DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Memorandum

Date JUL 30 1993

From Bryan B. Mitchell
Principal Deputy Inspector General

Subject Audit of the Arkansas Department of Human Services' Medicaid Prescription Drug Rebate Program (A-06-93-00003)

To

Bruce C. Vladeck
Administrator
Health Care Financing Administration

This is to alert you to the issuance on August 2, 1993, of our final report. A copy is attached.

The Omnibus Budget Reconciliation Act of 1990 enables State Medicaid agencies to receive rebates from drug manufacturers for drug purchases made under the Medicaid program. Our review disclosed that 72 drug manufacturers had disputed $768,962 of rebate billings for drug purchases by the Arkansas Department of Human Services (State agency) for the quarter ended March 31, 1992. The value of this disputed amount plus our work at various States shows that disputed rebates is a significant issue nationwide.

A portion of the disputed amount, $282,205, was the result of a billing error by the State agency. However, we believe that the remaining $486,757 could be collected if the State agency pursued the disputes. Accordingly, we recommended that the State agency aggressively seek collection by: identifying the amount of and reasons for the disputes; prioritizing its efforts on the resolution of disputes by developing profiles of manufacturers to identify those with the greatest potential for final resolution; investigating and analyzing the specific manufacturer disputes; revising and expanding the on-site pharmacy reviews; and considering either legal action or restricted participation of manufacturers that do not attempt to resolve disputes.

In a letter dated May 19, 1993, the Deputy Director of the Arkansas Department of Human Services agreed with four of our six recommendations, and partially agreed with the other two. Specifically, the Deputy Director responded that the State's auditors cannot expand the on-site pharmacy reviews and that the Health Care Financing Administration, not the State, should restrict participation of manufacturers.

This audit is the pilot for a nationwide review that is currently being planned and we, therefore, wanted to share the results with you and solicit any comments you may have as we finalize our plans.

For further information, contact:

Donald Dille
Regional Inspector General
for Audit Services, Region VI
(214) 767-8414

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

AUDIT OF THE ARKANSAS DEPARTMENT OF HUMAN SERVICES' MEDICAID PRESCRIPTION DRUG REBATE PROGRAM

JULY 1993 A-06-93-00003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Office of Audit Services
1100 Commerce, Room 4E1A
Dallas, TX 75242

Our Common Identification No. A-06-93-00003

Mr. Thomas Dalton, Director
Department of Human Services
P.O. Box 1437 Slot 329
Little Rock, Arkansas 72203

Dear Mr. Dalton:

This report provides you with the results of our audit of the Arkansas Department of Human Services' (State agency) Medicaid outpatient prescription drug rebate program. The objectives of our audit were to (1) determine the amount of and reasons for disputed rebate billings that related to pharmacy utilization data and (2) review the State agency's procedures for responding to disputed utilization data.

The State agency has taken limited steps to resolve a total of $768,962 of rebate billings disputed by 72 drug manufacturers for the quarter ended March 31, 1992. One significant dispute resulted from the State agency's billing error. The remainder of the disputes will require investigations, analyses and possible legal actions by the State agency for resolution. The manufacturers disputed the billings for a variety of reasons but were generally attributable to four basic causes.

- The manufacturers claimed that the drug utilization data which they obtained from third party sources did not agree with the State agency's utilization data for $354,034, or 46 percent, of the disputes.

- The State agency used different units of measure than the manufacturers for $335,201, or 44 percent, of the disputes. One manufacturer disputed $282,205 of the $335,201 because the State agency used the incorrect unit of measure.

- The manufacturers used unit rebate amounts that were different from those used by the State agency for $64,696, or 8 percent, of the disputes.

- The remaining $15,030, or 2 percent, of manufacturer disputes occurred for miscellaneous reasons.

We believe that as much as $486,757 ($768,962 - $282,205) could be collected if the State agency pursued the disputes. However, the State agency had not analyzed the disputes to: (1) determine the amount of and reasons for the disputes and (2) prioritize the disputes based on potential for resolution. One method of prioritizing would be to identify and develop a profile of those manufacturers with significant amounts of disputes on which the State agency should concentrate its resources.

