DEPARTMENT OF HEALTH AND HUMAN SERVICES **Office of Inspector General**
Office of Audit Services

REGION 1V
61 Forsyth Street, S.W., Suite 3T41
Atlanta. Georgia 30303

August 29,2003

Report Number: A-04-03-06010

Mr. Gary B. Redding, Commissioner
Department of Community Health
2 Peachtree Street, N.W., 40th Floor
Atlanta, Georgia 30303-3159

Dear Mr. Redding:

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

We identified weaknesses in DCH's management of the Medicaid drug rebate program. Specifically, we found billing system procedures were inefficient, supporting records and reports were not accurate, and the dispute resolution process did not conform to Centers for Medicare & Medicaid Services' (CMS) guidelines. Also, we identified an undetermined amount of rebate accounts receivable write-offs that occurred during the transition to a new contractor in 1999. Additionally, the contractor had systems limitations in their billing system. As a result, there is not sufficient assurance that the program has provided CMS with an accurate picture of the drug rebate program and that all rebate accounts receivable have been pursued with due diligence.

To correct these weaknesses, we recommend that DCH more closely monitor contractor activities, accurately report drug rebate activities on the Form CMS 64.9R, and follow CMS guidelines in the collection process. We also recommend that the amount of any rebate write-offs related to the transition to a new contractor be determined and disposition made in accordance with proper accounting principles and within CMS guidelines.

DCH responded to our draft report in a letter dated June 19,2003. Although in some instances, DCH had semantic differences with the reported findings, they agreed they would review the Drug Rebate Program by taking into account the recommendations in our report. DCH comments are included as an Appendix to this report.

Final determination as to actions taken on all matters reported will be made by the HHS action official named on page 2 of this 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 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-04-03-06010 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 GEORGIA

AUGUST 2003
A-04-03-06010

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at http://oig.hhs.gov

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 **Office of Inspector General**
Office of Audit Services

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

August 29,2003

Report Number: A-04-03-06010

Mr. Gary B. Redding, Commissioner
Department of Community Health
2 Peachtree Street, N.W., 40th Floor
Atlanta, Georgia 30303-3159

Dear Mr. Redding:

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 Georgia.***

EXECUTIVE SUMMARY

The audit objective was to evaluate whether the Georgia Department of Community Health (DCH) had established adequate accountability and internal controls over the Medicaid drug rebate program. Our review covered Medicaid drug rebates through June 30,2002.

DCH has not provided effective control and accountability for drug rebate collections. We identified weaknesses in DCH's management of the Medicaid drug rebate program. Specifically, we found billing system procedures were inefficient, supporting records and reports were not accurate, and the dispute resolution process did not conform to Centers for Medicare & Medicaid Services' (CMS) guidelines. Also, we identified an undetermined amount of rebate accounts receivable write-offs that occurred during the transition to a new contractor in 1999.

In our opinion, the weaknesses occurred because DCH did not:

- Adequately monitor contractor activities;
- Retain an adequate record keeping system and audit trial to support the drug rebate activities reported to CMS; and
- Always follow CMS guidelines in the collection process.

Additionally, the contractor had systems limitations in their billing system. As a result, there is not sufficient assurance that the program has provided CMS with an accurate picture of the drug rebate program and that all rebate account receivables have been pursued with due diligence.

To correct these weaknesses, we recommend that DCH more closely monitor contractor activities, accurately report drug rebate activities on the Form CMS 64.9R, and follow CMS guidelines in the collection process.

We also recommend that the amount of any rebate write-offs related to the transition to First Health Services (FHS) be determined and disposition made in accordance with proper accounting principles and within CMS guidelines.

DCH responded to our draft report in a letter dated June 19, 2003. DCH officials stated that they would review the Drug Rebate Program by taking into account the recommendations in our report. In some instances, the State had semantic differences with the reported findings. Their complete response is included 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 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 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, 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 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 may consider 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. DCH reported to CMS approximately $90.1 million in Medicaid drug rebates from drug manufacturers for the 1-year period ending June 30, 2002. DCH reported $65,477,988 on the CMS 64.9R as the outstanding balance as of June 30, 2002. This balance includes $24.6 million outstanding over 90 days. Of the $24.6 million, $4.6 million has been outstanding over 1 year.

DCH contracts with a vendor, FHS, to perform the daily operations of the drug rebate program, including billing, accounting, and dispute resolution. Employees in other departments of DCH separately performed the functions of overall management, collections and preparing the CMS 64 reports.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The objective of our audit was to evaluate whether DCH 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 DCH and FHS' policies, procedures, and controls with regard to manufacturer's 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 DCH and FHS' internal control structure.

