390 drug products) of HCFA's upper limit drugs. We believe that the improved internal controls should enable the State agency to comply with HCFA's aggregate upper payment limit for periods subsequent to January 11, 1991.

Our testing also disclosed that subsequent to the release of the bulletin "brand medically necessary" billing violations initially decreased, but have since increased. We reviewed the results of our random sample of 100 "brand medically necessary" transactions from October 29, 1988 to October 28, 1989 to determine the effect of the medical assistance bulletin on pharmacy billing practices. As shown below, our analysis disclosed that billing violations decreased about 26 percent during the period following the issuance of the medical assistance bulletin.

Date Range of Errors	Number of Days for Range	Actual Errors for Range	Expected Number of Errors - Annualized
10/29/88 - 5/21/89	205	43	(43/205) (365) = 76.56
5/22/89 - 10/28/89	160	25	(25/160) (365) = 57.03
Totals	365	68	(76.56 - 57.03) / 76.56 = 26%

To determine whether this positive trend continued, we examined the results of pharmacy reviews conducted by an independent reviewer under contract with the State agency. The State agency contracts with a third party to conduct program compliance reviews at 400 pharmacies each year. The scope of the contractor's review includes determining compliance with "brand medically necessary" billing regulations. We reviewed the "brand medically necessary" portion of the contractor's review and found that the number of violations decreased significantly from the first review period to the second review period (594 violations to 147 violations). However, the number of violations increased significantly from the second review period to the third review period (147 violations to 461 violations).

<u>Review Period</u>	<u>Violations</u>	<u>Pharmacies with Violations</u>
1. 8/1/89 to 5/31/90	594	125
2. 7/1/90 to 6/30/91	147	85
3. 5/1/91 to 6/30/92	461	123

The review period above refers to the period in which the review was conducted by the contractor. According to the State agency, the contractor normally reviews claims data covering the most recent 6-month period.

We believe the State agency's efforts to detect violations is sound. The number of violations being detected, however, indicates that once more there is a need to reemphasize to participating physicians and pharmacies the importance of complying with Federal and State regulations and policies.

Continued Non-Compliance With HCFA's Upper Payment Limit

We believe that the above actions taken by the State agency should assist it in complying with HCFA's aggregate upper payment limit. The actions, however, had no effect on State agency operations during the period of our review. Based on our prior audit, we suspected that the State agency would be out of compliance for that period. That is why we recommended that it do a self-review to determine its compliance and make an appropriate financial adjustment based on the self-review. The State agency declined to do this, therefore, we reviewed compliance for the period October 29, 1988 to October 28, 1989.

The OAS computer program identified 4,124,815 claims for upper limit drugs and 330,712 claims for "brand medically necessary" drugs. We determined that the State agency was not in compliance with HCFA's aggregate upper payment limit and, as a result, it was reimbursed excess FFP of between \$2,402,813 and \$6,757,991. As shown below, the excess FFP varies depending on whether the dispensing fee used in the aggregate upper limit calculation is the State agency's imputed dispensing fee of \$4.50 or the State agency's actual dispensing fee paid to providers of \$2.75.

	<u>EXCESS PAYMENTS IN FFP</u>	
	<u>DISPENSING FEE</u>	
	<u>\$4.50</u>	<u>\$2.75</u>
Claim Value	\$21,295,130	\$28,513,556
Less:		
Upper Limit	<u>17,518,934</u>	<u>17,518,934</u>
Excess Payments	<u>\$ 3,776,196</u>	<u>\$10,994,622</u>
FFP in Excess Payments	\$ 2,172,293	\$ 6,308,053
Add:		
FFP for erroneous "brand medically necessary" claims	<u>230,520</u>	<u>449,938</u>
Total Excess FFP	<u>\$ 2,402,813</u>	<u>\$ 6,757,991</u>

The FFP amounts are based on FFP rates of 57.42 percent for October 29, 1988 through September 30, 1989; and 56.86 percent for October 1, 1989 through October 28, 1989.

State Agency Assurance of Compliance

On January 26, 1989 the State agency submitted its annual assurance regarding upper limit drugs for the year ended October 28, 1989. The State agency maintained that it was unfair to use its \$2.75 actual dispensing fee in making its annual assurance to HCFA. The State agency contended that \$4.50 was a reasonable dispensing fee (\$1 higher than its \$3.50 imputed fee used for the prior year). It defined "reasonable dispensing fee" as the dispensing fee established by HCFA in the Medicare Catastrophic Coverage Act. This Act was repealed by Congress and, therefore, was not implemented.

The State agency believed a \$4.50 dispensing fee was appropriate and reasonable for its Medicaid program which must use low drug costs on which to base its aggregate upper payment limit. By defining \$4.50 as its "reasonable dispensing fee" and applying this figure to the HCFA upper payment limit for multiple source drugs, the State agency assured that the actual aggregate upper payment limit for these drugs would not be exceeded. Other than the above explanation, the State agency did not provide documentation or analysis to support its imputed dispensing fee of \$4.50 when it filed its annual assurance to HCFA.

We processed the State agency paid claim history file using the \$4.50 dispensing fee against the OAS computer program and determined that the State agency's assurance was incorrect. The OAS computer program computed the HCFA aggregate upper payment limit to be \$17,518,934 and the State agency's payments to be \$21,295,130. Therefore, the State agency would have claimed FFP on overpayments of \$3,776,196. The FFP in these overpayments would have been \$2,172,293.

Our computer program demonstrates that the State agency would not have been in compliance with the upper payment limit regulations when defining the dispensing fee as \$4.50. The overpayment of \$2,172,293 demonstrates that: (1) the State agency had a significant problem complying with the Federal upper limit regulations during the year ended October 28, 1989; and (2) the State agency's assurance of compliance with HCFA's upper payment limit was inaccurate.

