



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

AUG 25 2008

Report Number: A-07-08-03108

Ms. Joan Henneberry  
Executive Director  
Colorado Department of Health Care Policy and Financing  
1570 Grant Street  
Denver, Colorado 80203

Dear Ms. Henneberry:

Enclosed is the U.S. Department of Health and Human Services, Office of Inspector General (OIG), final report entitled "Follow-Up Audit of the Medicaid Drug Rebate Program in Colorado." We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this 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, or contact Greg Tambke, Audit Manager, at (573) 893-8338, extension 30, or through e-mail at [Greg.Tambke@oig.hhs.gov](mailto:Greg.Tambke@oig.hhs.gov). Please refer to report number A-07-08-03108 in all correspondence.

Sincerely,

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

Patrick J. Cogley  
Regional Inspector General  
for Audit Services

Enclosure

**Direct Reply to HHS Action Official:**

Ms. Jackie Garner  
Consortium Administrator  
Consortium for Medicaid and Children's Health Operations  
Centers for Medicare & Medicaid Services  
233 North Michigan Avenue, Suite 600  
Chicago, Illinois 60601

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

August 2008  
A-07-08-03108

# ***Office of Inspector General***

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## **OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS**

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

## EXECUTIVE SUMMARY

### BACKGROUND

The Medicaid drug rebate program, which began in 1991, is set forth in section 1927 of the Social Security Act. For a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the program, the manufacturer must enter into a drug rebate agreement with the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each undertake certain functions in connection with the drug rebate program. In Colorado, the Department of Health Care Policy and Financing (the State agency) administers the Medicaid drug rebate 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).

In 2005, we issued a report on the results of audits of the Medicaid drug rebate programs in 49 States and the District of Columbia (A-06-03-00048). Those audits found that only four States had no weaknesses in accountability for and internal controls over their drug rebate programs. As a result of the weaknesses, we concluded that States lacked adequate assurance that all of the drug rebates due to the States were properly recorded and collected. Additionally, CMS did not have reliable information from the States to properly monitor the drug rebate program.

In our previous audit of the Colorado drug rebate program, we determined that the State agency 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. However, we also found that the State agency: (1) continued to allocate an estimated percentage of Medicaid drug rebates to the OAP program; (2) could not properly process OAP adjustments submitted by two manufacturers; (3) had disputes with drug manufacturers pending for 3 years because it did not adequately resolve disputes and did not offer the State's hearing mechanism to manufacturers; and (4) did not verify, record, or report rebate interest. These errors occurred because the State agency lacked sufficient accountability and internal controls.

We recommended the State agency:

- refund \$1,925,367 to the Federal Government, which consisted of \$1,880,565 relating to questioned OAP program rebates, \$4,994 for unreported interest, and \$39,808 for manufacturer disputes relating to the OAP program;
- 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.

The State agency did not concur in total that \$1,925,367 be refunded to the Federal Government. It concurred that it had underreported \$9,987 (\$4,994 Federal share) in rebate interest collected during calendar year 2004 and stated that it would seek to resolve the manufacturer disputes relating to the \$39,808 (Federal share) for the OAP program. However, the State agency did not agree that the entire \$1,880,565 it allocated to the OAP program should be returned to the Federal Government. The State agency indicated that it began system changes in July 2004 that would allow it to “retroactively” identify specific drug utilization amounts related to the OAP. These changes were to be completed by October 31, 2005.

This current review of the Colorado drug rebate program is part of a nationwide series of reviews conducted to determine whether States have addressed the weaknesses in accountability for and internal controls over their drug rebate programs found in the previous reviews. Additionally, because the Deficit Reduction Act required States as of January 2006 to begin collecting rebates on single source drugs administered by physicians, this series of reviews will also determine whether States have complied with the new requirement.

## **OBJECTIVES**

Our objectives were to determine whether the State agency had (1) implemented the recommendations made in our previous audit of the Colorado drug rebate program and (2) established controls over the drug rebate program, including the collection of rebates on single source drugs administered by physicians.

