



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

NOV 17 2005

Report Number: A-07-05-04048

Ms. Barbara Prehmus, Medicaid Director
Medical Assistance Office
1570 Grant Street
Denver, Colorado 80203-1818

Dear Ms. Prehmus:

Enclosed are two copies of the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG) report entitled "Follow-up Audit of the Medicaid Drug Rebate Program in Colorado." A copy of this report will be forwarded to the HHS action official noted on the next page for his review and any action deemed necessary.

The HHS action official will make final determination regarding actions taken on all matters in the report. 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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If you have any questions or comments about this report, please do not hesitate to call me at (816) 426-3591, ext. 274, or contact Raylene Mason, Audit Manager, at (816) 426-3591, ext. 227, or through e-mail at raylene.mason@oig.hhs.gov. Please refer to report number A-07-05-04048 in all correspondence.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Patrick J. Cogley".

Patrick J. Cogley
Regional Inspector General
for Audit Services

Enclosures

Direct Reply to HHS Action Official:

Mr. Alex Trujillo
Regional Administrator, Region VIII
Centers for Medicare & Medicaid Services
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1600 Broadway, Suite 700
Denver, Colorado 80202

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**FOLLOW-UP AUDIT OF THE
MEDICAID DRUG REBATE
PROGRAM IN COLORADO**



**Daniel R. Levinson
Inspector General**

**NOVEMBER 2005
A-07-05-04048**

Office of Inspector General

<http://oig.hhs.gov>

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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

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS), States, and drug manufacturers share responsibility for the Medicaid drug rebate program. CMS calculates the unit rebate amount, and the States receive rebates from the manufacturers for a portion of the costs of the drugs. Each manufacturer is required to have a rebate agreement with CMS to have its products covered under the Medicaid program.

In Colorado, the Department of Health Care Policy and Financing (Colorado) administers the Medicaid program and other health care programs funded fully by the State.

This audit is a followup to a prior audit report (A-07-03-04018) entitled “Audit of the Medicaid Drug Rebate Program in Colorado” issued to Colorado on October 7, 2003. Colorado generally agreed with our findings and recommendations and agreed to develop policies and procedures to bill and track \$0 unit rebate amounts properly, to stop adjusting collections for all unpaid or disputed claims, and to retain records for at least 3 years. However, it did not agree to segregate Medicaid drug rebate invoices from the Old Age Pension Health and Medical Care Program (OAP).

OBJECTIVE

Our objective was to determine whether Colorado had established adequate accountability for and internal controls over the Medicaid drug rebate program.

SUMMARY OF FINDINGS

Colorado had adopted measures to strengthen controls with regard to billing and tracking \$0 unit rebate amounts, adjusting collections, and retaining records for at least 3 years.

Colorado lacked sufficient accountability and internal controls in the following areas:

- Colorado continued to allocate an estimated percentage of Medicaid drug rebates to the OAP program.
- Colorado could not properly process OAP adjustments submitted by two manufacturers.
- Colorado had disputes pending for 3 years because it was not active enough in its efforts to resolve disputes and did not offer the State’s hearing mechanism to manufacturers.
- Colorado did not verify, record, or report rebate interest.

These issues occurred because Colorado had not developed or implemented adequate policies and procedures with regard to the Medicaid drug rebate program.

Colorado understated the Federal share of Medicaid drug rebates collected by \$1,880,565 because it allocated an estimated percentage of the rebates to the OAP program. In addition, \$39,808 (Federal share) in rebates was outstanding because Colorado had not resolved disputes with several manufacturers that had incorrectly challenged an estimated percentage of Medicaid drug utilization instead of specific units of utilization. Colorado also underreported rebate interest collected in calendar year 2004 by \$9,987 (\$4,994 Federal share) and may not have received all interest owed by the manufacturers because it did not accurately verify, record, and report interest. Finally, an additional \$388,592 in drug rebates remained outstanding for more than 3 years. Colorado may be able to collect the outstanding rebates if it improves its settlement activities.

RECOMMENDATIONS

We recommend that Colorado:

- refund \$1,925,367 to the Federal Government;
- establish procedures to enable separate billing for Medicaid drug rebates and OAP drug rebates;
- actively pursue settlement of disputed amounts (including \$388,592 in drug rebates that remained outstanding for more than 3 years) and utilize available dispute resolution resources; and
- develop controls to ensure that interest is properly verified, recorded, and reported as required.

COLORADO'S COMMENTS

Colorado's comments on our draft report are summarized below and included in their entirety as Appendix B.