Claims Not Coded "Brand Medically Necessary"

We also processed the State Agency's paid claim history file for the period October 29, 1988 to October 28, 1989 against the OAS computer program using the State agency's \$2.75 actual dispensing fee for the 4,124,815 claims for upper limit drugs that were not coded "brand medically necessary." The claims totaled \$28,513,556 and the State agency received \$16,359,974 in FFP for these payments.

According to Federal regulations, the State agency had flexibility in establishing prices for the individual drug products that comprised the total payment of \$28,513,556. However, because none of the claims for these drugs were coded "brand medically necessary," the State agency could not claim FFP in payments that exceeded the HCFA's aggregate upper payment limit (this is the total of HCFA upper payment limits for the drugs that comprised the total payment of \$28,513,556).

The OAS computer program computed these individual upper payment limits and calculated HCFA's aggregate upper payment limit at \$17,518,934 as compared to \$28,513,556 claimed. The State agency, therefore, claimed FFP in payments of \$10,994,622 that exceeded HCFA's aggregate upper payment limit. The FFP in these payments was \$6,308,053.

Our previous review demonstrated that the State agency included no more than 36 percent (103 of the 283 drug products) of HCFA's upper limit drugs in the MAC program during the entire time that HCFA's initial list was in effect. Moreover, for those drugs that were in the MAC program, MAC prices were generally higher than HCFA's upper payment limits.

During the year ended October 28, 1989, HCFA issued two lists of upper limit drugs and the State agency issued two lists of MAC drugs as follows:

- A HCFA list effective July 1, 1988 identified 324 drug products and their upper payment limits. The State agency issued two lists effective on August 15, 1988 and March 1, 1989.
- A HCFA list effective on June 1, 1989 identified 389 drug products and their upper payment limits. The State agency's drug list of March 1, 1989 was in effect at this time.

We compared each HCFA list to the MAC lists that were in effect. We found that the State agency included no more than 54 percent (174 of the 324 drug products) of HCFA's upper limit drugs in the MAC program during the October 29, 1988 to May 31, 1989 period. Moreover, for those prices that were in the MAC program, MAC prices were generally higher than HCFA's upper payment limits.

The HCFA added more upper limit drugs on June 1, 1989. At the end of our audit period, however, only 46 percent (178 of 389 drug products) of HCFA's upper limit drugs were in the MAC program and comparable pricing existed for only two of these drugs.

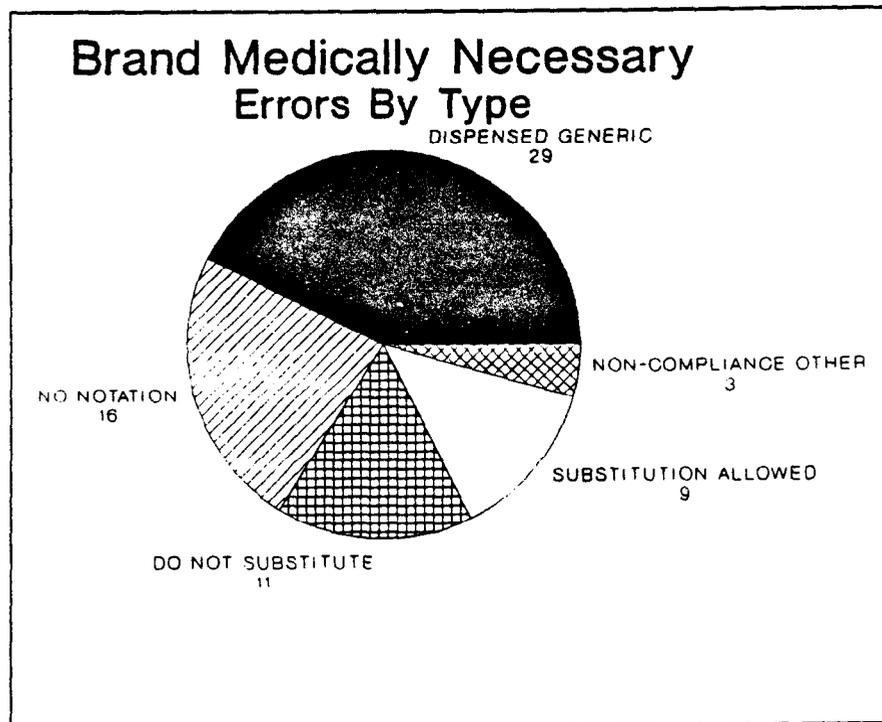
The State agency continued to exclude upper limit drugs from the MAC program because the drugs were not included in the

Pennsylvania Department of Health's Generic Drug Formulary. Continuing to exclude so many of HCFA's upper limit drugs from the MAC program and routinely establishing higher MAC prices for those drugs that were included in the program contributed to the State agency not being able to stay within HCFA's aggregate upper payment limit.

Claims Coded "Brand Medically Necessary"

The OAS computer program identified 330,712 transactions valued at \$4,521,950 for drugs which pharmacies coded "brand medically necessary." Because of the special code, the claims avoided the State agency's MAC payment controls and we excluded them from our computerized computation of HCFA's aggregate upper payment limit. These claims are not subject to the upper limit methodology if physicians annotated on prescription forms that brand name drugs were medically necessary.

We reviewed 100 randomly selected transactions to determine if these transactions should be excluded from HCFA's aggregate upper payment limit. As shown in the chart below, our review showed continued non-compliance by prescribing physicians and dispensing pharmacies.



There were several different categories of noncompliance.