## **SUMMARY OF FINDINGS**

The State agency partially corrected the weaknesses reported in our previous audit. Specifically:

- Although the State agency is currently working with CMS to negotiate a settlement regarding the \$1,925,367 in questioned costs relating to the prior audit, a final settlement has not been reached.
- The State agency reported drug rebates received for Family Planning drugs based on estimates and continued to withhold a portion of drug rebates received for the State funded OAP program invoiced prior to the quarter ending December 31, 2005. The State agency withheld 1.3 percent (\$765,988) for OAP drug rebates and claimed 1.44 percent (\$1,063,513) for Family Planning drug rebates based on estimates.
- Although the State agency had procedures in place to resolve outstanding disputes, it had \$861,924 in manufacturer balances that were over 3 years past due.
- While the State agency had developed policies and procedures to verify and record interest, it did not report \$44,797 (\$22,399 Federal share) in interest received.

- The State agency did not report all necessary data related to its Medicaid drug rebate program on the Form CMS-64.9R.

In addition, although the State agency, through its contractor Health Watch Technologies, established controls over collecting rebates on single source drugs administered by physicians, the State agency allowed the contract to expire effective June 30, 2007, and it has not collected rebates for single source drugs administered by physicians since the contract expired.

## **RECOMMENDATIONS**

We recommend the State agency:

- continue to work with CMS to determine and finalize a settlement of the prior recommendation that the State agency refund the Federal Government \$1,925,367;
- work with CMS to determine the actual amount of the \$1,829,501 in drug rebates from our current audit period, that relate to the Medicaid program, OAP program and Family Planning;
- actively pursue settlement of the disputed amounts (including \$861,924 in drug rebates that remained outstanding for more than 3 years) and utilize available dispute resolution resources;
- refund the Federal Government \$22,399 for the Federal share of interest that was received but not reported; and
- develop policies and procedures to accurately report the Medicaid Drug Rebate activity that include reporting beginning balances, adjustments, and ending balances on the Form CMS-64.9R.

Additionally, we recommend the State agency develop policies and procedures for invoicing single source physician-administered drug rebates and resume invoicing drug rebates on single source drugs administered by physicians, as required.

## **STATE AGENCY COMMENTS**

In written comments on our draft report, the State agency concurred with all of our recommendations. The State agency written comments included a discussion of implementation and corrective actions proposed. The State agency's comments are included in their entirety as the Appendix.



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## INTRODUCTION

### BACKGROUND

Pursuant to Title XIX of the Social Security Act (the Act), the Medicaid program provides medical assistance to certain low-income individuals and individuals with disabilities. The Federal and State Governments jointly fund and administer the Medicaid program. At the Federal level, the Centers for Medicare & Medicaid Services (CMS) administers the program. Each State administers its Medicaid program in accordance with a CMS-approved State plan. Although the State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements.

### Drug Rebate Program

The Medicaid drug rebate program, which began in 1991, is set forth in section 1927 of the Act. For a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the program, the manufacturer must enter into a drug rebate agreement with CMS and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each undertake certain functions in connection with the drug rebate program. In Colorado, the Department of Health Care Policy and Financing (the State agency) administers the Medicaid drug rebate 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). 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 age 60 and over.

Pursuant to section II of the rebate agreement and section 1927(b) of the Act, manufacturers are required to submit a list to CMS of all covered outpatient drugs and to report each drug's average manufacturer price and, where applicable, its best price. Based on this information, CMS calculates a unit rebate amount (URA) for each covered outpatient drug and provides the amounts to States on a quarterly basis.

Section 1927(b)(2)(A) of the Act requires States to maintain drug utilization data that identifies, by National Drug Code (NDC), the number of units of each covered outpatient drug for which the States have reimbursed providers. The number of units is applied to the URA to determine the actual rebate amount due from each manufacturer. Section 1927(b)(2) of the Act requires States to provide the drug utilization data to CMS and the manufacturer. States also report drug rebate accounts receivable data on CMS Form-64.9R. This is part of CMS Form-64, "Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program" (CMS-64 report), which summarizes actual Medicaid expenditures for each quarter and is used by CMS to reimburse States for the Federal share of Medicaid expenditures.

## **Physician-Administered Drugs**

Section 6002(a) of the Deficit Reduction Act of 2005 (DRA) amended section 1927 of the Act and requires States, as of January 1, 2006, to collect and submit utilization data for single source drugs administered by physicians so that States may obtain rebates for the drugs.<sup>1</sup> Single source drugs are commonly referred to as “brand name drugs” and do not have generic equivalents.