Colorado did not agree that the entire \$1,880,565 it allocated to the OAP program should be returned to the Federal Government. Colorado stated that we were inconsistent in asking it to separate OAP expenditures from the Medicaid Drug Rebate Program invoices and invoice the OAP expenditures separately while, at the same time, treating all costs invoiced under the Federal Medicaid Drug Rebate Program as Medicaid costs. Colorado stated that it began system changes in July 2004 that will allow it to "retroactively" identify specific drug utilization amounts related to the OAP. It stated that the changes should be completed by October 31, 2005.

Colorado concurred with our other findings and stated that it has taken steps to address our recommendations.

OFFICE OF INSPECTOR GENERAL'S RESPONSE

We commend Colorado for implementing system changes that will identify specific drug utilization amounts and for its actions to address our other findings and recommendations.

However, we disagree that our recommendations regarding the OAP-related drug expenditures were inconsistent. Colorado could not provide any support for the actual OAP-related drug utilization it claimed was included in the Medicaid drug rebate invoices. Consequently, the Federal share of drug rebates that Colorado deducted from the Medicaid rebate collections (\$1,880,565) should be returned to CMS.

In addition, during the audit, Colorado did not tell us that it intended to retroactively identify specific OAP-related drug utilization amounts and adjust prior years' CMS-64s accordingly. We believe that retroactively identifying the specific OAP-related drug utilization amounts and adjusting the prior years' CMS-64s is only part of a proper solution. Therefore, before Colorado is entitled to adjust prior CMS-64s to reflect OAP drug rebate collections, Colorado also must adjust all of the drug manufacturers' Medicaid drug rebate invoices that it billed in error. Furthermore, Colorado must either (1) enter into a retroactive rebate agreement with the drug manufacturers for the OAP drug program or (2) refund to the drug manufacturers the amount of drug rebates that was improperly invoiced to them. Until Colorado can document to CMS that these steps have been taken, Colorado should refund CMS's share of Medicaid drug rebate collections.

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INTRODUCTION

BACKGROUND

Medicaid Drug Rebate Program

The Omnibus Budget Reconciliation Act of 1990, which established the Medicaid drug rebate program, went into effect on January 1, 1991. The Centers for Medicare & Medicaid Services (CMS), States, and drug manufacturers share responsibility for the rebate program. CMS helps calculate the rebate information, and the States receive rebates from the manufacturers for a portion of the cost of each covered drug.

Each drug manufacturer is required to have a rebate agreement with CMS to have its products covered under the Medicaid program. The manufacturer is required to submit to CMS a list of all Medicaid-covered outpatient drugs and to report to CMS its average manufacturer price and best price information for each drug. Approximately 550 drug manufacturers participate in the program.

Each State agency is required to maintain drug utilization data, which must identify, by National Drug Code (code), the number of units paid for by the State for each covered outpatient drug. Each State agency is required to provide the drug utilization data to CMS and the manufacturer. Drug rebates are code-specific, and the rebates per unit for different codes vary extensively. Approximately 56,000 codes are available under the drug rebate program.

CMS calculates the unit rebate amount based on the price information provided by the manufacturer. CMS provides the unit rebate amount information to the State agency each quarter. The State agency then multiplies the unit rebate amount by its utilization data to determine the actual rebate amount due from each manufacturer. The State agency submits an invoice to the manufacturers for the rebate amount.

Dispute Resolution

The manufacturer has 30 days to remit payment from the date an invoice is sent. Interest begins accruing after 38 calendar days. The manufacturer provides the State agency with a Reconciliation of State Invoice detailing its payment by each code. If a manufacturer disagrees with the invoice, it can dispute the number of units included on the invoice, but it is required to pay the undisputed portion by the due date.

There are two ways for a manufacturer to dispute the State's utilization data. First, it may withhold payment for the number of units in dispute and remit payment for the undisputed portion. The manufacturer is required to calculate and remit interest for any late payments or disputed rebates after the dispute is settled. Second, a manufacturer may remit payment for the entire rebate amount invoiced and notify the State agency of the disputed units. The manufacturer is not liable for interest if it pays the invoice in full.

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 offer to the manufacturer the State's hearing mechanism available under the Medicaid program.

CMS makes additional dispute resolution assistance available through its Drug Resolution Program (DRP). CMS's DRP team facilitates dispute resolution by scheduling national meetings during the year to give manufacturers and States the opportunity to meet to resolve disputes.

Reporting Requirements

Each State agency reports on its quarterly Form CMS-64.9R Medicaid drug rebate amounts billed and collected. This form is part of the CMS-64 report, which summarizes actual Medicaid expenditures for each quarter and is used by CMS to reimburse States for the Federal share of drug rebate program expenditures.

