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: Final Region VIII Rollup Report for 6-State Review of Medicaid Drug Rebate Collections (Report Number: A-07-04-04030)

To: Mr. Alex Trujillo
Regional Administrator
Centers for Medicare & Medicaid Services

The attached final regional rollup report presents the results of our self-initiated audits of Medicaid drug rebate programs operated by the State agencies in Colorado, Utah, Montana, North Dakota, South Dakota and Wyoming.

The objective of the audit was to determine whether the State agencies in Region VIII had established adequate accountability and 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.

Three of the six State agencies (Utah, Wyoming, and Montana) 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.

Specific recommendations were made to each of the State agencies that addressed drug rebate accountability and control weaknesses. All but one of the six State agencies generally agreed with our findings and recommendations and indicated that corrective action had been enacted or was planned. Wyoming did not fully concur with our findings and appeared reluctant to adopt our recommendations.

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 recommended that CMS follow up on each of the recommendations and ensure that corrective action is implemented by each State agency.

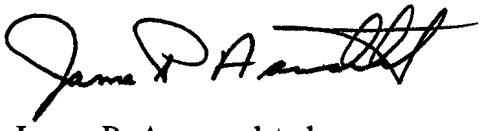
CMS concurred with our findings and recommendations and have begun monitoring the States' progress in taking appropriate corrective actions. The CMS Region VIII Office

provided a written response to our recommendations and your 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, OIG 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 Internet at *http://oig.hhs.gov*.

To facilitate identification, please refer to report number A-07-04-04030 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

6-STATE ROLLUP REVIEW OF MEDICAID DRUG REBATE COLLECTIONS

FEBRUARY 2004
A-07-04-04030

Office of Inspector General

http://oig.hhs.gov/

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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 six State agencies in Region VIII (Utah, Wyoming, Colorado, Montana, North Dakota, and South Dakota) 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.

FINDINGS

The State agencies in Utah, Wyoming and Montana 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. North Dakota, Colorado and South Dakota had generally established adequate controls and procedures. However, we did make specific recommendations regarding their programs 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 (Utah, Wyoming and Montana);
- Reconciling the Form CMS 64.9R to the general ledger (South Dakota, Utah, Wyoming and Montana);
- Interest accrual, collection and/or reporting (Utah, Wyoming and South Dakota);
- Dispute resolution (South Dakota, Utah, Wyoming and Montana
- Records retention (Utah and Colorado);
- Tracking and/or billing $0 unit rebate amounts (URA's) to ensure payment (All six State agencies);
- Segregation of Medicaid and non-Medicaid programs (Colorado); and
- Write-offs and Adjustments (South Dakota and Colorado).

Specific recommendations were made to each of the State agencies that addressed the weaknesses described above. All but one of the six State agencies generally agreed with our findings and recommendations and indicated that corrective action had been enacted or was planned. Wyoming did not 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 VIII 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. The 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. The 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 six States in Region VIII reported to CMS on their Form CMS 64 reports, average billings totaling more than $23.8 million and average collections totaling nearly $26.8 million per quarter. These States also reported an accounts receivable balance for the drug rebate program totaling nearly $16.5 million.

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

- Utah-Department of Health, Division of Health Care Financing;
- Wyoming-Department of Health-Pharmacy Unit;
- Montana-Department of Public Health and Human Services;
- North Dakota-Department of Human Services;
- Colorado-Department of Health Care Policy and Financing; and
- South Dakota-Department of Social Services, Office of Recoveries and Fraud Investigations.

OBJECTIVE, SCOPE AND METHODOLOGY

Objective

The audit objective was to determine whether the State agencies 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 October 2003. The State agencies were located in Salt Lake City, Utah; Denver, Colorado; Helena, Montana; Pierre, South Dakota, Bismarck, North Dakota, and Cheyenne, Wyoming.

FINDINGS AND RECOMMENDATION

We determined that three of the State agencies (Utah, Wyoming, and Montana) 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. North Dakota, South Dakota, and Colorado had generally established adequate controls and procedures. However, we did make specific recommendations regarding their programs 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 (Utah, Wyoming and Montana);
- Reconciling the Form CMS 64.9R to the general ledger (South Dakota, Utah, Wyoming and Montana);
- Interest accrual, collection and/or reporting (Utah, Wyoming and South Dakota);
- Dispute resolution (South Dakota, Utah, Wyoming and Montana);

- Records retention (Utah and Colorado);
- Tracking and/or billing $0 URA's to ensure payment (All six State agencies);
- Segregation of Medicaid and non-Medicaid programs (Colorado); and
- Write-offs and Adjustments (South Dakota and Colorado).

