DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General
Office of Audit Services

Region VII
601 East 12th Street
Room 284A
Kansas City, Missouri 64106

May 8, 2003

Report Number A-07-03-04017

Mr. Ray Dalton
Director of Accounting and Administrative Operations
Department of Social & Rehabilitation Services
Docking State Office Building, Floor 11
915 Harrison
Topeka, KS 66612

Dear Mr. Dalton:

Enclosed are two copies of the U.S. Department of Health and Human Services (HHS), Office of Inspector General, Office of Audit Service's (OAS) final report entitled *"Audit of the Medicaid Drug Rebate Program in Kansas."*

The HHS action official named below will make final determination as to actions taken on all matters reported. 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 U.S.C. 552, as amended by Public Law 104-231, Office of Inspector General, OAS 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. (See 45 CFR Part 5.) As such, within 10 business days after the final report is issued, it will be posted on the worldwide web at *http://oig.hhs.gov*.

To facilitate identification, please refer to Report Number A-07-03-04011 in all correspondence relating to this report. If you have any questions or need additional information, please contact Randy Parker of our Des Moines office at (515) 284-4674 extension 27 or Patrick Cogley of our Kansas City Office at (816) 426-3591, extension 274.

Sincerely,

James P. Aasmundstad
Regional Inspector General
for Audit Services

Direct Reply to HHS Action Official:

Mr. Joe Tilghman
Centers for Medicare and Medicaid Services
Regional Administrator, Region VII
601 East 12th Street, Room 235
Kansas City, Missouri 64106

Enclosures—As stated

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN KANSAS

JANET REHNQUIST
INSPECTOR GENERAL

MAY 2003
A-07-03-04017

Office of Inspector General

http://oig.hhs.gov/

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OAS FINDINGS AND OPINIONS

The designation of financial or management practices as questionable or a recommendation for the disallowance of costs incurred or claimed as well as other conclusions and recommendations in this report represent the findings and opinions of the HHS/OIG/OAS. Authorized officials of the awarding agency will make final determination on these matters.

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Report Number: A-07-03-04017

Mr. Ray Dalton
Director of Accounting and Administrative Operations
Department of Social & Rehabilitation Services
Docking State Office Building, Floor 11
915 Harrison
Topeka, KS 66612

Dear Mr. Dalton:

This final report provides you with the results of our ***Audit of the Medicaid Drug Rebate Program in Kansas.***

EXECUTIVE SUMMARY

OBJECTIVE

The audit objective was to evaluate whether the Kansas Department of Social & Rehabilitation Services (SRS) had established adequate accountability and internal controls over the Medicaid drug rebate program.

FINDINGS

We found that the SRS lacked sufficient internal controls with regard to the Medicaid drug rebate program as required by federal rules and regulations. Areas that lacked sufficient internal controls included:

- Recording accounts receivable.
- Reconciliation of Form CMS 64.9R and the general ledger.
- Interest accrual.
- Interest reporting.
- Invoice verification.

These issues occurred because the SRS did not develop or follow adequate policies and procedures with regard to the drug rebate program. Federal regulations require 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 manufacturers require the payment of interest on all disputed, late, and unpaid drug rebates. Also, the State Medicaid Manual requires interest revenue to be reported on the Form CMS 64 Summary Sheet.

Our review showed that drug rebate receivables were perpetually understated and it is likely that the SRS did not receive all drug rebates and interest on disputed or late rebate payments due from manufacturers. In addition, the SRS did not have reasonable assurance that drug rebate balances and collections reported to CMS were accurate. Moreover, the lack of sufficient internal controls increased the risk for fraud, waste, or abuse of drug rebate program funds.

RECOMMENDATIONS

We recommend that the SRS develop and follow policies and procedures that include:

- Ensuring that the Form CMS 64.9R report is adjusted for the additional rebates billed for the first quarter 2002 and the invalid receivables that were included in the receivable balance reported for June 30, 2002.
- Establishing a general ledger control account for drug rebate receivables.
- Reconciling quarterly the general ledger control account to the Form CMS 64.9R and subsidiary ledgers.
- Reconciling quarterly the drug rebate collections on the cash receipts log to collections on the Form CMS 64.9R.
- Estimating and accruing interest on all overdue rebate balances.
- Reporting drug rebate interest revenue on the Form CMS 64 Summary Sheet.
- Verifying that drug rebate invoices include total units dispensed for each quarter.