Federal regulations (42 CFR § 430.30(c)(2)) require States to report actual recorded Medicaid expenditures and specifically bar States from estimating expenditures. States report on Form CMS-64.9R rebates invoiced to the manufacturer in the current quarter, rebates received from the manufacturer during the current quarter, and uncollected rebate balances for the current and prior quarters. The CMS Medicaid Drug Rebate Operational Training Guide prohibits Medicaid drug rebate invoices from including any drugs paid for under programs funded fully by the State.

Colorado Drug Rebate Program

In Colorado, the Department of Health Care Policy and Financing (Colorado) administers the Medicaid program as well as other health care programs funded fully by the State, such as the Old Age Pension Health and Medical Care Program (OAP).

Colorado's Old Age Pension and Medical Care Program

Article XXIV of Colorado's State constitution established the OAP program, which provides medical care to persons who qualify for old age pensions but are not eligible for Medicaid. Eligibility is limited to Colorado residents or legal immigrants 60 and over. The program is funded fully by the State.

Prior Colorado Drug Rebate Audit

Our audit is a followup to a prior audit report (A-07-03-04018) entitled "Audit of the Medicaid Drug Rebate Program in Colorado" issued to Colorado on October 7, 2003. We determined that Colorado had adequate controls over the drug rebate program except for (1) deductions for the OAP program, (2) \$0 unit rebate amounts¹, (3) adjustments, and (4) records retention.

¹The information CMS provides to States may contain \$0 unit rebate amounts if the pricing information is not provided in a timely manner or if the computed unit rebate amount has a 50-percent variance from the previous quarter. The State agency is instructed to invoice the units, and the manufacturer is required to calculate the unit rebate amount and remit the appropriate amount to the State agency.

We recommended that Colorado develop and follow policies and procedures that included:

- ensuring proper segregation of the Medicaid drug rebate program and programs funded fully by the State,
- billing and tracking \$0 unit rebate amounts to ensure payment as required by CMS,
- limiting adjustments for unpaid claims and disputed amounts based on CMS's thresholds, and
- ensuring that records are kept for an appropriate amount of time.

Colorado generally agreed with our findings and recommendations and agreed to develop policies and procedures to correct the related conditions. However, it did not agree to segregate Medicaid drug rebate invoices from the OAP program because it stated that its fiscal agent's system did not permit or allow such a distinction. Colorado instead proposed to annually determine the percentage of rebates related to the OAP program. It stated it would deduct the OAP-related percentage from the total Medicaid drug rebates billed to manufacturers to ensure that reported Medicaid drug rebate collections were accurate.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Colorado had established adequate accountability for and internal controls over the Medicaid drug rebate program.

Scope

We limited our review to the drug rebate amounts reported by Colorado on the CMS-64 reports for State fiscal years (SFY) 2001-2004 and the first two quarters of SFY 2005.

Our audit is a followup to a prior audit report (A-07-03-04018) entitled "Audit of the Medicaid Drug Rebate Program in Colorado" issued to Colorado on October 7, 2003. We determined that a follow-up review was necessary to understand the effects of Colorado's decision not to segregate OAP-related drug rebates from the Medicaid drug rebates.

Colorado changed to a cash basis for reporting Medicaid drug rebates beginning with the CMS-64 report submitted for the quarter that ended June 30, 2003. Prior to the change in methodology, Colorado reported all rebates billed as having been collected during the quarter; thus mitigating the need for some internal controls from our perspective. Therefore, we reviewed the need for additional internal controls required as a result of the change in reporting methodology.

We conducted our fieldwork at Colorado's office in Denver, CO, from November 2004 through March 2005.

Family Planning Drugs

The Medicaid family planning program is an enhanced-rate program (90-percent Federal share) under Medicaid. Family planning drugs purchased by the State on behalf of Medicaid recipients are eligible for rebates from the manufacturer. Because CMS reimburses the State at an enhanced rate for family planning expenditures, the State is required to provide CMS with 90 percent of drug rebate collections associated with family planning drugs. To facilitate the reimbursement process, family planning drug rebates are reported separately on the CMS-64 report.

Colorado officials asserted to us that they had consistently reported family planning drug rebates at a higher amount than actual collections on the quarterly CMS-64 reports thus overpaying CMS. Colorado officials requested that we consider Medicaid drug rebate amounts allocated to the family planning program that were offset against that program's drug expenditures on the CMS-64 report. However, Colorado was unable to provide us with itemized Medicaid family planning drug rebate amounts. Without the actual collections, we were unable to determine the amount of family planning drug rebates that should have been reported as an offset to that program's expenditures.

