DEPARTMENT OF HEALTH & HUMAN SERVICES **OFFICE OF INSPECTOR GENERAL**

Region IX
Office of Audit Services
50 United Nations Plaza, Room 171
San Francisco, CA 94102

July 31,2003

Report Number A-10-03-00007

Mr. Douglas Porter, Assistant Secretary
Washington Department of Social and Health Services
Medical Assistance Administration
P.O. Box 45500
Olympia, Washington 98504

Dear Mr. Porter:

Enclosed are two copies of the Department of Health and Human Services (HHS), Office of Inspector General (OIG) Report entitled, "Audit of the Medicaid Drug Rebate Program in Washington State."

Final determination as to actions taken on all matters reported will be made by the HHS action official named on page 2 of this transmittal letter. We request that you respond to the HHS action official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), OIG Reports issued to the Department's grantees and contractors are made available 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.) As such, within 10 business days after the final report is issued, it will be posted on the Internet at ***http://oig.hhs.gov.***

To facilitate identification, please refer to report number A-10-03-00007 in all correspondence relating to this report. If you have any questions or need additional information, please contact Doug Preussler at (415) 437-8309 or Juliet Lo at (415) 437-8350.

Sincerely,

Lori A. Ahlstrand
Regional Inspector General
for Audit Services

Direct Reply to HHS Action Official:

Ms. Linda **A.** Ruiz
Centers for Medicare & Medicaid Services
Regional Administrator, Region X
2201 Sixth Avenue, MS-40
Seattle, WA 98121

Enclosures – As stated

Departmentof Health and Human Services

OFFICE OF
INSPECTOR GENERAL

AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN WASHINGTON STATE

JULY 2003
A-10-03-00007

Office of Inspector General

http://oig.hhs.gov

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OAS FINDINGS AND OPINIONS

The designation of financial or management practices as questionable or a recommendation for the disallowance of costs incurred or claimed, as well as other conclusions and recommendations in this report, represent the findings and opinions of the HHS/OIG/OAS. Authorized officials of the HHS divisions will make final determination on these matters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

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July 31, 2003

Report Number A-10-03-00007

Mr. Douglas Porter, Assistant Secretary
Washington Department of Social and Health Services
Medical Assistance Administration
P.O. Box 45500
Olympia, Washington 98504

Dear Mr. Porter:

This report provides you with the results of our "Audit of the Medicaid Drug Rebate Program in Washington State." The Medicaid drug rebate program was established to allow Medicaid to receive pricing benefits commensurate with its position as a high-volume purchaser of prescription drugs.

EXECUTIVE SUMMARY

OBJECTIVE

The objective of our review was to evaluate whether the State of Washington's Department of Social and Health Services (State Agency) had established adequate accountability and internal controls over the Medicaid drug rebate program.

SUMMARY OF FINDINGS

The State Agency had an adequate system to account for drug rebate activity that tracked receivables to the National Drug Code (NDC) level. However, the State Agency had not established formal policies and procedures over the Medicaid drug rebate program as required by Federal rules and regulations. We also identified internal control and accountability weaknesses in the State Agency's informal procedures regarding:

Segregation of Duties - The State Agency did not properly segregate duties between the rebate billing and collection functions.

- **Adjustments and Write-Offs** - Management review was not required by the State Agency for any account adjustments or write-offs.
- **Subsidiary Ledger** - The State Agency did not always post prior quarter adjustments to its subsidiary ledger in a timely manner resulting in incorrectly reported receivable balances.
- **Interest** - The State Agency did not calculate interest on disputed, late, and unpaid rebate amounts; verify the accuracy of interest payments received; nor post interest to the applicable subsidiary ledger accounts.
- **Dispute Resolution** - The State Agency did not actively resolve the backlog of manufacturer drug rebate disputes.

RECOMMENDATIONS

We recommend the State Agency establish:

(1) formal policies and procedures over its Medicaid drug rebate program; and

(2) internal controls to:

- provide for the proper segregation of duties between the rebate billing and collection functions;
- provide management oversight over adjustments and write-offs;
- update subsidiary ledger accounts in a timely manner;
- calculate interest due, verify the accuracy of interest payments received, and accurately report interest received; and
- actively work to resolve manufacturer disputes and, when appropriate, use the State hearing mechanism to resolve long-standing disputes.