In Colorado, physician-administered drugs are billed electronically to the State Medicaid program on the Health Insurance Portability & Accountability Act (HIPAA) A37P form. Manual claims are submitted to the State agency on a Colorado 1500 form. The Colorado 1500 form is based on the CMS 1500 form. Both forms use the procedure codes that are part of the Healthcare Common Procedure Coding System (HCPC). The HCPC procedure code identifies a drug by its active ingredient(s) and identifies the number of drug units (billing units) allowed per reimbursement for that procedure code. Because rebates are calculated and paid based on NDCs, each procedure code must be converted to an NDC. Additionally, the billing units for a procedure code may differ from the units used for rebate purposes (e.g., grams versus liters). Therefore, to determine rebates, the procedure codes must be converted into NDCs for single source drugs, and procedure code billing units must be converted into equivalent NDC billing units.

## **Family Planning Drugs**

The Medicaid family planning program is an enhanced-rate program (90-percent Federal share) under Medicaid. Under this program, family planning drugs purchased by a 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.

## **Prior Office of Inspector General Reports**

In 2005, we issued a report on the results of audits of the Medicaid drug rebate programs in 49 States and the District of Columbia.<sup>2</sup> Those audits found that only four States had no weaknesses in accountability for and internal controls over their drug rebate programs. As a result of the weaknesses, we concluded that States lacked adequate assurance that all of the drug rebates due to the States were properly recorded and collected. Additionally, CMS did not have reliable information from the States to properly monitor the drug rebate program.

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<sup>1</sup>This provision of the DRA expands the requirement to certain multiple source drugs administered by physicians after January 1, 2008.

<sup>2</sup>“Multistate Review of Medicaid Drug Rebate Programs” (A-06-03-00048), issued July 6, 2005; Arizona was not included because it did not operate a drug rebate program.

In our previous audit of the Colorado drug rebate program,<sup>3</sup> we determined the State agency had adopted measures to strengthen controls with regard to billing and tracking \$0 URAs, adjusting collections, and retaining records for at least 3 years. However, the State agency lacked sufficient accountability and internal controls in the following areas:

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

We recommended that the State agency:

- refund \$1,925,367 to the Federal Government, which consisted of \$1,880,565 relating to questioned OAP program rebates, \$4,994 for unreported interest, and \$39,808 for manufacturer disputes relating to the OAP program;
- 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.

The State agency did not concur in total that \$1,925,367 be refunded to the Federal Government. It concurred that it had underreported \$9,987 (\$4,994 Federal share) in rebate interest collected during calendar year 2004 and stated that it would seek to resolve the manufacturer disputes relating to the \$39,808 (Federal share) for the OAP program. However, the State agency did not agree that the entire \$1,880,565 it allocated to the OAP program should be returned to the Federal Government. The State agency indicated that it began system changes in July 2004 that would allow it to “retroactively” identify specific drug utilization amounts related to the OAP. These changes were to be completed by October 31, 2005.

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<sup>3</sup>The previous audit (“Follow-up Audit of the Medicaid Drug Rebate Program in Colorado,” A-07-05-04048, issued November 17, 2005) was a follow-up to an earlier audit of the Medicaid drug rebate program in Colorado (A-07-03-04018) issued October 7, 2003.

The State agency concurred with the remaining findings and stated that it took steps to address our recommendations.

### **Colorado Drug Rebate Program**

The State agency contracted with Affiliated Computer Systems (ACS) to prepare and mail invoices to manufacturers for Medicaid drug rebates. The State agency was responsible for (1) monitoring and maintaining the drug rebates accounts receivable, to include posting payments to subsidiary ledgers; (2) monitoring outstanding balances; and (3) resolving disputes. The State agency was also responsible for depositing funds and preparing the CMS-64 reports discussed earlier.

The State agency also contracted with Health Watch Technologies (HWT) to administer the physician-administered drug rebates. HWT's responsibilities included the processing of quarterly claims, invoicing, receiving payments, developing crosswalks for physician-administered drug rebates, and handling dispute resolution related to physician-administered drug rebates.

