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 6, 2003

Report Number A-07-03-04011

Mr. Gregory A. Vadner, Director
Missouri Department of Social Services
Division of Medical Services
P.O. Box 6500
Jefferson City, MO 65102-6500

Dear Mr. Vadner:

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 Missouri."*

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-07-03-04011 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

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 MISSOURI

JANET REHNQUIST
INSPECTOR GENERAL

MAY 2003
A-07-03-04011

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

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May 6, 2003

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Report Number A-07-03-04011

Mr. Gregory A. Vadner, Director
Missouri Department of Social Services
Division of Medical Services
P.O. Box 6500
Jefferson City, MO 65102-6500

Dear Mr. Vadner:

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

EXECUTIVE SUMMARY

OBJECTIVE

The audit objective was to evaluate whether the Missouri Department of Social Services, Division of Medical Services (DMS) had established adequate accountability and internal controls over the Medicaid drug rebate program.

FINDINGS

We determined the DMS had adequate controls over the drug rebate program as required by Federal regulations except for the following areas:

- Form CMS 64.9R and the general ledger reconciliation.
- Dispute resolution.
- Interest accrual and collection.

These issues occurred because the DMS 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 CMS and the drug manufacturers require the payment of interest on all disputed, late, and unpaid drug rebates, and the use of the State hearing mechanism to resolve disputes.

Our review showed that drug rebate receivables were perpetually understated and it is likely that the DMS did not receive all drug rebates and interest on disputed or late rebate payments due from manufacturers. In addition, without routine reconciliations, the DMS did not have reasonable assurance that the rebate receivables were effectively safeguarded.

RECOMMENDATIONS

We recommend the DMS:

- Amend the Form CMS 64.9R to reflect a total receivable balance of $32,611,144.
- Reconcile the general ledger control account to the subsidiary ledgers/records and to the Form CMS 64.9R.
- Develop policies and procedures, changing regulations if necessary, to utilize a State hearing mechanism to settle disputes.
- Estimate and accrue interest on all overdue rebate balances.

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 the 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. 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 the current and prior quarters on the Form CMS 64.9R.

The DMS reported a receivable balance of $33,787,765 on the June 30, 2002 Form CMS 64.9R. Interest collected by DMS from the manufacturers was reported on the Form CMS 64 Summary Sheet. The DMS reported $116,309,974 in collections for the 12-month period ending June 30, 2002.

The DMS contracted with its fiscal intermediary to prepare and mail the rebate invoices to manufacturers, but performed all other functions of the drug rebate program. The Drug Rebate Unit was responsible for 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. Staff in other departments separately performed the functions of depositing funds and preparing the Form CMS 64 reports.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objectives

The audit objective was to evaluate whether the DMS 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 DMS. We also reviewed accounts

receivable information related to prior periods and interviewed DMS staff to understand how the Medicaid drug rebate program has operated since 1991.

Methodology

To accomplish our objectives, we interviewed DMS 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 DMS office in Jefferson City, Missouri during October and November 2002.

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

FINDINGS AND RECOMMENDATIONS

We determined the DMS had adequate controls over the drug rebate program as required by federal regulations except for the following areas:

- Form CMS 64.9R and the general ledger reconciliation.
- Dispute resolution.
- Interest accrual and collection.

INTERNAL CONTROLS

Form CMS 64.9R and General Ledger Account Reconciliations

The DMS 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. Moreover, the DMS did not routinely reconcile the general ledger account balance to the detailed subsidiary accounts receivable records.

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 Missouri Department of Social Services, Division of Budget and Finance prepared the Form CMS 64.9R based on data it received from the DMS. However, the DMS did not reconcile the rebate figures reported to CMS to a general ledger control account. Moreover, there was no reconciliation between the drug rebates received from manufacturers and the drug rebate collections reported on the Form CMS 64.9R.

In addition, the general ledger control account balance for manufacturer drug rebates receivable was not reconciled to the total of all subsidiary accounts receivable accounts for each manufacturer. The DMS does not believe this reconciliation is necessary because the subsidiary ledger acts in concert with the general ledger by posting the same amount to the general and subsidiary ledgers simultaneously. However, in any computerized system, there is a risk for changing the flow of information as programming changes, upgrades, or other adjustments are made to the system.

Without routine reconciliations, the DMS does not have reasonable assurance that receivables were adequately safeguarded or that drug rebate information reported to CMS was accurate. For example, the Form CMS 64.9R filed by the DMS for the quarter-ending June 30, 2002, reported drug rebate receivables totaling $33,787,765. That amount was $1,176,621 greater than the amount ($32,611,144) reported on their *Drug Rebate Outstanding Balance Report* for June 30, 2002.