- **Dispensed Generic** indicates that 29 percent of the sample (29 of 100) were coded "brand medically necessary" but were for generic drugs. For purposes of our review, we considered these transactions to be subject to HCFA's aggregate upper payment limit.
- **No Notation** indicates that 16 percent of the sample (16 of 100) did not contain any notation whatsoever by prescribing physicians concerning substitution or the medical necessity for brand name drugs.
- **Do Not Substitute** indicates that for 11 percent of the sample (11 of 100), physicians specifically instructed pharmacies to dispense brand name drugs though they failed to write on the prescription form that the brand name drugs were medically necessary. The pharmacies failed to comply with State agency instructions in that they entered a code "1" on the invoice in spite of the absence of the written certification.
- **Substitution Allowed** indicates that for 9 percent of the sample (9 of 100), prescribing physicians gave pharmacies latitude to substitute less expensive generic drugs. The pharmacies chose to dispense higher price brand name drugs and placed a code "1" on the invoice in spite of the absence of the written certification.
- **Non-Compliance Other** indicates that 3 percent of the sample (3 of 100) had other discrepancies.

Our sample showed that 68 percent of the transactions coded "brand medically necessary" did not meet the Federal requirements for such a designation. Therefore, these transactions were subject to HCFA's aggregate upper payment limit. We compared the amounts of the transactions to HCFA's upper payment limits for the drugs associated with the transactions to determine if HCFA's aggregate upper payment limit was exceeded. We made two excess payment calculations: first, using the State agency imputed dispensing fee of \$4.50; and, second, using the State agency actual dispensing fee of \$2.75. We then projected the results of our sample to the universe of 330,712 transactions. We are 95 percent confident that the State agency received at least \$230,520 in excess FFP if the dispensing fee is \$4.50, and \$449,938 in excess FFP if the dispensing fee is \$2.75. These amounts represent the Federal share of State agency claims for FFP in payments in excess of HCFA's aggregate upper payment limit. They do not

take into account that some payments made by the State agency were in error.

CONCLUSIONS AND RECOMMENDATIONS

For the year ended October 28, 1989, the State agency's internal controls were inadequate to ensure that payments for upper limit drugs did not exceed HCFA's aggregate upper payment limit. Based on the results of the OAS computer program designed to test State agency compliance with the aggregate upper payment limit, and our follow-up work at pharmacies to test compliance with both Federal and State regulations and policies, we have determined that the State agency claimed FFP in payments that exceeded HCFA's aggregate upper payment limit. As a result, the State agency received between \$2,402,813 and \$6,757,991 of FFP more than it was entitled to under Federal regulations. The actual amount of excess payments depends on whether the dispensing fee used in the upper payment limit calculation is the State agency's imputed dispensing fee of \$4.50 (\$2,402,813 of excess payments) or the State agency's actual dispensing fee paid to providers of \$2.75 (\$6,757,991 of excess payments).

On March 18, 1992, the DAB concluded that the regulations permit a State to calculate the aggregate upper payment limit using an amount other than the dispensing fee which it actually paid. However, unless the State provides documentation or analysis that the "reasonable dispensing fee" which it established is based on actual dispensing costs, HCFA reasonably may presume that the amount actually paid represents a reasonable dispensing fee. The State agency did not provide documentation to support its imputed dispensing fee of \$4.50 when it filed its annual assurance to HCFA on January 26, 1989. Because the State agency was unaware of the need to provide documentation to support its imputed dispensing fee at the time it filed its assurance, we believe that HCFA should provide the State with a reasonable amount of time to do so.

The reasons for non-compliance varied. Most upper limit drugs identified by HCFA were not in the State agency's MAC program and thus could not be substituted for higher priced brand name drugs in Pennsylvania. The State agency's practice of routinely paying more than HCFA's upper payment limits also had a cumulative effect on their inability to stay within the aggregate upper payment limit. There was also widespread violation of Federal and State regulations and policies by physicians and pharmacies that participated in the Medicaid program. Moreover, our examination of the results of pharmacy compliance reviews conducted by a State contractor disclosed that pharmacy violations have recently increased.

The State agency took certain actions to help ensure compliance with HCFA's aggregate upper payment limit. Perhaps the most significant action taken was the State agency's adoption of the HCFA's upper limits for identified drugs. We believe, however, that there is still a need for procedural improvements and for a financial adjustment for excess FFP reimbursed during the period of our review.

We, therefore, recommend that the State agency:

1. Reemphasize to participating physicians and pharmacies the need to comply with Federal and State regulations and policies.
2. Adequately document and support all future assurances to HCFA.
3. Make a financial adjustment to the Federal account in the amount of \$2,402,813 which consists of:
 - \$2,172,293 of FFP in payments in excess of HCFA's aggregate upper payment limit for claims not coded as "brand medically necessary."
 - \$230,520 of FFP in excess of HCFA's aggregate upper payment limit for transactions erroneously coded as "brand medically necessary."

These amounts are calculated using the State agency imputed dispensing fee of \$4.50.

4. Provide documentation to HCFA which establishes the reasonableness of the \$4.50 fee (or some lesser amount which exceeds the \$2.75 fee actually paid). If sufficient documentation is not furnished, make another financial adjustment to the Federal account of up to \$4,355,178 (\$6,757,991 less \$2,402,813) which consists of:
 - \$4,135,760 of FFP in additional payments in excess of HCFA's aggregate upper payment limit for claims not coded as "brand medically necessary."
 - \$219,418 of FFP in additional payments in excess of HCFA's aggregate upper payment limit for transactions erroneously coded as "brand medically necessary."
5. Perform a review of its compliance with HCFA's aggregate upper payment limit for periods subsequent to October 23, 1989 and make the appropriate financial adjustment.

State Agency Response

(OIG Comment - The draft report sent to the State agency for comment only recommended a disallowance based on the actual \$2.75 dispensing fee reimbursed by the State agency. As explained on page 21, the OIG modified its findings and recommendations based on comments received from the State agency and HCFA and the DAB's decision.)