For State fiscal year 2006, the State agency reported collections on the Form CMS-64.9R of \$79,063,983. We determined (based on the State agency accounts receivable records) that as of June 30, 2006, the State agency had an outstanding drug rebate balance of \$15,570,667. However, \$13,281,137 of this amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining \$2,289,530 that was past due, \$2,144,855 was more than 1 year past due.

This current review of the Colorado drug rebate program is part of a nationwide series of reviews conducted to determine whether States have addressed the weaknesses in accountability for and internal controls over their drug rebate programs found in the previous reviews. Additionally, because the DRA required States as of January 2006 to begin collecting rebates on single source drugs administered by physicians, this series of reviews will also determine whether States have complied with the new requirement.

## **OBJECTIVES, SCOPE, AND METHODOLOGY**

### **Objectives**

Our objectives were to determine whether the State agency had (1) implemented the recommendations made in our previous audit of the Colorado drug rebate program and (2) established controls over the drug rebate program, including the collection of rebates on single source drugs administered by physicians.

### **Scope**

We reviewed the State agency's current policies, procedures, and controls over the drug rebate program and the accounts receivable data reported on Form CMS-64.9R as of June 30, 2006.

We conducted fieldwork at the State agency, located in Denver, Colorado, during March and April 2008.

## **Methodology**

To accomplish our objectives, we

- reviewed section 1927 of the Act, section 6002(a) of the DRA, CMS guidance issued to State Medicaid directors, and other information pertaining to the Medicaid drug rebate program;
- reviewed the previous Office of Inspector General report concerning the drug rebate program in Colorado;
- held meetings with CMS officials to determine status of prior findings and to obtain information regarding Medicaid drug rebate program reporting procedures;
- reviewed the policies and procedures relating to the State agency's drug rebate accounts receivable system;
- interviewed State agency officials to determine the policies, procedures, and controls that related to the Medicaid drug rebate program;
- reviewed copies of Form CMS-64.9R for the period July 1, 2005, through June 30, 2006;
- reviewed accounts receivable records for the State fiscal year ended June 30, 2006; and
- interviewed State agency officials to determine the processes used in converting physician services claims data into drug rebate data related to single source drugs administered by physicians.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

## **FINDINGS AND RECOMMENDATIONS**

The State agency partially corrected the weaknesses reported in our previous audit. Specifically:

- Although the State agency is currently working with CMS to negotiate a settlement regarding the \$1,925,367 in questioned costs relating to the prior audit, a final settlement has not been reached.

- The State agency reported drug rebates received for Family Planning drugs based on estimates and continued to withhold a portion of drug rebates received for the State funded OAP program invoiced prior to the quarter ending December 31, 2005. The State agency withheld 1.3 percent (\$765,988) for OAP drug rebates and claimed 1.44 percent (\$1,063,513) for Family Planning drug rebates based on estimates.
- Although the State agency had procedures in place to resolve outstanding disputes, it had \$861,924 in manufacturer balances that were over 3 years past due.
- While the State agency had developed policies and procedures to verify and record interest, it did not report \$44,797 (\$22,399 Federal share) in interest received.
- The State agency did not report all necessary data related to its Medicaid drug rebate program on the Form CMS-64.9R.

In addition, although the State agency, through its contractor HWT, established controls over collecting rebates on single source drugs administered by physicians, the State agency allowed the contract to expire effective June 30, 2007, and it has not collected rebates for single source drugs administered by physicians since the contract expired.

## **IMPLEMENTATION OF PRIOR RECOMMENDATIONS**

In our prior audit of the Colorado drug rebate program,<sup>4</sup> we determined that the State agency had adopted measures to strengthen controls with regard to billing and tracking \$0 URAs,<sup>5</sup> adjusting collections, and retaining records for at least 3 years. However, we also found that the State agency: (1) continued to allocate an estimated percentage of Medicaid drug rebates to the OAP program; (2) could not properly process OAP adjustments submitted by two manufacturers; (3) had disputes with drug manufacturers pending for 3 years because it did not adequately resolve disputes and did not offer the State’s hearing mechanism to manufacturers; and (4) did not verify, record, or report rebate interest. These errors occurred because the State agency lacked sufficient accountability and internal controls.

