DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General
Office of Audit Services

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

AUG 29 2003

Report Number: A-04-03-06016

Ms. Rhonda M. Medows, M.D., Secretary
Agency for Health Care Administration
2727 Mahan Drive
Tallahassee, Florida 32308

Dear Dr. Medows:

Enclosed are two copies of an Office of Inspector General final report entitled, ***Audit of the Medicaid Drug Rebate Program in the State of Florida.*** The objective of our review was to evaluate whether the Florida Agency for Health Care Administration (AHCA) had established adequate accountability and internal controls over the Medicaid drug rebate program. Our audit covered Medicaid drug rebates through June 30, 2002.

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 & Medicaid Services (CMS) and the drug manufacturer(s) require the payment of interest on all disputed, late, and unpaid drug rebates.

Our review showed that AHCA was not able to track or verify whether interest payments received from manufacturers were accurate. There was no certainty AHCA was collecting all interest due on late, unpaid, or disputed rebates. In addition, there was no reasonable assurance that drug rebate balances reported to CMS were accurate. AHCA reported $94,411,401 as drug rebates outstanding on the CMS 64.R report as of June 30, 2002. Of this amount, $26,978,163 was for rebates outstanding over 90 days.

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

- Make it a priority to program the existing computer system to calculate interest and verify that interest payments are accurate.

- Develop policies and procedures that establish 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).

Subsequent to our audit period, AHCA implemented a computer system for processing drug rebates. This system will be able to maintain a subsidiary accounts receivable account for each manufacturer and provide an aging schedule report. If these items were utilized to reconcile the outstanding balances reported on the CMS 64.9R, then this would create a reasonable assurance that the figures are accurate. Therefore, no recommendation related to the reconciliation of Form CMS 64.9R is necessary.

AHCA officials agreed with our findings and have taken steps to correct the identified weaknesses. AHCA 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-04-03-06016 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 & Medicaid Services
Division of Medicaid and State Operations
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 FLORIDA

AUGUST 2003
A-04-03-06016

Notices

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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 HHS/OIG/OAS. Authorized officials of the HHS divisions will make final determination on these matters.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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REGION IV
61 Forsyth Street, S.W., Suite 3T41
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August 29, 2003

Report Number: A-04-03-06016

Ms. Rhonda M. Medows, M.D., Secretary
Agency for Health Care Administration
2727 Mahan Drive
Tallahassee, Florida 32308

Dear Dr. Medows:

This final 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 Florida.***

EXECUTIVE SUMMARY

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

We determined that AHCA generally followed adequate accounting procedures and had sufficient controls over the drug rebate program as required by Federal rules and regulations. However, improvements should be considered in the following areas:

- Accrual and collection of interest.
- Dispute resolution.
- Reconciliation of Form CMS 64.9R.

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 & Medicaid Services (CMS) and the drug manufacturer(s) require the payment of interest on all disputed, late, and unpaid drug rebates.

Our review showed that AHCA was not able to track or verify whether interest payments received from manufacturers were accurate. There was no certainty AHCA was collecting all interest due on late, unpaid, or disputed rebates. In addition, there was no reasonable assurance that drug rebate balances reported to CMS were accurate. AHCA reported $94,411,401 as drug rebates outstanding on the CMS 64.R report as of June 30, 2002. Of this amount, $26,978,163 was for rebates outstanding over 90 days.

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

- Make it a priority to program the existing computer system to calculate interest and verify that interest payments are accurate.

- Develop policies and procedures that establish 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).

Subsequent to our audit period, AHCA implemented a computer system for processing drug rebates. This system will be able to maintain a subsidiary accounts receivable account for each manufacturer and provide an aging schedule report. If these items were utilized to reconcile the outstanding balances reported on the CMS 64.9R, then this would create a reasonable assurance that the figures are accurate. Therefore, no recommendation related to the reconciliation of Form CMS 64.9R is necessary.

AHCA responded to our draft report in a letter dated August 21, 2003. AHCA officials agreed with our findings and have taken steps to correct the identified weaknesses. Their complete response is included in the appendix.

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 States 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 to CMS its average manufacturer price and best price information for each covered outpatient drug. Approximately 520 pharmaceutical companies participate in the rebate program.

CMS provides the unit rebate amount (URA) information to the State agency on a quarterly computer tape. However, 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, a

manufacturer can 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 outpatient drug. Approximately 56,000 National Drug Codes (NDC) are available under the rebate program. Each State agency uses the URA from CMS and the utilization data 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 to avoid interest. The manufacturer submits 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 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. AHCA reported to CMS an average of $82.7 million in billings per quarter and collections of $86.4 million per quarter during the 1-year period ending June 30, 2002. AHCA reported $94,411,401 on the CMS 64.9R report as the outstanding balance as of June 30, 2002, but only $26,978,163 was for rebates outstanding over 90 days.

During our audit period, AHCA had contracted with its Medicaid fiscal agent, Affiliated Computer Systems (ACS). ACS processed all the pharmacy claims that resulted in the utilization data that AHCA used in creating all of the drug rebate invoices. AHCA 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.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The audit objective was to evaluate whether AHCA 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 concentrated our review on the current policies, procedures and controls of AHCA. 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 AHCA.

Methodology

To accomplish our objective, we interviewed AHCA 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 AHCA in Tallahassee, Florida during May 2003, and continued in the Miami, Florida Field Office through June 2003.

