DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General
Offices of Audit Services

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

FEB 2 6 2004

From: Regional Inspector General for Audit Services, Region VII

Subject: Region VII Rollup Report for 4-State Review of Medicaid Drug Rebate Collections (Report Number: A-07-03-04010)

To: Mr. Joe Tilghman
Regional Administrator
Centers for Medicare & Medicaid Services

Attached are two copies of our final regional rollup report presenting the results of our self-initiated audits of Medicaid drug rebate programs operated by the State agencies in Iowa, Nebraska, Missouri, and Kansas.

The objective of the audit was to determine whether the State agencies in Region VII had established adequate accountability and controls over their respective Medicaid drug rebate programs.

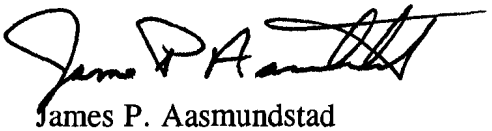
Three of the four State agencies (Iowa, Nebraska, and Kansas) had not established adequate accountability and controls over their Medicaid drug rebate programs. As a result, there was no assurance that all drug rebates due the State agencies were collected. Title 45 Sec. 74.21 paragraph (b)(3) of the Code of Federal Regulations requires that financial management systems provide for effective control over and accountability for all funds, property, and other assets.

We recommended that CMS follow up on each of the recommendations made to the States to ensure that corrective action is implemented by each State agency. CMS concurred with our findings and recommendations and have begun monitoring the States' progress in taking appropriate corrective actions. The CMS Region VII Office provided a written response to our recommendations and their response is included in its entirety as Appendix A.

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-07-03-04010 in all correspondence relating to this report.

Sincerely,



James P. Aasmundstad
Regional Inspector General
for Audit Services

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REGION VII ROLLUP REPORT FOR 4-STATE REVIEW OF MEDICAID DRUG REBATE COLLECTIONS

FEBRUARY 2004
A-07-03-04010

Office of Inspector General

http://oig.hhs.gov/

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The OIG's Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout the Department.

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The OIG's Office of Evaluation and Inspections (OEI) conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The findings and recommendations contained in the inspections reports generate rapid, accurate, and up-to-date information on the efficiency, vulnerability, and effectiveness of departmental programs.

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The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. The OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within the Department. The OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops model compliance plans, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

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 information contained therein 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 awarding agency will make final determination on these matters.

EXECUTIVE SUMMARY

OBJECTIVE

The audit objective was to determine whether the four State agencies in Region VII (Missouri, Kansas, Iowa and Nebraska) had established adequate accountability and internal controls over their respective Medicaid drug rebate programs. Individual reports were issued to each State agency, and this report summarizes the issues identified in those reports.

SUMMARY OF FINDINGS

Three of the State agencies had not established adequate accountability and controls over their Medicaid drug rebate programs. As a result, there was no assurance that all drug rebates due to those States were collected. Missouri had generally established adequate controls and procedures. However, we did make specific recommendations regarding their program to address minor weaknesses.

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.

Specifically, the weaknesses we reported included:

- Recording accounts receivable (Kansas, Iowa and Nebraska);
- Reconciling the Form CMS 64.9R to the general ledger (all four States);
- Interest accrual, collection and/or reporting (all four States);
- Dispute resolution (Missouri, Iowa and Nebraska);
- Records retention (Iowa);
- Reporting rebates received (Iowa); and
- Invoice verification (Kansas).

Specific recommendations were made to each of the State agencies that addressed the weaknesses described above. Missouri and Kansas generally agreed with the findings and recommendations and indicated that corrective action had been enacted or was planned. Iowa and Nebraska did not fully concur with our findings and appeared reluctant to adopt our recommendations.

RECOMMENDATION

The Medicaid drug rebate program produces millions of dollars each quarter for each State agency and is a very complex program. Thus, the State agencies should ensure that proper policies, procedures, and controls exist to safeguard program funds. We believe the corrective action we recommended will provide State agencies the opportunity to increase drug rebate revenue and report more reliable accounts receivable information to

CMS. Therefore, we recommend that CMS follow up on each of the recommendations and ensure that corrective action is implemented by each State agency.

CMS concurred with our findings and recommendations and have begun monitoring the States' progress in taking appropriate corrective actions. The CMS Region VII Office provided a written response to our recommendations and their response is included in its entirety as Appendix A.

INTRODUCTION

BACKGROUND

On November 5, 1990, Congress enacted the Omnibus Budget Reconciliation Act of 1990 legislation, which among other provisions established the Medicaid drug rebate program. Responsibility for the rebate program is shared among the drug manufacturer(s), the Centers for Medicare and Medicaid Services (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 its average manufacturer price and best price information for each covered outpatient drug to CMS. 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 a record of the units dispensed, by manufacturer, for each covered drug. Approximately 56,000 National Drug Codes (NDCs) are available under the program. Each State agency uses the URA from CMS and the 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 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, accounts receivable and rebate collection information for the drug rebate program 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.

For the 1-year period ending June 30, 2002, the four States in Region VII reported to CMS on their Forms CMS 64.9R, average billings totaling more than $67.4 million and average collections totaling nearly $70.5 million per quarter. These States also reported an accounts receivable balance for the drug rebate program totaling nearly $58.9 million.

