DEPARTMENT OF HEALTH & HUMAN SERVICES



Region VII 601 East 12th Street Room 284A Kansas City, Missouri 64106

FEB 1 5 2008

Report Number: A-07-07-04113

Ms. Laurie A. Simon Audit Coordinator Colorado Department of Health Care Policy & Financing 1570 Grant Street Denver, Colorado 80203-1818

Dear Ms. Simon:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG) final report entitled "Review of Medicaid Outpatient Drug Expenditures in Colorado for the Period October 1, 2002, Through September 30, 2004." A copy of this report will be forwarded 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.

Pursuant to the principles of the Freedom of Information Act, 5 U.S.C. § 552, as amended by Public Law 104-231, OIG reports generally are made available to the public to the extent the information is not subject to exemptions in the Act (45 CFR part 5). Accordingly, within 10 business days after the final report is issued, it will be posted on the Internet at http://oig.hhs.gov.

If you have any questions or comments about this report, please do not hesitate to call me at (816) 426-3591, or contact Raylene Mason, Audit Manager, at (816) 426-3203 or by e-mail at Raylene.Mason@oig.hhs.gov. Please refer to report number A-07-07-04113 in all correspondence.

Sincerely,

Patrick J. Cogley

Regional Inspector General

for Audit Services

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

REVIEW OF MEDICAID OUTPATIENT DRUG EXPENDITURES IN COLORADO FOR THE PERIOD OCTOBER 1, 2002, THROUGH SEPTEMBER 30, 2004



Daniel R. Levinson Inspector General

> February 2008 A-07-07-04113

Office of Inspector General

http://oig.hhs.gov

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Pursuant to the principles of the Freedom of Information Act, 5 U.S.C. § 552, as amended by Public Law 104-231, Office of Inspector General reports generally are made available to the public to the extent the information is not subject to exemptions in the Act (45 CFR part 5).

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

Pursuant to Title XIX of the Social Security Act, the Medicaid program provides medical assistance to 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. In Colorado, the Department of Health Care Policy and Financing (the State agency) administers Medicaid.

In addition to providing mandatory Medicaid services, States may offer certain optional services, such as outpatient prescription drugs, to eligible Medicaid beneficiaries. Most States, including Colorado, administer their Medicaid prescription drug programs in accordance with the Medicaid drug rebate program. The program generally pays for covered outpatient drugs if the drug manufacturers have rebate agreements with CMS and pay rebates to the States. Under the drug rebate program, CMS provides the States with a quarterly Medicaid drug tape, which lists all covered outpatient drugs and indicates a drug's termination date, if applicable. CMS guidance instructs the States to use the tape to verify coverage of the drugs for which they claim reimbursement.

In Colorado, the State agency claims Medicaid expenditures on Form CMS-64, "Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program." CMS reimburses the State agency based on the Federal medical assistance percentage for the majority of claimed Medicaid outpatient drug expenditures.

OBJECTIVE

Our objective was to determine whether the State agency's claims for reimbursement of Medicaid outpatient drug expenditures complied with Federal requirements.

SUMMARY OF FINDINGS

The State agency's claims for reimbursement of Medicaid outpatient drug expenditures for fiscal years 2003 and 2004 did not fully comply with Federal requirements. Of the \$489 million (\$255 million Federal share) claimed, \$21,678 (Federal share) represents expenditures for drug products that were not eligible for Medicaid coverage because they were terminated drugs for which the termination dates were listed on the CMS quarterly drug tape before the drugs were dispensed. An additional \$459,604 (Federal share) represents expenditures for drug products that were not listed on the quarterly drug tapes. Because the State agency did not verify whether the drugs missing from the tapes were eligible for Medicaid coverage, these drug expenditures may not be allowable for Medicaid reimbursement. For the remainder of the \$489 million (\$255 million Federal share) claimed, we identified no other errors with respect to whether the drugs were either terminated or included on the CMS quarterly drug tapes.

The State agency had inadequate controls to ensure that all of its outpatient drug expenditures complied with Federal requirements.