STATE AGENCY COMMENTS

In written comments to our draft report, the State Agency disagreed with our finding that duties are not properly segregated between billing and collection functions. The State Agency generally concurred with the remaining findings and recommendations with some added clarification. The complete text of the State Agency's comments is included as an appendix to this report.

OFFICE OF INSPECTOR GENERAL (OIG) RESPONSE

We consider dispute resolution a collection activity and, therefore, believe the rebate billing and collection functions were not properly segregated.

INTRODUCTION

BACKGROUND

On November 5, 1990, Congress enacted the Omnibus Budget Reconciliation Act of 1990 legislation (OBRA '90), which established the Medicaid drug rebate program that became effective January 1, 1991. The Medicaid drug rebate program was established to allow Medicaid to receive pricing benefits commensurate with its position as a high-volume purchaser of prescription drugs. Responsibility for the rebate program was shared among the drug manufacturers, Centers for Medicare & Medicaid Services (CMS), and participating States. Throughout the program, CMS issued memoranda to State agencies and manufacturers to provide guidance on numerous issues related to the Medicaid drug rebate program.

The OBRA '90 required a drug manufacturer to enter into, and have in effect, a rebate agreement with CMS in order to have its products covered under the Medicaid program. After a rebate agreement was signed, the manufacturer was required to submit to CMS a listing of all covered outpatient drugs, including the average manufacturer price and best price information for each drug. A covered outpatient drug is one of approximately 56,000 drugs listed in the NDC listing. Approximately 550 pharmaceutical companies participated in the program nationally.

Based on the information received from the manufacturers, CMS calculated and provided the unit rebate amount (URA) for each covered drug to States quarterly on a computer tape. However, the CMS tape may have contained a $0 URA if the pricing information was not provided timely by a manufacturer or if the computed URA had a 50 percent variance from the previous quarter. In instances of $0 URAs, States were instructed to invoice the units and the manufacturers were required to calculate the URAs and remit the appropriate amounts to the State. In addition, the manufacturers could change any URA based on updated pricing information, and submit this information to States.

Each State was required to maintain, by manufacturer, the number of units dispensed for each covered drug. That number was applied to the URA to determine the actual rebate amount due from each manufacturer. States were required to provide drug utilization data to the manufacturers and CMS on a quarterly basis.

From the date an invoice was postmarked, each manufacturer had 38 days to remit the drug rebate amount owed to the State. The manufacturers were to provide the State with a Reconciliation of State Invoice detailing its rebate payment by NDC. A manufacturer could dispute utilization data it believed to be erroneous, but was required to pay the undisputed portion of the rebate by the due date. If the manufacturer and the State could not, in good faith, resolve the discrepancy, the manufacturer was required to provide written notification of the dispute to the State by the due date. The manufacturer was required to calculate and remit interest for disputed rebates when settlement was made in favor of the State. If the State and manufacturer were not able to resolve the discrepancy within 60 days, the State was required to make available a hearing mechanism under the State's Medicaid program for the manufacturer to resolve the dispute. In addition, States had the option to attend conferences such as the Dispute Resolution Project sponsored by CMS to resolve disputes with manufacturers.

States were required to report, on a quarterly basis, rebate collections on the CMS 64.9R report. Specifically, States were required to report rebates invoiced in the current quarter, adjustments and rebates received during the current quarter, and uncollected rebate balances for the current and prior quarters. The CMS 64.9R report was part of the CMS 64 report, which summarized actual Medicaid expenditures for each quarter and was used by CMS to reimburse the Federal share of these expenditures.

The State Agency reported (1) an average of $25.7 million in billings and $27.1 million in collections per quarter during the 1-year period ending June 30, 2002, and (2) $25.4 million as the outstanding receivable balance as of June 30, 2002. Of this amount, $6.8 million had been outstanding for 90 days or longer.

The Washington drug rebate program was established on January 1, 1991. The State Agency contracted with a private company to print manufacturer's invoices, prepare invoice diskettes and mailing labels. The State Agency performed all the other functions of the drug rebate program.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The objective of our review was to evaluate whether the State Agency had established adequate accountability and internal controls over the Medicaid drug rebate program.

Scope

We focused our audit on the current policies, procedures, and internal controls established by the State Agency for the Medicaid drug rebate program. We also reviewed accounts receivable information related to prior periods and interviewed State Agency employees to gain an understanding of how the Medicaid drug rebate program had operated since its inception.

