DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General

Office of Audit Services
1100 Commerce, Room 632
Dallas, TX 75242

May 13, 2003

Common Identification Number: A-06-03-00042

Suzette Bridges, Registered Pharmacist
Pharmacy Program Director
Department of Human Services/Division of Medical Services
P.O. Box 1437 Slot S415
Little Rock, AR 72203

Dear Ms. Bridges:

Enclosed are two copies of the Department of Health and Human Services (HHS), Office of Inspector General (OIG), Office of Audit Services' (OAS) report entitled "Review of Medicaid Drug Rebate Collections-State of Arkansas." A copy of this report will be forwarded to the action official noted below for his review and any action deemed necessary.

Final determination as to actions taken on all matters reported will be made by the HHS action official named below. 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, OAS 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 ten business days after the final report is issued, it will be posted on the OIG web site at http://oig.hhs.gov.

To facilitate identification, please refer to Common Identification Number A-06-03-00042 in all correspondence relating to this report.

Sincerely yours,

Gordon L. Sato

Gordon L. Sato
Regional Inspector General
for Audit Services

Enclosures - as stated

Direct Reply to HHS Action Official:
Dr. James R. Farris, M.D.
Regional Administrator
Centers for Medicare and Medicaid Services
1301 Young Street, Suite 714
Dallas, TX 75202

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF MEDICAID DRUG REBATE COLLECTIONS STATE OF ARKANSAS

JANET REHNQUIST
Inspector General

MAY 2003
A-06-03-00042

EXECUTIVE SUMMARY

OBJECTIVE

The audit objective was to evaluate whether the Arkansas Department of Human Services (DHS) had established adequate accountability over the Medicaid drug rebate program.

FINDINGS

Generally, the DHS had established adequate controls over the drug rebate program, as required by federal rules and regulations. It had extensive policies and procedures in place that enabled it to keep detailed and accurate records, resolve disputes with drug manufacturers, and safeguard rebate program funds. However, we identified one area where the DHS could improve accountability over drug rebates. Specifically, the DHS could improve its accounting for interest payments received from drug manufacturers.

Title 45 Sec. 74.21 paragraph (b)(3) of the Code of Federal Regulations requires that financial management systems provide for effective control over and accountability for all funds, property, and other assets. Section 2500.1 of the State Medicaid Manual requires interest received from the drug rebate program to be reported on the CMS 64, Line 5.

The DHS recorded interest payments in the Rebate Management System (RMS) without a corresponding entry to establish the interest as a receivable. In addition, the DHS did not verify that interest payments were accurate. As a result, the balance of uncollected rebates was understated by the amount of interest received, and the DHS cannot be assured that all interest due was paid. Also, the understated balance of uncollected rebates was reported on the CMS 64.9R. The amount of the understatement was $537,979, which represented the amount of interest received through June 30, 2002. Additionally, interest should be reported separately on CMS 64, Line 5.

According to DHS officials, accrued interest could not be recorded as a receivable in the RMS. However, interest payments were accounted for on a separate schedule in order to calculate the true amount of uncollected rebates, but this schedule was not used in the preparation of the CMS 64.9R. The DHS officials stated that a proposal exists for the next RMS upgrade to allow for the proper recording of interest. The DHS officials also stated that they were unaware of the requirement to separately report interest payments on the CMS 64, Line 5.

RECOMMENDATIONS

We recommend that DHS:

- Adjust the outstanding balance to account for interest received and correctly report (1) the interest on the CMS 64, Line 5, and (2) the outstanding balance on the CMS 64.9R on the next quarterly report, and
- Implement a procedure to verify that interest payments are accurate.

The DHS responded to our draft report in a letter dated May 7, 2003. The DHS was in agreement with our findings in the report. The complete text of DHS's response is included as **Appendix 1**.

INTRODUCTION

BACKGROUND

On November 5, 1990, Congress enacted the Omnibus Budget Reconciliation Act (OBRA) of 1990 legislation, which, among other provisions, established the Medicaid drug rebate program. Responsibility for the rebate program is shared among the drug manufacturer(s), the Centers for Medicare and Medicaid Services (CMS), and the state(s). The legislation was effective January 1, 1991. The CMS also issued release memorandums to state agencies and manufacturers throughout the history of the rebate program to give guidance on numerous issues related to the Medicaid drug rebate program.