DISPUTE RESOLUTION

The State did not utilize State hearings to resolve disputes as required by the rebate agreement. Specifically, the rebate agreement requires that the State and the manufacturers resolve rebate discrepancies within 60 days of receipt of notification of a dispute. 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 DMS did not use this State hearing mechanism, but instead, contacted manufacturers directly, and used Dispute Resolution Project (DRP) meetings for those manufacturers who attended. State officials said they could not use the State hearing mechanism for the collection of disputed drug rebates until State regulations are changed to allow hearings for this use. To justify a regulation change, they believe that Medicaid Drug Rebate Regulations should be finalized.

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 that the DMS could increase its drug rebate collections by using the State Hearing mechanism.

INTEREST

The DMS 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 standards require the States to accrue revenue (interest) when it is measurable (a reasonable estimate) and available.

The DMS 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 DMS did not accrue revenue as required, the drug rebate receivables were perpetually understated, and it is likely that the DMS did not receive interest owed by the manufacturers.

RECOMMENDATIONS

We recommend the DMS:

- Amend the Form CMS 64.9R to reflect a total receivable balance of $32,611,144.
- Reconcile the general ledger control account to the subsidiary ledgers/records and to the Form CMS 64.9R.
- Develop policies and procedures, changing regulations if necessary, to utilize a State hearing mechanism to settle disputes.
- Estimate and accrue interest on all overdue rebate balances.

AUDITEE'S COMMENTS

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

1) **Amend the Form CMS 64.9R to reflect a total receivable balance of $32,611,144.**

The DMS concurred that the June 30, 2002 balance should be corrected to reflect a total receivable balance of $32,611,144 and have indicated the appropriate adjustment was made on the September 30, 2002 Form CMS 64.9R.

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

The DMS agreed to compare the balance in the general ledger control account to the balance in the subsidiary ledger on the same date to ensure that the balances reconcile. However, the DMS did not agree to reconcile the accounts receivable balances reported on the CMS Form 64-9R to the general ledger because of different cutoff dates that would make the process extremely difficult.

3) **Develop policies and procedures, changing regulations if necessary, to utilize a State hearing mechanism to settle disputes.**

The DMS asserted that the State's hearing process was not required for dispute resolution because (1) the Medicaid drug rebate program rules were never finalized, (2) OBRA Section 1927 did not legislate timelines for dispute resolutions or hearings, and (3) the hearing mechanism is only imposed by the rebate agreement at the manufacturer's request.

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

The DMS contended that it fulfilled its obligation to collect and report interest paid to CMS. However, DMS asserted that accruing "estimated" interest owed could easily inaccurately inflate balances on the accounts receivable. They further asserted that the rebate agreement is a contract between the CMS and the manufacturers and that it is CMS' responsibility to ensure both the accuracy and payment of interest. However, they did agree to invoice estimated interest and to re-calculate interest payments received from manufacturers to verify the amounts remitted. The methodology for calculating interest will be implemented in April 2003.

OIG RESPONSE

1) **Amend the Form CMS 64.9R to reflect a total receivable balance of $32,611,144.**

The DMS' correction to the Form CMS 64.9R resolves this issue.

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

Reporting requirements put forth in the State Medicaid Manual section 2500.7, part B, required "complete, accurate, and full disclosure" of all drug rebates and collections. To ensure that the drug rebate balances and collections reported to CMS on Form 64-9R are accurate and complete, we believe that the DMS needs to add a reconciliation procedure to verify the rebate data on the CMS 64-9R is accurate

3) **Develop policies and procedures, changing regulations if necessary, to utilize a State hearing mechanism to settle disputes.**

State officials indicated that they have not received any requests for a hearing from a manufacturer. However, there is no provision in the rebate agreement that requires a manufacturer to request a hearing. Instead, the manufacturer is required to notify the State, in writing, of any unresolved discrepancies prior to the due date. Furthermore, the rebate agreement states that 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.

Some manufacturers interpret these provisions to mean the disputes are automatically resolved in their favor if the States do not formally respond to their written disputes within 60 days offering a hearing. Therefore, we believe, at a minimum, the DMS should offer the State hearing mechanism to settle disputes when the State has received a written notice of dispute from a manufacturer.

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

We commend the DMS for the considerable efforts it has made to automate the interest computation process that were in process prior to the audit. However, we disagree with the DMS' position that the rebate agreement is a contract between CMS and the manufacturer. We believe that the States are parties to these agreements as well. Specifically, the Social Security Act, Section 1927, states: "In order for payment to be available under section 1903(a) for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer)..."

Although DMS has agreed to invoice for interest in the future, DMS officials have determined that accruing the interest could inaccurately inflate balances on the accounts receivable. We agree with DMS' decision to not record interest that is in dispute if they do not expect to collect it. However, we believe that DMS should consider accruing interest on receivables that are delinquent if the manufacturer has not notified the State of a dispute.

Sincerely,

James P. Aasmundstad

James P. Aasmundstad
Regional Inspector General
for Audit Services

BOB HOLDEN
GOVERNOR

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March 26, 2003

James P. Aamundstad
Regional Inspector General
for Audit Services
Office of Inspector General
Federal Office Building
601 East 12th Street, Room 284A
Kansas City, MO 64106

Re: A-07-03-04011

Dear Mr. Aasmundstad:

This letter is in response to the recommendations in the March 7, 2003 draft report entitled, "Audit of the Medicaid Drug Rebate Program in Missouri." Enclosed please find detailed responses to the recommendations listed in the above named report.