Methodology

We reviewed the applicable Federal laws, regulations, and program requirements, including sections 1903 and 1927 of the Social Security Act (the Act) and 42 CFR § 430; the CMS Medicaid Drug Rebate Operational Training Guide; program releases issued by CMS; and the State Medicaid Manual, to determine the program requirements.

We examined copies of Form CMS-64.9R and applicable line items of the CMS-64 reports for the period July 1, 2001, through December 31, 2004, to determine the drug rebate amounts Colorado reported to CMS. We obtained and reviewed Medicaid drug rebate accounts receivable records to determine whether Colorado records supported the reported amounts. We also interviewed State agency staff who performed functions related to the drug rebate program.

We compared the total Medicaid drug program rebates collected during each quarter to what Colorado reported on the quarterly CMS-64 report (see Appendix A) to determine the effect of Colorado's OAP program allocation on the Federal share amount. We also examined the Reconciliation of State Invoice forms submitted by certain manufacturers that disputed their rebate payments because of allocations Colorado made to the OAP program.

We performed our audit in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

We commend Colorado for adopting measures to strengthen controls with regard to most of our prior audit findings. Colorado developed sufficient controls to bill and track \$0 unit rebate amounts properly, to stop adjusting collections for all unpaid or disputed claims, and to retain records for at least 3 years.

Colorado lacked sufficient accountability and internal controls in the following areas:

- Colorado continued to allocate an estimated percentage of Medicaid drug rebates to the OAP program.
- Colorado could not properly process OAP adjustments submitted by two manufacturers.
- Colorado had disputes pending for 3 years because it was not active enough in its efforts to resolve disputes and did not offer the State's hearing mechanism to manufacturers.
- Colorado did not verify, record, or report rebate interest.

These issues occurred because Colorado had not developed or implemented adequate policies and procedures with regard to the Medicaid drug rebate program.

Colorado understated the Federal share of Medicaid drug rebates collected by \$1,880,565 because it allocated an estimated percentage of the rebates to the OAP program. In addition, \$39,808 (Federal share) in rebates was outstanding because Colorado had not resolved disputes with several manufacturers that had incorrectly challenged an estimated percentage of Medicaid drug utilization instead of specific units of utilization. Colorado also underreported rebate interest collected in calendar year 2004 by \$9,987 (\$4,994 Federal share) and may not have received all interest owed by the manufacturers because it did not accurately verify, record, and report interest. Finally, an additional \$388,592 in drug rebates remained outstanding for more than 3 years. Colorado may be able to collect the outstanding rebates if it improves its settlement activities.

ALLOCATIONS TO THE OLD AGE PENSION PROGRAM

Criteria

Federal regulations (42 CFR § 430.30(c)(2)) require States to report actual recorded expenditures and specifically bar the use of estimates to report expenditures. Furthermore, the CMS Medicaid Drug Rebate Operational Training Guide prohibits Medicaid drug rebate invoices from including any drug codes paid for under programs funded fully by the State.

Condition

In the prior audit report, we reported that Colorado deducted 2.3 percent from the Medicaid rebate collections for drugs related to the OAP program. We determined that the OAP program was not Medicaid related and should not have been included in the Medicaid drug rebate program. We recommended that Colorado ensure the proper segregation of the OAP and Federal drug rebate programs. Colorado responded that it did not plan to change its practice, but it proposed to annually determine the percentage of rebates related to the OAP program. It stated it would deduct the OAP-related percentage from the total Medicaid drug rebates billed to manufacturers to ensure that reported Medicaid drug rebate collections were accurate.

However, for this audit, Colorado was unable to determine to what extent, if any, OAP drugs were included in the amounts billed as Medicaid drug rebate amounts. Colorado could not identify specific drug code utilization amounts associated with OAP deductions. OAP drugs should not have been included on the Medicaid drug rebate invoices because the OAP program was funded fully by the State.

The amounts billed to manufacturers were presented on detailed invoices to the manufacturers as Medicaid drugs, not OAP drugs, and absent any specific utilization data to the contrary, we consider the amounts billed to be Medicaid related and reportable to CMS.

Cause

Colorado did not have procedures to segregate the data on drug utilization under the Medicaid drug rebate and OAP programs. Specifically, the State should have had procedures to prepare separate rebate invoices to bill the manufacturers for Federal and State-funded programs.