A drug manufacturer is required 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 is signed, the manufacturer is required to submit a listing to CMS of all covered outpatient drugs, and to report its average manufacturer price and best price information for each covered outpatient drug to CMS. Approximately 520 pharmaceutical companies participate in the program.

The CMS provides the unit rebate amount (URA) information to the state agency on a quarterly computer tape. The CMS tape may contain a $0 URA if the pricing information was not provided timely or if the pricing information has a 50 percent variance from the previous quarter. In instances of $0 URAs, the state agency is instructed to invoice the units and the manufacturer should pay the rebate based on the manufacturer's information. In addition, the manufacturers often change the URA based on updated pricing information, and submit this information to the state agency in the Prior Quarter Adjustment Statement.

Each state agency is required to maintain the number of units dispensed, by manufacturer, for each covered drug. Approximately 56,000 National Drug Code (NDC) are available under the program. Each state agency uses the URA from CMS and the utilization for each drug to determine the actual rebate amounts due from the manufacturer. The CMS requires each state agency to provide drug utilization data to the manufacturer.

The manufacturer has 38 days from the day a state agency sends an invoice to pay the rebate to avoid interest. The manufacturers submit to the state agency a Reconciliation of State Invoice that details the current quarter's payment by NDC. A manufacturer can dispute utilization data that it believes is erroneous, but the manufacturer is required to pay the undisputed portion by the due date. If the manufacturer and the state agency cannot in good faith resolve the discrepancy, the manufacturer must provide written notification to the state agency by the due date. If the state agency and the manufacturer are not able to resolve the discrepancy within 60 days, the state agency must make a hearing mechanism available under the Medicaid program to the manufacturer in order to resolve the dispute.

Each state agency reports, on a quarterly basis, outpatient drug expenditures and rebate collections on the Form CMS 64.9R. This report is part of the Form CMS 64 report, which summarizes actual Medicaid expenditures for each quarter and is used by CMS to reimburse the federal share of these expenditures. The DHS reported to CMS an average of $13.3 million in billings per quarter and collections of $13.5 million per quarter during the 1-year period ending June 30, 2002. The DHS reported $9,638,177 of outstanding drug rebate program accounts receivable as of June 30, 2002 on the CMS 64.9R. However, only $436,705 of the $9,638,177 was more than 90 days old, according to DHS records.

The DHS received the drug rebate program funds and prepared the CMS 64.9R. The DHS had a contract with its fiscal agent to perform all other drug rebate program functions, such as invoicing manufacturers, maintaining detailed accounts receivable balances, researching utilization data for errors, and corresponding with manufacturers to resolve disputes.

OBJECTIVE, SCOPE AND METHODOLOGY

Objective

The audit objective was to evaluate whether the DHS had established adequate accountability over the Medicaid drug rebate program.

Scope

The drug rebate program was effective January 1, 1991. We concentrated our review on the current policies, procedures and controls of DHS. We also reviewed accounts receivable information related to prior periods and interviewed a DHS official to understand how the Medicaid drug rebate program had operated since 1991.

Methodology

To accomplish our objectives, we interviewed DHS officials and fiscal intermediary staff to determine the policies, procedures and controls that existed with regard to the Medicaid drug rebate program. Also, we interviewed DHS and fiscal intermediary staff members that performed functions related to the rebate program. In addition, we obtained and reviewed drug rebate accounts receivable records and compared this data to the Form CMS 64.9R report for June 30, 2002. Finally, we selected and tested a sample of labelers to determine that source documents agreed to detailed accounts receivable records in the Rebate Management System (RMS).

Fieldwork was performed at DHS's office in Little Rock, Arkansas during May 2002, and continued in the Little Rock, Arkansas field office through April 2003.

Our audit was performed in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

Generally, the DHS had established adequate controls over the drug rebate program, as required by federal rules and regulations. It had extensive policies and procedures in place that enabled it to keep detailed and accurate records, resolve disputes with drug manufacturers, and safeguard rebate program funds. However, we identified one area where the DHS could improve accountability over drug rebates. Specifically, the DHS could improve their accounting for interest payments received from drug manufacturers.