Please feel free to contact Michael Rehagen, Assistant Deputy Director, Division of Medical Services at 573-526-4383 if you have additional questions.

Sincerely,

Gregory A. Vadner
Director

GAV/rjs

Enclosure

Audit of the Medicaid Drug Rebate Program in Missouri

1. Amend the quarter-ending June 30, 2002 Form CMS 64.9R to reflect a total receivable balance of $32,611,144.

Response: The incorrect balance ($33,787,765) originally reported for the quarter ending June 30, 2002 was corrected and included in the balance reported ($40,425,357) on the CMS 64.9R filed for September 30, 2002.

2. Reconcile the general ledger control account to the subsidiary ledgers/ records and the form CMS 64.9R.

Response: The Division of Medical Services (DMS) does not agree that a routine reconciliation of the "general ledger" and the "subsidiary ledger" is necessary as it considers its accounts receivable to be the same ledger. Both reports identified in this finding are from the same source document so would have the same balances if generated on the same date. The CMS 64.9R requires balances as of the end of the reporting quarter (i.e., March 30, June 30, September 30, December 30) and drug rebate reports were requested to obtain that data. The financial reports generated in the accounting area required balances to be reported for the close of the state quarter (i.e., March 15, June 15, September 15, December 15). Consequently, the balances would not match, even though the same database was used because the accounts receivable is constantly revolving. It would be extremely difficult to reconcile the transactions that occurred during the two-week lag.

DMS will generate reports GMQC 8170-R001 "Drug Rebate Outstanding Balance Report" and GMDM 3100-R001 "Accounts Receivable Summary Report" on the same date to ensure the "general ledger" account balance report and the detailed "subsidiary" accounts receivable report reconcile.

3. Develop policies and procedures, changing regulations if necessary, to utilize a state hearing mechanism to settle disputes.

Response: OBRA 90 Section 1927 did not legislate any time lines for dispute resolution or a State hearing process. In addition, the Centers for Medicare and Medicaid Services (CMS) has not published final rules or regulations for the Medicaid Drug Rebate program that was implemented in 1991. To date, two proposed rules were drafted and never finalized. Eight years ago Missouri submitted comments to the first proposal concerning these areas within the thirty-day requirement. According to information from CMS – Baltimore, these proposed rules are not scheduled to be acted upon for at least this year and possibly next year and will likely be rewritten. It is not clear to the states or manufacturers that the time lines for dispute resolution and hearings will remain as proposed in the two regulations drafted.

The manufacturer agreement imposes the requirement that a hearing process be available if dispute resolution is not accomplished within 60 days at the manufacturer's request. To date, Missouri has not received a request for a hearing from a manufacturer.

Until the process is mandated by CMS through regulation and a mechanism provided to states to enforce the decision from a state hearing, DMS does not see the benefit of drafting its state rules and regulations for a hearing. OBRA90 does not allow a state to remove a manufacturer from the drug rebate program for failing to pay; only CMS has that authority.

The Missouri drug rebate collections are currently over 99% of the invoiced amount. The outstanding balances for quarters 1991 through 2001 total $545,886 and generally hold individual manufacturer balances that would not be cost effective to elevate to a hearing process on a quarterly basis. DMS staff efforts, along with the national Drug Rebate Dispute Resolution meetings (DRP) organized by CMS, are a more cost effective process than a state hearing process.

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

Response: DMS has fulfilled its obligation to collect and report to CMS interest paid to date in the drug rebate program as required by the Program Releases #29 and #65. Interest payments are tracked and monitored through the accounts receivable database for all quarters since the beginning of the program. The DMS has collected over $1 million in interest and estimates another $1 million is outstanding.

Efforts to collect interest from manufacturers are a focus after final dispute resolution has been accomplished as stated in Section V, paragraph (b) of the manufacturer rebate agreement. CMS drug rebate dispute resolution staff has stated interest is not due and cannot be accurately calculated until final payment has been made; interest can only be estimated prior to that time. To accrue "estimated" interest could easily inaccurately inflate balances on the accounts receivable.

It remains DMS' position that the contract agreement is between CMS and the manufacturer. It is CMS' responsibility to ensure the manufacturers are calculating and paying interest according to the terms of the agreement. However, realizing manufacturers do not calculate interest or may not calculate it accurately, DMS rebate staff is developing an accounts receivable enhancement to calculate interest. The new process will allow Missouri to invoice "estimated" interest due and compare interest received from manufacturers to our estimates. Because the methodology for calculating interest is complex, Missouri has spent over three years in its development. The enhancement will be implemented in April 2003.

ACKNOWLEDGMENTS

Report Number: A-07-03-04011
Audit of the Medicaid Drug Rebate Program in Missouri

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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Dan Owens, *Auditor*
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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.