During our analysis of the rebate disputes, we found that $702,918 or about 91 percent was disputed by 13 different manufacturers. The State agency could maximize its efforts to resolve these disputes by concentrating its efforts on 13 of the 72 manufacturers with disputes.

We are recommending that the State agency aggressively seek collection of the $486,757 which, we believe, is collectable for the quarter by: identifying the amount of and reasons for the disputes; prioritizing its efforts on the resolution of disputes by developing profiles of manufacturers to identify those with greatest potential for final resolution; investigating and analyzing the specific manufacturer disputes; revising and expanding the on-site pharmacy reviews; and considering either legal action or restricted participation of manufacturers that do not attempt to resolve disputes.

In a letter dated May 19, 1993, the Deputy DHS Director concurred with four of our six recommendations, and partially concurred with the other two. See page 9 of this report for a more detailed discussion, and see Attachment I for the complete text of the Deputy Director's comments.

BACKGROUND

Medicaid is a federally-aided, State operated and administered program that provides medical benefits to low income people who are aged, blind, disabled, or members of families with dependent children. The program, authorized by Title XIX of the Social Security Act, requires States to provide certain medical services and permits them to provide other services, such as outpatient prescription drugs, on an optional basis. Federal oversight is the responsibility of the Health Care Financing Administration (HCFA) of the Department of Health and Human Services.

The Congress enacted Section 4401 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) to allow States to receive rebates for drug purchases. Under OBRA '90, for payment to be made for Medicaid-covered outpatient drugs, a manufacturer must enter into a rebate agreement with the Department of Health and Human Services (acting for the States). In return, the States pay for all of the manufacturers' covered outpatient drugs used

by Medicaid recipients. The rebate program was implemented on January 1, 1991.

Determining Rebates Amounts

The HCFA receives pricing information from manufacturers that includes the average manufacturer price and best price. From this information, a unit rebate amount is computed for each drug and is furnished to the States for use in calculating the rebate amount due from the manufacturer. The States are responsible for identifying the number of units dispensed by manufacturers for each covered drug. The State agencies have the option of either calculating the rebate amounts due from a manufacturer or supplying only the utilization data to the manufacturer without actually computing the rebate amount due. The State agencies must submit the billing information to the drug manufacturers within 60 days after the end of each quarter. The manufacturers then have 30 days after receipt of the utilization data to make the rebate payments to the State agencies.

The HCFA enters into rebate agreements with drug manufacturers on behalf of the States. The rebate agreements state that if a manufacturer discovers a material discrepancy in a State's drug utilization data, which the manufacturer and the State in good faith are unable to resolve, the manufacturer is to provide written notice of the discrepancy to the State. The State and the manufacturer are required to use their best efforts to resolve the discrepancy within 60 days of receipt by the State. The HCFA's Program Release Number 19 requires the State agencies to take steps to resolve questionable data. The States may provide zip code level data or pharmacy level data which the manufacturer can compare with its records to identify discrepancies. If the State and the manufacturer are not able to resolve the discrepancy within 60 days, the State must make a hearing mechanism available to the manufacturer in order to resolve the dispute. After the dispute is resolved, (if it is in the State agency's favor), the balance due, plus a reasonable rate of interest, must be paid.

It is important for the State Medicaid programs to maintain a database by manufacturer to reliably produce data by quantity of the drugs dispensed and for which payment has been made. The validity of the Medicaid utilization information is also of importance to HCFA. The State agencies must report their utilization data by full national drug code. The HCFA is also considering requiring States to report their claims paid by zip code level (or if they are unable to do so, to provide a claims history file) starting no later than March 1, 1993.

Arkansas' Medicaid Drug Program

The Arkansas Medicaid prescription drug program is operated by the Division of Medical Services of the Arkansas Department of Human Services. Each Medicaid recipient is normally entitled to receive three covered prescriptions per month. Each prescription may be filled for a maximum of one month's supply (prescriptions resulting from Child Health Services screening and referral are unrestricted). However, a 33 day supply may be allowed to cover circumstances such as the first day of the month falling on a weekend.

For the quarter ended March 31, 1992, the Arkansas Medicaid prescription drug program expenditures amounted to $19,587,950. The rebate amount billed to manufacturers for this same period was $3,989,668.

