DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General
Office of Audit Services

JUL 21 2003

REGION IV
61 Forsyth Street, S.W., Suite 3T41
Atlanta, Georgia 30303

Report Number: A-04-03-06015

Ms. Rica Lewis-Payton, Executive Director
Mississippi Division of Medicaid
239 North Lamar Street, Suite 801
Jackson, Mississippi 39201-1399

Dear Ms. Lewis-Payton:

Enclosed are two copies of the U.S. Department of Health and Human Services (HHS), Office of Inspector General report providing the results of our ***Audit of the Medicaid Drug Rebate Program in the State of Mississippi.*** The objective of this review was to evaluate whether the Mississippi Division of Medicaid (DOM) had established adequate accountability and internal controls over the Medicaid drug rebate program. Our audit covered Medicaid drug rebates through June 30, 2002.

DOM generally followed adequate accounting procedures and had sufficient controls over the drug rebate program as required by Federal rules and regulations. However, we noted that DOM did not verify the accuracy of the accrual and collection of interest. Federal regulations require that financial management systems provide for effective control over and accountability for all funds, property, and other assets. The rebate agreements between the Centers for Medicare and Medicaid Services and the drug manufacturer(s) require the payment of interest on all disputed, late, and unpaid drug rebates.

In our opinion, the weakness occurred because the drug rebate computer system did not have the capability to calculate the interest. DOM was not able to track or verify whether interest payments received from manufacturers were correct. As a result, there was no assurance that the DOM was collecting all of the interest due on late, unpaid, or disputed rebates. Subsequently, this problem was corrected by the DOM's utilization of a new computer system, the Drug Rebate Analysis and Management System. Therefore, no recommendation was necessary. In written comments to the draft report, DOM concurred with our assessment.

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 (Public Law 90-23), Office of Inspector General 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 Code of Federal Regulations Part 5).

To facilitate identification, please refer to report number A-04-03-06015 in all correspondence relating to this report.

Sincerely,

Charles J. Curtis
Regional Inspector General
for Audit Services, Region IV

Enclosures – as stated

HHS Action Official

Associate Regional Administrator
Centers for Medicare and Medicaid Services, Region IV
Division of Medicaid and State Operations
61 Forsyth Street, S.W., Suite 4-T20
Atlanta, Georgia 30303

Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN THE STATE OF MISSISSIPPI

July 2003
A-04-03-06015

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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
Office of Audit Services

REGION IV
Room 3T41
61 Forsyth Street, S.W.
Atlanta, Georgia 30303-8909

JUL 21 2003

Report Number: A-04-03-06015

Ms. Rica Lewis-Payton, Executive Director
Mississippi Division of Medicaid
239 North Lamar Street, Suite 801
Jackson, Mississippi 39201-1399

Dear Ms. Lewis-Payton:

This report provides you with the results of an Office of Inspector General review entitled, ***Audit of the Medicaid Drug Rebate Program in the State of Mississippi.***

EXECUTIVE SUMMARY

The audit objective was to evaluate whether the Mississippi Division of Medicaid (DOM) had established adequate accountability and internal controls over the Medicaid drug rebate program. Our audit covered Medicaid drug rebates through June 30, 2002.

DOM generally followed adequate accounting procedures and had sufficient controls over the drug rebate program as required by Federal rules and regulations. However, we noted that DOM did not verify the accuracy of the accrual and collection of interest.

Federal regulations require that financial management systems provide for effective control over and accountability for all funds, property, and other assets. The rebate agreements between the Centers for Medicare and Medicaid Services (CMS) and the drug manufacturer(s) require the payment of interest on all disputed, late, and unpaid drug rebates.

In our opinion, the weakness occurred because the drug rebate computer system did not have the capability to calculate the interest. DOM was not able to track or verify whether interest payments received from manufacturers were correct. As a result, there was no assurance that DOM was collecting all of the interest due on late, unpaid, or disputed rebates. Subsequently, this problem has been corrected by the DOM's utilization of a new computer system, the Drug Rebate Analysis and Management System (DRAMS). Therefore, no recommendation is necessary. In written comments to the draft report, DOM agreed with our findings. DOM's comments are enclosed in their entirety as an Appendix to this report.

INTRODUCTION

BACKGROUND

On November 5, 1990, Congress enacted the Omnibus Budget Reconciliation Act of 1990, which among other provisions established the Medicaid drug rebate program. Responsibility for the rebate program is shared among the drug manufacturer(s), CMS, and the State(s). The legislation was effective January 1, 1991. CMS also issued release memorandums to State agencies and manufacturers 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 report to CMS its average manufacturer price and best price information for each covered outpatient drug. Approximately 520 pharmaceutical companies participate in the program.

CMS provides the unit rebate amount (URA) information to the State agency on a quarterly computer tape. However, 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 Codes (NDC) are available under the program. Each State agency multiplies the URA by the drug utilization for each drug to determine the actual rebate amounts due from the manufacturer. CMS requires each State agency to provide the manufacturer drug utilization data.

The manufacturer has 38 days from the day a State agency sends an invoice to pay the rebate. The manufacturers submit to the State agency a Reconciliation of State Invoice that details, by NDC, the current quarter's payment.

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 may consider using a hearing mechanism, available to the manufacturer under the Medicaid program, in order to resolve the dispute.

Each State agency reports, on a quarterly basis, outpatient drug 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. DOM reported to CMS an average of $26.2 million in billings per quarter and collections of $26.6 million per quarter during the 1-year period ending June 30, 2002. DOM reported $37,433,059 on the CMS 64.9R report as the outstanding balance as of June 30, 2002, but only $7,867,747 were rebates outstanding over 90 days.