Effect

As a result, Colorado understated the Federal share of Medicaid drug rebate collections during our audit period by \$1,880,565.

MANUFACTURER ADJUSTMENTS RELATED TO OLD AGE PENSION PROGRAM

Criteria

According to the CMS Medicaid Drug Rebate Operational Training Guide, manufacturers are entitled to dispute units billed to them that they believe are not allowable for rebates under the Medicaid drug rebate agreement.

Federal regulations (42 CFR § 430.30(c)(2)) require States to report actual recorded expenditures and specifically bar the use of estimates to report expenditures. Furthermore, the CMS Medicaid Drug Rebate Operational Training Guide prohibits Medicaid drug rebate invoices from including any drug codes paid for under programs funded fully by the State.

Condition

Colorado could not properly process manufacturer OAP adjustments. At least two manufacturers began deducting the estimated OAP percentage of the Medicaid drug invoices when remitting payment as a result of our prior report. Those deductions were made through the dispute mechanism of the Medicaid drug rebate program.

Cause

Colorado did not have procedures to segregate the data on drug utilization under the Medicaid drug rebate and OAP programs to prepare separate rebate invoices to bill the manufacturers for Federal and State-funded programs.

Effect

The Federal share totaling \$39,808 was not reported. Absent any specific utilization data to the contrary, we consider the amounts billed to be Medicaid related and reportable to CMS.

UTILIZATION OF AVAILABLE RESOURCES FOR DISPUTE RESOLUTION

Criteria

The Medicaid drug rebate agreements require that States and manufacturers resolve rebate discrepancies within 60 days of receipt of notification of a dispute. The agreements further state 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."

Condition

Colorado and 46 manufacturers had not resolved disputes that were pending for more than 3 years.

Cause

Colorado was not active enough in its efforts to resolve disputes with manufacturers. It did not directly contact the manufacturers, regularly attend CMS DRP meetings, or utilize available resources at the regional CMS office. Furthermore, Colorado did not offer the manufacturers the State's hearing mechanism as required by the rebate agreements.

Effect

Medicaid drug rebate invoices totaling \$388,592 remained unresolved for more than 3 years because Colorado did not actively try to resolve disputes.

INTEREST VERIFICATION, RECORDING, AND REPORTING

Criteria

According to the rebate agreements, manufacturers are required to pay interest on disputed or unpaid amounts and late rebate payments. The interest rate pursuant to section 1903(d)(5) of the Act is "based on the yield of the weekly 90-day Treasury bill auction rates" during such period. Section V(b) of the rebate agreement states:

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.

According to the State Medicaid Manual, interest should be reported separately on the CMS-64 report summary sheet.

Condition

Colorado did not verify, record, or report drug rebate program interest received during calendar year 2004 totaling \$9,987. Furthermore, it relied solely on the manufacturers to voluntarily calculate and remit interest owed on all disputed or late drug rebate payments. It did not recalculate interest voluntarily paid by manufacturers to verify that the correct amounts were paid, nor did it make significant efforts to collect interest from manufacturers that did not voluntarily remit interest owed.

Cause

Colorado did not develop or implement adequate controls to ensure that interest for late, disputed, or unpaid rebate payments was verified, recorded, and reported properly.

Effect

As a result, Colorado did not report the Federal share of interest collected from late, disputed, or unpaid rebate payments totaling \$4,994, and it is likely Colorado did not receive all interest owed by the manufacturers.

RECOMMENDATIONS

- refund \$1,925,367 to the Federal Government;
- establish procedures to enable separate billing for Medicaid drug rebates and OAP drug rebates;
- actively pursue settlement of disputed amounts (including \$388,592 in drug rebates that remained outstanding for more than 3 years) and utilize available dispute resolution resources; and
- develop controls to ensure that interest is properly verified, recorded, and reported as required.

COLORADO'S COMMENTS AND OFFICE OF INSPECTOR GENERAL'S RESPONSE

Colorado's comments on our draft report are summarized below and included in their entirety as Appendix B.

Allocations to the Old Age Pension Program

Colorado's Comments

Colorado did not agree that the entire \$1,880,565 it allocated to the OAP program should be returned to the Federal Government. Colorado insisted "that actual data be used to determine the amount to be refunded." However, it agreed "that there is currently no specific utilization data related to OAP Health and Medical Program invoices and that some amount was invoiced on behalf of this state funded program under the Medicaid drug rebate invoices." Colorado stated that it began system changes in July 2004 that will allow it to "retroactively" identify specific drug utilization amounts related to the OAP. It stated that the changes should be completed by October 31, 2005.