SCOPE OF AUDIT

The objectives of our audit were to (1) determine the amount of and reasons for disputed rebate billings that related to pharmacy utilization data, and (2) review the procedures of the State agency for responding to manufacturers' disputes. Our audit was conducted in accordance with generally accepted government auditing standards. Achieving our audit objectives did not require that we review the entire internal control structure of the State agency. Instead, we reviewed only those controls that related to the utilization data.

To accomplish our objectives, we reviewed the provisions of OBRA '90 and the standard rebate agreement pertaining to Medicaid drugs and pertinent Federal drug regulations, polices and procedures. We also interviewed State agency officials responsible for administering the Medicaid drug rebate program, the fiscal agent for the State medicaid drug program, pharmacy auditors contracted by the State and other professionals involved with the program.

The State agency's rebate files contained billings, remittances, and correspondence from drug manufacturers that provide drugs to the 763 pharmacies in the State. We reviewed the rebate files for 243 manufacturers that had been billed for the quarter ended March 31, 1992. Our review was performed during the month of October 1992 at the State agency's offices in Little Rock, Arkansas.

RESULTS OF AUDIT

The State agency had not resolved rebate billings totaling $768,962 which drug manufacturers disputed for the quarter ended March 31, 1992. The disputes included:

- o $354,034 or 46 percent because the State's utilization data did not agree with manufacturers' data;
- o $335,201 or 44 percent because of disagreement and errors on unit of measure;
- o $64,696 or 8 percent because of differing unit rebate amounts; and
- o $15,030 or about 2 percent for miscellaneous reasons.

Seventy-two manufacturers disputed rebate billings totaling $768,962. Of the billings in dispute, $702,918 or 91 percent involved 13 manufacturers.

State agency officials had taken limited steps to resolve these disputes, performing detailed analyses on two manufacturers. To resolve this problem, the State agency should aggressively seek collection of the $486,757 which, we believe, is collectable for the quarter. This could be done through identifying manufacturers with the largest rebate amounts in dispute, investigating and analyzing specific manufacturer disputes to determine the nature of the disputes, revising and expanding on-site pharmacy review to assure the accuracy of utilization data, and considering legal action or restricted participation of manufacturers that do not cooperate with the State's efforts to resolve disputes.

See Appendix I to this report for a complete analysis of the disputes for the January-March 1992 quarter.

Disputes Based On Unproven Utilization Data

Of the $768,962 disputed by the drug manufacturers, $354,034 or 46 percent was disputed because the State's utilization data did not agree with utilization data used by the manufacturers. This data was obtained from either third party sources or in some cases from the manufacturers' sales information. In making the disputes, however, the manufacturers did not provide information to the State agency regarding the accuracy, reliability or sources of their utilization data. For example, the following are typical direct quotes provided by manufacturers and the amounts disputed:

"Utilization data in error, it overstates actual use of product."	$181,877
"Exceeds expected utilization"	$47,947
"Utilization erroneous based on third party data."	$20,964

The manufacturers have not provided specific factual bases for their disputes. In our opinion, the State agency's utilization data should be considered more reliable than the manufacturers' data because: (1) it is provided directly to the State by the pharmacies and is based on actual sales of drugs; (2) the State agency's utilization data is accepted by the Federal government as the basis for paying Medicaid drug claims, (3) the State agency conducts pharmacy reviews of Medicaid prescribing practices which provide a measure of quality control over utilization data; and (4) manufacturers should not normally have pharmacy level information available on Medicaid utilization in a specific State.

See Appendix II for a complete list of the manufacturers' responses regarding disputed utilization data.

Disputes Based on Unit-of-Measure Problems

Of the $768,962 total amount disputed for the quarter, $335,201 or 44 percent was disputed by the manufacturers because of unit of measure problems. Such problems result from differences in the way quantities of products such as liquids, creams, ointments, etc. are measured. In implementing the drug rebate program, HCFA originally required, in Definition I (cc) of the rebate agreement, that the unit rebate amounts be calculated based on the "lowest identifiable amount" for a product. For example, the unit rebate amount was to be calculated based on a pill rather than on the entire bottle of pills, and an ounce or milliliter (ml) of liquid rather than on the entire bottle of liquid. Therefore, in the case of a tube of ointment containing 50 grams, the manufacturer was required to compute the unit rebate amount for each gram, rather than for each tube.