Since then, the State agency has partially corrected the weaknesses related to our prior finding. However, in some cases the action taken was not sufficient to correct the problem.

### **Prior Report’s Questioned Costs**

In our prior audit, we noted that the State agency 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) was incorrectly disputed by the

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<sup>4</sup>“Follow-up Audit of the Medicaid Drug Rebate Program in Colorado” (A-07-05-04048), issued November 17, 2005.

<sup>5</sup>The term “\$0 URAs” refers to drugs included on CMS’s quarterly Medicaid drug data tape, distributed to the States, that lack pricing information.

manufacturers, who had challenged the State agency's estimated percentage of Medicaid drug utilization instead of challenging specific units of utilization. The State agency also underreported rebate interest collected in calendar year 2004 by \$9,987 (\$4,994 Federal share).

In its comments on our prior audit finding, the State agency did not agree that the entire \$1,880,565 it allocated to the OAP program should be returned to the Federal Government. It said "that actual data [should] be used to determine the amount to be refunded." However, the State agency agreed "that there is currently no specific utilization data related to OAP Health and Medical Program invoices and that some amounts were invoiced on behalf of this State funded program under the Medicaid drug rebate invoices." The State agency added that it began system changes in July 2004—changes that were to be completed by October 31, 2005—that would allow it to "retroactively" identify specific drug utilization amounts related to the OAP.

The State agency also concurred with the finding that the State agency underreported rebate interest collected in calendar year 2004 in the amount of \$9,987 (\$4,994 Federal share) and stated that it would seek to resolve the manufacturer disputes relating to the \$39,808 (Federal share) for the OAP program.

Federal regulations at 42 CFR § 430.30(c)(2) require States to report actual recorded Medicaid expenditures. Pursuant to these regulations, States may not report the disposition of Federal funds on the basis of estimates.

During this current audit, the State agency indicated that it is currently negotiating with CMS to settle the prior finding relating to the questioned rebates and unreported interest. On March 17, 2008, the State agency issued a letter to CMS proposing a payment of \$102,725. The State agency indicated that the \$102,725 represented the difference between \$554,777, the actual amount owed to CMS for Medicaid drug rebates that were initially withheld as OAP drug rebates, and \$452,052, the actual amount owed to the State agency for the Family Planning drug rebate claims. The State agency's correspondence did not address either the unreported interest or the disputed OAP program rebates. As of March 31, 2008, CMS has not made a final settlement with the State agency relating to this finding.

### **Allocations to the Old Age Pension Program and Family Planning Drug Rebates**

In our prior audit, we noted that the State agency did not have procedures to segregate the data for drug utilization under the Medicaid drug rebate program from the data for drug utilization under the OAP program. (This segregation would have enabled the State agency to prepare separate rebate invoices to bill the manufacturers for Federal and State-funded programs.) In its comments on our prior audit finding, the State agency concurred with our finding and stated that it had implemented system changes to invoice OAP drugs separately. The changes were to be completed by October 31, 2005.

During the audit period, the State agency stopped including the OAP drug rebates with the Medicaid drug rebates beginning with the quarter ending December 31, 2005. However, the State agency continued to withhold 1.3 percent of the drug rebates received for the OAP program for rebates that were invoiced prior to the quarter ending December 31, 2005. Additionally, the



State agency reported 1.44 percent of the drug rebates received for Family Planning drug rebates. This report period also included the six months ending June 30, 2005, a timeframe which fell between the end of the prior audit's scope and the start of the current audit's review. The 1.3 percent for the OAP program and the 1.44 percent for Family Planning drug rebates represented estimates based on expenditures, rather than the actual amounts of rebates that were received for the respective programs.

Federal regulations at 42 CFR § 430.30(c)(2) require States to report actual recorded Medicaid expenditures. Pursuant to these regulations, States may not report the disposition of Federal funds on the basis of estimates.

Based upon this review, we calculated that the State agency withheld \$765,988 relating to estimated rebates for the OAP program and reported \$1,063,513 in estimated drug rebates under Family Planning drugs on the Form CMS-64.9R. During fieldwork, the State agency was unable to determine the actual amount of the rebates that related to the OAP and Family Planning programs. Therefore, we are setting aside \$1,829,501 for adjudication by CMS.

