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 2 9 2003

Report Number: A-04-03-06011

Robert M. Kerr, Director
South Carolina Department of Health and Human Services
P.O. Box 8206
Columbia, South Carolina 29202-8206

Dear Mr. Kerr:

Enclosed are two copies of an Office of Inspector General final report entitled, ***Audit of the Medicaid Drug Rebate Program in the State of South Carolina.*** The objective of our review was to evaluate whether the South Carolina Department of Health and Human Services (SC-DHHS) had established adequate accountability and internal controls over the Medicaid drug rebate program. Our audit covered Medicaid drug rebates through June 30, 2002 and, because of considerable operational changes shortly after June 2002, we also reviewed drug rebates reported as of December 31, 2002.

Through June 30, 2002, SC-DHHS did not have adequate accounting procedures and internal controls with regard to the Medicaid drug rebate program. For the most part, the State could not support the drug rebate information reported to the Centers for Medicare & Medicaid Services (CMS) in the Form CMS 64.9R report, did not reconcile drug rebate information to its accounting records, and did not accrue or verify interest for late or disputed rebate payments from drug manufacturers.

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 CMS and the drug manufacturers require the payment of interest on all disputed, late, and unpaid drug rebates.

As of December 31, 2002, SC-DHHS had noticeably enhanced its ability to monitor and report drug rebate information due to significant staffing, structural, and procedural changes. However, improvements over drug rebate accountability are still needed with the accrual and collection of interest and with data integrity, including records retention. As a result, there was no assurance that SC-DHHS was collecting all the interest due on late or disputed rebates. Also, improper data protection may limit the State's ability to actively pursue outstanding receivables from drug manufacturers and may increase the potential risk for waste and abuse of funds from drug rebates.

We recommend that SC-DHHS implement adequate procedures and controls that would account for the accrual and collection of interest on late, disputed, or unpaid rebate payments and implement strict controls to safeguard drug rebate data.

SC-DHHS officials agreed with our findings and have taken steps to correct the identified weaknesses. SC-DHHS 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-04-03-06011 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 SOUTH CAROLINA

AUGUST 2003
A-04-03-06011

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., Suite 3T41
Atlanta, Georgia 30303

AUG 29 2003

Report Number: A-04-03-06011

Robert M. Kerr, Director
South Carolina Department of Health and Human Services
P.O. Box 8206
Columbia, South Carolina 29202-8206

Dear Mr. Kerr:

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

EXECUTIVE SUMMARY

The objective of our review was to evaluate whether the South Carolina Department of Health and Human Services (SC-DHHS) had established adequate accountability and internal controls over the Medicaid drug rebate program. Our audit covered Medicaid drug rebates through June 30, 2002 and, because of considerable operational changes shortly after June 2002, we also reviewed drug rebates reported as of December 31, 2002.

Through June 30, 2002, SC-DHHS did not have adequate accounting procedures and internal controls with regard to the Medicaid drug rebate program. For the most part, the State could not support the drug rebate information reported to the Centers for Medicare & Medicaid Services (CMS) in the Form CMS 64.9R report, did not reconcile drug rebate information to its accounting records, and did not accrue or verify interest for late or disputed rebate payments from drug manufacturers.

As of December 31, 2002, SC-DHHS had noticeably enhanced its ability to monitor and report drug rebate information due to significant staffing, structural, and procedural changes. However, improvements over drug rebate accountability are still needed in the following areas:

- Interest accrual and collection; and

- Data integrity, including records retention.

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 CMS and the drug manufacturers require the payment of interest on all disputed, late, and unpaid drug rebates.

After June 30, 2002, State officials addressed the majority of the problems we initially encountered by improving supervision, staffing, and by developing and implementing written policies, procedures, and internal controls over the daily operation of the drug rebate program. However, the weaknesses we found as of December 2002 occurred because SC-DHHS has yet to implement adequate controls over the accrual and collection of interest on outstanding rebates, and has not maintained adequate controls to safeguard drug rebate data.

As a result, there was no assurance that SC-DHHS was collecting all the interest due on late or disputed rebates. Also, improper data protection may limit the State's ability to actively pursue outstanding receivables from drug manufacturers and may increase the potential risk for waste and abuse of funds from drug rebates.

We believe that SC-DHHS has the opportunity to increase the amount of revenue that is realized from drug rebates and to maintain better control over drug rebate information. Therefore, we recommend that SC-DHHS implement adequate procedures and controls that would enable the State to account for the accrual and collection of interest on late, disputed, or unpaid rebate payments. SC-DHHS should also review existing procedures and implement strict controls to safeguard drug rebate data.

