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

June 9, 2003

Report Number A-07-03-04013

Bob Seiffert
Administrator
Nebraska Health and Human Services System
301 Centennial Mall South
Lincoln, NE 68509

Dear Mr. Seiffert:

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

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.

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To facilitate identification, please refer to Report Number A-07-03-04013 in all correspondence relating to this report.

Sincerely,

Thomas L. Sattler for

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 NEBRASKA

JUNE 2003
A-07-03-04013

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.

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

June 9, 2003

Report Number A-07-03-04013

Mr. Bob Seiffert, Administrator
Medicaid Division/Long Term Care
Nebraska Health and Human Services System
301 Centennial Mall South
Lincoln, Nebraska 68509

Dear Mr. Seiffert:

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

EXECUTIVE SUMMARY

OBJECTIVE

The audit objective was to evaluate whether the Nebraska Health and Human Services System (HHSS) had established adequate accountability and internal controls over the Medicaid drug rebate program.

FINDINGS

We determined the HHSS 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.
- Form CMS 64.9R and general ledger reconciliations.
- Interest accrual, collection, and reporting.
- Dispute resolution.

These issues occurred because the HHSS 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; and the use of the State's hearing mechanism to resolve disputes. 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 HHSS did not receive all drug rebates and interest on disputed or late rebate payments due from manufacturers. In addition, the HHSS 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 HHSS develop and follow policies and procedures that include:

- Developing a subsidiary accounts receivable system that details all drug rebate transactions, including adjustments.
- Reconciling the general ledger control account to the subsidiary ledgers and to the Form CMS 64.9R.
- Reconciling the quarterly cash receipts log to the Form CMS 64.9R.
- Estimating and accruing interest on all overdue rebate balances.
- Reporting interest collections on the Form CMS 64 Summary Sheet.
- Utilizing the State's hearing mechanism to settle disputes after 60 days.

The HHSS did not concur with most of our findings and recommendations. They did agree to take corrective action on the last two recommendations. Their response is included as Appendix A.

INTRODUCTION

BACKGROUND

On November 5, 1990, Congress enacted the Omnibus Budget Reconciliation Act (OBRA '90) 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 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 computed URA 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 is required to calculate the URA and remit the

appropriate amount to the State agency. 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 (PQAS).

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. Each State agency is required to provide drug utilization data to the manufacturer and CMS on a quarterly basis. 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 postmarked. The manufacturers provide the State agency with a Reconciliation of State Invoice (ROSI) 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.

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. The HHSS reported to CMS an uncollected rebate balance of $2,483,849 on the Form CMS 64.9R as of June 30, 2002. Of that amount, ($7,539,294) was reported as outstanding for 90 days or longer. However, the subsidiary ledger maintained by the HHSS did not support that figure. For the period July 1, 2001 through June 30, 2002, the State agency reported total rebate collections of $41,086,969 or an average of $10,271,742 per quarter.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

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

Scope

The drug rebate program became effective January 1, 1991. We concentrated our audit on current policies, procedures and controls of the HHSS.

Methodology

To achieve our objective, we reviewed the applicable Federal laws, regulations, and requirements including sections 1903 and 1927 of the Social Security Act , the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) and the OMB Circular A-87.

We examined copies of the CMS 64.9R reports for the period July 1, 2001 through June 30, 2002 submitted to CMS by the State of Nebraska. We obtained and reviewed drug rebate accounts receivable records. Finally, we interviewed HHSS staff that performed functions related to the drug rebate program.

Our fieldwork was conducted at the HHSS office in Lincoln, Nebraska during November 2002, and continued in the Office of Audit Services field office in Omaha, Nebraska through April 2003.

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

FINDINGS AND RECOMMENDATIONS

We determined the HHSS 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.
- Form CMS 64.9R and general ledger reconciliations.
- Interest accrual, collection, and reporting.
- Dispute resolution.

INTERNAL CONTROLS

Recording Accounts Receivable

The HHSS did not have a sufficient subsidiary accounts receivable system to ensure that asset balances reported to CMS were accurate as required by Federal regulations.

Title 45 CFR 74.21, paragraph (b)(2) of the Code of Federal Regulations states:

> *"Recipients' financial management systems shall provide for the following: Records that identify adequately the source and application of funds for HHS-sponsored activities. These records shall contain information pertaining to Federal awards, authorizations, obligations, unobligated balances, assets, outlays, income and interest."*

Although the HHSS maintained a detailed subsidiary ledger for the accounts receivable, the adjustment figures reported on the Form CMS 64.9R were not supported by that ledger.

