

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

JUL 30 2003

Report Number: A-04-03-06005

Mr. Mike Lewis, Acting Commissioner
Alabama Medicaid Agency
501 Dexter Avenue
P.O. Box 5624
Montgomery, Alabama 36103-5624

Dear Mr. Lewis:

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

AMA generally followed adequate accounting procedures and had controls over the drug rebate program as required by Federal rules and regulations. However, we noted AMA did not account for the collection of interest or utilize write-off criteria for dispute resolution.

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.

There was no assurance that AMA was collecting all of the interest due on late, unpaid, or disputed rebates. Additionally, while the rebate amounts outstanding for over 90 days are not excessive, they could be reduced. We believe that AMA has the opportunity to increase the amount of revenue that is realized from drug rebates. Therefore, we recommend that AMA account for the collection of interest on disputed or unpaid amounts, and late rebate payments, and utilize write-off criteria, within CMS guidelines, for dispute resolution.

In written comments, AMA officials agreed with our finding on the collection of interest. They plan to upgrade their computer system to calculate interest due. We agree that this procedural change will address the finding. AMA officials disagreed with our finding on dispute resolution, stating that they have a formal resolution process in place and are making every effort to resolve the outstanding disputes. We found no evidence that the State actually utilized the write-off procedure, Law Judge Hearing mechanism, or participated in the Dispute Resolution Process meetings sponsored annually by CMS. AMA comments are included as an Appendix to our report.

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 United States Code 552, as amended by Public Law 104-231, Office of Inspector General reports are made available to members of the 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.) As such, within 10 business days after the final report is issued, it will be posted on the World Wide Web at <http://oig.hhs.gov>.

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

Enclosure – as stated

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

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**AUDIT OF THE MEDICAID DRUG
REBATE PROGRAM IN THE
STATE OF ALABAMA**



July 2003
A-04-03-06005

Office of Inspector General

<http://oig.hhs.gov>

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In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), Office of Inspector General, Office of Audit Services reports are made available to members of the public to the extent the information is not subject to exemptions in the act. (See 45 CFR Part 5.)

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 HHSIOIGIOAS. Authorized officials of the HHS divisions will make final determination on these matters.





JUL 30 2003

Report Number: A-04-03-06005

Mr. Mike Lewis, Acting Commissioner
Alabama Medicaid Agency
501 Dexter Avenue
P.O. Box 5624
Montgomery, Alabama 36103-5624

Dear Mr. Lewis:

This report provides you with the results of an Office of Inspector General (OIG), Office of Audit Services' review entitled, *Audit of the Medicaid Drug Rebate Program in the State of Alabama*.

EXECUTIVE SUMMARY

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

AMA generally followed adequate accounting procedures and had controls over the drug rebate program as required by Federal rules and regulations. However, we noted AMA did not account for the collection of interest or utilize write-off criteria for dispute resolution.

Federal regulations require that financial management systems provide for effective control over and accountability for all funds, property, and other assets. In addition, 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.

As a result, there was no assurance that AMA was collecting all of the interest due on late, unpaid, or disputed rebates. Additionally, while the rebate amounts outstanding for over 90 days are not excessive, they could be reduced. AMA reported approximately \$27.2 million on the CMS 64.9R as the outstanding balance as of June 30, 2002, but only about \$3.9 million were rebates outstanding over 90 days.

We believe that AMA has the opportunity to increase the amount of revenue that is realized from drug rebates. Therefore, we recommend that AMA:

1. account for the collection of interest on disputed or unpaid amounts, and late rebate payments; and

2. utilize write-off criteria, within CMS guidelines, for dispute resolution including appropriate use of the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturer(s).

AMA responded to our report in a letter dated May 29, 2003. Their complete response is included in the Appendix. AMA officials agreed with our finding on the collection of interest; They plan to upgrade their computer system to calculate interest due. We agree that this procedural change will address the finding. AMA officials disagreed with our finding on dispute resolution, stating that they have a formal resolution process in place and are making every effort to resolve the outstanding disputes. We found no evidence that the State actually utilized the write-off procedure, Law Judge Hearing mechanism, or participated in the Dispute Resolution Process meetings sponsored annually by CMS.

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 to 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 (PQAS).

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 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 drug utilization data to the manufacturer.

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 (ROSI) 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 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 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. AMA reported to CMS an average of \$21.2 million in billings per quarter and collections of \$20.8 million per quarter during the 1-year period ending June 30,2002. AMA reported approximately \$27.2 million on the CMS 64.9R as the outstanding balance as of June 30,2002, but only about \$3.9 million were rebates outstanding over 90 days.

AMA contracts with its Medicaid fiscal agent, Electronic Data Systems (EDS), to perform various operations of the drug rebate program, including the preparation and mailing of invoices and collection letters. Employees in the Drug Rebate and the Accounts Receivable Units of the AMA Finance Division separately perform the functions of depositing funds, posting payments to the drug rebate system, and preparing the CMS 64.9R report.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The audit objective was to evaluate whether AMA 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 AMA's and EDS' policies, procedures, and controls with regard to manufacturers' drug rebates as of 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 AMA and EDS' internal control structure.

Methodology

To accomplish our objective, we interviewed AMA 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 AMA in Montgomery, Alabama during February and March 2003, and continued in the Miami, Florida field office through April 2003.