The State agency responded that it found our audit to be seriously flawed and, therefore, unreliable as it pertained to the State agency's compliance with the Federal aggregate spending limits for multiple source drugs for the periods October 29, 1987 to October 28, 1988 and October 29, 1988 to October 28, 1989. The State agency contends that the audit was based entirely on the premise that a reasonable dispensing fee for the State was \$2.75 when the State agency has documented otherwise. The State agency also responded that the audit ignored the State agency's subsequent appeal of the previous disallowances for the period October 29, 1987 to October 28, 1988 before the DAB and the decision of the DAB.

In support of its position, the State agency raised five issues that it believes our audit did not consider. First, the State agency stated that it had provided the OIG auditors with the State agency's documentation of the actual costs involved in dispensing a prescription. Yet, when the draft report was provided to the State agency any reference to this information was conspicuously absent.

Second, both audits derived the State agency's expenditures by subtracting \$2.75 from each claim reviewed. According to the State agency this method relies on the false assumption that \$2.75 is a reasonable dispensing fee and incorrectly compares drug cost to drug cost.

Third, the State agency stated that the regulations do not require that a State's actual dispensing fee must be used to calculate the aggregate spending limit. The regulations do not define what constitutes a reasonable dispensing fee and, in fact, allow the State to establish this component.

Fourth, the State agency contends that the DAB decision supported the State agency's principle in that the regulations permitted a State to define a reasonable fee that was different from the one the State actually used in its reimbursement formula.

The last issue was the conclusion of a Federal judge from the U.S. Middle District Court, in which he ruled that Pennsylvania was in compliance with the Federal upper limit regulations based largely on the DAB's decision. Shortly after the State

agency adopted the Federal upper limits, the Pennsylvania Pharmaceutical Association (PCA) filed suit against the State. The PCA maintained that the lower reimbursement violated moratorium provisions of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) because the State agency was already in compliance with Federal regulations before adoption of the Federal upper limits. On September 16, 1992, the U.S. District Court ruled in favor of the PCA, therefore, the State agency was not permitted to enforce the Federal upper limit prices as provided in its State plan amendment and was ordered to revert to the previous State agency MAC prices or the average wholesale prices in place prior to January 11, 1991.

Based on the U.S. District Court's ruling, the State agency contends that it was in compliance with Federal regulations for prescription reimbursement and, therefore, should not be held accountable for any Federal sanctions resulting in the return of FFP between October 1987 and January 1991 and during the period of the OBRA 90 moratorium. The State agency does not accept the OIG's findings and cannot concur with the recommendation to make financial adjustments for the two periods in question. Also, the State agency does not concur with our recommendation to perform a review of its compliance with HCFA's aggregate payment limit for periods subsequent to October 28, 1989, or to make any subsequent financial adjustments.

The State agency agreed that there may be isolated incidents of claims incorrectly coded as "Brand Medically Necessary," although it does not acknowledge the degree of occurrences alleged in the report nor does it concur with the dollar amount stated. The State agency stated that it conducts routine audits of pharmacies and seeks restitution from any pharmacy found miscoding claims as "Brand Medically Necessary." The State agency contends that the OIG audit did not consider these reviews in the audit report. The State agency also plans to require prior authorization for all brand name drugs that have generically equivalent substitutes available. This change will probably take place before the end of 1993 and should resolve the problem of miscoded claims.

HCFA Response

The HCFA provided written comments to clarify the current circumstances involving Medicaid reimbursements for multiple source drugs in Pennsylvania. The HCFA stated that its approval of the State plan amendment, effective January 11, 1991, which incorporated the Federal upper payment limits brought the State agency into compliance with the applicable Federal upper limits for multi-source drugs.

The PCA subsequently sued the State in U.S. District Court for violating the OBRA 90 moratorium on reducing drug payments. The court ruled in favor of PCA. The State appealed the U.S. District Court's ruling. While the appeal was pending, the parties settled the case and the appeal was dismissed.

The HCFA noted that the U.S. District Court's ruling relied, in part, upon the DAB decision in finding that the State was in compliance with the upper payment limits before the implementation of the State plan amendment. The HCFA informed the State agency that HCFA does not agree with the U.S. District Court's conclusion that the DAB found the State in compliance with the upper limits. In fact, in HCFA's view, the DAB held to the contrary, finding that the State was not in compliance with the upper payment limits.

The HCFA advised the State that should the proposed settlement with PCA result in payments for multi-source drugs which exceed the amounts set by the State plan, HCFA would, after appropriate review, disallow FFP for any amounts paid which are not according to the approved State Plan methodology.

Upon receiving the State agency's written comments we met with HCFA to discuss the impact of the U.S. District Court's ruling on State agency compliance with HCFA upper limit requirements. We were provided an August 30, 1993 letter to the State agency that details HCFA's position in this matter. In HCFA's opinion, the compliance issue has been confused with the issue of the appropriate methodology for establishing the aggregate upper payment limit. The DAB ruled that the State agency may use an imputed dispensing fee as long as it could show that the fee was representative of the actual costs of dispensing a prescription in Pennsylvania. The DAB did not examine the issue of whether the State agency would have been in compliance with the aggregate upper payment limit if it used its \$3.50 imputed dispensing fee in the upper limit calculation.

In regard to the current situation, HCFA's position is that the State agency should pay for multiple source drugs according to its State Plan amendment effective January 11, 1991. If the State agency does not follow its approved State Plan methodology, its aggregate payout for multiple source drugs could exceed the upper payment limit and be subject to future disallowance.

OIG Comments

After review of the State agency's and HCFA's comments, we continue to believe that the State agency was not in compliance with HCFA's aggregate upper payment limit for the period October 29, 1988 to October 28, 1989. However, we have revised this report to show that the State agency would have received

\$2,402,813 of excess payments in FFP if the State agency's imputed dispensing fee of \$4.50 is used as the "reasonable dispensing fee" in the aggregate upper limit calculation. We also added a section entitled, "State Agency Appeal" beginning on page 6 of this report that specifically addresses the DAB's decision and the State agency's documentation to support its \$3.50 imputed dispensing fee. The HCFA had concluded, and we agree, that the State agency's documentation did not establish that the \$3.50 imputed dispensing fee reflected actual dispensing costs in Pennsylvania. Regarding our current audit period, the State agency did not provide any documentation to support its imputed dispensing fee of \$4.50.