Specific recommendations were made to each of the State agencies that addressed the weaknesses described above. All but one of the six State agencies generally agreed with our findings and recommendations and indicated that corrective action had been enacted or was planned. Wyoming did not 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 State agencies in Utah, Wyoming, and Montana 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 States develop and utilize a general ledger control account for Medicaid drug rebate receivables.

Form CMS 64.9R Reconciliations

The State agencies in South Dakota, Utah, Wyoming and Montana did not perform 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

The State agencies in South Dakota, Utah and Wyoming 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. Wyoming incorrectly reported interest they collected as a drug rebate collection on the Form CMS 64.9R.

The rebate agreement between CMS and the drug manufacturers requires interest to be paid for late rebate payments. In addition, the CMS Medicaid Drug Rebate Program Release #65 states 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. Also, 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. Furthermore, according to the State Medicaid Manual, interest should be reported separately on the Form 64 summary sheet.

As a result, these State agencies' drug rebate receivables were perpetually understated, and it is likely that they did not receive interest owed by the manufacturers. As for Wyoming, reporting interest revenue on the Form CMS 64.9R caused their drug rebate collections to be overstated and their receivable balances to be understated for all quarterly results that were erroneously reported on the Form CMS 64.9R.

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

Dispute Resolution

The State agencies in South Dakota, Utah, Wyoming and Montana 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 agencies in Utah and Colorado did not adequately retain records pertaining to the Medicaid drug rebate program as required by Federal regulations. Title 45 Sec. 92.42 paragraph (b)(3) of the Code of Federal Regulations requires that records for a cooperative agreement (continued or renewed quarterly) be kept three years from:

> "…the day the grantee submits its expenditure report for the last quarter of the Federal fiscal year."

Furthermore, the CMS "Best Practices for Dispute Resolution" states that:

> "States should maintain completed and accurate records of all checks received, unit adjustments, write-offs, resolutions, interest paid, outstanding balances, and contacts with manufacturers. The lack of adequate and accurate documentation prolongs the process of rebate payment, as well as the process of resolution of disputes…. records should be maintained indefinitely at this point."

Colorado regularly adjusted invoices by hand before sending them to the manufacturers but did not retain the adjusted invoices as original records to support their subsidiary ledger. Utah routinely destroyed a reconciliation document that manufacturers were required to submit with their payments.

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

Tracking and/or Billing $0 URA's

None of the six State agencies had adequate controls in place to track $0 URA's and ensure that proper payment was made for them. For example, a 1998 internal audit of the State agency in Utah reported that 80 of 381 invoices reviewed contained $0 URA's, but payments had been received for only 18 of those invoices.

There was no consistent treatment of $0 URA's amongst the State agencies.

- The State agencies in Montana, South Dakota, North Dakota, and Utah generally treated unpaid $0 URA's as disputed items and were unable to distinguish between the two classifications without manually researching the history of the invoice. Disputed items are not subject to interest penalties until the dispute is settled. However, unpaid and undisputed $0 URA's are considered late payments that are subject to interest.

- The State agency in Wyoming considered an invoice containing $0 URA's as paid in full if the invoice total was remitted, even though $0 URA's were not reflected in that total.

- The State agency in Colorado often substituted an estimated amount for $0 URA's but did not keep a list of them to ensure accurate and timely payment.

- The State agency in Montana created incorrect receivable balances in their subsidiary records by updating the $0 URA's only as they received them from CMS tapes, without regard to whether or not they had received payment or if that payment was for a different amount.

As a result, the drug rebate receivables for each State agency were perpetually understated and it is likely that they did not receive all drug rebate payments due from manufacturers. At a minimum, the State agencies should maintain a list of all the $0 URA's that were not calculated and paid by the manufacturer as required in order to facilitate follow-up inquiries and to identify items that are subject to interest penalties.

We recommended that the State agencies develop policies and procedures to ensure that $0 URA's are adequately tracked until payments are received from the manufacturers.

Segregation of State/Federal Programs

The State agency in Colorado deducted 2.3 percent from Medicaid drug rebate collections for drugs related to the State's old age pension program. According to the CMS Medicaid Drug Rebate Program Guide:

Invoices must not reflect any NDCs paid for under:

1. *A state-funded only General Assistance program;*
2. *Other state-funded only programs; or*
3. *Other Federal drug rebate programs.*

We determined that the pension program was not Medicaid related and should not have participated in the Medicaid drug rebate program. As a result, the Medicaid drug rebate collections reported by the Department on the Form CMS 64.9R were inaccurate.

We recommended that the State agency develop policies and procedures to ensure the proper segregation between their State-funded only and Federal drug rebate programs.

Write-offs and Adjustments

The State agencies in South Dakota and Colorado made unallowable adjustments to their receivables. Such write-offs were not allowed by CMS program releases or program instructions.