RECOMMENDATIONS

We recommend that the State agency:

- refund \$21,678 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;
- work with CMS to resolve \$459,604 in payments for drugs that were not listed on the quarterly drug tapes and that may not have been eligible for Medicaid coverage; and
- strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements, specifically:
 - o claim expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes, and
 - o verify whether drugs not listed on the quarterly drug tapes are covered under the Medicaid program and notify CMS when drugs are missing from the tapes.

STATE AGENCY'S COMMENTS

In written comments on our draft report, the State agency concurred with our first recommendation. The State agency did not concur with our second recommendation, and stated that it had used a private industry database as its source for determining whether the drug expenditures it claimed were eligible for Medicaid coverage. The State agency added that while performing its own research, it found "many instances that the data from OIG [i.e., data from the CMS quarterly drug tapes] did not match the data from [the private industry database]." The State agency said that it "continues to believe that it could rely on" the private industry database because that private company "is a preferred vendor of CMS."

The State agency partially concurred with our third recommendation. The State agency said that it has made several changes to strengthen its internal controls and thus ensure that claimed Medicaid drug expenditures comply with Federal requirements; one of those changes "[u]tilizes the CMS tape as the source of drug rebate claims." In addition, the State agency agreed to claim expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes. However, the State agency did not concur with our recommendation that it verify whether drugs not listed on the quarterly drug tapes are covered under the Medicaid program. The State agency suggested that CMS should be responsible for verifying the accuracy of the CMS quarterly drug tapes.

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

OFFICE OF INSPECTOR GENERAL'S RESPONSE

After reviewing the State agency's comments, we emphasize that CMS guidance requires the State agency to verify whether the drugs claimed for Federal reimbursement are included on the CMS quarterly drug tapes and, if not, to contact CMS to verify that the missing drugs are eligible for Medicaid coverage. Had the State agency verified its drug purchases using the CMS quarterly drug tapes – rather than relying upon a private industry database – the State agency could have notified CMS that some drug products were missing from the quarterly drug tapes. CMS could then have adjusted subsequent quarterly drug tapes to include the missing drugs eligible for Medicaid coverage for the periods claimed. Accordingly, we continue to recommend that the State agency work with CMS to resolve \$459,604 in payments for drugs that were not listed on the quarterly drug tapes. We also continue to recommend that the State agency strengthen internal controls by verifying whether drugs not listed on the quarterly drug tapes are covered under the Medicaid program and by notifying CMS when drugs are missing from the tapes.

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STATE AGENCY'S COMMENTS

INTRODUCTION

BACKGROUND

Medicaid Program

Pursuant to Title XIX of the Social Security Act (the Act), the Medicaid program provides medical assistance to 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. In Colorado, the Department of Health Care Policy and Financing (the State agency) administers the Medicaid program.

State Medicaid programs must provide certain medical services, including inpatient and outpatient hospital, physician, and family planning services. States also may offer certain optional services, such as outpatient prescription drugs, as long as the services are included in their approved State plans.

Medicaid Outpatient Prescription Drug Program

All States offer outpatient prescription drugs to eligible Medicaid beneficiaries. Most States, including Colorado, administer their Medicaid prescription drug programs in accordance with the Medicaid drug rebate program. The program generally pays for covered outpatient drugs if the drug manufacturers have rebate agreements with CMS and pay rebates to the States. The rebate agreements require manufacturers to provide a list of all covered outpatient drugs to CMS quarterly. CMS includes these drugs on a quarterly Medicaid drug tape, makes adjustments for any errors, and sends the tape to the States. The tape indicates a drug's termination date, if applicable, specifies whether the drug is less than effective, and includes information that the States use to claim rebates from drug manufacturers. CMS guidance instructs the States to use the tape to verify coverage of the drugs for which they claim reimbursement and to calculate the rebates that the manufacturers owe.

¹The Omnibus Budget Reconciliation Act of 1990 established the Medicaid drug rebate program effective January 1, 1991. The program is set forth in section 1927 of the Act. Arizona is the only State that does not participate in the program.

²The termination date, which the manufacturer submits to CMS, reflects the shelf-life expiration date of the last batch sold for a particular drug code. However, if the drug is pulled from the market for health or safety reasons, the termination date is the date that the drug is removed from the market.