Criteria

Title 45 Sec. 74.21 paragraph (b)(3) of the Code of Federal Regulations requires that financial management systems provide for effective control over and accountability for all funds, property, and other assets. Section 2500.1 of the State Medicaid Manual requires interest received from the drug rebate program to be reported on the CMS 64, Line 5.

Adequate Controls Established

As part of the DHS controls over the Medicaid drug rebate program, the fiscal intermediary contract employees kept detailed and accurate records by (1) recording all transactions at the NDC level, and (2) reconciling payments to the original invoices. By keeping such a detailed information system, the fiscal intermediary staff could accurately monitor accounts receivable and effectively pursue collection of outstanding balances from drug manufacturers.

The DHS also had policies and procedures in place to resolve disputes with manufacturers. Before the invoices were sent out, fiscal intermediary staff reviewed the number of units dispensed for reasonableness. If some portion of the figures appeared to be unreasonable, the number of units dispensed by the dispensing pharmacy was verified. After the invoices were sent and the payments received, the fiscal intermediary staff identified disputed units during the posting of payments from the manufacturers. When a dispute was identified, a file was created and utilization research could verify the correct utilization. A staff member would then contact the manufacturer and work to resolve the dispute.

Interest Reporting

The DHS understated the outstanding drug rebate accounts receivable on the CMS 64.9R. This occurred because interest payments were recorded in the RMS without a corresponding entry to establish the interest as a receivable. The DHS reported $9.6 million of outstanding drug rebate accounts receivable on the June 30, 2002 CMS 64.9R report. The amount of the understatement was $537,979, which represented the amount of interest received through June 30, 2002. Additionally, interest should be reported separately on CMS 64, Line 5.

According to DHS officials, accrued interest could not be recorded as a receivable in the RMS. However, interest payments were tracked on a separate schedule in order to determine the true amount of uncollected rebates, but this information was not used in the preparation of the CMS 64.9R. Additionally, DHS officials stated that a proposal exists for the next RMS upgrade to allow for the proper recording of interest. The DHS officials stated that they were unaware of the requirement to separately report interest payments on the CMS 64, Line 5.

Further, the DHS did not verify that interest payments were accurate. The DHS used a computerized program to calculate interest owed. Statements of interest due were periodically mailed to labelers along with the regular quarterly invoice. However, there was no procedure in place to verify that interest payments were accurate. As a result, the DHS cannot be assured that all interest due was paid.

RECOMMENDATIONS

We recommend that DHS:

- Adjust the outstanding balance to account for interest received and correctly report (1) the interest on the CMS 64, Line 5, and (2) the outstanding balance on the CMS 64.9R on the next quarterly report, and
- Implement a procedure to verify that interest payments are accurate.

AUDITEE RESPONSE

The DHS responded to our draft report in a letter dated May 7, 2003. The DHS was in agreement with our findings in the report. The complete text of DHS's response is included as **Appendix 1**.

Arkansas Department of Human Services
Division of Medical Services
P.O. Box 1437, S415
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May 7, 2003

Common Identification Number: A-06-03-00042

Gordon L. Sato
Regional Inspector General
for Audit Services
Office of Inspector General
Office of Audit Services
1100 Commerce, Room 632
Dallas, TX 75242

Dear Mr. Sato:

We have received the copies of the Department of Health and Human Services, Office of Inspector General, Office of Audit Services' draft report of the "Review of Medicaid Drug Rebate Collections-State of Arkansas.

I have had the opportunity to review the report and discuss the findings with Dana Boyer, a rebate
analyst with the State. We are in agreement with the findings of the report.

In response to the recommendations within the report to the Arkansas Department of Human Services , review has already begun to correctly report interest on the CMS 64, Line 5 and the outstanding balance on CMS 64.9R for the next quarterly report. We have also requested a systems change for drug rebate that will implement a procedure to verify that interest payments are accurate.

If you have further questions please feel free to contact me at (501) 683-4120.

Sincerely,

Suzette Bridges

Suzette Bridges, PD
Director, Pharmacy Program
Arkansas Medicaid