The HCFA later expanded on that policy in Medicaid Drug Rebate Program Release Number 18, dated February 14, 1992. This document provided that the unit rebate amount could be computed based on a package dispensed if the manufacturer notified HCFA that the product is marketed as a package. In our above example, the package would be the tube. It is critical, however, that at the time the State agency bills the drug manufacturer for the rebate on the tube of ointment, it claims that one tube was dispensed rather than 50 grams, if the unit rebate amount was computed for the tube. Otherwise, the rebate claim to the manufacturer would be 50 times greater.

One manufacturer accounted for $284,078 of the $335,201 of disputes related to units of measure differences. We analyzed this dispute and found that the State agency billed the manufacturer for a rebate based on utilization of 22,195 units of a drug. However, the State agency had reimbursed pharmacists for dispensing 22,195 milligrams of this drug. The manufacturer had required that the rebate be based on packages (each package

contained 42.5 milligrams) dispensed rather than the number of milligrams dispensed. This resulted in the State agency over billing the manufacturer by $282,205.

Disputes From Comparing Differing Unit Rebate Amounts

Of the $768,962 in total disputes for the quarter, $64,696, or 8 percent, was the result of manufacturers recalculating the unit rebate amounts using data which the State was not familiar with. Unit rebate amounts are calculated by HCFA and furnished to the States which calculate the total rebates using their utilization data. The HCFA calculates the unit rebate amount using average manufacturer price and best price data supplied by the manufacturers. The manufacturers are permitted to recalculate the unit rebate amounts, however, they must notify HCFA of the basis for the recalculation.

In such cases, we believe the State agency should determine whether HCFA was notified of and accepted the unit rebate amount recalculations. If HCFA did not sanction the recalculations, the State agency should pursue collection of the dispute.

Most Disputes Come From a Few Manufacturers

We reviewed all manufacturers' disputes for the State of Arkansas for the quarter ended March 31, 1992 and found that $768,962 was disputed by 72 different manufacturers. However, $702,918, (91 percent) resulted from disputes from only 13 different manufacturers, with the top three manufacturers totaling $504,214 (66 percent). Therefore, we believe that the State agency should concentrate most of its resources and efforts on manufacturers with the largest amounts in dispute.

Pharmacy Reviews Should Include Dispute Issues

The State agency's pharmacy reviews were not effective in resolving manufacturers' disputes because these reviews did not address specific utilization data disputed by the manufacturers. The State agency conducts periodic, routine reviews of pharmacies. These reviews were conducted, in part, to ensure compliance with State pharmacy laws, to determine if generic substitution was occurring, and to some extent evaluate drug utilization data. Specifically, the State agency officials advised us that the reviewers, among other things:

- send the pharmacy a pre-review questionnaire that asks about Medicaid versus non-Medicaid pricing policies, patient profiles and types of computer software used,

- verify that the top 25 drugs were purchased by looking at the invoices,

- identify the top 25 drugs reimbursed to the pharmacy under review for a 6-month period,
- verify that prescription prices were consistently charged to Medicaid and non-Medicaid recipients alike,
- verify that the proper national drug code was used, and
- verify that the prescription and proper documentation was on file.

While these verifications are important, we believe the reviews should be expanded to provide specific validation of utilization data that are subject to manufacturer disputes. More specifically, we believe that expanded reviews would provide the State agency the evidence with which to resolve the disputes. This should pay significant dividends to the program in the form of increased rebate collections.

CONCLUSIONS AND RECOMMENDATIONS

Of $768,962 in drug rebate billings that were disputed for the first quarter of 1992, none were resolved as of October 1992. Forty-six percent of the total was disputed by the manufacturers based on unproven utilization data which the manufacturers apparently obtained from other third party sources. Additionally, 44 percent of the total disputes for the quarter were for units of measure differences, and most of that amount was from one manufacturer. Further, 8 percent of the total was disputed based on manufacturers recalculating the unit rebate amounts, and most of that was from one manufacturer.