Methodology

Our audit was performed in accordance with generally accepted government auditing standards. To accomplish our objectives, we interviewed State Agency officials to determine the policies, procedures and internal controls that existed with regard to the Medicaid drug rebate program. We interviewed the State Agency staff that performed functions related to the drug rebate program, including gathering information on their roles in the invoicing and dispute resolution processes. In addition, we reviewed the drug rebate accounts receivable balance reported in the State Agency's subsidiary ledger system and compared the data to the CMS 64.9R report for the quarter ending June 30, 2002.

Our fieldwork was conducted during the period February 2003 through April 2003, and included site visits to State Agency offices in Olympia, Washington.

FINDINGS AND RECOMMENDATIONS

We found that the State Agency had an adequate system to account for drug rebate activity that tracked receivables to the National Drug Code (NDC) level. However, the State Agency had not established formal policies and procedures over the Medicaid drug rebate program as required by Federal rules and regulations. We also identified internal control and accountability weaknesses in the informal procedures followed by the State Agency regarding:

- Segregation of Duties
- Adjustments and Write-Offs
- Subsidiary Ledger
- Interest
- Dispute Resolution

FORMAL POLICIES AND PROCEDURES

The State Agency did not have formal written policies and procedures over its Medicaid drug rebate program. Employees compiled informal written procedures describing the invoicing and dispute resolution functions for the rebate program, but these were never formally adopted by the State Agency.

INTERNAL CONTROLS AND ACCOUNTABILITY

Segregation of Duties

The State Agency did not properly segregate duties for rebate billings and collections. State Agency employees were responsible for the billing functions of reviewing rebate invoices for utilization errors and correcting any errors identified. These same employees were responsible for the collection functions of dispute resolution, adjustments and write-offs. The lack of segregation of duties between the billing and collection functions increased the potential risk for fraud, waste, and abuse of drug rebate program funds.

Adjustments and Write-Offs

The State Agency did not provide adequate management oversight over adjustments and write-offs. As a result, large outstanding balances could be adjusted and written-off without management review or approval. For example, an adjustment of $31,264 was made from the receivable account of a manufacturer without evidence of management approval. In most instances, the staff handling dispute resolution cases initiated the adjustments and write-offs, and forwarded the adjustment forms to the accounting department. The accounting staff processed the adjustments and write-offs in the subsidiary ledger system without requiring supporting documentation or evidence of management approval. The lack of management oversight over account adjustments and write-offs increased the potential risk for fraud, waste, and abuse of drug rebate program funds.

Subsidiary Ledger

The State Agency did not always process prior quarter adjustments in a timely manner. The manufacturers submitted prior quarter adjustments along with their payments for current period rebate billings and adjustments. The State Agency processed the current period payments in a timely manner but did not always process the prior quarter adjustments timely. As a result, the uncollected rebate balances reported to CMS were incorrect.

Interest

The State Agency did not have adequate controls in place to accurately account for interest on disputed, late, and unpaid rebate payments nor ensure that interest collections received from manufacturers were accurate and reported to CMS. Since the State Agency did not calculate interest due, nor verify that the interest voluntarily paid by the manufacturers was accurate, there was no assurance the State Agency collected all of the interest owed on disputed, late, and unpaid rebates.

According to the rebate agreements between drug manufacturers and CMS, as stipulated by Section 1927 of the Social Security Act (the Act), manufacturers were required to pay interest on disputed, late and unpaid rebates. Section V, paragraph (b) of the rebate agreement states:

> *(b) If the Manufacturer in good faith believes the State Medicaid Agency's Medicaid Utilization Information is erroneous, the Manufacturer shall pay the State Medicaid Agency that portion of the rebate amount claimed which is not disputed within the required due date in II (b). The balance due, if any, plus a reasonable rate of interest as set forth in section 1903(d)(5) of the Act, will be paid or credited by the Manufacturer or the State by the due date of the next quarterly payment in II(b) after resolution of the dispute.*

According to CMS Program Release #29 issued to State Medicaid Directors, interest must be collected and could not be disregarded as part of the dispute resolution process by either the manufacturer or the State. The calculation of interest, as set forth in section 1903(d)(5) of the Act and Program Release #29 to the State Medicaid Directors, involved applying simple interest to the average yield of the weekly 90-day Treasury bill auction rates during the period in which interest was charged. In addition, Program Release #65 to the State Medicaid Directors stated that it was the manufacturers' responsibility to calculate and pay interest for applicable rebate invoices and the State's responsibility to track collections and report those amounts to CMS.