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INTRODUCTION

BACKGROUND

On November 5, 1990, Congress enacted the Omnibus Budget Reconciliation Act of 1990 legislation, which 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. The CMS also issued release memorandums to State agencies and manufacturers throughout the history of the rebate program to give guidance related to the Medicaid drug rebate program.

A drug manufacturer is required to have a rebate agreement in effect with CMS in order to have its products covered under the Medicaid program. The manufacturer is required to submit a listing to CMS of all covered outpatient drugs, and to report its average manufacturer price and best price information for each covered outpatient drug to CMS. Approximately 520 pharmaceutical companies participate in the program.

The 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 had 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 can change any URA based on updated pricing information, and submit this information to the State agency in a Prior Quarter Adjustment Statement.

Each State agency is required to maintain drug utilization data for total units dispensed, by manufacturer, for each covered drug. That number is applied to the URA to determine the actual rebate amount due from each manufacturer. The CMS requires each State agency to provide drug utilization data to the manufacturer. Approximately 56,000 National Drug Codes (NDC) are available under the program.

The manufacturer has 38 days to remit payment from the date an invoice is sent. The manufacturers provide the State agency with a Reconciliation of State Invoice detailing their payment by each NDC. A manufacturer can dispute utilization data that is believed to be erroneous, but they are 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 under the Medicaid program to the manufacturer in order to resolve the dispute.

The manufacturer is required to calculate and remit interest for any late payments or disputed rebates when settlement is made. Governmental Accounting and Financial Reporting Standards require States to calculate and accrue a reasonable estimate of the interest owed. Tracking interest owed to the State agency is required by CMS.

Each State agency reports, on a quarterly basis, 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. Specifically, the States report rebates invoiced in the current quarter, rebates received during the current quarter and uncollected rebate balances for current and prior quarters on the Form CMS 64.9R.

The SRS reported a receivable balance of $5,445,397 on the June 30, 2002 Form CMS 64.9R. Receivables older than 90 days total $1,627,873. Interest collected by SRS from the manufacturers was not reported on the Form CMS 64 Summary Sheet. The SRS reported $42,464,981 in rebate collections for the 12-month period ending June 30, 2002.

The SRS contracted with its fiscal agent, Electronic Data Systems (EDS), to prepare and mail the rebate invoices to manufacturers, monitoring and working on drug rebate accounts receivable, including posting payments to the subsidiary ledgers, resolving disputes, researching utilization data to resolve errors, communicating with manufacturers, and monitoring outstanding balances. SRS staff separately performed the functions of depositing funds and preparing the Form CMS 64.9R reports.

OBJECTIVE, SCOPE AND METHODOLOGY

Objective

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

Scope

The drug rebate program was effective January 1, 1991. We concentrated our review on the current policies, procedures and controls of the SRS and EDS. We also reviewed accounts receivable information related to prior periods and interviewed EDS staff to understand how the Medicaid drug rebate program has operated since 1991.

Methodology

To accomplish our objectives, we interviewed SRS and EDS officials to determine the policies, procedures and controls that existed with regard to the Medicaid drug rebate program. Also, we interviewed staff members that performed functions related to the drug rebate program. In addition, we obtained and reviewed drug rebate accounts receivable records and compared this data to the quarter-ending June 30, 2002 Form CMS 64.9R report.

Our fieldwork was conducted at the SRS and EDS offices in Topeka, Kansas during December 2002 and January 2003.

Our audit was performed in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

We found that the SRS lacked sufficient internal controls with regard to the Medicaid drug rebate program as required by federal rules and regulations. Areas that lacked sufficient internal controls included:

- Recording accounts receivable
- Reconciliation of Form CMS 64.9R and the general ledger.
- Interest accrual.
- Interest reporting.
- Invoice verification.

INTERNAL CONTROLS

Accounts Receivable

The State did not maintain a general ledger accounts receivable control account to account for uncollected rebate balances. Drug rebates are "other assets" to the State that should be accounted for properly.

Title 45 Sec. 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. Recipients shall adequately safeguard all such assets and assure they are used solely for authorized purposes." Additionally, generally accepted accounting principles (GAAP) require the use of a general ledger. The National Council on Governmental Accounting (NCGA)[1] issued *Statement 1, Governmental Accounting and Financial Reporting Principles*. It states in part,

> "A governmental accounting system must make it possible both: (a) to present fairly and with full disclosure the financial position and results of financial operations of the funds and account groups of the governmental unit in conformity with generally accepted accounting principles; and (b) to determine and demonstrate compliance with finance-related legal and contractual provisions."