According to the Form CMS 64.9R dated June 30, 2002, the HHSS had a drug rebate receivable balance totaling $2.5 million. However, the Form CMS 64.9R showed a credit balance of $7.5 million for receivables outstanding 90 days or longer while the subsidiary ledger showed a debit balance of $2.5 million for receivables outstanding 90 days or longer. Balances and activity on the Form CMS 64.9R should be consistent with the general ledger and be supported by the subsidiary ledgers. While the $2.5 million balance on the Form CMS 64.9R was consistent with the subsidiary ledger accounts receivable balance, unsupported adjustments were recorded on the Form CMS 64.9R to ensure that balance was consistent with the subsidiary ledger.

Because the subsidiary ledger did not support the receivable figures reported to CMS, the HHSS did not have reasonable assurance that receivable balances reported to CMS were accurate.

Form CMS 64.9R and General Ledger Reconciliations

The HHSS did not perform a reconciliation to verify the accuracy of the uncollected rebate balance reported on the Form CMS 64.9R as required by federal regulations. They did not reconcile the general ledger accounts receivable control account balance to the detailed subsidiary accounts receivable records. However, the HHSS did reconcile the rebate collections on the cash receipts log to the collections reported on the Form CMS 64.9R. This reconciliation was not included in their written policies and procedures.

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."

Without routine reconciliations, the HHSS did not have reasonable assurance that the receivables were adequately safeguarded, or that drug rebate information reported to CMS was accurate. Written policies and procedures would help ensure that a reconciliation of cash receipts continues to be performed.

Interest Accrual and Collection

The HHSS did not have adequate procedures to accrue interest for late or disputed rebate payments as required by Federal rules and regulations.

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 disputed or unpaid amounts and late rebate payments. The interest rate according to Section 1903 (d)(5) of the Social Security Act is "based on the

yield of the weekly 90-day Treasury bill auction rates" during such period. 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 # 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 # 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. Finally, *Governmental Accounting and Financial Reporting Principles* require states to accrue revenue (interest) when it is measurable (a reasonable estimate) and available.

The HHSS did not calculate and accrue interest for late or disputed payments as required by Federal regulations, nor did they recalculate interest voluntarily paid by manufacturers to verify that the correct amounts were paid. Moreover, they did not make significant efforts to collect from manufacturers that did not voluntarily remit interest owed.

Because the HHSS did not accrue revenue as required, the drug rebate receivables were perpetually understated, and it is likely they did not receive all interest owed to them by the manufacturers.

Interest Reporting

The HHSS 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. However, the HHSS has included interest received as rebate collections on the Form CMS 64.9R since the program began in 1991. As a result, interest revenue reported on the Form CMS 64.9R has caused receivables to be understated by $75,954 as of June 30, 2002.

Dispute Resolution

The HHSS did not utilize state hearings to resolve disputes as required by the rebate agreement. Specifically, the rebate agreement requires that the states and the manufacturers resolve rebate discrepancies within 60 days of receipt of notification of a

dispute. It further states, "In the event that the State and the manufacturer are not able to resolve a discrepancy within 60 days, CMS shall require the State to make available to the manufacturer the State's hearing mechanism available under the Medicaid Program."

The HHSS did not establish procedures for using the State's hearing mechanism. Instead, they contacted manufacturers directly and attended Dispute Resolution Project (DRP) meetings. Because manufacturers were not required to attend DRP meetings, there were no incentives for them to resolve claims and there were no other sanctions provided in the regulations. Therefore, we believe the HHSS could increase its drug rebate collections by utilizing the State's hearing mechanism.

RECOMMENDATIONS

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

- Developing a subsidiary accounts receivable system that details all drug rebate transactions, including adjustments.
- Reconciling the general ledger control account to the subsidiary ledgers and to the Form CMS 64.9R.
- Reconciling the quarterly cash receipts log to the Form CMS 64.9R.
- Estimating and accruing interest on all overdue rebate balances.
- Reporting interest collections on the Form CMS 64 Summary Sheet.
- Utilizing the State's hearing mechanism to settle disputes after 60 days.

AUDITEE'S RESPONSE AND OIG COMMENTS

The HHSS did not concur with most of our findings and recommendations. Their comments are summarized below and included in their entirety as Appendix A.