Most of the disputes were made by a few manufacturers. In fact, 91 percent were from 13 different drug manufacturers. We believe that most disputes that have occurred in the past or that will occur in the future can be resolved. We recommend that the State agency aggressively seek collection of the rebates of up to $486,757 which, we believe, is collectable for the quarter plus amounts owed the State agency for other periods by:

- determining the amount of and the reasons for disputes,
- prioritizing the resolution of disputes by developing profiles of manufacturers to identify those with the greatest potential for final resolution,
- providing on-going investigations and analyses of specific manufacturer disputes,
- revising and expanding the on-site pharmacy reviews to provide validation of utilization data that has been disputed,

- providing the results of the analyses, investigations and reviews to the disputing manufacturers, and dispute resolution process.

- considering either legal action against or restricted participation of manufacturers that do not attempt to resolve the disputes.

AUDITEE COMMENTS

The Deputy Director of the Arkansas Department of Human Services responded to our draft report in a letter dated May 19, 1993. In that letter, the Deputy Director fully concurred with our recommendations for (1) determining the amount of and the reasons for disputes, (2) prioritizing the resolution of disputes by developing profiles of manufacturers, (3) providing ongoing investigations and analyses of specific manufacturer disputes, and (4) providing the results of these analyses, investigations and reviews to the disputing manufacturers.

We also recommended that the State agency revise and expand the on-site pharmacy reviews to provide validation of utilization data that has been disputed. The Deputy Director partially concurred and responded that the auditors have validated the utilization of specifically disputed products, but their overall function is to ensure that the providers are following Medicaid policies. He added that the auditors do not have the time to analyze every provider and every NDC. Additionally, we recommended that the State agency consider either legal action or restricted participation of manufacturers that do not attempt to resolve the disputes. The Deputy Director also partially concurred and responded that the State has considered requesting hearings with some manufacturers that continue to dispute the rebate claims. He added that HCFA, not the State, should restrict the participation of manufacturers that do not attempt to resolve the disputes. In addition, he stated that we did not address the State's biggest problem, and that is the need for more personnel to perform the rebate dispute resolution function.

OIG RESPONSE

We appreciate the Deputy Director's comments and believe that we are virtually in complete agreement over the issues raised in the report. We would only add that we believe the State agency should consider taking a more pro-active role in solving the dispute resolution problems with drug manufacturers. This could apply to conducting on-site pharmacy reviews, taking legal action against manufacturers and allocating State resources to the dispute resolution process.

- - - - -

Final determination as to actions to be taken on all matters reported will be made by the HHS official named below. We request that you respond to the recommendations in this report within 30 days from the date of this letter to the HHS official named below, presenting any comments or additional information that you believe may have a bearing on his final decision.

In accordance with the principles of the Freedom of Information Act (Public Law 90-23), Office of Inspector General 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 45 CFR Part 5.)

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

Sincerely,

Donald L. Dille

DONALD L. DILLE
Regional Inspector General
for Audit Services

Enclosures

Direct Reply to:

Associate Regional Administrator
for Medicaid
Health Care Financing Administration
1200 Main Tower Building, Room 2030
Dallas, Texas 75202

ARKANSAS DEPARTMENT OF HUMAN SERVICES
MEDICAID OUTPATIENT PRESCRIPTION DRUG REBATE PROGRAM
SCHEDULE OF MANUFACTURERS WITH DISPUTED REBATE BILLING AMOUNTS
FOR THE QUARTER ENDED MARCH 31, 1992