Our revised position is consistent with the DAB decision that the regulations permit a State to calculate the aggregate upper payment limit using an amount other than the dispensing fee which it actually paid. However, unless the State provides documentation or analysis that the "reasonable dispensing fee" which it established is based on actual dispensing costs, HCFA reasonably may presume that the amount actually paid represents a reasonable dispensing fee.

Therefore, we are recommending that the State agency make a financial adjustment for \$2,402,813 which represents the excess payments in FFP using the State agency imputed dispensing fee of \$4.50 in the aggregate upper limit calculation. The State agency, however, must provide HCFA with documentation or analysis to support the \$4.50 imputed fee or some lesser amount which exceeds the \$2.75 actually paid. If the State agency is unable to support its imputed fee it must make additional financial adjustments as described in this report.

We continue to believe that the primary causes for the State agency's non-compliance during both review periods were that most upper limit drugs identified by HCFA were not included in the State agency's MAC program and many MAC program prices were higher than HCFA's upper limit prices.

The DAB decision clearly indicates that the DAB ruled that the State agency may use an imputed dispensing fee as long as it could show that the fee was representative of the actual costs of dispensing a prescription in Pennsylvania. The DAB specifically did not find that the \$3.50 was reasonable and upheld a disallowance based on the actual \$2.75 dispensing fee unless the State demonstrated a higher actual cost. The State has not done so. Additionally, the DAB did not specifically examine the issue of whether the State agency would have been in compliance with the aggregate upper limit if it used its \$3.50 imputed dispensing fee in the upper limit calculation. The DAB merely assumed that the State would have been in compliance if the \$3.50 fee were properly used. Our report clearly demonstrates that the DAB's assumption was incorrect and that the State agency would have been out of compliance

with the upper payment limit during both audit periods regardless of whether the State agency's imputed dispensing fees or actual dispensing fees were used in the upper payment limit calculations.

Therefore, we concur with HCFA's position that the U.S. District Court erroneously concluded that the State was in compliance with the upper payment limits before the implementation of its January 11, 1991 State Plan amendment. Since the Department of Health and Human Services was not a party to this litigation, the court's decision is not binding on HCFA or the OIG. Moreover, in our opinion, if the State agency does not implement its State Plan amendment to adopt HCFA's upper limits for identified drugs, the State agency's aggregate payout for multiple source drugs will likely continue to exceed the HCFA upper payment limit and place the State agency at risk of additional HCFA disallowance actions.

Regarding the "brand medically necessary" portion of our audit, we agree that the State agency's plans to require prior authorizations for these type claims should resolve the problem of miscoded claims. Although the State agency did not concur with the number of errors we identified or the recommended financial adjustment, it did not say what the correct amounts should be. We agree, however, that our recommended financial adjustment did not take into account any restitution related to miscoded "brand medically necessary" claims identified during State agency pharmacy audits. To the extent that the State agency can document such recoveries it may properly offset them against our recommended financial adjustment. If necessary, our audit working papers and audit staff are available to assist HCFA in this matter.

**Sample Plan
Aggregate Upper Limit Drugs
Follow-up Review of Pennsylvania Medicaid
Upper Limit Drug Program
CIN: A-03-92-00602**

Audit Objective:

The objective of our audit is to determine the total dollars that the State agency reimbursed for drug payments that exceeded HCFA's aggregate upper payment limit during the period October 29, 1988 through October 28, 1989.

Universe:

The universe will consist of all upper limit drug claims obtained by matching the State agency paid claim history file against the First Data Bank list of upper limit National Drug Codes. The universe does not include claims coded as "brand medically necessary".

Sampling Unit:

An upper limit drug claim.

Survey and Background Information:

Federal regulations (42 C.F.R. 447.332) issued in July 1987 and effective October 29, 1987, require HCFA to identify multiple source drugs and to establish a specific upper payment limit for each of them. The HCFA designates a multiple source drug as an upper limit drug when two conditions are met:

- All formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically equivalent and listed in the most current edition of the FDA publication, Approved Drug Products with Therapeutic Equivalence Evaluations; and
- At least three suppliers list the drug in current editions of published national drug compendia such as the Red Book, Blue Book, and Medispan.

Once a multiple source drug is identified as an upper limit drug, HCFA establishes an upper payment limit for that drug based on:

- 150 percent of the published price in any of the above drug compendia for the least costly therapeutically equivalent drug; and
- A reasonable dispensing fee established by the State agency.

Under Federal regulations, States have the flexibility to pay more for some upper limit drugs and less for others. However, a State's claims for FFP cannot be based on payments that exceed the aggregate of the individual upper payment limits for all upper limit drugs included in FFP claims. This provision assures that, whether or not States routinely pay for brand name drugs, the Federal government will share only in the costs of the less expensive generic drugs.

There is one major exception to the upper payment limit methodology. According to 42 C.F.R. 447.331, the upper payment limit does not apply to drug purchases for which prescribing physicians certify, in their handwriting on the prescription form, that a specific brand name drug is medically necessary. This provision was included to assure that physicians' judgments on quality of care will not be overridden by cost considerations. We will test the State's compliance with HCFA's aggregate upper payment limit through the use of the OAS developed computer program. When run against a State agency's paid claim history file, the OAS computer program will:

1. Compute the total amount paid by the State agency for all drugs subject to HCFA's aggregate upper payment limit. This amount is derived by subtracting the dispensing fees from the total amount reimbursed. Claims coded as "brand medically necessary" are totaled separately since they may not be subject to the aggregate upper payment limit.
2. Compute the total amount that should have been claimed by the State agency based on HCFA's aggregate upper payment limit. This amount is obtained by summing the results obtained from multiplying the quantity dispensed by the HCFA upper limit price for a drug group.
3. Compute the difference between both amounts to determine if the State agency exceeded the HCFA's aggregate upper payment limit.