1) **Develop a subsidiary accounts receivable system that details all drug rebate transactions, including adjustments. And,**

2) **Reconcile the general ledger control account to the subsidiary ledgers and to the Form CMS 64.9R.**

Auditee Response:

The HHSS stated that the credit balance of $7.5 million cited in the OIG report was due to adjustments on the quarterly CMS tape, which were further adjusted on tapes from subsequent quarters. According to them, the CMS adjustments were not controlled by HHSS, but were posted to the general ledger and subsidiary accounts as required.

The HHSS asserted that the general ledger control account ***can*** be reconciled to the subsidiary ledger at any point in time but that would be redundant because their software posts each transaction to both the general ledger and the subsidiary ledger at the same

time. Furthermore, the HHSS contended that the general ledger control account was the source for data reported on the Form CMS 64.9R.

OIG Comments:

The HHSS did not regularly maintain a general ledger control account. They posted drug rebate collections and receivables to the general ledger once a year from a summary report of their computerized subsidiary ledger. That summary report was what they considered to be a general ledger control account.

A general ledger control account should be part of the State's formal accounting system characterized by dual entries to actual accounts that flow directly into the State's financial statements. Actual account receivable totals from the general ledger should have been reconciled regularly to the subsidiary ledger. That reconciliation would involve identifying and posting ***actual adjustments*** from the subsidiary ledger system. Such reconciliations were necessary to ensure that errors such as mis-postings, unauthorized adjustments or omitted transactions were detected in a timely manner.

The following table shows the unsupported adjustments and compares the balances reported on the Form CMS 64.9R and those entered in the subsidiary ledger for the period ended June 30, 2002.

Comparison of Drug Rebate Balances

	Qtr Ending 6/30/2002	Qtr Ending 3/31/2002	Qtr Ending 12/31/2001	Qtr Ending 9/30/2001	Prior Periods	Total
Unsupported Adjustments						
64.9R	$ -0-	$ (9,273,707)	$28,201,919	$(7,444,014)	$(11,244,242)	$ 239,956
Balances						
64.9R	10,023,143	94,046	344,122	770,824	(8,748,286)	2,483,850
Ledger	-0-	94,046	344,122	770,824	1,274,858	2,483,850
Variance	**$10,023,143**	**$ -0-**	**$ -0-**	**$ -0-**	**$(10,023,144)**	**$ -0-**

This condition would not have occurred if the HHSS had properly posted receivables to the State's general ledger regularly and, as a control measure, regularly reconciled the general ledger receivable amount to the subsidiary ledger. An additional reconciliation to the Form CMS 64.9R would insure that the actual amounts recorded in the State's general ledger were accurately reported to CMS.

3) Reconcile the quarterly cash receipts log to the Form CMS 64.9R.

Auditee Response:

The HHSS asserted that this recommendation was contrary to our finding.

OIG Comments:

There was no contradiction between our finding and our recommendation. We reported that the HHSS did reconcile the cash receipts log but that it was not included in their written policies and procedures. Our recommendation was that the HHSS "develop and follow policies and procedures that include...reconciling the quarterly cash receipts log to the Form CMS 64.9R." We believe it is important to document written procedures to ensure that controls are maintained in the event of employee turnover.

4) Estimate and accrue interest on all overdue rebate balances.

Auditee Response:

The HHSS stated that they collected and reported interest on settled disputes and late rebate payments, but interest on disputed rebate amounts was not owed until settlement is determined.

OIG Comments:

The HHSS did not respond directly to our recommendation. We agree that interest should not be considered for disputed rebate amounts until a settlement is determined. However, we believe that merely collecting and reporting interest is not sufficient. The HHSS should estimate, accrue, and re-bill if necessary, interest on late or unpaid rebate amounts that are not in dispute.

5) Report interest collections on the Form CMS 64 Summary Sheet.

Auditee Response:

The HHSS concurred with the finding and recommendation and has taken appropriate corrective action.

6) Utilize the State's hearing mechanism to settle disputes after 60 days.

Auditee Response:

The HHSS agreed to take appropriate corrective action.