We found that the State Agency did not accrue interest on disputed, late, and unpaid rebate payments. When the State Agency received interest payments from drug manufacturers, it did not verify that the amounts received were accurate. Additionally, interest collected since the third quarter of 1999 was maintained by the State Agency in a suspense account and had not been reported to CMS.

Dispute Resolution

The State Agency had not actively worked to resolve a portion of the long-standing disputes with manufacturers over drug rebate amounts. The employees responsible for dispute resolution also had to request necessary information on current disputed cases from another department, lengthening the process time. In addition, the State Agency did not utilize the State hearing mechanism to resolve long-standing disputes with manufacturers.

The State Agency had a backlog of long-standing dispute cases. In some instances, State Agency employees had not yet contacted manufacturers to begin the dispute resolution process. In addition, before they could work current disputes, State Agency employees responsible for the dispute resolution process had to request information from another department for cases disputed on billings from the third quarter of 1999 to the present.

The State Agency did not utilize the State hearing mechanism to resolve long-standing disputes with manufacturers. The drug rebate agreement between CMS and manufacturers required the States and manufacturers to use their best efforts to resolve rebate discrepancies within 60 days of receipt of a dispute notification. However, in the event that the State and manufacturer were unable to resolve a discrepancy, CMS required the State to make available to the manufacturer a State hearing mechanism under the Medicaid Program. The CMS Program Release #44 issued to the State Medicaid Directors, indicated that CMS believed the State hearing process was the appropriate mechanism for both the manufacturers and States to resolve disputes.

Instead of using the State hearing mechanism, the State Agency contacted the manufacturers directly and attended program conferences to resolve disputes with those manufacturers who attended. However, manufacturers were not required to attend these conferences. A CMS representative was available at these conferences to mediate the process.

As of January 2003, the State Agency had an outstanding disputed rebate balance of $2.1 million dating from 1991 through the second quarter of 1999. We believe the State hearing mechanism is an appropriate method to resolve these long-standing disputes and increase rebate collections.

RECOMMENDATIONS

We recommend the State Agency establish:

(1) formal policies and procedures over its Medicaid drug rebate program; and

(2) internal controls to:

- provide for the proper segregation of duties between the rebate billing and collection functions;
- provide management oversight over adjustments and write-offs;
- update subsidiary ledger accounts in a timely manner;

- calculate interest due, verify the accuracy of interest payments received, and report interest received to CMS; and
- actively work to resolve manufacturer disputes and, when appropriate, use the State hearing mechanism to resolve long-standing disputes.

STATE AGENCY COMMENTS

In written response to our draft report, State Agency officials concurred with our finding and recommendation regarding developing formal policies and procedures. They disagreed with our finding and recommendation on segregation of duties. The State Agency generally concurred with our findings and recommendations regarding adjustments and write-offs, updating the subsidiary ledger, interest and dispute resolution.

State Agency officials concurred with our finding regarding policies and procedures and indicated that they would develop a process to formally adopt the drug rebate procedures. They also planned to undertake projects to organize, standardize and enhance drug rebate policies and procedures agency-wide.

State Agency officials disagreed with our finding regarding segregation of duties. They defined a billing function as the invoicing action and the collection function as the receiving of checks. Using these definitions as guidelines, they believed duties were properly segregated.

State Agency officials concurred with our finding regarding adjustments and write-offs. They indicated additional procedures would be established to ensure that management approval is documented for adjustments and write-offs. They also concurred with our findings regarding the subsidiary ledger and interest. In addition, they indicated additional resources and timelines for resolving each of these issues would be developed.

State Agency officials generally concurred with our findings and recommendations regarding dispute resolution. However, they provided the following clarifying remarks: (1) the State Agency actively worked to resolve long-standing disputes, (2) the disputed balance included in the report did not reflect the progress made by the State Agency in collecting disputed amounts, and (3) CMS guidance regarding the appropriate timeframes for dispute resolution are inconsistent. Finally, they believed the utilization of the State hearing process was not the best forum to resolve drug rebate disputes.