The State agency in South Dakota routinely wrote-off disputed amounts with out regard to CMS requirements for up to $1000 per NDC prior to 1998. As a result, there may have been additional drug rebate receivables that should have been collected through the dispute resolution process.

The State agency in Colorado made unallowable adjustments for disputed or unpaid amounts if the manufacturer had paid at least 93 percent of the amount owed. As a result, there may have been additional drug rebates that should have been collected by the State agency and a portion remitted to the Federal government.

We recommended that the State agencies develop policies and procedures to ensure that they adhere to thresholds and requirements for any write-offs or adjustments as established by 45 CFR 74.21 (b) (1), (3) and CMS program release 19.

RECOMMENDATION

All but one of the six State agencies generally agreed with our findings and recommendations and indicated that corrective action had been enacted or was planned. Wyoming 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.

CMS concurred with our findings and recommendations and have begun monitoring the States' progress in taking appropriate corrective actions. The CMS Region VIII 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
Region VIII
1600 Broadway, Suite 700
Denver, Colorado 80202-4967

February 17, 2004

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

Dear Mr. Aasmundstad:

This letter is in regards to your memo dated December 18, 2003 regarding the Drug Rebate Audits your office completed for the States of Colorado, Montana, North Dakota, South Dakota, Utah and Wyoming. The official title of your reports is Draft Regional VIII Rollup Report for the 6 State Review of Medicaid Drug Rebate Collections (Report Number: A-07-04-04030). Please be advised the Regional Office is very appreciative of the fine work completed by your office of the Drug Rebate program in the States. The Region has completed a plan to assure follow up to the States on the Recommendations to the States in your reports.

Recommendations with State Concurrence:

Generally, the State's agreed with the auditor's recommendations. There were some notable exceptions and the next action step will address these exceptions. However for the recommendation with concurrence the Regional Office will take the following action.

Each State will receive a follow up letter acknowledging the States commitment to change and improve their Drug Rebate program. The Regional Office will request of the States that as each recommendation is implemented we be informed of the changes made to their program. In some cases the States indicated a time specific change and the Regional Office will monitor the States progress in meeting these self imposed timelines. In other cases the States did not indicate a time line for making the changes. The Regional Office will ask the States to be more specific as to when the change will occur.

Recommendations without State Concurrence:

There were three notable areas of non-concurrence with the Auditors recommendations.

The Colorado State Medicaid agency includes in their Medicaid rebate invoices drugs that are paid under the State only Old Age Pensioner program. The inclusion of such non-Medicaid expenditures in the drug invoices to manufactures in not in compliance with the Medicaid Drug Rebate guidelines. Colorado did not concur with Auditors recommendation that this practice be stopped as part the Medicaid Rebate program. The Regional Office recently discussed this issue

with Colorado, however the State remains unchanged in its position. The Regional Office intends to follow up with the State with a face-to-face meeting between Diane Livesay, Associate Regional Administrator and Vivianne Chaumont, Medicaid Director to reiterate the need for change in the current inclusion of non-Medicaid drug claims in the rebate program. This face-to-face meeting will occur in March 2004.

The Wyoming State Medicaid agency did not agree with any of the recommendations of the auditor. Many of the recommendations for the Wyoming Drug Rebate program were very similar to the recommendations made to the other States in the Region. Typically the States agreed to these common recommendations. Yet, Wyoming was not willing to accept the same changes in the Rebate program. Diane Livesay, Associate Regional Administrator is scheduled to meet with Iris Oleske, the Medicaid Director in March of 2004 to discuss the Drug Rebate report and begin the process of assisting the State with any corrective action.

The South Dakota State Medicaid agency did not agree with the characterization of past write offs in the Auditors report as being done in part for administrative convenience and not because the rebates invoices were incorrect. The Regional Office intends to re-examine these sizable write off amounts to assure they were appropriate under the CMS guidance governing drug rebate write offs. We intend to complete this activity by July 2004. If the write offs were inappropriate then the Regional Office will work with the State to revisit the rebates as appropriate.

In your report you asked the Regional office for any additional comments on the Drug Rebate Program. One comment we have for the report is to discuss in greater detail the informal drug rebate resolution process that is administered by CMS and has been very successful in resolving disputes. The informal process is a meeting convened by CMS with the active participation of the States and the Manufacturers. The participants sit down and review any outstanding disputes and typically come to an agreement on the amount of the rebates owed from the Manufacturers to the States. These highly successful meeting have been taking place for the past 9 years. The report may want to include information on these dispute resolution meetings and mention the need for a mechanism to coordinate this informal process with the requirement of formal State hearings.

If you have any questions regarding this letter please contact Diane Livesay at 303.844.7057 or via e-mail at dlivesay@cms.hhs.gov. . Please accept our appreciation for the fine work represented by your agency in these reports.

Sincerely,

Alex Trujillo
Regional Administrator
Denver Regional Office