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

Report Number A-07-03-04018

October 7, 2003

Ms. Vivianne Chaumont, Deputy Director
Department of Health Care Financing and Policy
1570 Grant Street
Denver, Colorado 80203-1818

Dear Ms. Chaumont:

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 Colorado."*

The audit objective was to evaluate whether the Colorado Department of Health Care Policy and Financing (Department) had established adequate accountability and internal controls over the Medicaid drug rebate program.

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

- Deductions for a State-funded only program.
- Billing and Tracking $0 unit rebate amounts (URAs).
- Adjustments.
- Records retention.

These issues occurred because the Department did not develop or follow adequate policies and procedures with regard to the Medicaid drug rebate program.

Federal regulations require effective control over and accountability for all funds, property and other assets; and the establishment of minimum records retention requirements.

Our review showed that although the Department intended to pay the Federal share of drug rebate collections upfront as determined by the billed amount, subsequent adjustments were made to rebate accounts that affected the amounts due to the Federal Government.

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

- Ensuring proper segregation of State-funded only and Federal drug rebate programs.
- Billing for $0 URA's as required by CMS.
- Tracking $0 URA's to ensure payment.

- Limiting adjustments for unpaid claims and disputed amounts based on CMS' thresholds.
- Ensuring that records are kept for an appropriate period of time.

The Department concurred with our findings and recommendations and agreed to take appropriate corrective actions with one exception. With regard to ensuring proper segregation of State-funded only and Federal drug rebate program funds, the Department asserted that their fiscal agent could not make such a distinction within its system and that they do not plan to change their practice.

The HHS action official named below will make final determination as to actions taken on all matters reported. We request that you respond to the HHS action official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

In accordance with the principles of the Freedom of Information Act, 5 U.S.C. 552, as amended by Public Law 104-231, Office of Inspector General, OAS reports issued to the Department's grantees and contractors are made available to members of the press and general public to the extent information contained therein is not subject to exemptions in the Act. (See 45 CFR Part 5.) As such, within 10 business days after the final report is issued, it will be posted on the worldwide web at *http://oig.hhs.gov*. To facilitate identification, please refer to Report Number A-07-03-04018 in all correspondence relating to this report.

Sincerely,

James P. Aasmundstad
Regional Inspector General
for Audit Services

Direct Reply to HHS Action Official:

Mr. Alex Trujillo
Centers for Medicare and Medicaid Services
Regional Administrator, Region VII
1600 Broadway, Suite 700
Denver, CO 80202

Enclosures---As stated

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN COLORADO

OCTOBER 2003
A-07-03-04018

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 evaluate whether the Colorado Department of Health Care Policy and Financing (Department) had established adequate accountability and internal controls over the Medicaid drug rebate program.

FINDINGS

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

- Deductions for a State-funded only program.
- Billing and Tracking $0 unit rebate amounts (URA's).
- Adjustments.
- Records retention.

These issues occurred because the Department did not develop or follow adequate policies and procedures with regard to the Medicaid drug rebate program. Federal regulations require effective control over and accountability for all funds, property and other assets; and the establishment of minimum records retention requirements.

Our review showed that although the Department intended to pay the Federal share of drug rebate collections upfront as determined by the billed amount, subsequent adjustments were made to rebate accounts that changed the amounts due to the Federal Government. As a result, the collections reported by the Department to the Centers for Medicare and Medicaid Services (CMS) were incorrect and CMS did not receive its share of all collections. In addition, drug rebate receivables were perpetually understated.

RECOMMENDATIONS

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

- Ensuring proper segregation of State-funded only and Federal drug rebate programs.
- Billing for $0 URA's as required by CMS.
- Tracking $0 URA's to ensure payment.
- Limiting adjustments for unpaid claims and disputed amounts based on CMS' thresholds.
- Ensuring that records are kept for an appropriate period of time.

The Department concurred with our findings and recommendations and agreed to take appropriate corrective actions with one exception. With regard to ensuring proper segregation of State-funded only and Federal drug rebate program funds, the Department asserted that their fiscal agent could not make such a distinction within its system and that they do not plan to change their practice.

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 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 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 a $0 URA, 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.

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's) are available under the program.

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, 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 State of Colorado is unique with regard to how it accounts for and reports drug rebates to CMS. In an effort to simplify the process, the Department reports that all drug rebates billed during the quarter were paid in full. Therefore, they do not report any accounts receivable for subsequent periods on the Form CMS 64.9R.