### **Dispute Resolution**

In our prior audit, we noted that the State agency and 46 drug manufacturers had not resolved disputes that were pending for more than 3 years.

The CMS Drug Rebate Agreement states: "The State and the Manufacturer will use their best efforts to resolve [a] discrepancy within 60 days of receipt of such notification. 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 hearing mechanism available under the Medicaid Program . . . ."

The State agency did not adequately resolve disputes with manufacturers. It did not directly contact the manufacturers, regularly attend CMS drug rebate program meetings, or utilize available resources at the regional CMS office.

Furthermore, the State agency did not offer the manufacturers the State's hearing mechanism as required by the rebate agreements. Therefore, Medicaid drug rebate invoices totaling (at the time) \$388,592 remained unresolved for more than 3 years. The State agency agreed with our finding and stated that it had contacted manufacturers to resolve outstanding disputes. It reported that it had resolved nearly half of the disputes cited in our audit through collections and adjustments.

As of the time period covered by this current audit, the State agency had developed policies and procedures to resolve disputed drug rebates. However, as of February 2008, the State agency had a total outstanding balance due of \$2,885,945 that related to invoices still unresolved due to disputed drug rebates, with \$861,924 relating to balances that were over 3 years past due.

## **Interest Verification, Recording, and Reporting**

In our prior audit, we noted that the State agency did not verify, record, or report drug rebate program interest received during calendar year 2004 totaling \$9,987 (\$4,994 Federal share). Furthermore, it relied solely on the manufacturers to voluntarily calculate and remit interest owed on all disputed or late drug rebate payments. The State agency did not recalculate interest voluntarily paid by manufacturers to verify that the correct amounts were paid; nor did it make adequate efforts to collect interest from manufacturers who did not voluntarily remit interest owed. As a result, the State agency did not report the Federal share of interest collected from late, disputed, or unpaid rebate payments totaling \$4,994. Moreover, the State agency likely did not receive all interest owed by the manufacturers. In its comments on our prior audit finding, the State agency agreed with our finding and stated that it is “implementing a manual process to verify, record, and report interest.” It stated it also was considering implementing an automated system.

The State Medicaid Manual § 2500.1 instructs the States to prepare a Form CMS-64 Summary Sheet reporting the Federal share of interest received on drug rebate collections.

As of the time period covered by this current audit, the State agency only had procedures in place to verify that the interest paid by the manufacturers was correctly calculated. However, in December 2006, the State agency began using ACS’s Drug Rebate Administration and Management System to maintain its drug rebate system. This system allowed the State agency to accrue, bill, and record interest relating to outstanding drug rebates. However, even though the State agency began tracking the interest, it did not report interest received during the audit period. During State fiscal year 2006, the State agency received \$44,797 (\$22,399 Federal share) in interest relating to Medicaid drug rebates.

## **MEDICAID DRUG REBATE ACTIVITY REPORTING**

During this current review, we noted that the State agency was not reporting Medicaid drug rebate activity on Form CMS-64.9R correctly.

Federal regulations at 42 CFR § 433.32 require that the State agency “. . . (a) [m]aintain an accounting system and supporting fiscal records to assure that claims [reported on the CMS-64 reports] for Federal funds are in accord with applicable Federal requirements.” Federal regulations at 45 CFR § 92.20(a) also state: “. . . Fiscal control and accounting procedures of the State, as well as its subgrantees . . . must be sufficient to . . . establish that such [Medicaid] funds have not been used in violation of the restrictions and prohibitions of applicable statutes.” CMS prescribes the information that is included on the Form CMS-64.9R. This required information includes beginning balances, adjustments, current rebates invoiced, rebates collected, and ending balances.

While the State agency reported rebates collected on the Form CMS-64.9R, it did not report beginning balances, adjustments, current rebates invoiced, or ending balances.

## **PHYSICIAN-ADMINISTERED SINGLE SOURCE DRUGS**

The State agency, through its contractor HWT, established controls over collecting rebates on single source drugs administered by physicians. However, the State agency allowed the contract to expire, and it has not collected rebates for single source drugs administered by physicians since the contract expired.