Sincerely,

Thomas L Sattler for

James P. Aasmundstad
Regional Inspector General
for Audit Services

NEBRASKA HEALTH AND HUMAN SERVICES SYSTEM
DEPARTMENT OF SERVICES • DEPARTMENT OF REGULATION AND LICENSURE
DEPARTMENT OF FINANCE AND SUPPORT

STATE OF NEBRASKA
MIKE JOHANNS, GOVERNOR

May 14, 2003

James P. Aasmundstad
Office of Inspector General for Audit Services
Region VII
601 East 12th Street, Room 284A
Kansas City, MO 64106

Dear Mr. Aasmundstad

The Nebraska Health and Human Services System (HHSS) has received and reviewed your Draft Report entitled "Audit of the Medicaid Drug Rebate Program in Nebraska", Report Number A-07-03-04013. The Department does not agree that the HHSS lacked sufficient controls with regard to the Medicaid drug rebate program. We have the following responses to the Draft Report's Findings and Recommendations:

OIG FINDING: Recording Accounts Receivable
OIG RECOMMENDATION: Develop a subsidiary accounts receivable system that details all drug rebate transactions, including adjustments.
HHSS RESPONSE:
A detailed subsidiary accounts receivable system already exists. Enclosure #1 is a sample copy of a manufacturer's individual accounts receivable report. Each quarter's transactions are supported by detailed information on the manufacturer's various Drug Rebate Invoice Reports (samples included with Enclosure #1). These reports contain specific invoice, payment and adjustment information which are documented with additional on-line data and hard-copy documentation located in our files. All of this information was available for inspection at the time of the field audit.

Enclosure #2 contains copies of all CMS 64.9R reports for the quarters ended 9/30/01 to 3/31/03. The 6/30/02 credit balance of $7.5 million for receivables outstanding for 90 days or longer, cited in the OIG Draft Report, was due to adjustments on the quarterly CMS tape which were further adjusted on tapes from subsequent quarters. These CMS adjustments are not controlled by HHSS, but are posted to our general ledger and subsidiary ledger accounts, as required.
The balance for receivables outstanding for 90 days or longer at 3/31/03 was a debit balance of $3.3 million.

OIG FINDING: Form CMS 64.9 R and General Ledger Reconciliations
OIG RECOMMENDATIONS: 1. Reconcile the general ledger control account to the subsidiary ledgers and to the Form CMS 64.9R.
2. Reconcile the quarterly cash receipts log to the Form CMS 64.9R.

HHSS RESPONSE:
The general ledger control account can be reconciled to the subsidiary ledgers at any point in time. Enclosure #3 reconciles the ledgers as of May 13, 2003. The software package used by the HHSS posts each accounts receivable transaction to both the general ledger and to the appropriate manufacturer account in the accounts receivable subsidiary ledger. These systems and procedures were available for inspection at the time of the field audit.

The general ledger control account is the source of data on the Form CMS 64.9R, making a reconciliation somewhat redundant (see Enclosure #4).

The second recommendation is contrary to the findings. As stated in the Findings and Recommendations section of the OIG Draft Report, "However, the HHSS did reconcile the rebate collections on the cash receipts log to the collections reported on the Form CMS 64.9R."

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

OIG FINDING: Interest Accrual, Collection and Reporting
OIG RECOMMENDATIONS: 1. Estimate and accrue interest on all overdue rebate balances. **2.** Report interest collections on the Form CMS 64 Summary Sheet.
HHSS RESPONSE:
HHSS collects and reports interest on settled disputes and late rebate payments. The HHSS does not calculate and accrue interest on unsettled disputes as these amounts constantly change and are not owed until the dispute is settled.

Interest collections are currently being reported on the Form CMS 64 Summary Sheet. See Enclosure # 7, (quarter ended 3/31/03; reported $94 of interest recoveries).

OIG FINDING: Dispute Resolution
OIG RECOMMENDATION: Utilize the State's hearing mechanism to settle disputes after 60 days.
HHSS RESPONSE:

The HHSS agrees that it did not utilize state hearings to resolve disputes as required by the rebate agreement.

The HHSS agrees that it did not establish procedures for using the state hearing mechanism.

The HHSS agrees that it contacted manufacturers directly and attended drug rebate dispute resolution meetings. HHSS understands that manufacturers were not required to attend these dispute resolution meetings.

The HHSS disagrees that there are no incentives to resolve claims and that there were no other sanctions provided in the regulations. The HHSS believes that the imposition of interest charges on late payments was the mechanism established by OBRA 90 to incentivize manufacturers to resolve claims. In addition, the State has acted to suspend coverage of manufacturers' drugs who were recalcitrant to requests to resolve disputes.

The HHSS will establish procedures for using the State hearing mechanism to resolve disputes as required by the rebate agreement.

Sincerely,

Robert J. Seiffert, Administrator

enclosures

ACKNOWLEDGMENTS

Report Number: A-07-03-04013
Review of the Medicaid Drug Rebate Program in Nebraska

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