During our audit period, DOM had contracted with Affiliated Computer Systems (ACS) to prepare and mail invoices to manufacturers. DOM personnel performed all other functions for the drug rebate program. Employees in the accounting and finance divisions separately perform the functions of depositing funds, posting payments to the general ledger, and preparing the CMS 64 reports.

As of January 2002, the new fiscal agent, ACS, undertook the prior fiscal agent's duties. By January 2003, ACS assumed other responsibilities in addition to preparing and mailing invoices. These included the resolution of disputes, which occurred from the third quarter of 2002 through the present and the inputting of drug rebate information into DRAMS.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The audit objective was to evaluate whether DOM had established adequate accountability and internal controls over the Medicaid drug rebate program.

Scope

Our audit was performed in accordance with generally accepted government auditing standards. We reviewed DOM's and ACS' policies, procedures, and controls with regard to manufacturers' drug rebates during the audit period. In addition, we examined ACS' role and responsibilities after June 30, 2002. Our review of internal controls was limited to the controls concerning drug rebate billing, collection, and dispute resolution. This was accomplished through interviews and testing pertaining exclusively to the drug rebate program. We limited the scope of our review of internal controls because our audit objective did not require a full assessment or understanding of the internal control structure for DOM and ACS.

Methodology

To accomplish our objective, we interviewed DOM officials to determine the policies, procedures and controls that existed with regard to the Medicaid drug rebate program. Also, we interviewed staff members to determine their roles in the drug 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.

Our fieldwork was performed at the DOM in Jackson, Mississippi during April 2003, and continued in the Miami, Florida field office through May 2003.

FINDINGS AND RECOMMENDATIONS

DOM generally followed adequate accounting procedures and had sufficient controls over the drug rebate program as required by federal rules and regulations. However, we noted that DOM did not verify the accuracy of the accrual and collection of interest.

Title 45, Section 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. In addition, the rebate agreements between CMS and the drug manufacturer(s) require the payment of interest on all disputed, late, and unpaid drug rebates.

Interest on Late, Disputed, and Unpaid Rebates

DOM did not have adequate controls to track or verify whether interest payments received from manufacturers were correct. According to the rebate agreements between the manufacturers and CMS, required by Section 1927 of the Social Security Act, manufacturers are required to pay interest on late, disputed, or 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 Medicaid Drug Rebate Program Release No. 65, it is 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. In addition, Program Release No. 29 requires that interest must be collected and cannot be disregarded as part of the dispute resolution process by either the manufacturer or the State.

Because DOM was not tracking or verifying interest, there was no assurance that DOM was collecting all of the interest payments for late, unpaid, or disputed rebates.

RECOMMENDATIONS

During our audit period, DOM did not verify the accuracy of the accrual and collection of interest. Subsequently, this problem has been corrected by DOM's utilization of a new computer system, DRAMS. Therefore, no recommendation is necessary.

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To facilitate identification, please refer to report number A-04-03-060015 in all correspondence relating to this report.

Sincerely yours,

Charles J. Curtis
Regional Inspector General
for Audit Services

Direct Reply to HHS Action Official:

Associate Regional Administrator,
Centers for Medicare and Medicaid Services
Division of Financial Management and Program Initiatives
61 Forsyth Street, S.W., Suite 4T20
Atlanta, Georgia 30303

APPENDIX

STATE OF MISSISSIPPI
OFFICE OF THE GOVERNOR
DIVISION OF MEDICAID
RICA LEWIS-PAYTON
EXECUTIVE DIRECTOR

RECEIVED
JUN 11 2003
Office of Audit Svcs.

June 6, 2003

Mr. Charles J. Curtis
Regional Inspector General
for Audit Services, Region IV
Department of Health & Human Services
Region IV, Room 3T41
61 Forsyth Street, S.W.
Atlanta, Georgia 30303-8909

Ref: Report Number A-04-03-06015

Dear Mr. Curtis:

We acknowledge receipt of your letter dated May 20, 2003 regarding the Audit of the Mississippi Division of Medicaid's Drug Rebate Program for the period ending June 30, 2002.

We have reviewed the draft copy of the audit findings and recommendations of this report which addresses the interest on late, disputed, and unpaid rebates in accordance with rebate agreements between the manufacturers and CMS as required by Section 1927 of the Social Security Act.

The Division of Medicaid does not dispute the findings of the auditors and agrees that any deficiencies found during the audit period have subsequently been corrected with the implementation of a new computerized system operated by contractual agreement with our fiscal agent, Affiliated Computer System, Inc.

The Division will continue to monitor the fiscal agent in the collection of interest on past due rebates to ensure full compliance with Title 45 Section 74.21 paragraph (b)(3) of the Code of Federal Regulations.

If there are questions regarding this matter, please feel free to contact Michael Bailey, Ph.D., Director, Office of Finance & Administration at (601) 359-6115.

Sincerely,

Rica Lewis-Payton

Cc: Sharon Reed
Michael Bailey
Betty Sullivan

ACKNOWLEDGMENTS

This report was prepared under the direction of Charles J. Curtis, Regional Inspector General for Audit Services, Region IV. Other principal Office of Audit Services staff who contributed include:

Mary Ann Moreno, *Audit Manager*
Charlene Roomes, *Auditor In Charge*
Barbara Goldstein, *Staff Auditor*

For information or copies of this report, please contact the Office of Inspector General's Public Affairs office at (202) 619-1343.