MANUFACTURER	TOTAL BILLED	TOTAL PAID	AMOUNT DUE	UTILIZATION	UNITS OF MEASURE	REBATE AMTS. DIFFERENT	MISCELLANEOUS
1	$331,879.51	$47,801.30	$284,078.21	$1,873.57	$282,204.64		
2	$237,959.05	$115,886.29	$122,072.76	$122,072.76			
3	$153,046.86	$54,983.51	$98,063.35	$10,572.73	$45,714.45	$41,776.17	
4	$67,934.59	$53,087.51	$14,847.08	$12,046.67			$2,800.41
5	$77,759.97	$40,266.37	$37,493.60	$38,545.28			
6	$130,885.54	$95,506.65	$35,378.89	$41,454.84			
7	$204,247.33	$190,158.29	$14,089.04	$5,998.66		$8,090.38	
8	$20,607.55	$15.07	$20,592.48	$20,592.48			
9	$92,101.51	$78,347.94	$13,753.57	$13,616.49		$13.49	$123.59
10	$23,033.31	$10,333.96	$12,699.35	$12,699.35			
11	$68,446.33	$55,770.24	$12,676.09	$12,676.09			
12	$67,308.22	$55,086.03	$12,222.19		$5,067.31	$7,154.88	
13	$75,623.43	$67,117.01	$8,506.42	$17,824.00			
14	$67,517.90	$59,582.08	$7,935.82				$7,935.82
15	$53,250.07	$45,832.13	$7,417.94	$1,897.69		$5,520.33	
16	$36,914.62	$31,165.74	$5,748.88	$4,371.05			$1,377.89
17	$14,245.94	$8,734.69	$5,511.25	$9,212.18			
18	$71,129.69	$66,055.82	$5,073.87	$5,073.87			
19	$50,006.29	$45,608.98	$4,397.31	$7,240.42			
20	$15,936.24	$13,161.20	$2,775.04	$3,144.94	$369.90		
21	$84,214.00	$81,828.00	$2,386.00	$2,386.00			
22	$2,335.90	$112.16	$2,223.74	$2,223.74			
23	$268,846.46	$266,960.64	$1,885.82	$1,885.82			
24	$3,043.75	$1,173.18	$1,870.57	$1,870.57			
25	$79,032.02	$77,199.57	$1,832.45			$1,832.45	
26	$5,539.09	$3,713.27	$1,825.82				$1,825.82
27	$71,272.64	$69,764.06	$1,508.58	$874.00			$634.58
28	$3,487.82	$2,164.42	$1,323.40	$1,323.40			
29	$26,168.22	$25,563.55	$604.67		$604.67		
30	$4,869.47	$4,345.72	$523.75	$442.12			$81.63
31	$9,903.33	$9,392.01	$511.32		$511.32		
32	$2,657.22	$2,318.99	$338.23		$338.23		
33	$41,769.61	$41,432.98	$336.63	$975.61			
34	$13,810.95	$13,564.16	$246.79	$332.11	$19.08		$47.35
35	$6,919.60	$6,703.00	$216.60		$216.60		
36	$12,203.11	$12,020.73	$182.38	$182.38			
37	$201,903.51	$201,754.88	$148.63		$148.63		
38	$19,764.85	$19,623.14	$141.71	$141.71			
39	$766.37	$629.40	$136.97			$136.97	
40	$11,650.48	$11,518.88	$131.60				$131.60
41	$13,623.49	$13,494.29	$129.20			$129.20	
42	$1,403.54	$1,276.42	$127.12	$127.12			
43	$11,502.32	$11,376.42	$125.90	$125.90			
44	$2,172.58	$2,063.39	$109.19	$109.19			
45	$361.41	$273.06	$88.35				
46	$86.56	$29.00	$57.56	$57.56			
47	$358.41	$304.53	$53.88				
48	$3,215.10	$3,174.73	$40.37				$40.37
49	$498.73	$466.74	$31.99	$31.99			
50	$34.29	$3.95	$30.34				$30.34

ARKANSAS DEPARTMENT OF HUMAN SERVICES
MEDICAID OUTPATIENT PRESCRIPTION DRUG REBATE PROGRAM
SCHEDULE OF MANUFACTURERS WITH DISPUTED REBATE BILLING AMOUNTS
FOR THE QUARTER ENDED MARCH 31, 1992