Methodology

To accomplish our objective, we obtained the State's Medicaid Drug Rebate Schedule (Form CMS 64.9R) for the 1-year period ending June 30, 2002 and reviewed supporting documentation to assess the reliability of the outpatient drug rebate information reported to CMS. We reviewed accounts receivable and subsidiary records and compared the information with the data presented in the Form CMS 64.9R report. We interviewed DCH and FHS staff that performed functions

related to the drug rebate program to determine existing policies, procedures, and controls as of June 30,2002.

Fieldwork was performed at DCH and FHS offices in Atlanta, Georgia and at our field offices in Miami and Jacksonville, Florida from February through April 2003.

FINDINGS AND RECOMMENDATIONS

We identified weaknesses in the Georgia DCH's management of the Medicaid drug rebate program. Specifically, we found billing system procedures were inefficient, supporting records and reports were not accurate, and the dispute resolution process did not conform to CMS guidelines. Also, an undetermined amount of rebate accounts receivable write-offs occurred during the transition to a new contractor in 1999.

Billing Procedures

The billing of drug rebates is performed by FHS. Their billing system produces invoices containing large, obvious and preventable errors that are sent to drug manufacturers resulting in unnecessary disputes. An FHS memo dated January 27,2003 states:

> "The report indicates $87,957,897.68 was billed to labelers. While that is what was invoiced, I would guess that appx. 46 to 48 million of that invoice amount is in error due to wrong rates and units."

The FHS billing system does not contain "edits" or steps designed to detect unreasonable or aberrant error conditions. As a result, unnecessary resources are being expended on the dispute process.

Reconciliation of Records

We found variances between internal reports at FHS and between FHS and DCH records. The FHS GARBT440-A report is intended as a facsimile of the CMS 64.9R report. The report is forwarded to DCH for use in preparing the CMS 64.9R. We found a variance of $1,052,809 for reported rebates for the June 30,2002 quarter. A FHS official stated that there was a "glitch in their database system that caused a misread. Further, the official stated that this problem was subsequently rectified.

In another example, DCH reported collections of $90,057,762 on the CMS 64.9R report for the year ending June 30,2002. For the same period, FHS recorded collections of $54,246,387. We attempted to reconcile the difference by totaling the actual deposits for the quarter, which amounted to $60,953,233. A DCH accounting official stated that the variance was due to a timing difference between the deposits posted by DCH and FHS. A DCH accounting official agreed to order a special ad hoc report and stated that the reconciliation would take some time

because of the conversion to the new Medicaid Management Information Systems (MMIS) contractor April 1, 2003. Thus, the reconciliation was not available for review.

The obvious differences in these various management reports indicate a lack of oversight, checks and balances and documentation retention that lessens DCH's ability to accurately report the drug rebate activities to CMS.

Dispute Resolution

We found that drug rebates totaling $4.6 million were reported as over a year old on the June 30, 2002 CMS 64.9R. However, FHS did not have a report showing the age of receivables. A DCH official stated that their policy does not allow for the write off of drug rebate accounts receivable. They try to work with manufacturers to collect the rebates however long it takes. In addition, we were told that DCH has never used the services of an Administrative Law Judge, as suggested under CMS directives.

Write-offs

An undetermined amount of drug rebate accounts receivable have been written off during the transition to a new contractor in 1999.

A 1996 State audit cited numerous findings in the management of the Medicaid Drug Rebate Program. The report concluded that the State wrote off $1.7 million in rebates for the period 1992 through 1995 without contacting drug manufacturers to determine why they withheld payments.

In response to the audit, DCH stated that they would address several of the findings through the procurement of a contractor, FHS. The effective date of the contract was June 1, 1999. The contract was for the development and administration of a drug rebate processing system on behalf of the Georgia Medicaid program. An amendment to the contract calls for FHS to convert DCH rebate claims from the first quarter of 1991 forward to the first quarter of 1998 for use in the FHS rebate system. However, the scope of the transition terms also stated that FHS would "zero balance" all manufacturers transactions by posting a corresponding debit or credit so that all manufactures will be considered "fully paid." As a result of this process, FHS officials stated that they began the rebate program with no accounts receivable outstanding. DCH officials could not provide the auditors with the amount of this "write-off."

RECOMMENDATIONS

DCH has not provided effective control and accountability for drug rebate collections. To correct the identified weaknesses, we recommend that DCH more closely monitor contractor activities, accurately report drug rebate activities on the Form CMS 64.9R, and follow CMS guidelines in the collection process.

In addition, we recommend that DCH determine and document the amount of rebate write-offs that occurred during the 1999 transition to FHS.