As stated earlier, the DRA amended Section 1927(a) of the Act by adding the requirement for submission of utilization data for certain physician-administered drugs. Specifically, section 6002 of the DRA added section 1927(a)(7) to the Act to require States to collect rebates on physician-administered drugs. The section requires that States begin submitting rebate invoices for single source physician-administered drugs by January 1, 2006.

During State fiscal year 2006, the State agency had a contract with HWT to prepare the State agency's invoices for physician-administered single source drugs. For the 6 months ending June 30, 2006, the State agency invoiced \$1,282,690 for rebateable physician-administered drugs, based upon \$3,756,089 in claims. However, the State agency's contract with HWT expired effective June 30, 2007. Since that time, the State agency has not invoiced for the physician-administered drugs. The State agency is currently working to develop its own in-house process for invoicing for physician-administered single source drug rebates. The State agency informed us that it plans to begin invoicing for the single source physician-administered drugs in May 2008, and to do a retroactive invoicing to June 30, 2007.

## **RECOMMENDATIONS**

We recommend the State agency:

- continue to work with CMS to determine and finalize a settlement of the prior recommendation that the State agency refund the Federal Government \$1,925,367;
- work with CMS to determine the actual amount of the \$1,829,501 in drug rebates from our current audit period, that relate to the Medicaid program, OAP program and Family Planning;
- actively pursue settlement of the disputed amounts (including \$861,924 in drug rebates that remained outstanding for more than 3 years) and utilize available dispute resolution resources;
- refund the Federal Government \$22,399 for the Federal share of interest that was received but not reported; and
- develop policies and procedures to accurately report the Medicaid Drug Rebate activity that include reporting beginning balances, adjustments, and ending balances on the Form CMS-64.9R.

Additionally, we recommend the State agency develop policies and procedures for invoicing single source physician-administered drug rebates and resume invoicing drug rebates on single source drugs administered by physicians, as required.

### **STATE AGENCY COMMENTS**

In written comments on our draft report, the State agency concurred with all of our recommendations. The State agency written comments included a discussion of implementation and corrective actions proposed.

The State agency's comments are included in their entirety as the Appendix.

# **APPENDIX**



**COLORADO DEPARTMENT OF HEALTH CARE POLICY & FINANCING**

1570 Grant Street, Denver, CO 80203-1818 • (303) 866-2993 • (303) 866-4411 Fax • (303) 866-3883 TTY  
Bill Ritter, Jr., Governor • Joan Henneberry, Executive Director

August 11, 2008

Mr. Patrick Cogley  
Department of Health & Human Services  
Office of Inspector General, Office of Audit Services  
601 East 12th Street, Room 284A  
Kansas City, MO 64106

Audit Identification Number: CIN A-07-08-03108

Dear Mr. Cogley:

Please find attached the Department of Health Care Policy and Financing's (the Department) responses to the draft Colorado Medicaid Drug Rebate Program follow-up audit report.

If you have any questions or concerns, please contact Laurie Simon at (303) 866-2590 or [laurie.simon@state.co.us](mailto:laurie.simon@state.co.us).

Sincerely,

A handwritten signature in black ink, appearing to read 'Joan Henneberry'.

Joan Henneberry  
Executive Director

JH:las

cc: Greg Tamke, Office of Inspector General Audit Manager  
Sandeep Wadhwa, M.D., M.B.A., Medicaid Director, Medical and Child Health Plan *Plus* Administration  
Jennifer Evans, Deputy Director, Administration & Operations Office  
Cathy Traugott, Pharmacy Section Manager  
Laurie Simon, HCPF Audit Coordinator

Department of Health Care Policy and Financing's Initial Response  
Office of the Inspector General's Follow-up Audit of  
Medicaid Drug Rebate (A-07-08-03108)  
August 11, 2008

**Recommendation #1: We recommend the State agency continue to work with CMS to determine and finalize a settlement of the prior recommendation that the State agency refund the Federal Government \$1,925,367.**

*The Department of Health Care Policy and Financing's response to Recommendation #1:*

*Concur.*

*The Department could not agree that the amount calculated in the OIG's 2005 audit report was accurate. The Department continues to work with CMS to bring resolution to this prior recommendation. The Department has submitted to CMS data that can be used to determine the amount refunded rather than using the estimates presented in the OIG's 2005 audit report. The Department did provide CMS with a settlement offer in July 2007, which was supported with claim level data provided in October 2007 and then additional information was provided in March 2008. The Department continues to be available to address further questions from CMS and looks forward to bringing this issue to resolution.*