Because there was no general ledger for accounts receivable to reconcile to the subsidiary ledger, the SRS did not have reasonable assurance that rebate receivables were accurate or effectively safeguarded.

Form CMS 64.9R and General Ledger Reconciliations

The SRS did not perform a reconciliation to verify the accuracy of the uncollected rebate balance or collections reported on the Form CMS 64.9R as required by federal regulations.

Title 45 Sec. 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. Recipients shall adequately safeguard all such assets and assure they are used solely for authorized purposes."

The SRS did not reconcile the general ledger account balance to the detailed subsidiary accounts receivable records. Moreover, the SRS did not reconcile the rebate collections on the cash receipts log to the collections reported on the Form 64.9R.

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[1] The Governmental Accounting Standards Board (GASB) establishes standards for activities and transactions of State and local governmental entities. Its pronouncements are authoritative for State and local governmental entities. Following the jurisdictional approach discussed in the GASB Codification of Governmental Accounting and Financial Reporting Standards, the hierarchy of GAAP for governmental entities begins with GASB pronouncements and all pronouncements of the NCGA acknowledged as applicable by the GASB.

This occurred because the State did not have a general ledger or procedures to perform the reconciliation of cash receipts. Without routine reconciliations, the SRS did not have reasonable assurance that receivables and collections were adequately safeguarded or that drug rebate information reported to CMS was accurate. In fact, EDS officials indicated the quarter-ending June 30, 2002 Form CMS 64.9R receivable balance of $5,445,397 included invalid receivables. The receivable balance was overstated by $297,407.

Interest Accrual

The SRS did not accrue interest for late or disputed payments as required. Governmental Accounting and Financial Reporting standards require the States to accrue revenue (interest) when it is measurable (a reasonable estimate) and available. Interest was not accrued at EDS or on a State general ledger because policies and procedures had not been established. Because the SRS did not accrue revenue as required, the amount manufacturers owed the State (rebate principal and interest) was perpetually understated.

Interest Reporting

The SRS did not report drug rebate interest revenue received in accordance with Medicaid rules. The State Medicaid Manual Section 2500.1 instructs the states to prepare a Form CMS 64 Summary Sheet for interest received on drug rebate collections.

SRS reported interest revenue on the quarter-ending June 30, 2002 Form CMS 64.9R rather than the Form CMS 64 Summary Sheet for at least two years. Interest revenue was not reported on the proper CMS form because the State had not established policies and procedures. Reporting interest revenue on Form CMS 64.9R caused receivables to be understated by $31,531.94 for the two-year period ending June 30, 2002.

Invoice Verification

The SRS sent inaccurate drug rebate invoices to manufacturers for the first quarter of 2002. Each State agency is required to compile drug utilization data for total units dispensed, by manufacturer, for each covered drug in order to calculate rebate amounts to bill each manufacturer on a quarterly basis.

The billing errors occurred because utilization amounts were not added to the accounts receivable subsystem for several weeks during the first quarter of 2002. Corrected invoices were issued four months later. As a result, the rebate balance reported on the June 30, 2002 Form 64.9R was understated by about $2.3 million.

RECOMMENDATIONS

We recommend that the SRS develop and follow policies and procedures that include:

- Ensuring that the Form CMS 64.9R report is adjusted for the additional rebates billed for the first quarter 2002 and the invalid receivables that were included in the receivable balance reported for June 30, 2002.

- Establishing a general ledger control account for drug rebate receivables.

- Reconciling quarterly the general ledger control account to the Form CMS 64.9R and subsidiary ledgers.

- Reconciling quarterly the drug rebate collections on the cash receipts log to collections on the Form CMS 64.9R.

- Estimating and accruing interest on all overdue rebate balances.

- Reporting drug rebate interest revenue on the Form CMS 64 Summary Sheet.

- Verifying that drug rebate invoices include total units dispensed for each quarter.

Auditee Response

The SRS responded to our draft report on April 24, 2003. Their complete response is included in Appendix A. The SRS officials concurred with most of the findings and have agreed to establish new policies and procedures to: 1) reconcile quarterly drug rebate collections with the cash receipts log, 2) report interest separately on Line 5 of the Form CMS 64.9R Summary Sheet beginning with quarter ending 03/31/03, and 3) verify invoice total units and total dollars by comparing to previous quarters. In addition, a new subsidiary ledger report has been created that will summarize quarter-ending provider receivables ending balances and compare that total with information on the Form CMS 64.9R.