FINDINGS AND RECOMMENDATIONS

AHCA generally followed adequate accounting procedures and had sufficient controls over the drug rebate program as required by Federal rules and regulations. However, improvements should be considered in the following areas:

- Accrual and collection of interest.
- Dispute resolution.
- Reconciliation of Form CMS 64.9R.

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

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

Dispute Resolution

AHCA lacked adequate policies and procedures for resolving disputes with manufacturers. These disputes are identified when the manufacturers send the ROSI to the State with the rebate payment.

An AHCA official stated that there was no formal system for monitoring outstanding disputes. Moreover, aged uncollected drug rebates remained on the books because the State had no 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.

Reconciliation of Form CMS 64.9R and the Subsidiary Ledger

AHCA reported on the CMS 64.9R for the quarter ended December 31, 2001 that the State owed manufacturers $751,490,545. In addition, on this report drug rebates collected were added instead of subtracted from the subtotals found on Line 4 of the CMS 64.9R. This resulted in an overstated outstanding drug rebate for each of the quarters shown.

As of June 30, 2002, the reported drug rebates outstanding was $94,411,401. No back up documentation was provided for the adjustment figures. Due to the various inconsistencies in the previous quarters' amounts for adjustments and uncollected balances, there was no reasonable assurance that the figures shown on the CMS 64.9R as of June 30, 2002 were accurate.

RECOMMENDATIONS

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

- Make it a priority to program the existing computer system to calculate interest and verify that interest payments are accurate.

- Develop policies and procedures that establish 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).

Subsequent to our audit period, AHCA implemented a computer system for processing drug rebates. This system will be able to maintain a subsidiary accounts receivable account for each manufacturer and provide an aging schedule report. If these items were utilized to reconcile the outstanding balances reported on the CMS 64.9R, then this would create a reasonable assurance that the figures are accurate. Therefore, no recommendation related to the reconciliation of Form CMS 64.9R.is necessary.

AHCA's Response and OIG's Comments

AHCA responded to our draft report in a letter dated August 21, 2003. AHCA officials agreed with our findings and have taken steps to correct the identified weaknesses. Their complete response is included in the appendix. AHCA's response and OIG's comments are summarized below.

AHCA's Response

AHCA concurred with the recommendation to calculate interest and verify the accuracy of interest payments. In this regard, they plan to issue and submit a request for proposal within the next 6 months that will include a component for the calculation, tracking and verification of interest payments. Additionally, AHCA reported that they have established interim procedures to identify and calculate interest due. In response to the recommendation to develop policies and procedures that establish write-off criteria for dispute resolution, AHCA responded that their development of policies and procedures is ongoing. AHCA's goal is to incorporate specific guidelines related to the establishment of write-off criteria as soon as possible.

OIG's Comments

We agree with AHCA's efforts to improve their drug rebate program.

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To facilitate identification, please refer to report number A-04-03-06016 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 & Medicaid Services
Division of Medicaid and State Operations
61 Forsyth Street, S.W., Suite 4T20
Atlanta, Georgia 30303

APPENDIX

FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION

JEB BUSH, GOVERNOR

RHONDA M. MEDOWS, MD, FAAFP, SECRETARY

August 21, 2003

Mr. Charles J. Curtis
Office of the Inspector General
Office of Audit Services – Region IV
61 Forsyth Street, Southwest., Suite 3T41
Atlanta, GA 30303

RE: CIN A-04-03-06016

Dear Mr. Curtis:

Thank you for the opportunity to respond to the U.S. Department of Health and Human Services Office of the Inspector General draft report entitled *Audit of the Medicaid Drug Rebate Program in the State of Florida,* dated July 22, 2003. Each of the report recommendations and the Agency's response follows:

We recommend that AHCA make it a priority to program the existing computer system to calculate interest and verify that interest payments are accurate.

Agency Response:
In early May 2003, AHCA implemented a drug rebate payments database as a means to integrate the existing automated invoice database with the paper payments documents. As soon as data entry is completed for the paper payments documents, AHCA will be able to query this database for interest-related data.

AHCA plans to issue an RFP within the next six (6) months that will address all aspects of the drug rebate process. Included in this RFP will be a comprehensive component for the calculation, tracking and verification of interest payments owed by drug manufacturers to the State.

In the interim, AHCA has established a process to identify and calculate interest due and verify that interest payments are accurate.

Recommendation 2:
We recommend that AHCA develop policies and procedures that establish 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).

Agency Response:
AHCA's development of policies and procedures for dispute resolution is ongoing. With one staff person dedicated to the reconciliation of drug rebate invoices and payments, more immediate attention has been focused on the timely processing of payments and resolving matters related to larger dollar issues.

AHCA has begun researching manufacturers' past disputes relative to frequency, National Drug Codes, percentage of total billed/paid, and total amounts disputed. With the limited manpower and the volume of sales in the State, AHCA will have to consider multiple factors, including benchmarking best practices of other States, in order to determine the best methodology for drug rebate write-offs. It is AHCA's goal to incorporate specific guidelines related to the establishment of write-off criteria as soon as possible, as recommended by the auditors.

If you have any questions regarding this response, please contact George Kitchens, Bureau of Pharmacy Services Chief, at (850) 487-4441.

Sincerely,

Rhonda M. Medows, M.D.
Secretary

RMM/jw

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 that contributed includes:

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.