³The Food and Drug Administration determines whether drugs are less than effective. Such drugs lack substantial evidence of effectiveness for all conditions of use prescribed, recommended, or suggested in their labeling.

Reimbursement of Medicaid Expenditures

In Colorado, the State agency claims Medicaid expenditures on Form CMS-64, "Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program" (CMS-64). CMS reimburses the State agency based on the Federal medical assistance percentage (reimbursement rate) for the majority of claimed Medicaid expenditures, including outpatient drug expenditures.

For Federal fiscal years (FY) 2003 and 2004, Colorado's Federal reimbursement rate for Medicaid expenditures varied from 50.00 percent to 52.95 percent.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether the State agency's claims for reimbursement of Medicaid outpatient drug expenditures complied with Federal requirements.

Scope

The audit scope included \$489 million (\$255 million Federal share) in Medicaid outpatient drug expenditures that the State agency claimed for FYs 2003 and 2004. We limited our testing of these expenditures to determining compliance with specific Federal requirements related to whether the drugs were terminated and included on the CMS quarterly drug tapes.

We limited our internal control review to the State agency's procedures for determining whether the outpatient drugs were eligible for Medicaid coverage and were accurately claimed for Federal reimbursement. We did not review the accuracy or completeness of the quarterly Medicaid drug tapes.

We conducted fieldwork at the State agency's offices in Denver, Colorado.

Methodology

To accomplish our objective, we reviewed applicable Federal laws, regulations, and program guidance and the State plan. We interviewed State agency officials responsible for identifying and monitoring drug expenditures and rebate amounts. We also interviewed staff responsible for reporting drug expenditures to CMS.

We used the quarterly drug tapes for the period October 1, 1999, through March 31, 2005. We reconciled the amounts that the State agency reported on its CMS-64s to a detailed list of the State agency's outpatient drug expenditures. We also used the detailed list of drug expenditures to determine whether the expenditures complied with Federal requirements. Specifically, we determined whether the drugs for which the State agency claimed reimbursement were dispensed after the termination dates listed on the quarterly drug tape. In addition, we determined whether CMS had included the termination dates on the quarterly drug tape in a timely manner – that is, before terminated drugs could be dispensed. To account for reasonable delays in processing data

for terminated drugs, we used the first day of the quarter after the State received the tape as the termination date if the termination dates were provided to the State retroactively.

We also determined whether the drugs claimed for reimbursement were listed on the applicable quarterly drug tape. If the drugs were not listed on the tape, we determined whether the State agency had verified whether the drugs were eligible for Medicaid coverage.

We calculated the Federal share of the expenditures using the lowest percentage (50.00 percent to 52.95 percent) applicable for each quarter. We did not reduce the questioned drug expenditures by the rebate amounts that the State received.

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's claims for reimbursement of Medicaid outpatient drug expenditures for FYs 2003 and 2004 did not fully comply with Federal requirements. Of the \$489 million (\$255 million Federal share) claimed, \$21,678 (Federal share) represents expenditures for drugs products that were not eligible for Medicaid coverage because they were terminated drugs for which the termination dates were listed on the CMS quarterly drug tape before the drugs were dispensed. An additional \$459,604 (Federal share) represents expenditures for drug products that were not listed on the quarterly drug tapes. Because the State agency did not verify whether the drugs missing from the tapes were eligible for Medicaid coverage, these drug expenditures may not be allowable for Medicaid reimbursement. For the remainder of the \$489 million (\$255 million Federal share) claimed, we identified no other errors with respect to whether the drugs were either terminated or included on the CMS quarterly drug tapes.

The State agency had inadequate controls to ensure that all of its outpatient drug expenditures complied with Federal requirements.

CLAIMS FOR TERMINATED DRUGS

Pursuant to 21 CFR § 211.137, each drug must have an expiration date to ensure that the drug meets certain standards, including strength and quality, at the time of its use. The expiration date effectively establishes a shelf life for the product. The termination date equals the expiration date of the last batch sold, except in cases when the product is pulled from the market. In those cases, the termination date may be earlier than the expiration date.

According to the CMS Medicaid drug rebate program memorandum to State Medicaid directors, number 19, the States "must . . . assure that claims submitted by pharmacists are not for drugs dispensed after the termination date. These should be rejected as invalid since these drugs cannot be dispensed after this date."