The SRS did not agree to accrue interest for late or disputed payments as required due to the complexity of the calculation. They have requested guidance from the OIG on how interest accrual is to be accomplished given the complexity of the calculation.

OIG Comments

We commend the SRS for establishing new policies and procedures for its drug rebate program. We agree that the interest calculation is complex because of the weekly change in rates and prior period adjustments. Due to the complexity of the interest calculation, we believe that interest accrual can only be accomplished as part of an automated system. We have reviewed other States that are adding interest computations to their automated drug rebate systems. We recognize that there is a substantial expense associated with such an endeavor. Accordingly, we suggest that the State consider the costs and benefits associated with making the necessary changes to compute interest.

Sincerely,

James P. Aasmundstad
Regional Inspector General
for Audit Services

JANET SCHALANSKY, SECRETARY

KANSAS

SOCIAL AND REHABILITATION SERVICES

KATHLEEN SEBELIUS, GOVERNOR

Health Care Policy / Medical Policy Division
Robert M. Day, Director

April 24, 2003

Mr. James P. Aasmundstad
Regional Inspector General For Audit Services
Office of Inspector General
Department of Health and Human Services, Region VII
601 East 12th Street. Room 284A
Kansas City, MO 64106

RE: Report Number A-07-03-04017

Dear Mr. Aasmundstad:

The Kansas Department of Social and Rehabilitation Services (SRS) has reviewed the draft report entitled "Audit of the Medicaid Drug Rebate Program in Kansas" by the U.S. Department of Health and Human Services, Office of Inspector General, Office of Audit Services (OIG), and appreciate the opportunity to offer factual information relative to the validity and reasonableness of the draft report that will be taken into account as the final report is prepared and included as an Appendix to the report.

The responses provided below follow the format outlined in the draft report.

Accounts Receivables

The draft report states "The State did not maintain a general ledger accounts receivable control account for uncollected rebate balances as required....Because there was no general ledger for accounts receivable to reconcile to the subsidiary ledger, the SRS did not have reasonable assurance that rebate receivables were accurate or effectively safeguarded."

The State of Kansas financial accounting system does not allow for SRS to establish general ledger control accounts for any SRS programs, including drug rebate receivables. SRS will use internal reports and controls to accomplish the same function.

Form CMS 64.9R and General Ledger Reconciliations

As reported in the draft, "The SRS did not perform a reconciliation to verify the accuracy of the uncollected rebate balance or collections reported on the Form CMS 64.9R as required by federal

regulations....The SRS did not reconcile the general ledger account balance to the detailed subsidiary accounts receivable record." And "Moreover, the SRS did not reconcile the rebate collections on the cash receipts log to the collections reported on the Form 64.9R."

As mentioned above, SRS does not intend to establish accounting procedures that use "general ledger control accounts" because the State's financial accounting system does not allow this to occur. However, SRS has created a report that, at a minimum, summarizes quarter ended provider receivables ending balances and will compare that total with the Column F Total of Line 6, Balance As Of The End of The Quarter on the CMS 64.9R, Medicaid Drug Rebate Schedule.

Additionally, the SRS Federal Financial Reporting Unit will begin receiving copies of the Cash Receipts Log from the SRS Central Receivables Unit (CRU) and from EDS, the SRS Fiscal Agent. A weekly reconciliation procedure is currently in place to ensure that the CRU and EDS cash logs reconcile. EDS will identify, at quarter end, the total amount received from CRU and compare that with the amount they report as Collections on the CMS 64.9R. EDS will identify the variance at the end of each quarter between the total collected and the total reported to CMS. (e.g. collections posted in the current quarter that were collected during previous quarters and collections received but not yet posted by EDS)

Auditor's Note: Comments deleted because they are no longer relevant.

[redacted]

Auditor's Note: Comments deleted because they are no longer relevant.

Interest Accrual

The draft report states "The SRS did not accrue interest for late or disputed payments as required."