Colorado stated that we were inconsistent in asking it to separate OAP expenditures from the Medicaid Drug Rebate Program invoices and invoice the OAP expenditures separately while, at the same time, treating all costs invoiced under the Federal Medicaid Drug Rebate Program as Medicaid costs. It also stated that the proper solution would be to identify the "actual amount" associated with the OAP and adjust the CMS-64 accordingly. Colorado stated that it "produced several estimates of these amounts . . . which were omitted from the audit report."

Colorado noted that it notified the CMS Region VIII office of Colorado's "process to manually calculate the percentage that the OAP Health and Medical Care Program claims represented of the total Medicaid drug rebate expenditure" and allocate that percentage of the drug rebates collected to the OAP program. According to Colorado, CMS did not "mention . . . the process to exclude" the OAP amount from the CMS-64.

Office of Inspector General's Response

We commend Colorado for implementing system changes that will identify specific drug utilization amounts. However, we disagree that our recommendations regarding the OAP-related drug expenditures were inconsistent.

The CMS Medicaid Drug Rebate Operational Training Guide prohibits Medicaid drug rebate invoices from including any drug codes paid for under programs funded fully by the State. Therefore, Colorado should not have included any OAP-related codes in the Medicaid drug rebate invoices. However, Colorado agreed that some amount of the State-funded OAP program was invoiced on the Medicaid drug rebate invoices. Although Colorado created estimates of how many OAP-related drug amounts were included in the invoices, Federal regulations (42 CFR § 430.30(c)(2)) require States to report actual recorded expenditures and specifically bar the use of estimates to report expenditures. Therefore, we did not include the estimates that Colorado created in the audit report.

Colorado could not provide any support for the actual OAP-related drug utilization it claimed was included in the Medicaid drug rebate invoices. Colorado collected these drug rebates from the manufacturers by billing them for Medicaid drug utilization under the terms of the Medicaid drug rebate agreements. Absent any specific utilization data to the contrary, we consider the amounts Colorado billed and collected from drug manufacturers for Medicaid drug rebates to be entirely Medicaid related for the purpose of computing the Federal share. Consequently, the Federal share of drug rebates that Colorado deducted from the Medicaid rebate collections (\$1,880,565) should be returned to CMS.

In addition, during the audit, Colorado did not tell us that it intended to retroactively identify specific OAP-related drug utilization amounts and adjust prior years' CMS-64s accordingly. We believe that retroactively identifying the specific OAP-related drug utilization amounts and adjusting the prior years' CMS-64s is only part of a proper solution. Therefore, before Colorado is entitled to adjust prior CMS-64s to reflect OAP drug rebate collections, Colorado also must adjust all of the drug manufacturers' Medicaid drug rebate invoices that it billed in error. Furthermore, Colorado must either (1) enter into a retroactive rebate agreement with the drug manufacturers for the OAP drug program or (2) refund to the drug manufacturers the amount of drug rebates that was improperly invoiced to them. Until Colorado can document to CMS that these steps have been taken, Colorado should refund CMS's share of Medicaid drug rebate collections.

Manufacturer Adjustments Related to Old Age Pension Program

Colorado's Comments

Colorado concurred with our finding and stated that it had implemented system changes to invoice OAP drugs separately. The changes should be completed by October 31, 2005.

Office of Inspector General's Response

We commend Colorado for implementing system changes that will identify specific drug utilization amounts.

Utilization of Available Resources for Dispute Resolution

Colorado's Comments

Colorado agreed with our finding and stated that it has contacted manufacturers to resolve outstanding disputes. It reported that it has resolved nearly half of the disputes cited in our audit through collections and adjustments.

Office of Inspector General's Response

We commend Colorado for taking prompt action to resolve its longstanding disputes with manufacturers.

Interest Verification, Recording, and Reporting

Colorado's Comments

Colorado agreed with our finding and stated that it is “implementing a manual process to verify, record, and report interest.” It stated it also is considering an automated system.

Office of Inspector General's Response

We commend Colorado for taking prompt action to verify, record, and report interest as required.