MANUFACTURER	TOTAL BILLED	TOTAL PAID	AMOUNT DUE	UTILIZATION	UNITS OF MEASURE	REBATE AMTS. DIFFERENT	MISCELLANEOUS
51	$112.00	$88.20	$23.80	$23.80			
52	$3,978.56	$3,959.56	$19.00			$19.00	
53	$50.59	$38.24	$12.35				
54	$90.99	$81.62	$9.37			$9.37	
55	$55,681.77	$55,672.50	$9.27			$9.27	
56	$299.62	$293.00	$6.62	$6.62			
57	$81.35	$74.86	$6.49		$6.49		
58	$10.89	$8.76	$2.13			$2.13	
59	$42.72	$40.92	$1.80	$1.80			
60	$2,259.06	$2,257.86	$1.20			$1.20	
61	$15,344.41	$15,343.93	$0.48			$0.48	
62	$7,929.04	$7,928.62	$0.42	$0.42			
63	$266.37	$266.00	$0.37			$0.37	
64	$88,239.45	$88,239.26	$0.19			$0.19	
65	$19.64	$19.46	$0.18			$0.18	
66	$1.36	$1.33	$0.03			$0.03	
67	$11,371.94	$11,371.92	$0.02			$0.02	
68	$1,129.73	$1,129.71	$0.02			$0.02	
69	$162.40	$162.39	$0.01			$0.01	
70	$41.48	$41.47	$0.01			$0.01	
71	$455.53	$455.52	$0.01			$0.01	
72	$301.71	$301.70	$0.01			$0.01	
	$2,951,119.39	$2,206,522.91	$744,596.48	$354,034.93	$335,201.32	$64,696.17	$15,029.40

Total Amount Disputed $768,961.82

Jim Guy Tucker
Governor

Arkansas Department of Human Services
Office of the Director

329 Donaghey Building
P.O. Box 1437
Little Rock, Arkansas 72203-1437
Telephone (501) 682-8650
FAX (501) 682-6836

May 19, 1993

Mr. Donald L. Dille
Regional Inspector General
for Audit Services
Department of Health & Human Services
Office of Inspector General
1100 Commerce, Room 4E1A
Dallas, TX 75242

RE: Common Identification Number A-06-93-00003

Dear Mr. Dille:

Thank you for your letter of April 9, 1993, and the draft Office of Inspector General report on the results of an audit of the Arkansas Department of Human Services' Medicaid outpatient prescription drug rebate program.

You requested the State's comments on the recommendations listed in your report. The recommendations and my comments follow:

1. The State Agency should determine the amount of and the reasons for disputes.

   Response: The State Agency concurs with this recommendation and offers the following comments:

   Pharmacy personnel currently identify the amount of the dispute. When the amount of the rebate check is compared to the invoiced amount, the difference is readily apparent. The reason for the dispute is much more difficult to determine. Each manufacturer has a different way of describing the reason for the dispute and it becomes quite difficult to determine the exact reason. It also takes a great deal of time to research each NDC number by line item to make a determination of the reason for dispute since the reason varies from one NDC to the next. We certainly make a definite effort to discover the reasons for the disputes.

2. The State Agency should prioritize the resolution of disputes by developing profiles of manufacturers to identify those with the greatest potential for final resolution.

RESPONSE: The State Agency concurs with this recommendation and offers the following comments:

The Pharmacy personnel do prioritize the resolution to disputes by developing profiles of manufacturers to identify those with the greatest potential for final resolution.

A file is kept for every manufacturer that we invoice for a rebate. After the rebate check is compared to the invoice and a determination is made that there is a definite discrepancy between the rebate amount received and the amount invoiced, the information is placed in a file and given to the person responsible for resolving disputes.

At this point, a dialogue begins between the Pharmacy unit and the manufacturer. The manufacturer is called to discuss the disputes. The Pharmacy unit writes to the manufacturer to document that dispute resolution has begun. We have a packet of specific information concerning the number of wholesalers in Arkansas, the number of pharmacy providers in bordering states, zip-code information, utilization information that we provide to manufacturers when a dispute is identified. We also provide any additional information that is subsequently requested by the manufacturer. We have also had our auditors survey the pharmacies in specific zip codes to obtain invoices to document that a specific drug manufacturers product was bought by the pharmacy and in stock during the quarter in question. Even after we have provided all these explanations, the manufacturer still may not pay the disputed amount. We have met face to face with manufacturer representatives and discussed disputes. Some of them pay us and some do not.

We definitely know the manufacturers who dispute the largest amount of money. Collecting it, even after providing extensive information, is where the problem lies.