The CMS Medicaid drug rebate program memorandum to State Medicaid directors, number 130, states that ". . . the CMS [quarterly drug tape] is the one to use for ALL data when you are dealing with the drug rebate program" The quarterly drug tapes list the Medicaid-covered drugs' termination dates as reported by the drug manufacturers.

For FYs 2003 and 2004, the State agency claimed \$41,660 (\$21,678 Federal share) in expenditures for drugs that, according to the State's records, were dispensed after the termination dates shown on the quarterly drug tapes. For example, the State agency paid for the drug Megestrol, which was dispensed on March 9, 2004. However, the drug's termination date was July 19, 2003, according to the tapes beginning with the quarter that ended March 31, 2002. The claimed expenditure was unallowable because it occurred after the drug's termination date, which was listed on the quarterly drug tape at the time the State agency made the expenditures.

CLAIMS FOR DRUGS NOT LISTED ON QUARTERLY DRUG TAPES

Section 1927(a)(1) of the Act generally conditions Medicaid reimbursement for covered outpatient drugs on a requirement that manufacturers of those products enter into rebate agreements with CMS under which they pay rebates to the States. The rebate agreements require manufacturers to provide a list of all covered outpatient drugs to CMS quarterly. CMS includes these drugs on the quarterly drug tapes and makes adjustments for any errors. According to the CMS Medicaid drug rebate program memorandum to State Medicaid directors, number 130: "... the CMS [quarterly drug tape] is the one to use for ALL data when you are dealing with the drug rebate program If [a drug code] that is not on the last CMS [quarterly drug tape] you received is billed to you by a pharmacy, ... check with CMS to assure that the [drug code] is valid" Furthermore, the CMS Medicaid drug rebate program memorandum to State Medicaid directors, number 44, provides that "States must check the [quarterly drug tape] to ensure the continued presence of a drug product"

The CMS "Medicaid Drug Rebate Operational Training Guide," page S13, states: "If you have paid for [a drug code] that is NOT on [the quarterly drug tape] you should have checked to make sure it was correct. If you paid a pharmacy for utilization on an invalid [drug code], you may have to . . . recoup your funds."

For FYs 2003 and 2004, the State agency claimed \$889,613 (\$459,604 Federal share) in expenditures for drug products that were not listed on the quarterly drug tapes. The State agency did not contact CMS to ensure that these drugs were eligible for Medicaid coverage under the Act. As a result, the State agency did not have conclusive evidence that these payments were allowable Medicaid expenditures.

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⁴Pursuant to Section 1927(a)(3) of the Act, a State may exempt certain drugs from the requirement to be covered by a drug rebate agreement if the State has determined that availability of the drug is essential to the health of Medicaid beneficiaries.

INADEQUATE CONTROLS TO DETECT UNALLOWABLE AND POTENTIALLY UNALLOWABLE CLAIMS FOR DRUG EXPENDITURES

The State agency did not have adequate controls to ensure that all Medicaid drug expenditures complied with Federal requirements or to detect unallowable and potentially unallowable claims for reimbursement. The State agency did not check the quarterly drug tapes to ensure that the drugs were eligible for Medicaid coverage.

REIMBURSEMENT OF UNALLOWABLE AND POTENTIALLY UNALLOWABLE CLAIMS FOR DRUG EXPENDITURES

The State agency claimed Federal reimbursement for certain drugs that were not eligible for Medicaid coverage because they were terminated. As a result, for FYs 2003 and 2004, the State agency claimed unallowable expenditures totaling \$41,660 (\$21,678 Federal share) for these drugs. The State agency also claimed Federal reimbursement for drug products that were not listed on the quarterly drug tapes. For these drugs, we set aside potentially unallowable expenditures totaling \$889,613 (\$459,604 Federal share) for CMS adjudication because the State agency did not determine whether the drugs were covered by Medicaid.

RECOMMENDATIONS

We recommend that the State agency:

- refund \$21,678 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;
- work with CMS to resolve \$459,604 in payments for drugs that were not listed on the quarterly drug tapes and that may not have been eligible for Medicaid coverage; and
- strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements, specifically:
 - o claim expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes, and
 - o verify whether drugs not listed on the quarterly drug tapes are covered under the Medicaid program and notify CMS when drugs are missing from the tapes.