Theoretically, since the Department pays the Federal share of drug rebate claims upfront each quarter, CMS would have no concern whether the Department actually collects what was billed, pursues disputed amounts, or collects interest. However, use of this methodology requires careful consideration for any adjustments made to ensure that the Federal government receives its full share. Since some NDC's are billed at $0 until the manufacturer calculates and remits the proper amount, adjustments are necessary.

Department officials indicated that this methodology might not be used in the near future due to recent changes in State law. In order to facilitate a smooth transition to a new drug rebate reporting system, we reviewed CMS requirements with them regarding use of a general ledger control account, reconciliations between the Form CMS 64.9R and the general and subsidiary ledgers, tracking $0 URA's, accruing interest, and resolving disputes.

The Department reported no uncollected rebates on the CMS 64.9R for the quarter ending June 30, 2002. However, they billed and reported $10.5 million as collected during that period. The average drug rebates reported as billed and collected per quarter for the year ended June 30, 2002 was $9.6 million.

OBJECTIVE, SCOPE AND METHODOLOGY

Objectives

The audit objective was to evaluate whether the Department 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 Department. We also interviewed Department staff to understand how the Medicaid drug rebate program has operated since 1991.

Methodology

To accomplish 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 and the Office of Management and Budget Circular A-87.

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

Our fieldwork was conducted at the Department's office in Denver, Colorado during January 2003, and continued in the Office of Audit Services field office in Denver, Colorado through June 2003.

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

FINDINGS AND RECOMMENDATIONS

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

- Deductions for a State-funded only program.
- Billing and Tracking $0 URA's.
- Adjustments.
- Records retention.

INTERNAL CONTROLS

State Program Drugs

The Department deducted 2.3 percent from Medicaid drug rebate collections for drugs related to the State's old age pension program. We determined that the pension program was not Medicaid related and should not have participated in the Medicaid drug rebate 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.*

State officials indicated that their system was unable to distinguish between Federal rebate drugs and the pension program drugs. Therefore, they applied an estimated rate to the collected drug rebate amounts to account for the pension program drug rebate collections. However, the rate was developed long ago, perhaps even before the Medicaid drug rebate program was implemented. As such, the rate was not appropriate. In our opinion, such rates should be approved by CMS, for both application and development.

As a result, the Medicaid drug rebate collections reported by the Department on the Form CMS 64.9R were inaccurate.

$0 URA Billing and Tracking

The Department did not follow CMS program guidance with regard to the billing of $0 URA's. Instead of billing the URA at $0, the Department substituted an estimate or a prior quarter URA. In some cases, they substituted $1 for the $0 URA.

According to the CMS Medicaid Drug Rebate Program Guide: "State invoices must include utilization data for these NDCs and report the rebate per unit as zero."

Furthermore, the Department did not adequately track $0 URA's. Additional controls were necessary to ensure that those URA's were paid correctly. The Department did not keep a listing of $0 URA's to facilitate tracking their status and were unable to report how many have been received or paid.

We analyzed $0 URA data for six manufacturers during 15 quarters between December 1998 and June 2002. We found that for 142 $0 URAs billed during that period, only 45 were paid. The remaining 97 remain unverified, unpaid, and/or disputed by the manufacturer.

The Code of Federal Regulations, Title 45 Sec. 74.21 paragraph (b)(3) requires states to adequately safeguard assets. According to CMS Medicaid Drug Rebate Program Release #33, States are required to include $0 URA's on the quarterly invoices sent to the manufacturers. Manufacturers are required to calculate the correct URA and remit the appropriate rebate to the State. In many cases, the manufacturer does not comply, requiring the Department to track those amounts until payment is made in order to adequately safeguard assets.

At a minimum, the Department should have listed the $0 URA items separately in order to identify the number of items and actual NDC's that were not calculated and paid by the manufacturer as required. As a result, the drug rebate receivables were perpetually understated and it is likely that the Department did not receive all drug rebate payments due from manufacturers.

Adjustments

The Department made adjustments for disputed or unpaid amounts if the manufacturer had paid at least 93 percent of the amount owed. Such write-offs were not allowed by CMS program releases or program instructions. Net adjustments totaling $721,846 were reported on the Forms CMS 64.9R for the year ended June 30, 2002.

Federal regulations codified in 45 CFR 74.21 (b) (1) and (3) require "accurate, current and complete disclosure" of financial results and "effective control over and accountability for all funds, property and other assets."

The Department intended to pay the Federal share upfront by claiming all billed amounts were paid in the quarter billed. For that methodology to be valid, care must be taken to ensure that adjustments are only made for $0 URA amounts paid or prior period adjustments. The Department should assume responsibility for all receivables written-off without having been given the authority to do so by CMS.