OIG RESPONSE

In our opinion, the definitions used by the State Agency regarding segregation of duties between billing and collection were too narrowly defined. Dispute resolution should be considered a collection function when determining proper segregation of duties.

The State Agency actively worked to resolve some long-standing disputes with manufacturers. However, it had not made any attempt to contact several manufactures. Our report has been

changed to indicate that only a portion of the long-standing disputes were not actively being worked by the State Agency.

The purpose of including the long-standing disputed amount in our report was not intended to address the collection of long-standing disputes, but rather to indicate that there are still some long-standing disputes that the State Agency may want to consider using the State hearing mechanism to resolve.

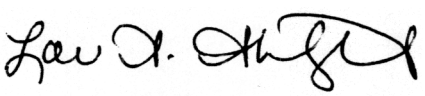
The State Agency should work with CMS regarding any perceived inconsistencies in the guidance on timelines for dispute resolution or the appropriateness of including the State hearing mechanism as part of its dispute resolution process.

* * * * * * *

In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), OIG reports issued to the Department's grantees and contractors are made available 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 report number A-10-03-00007 in all correspondence relating to this report.

Sincerely,



Lori A. Ahlstrand
Regional Inspector General
for Audit Services

Enclosure

APPENDIX

STATE OF WASHINGTON

DEPARTMENT OF SOCIAL AND HEALTH SERVICES

P.O. Box 45500, Olympia, Washington 98504-5500

July 14, 2003

Lori A. Ahlstrand, Regional Inspector General
Region IX, Office of Audit Services
50 United Nations Plaza
Room 171
San Francisco, California 94102

Dear Ms. Ahlstrand:

Enclosed is the Department of Social and Health Services response to your Draft of the Audit of the Medicaid Drug Rebate Program in Washington State, (A-10-03-00007). These responses include the status of actions taken on your recommendations.

The final audit report, which contains the findings and responses, is an official public document and will be filed once you receive our responses. I am requesting that you notify my office when the report becomes public so we may prepare for any media coverage.

If you have any questions, or would like to discuss the responses or any new information being presented, please contact Chuck Cummings at (360) 725-1247 or Don Mercer at (360) 664-5500.

Sincerely,

Douglas Porter, Assistant Secretary
Medical Assistance Administration

Enclosure

cc: Stan Marshburn, Chief Financial Officer
Judy Devine, Deputy Financial Officer
Heidi Robbins Brown, Director
Don Mercer, Financial Recovery Chief
Scott Kibler, Accounting Services Chief
Mariann Schols, Financial Services Manager

Washington State Department of Social and Health Services
Report Number A-10-03-00007

RESPONSE TO THE OIG "AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN WASHINGTON STATE"

FORMAL POLICIES AND PROCEDURES

The State did not have formal written policies and procedures over its Medicaid drug rebate program. Employees compiled informal written procedures describing the invoicing and dispute resolution functions for the rebate program, but these were never formally adopted by the State.

DSHS Response: DSHS concurs with this finding.

The Medical Assistance Administration (MAA) and the Office of Financial Recovery (OFR) will develop a process to formally adopt the drug rebate procedures.

DSHS does appreciate the value of formal written policies and procedures in addition to existing desk manuals. Both MAA and OFR are currently undertaking projects to organize, standardize and enhance drug rebate policies and procedures agency-wide.

INTERNAL CONTROLS AND ACCOUNTABILITY

Segregation of Duties

The State did not properly segregate duties for rebate billings and collections. State employees were responsible for the billing functions of reviewing rebate invoices for utilization errors and correcting any errors identified. These same employees were responsible for the collection functions of dispute resolution, adjustments and write-offs. The lack of segregation of duties between the billing and collection functions increased the potential risk for fraud, waste, and abuse of drug rebate program funds.

DSHS Response: DSHS disagrees with this finding.

Absent specific definitions of the terms "billing functions" and "collections functions" from the auditors, MAA defines a billing function as the invoicing action and the collection function would be the receiving of the checks. Since Office of Financial Recovery perform both the billing or invoicing functions of the Drug Rebate program, MAA believes that an appropriate "separation of duties" is currently in place. At no time does MAA staff perform collection functions. MAA staff are never involved in the receiving, tracking or posting of rebate checks.