The State of Kansas financial accounting system operates on a cash basis. Further complicating drug rebate interest is the fact that it is calculated using weekly T-bill rates. In order for interest to be accrued, the interest on each NDC for each quarter in dispute would have to be calculated based on the weekly T-bill rate back to 38 days from the original invoice date or six months after the last prior period adjustment (PPA) activity. When discussing interest accrual with the OIG auditor, Dan Owens, during the site audit and during a telephone conversation after issuance of the draft report, he agreed this was an impossible task. We seek guidance from the OIG on how interest accrual is to be accomplished, including how it is to be adjusted when manufacturers submit prior period adjustments as far back as 1991.

Interest Reporting

As stated in the draft report "The SRS did not report drug rebate interest revenue received in accordance with Medicaid Rules." And "SRS reported interest revenue on the quarter-ending June 30, 2002 Form CMS 64.9R rather than the Form CMS 64 Summary Sheet for at least two years."

SRS has been reporting interest to CMS, but it was reported within total drug rebates and not as a separate line item on the Summary Sheet. A new policy and procedure has been instituted to report interest separately. Beginning with quarter ending 03/31/03, SRS will report interest revenue on Line 5, other, on the Form CMS 64 Summary Sheet.

I would also like to point out that Kansas is one of very few states that charges manufacturers interest on outstanding rebates, a point that was recognized by the OIG on-site auditors in the exit interview.

Invoice Verification

The OIG indicates in the draft report that "The SRS sent inaccurate drug rebate invoices to manufacturers for the first quarter of 2002....Corrected invoices were issued four months later. As a result, the rebate balance reported on the June 30, 2002 Form 64.9R was understated by about $2.3 million."

In regard to the OIG recommendation that Form CMS 64.9R be adjusted for additional rebates billed for the first quarter 2002, SRS has accomplished this. SRS included the correct invoicing for the first quarter of 2002 on the CMS 64.9R for the quarter ending 09/30/02. The corrected invoices were mailed on 09/30/02, prior to the OIG audit. Additionally, a new policy and procedure has been instituted to verify invoices against the total number of NDCs and total dollars billed for that quarter in comparison to the previous quarter.

There is another topic that is important to address in the context of States maintaining drug rebate records and that is prior period adjustments. CMS allows manufacturers to make prior period adjustments (PPAs) back to the inception of the drug rebate program, or first quarter of 1991. It is extremely burdensome for States to adjust drug rebate quarters for PPAs this aged. Interest accrual would be much less complex to accomplish if such a time limit were established.

Additionally, a manufacturer has an incentive to file a PPA because doing so allows them a six-month interest-free abatement before the rebates are considered delinquent. This six-month allowance then delays the dispute resolution process as well. We strongly believe that CMS should set a reasonable time limit, such as three years (twelve quarters) for PPAs. As mentioned previously, we also recommend that CMS set an interest rate that gives manufacturers incentive to settle disputes in a timely fashion.

In summary, new policies and procedures have been established to 1) reconcile quarterly drug rebate collections with the cash receipts log, 2) report interest separately on Line 5 of the CMS 64.9R Summary Sheet beginning with quarter ending 03/31/03 and 3) verify invoice total units and total dollars by comparing to previous quarters. In addition, a new subsidiary ledger report has been created that will summarize quarter-ending provider receivables ending balances and compare that total with the Column F Total of Line 6 on the CMS 64.9R. In regard to dispute resolution, SRS

does utilize the State hearing mechanism as part of standard policy and procedures.

The Kansas Medicaid Drug Rebate Program is very successful in terms of invoicing and collecting drug rebates and resolving disputes. The program enjoys a drug rebate collection rate of 99%. Since fiscal year 1997, drug rebates as a percent of total drug expenditures have increased from 16.5% to 19.9% in fiscal year 2002. Rebate dollars collected in fiscal year 2002 totaled $42,464,980, while disputed rebates remain very low, and at quarter ending 06/30/02 were $187,602.83.

Thank you for the opportunity to comment on the draft OIG report and provide information about the Kansas Medicaid Drug Rebate Program. Please contact me if you have additional questions.

Sincerely,

Robert M. Day, Ph.D.
Medical Policy / Medicaid Director
Health Care Policy Division

RMD:KSB:rjb

Enclosures

cc: Laura Howard *(SRS)*
Ray Dalton *(SRS)*

ACKNOWLEDGMENTS

Report Number: A-07-03-04017
Audit of the Medicaid Drug Rebate Program in Kansas.

This report was prepared under the direction of James P. Aasmundstad, Regional Inspector General for Audit Services. Other principal Office of Audit Services staff that contributed include:

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