By making these adjustments on the Form CMS 64.9R, reported collections were reduced in subsequent quarters. As a result, the Federal government did not receive its share of all possible collections.

Records Retention

The Department did not adequately retain records pertaining to the Medicaid drug rebate program as required. According to 45 CFR 92.42 (c)(1), records for a cooperative agreement (continued or renewed quarterly) are required to be kept three years from:

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

Furthermore, the "Best Practices Under the Medicaid Drug Rebate Program" provided by CMS 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.*

Although the Department employed a contractor to generate drug rebate invoices, they screened those invoices and made adjustments to some URA's on the invoices prior to mailing them. Those adjusted invoices were not retained as original documents in support of their accounts receivable subsidiary ledger.

As a result, the subsidiary records were not adequately supported by original documentation.

RECOMMENDATIONS

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

- Ensuring proper segregation between the State-funded only and Federal drug rebate programs.
- Billing for $0 URA's as required by CMS.
- Tracking $0 URA's until payment is made.

- Limiting adjustments for unpaid claims and disputed amounts based on CMS' thresholds.
- Ensuring that records are kept for an appropriate period of time.

AUDITEE RESPONSE AND OIG COMMENTS

The Department provided a written response to our draft report. Their response is included in its entirety as Appendix A.

The Department concurred with our findings and recommendations and agreed to take appropriate corrective actions with one exception. With regard to ensuring proper segregation of State-funded only and Federal drug rebate program funds, the Department asserted that their fiscal agent could not make such a distinction within its system and that they do not plan to change their practice.

We would remind the Department that such practice is not allowable under CMS Medicaid drug rebate program guidance and they should reconsider their approach in accounting for these rebates.

Appendix

STATE OF COLORADO

DEPARTMENT OF HEALTH CARE POLICY & FINANCING

1570 Grant Street
Denver, Colorado 80203-1818
(303) 866-2993
(303) 866-4411 FAX
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Bill Owens
Governor

Karen Reinertson
Executive Director

September 26, 2003

James P. Aasmundstad
Regional Inspector General for Audit Services
Department of Health and Human Services
Office of Inspector General
Region VII
601 East 12th Street, Room 284A
Kansas City, MO 64108

Dear Mr. Aasmundstad:

The following is the response from the Colorado Department of Health Care Policy and Financing to your draft report, Number A-07-03-04018, entitled "Audit of the Medicaid Drug Rebate Program in Colorado". Each of your audit recommendations is followed by the Department's response.

RECOMMENDATION: Ensuring proper segregation of State-funded only and Federal drug rebate programs.

RESPONSE: Colorado partially agrees with the finding. Pursuant to the recommendation, Colorado will make annual determinations of the percentage of drugs related to the Old Age Pension program. This will ensure that Medicaid drug rebate collections reported by the State on the form CMS 64.9 are accurate.

According to the Centers for Medicare and Medicaid Services (CMS) Medicaid Drug Rebate Program Guide, invoices must not reflect any pharmaceuticals paid under a state-fund-only General Assistance program, other state-fund-only programs, or other Federal drug rebate programs. Colorado's fiscal agent's system does not permit or allow such a distinction. Thus, the state-funded claims are included in the total drug rebate invoices each quarter. Colorado does not plan to change this practice.

RECOMMENDATION: Billing for $0 Unit Rebate Amounts (URAs) as required by CMS.

RESPONSE: Colorado agrees with the finding. Colorado has always billed for $0 URAs and will continue to do so. In those cases where the entire invoice had

$0 URAs, Colorado was estimating a non-zero amount due. Colorado will cease this procedure and mail out the invoice with a zero amount due the state effective with the mailing of the second quarter 2003 invoices.

RECOMMENDATION: Tracking $0 URAs to ensure payment.

RESPONSE: Colorado agrees with the finding. Colorado will develop a methodology to track $0 URAs beginning with first quarter 2003 invoices.

RECOMMENDATION: Limiting adjustments for unpaid claims and disputed amounts based on the CMS thresholds.

RESPONSE: Colorado agrees with the finding. Effective immediately, Colorado has ceased its prior threshold policy and instead pursues all disputed amounts until resolved. Write-offs will be based on unit adjustments only, using the CMS guidelines.

RECOMMENDATION: Ensuring that records are kept for an appropriate period of time.

RESPONSE: Colorado agrees with the finding. Effective immediately, Colorado will keep all original documents and data for at least three years.

Thank you for this opportunity to respond to these audit findings. Should you have any questions or comments, please do not hesitate to contact Vince Sherry at 303-866-5408.

Sincerely,

Vivianne M. Chaumont
Director
Medical Assistance Office

VS:VMC/sq