APPENDIXES

SCHEDULE OF UNCLAIMED MEDICAID DRUG REBATES

**STATE OF COLORADO
DEPARTMENT OF HEALTH CARE FINANCING AND POLICY
DENVER, COLORADO**

JULY 1, 2000, TO DECEMBER 31, 2004

Quarter That Ended:	FEDERAL SHARE OF DRUG REBATES:		
	<u>CLAIMED</u> ²	<u>COLLECTED</u> ³	<u>QUESTIONED</u> ⁴
September 30, 2000	\$3,889,556	\$3,980,055	\$90,499
December 31, 2000	3,486,404	3,567,523	81,119
March 31, 2001	4,641,392	4,749,384	107,992
June 30, 2001	4,582,763	4,689,391	106,628
September 30, 2001	4,623,737	4,731,318	107,581
December 31, 2001	4,478,865	4,583,075	104,210
March 31, 2002	4,873,652	4,987,048	113,396
June 30, 2002	5,111,357	5,230,284	118,927
September 30, 2002	5,293,443	5,416,606	123,163
December 31, 2002	4,801,331	4,913,044	111,713
March 31, 2003	5,875,887	6,012,601	136,714
June 30, 2003	228,988	234,323	5,335
September 30, 2003	5,837,569	5,913,708	76,139
December 31, 2003	5,978,002	6,055,944	77,942
March 31, 2004	7,923,170	8,026,473	103,303
June 30, 2004	8,929,373	9,046,560	117,187
September 30, 2004	8,856,917	8,979,478	122,561
December 31, 2004	15,819,448	15,995,604	176,156
TOTAL	\$105,231,854	\$107,112,419	\$1,880,565

²Amount claimed by Colorado on the CMS-64 quarterly expenditure report.

³Total rebate amount received by Colorado before it allocated 2.3 percent to the OAP program.

⁴Difference between the amount of rebates collected and the amount claimed.

STATE OF COLORADO

DEPARTMENT OF HEALTH CARE POLICY & FINANCING

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Bill Owens
Governor

Karen Reinertson
Executive Director

September 14, 2005

Jack Morman
Acting Regional Inspector General for Audit Services
Office of the Inspector General
Office of Audit Services
Region VII
601 East 12th Street, Room 284A
Kansas City, Missouri 64106

Subject: Response to *Follow-up Audit of the Medicaid Drug Rebate Program in Colorado* (Report Number A-07-05-04048)

Dear Mr. Morman:

The Colorado Department of Health Care Policy and Financing (the Department) has reviewed your draft report of the "Follow-up Audit of the Medicaid Drug Rebate Program in Colorado" (Report Number A-07-05-04048) submitted to Barbara Prehmus on July 22, 2005 and has the following responses.

RECOMMENDATION:

- We recommend that Colorado refund \$1,925,367 to the Federal Government.

DEPARTMENT RESPONSE:

- The Department does not concur in total that \$1,925,367 be refunded to the Federal Government. The Department concurs with the finding that the State underreported rebate interest collected in calendar year 2004 in the amount of \$9,987 (\$4,994 Federal share). The Department concurs that Old Age Pension (OAP) Health and Medical Program adjustments may have been processed incorrectly. The Department will seek to resolve disputes and will refund the Federal Government its share of the rebate to the extent that the \$39,808 (Federal share) amount is truly from Medicaid utilization. The Department does not agree that the remaining amount of \$1,880,565 be refunded to the Federal Government but instead insists that actual data be used to determine the amount to be refunded.

The Department agrees that there is currently no specific utilization data related to OAP Health and Medical Program invoices and that some amount was invoiced on behalf of this

"The mission of the Department of Health Care Policy & Financing is to purchase cost effective health care for qualified, low-income Coloradans"

<http://www.chcpf.state.co.us>

state funded program under the Medicaid drug rebate invoices. The Department began a process to separate the OAP Health and Medical Program invoices from the Medicaid invoices in July 2004.

There is an inconsistency between the OIG's recommendations. The OIG recommended that the OAP Health and Medical Program invoices be separated from the Medicaid drug rebate invoices. Then, the OIG recommended that any amount previously billed under the Medicaid drug rebate invoices be considered a Medicaid collection on the Centers for Medicare and Medicaid Services' form 64 (CMS 64) even though it is clear from the OIG's findings that there were some substantial amount of state funded program collections included within the Medicaid drug rebate invoice amounts. To remove this inconsistency, the proper solution is to identify the actual amount associated with the state funded program from the amount billed previously under the Medicaid drug rebate invoice and adjust the CMS 64 accordingly. The Department produced several estimates of these amounts, under the direction of the Office of the Inspector General (OIG), which were omitted from the audit report.

In July 2004, the Department began the system changes necessary to exclude all National Drug Codes for OAP Health and Medical Program participants from the drug rebate invoice. The Department is on schedule to complete the system changes by October 31, 2005. Using the reports that will be generated by these system changes, the Department can identify specific drug code utilization amounts associated with OAP Health and Medical Program deductions from the amount billed under the Medicaid drug rebate invoice retroactively and can then make the necessary adjustments to the CMS 64, which will be significantly less than the amount reported by the OIG.