STATE AGENCY'S COMMENTS

In written comments on our draft report, the State agency concurred with our first recommendation. The State agency did not concur with our second recommendation, stating that it "continues to believe that the analysis that resulted in the above stated dollar amount" [i.e., \$459,604] is flawed." The State agency stated that it had used a private industry database as its source for determining whether the drug expenditures it claimed were eligible for Medicaid coverage. The State agency added that while performing its own research, it found "many

instances that the data from OIG [i.e., data from the CMS quarterly drug tapes] did not match the data from [the private industry database]." The State agency said that it "continues to believe that it could rely on" the private industry database because that private company "is a preferred vendor of CMS."

The State agency partially concurred with our third recommendation. The State agency said that it has made several changes to strengthen its internal controls and thus ensure that claimed Medicaid drug expenditures comply with Federal requirements; one of those changes "[u]tilizes the CMS tape as the source of drug rebate claims." In addition, the State agency agreed to claim expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes. However, the State agency did not concur with our recommendation that it verify whether drugs not listed on the quarterly drug tapes are covered under the Medicaid program. The State agency stated: "The Department does not have the authority, responsibility or resources to verify the information on the CMS quarterly tape [and] respectfully suggests that CMS should be responsible to determine the accuracy of the information that is sent to the states."

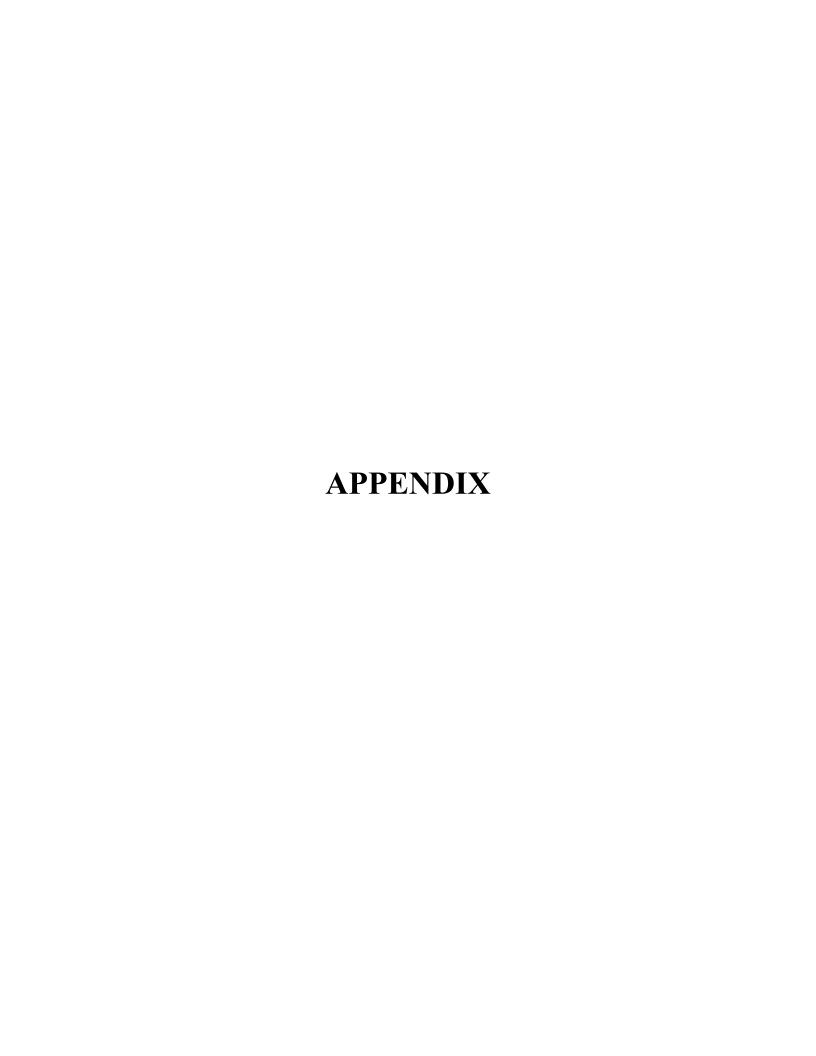
The State agency's comments are included in their entirety as the Appendix.