SC-DHHS responded to our draft report in a letter dated July 17, 2003. SC-DHHS 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 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's 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.

Manufacturers have 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 the NDC by 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 expenditures and rebate collections on the Form CMS 64.9R. This report is part of the Form CMS 64 report, which summarizes actual Medicaid expenditures for each quarter, and is used by CMS to reimburse the Federal share of these expenditures.

SC-DHHS administers the Medicaid program in the State of South Carolina. SC-DHHS reported to CMS $54,510,146 in drug rebate billings and $26,226,831 in collections during the 1-year period ending June 30, 2002. SC-DHHS reported $28,283,315 on the CMS 64.9R report as the outstanding balance as of June 30, 2002, but only $3,747,235 were rebates outstanding over 90 days. For the 1-year period ending December 31, 2002, SC-DHHS reported $61,456,191 in drug rebate billings and $39,539,152 in collections. As of December 31, 2002, SC-DHHS reported $21,917,039 in outstanding rebates of which $6,055,157 were outstanding over 90 days.

Since 2001, the SC-DHHS has contracted with its fiscal agent, First Health Services Corporation (FH), to perform the billing, subsidiary record keeping, and dispute resolution of the drug rebate program, while SC-DHHS employees perform other functions such as drug rebate collections, reconciliation and posting of payments to the State's general ledger, and preparing the Form CMS 64 reports. Prior to 2001, State employees performed most of the day-to-day operations of the drug rebate program, but the State contracted with Med Data Resources to handle dispute resolution.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The objective of our audit was to evaluate whether the SC-DHHS 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 SC-DHHS policies, procedures, and controls with regard to Medicaid drug rebates through June 30, 2002 and December 31, 2002. Our review of internal controls was limited to the controls concerning drug rebate receivables, collections, 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 SC-DHHS and its contractor internal control structure.

Methodology

To accomplish our audit objective, we obtained the State's Medicaid Drug Rebate Schedules (Form CMS 64.9R) for June 30, 2002 and December 31, 2002 and reviewed supporting documentation to assess the reliability of the outpatient drug rebate information reported to CMS. We reviewed accounts receivable and subsidiary record balances and compared the information with the data presented in the Form CMS 64.9R report. We also interviewed the SC-DHHS staff that performed functions related to the drug rebate program to determine existing policies, procedures, and internal controls.

Fieldwork was performed from February through May 2003 at the SC-DHHS Offices in Columbia, South Carolina and at our field offices in Miami and Jacksonville, Florida.

FINDINGS AND RECOMMENDATIONS

Through June 30, 2002, the SC-DHHS did not have adequate accounting procedures and internal controls with regard to the Medicaid drug rebate program. For the most part, the State could not support the drug rebate information reported to CMS in the Form CMS 64.9R report, did not reconcile drug rebate information to its accounting records, and did not accrue or verify interest for late or disputed rebate payments from drug manufacturers.

However, as of December 31, 2002, SC-DHHS had addressed the majority of the problems we initially encountered and noticeably enhanced its ability to monitor and report drug rebate information, as required by Federal regulations. Because of significant staffing, structural, and

procedural changes, SC-DHHS has developed and implemented written policies, procedures, and internal controls that enable them to better manage the State's drug rebate program. Nevertheless, improvements over drug rebate accountability are still needed in the following areas:

- Interest accrual and collection; and
- Data integrity, including records retention.

Interest on Late, Disputed, or Unpaid Drug Rebate Payments

SC-DHHS, through its contractor FH, did not follow appropriate procedures to accrue and properly verify interest for late, disputed, or unpaid rebate payments. The State did not accrue or track interest from drug manufacturers and did not have adequate controls to validate 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.

Although FH's written rebate procedures acknowledge that CMS regulations require the collection of interest by the States and assert that the FH system calculates interest pursuant to CMS guidelines, FH representatives indicated they do not bill the manufacturers for interest owed to the State of South Carolina. Also, we found no assurance that the interest paid by the manufacturers is properly verified as correct.

FH representatives stated that they test the manufacturer's interest calculations using a sample of interest payments received. However, we were not provided criteria describing the sample selection methodology and we found no reconciliation of the variances between the amount due and the interest amount received in the items we reviewed. Further, we found no explanation

about the steps, if any, FH would have taken if the interest received was not being calculated accurately, and no evidence that FH keeps track of unpaid interest.

Because SC-DHHS, through its contractor FH, was not accruing, tracking, or properly verifying interest from drug manufacturers, there was no assurance that they were collecting all of the interest payments for late, unpaid, or disputed rebates.