3. The State Agency should provide on-going investigations and analyses of specific manufacturer disputes.

RESPONSE: The State Agency concurs with this recommendation and offers the following comments:

The State does keep records on every manufacturer that receives an invoice from Arkansas Medicaid. We do continue to have dialog with the companies that do not resolve disputes. It has been our experience if we do resolve a dispute for a particular quarter, the same manufacturer disputes the exact same product the following quarter. We have also observed that after requested documentation has been sent to a manufacturer, additional requests for information continue in an effort to delay paying the disputed amount.

4. The State Agency should revise and expand the on-site pharmacy reviews to provide validation of utilization data that has been disputed.

RESPONSE: The State Agency partially concurs, and offers the following comments:

The function of the pharmacy auditors is to determine that the providers are following Medicaid policy. Certainly, it is unrealistic to assume that they have the time to analyze every store and validate every NDC entered in the pharmacy computer. We have repeatedly notified pharmacies of the importance of billing for the exact NDC that was dispensed.

The auditors have validated the utilization of products when there has been a dispute for a specific product.

5. The State Agency should provide the results of the analyses, investigations and reviews to the disputing manufacturers.

RESPONSE: The State Agency concurs with this recommendation and offers the following comments:

The pharmacy unit provides the results of the reviews to the disputing manufacturers. Invoices have been sent to verify that the product had been ordered and was in stock during the quarter that the dispute covers. We provide them with any information that they request or that we feel will be useful in resolving the dispute.

6. The State Agency should consider either legal action against or restricted participation of manufacturers that do not attempt to resolve the disputes.

RESPONSE: The State Agency partially concurs with this recommendation and offers the following comments:

The State has considered requesting a hearing with some of the manufacturers who continue to dispute and do not resolve disputes of previous quarters.

HCFA should be the agency that restricts participation of manufacturers that do not attempt to resolve the disputes. The states are bound to pay for the products of all manufacturers if they signed a rebate agreement with HCFA.

The biggest problem, and one that you did not address, is the need for personnel to perform the rebate dispute resolution function. The rebate dispute resolution process is very tedious and it takes a great deal of time.

It may also be of interest to point out the time element involved in billing and collecting. The time period you reported on was the first quarter of 1992. The invoices for this time period would have been sent out 60 days after the quarter ended (if the HCFA tape arrived promptly). Therefore, the invoices would have been mailed at the end of May or the first of June. The manufacturers have 30 days in which to pay the rebate, so the checks were received at the end of June or the first of July, (assuming they were all received on time). That leaves July, August and September to resolve all the disputes for the first quarter of 1992, since your study was conducted during the month of October, 1992. During this time period, the checks from 243 manufacturers had to be entered into our computer, phone calls made, letters written to manufacturers, information packets mailed, additional information provided, etc. I'm confident these disputes were being worked on, but sufficient time had not been allowed to resolve them.

I hope the above information has been helpful to you. If I can provide additional information, please contact me. I am not requesting an Exit conference.

Sincerely,

Rich Howell

Rich Howell
Deputy Director

ARKANSAS DEPARTMENT OF HUMAN SERVICES
MEDICAID OUTPATIENT PRESCRIPTION DRUG REBATE PROGRAM
SUMMARY OF UTILIZATION DISPUTES
FOR THE QUARTER ENDED MARCH 31, 1992

APPENDIX II

Description of Dispute	Quarterly Total By Manufacturer	Totals
Utilization unreasonable acccording to independent sources	$1,871	$1,871
Utilization data in error, it overstates actual use of product	$122,073 $38,545 $12,047 $9,212	$181,877
Utilization data exceeds reputable industry survey information by > 25%	$1,874 $2,224 $13,616 $874	$18,588
Utilization erroneous based on 3rd party data	$10,573 $5,999 $4,157 $126 $109	$20,964
Exceeds expected utilization	$41,455 $5,074 $442 $976	$47,947
Utilization unreasonable	$20,592 $7,240 $127	$27,959
Utilization units disputed	$12,699 $12,676 $3,145 $142 $24 $2	$28,688
Lower priced drug dispensed or other drug used	$17,824 $1,897 $1,886 $332 $32	$21,971
Adjusted to national average units per Rx	$214	$214
Exceeds threshold	$2,386 $58 $7	$2,450
Recalculated based on their sales volume	$1,323	$1,323
Miscoded/adjusted	$182	$182
		$354,034