FINDINGS AND RECOMMENDATIONS

AMA generally followed adequate accounting procedures and had controls over the drug rebate program as required by Federal rules and regulations. However, we noted AMA did not account for the collection of interest or establish write-off criteria for dispute resolution.

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.

Collection of Interest

AMA 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 11(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 AMA was not tracking or verifying interest, there was no assurance that AMA was collecting all of the interest payments for late, unpaid, or disputed rebates.

Resolution of Disputes

AMA did not utilize procedures for resolving disputes with manufacturers. These disputes are identified when the manufacturers send the ROSI to the State with the rebate payment, or when the manufacturer contacts the State.

An AMA official stated that there was no formal system for monitoring outstanding disputes and that the three persons assigned to dispute resolution were insufficient to handle the workload of outstanding disputes. Moreover, aged uncollected drug rebates remained on the books because the State did not utilize write-off procedures. Program Release No. 19 provides that:

In any quarter, States need not enter into further dispute resolution processes with a manufacturer if the disputed amount is: under \$10,000 per manufacturer and under \$1,000 per product code. States maintain discretion to enter into the dispute resolution process in cases that fall below these thresholds.

Thus, States have CMS' approval to write-off amounts under \$10,000 per manufacturer and under \$1,000 per product code.

RECOMMENDATIONS

AMA reported approximately \$27.2 million on the CMS 64.9R as the outstanding balance as of June 30, 2002; but only about \$3.9 million were rebates outstanding over 90 days.

We believe that AMA has the opportunity to increase the amount of revenue that is realized from drug rebates. Therefore, we recommend that AMA:

1. account for the collection of interest on disputed or unpaid amounts, and late rebate payments; and
2. utilize write-off criteria, within CMS guidelines, for dispute resolution including appropriate use of the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturer(s).

AMA RESPONSE AND OIG COMMENTS

AMA responded to our report in a letter dated May 29, 2003. Their complete response is included in the Appendix. AMA's response and OIG comments are summarized below.

AMA Response

AMA officials agreed with our finding on the collection of interest. They plan to upgrade their computer system to calculate interest due. AMA officials disagreed with our finding on dispute resolution, stating that they have a formal resolution process in place and are making every effort to resolve the outstanding disputes.

OIG Comments

We agree that the procedural change to upgrade the computer system will address the finding of uncollected interest. In regard to dispute resolution, while we agree that Alabama is making significant efforts to resolve disputed amounts, we believe their efforts could be enhanced. We found no evidence that the State actually utilized the write-off procedure, Law Judge Hearing mechanism, or participated in the Dispute Resolution Process meetings sponsored annually by CMS.

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In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), OIG, Office of Audit Services 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-04-03-06005 in all correspondence relating to this report.

Sincerely,



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

Enclosure – as stated

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



BOB RILEY
Governor

Alabama Medicaid Agency

501 Dexter Avenue
P.O. Box 5624
Montgomery, Alabama 36103-5624

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MIKE LEWIS
Acting Commissioner

May 29, 2003

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JUN 23 2003

Office of Audit Svcs.

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

Dear Mr. Curtis:

This letter is in response to your office's report entitled *Audit of the Medicaid Drug Rebate Program in the State of Alabama* (Report Number: A-04-03-06005). The review was designed to evaluate whether the Alabama Medicaid Agency had established adequate accountability and internal controls over the Medicaid drug rebate program.

In response to the first finding, "Collection of Interest", we agree that we are unable to verify whether interest received from manufacturers is correct. We have discussed the matter with our fiscal agent, Electronic Data Systems, and have been assured that this issue will be resolved. However, we disagree with the recommendation that official policies and procedures are needed to account for the collection of interest on disputed, unpaid amounts and late rebate payments. We believe that our computer system simply needs to be upgraded to calculate the amount of interest due, compare that amount to the interest received, and calculate the difference. Collection of any difference would then become part of the dispute resolution process and would be handled by the appropriate staff.

In response to the second finding, "Resolution of Disputes", we disagree with the finding that we lack adequate policies and procedures for resolving disputes with manufacturers. Disputes are identified not only when ROSIs are sent in or when manufacturers contact us but also by utilizing the "Inflated Rebate Amounts" report. A copy of this report was provided to your office during the site visit. We consider these three means of identifying disputes to be a "formal" system. We also disagree with the finding and recommendation concerning aged uncollected drug rebate amounts. The report states that aged uncollected drug rebate amounts remain on the books because we have no write-off procedures. Alabama Medicaid Internal Memorandum (AIM) No. 603 dated January 1, 1995 addresses the write-off issue. The AIM states that "\$1,000 per quarter per drug or \$10,000 per labeler per quarter" may be written off. Uncollected rebate amounts remain on the books because we are making every effort to resolve the amounts in dispute and federal law requires us to

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keep every quarter open. Moreover, given the fact that we are in constant communication with manufacturers concerning disputed amounts, we believe that we are appropriately using the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturer(s).

To summarize, although the Alabama Medicaid Agency agrees with the finding concerning the collection of interest, we disagree with the recommendation concerning this matter and with the finding and recommendation concerning the resolution of disputes.

Sincerely,

A handwritten signature in black ink, appearing to read "Mike Lewis". The signature is written in a cursive, flowing style.

Mike Lewis
Acting Commissioner

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.