Further, Colorado had started work on obtaining the specific, itemized Medicaid family planning drug rebate amounts prior to the inception of this audit (October 27, 2004). This data will also be available by October 31, 2005. Making the necessary adjustments related to the Medicaid family planning will reduce the amount of rebate refunded at an enhanced rate (90-percent Federal share) and will increase the amount of rebate refunded at the standard federal match rate. Based on initial estimates, the increased federal financial participation, will offset, or even exceed the amount that the State will need to refund to the Federal Government. To determine this amount, the Department will identify the specific drug code utilization amount associated with OAP Health and Medical Program deductions from the amount billed under the Medicaid drug rebate invoice. Following the release of this audit report and if requested, the Department will work with CMS Region VIII office to make the necessary adjustments related to the OAP Health and Medical Program and Medicaid family planning drug rebate amounts.

It should be noted that the CMS Region VIII office was aware of the Department's process to deduct the OAP Health and Medical Program related percentage from the amount billed under the Medicaid drug rebate invoice following the audit report entitled "Medicaid Rebate Program in Colorado" issued October 7, 2003. In addition, on March 14, 2005, the

Department provided a subsequent correspondence to the Region VIII office, notifying them of the process to manually calculate the percentage that the OAP Health and Medical Care Program claims represented of the total Medicaid drug rebate expenditure on a quarterly basis and exclude the state funded program amount from the CMS 64. Correspondence from the CMS Region VIII office required that the Department implement a process to separate the OAP Health and Medical Care Program claims from the Medicaid drug rebate invoice and made no mention of the process to exclude the state funded program amount from the CMS 64.

RECOMMENDATION:

- We recommend that Colorado establish procedures to enable separate billing for Medicaid drug rebates and OAP drug rebates.

DEPARTMENT RESPONSE

- The Department concurs, but comments that in June 2004, the Department began the system changes necessary to implement this recommendation prior to the inception of this audit in October 27, 2004. Following the audit report entitled "Medicaid Rebate Program in Colorado" issued October 7, 2003, the CMS Region VIII office requested on July 1, 2004 that the Department implement a process to exclude all National Drug Codes for Old Age Pension (OAP) Health and Medical Program participants from the Medicaid Drug Rebate Program. On July 30, 2004, the Department responded affirmatively to that request and began implementing a programming change to the Medicaid Management Information System (MMIS) to accomplish the request. On March 14, 2005, the Department provided subsequent correspondence to the CMS Region VIII office, notifying them that the programming changes to the MMIS would be completed by October 31, 2005. The Department is on schedule to segregate the National Drug Codes for the OAP Health and Medical Program participations from the Medicaid drug rebate invoice and will notify the CMS Region VIII office once the programming changes have been completed.

RECOMMENDATION:

- We recommend that Colorado actively pursue settlement of disputed amounts (including \$388,592 in drug rebates that remained outstanding for more than 3 years) and utilize available dispute resolution resources.

DEPARTMENT RESPONSE

- The Department concurs with the finding and has taken action to comply. In order to resolve outstanding disputes, the Department contacted drug manufacturers via a special mailing with phone follow up. In addition, Department staff attended a dispute resolution meeting moderated by CMS. The Department has resolved 47% of the \$388,592 cited in the audit through collections and adjustments. The Department has reported these collections on the

CMS 64. The Department will continue to work to resolve outstanding disputes and report the amounts on the CMS 64.

RECOMMENDATION:

- We recommend that Colorado develop controls to ensure that interest is properly verified, recorded, and reported as required.

DEPARTMENT RESPONSE

- The Department concurs with the recommendation. The Department is exploring procurement options for an automated drug rebate system that, among other things, would: calculate interest due, record the interest due as an increase to the receivable, and offset manufacturer/labeler payment against that receivable as appropriate. As an interim measure, the Department is implementing a manual process to verify, record, and report interest. Due to the limitations of manual processing, this interim measure will not provide the level of control and timeliness of an automated drug rebate system.

Thank you for the opportunity to respond to these audit recommendations. If you have any questions or comments please do not hesitate to contact me (303) 866-3676 or at donna.kellow@state.co.us.

Sincerely,



Donna Kellow

Audit and Operational Contract Manager

cc: Steve Tool, Executive Director
Barbara Prehmus, Medicaid Director
Lisa Esgar, Director, Office of Operations and Finance

bc: Jed Zigenhagen
Chris Underwood
Annmarie Maynard