The State agencies responsible for the drug rebate program in Region VII are:

- Missouri-Department of Social Services, Division of Medical Services;
- Kansas-Department of Social and Rehabilitation Services;
- Iowa-Department of Human Services; and
- Nebraska-Health and Human Services System.

OBJECTIVE, SCOPE AND METHODOLOGY

Objective

The audit objective was to determine whether the four State agencies in Region VII had established adequate accountability and internal controls over their respective Medicaid drug rebate programs. Individual reports were issued to each State agency, and this report summarizes the issues identified in those reports.

Scope

The drug rebate program was effective January 1, 1991. We concentrated our review on the current policies, procedures and controls of each State agency. We also reviewed accounts receivable information related to prior periods and interviewed staff of each State agency to understand how the Medicaid drug rebate program was administered in each State.

Methodology

Our audit was performed in accordance with generally accepted government auditing standards. To accomplish our objective we interviewed State agency officials to determine the policies, procedures and internal controls that existed with regard to the Medicaid drug rebate program. We also interviewed staff that performed functions related to the drug rebate program for each State. In addition, we obtained and reviewed accounts receivable records and compared that data to the Form CMS 64.9R reports filed by each State for the year ended June 30, 2002.

Fieldwork for this review was performed on-site at each State agency and in our field offices from October 2002 through March 2003. The State agencies were located in Jefferson City, Missouri; Topeka, Kansas; Lincoln, Nebraska; and Des Moines, Iowa.

FINDINGS AND RECOMMENDATION

Three of the State agencies had not established adequate accountability and controls over their Medicaid drug rebate programs. As a result, there was no assurance that all drug rebates due to those States were collected. Missouri had generally established adequate controls and procedures. However, we did make specific recommendations regarding their program to address minor weaknesses.

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.

Specifically, the weaknesses we reported included:

- Recording accounts receivable (Kansas, Iowa and Nebraska);
- Reconciling the Form CMS 64.9R to the general ledger (all four States);
- Accounting for interest on late rebate payments (all four States
- Dispute resolution (Missouri, Iowa and Nebraska);
- Records retention (Iowa);
- Reporting rebates received (Iowa); and
- Invoice verification (Kansas).

Specific recommendations were made to each of the State agencies that addressed the weaknesses described above. Missouri and Kansas generally agreed with the findings and recommendations and indicated that corrective action had been enacted or was planned. Iowa and Nebraska did not fully concur with our findings and appeared reluctant to adopt our recommendations.

Criteria

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.

Recording Accounts Receivable

The three State agencies in Iowa, Nebraska and Kansas did not regularly maintain a general ledger control account for uncollected drug rebates. 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. Proper utilization of a general ledger control account is necessary to provide effective control and accountability for the receivable and to ensure that the receivables are properly reported in their financial statements.

We recommended that each of these State agencies develop and utilize a general ledger control account for Medicaid drug rebate receivables.

Form CMS 64.9R Reconciliations

None of the four State agencies performed routine reconciliations of their receivable balance between the Form CMS 64.9R, the general ledger control account, and the subsidiary ledger.

We recommended that each State agency reconcile the receivable balance reported in their general ledger control account to the detail totals reflected in the subsidiary ledger and to the amount reported to CMS on the Form CMS 64.9R.

Accounting for Interest on Late Rebate Payments

None of the four State agencies calculated and accrued interest for late or disputed payments as required by Federal rules and regulations, nor did they recalculate interest voluntarily paid by manufacturers to verify that the correct amounts were paid. The rebate agreement between CMS and drug manufacturers requires interest to be paid for late rebates. Additional guidance from CMS stated that it is the manufacturer's responsibility to calculate and pay interest for applicable rebate invoices and the State's responsibility to track collections and report these amounts to CMS.

However, the States did not make significant efforts to collect from manufacturers that did not voluntarily remit interest owed nor did they verify that interest remitted by the manufacturers was computed correctly. As a result, their drug rebate receivables were perpetually understated, and it is likely that they did not receive all interest owed by the manufacturers.

In addition, the three State agencies in Iowa, Nebraska and Kansas had not established procedures to report interest received as required by Federal rules and regulations. According to the State Medicaid Manual, interest should be reported separately on the Form 64 summary sheet. Instead, those States included interest as a rebate collection on their Form CMS 64.9R.

Reporting interest revenue on the Form CMS 64.9R caused drug rebate collections to be overstated and their receivable balances were understated for all quarterly results that were reported using that methodology.

We recommended that each State accrue interest owed to them, recalculate and verify interest paid to them and report interest collections on the Form 64 summary sheet as required.

Dispute Resolution and Collection

The State agencies of Iowa, Nebraska and Kansas did not offer their State hearing mechanisms to resolve disputes as required by the Medicaid rebate agreement. Instead, they contacted some manufacturers directly and also attended Dispute Resolution Program (DRP) meetings to resolve disputes with those manufacturers who attended. Because manufacturers were not required to attend DRP meetings, and there were no other sanctions provided in the regulations, there were no incentives for the manufacturers to resolve claims.