Data Integrity and Records Retention

Our audit disclosed that FH did not maintain adequate controls over data processing records under its care.

Title 45, Section 74.21 (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.

When FH could not comply with our request for supporting information for part of the December 2002 CMS 64.9R report, its representatives explained that their inability to produce detailed rebate adjustment transactions was caused by the failure to backup and archive drug rebate data. Also, they explained that file deletions in early February 2003 impacted adjustment transactions used to calculate totals on rebate invoices. However, FH stated that summary information was not affected and that the rebate invoices they had sent drug manufacturers were correct. At the time of our audit, FH representatives indicated that they were trying to identify the months and quarters affected by this problem and were taking steps to improve management and data backup and recovery processes. SC-DHHS officials stated that they were not aware of this situation prior to our audit.

Because of the nature of FH's data integrity and records retention problem, and because a detailed review of the State's or its contractors' computerized information system was not part of the scope of our audit, we make no assertions as to the appropriateness of the rebate invoices FH sent to drug manufacturers. However, we recognize that improper data protection may limit the State's ability to actively pursue outstanding receivables from drug manufacturers and may increase the potential risk for waste and abuse of funds from drug rebates.

RECOMMENDATIONS

We recommend that SC-DHHS implement procedures and controls that would enable the State to account for the accrual and collection of interest on late, disputed, or unpaid rebate payments. SC-DHHS should also review existing procedures and implement strict controls to safeguard drug rebate data.

SC-DHHS' Response And OIG's Comments

SC-DHHS responded to our draft report in a letter dated July 17, 2003. SC-DHHS officials agreed with our findings and have taken steps to correct the identified weaknesses. Their complete response is included in the appendix. SC-DHHS' response and OIG's comments are summarized below.

SC-DHHS's Response

SC-DHHS concurred with the recommendation to implement procedures and controls relating to the accrual and collection of interest on late, disputed, or unpaid rebates. The State reported that written procedures and controls have been developed and will be implemented with the invoice cycle for 2003. In regard to the safeguarding of drug rebate data, SC-DHHS commented that they have taken steps to improve data integrity and the records retention process. The steps include improved data recovery and backup practices, daily balancing of rebate data and the use of a new database analysis tool.

OIG's Comments

We agree with SC-DHHS' efforts to improve their drug rebate program.

- - - - -

To facilitate identification, please refer to report number A-04-03-06011 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

State of South Carolina
Department of Health and Human Services

Mark Sanford
Governor

Robert M. Kerr
Director

July 17, 2003

Mr. Charles Curtis
Regional Inspector General for
Audit Services
Office of Inspector General
Region IV
61 Forsyth Street, S.W., Suite 3T41
Atlanta, Georgia 30303

Dear Mr. Curtis:

We have reviewed the draft report (number A-04-03-06011) entitled *Audit of the Medicaid Drug Rebate Program in the State of South Carolina.* Our response, with concurrence from our contractor, First Health (FH) is as follows:

With regards to the findings on Interest Accrual and Collection on Late, Disputed, or Unpaid Drug Rebates, the State agrees with the findings and has instituted, through FH, written procedures and controls to allow for the calculation and invoicing of interests. Such procedures will begin with the invoice cycle for 2003, first quarter. The calculation process will follow the guidelines contained within the Centers for Medicare and Medicaid Services (CMS) regulations for conducting Medicaid rebate programs.

The second finding addressed Data Integrity and Records Retention. The State agrees with the findings outlined in the report and have consulted with FH to implement additional procedures, practices, and controls to ensure the integrity of the rebate data. The following information details the procedures currently in place:

Modifications have been made to FH's data backup plans to improve data protection. FH now utilizes a system infrastructure and architecture that provides minimal risk to system outages and greater data protection. This hardware redundant environment includes:

- Data on Raid 5 (multiple disk drives)
- Mirrored system partitions
- Redundant Power Supply
- Dual LAN connectors
- Multi processors
- Automated generator failover
- Offsite data backup storage

First Health has also taken steps to improve its data integrity and records retention processes. These include:

1. Improved data backup and recovery practices
2. Daily balancing of rebate data
3. Purchase and use of new database analysis tool, Log Explorer v3.3

We believe these procedures will effectively safeguard the drug rebate data and exceeds the recommendations set forth in the report.

Should you have any questions concerning these responses, please do not hesitate to contact David Schaefer at (803) 898-1078.

Sincerely,

Robert M. Kerr
Director

RMK/wslh

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*
Lourdes Puntonet, *Senior Auditor*
Lynn Stevens, *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.