DCH's Response and OIG's Comments

DCH responded to our report in a letter dated June 19, 2003. DCH officials agreed that they would review the Drug Rebate Program by taking into account the recommendations in our report. In some instances, the State had semantic differences with the reported findings. DCH's response and OIG comments are summarized below. Their complete response is included in the Appendix.

Billing Procedures

DCH Response

DCH believes that the statement that the FHS system produces "large, obvious and preventable errors" is not a function of the system, but rather an issue of manufacturers submitting information incorrectly and providers billing incorrectly. The rates-per-unit sent to the States by CMS are the rates by which the collective units of utilization are invoiced. Their rebate vendor will begin using the "First Rebate" system to process the invoices later this year to assist in detecting these types of incorrect submissions on the CMS tape before invoices are printed. CMS has not given the States/vendors authorization to alter the submitted rates prior to invoicing. They will require this ability to detect unreasonable or abberrant error conditions in all future work with contractors.

OIG Comments

We agree with the State's observation that the manufacturers submit rate information incorrectly and providers bill incorrectly thereby causing significant dollar discrepancies in the State agency's billing. However, our issue is not with the error itself; our concern is the failure of the State agency's internal control system to detect errors in units billed by pharmacies, not submitted rates, in a timely manner. We believe that this demonstrates the internal controls are not adequate to prevent or correct significant errors.

Reconciliation of Records

DCH Response

In regard to the reconciliation of records referred to on page 4 of the draft, DCH stated that they had ordered a special ad hoc report. They told the auditors that this reconciliation would take some time and was on hold because of the conversion to the new MMIS contractor April 1, 2003. The Commissioner had made the conversion a top priority. DCH agreed to resume work on the reconciliation as soon as possible.

OIG Comments

The auditors were advised by a DCH accounting official that the reconciliation would take some time because of the conversion to the new MMIS contractor. The report has been modified to include this explanation. While we appreciate the fact that the conversion to the new MMIS

contractor April 1, 2003 is a top priority with DCH employees, we believe that the State agency should have had a contemporaneous reconciliation of the payments received with a complete audit trail to verify that the amount reported on the CMS 64.9R was properly supported by source documentation.

Write-Offs

Auditee Response

According to DCH, the write-offs referred to on page 5 of the draft report were not true write-offs. DCH stated that write-offs in reference to Medicaid rebates means that it was determined that the number of units invoiced were incorrect. FHS accounted for drug rebates once they took over the drug rebate program and Electronic Data Systems (EDS) accounted for the drug rebates prior to FHS taking over the program. When a correction is made to a rebate invoice, it changes the number of units correctly and thereby changes the dollar amount that is actually owed as agreed upon by both parties. These adjustments are not write-offs as meant by the accounting principles, in which a real debt is forgiven.

Additionally, DCH stated that the process by which the accounts were zeroed out was the result of there being no electronic transfer of data from EDS to FHS and therefore; FHS, as a new vendor, started with no outstanding debits in the system. When manufacturers submitted outstanding (pre-2nd calendar quarter 1998) amounts not collected by DCH or EDS, FHS entered the submitted amount as a payment and offset it by entering an equal amount as a debit, which in effect left a zero balance. This was the procedure agreed upon by DCH and FHS to enable the vendor to begin with a clean slate going forward. The term "zeroed-out" does not mean that there were any write-offs as all monies invoiced by EDS and FHS should have been accounted for in their systems.

OIG Comments

While the State agency states it did not write off receivables in a strict accounting sense, we believe that they did. An FHS official explained that a DCH official directly contacts the manufacturer and tries to resolve the issue if FHS cannot reach an agreement with the manufacturer. It is also this FHS officials' understanding that DCH has negotiated settlements with the manufacturers when unable to reach an agreement and resolve the dispute. Whenever DCH negotiates a settlement with a manufacturer for an amount that is less than the correct amount billed; this difference should be considered a write off because a real debt is forgiven.

According to FHS officials, EDS did not keep accurate records of amounts owed by the manufacturers, therefore, FHS had no way of knowing the amount of outstanding invoices at the time of conversion from EDS to FHS. Because FHS did not have any accounts receivable outstanding amounts prior to the 2nd calendar quarter in 1998, FHS would not likely be aware of any previous balances outstanding. This increases the likelihood that FHS may not collect past due balances.

Whenever a manufacturer paid an invoice amount that was not shown outstanding in FHS records, FHS would post the payment as required to the manufacturer's receivable. Then FHS would post a debit to the manufacturer's receivable account for the same amount in order for the receivables' balance to be correct. This in effect "zeroed out" the manufacturer's receivables amount and thus, resulted in an undetermined amount of write-offs.

In addition, an EDS official stated that they could not provide any documentation that would show the amounts outstanding at the time of conversion from EDS to FHS.