We will verify the accuracy of the information on the State agency's paid claim history file through a sample of 100 claims from the computer generated upper limit drug output tapes.

Sample Design:

Simple random sampling will be used for reporting the results.

Sample Size:

100 upper limit drug claims.

Source of Random Numbers:

Office of Audit Services Statistical Sampling Software.

Method of Selecting Primary Sample Items:

1. Sequentially number all claims.
2. Generate random numbers to select 100 claims.

Characteristics To Be Measured:

An error will be the amount that a paid claim was over or under the HCFA upper payment limit amount.

Treatment of Missing Sample Items:

Claims will be judged based on the availability of the sample invoices. If a sample invoice cannot be located, the total amount of the overpayment generated by the computer program will be considered in our evaluation.

Estimation Methodology:

The estimation methodology will be contingent upon the review of the upper limit drug claims. If upon review of the State invoices we determine that all the fields on the computer output tapes are accurate, the total amount of the overpayment generated by the computer program will be subject to disallowance. The following estimation methodology will be employed in the event of a discrepancy between fields from the computer output tapes and items on the State invoices:

Appraisal Method: Difference Estimator and variable appraisal method.

Precision and Risk: 90% Confidence Level. We will accept a 5% risk that the confidence interval will not contain the actual minimum value.

Reporting the Results:

Reporting the results will be subject to the verification of the statistical sample. If upon review of the State agency invoices we determine that all the fields on the computer output tapes are accurate, we will report the total amount of the computed overpayment as the disallowance. However, in the event of a discrepancy between fields from the computer output tapes and items on the State agency invoices we will report the results in the following manner:

Based on the results of our sample of upper limit drugs, at the 90 percent confidence level, we are 95% confident that the State agency received \$xx in excess Federal financial participation.

Sample Plan
"Brand Medically Necessary" Drugs
Follow-up Review of Pennsylvania Medicaid
Upper limit Drug Program
CIN: A-03-92-00602

Audit Objective:

To determine the minimum dollar value of State agency identified Maximum Allowable Cost (MAC) override claims that were dispensed and paid in violation of Federal and State regulations. The MAC override claims are also referred to as "brand medically necessary" claims.

Universe:

The universe will consist of all MAC override drug claims obtained by matching the State agency's paid claim history file against the First Data Bank list of upper limit National Drug Codes.

Sampling Unit:

A State agency identified MAC override drug claim.

Survey and Background Information:

Federal regulations (42 C.F.R. 447.332) issued in July 1987 and effective October 29, 1987, require HCFA to identify multiple source drugs and to establish a specific upper payment limit for each of them. The HCFA designates a multiple source drug as an upper limit drug when two conditions are met:

- All formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically equivalent and listed in the most current edition of the FDA publication, Approved Drug Products with Therapeutic Equivalence Evaluations; and
- At least three suppliers list the drug in current editions of published national drug compendia such as the Red Book, Blue Book, and Medispan.

Once a multiple source drug is identified as an upper limit drug, HCFA establishes an upper payment limit for it based on:

- 150 percent of the published price in any of the above drug compendia for the least costly therapeutically equivalent drug; and
- A reasonable dispensing fee established by the State agency.

Under Federal regulations, States have the flexibility to pay more for some upper limit drugs and less for others. However, a State agency's claims for FFP cannot be based on payments that exceed the aggregate of the individual upper payment limits for all upper limit drugs included in FFP claims. This provision assures that, whether or not States routinely pay for brand name drugs, the Federal government will share only in the costs of the less expensive generic drugs.

According to the State Medicaid Manual, Section 6305, there is one major exception to the upper payment limit methodology. This occurs when a physician certifies in his or her handwriting on the prescription form that a specific brand name drug is medically necessary. In such a case, the Federal government shares in the cost of the brand name drug and the upper payment limit does not apply. A dual line prescription (a form where one line indicates substitution permitted and another line indicates substitution not permitted) or a check-off box (indicating that generic substitution is or is not permitted) on the prescription form does not satisfy the certification requirement. For telephone prescriptions, State agencies decide what certification form and procedures should be used.

We will examine 100 randomly selected MAC override claims identified by the OAS computer program. A claim will be subject to the upper payment limit calculation if it is in violation of Federal and State policy. The calculation will be executed as follows:

1. Determine the amount reimbursed by the State agency for the drug (State Paid Amount). This amount is derived by subtracting the dispensing fees from the amount reimbursed.
2. Compute the amount that should have been claimed by the State agency based on HCFA's upper payment limit (HCFA Allowed Amount). This amount is obtained by multiplying the quantity dispensed by the HCFA upper limit price for the applicable drug.

3. Compute the difference between the State Paid Amount and the HCFA Allowed Amount.

The results of the calculations will be projected to the universe of claims.

Sample Design:

Simple random sampling will be used for reporting the results.

Sample Size:

100 State agency identified MAC override drug claims.

Source of Random Numbers:

Office of Audit Services Statistical Sampling Software.

Method of Selecting Primary Sample Items:

1. Sequentially number all claims.
2. Generate random numbers to select 100 claims.

Characteristics To Be Measured:

Error - A claim will be considered an error if it is not in compliance with Federal and State regulations. The amount of the error will be the actual amount paid for the drug less the allowable upper limit amount.

Treatment of Missing Sample Items:

We will investigate the reason that the prescriptions are missing. We will base our conclusions on the result of this investigation. Missing prescriptions can be considered as valid or invalid.

Estimation Methodology:

We will project a dollar value and establish a reasonable minimum of the dollar value of the State agency identified MAC override claims that were dispensed and paid by the State agency without properly following Federal and State regulations.