OFFICE OF INSPECTOR GENERAL'S RESPONSE

After reviewing the State agency's comments, we emphasize that CMS guidance requires the State agency to verify whether the drugs claimed for Federal reimbursement are included on the CMS quarterly drug tapes and, if not, to contact CMS to verify that the missing drugs are eligible for Medicaid coverage.

We acknowledge the State agency's concerns regarding discrepancies between the CMS quarterly tapes and the private industry database the State agency was using. However, CMS has made it clear that all States must use the CMS quarterly drug tapes in administering their drug rebate programs. Specifically, the CMS "Medicaid Drug Rebate Operational Training Guide," page S12, states that the private industry database "does NOT necessarily contain all of the correct data for running your Drug Rebate System." Further, the CMS Medicaid drug rebate program memorandum to State Medicaid directors, number 130, states, "... the CMS [quarterly drug tape] is the one to use for ALL data when you are dealing with the drug rebate program. The data values reported to you by CMS are assumed to be correct unless we find otherwise and change it data that is wrong on the CMS file will be corrected by CMS and reported to you on the next quarterly file."

Had the State agency verified its drug purchases using the CMS quarterly drug tapes – rather than relying upon a private industry database – the State agency could have notified CMS that some drug products were missing from the quarterly drug tapes. CMS could then have adjusted subsequent quarterly drug tapes to include the missing drugs eligible for Medicaid coverage for the periods claimed. Accordingly, we continue to recommend that the State agency work with CMS to resolve \$459,604 in payments for drugs that were not listed on the quarterly drug tapes. We also continue to recommend that the State agency strengthen internal controls by verifying whether drugs not listed on the quarterly drug tapes are covered under the Medicaid program and by notifying CMS when drugs are missing from the tapes.





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

December 13, 2007

Mr. Patrick J. Cogley, Regional Inspector General U.S. Department of Health and Human Services Office of the Inspector General Offices of Audit Services 601 East 12th Street, Room 284A Kansas City, MO 64106

Subject: Audit Report #A-07-07-04113

Dear Mr. Cogley:

The Colorado Department of Health Care Policy and Financing (the Department) has reviewed your draft reports of the above-mentioned audit. Enclosed are the Department's responses.

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 at 303-866-2590 or at laurie.simon@state.co.us.

Sincerely,

Audit Coordinator

Saurie A. Semin

Laurie A. Simon

Joan Henneberry, Executive Director cc:

Jennifer Evans, Administration and Operations Office Director

Cathy Traugott, Pharmacy Benefits Section Manager

Adel Soliman, Controller

Enclosure

"The mission of the Department of Health Care Policy & Financing is to improve access to cost-effective, quality health care services for Coloradans" http://www.chepf.state.co.us

Department of Health Care Policy and Financing's Initial Responses to the Office of the Inspector General's Outpatient Drug Expenditures Audit Report #A-07-07-04113 December 13, 2007

Recommendation #1: Refund \$21,678 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage.

Response: Concurrence.

The amount will be reported on the CMS-64 report and credit will be given to the Federal Government in the current fiscal quarter.

Recommendation #2: Work with Centers for Medicare and Medicaid Services (CMS) to resolve \$459,604 in payments for drugs that were not listed on the quarterly drug tapes and that may not have been eligible for Medicaid coverage.

Response: Nonconcurrence.

The Department continues to believe that the analysis that resulted in the above stated dollar amount is flawed. While performing the Department's own research, the Department found numerous instances where the National Drug Codes included in the analysis were in fact rebateable. This research was included in the Department's response to the updated fact sheet date June 21, 2007 and was further discussed at the exit interview with the Office of the Inspector General (OIG). At the exit interview, the Department was asked to hold the final numbers and present them after the Department received the draft Medicaid Outpatient Drug Expenditure Audit Report. The Department's analysis is attached.

In addition, during the exit interview the Department was informed that it would not be held responsible for any portion of this amount. This amount was going to be set-aside and would be rolled up with other states to make a report to CMS regarding their control of this issue. As stated in the Department's response letter dated June 21, 2007, the Department continues to believe that it could rely on First Data Bank's (FDB) data because FDB is a preferred vendor of CMS.