For further clarification, MAA staff performs both "pre" and "post-invoice" dispute resolution activities with the manufacturers. These disputes are almost always over the number of units of medication dispensed. Pre-invoice dispute activities include: (1) reviewing the invoices to identify obvious unit errors, (2) working with the dispensing pharmacy to correct the errors, (3) correcting the information in the Point of Sale payment system so a prior period correction record can be created the next quarter, (4) contacting the manufacturer to inform them their invoice is incorrect, and (5) communicating the correct number of units. These preventative activities are extremely successful and are completed separate from the adjustment and write-off process managed within the Office of Financial Recovery. This pre-invoice resolution process essentially identifies pharmacy errors before reaching the manufacturer and resulting in a post-invoice dispute. We fail to see how this is any different than letting the manufacturer discover the error and initiate the dispute – post invoice.

Washington State Department of Social and Health Services
Report Number A-10-03-00007

Adjustments and Write-Offs

The State did not provide adequate management oversight over adjustments and write-offs. As a result, large outstanding balances could be adjusted and written-off without management review or approval. For example, an adjustment of $31,264 was made from the receivable account of a manufacturer without evidence of management approval. In most instances, the staff handling dispute resolution cases initiated the adjustments and write-offs, and forwarded the adjustment forms to the accounting department. The accounting staff processed the adjustments and write-offs in the subsidiary ledger system without requiring supporting documentation or evidence of management approval. The lack of management oversight over account adjustments and write offs increased the potential risk for fraud, waste and abuse of drug rebate program funds.

DSHS Response: DSHS concurs with this finding.

DSHS Administrative Policy 10.02 grants the authority to reduce or forgive debt only to the Chief of the Office of Financial Recovery. When MAA rebate staff determines such action is warranted, they complete an OFR Adjustment Form and submit it to OFR for final determination. MAA drug rebate staff never writes off debt.

DSHS will incorporate the following language into the Drug Rebate desk manual:

- When completing the OFR adjustment form and the adjustment is not supported by claim adjustments through the Point of Sale, and the adjustment is both over $10,000 per labeler code per quarter and over $1,000 per NDC per quarter, the Section Manager must co-sign the OFR adjustment form. The Section Manager's signature indicates (s)he has reviewed the adjustment request and the supporting documentation and agrees with the unit adjustment(s)

- It is the responsibility of the drug rebate program managers to ensure that adequate documentation to support the adjustments is available to the Section Manager before requesting their signature and is maintained in the manufacturers file.

- When the OFR Adjustment form is received by OFR, they will review the document to ensure that the appropriate signatures have been obtained and the necessary support documentation, if applicable, has been provided. Once it has been determined that all needed information has been received, OFR will process the adjustment.

This information will be incorporated into written policy as part of the agency wide policy enhancement initiative.

Subsidiary Ledger

The State did not always process prior quarter adjustments in a timely manner. The manufacturers submitted prior quarter adjustments along with their payments for current period rebate billings and adjustments. The State processed the current period payments in a timely manner but did not always process the prior quarter adjustments timely. As a result, the uncollected rebate balances reported to CMS were incorrect.

DSHS Response: DSHS concurs with this finding.

OFR is currently assigning additional resources and developing timelines for posting backlogged prior quarter adjustments to the subsidiary ledger.

Interest

Washington State Department of Social and Health Services
Report Number A-10-03-00007

The State did not have adequate controls in place to accurately account for interest on disputed, late, and unpaid rebate payments nor ensure that interest collections received from manufacturers were accurately and reported to CMS. Since the State did not calculate interest due nor verify that the interest voluntarily paid by the manufacturer was accurate, there was no assurance the State colleted all of the interest owed on disputed, late, and unpaid rebates.

DSHS Response: DSHS concurs with this finding.

OFR is currently assigning additional resources and developing a timeline for testing the account receivable system's interest module and implementing interest calculation, verification, posting, and reporting requirements.

Dispute Resolution

The State had not actively worked to resolve long-standing disputes with manufacturers over drug rebate amounts. The employees responsible for dispute resolution also had to request necessary information on current disputed cases from another department, lengthening the process time. In addition, the State did not utilize the State hearing mechanism to resolve long- standing disputes with manufacturers.

DSHS Response: DSHS will accept this finding with the following clarifications.

Reducing this backlog is a drug rebate priority. DSHS is exploring several possible solutions to speed their resolution. Process improvement, reassignment of existing resources, and adding new resources are possibilities. DSHS is committed to eliminating this backlog.