**Recommendation #2: We recommend the State agency work with CMS to determine the actual amount of the \$1,829,501 in drug rebates from our current audit period, that rebate to the Medicaid program, OAP program and Family Planning.**

*The Department of Health Care Policy and Financing's response to Recommendation #2:*

*Concur.*

*The Department appreciates the OIG's recommendation that provides the opportunity to work with CMS to determine the actual amount rather continuing to make use of estimates for the drug rebate for Medicaid, the Old Age Pension Health and Medical Care Program and the Medicaid family planning program. The Department believes that the resolution of this OIG recommendation should be consistent with the process already started in the above OIG recommendation. The Department will begin analyzing the data and will provide data to CMS following the release of this audit report. The Department expects the data will significantly reduce the questioned amount. By working with CMS, the Department looks forward to bringing this issue to resolution.*

**Recommendation #3: We recommend the State agency actively pursue settlement of the disputed amounts (including \$861,924 in drug rebates that remained outstanding for more than 3 years) and utilize available dispute resolution resources.**

*The Department of Health Care Policy and Financing's response to Recommendation #3:*

*Concur.*

*The Department agrees with the finding that we should continue to actively seek the prior period receivables, including the \$861,924. The Department has been diligently pursuing these amounts for a number of years. For example, one manufacturer has fifteen labeler numbers and it consumes nearly 46% of this outstanding amount due the Department. The Department's rebate analyst recently attended a convention at which dispute resolution meetings were conducted. Johnson and Johnson was present and the two parties resolved disputes going back to the fourth quarter of 2002. Two months ago, the Department began resolving the previous years and the Department anticipates that by the end of 2008, Johnson and Johnson will be current. The prior period noted has now been reduced by 32.5%.*

*In connection with the finding, the OIG stated that the Department was not adequately resolving nor directly contacting manufacturers, regularly attending CMS drug rebate program meetings or utilizing available resources at the regional CMS office. The Department engages the manufacturer not only by phone, but by follow-up letters as well. The Department's analyst has attended many CMS dispute resolution meetings as well as other meetings where dispute resolution has occurred. The Department's analyst did not attend last year's CMS dispute resolution meeting in Baltimore due to the fact that the manufacturers attending had no disputes with the Department. This year's meeting is being held here in Denver, and the Department's analyst will be attending all three days. The Department has used the regional CMS office in the past to attempt to resolve disputes. The Department works to resolve issues using other methods, including resources at the regional office, before implementing formal proceedings against a manufacturer.*

**Recommendation #4: We recommend the State agency refund the Federal Government \$22,399 for the Federal share of interest that was received but not reported.**

*The Department of Health Care Policy and Financing's response to Recommendation #4:*

*Concur.*

*The Department will refund the Federal Government its share of the interest in the amount of \$22,399.*



**Recommendation #5: recommend the State agency develop policies to accurately report the Medicaid Drug Rebate activity that include reporting beginning balances, adjustments, and ending balances on the Form CMS-64.9R.**

*The Department of Health Care Policy and Financing's response to Recommendation #5:*

*Concur.*

*The Department has actively been working with CMS to begin reporting the beginning balances on Form CMS-64.9R beginning with the quarter ending June 30, 2008. The Department will continue to work on developing policies and procedures to ensure accurate reporting on the Form CMS64.9R. Furthermore, the Department will continue communicating with CMS to ensure compliance in regard to the financial reporting on the Form CMS64.9R.*

**Recommendation #6: Additionally, we recommend the State agency develop policies and procedures for invoicing single source physician-administered drug rebates and resume invoicing drug rebates on single source drugs administered by physicians, as required.**

*The Department of Health Care Policy and Financing's response to Recommendation #6:*

*Concur.*

*The Department agrees with the recommendation to resume invoicing of the single source drugs administered by physicians. Once the system changes were completed, the Department resumed these efforts. As the Department informed the OIG, the Department sent invoices in May 2008 and did a retroactive invoicing back to June 30, 2007. The Department will continue to do quarterly invoicing of these drugs.*