Recommendation #3: Strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with federal requirements.

Response: Concurrence. The Department has made several changes to its processes including:

- Implemented the upgraded pharmacy claims adjudication system (PDCS X2) will lead to fewer systematic errors in payment;
- Implemented a new drug rebate system (DRAMS) will lead to improved rebate collections;

• Utilizes the CMS tape as the source of drug rebate status. Prior to this audit the Department used FDB as the source of this information. As stated above, the Department continues to believe that it should be able to rely on the FDB data. However, in the interest of avoiding any potential problems caused by errors between CMS and FDB, the Department is now using the CMS tape itself.

Recommendation #3a: Claim expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes.

Response: Concurrence.

The Department now uses the quarterly CMS tape as the source of drug termination dates. Prior to this Audit, the Department also used FDB as the source of this information.

In addition, the Department now uses the obsolete date as a backup to the termination date. Therefore, even if the Department does not receive the termination date from CMS, the Department will still deny a claim for a drug if it is for a date of service that is more than two years after the obsolete date of the drug.

Recommendation #3b: Verify whether drugs not listed on the quarterly drug tapes are covered under the Medicaid program and notify CMS when drugs are missing from the tapes.

Response: Nonconcurrence.

The Department does not have the authority, responsibility or resources to verify the information on the CMS quarterly tape. The Department believes that this is a quality assurance activity that should be completed by the entity responsible for creating the tape. The Department respectfully suggests that CMS should be responsible to determine the accuracy of the information that is sent to the states.

During the time period of the Audit, the Department was using FDB as the source for the Department's information. If corrections are needed, the Department respectfully suggests that those corrections should be made by CMS through FDB. Since FDB was a preferred vendor of CMS at that time, CMS and not the Department should be responsible for working with FDB to make any corrections.

Attachment for Rec. #2 OIG Pharmacy Audit - Non-Matching Rebates

ASSUMPTIONS - NON-MATCHING REBATES

Method 1. Payments Explained with FDB data

We compared the OIG audit to the First Data Bank data. We found in many instances that the data from OIG did not match the data from FDB. More specifically, we found that:

- 1.1. \$837,289 of the audited payments were actually paid during a currently rebatable quarter according to FDB. (current indicator = 1, means rebatable). See tab Method 1.1.
- 1.2. The audited NDCs are currently not rebatable (current indicator = 0) but were rebatable at the time the claim was paid (1s previous indicator =1). \$33,969 of audited payments were explained this way. See tab Method 1.2.
- 1.3. The audited NDCs were paid and rebatable between the 1st previous quarter and the 2nd previous quarter. \$121 were explained this way. See tab Method 1.3.

Therefore, only \$18,231 (2%) of the initial OIG audited payments for "non-rebatable" drugs remain unexplained at this point.

The NDCs associated with these payments either cannot be found in the CMS or FDB database or the quarter when we paid those claims does not correspond to a rebatable quarter in the CMS or FDB database (more detail on tab *Payments Unexplained_detail*).

Marie-Hélène Lussier Business Analysis Section

12/10/2007

OIG Pharmacy Audit - Non-Matching Rebates

SUMMARY OF RESULTS

Original OIG Audit for Non-Rebatable Drugs\$905,288.62DME and Vaccines NDCs\$15,676.39Payments Explained byMethod 1.1. (see Assumptions tab)\$837,289.53Payments Explained by Method 1.2 (see Assumptions tab)\$33,969.17Payments Explained by FDB data_3 (see Assumptions tab)\$121.92Audited Payments Still Unexplained\$18,231.61

Note: Virtually all payments that were explained by the CMS tape in the first draft were found to be legitimate in method 1.1 from the FDB database. The reason why the unexplained payments are now lower than in the first draft is that a negative payment of (\$2,534) was included in the CMS tape explained payments, which lowered that portion of explained payments in the first draft. Now that (\$2,534) is included in unexplained payments, it lowers the unexplained portion in this draft in comparison with the explained portion in the first draft.

Marie-Hélène Lussier Business Analysis Section

12/10/2007