Appraisal Method: Difference Estimator and variable appraisal method.

Precision and Risk: 90% Confidence Level. We will accept a 5% risk that the confidence interval will not contain the actual minimum value.

Reporting the Results:

Based on the results of our sample, at the 90 percent confidence level, we are 95% confident that the State agency received \$xx in excess Federal financial participation.



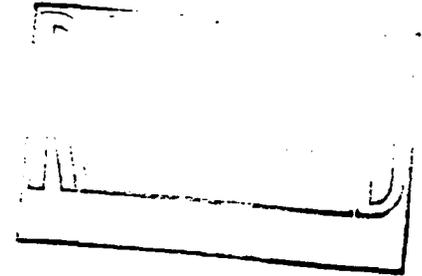
COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF PUBLIC WELFARE
BUREAU OF FINANCIAL OPERATIONS
302 Health & Welfare Building
Harrisburg, Pennsylvania 17120-2675

THOMAS P. ORR
DIRECTOR

TELEPHONE NUMBER
(717) 787-9088

AUG 6 1993

Mr. Thomas J. Robertson
Regional Inspector General for Audit Services
Office of Inspector General
P.O. Box 13716, Mail Stop 9
Philadelphia, Pennsylvania 19101



Dear Mr. Robertson:

Secretary Karen F. Snider asked me to respond to your letter of April 29, 1993, concerning your draft report entitled FOLLOW-UP REVIEW OF THE PENNSYLVANIA DEPARTMENT OF PUBLIC WELFARE'S COMPLIANCE WITH THE FEDERAL AGGREGATE UPPER PAYMENT LIMIT REQUIREMENTS FOR PRESCRIPTION DRUGS (A-03-92-00602).

After a thorough review of this draft report, the Department found the audit to be seriously flawed and, therefore, unreliable as it pertained to the Medical Assistance Program's compliance with the federal aggregate spending limits for multisource drugs for the periods October 29, 1987 to October 28, 1988 and October 29, 1988 to October 28, 1989. The audit was based entirely on the premise that a "reasonable dispensing fee" for Pennsylvania is \$2.75 when, in fact, the Department has documented otherwise. In addition, the audit completely and deliberately ignored the Department's subsequent appeal of the previous disallowances for the period October 29, 1987 to October 28, 1988 before the Department Appeals Board (DAB) and the decision of the DAB.

During the entrance conference, the auditors from the Office of Inspector General (OIG), admitted that they were fully aware of the Department's appeal and the DAB's decision. The Department, at their request, provided its documentation of the actual costs involved in dispensing a prescription. Yet, when the draft report was prepared, any reference to this information was conspicuously absent. This disregard for such considerably important issues not only raises questions about the accuracy of this report, but completely invalidates its findings and conclusions.

The Department's position presented before the DAB involved several very important issues, all of which should have been considered in this audit. The first issue was the method of determining the aggregate spending limit for multisource drugs and how it applies to the Medicaid program's expenditures for these drugs. The regulations, published in the Federal Register, July 31, 1987, clearly describe that the Medicaid program's total expenditures for multisource drugs may not exceed, in the aggregate, an amount calculated by the application of the "federal upper limits," established by the Health Care Financing Administration (HCFA) for

each drug, plus a reasonable dispensing fee. During both audits, the auditors derived the Department's expenditures by subtracting \$2.75 from each claim reviewed in the random sample. This method relies on the false assumption that \$2.75 is "a reasonable dispensing fee" and incorrectly compares drug cost to drug cost.

The second issue was the definition of "a reasonable dispensing fee." The regulations do not require that a state's "actual dispensing fee" must be used to calculate the aggregate spending limit. The regulations also do not define what constitutes a "reasonable dispensing fee" and, in fact, allow the state to establish this component. From the time of their publication, Pennsylvania maintained that the regulations allow the use of an imputed dispensing fee as the "reasonable dispensing fee" to determine the aggregate spending limit rather than the state's "actual fee." Pennsylvania claimed that the sum of the federal upper limits plus a "reasonable dispensing fee" would not exceed the Department's total expenditures.

The third issue was the decision of the DAB in which it supported the Department's principle in that the regulations permitted a state to define a "reasonable fee" that was different from the one the state actually used in its reimbursement formula. The DAB contended "the state could reasonably have concluded that it (the state) could offset a lower than reasonable dispensing fee with ingredient cost which was higher than HCFA's specific limits as well as higher than the costs of the pharmacies themselvesHCFA's approach of holding the State to the dispensing fee actually paid regardless of the circumstances under which it was set is thus inimical to the intent to give states greater flexibility expressed in the preamble" to the regulations. (Decision No. 1315; March 8, 1992.)

The fourth issue was the conclusion of a federal judge from the U.S. Middle District Court, in which he ruled that Pennsylvania was in compliance with the federal regulations based largely on the DAB's decision. The federal court became involved when the Department reluctantly adopted the federal upper limits as the cost component for multisource drugs on January 11, 1991, as a result of HCFA's threats to withhold federal funds from the State's Medical Assistance Program. Even though the Department was confident that it would prevail in its appeal before the DAB, the Department felt that it could no longer risk the loss of federal funds.

Shortly after the adoption of the federal upper limits, the pharmacy community filed a class action suit against Pennsylvania. The plaintiffs cited that the Department was already in compliance with federal regulations and that the adoption of the federal upper limits would result in lower reimbursement to pharmacies. They maintained that this lower reimbursement violated the provisions of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90). At no time during this litigation did HCFA attempt or offer to support the Department against the pharmacy community. In effect, HCFA's position and interpretations were on trial, yet HCFA remained silent, although fully aware of the occurrences taking place.