Several auditor statements require clarification for accuracy. The following paragraphs address several important issues.

MAA actively resolves long-standing disputes. The first line states "[t] he State had not actively worked to resolve long-standing disputes with manufacturers over drug rebate amounts." In fact, MAA staff has been and continue to actively work these old files. The outstanding balance has dropped from $4.4 million in April 2001 to $2.4 million in April 2002 and is under $2 million today. This progress is misrepresented in the last paragraph of the finding which reads, "The State had an outstanding disputed balance of $2.1 million dating from 1991 through the second quarter of 1999." The $2.1 million is the balance at the end of the period but the wording of the report finding suggests the balance had not changed during the entire 8-year period.

CMS guidelines are inconsistent regarding the appropriate timeframes for dispute resolution. The 60-day time frame cited in the audit report comes from the Medicaid Drug Rebate Agreement between Manufacturers and the Secretary of the Department of Health and Human Services. State Medicaid programs are beneficiaries of this agreement, but not a direct party in this contract. Washington, along with most other states, believe this time frame is both unrealistic and in conflict with other drug rebate sources. For example, the CMS publication "Best Practices Under the Medicaid Drug Rebate Program", under the heading "Best Practices in Medicaid Drug Rebate Dispute Resolution for Manufacturers" offers these time frames:

- According to HCFA guidelines, no later than 90 days after receipt of the Manufacturer's dispute, the State and Manufacturer should discuss, by NDC number, the items in dispute and the reason for the dispute. The State should present a report to the Manufacturer of preliminary response to the dispute resolution.
- According to HCFA guidelines, within 150 days after receipt of the Manufacturer's dispute, the State should attempt to resolve questions concerning data by reporting the findings of State research or by providing the documentation requested by the Manufacturer.

- Good faith negotiations between the Manufacturer and State should be completed within 240 days after receipt of the Manufacturer's dispute according to HCFA guidelines.
- If a State and a Manufacturer reach an impasse and are unable to agree on a settlement to the dispute, the State may request an administrative hearing. Requesting a hearing should be a State's last resort and should be pursued only if all other avenues have been tried and have failed.
- In lieu of a State hearing, the State and Manufacturer may agree to arbitration or mediation to resolve the dispute.

That same publication, under the heading "What Should States Do If the Process Fails?" is this:

- Contact the HCFA Regional Office to try to get the other party engaged and encourages them to attend a DRP meeting. If a State finds that repeated attempts to resolve a dispute with a Manufacturer remain unsuccessful, it may be necessary for the State to contact the appropriate HCFA RO and request their intervention. The HCFA RO can assist a State in persuading a Manufacturer to begin the resolution process with the State or to attend a DRP meeting.

The Medicaid Drug Rebate Agreement; Section VIII(c) empowers the Secretary to terminate the Agreement for violations of this agreement or other good cause upon 60 days prior written notice to the Manufacturer of the existence of such violation or other good cause.

MAA believes these time frames and recommended actions are more reasonable and current as they are more recent than the language in the Medicaid Drug Rebate Agreement and most likely reflect modifications based upon the experience of the states in administering the drug rebate program. In any event, the Rebate Agreement and subsequent CMS publications are in conflict. States look to CMS to decide the proper course of action (especially where there is conflicting information) and communicate those decisions to both the states and the drug manufacturers.

Utilization of "state hearing process" is not the best forum to resolve drug rebate disputes. While CMS guidelines offer the use of "state hearing processes" as a last resort to resolve rebate disputes with manufacturers, this is neither a practical or effective option within DSHS. DSHS hearing processes are conducted by a separate agency called the Office of Administrative Hearings (OAH). Jurisdiction is conferred on OAH by statute that currently does not cover drug rebate dispute resolution. Even if DSHS were to seek legislation, it is likely that an Administrative Law Judge would find that DSHS lacked standing to bring the cause of action because DSHS is not a direct party to the contract at issue (which is between HHS and the manufacturers). Therefore, we do not believe the administrative law judges in Washington State have the jurisdiction to hear the cases or the authority to enforce their decisions on most manufacturers. MAA already offers a dispute resolution process through its Drug Rebate program that follows CMS recommended actions. In the alternative, MAA suggests that the option for binding arbitration under the authority of CMS to resolve these disputes would be the most appropriate final resolution process in the event of impasse.