- - - - -

To facilitate identification, please refer to report number A-04-03-06010 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

GEORGIA DEPARTMENT OF
COMMUNITY HEALTH
Gary B. Redding, Commissioner
Sonny Perdue, Governor

2 Peachtree Street, NW
Atlanta, GA 30303-3159
www.communityhealth.state.ga.us

June 19, 2003

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

Re: A-04-03-06010

Dear Mr. Curtis:

We have reviewed your letter dated May 20, 2003, and accompanying draft report titled "Audit of the Medicaid Drug Rebate Program in the State of Georgia." We will review the Drug Rebate Program by taking into account your recommendations shown in the draft audit report. This will be accomplished by an internal review and/or assistance from the State of Georgia, Department of Audits and Accounts.

Our comments on the draft audit report are as follows:

Regarding the statement that addresses the billing procedures on page 4 of the draft, we are requesting that you take out the word "[Sic]" because this was an error made by labelers and corrected by FHS before the invoice was paid.

The statement that the FHS "system produces invoices containing large, obvious, and preventable errors" is not a function of the system but rather an issue of manufacturers submitting information incorrectly and providers billing incorrectly. The rates per unit (RPU) sent to the states by CMS are the rates upon which the collective units of utilization are invoiced. This is the CMS requirement per their pre-edits based on baseline calculations each quarter. Our rebate vendor will begin using the "First Rebate" system to process the invoices later this year to assist in detecting these types of incorrect submissions on the CMS tape before invoices are printed. To date, however, CMS has not given authorization to States/vendors to alter the submitted rates prior to invoicing. Currently the invoice is sent and subsequently corrected with the rates sent by CMS on the next quarter's tape to States. We will require this ability to detect unreasonable or unlikely error conditions in all future work with the contractors.

For the reconciliation of records referred to on page 4 of the draft, we had ordered a special ad hoc report and told your auditors that this reconciliation would take some time and was on hold because of the conversion to a new MMIS contractor April 1, 2003. This conversion is a major, complex undertaking, and as

Commissioner, I had stated this was top priority for all DCH employees. Your auditors understood this and did not indicate a problem with the delay. We will resume work on the reconciliation as soon as possible. In the first paragraph, the second to last sentence of this section should read FHS instead of "FSH". It also appears that the last part of the first sentence of the last paragraph on page 4 should state the report is for the year ending June 30, 2002, not for the "quarter ending June 30, 2002."

For dispute resolution referred to on page 5 of the draft, we will make sure we receive regular reports from FHS showing the age of the outstanding invoiced amounts and the documentation of efforts to resolve unit discrepancies. Utilization of the "First Rebate" system will allow for more pre-editing by FHS and possibly the manufacturers as well. We do not write off receivables, and although we have not used an Administrative Law Judge in the past, we could possibly use one in the future.

The write-offs referred to on page 5 of the draft were not true 'write-offs'. FHS accounted for drug rebates that they were responsible for once they took over the program and EDS accounted for the drug rebates that they were responsible for prior to FHS taking over the program. Write-offs in reference to Medicaid rebates means that it was determined that the number of units invoiced were incorrect. When the correction is made it changes the number of units correctly and thereby changes the dollar amount that is actually owed as agreed upon by both parties. These adjustments were not write-offs as meant by the accounting principle, in which a real debt is forgiven.

The process by which the accounts were zeroed out was the result of there being no electronic transfer of data from EDS to FHS and therefore FHS, as a new vendor started with no outstanding debits in the system. When manufacturers submitted outstanding (pre 2nd calendar quarter 1998) amounts not collected by DCH or EDS, First Health entered the submitted amount as a payment and offset it by entering an equal amount as a debit, which in effect left a zero balance. This was the procedure agreed to by DCH and FHS to enable the vendor to begin with a clean slate going forward. The term "zero out" does not mean there were any write-offs as all monies invoiced by EDS and FHS should have been accounted for in their systems. The actual amounts collected through the DCH lockbox are reported on the CMS 64 and accounted for in the DCH accounting system. We supplied your auditors with a drug rebate schedule given to us by EDS, which showed the amount accurately invoiced by EDS through the time FHS took over from them. The last paragraph, second sentence in this section states the effective date of the contract "was June 1, 1999" and our records indicate the contract began March 19,1998.

Thank you for the opportunity to respond to the draft report. If you need additional information, please contact Alan Sacks, Audit Coordinator, at (404) 657-7113.

Sincerely,

Gary B. Redding

GBR:as
cc: Mark Trail
Gregory Dixon
Patricia Zeigler-Jeter
Alan Sacks

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*
Bernard Rach, *Senior Auditor*
Manuel Guerrero, *Auditor in Charge*

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