Ultimately, on September 16, 1992, the U.S. District Court ruled in favor of the plaintiffs. As a result, the Department was not permitted to enforce the federal upper limit prices in determining its reimbursement for multisource drugs and was ordered to revert to the previous State MAC prices or the average wholesale prices (AWP) in place prior to January 11, 1991. According to the federal judge's conclusions, Pennsylvania was in compliance with the federal reimbursement regulations and, therefore, was precluded by the OBRA '90 moratorium from reducing the state's reimbursement rates for multisource drugs. Although the Department did lose the lawsuit, the Court's ruling clearly indicated that Pennsylvania was in compliance with federal regulations for prescription reimbursement, contrary to HCFA's allegations. Therefore, based on this conclusion, the Department should not be held accountable for any federal sanctions resulting in the return of federal funding between October 1987 and January 1991 and during the period of the OBRA '90 moratorium based on HCFA's accusations of noncompliance.

According to the federal court's ruling, Pennsylvania's past and present compliance with the federal aggregate spending limits should no longer be an issue. Therefore, the Department cannot accept the OIG's findings and cannot concur with the recommendation to make financial adjustments of \$3.5 million and \$6.8 million to the federal account for the two periods in question. In addition, the Department does not feel compelled to perform a review of its compliance with HCFA's aggregate payment limit for the periods subsequent to October 28, 1989, or to make any subsequent financial adjustments.

The Department does agree that there may be isolated incidents of claims incorrectly coded as "Brand Medically Necessary," although it does not acknowledge the degree or occurrences alleged in the report nor does it concur with the dollar amount stated. The Department has a continuous program to conduct routine audits on all pharmacists participating in the Medical Assistance Program. The Department will seek restitution from any pharmacy found miscoding claims as "Brand Medically Necessary." The Department contends that the OIG audit did not consider this in its report. Nevertheless, the Department, prior to receiving this audit report, already began to develop more restrictive criteria for the payment of claims certified as "Brand Medically Necessary." The Department plans to require prior authorization for all brand name drugs that have generically equivalent substitutes available. This revision will probably take place sometime before the end of 1993 and should resolve the problem of miscoded claims.

In conclusion, the Department is extremely disappointed with both the OIG and HCFA and the adversarial position each has assumed against the Department in this matter. Both agencies should realize that Pennsylvania is obligated under Federal Court Order to continue with the present payment

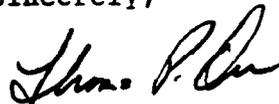
Mr. Thomas J. Robertson

-4-

system for the duration of the OBRA '90 moratorium period. In addition, ignoring the Court Order, as you have implied in your report, would certainly result in contempt charges against the Department, and could possibly involve the OIG and HCFA. Therefore, I suggest that you reevaluate your findings when you issue your final report.

Thank you for the opportunity to review and comment on this report.

Sincerely,

A handwritten signature in cursive script, appearing to read "Thom. P. Orr".

Thomas P. Orr



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financi

Refer to: R3-DMD(20)

Memorand

Date **MAY 20 1993**

From Associate Regional Administrator
Division of Medicaid

Subject Draft Audit Report - Follow-up Review of the Pennsylvania
Department of Public Welfare's Compliance with Federal
Aggregate Upper Payment Limit Requirements for Prescription
Drugs CIN: A-03-92-00602

To Regional Inspector General for Audit Services

The following are our comments on the draft OIG Office of Audit Services report on Pennsylvania's compliance with the federal upper payment limit on prescription drugs. We appreciate the opportunity to comment.

On March 25, 1991, Pennsylvania submitted Medicaid state plan amendment number 91-12 which incorporated the federal upper payment limits on multi-source drugs into its approved state plan (page Attachment 4.19-B, page 2a). The plan amendment was effective January 11, 1991. Our approval of this amendment brought Pennsylvania's state plan into compliance with the applicable federal upper limits for multi-source drugs.

The State was subsequently sued in federal court by the Pennsylvania Pharmaceutical Association for violating the moratorium on reducing drug payments enacted as part of OBI 1990. The federal court decision on Pennsylvania Pharmaceutical Ass'n v. Casey, No. 1:91 - 0378 (M.D. Pa. Sept. 16, 1992) found in favor of the plaintiff. The State has appealed the court ruling and the issue remains in litigation. The Regional Attorney's office has informed us that the State is currently attempting to reach a settlement in this case with the Pharmaceutical Association.

We have advised Pennsylvania that the State must continue to make reimbursements for multi-source drugs according to its approved state plan, notwithstanding the federal court ruling. In reference to the court's decision, HCFA was not a party to the litigation, and the court's decision does not bind HCFA. We have advised Pennsylvania that if the State fails to follow its approved state plan, federal financial participation for payments for multi-source drugs may be subject to a disallowance action to the extent that such payments fail to implement the methodology in the approved plan.

In consulting with the Regional Attorney's staff, we noted that the federal court's ruling relied, in part, upon a Departmental Appeals Board decision, Docket Number 91-113, in finding that Pennsylvania was in compliance with the upper payment limits before the implementation of state plan amendment 91-12. Following advice received from the Regional Attorney's Office, we informed the State that we do not agree with the court's conclusion that the Departmental Appeals Board found the State in compliance with the upper limits. In fact, in our view, the Board held to the contrary, finding that the State was not in compliance with the upper payment limits.

As we understand the situation at this moment, Pennsylvania's settlement offer would entail making additional payments for amounts that were initially withheld because the payments would have been in excess of the federal upper limits. Should the State work out an agreement with the Pharmaceutical Association, the State would then again be out of compliance with the federal upper payment limit.

Accordingly, with the concurrence of the Regional Attorney's Office, we advised the State that should the proposed settlement with the plaintiffs result in payments for multi-source drugs which exceed the amounts set by the state plan, we will, after appropriate review, disallow FFP for any amounts paid which are not according to the approved plan methodology.

We trust that this information clarifies the current circumstances involving Medicaid reimbursement for multi-source drugs in Pennsylvania. Please contact us if we can be of any other assistance.


Robert J. Taylor