We recommended that the States offer manufacturers the State's hearing mechanism to resolve disputes as required by the rebate agreement and we believe they could increase collections by doing so.

Records Retention

The State agency in Iowa did not adequately retain records pertaining to the Medicaid drug rebate program as required by Federal regulations.

Necessary drug rebate records were not adequately maintained because Iowa did not have effective policies and procedures to ensure that their contractors maintained proper records. Iowa's current fiscal agent did not pursue the collection of receivables totaling $547,456 because they inherited responsibility for these receivables from the previous fiscal agent and they had determined that the records supporting these receivables were missing or incomplete.

We recommended that the State develop policies and procedures to ensure that records are kept for an appropriate period of time.

Reporting Rebates Received

The State agency in Iowa reported inaccurate drug rebate collections on its Form CMS 64.9R. Specifically, they did not report collections made by their fiscal agent for the final month of a quarter on the Form CMS 64.9R for that quarter. Rather, they reported those collections in the following quarter.

Government Accounting and Financial Reporting standards require the States to use the modified accrual method and to accrue revenue when it is measurable and available.

Rebate checks were deposited in a State account managed by the fiscal agent and a single check was sent to the State agency the following month. For example, the State agency received a check from ACS, for June collections, dated July 10, 2002 which could have been reported on the Form CMS 64.9R for the quarter ending June 30, 2002. However, the DHS did not report June collections until the September 30, 2002 Form CMS 64.9R resulting in a $3 million overstatement of receivables and a $3 million understatement of collections for the June quarter.

We recommended that the State agency report collections in the proper time period.

Invoice Verification

The State agency in Kansas sent inaccurate drug rebate invoices to manufacturers during the first quarter of 2002 because drug utilization figures were not added to the drug rebate subsidiary records for several weeks during 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.

We recommended that the State agency develop policies and procedures to ensure that drug utilization data is included each quarter in the invoices they submit to the manufacturers.

RECOMMENDATION

Missouri and Kansas generally agreed with the findings and recommendations and indicated that corrective action had been enacted or was planned. Iowa and Nebraska did not fully concur with our findings and appeared reluctant to adopt our recommendations. Copies of our reports, including the States' responses to our findings, are available at http://oig.hhs.gov.

The Medicaid drug rebate program produces millions of dollars each quarter for each State agency and is a very complex program. Thus, the State agencies should ensure that proper policies, procedures, and controls exist to safeguard program funds. We believe the corrective action we recommended will provide State agencies the opportunity to increase drug rebate revenue and report more reliable accounts receivable information to

CMS. Therefore, we recommend that CMS follow up on each of the recommendations and ensure that corrective action is implemented by each State agency.

AUDITEE RESPONSE

CMS concurred with our findings and recommendations and have begun monitoring the States' progress in taking appropriate corrective actions. The CMS Region VII Office provided a written response to our recommendations and their response is included in its entirety as Appendix A.

Appendix

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
601 East 12th Street
Kansas City, Missouri 64106

CENTERS for MEDICARE & MEDICAID SERVICES

MEMORANDUM

Date: February 18, 2004

From: Regional Administrator
Centers for Medicare and Medicaid Services

Subject: Region VII Rollup Report – Four State Review of Medicaid Drug Rebate Collections

To: Jim Aasmundstad
Regional Inspector General for Audit Services, Region VII

On December 4, we responded to your draft report dated October 30, 2003. At that time, we commented on the specific recommendations made to each of the state agencies for this region. Your report indicated that Missouri and Kansas generally agreed with the recommendations of your report and that corrective action is being planned or had been enacted. Iowa and Nebraska did not fully concur with your recommendations.

At the time of our initial response, we indicated that we would be working with the states as they continued in their process to either implement corrective actions or to respond to assertions in your report.

This is an update on actions taken by the states regarding your report. At this time, only Missouri has any changes to report.

Missouri

The accountant assigned to Missouri has cleared the Missouri Drug Rebate Audit. Missouri's response covers the following points:

1. The State has amended the CMS form 64 to reflect a total receivable balance of $32.6 Million.
2. The State has agreed to compare the balance in the G/L control account to the balance in the subsidiary ledger on the same date, but did not agree to reconcile the A/R reported on the CMS 64.9R because of different cut-off dates.
3. The State did not agree to utilize the State hearing mechanism to settle disputes because final CMS guidance to do this has never been issued.
4. The State did not agree to accrue for interest on overdue rebate balances because it would inflate the A/R balance but did agree to invoice the drug companies for estimated amounts of interest.

Kansas

No change from the last report. The assigned accountant is working with the State to reconcile noted problems.

Iowa

A meeting had been held with the Iowa Audit Coordinator previously and the 8 findings were reviewed at that time. They have agreed to work on the resolution of the observed findings and will report at a future date.

Nebraska

It was previously reported that Nebraska did not agree with five of the six recommendations. Their position remains the same. CMS will continue to work with the State as they prepare a response to the comments contained in the report.

If you have any questions, please contact Tom Lenz, Associate Regional Administrator, at 816/426-6463.

Joe Tilghman