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

JAN 0 8 2008

Report Number: A-07-07-04103

Ms. Joan Miles
Director
Montana Department of Public Health and Human Services
P.O. Box 4210
Helena, Montana 59604

Dear Ms. Miles:

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 Montana for the Period October 1, 2001, 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.

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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 Raylene Mason, Audit Manager, at (816) 426-3203 or by e-mail at Raylene.Mason@oig.hhs.gov. Please refer to report number A-07-07-04103 in all correspondence.

Sincerely,

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

REVIEW OF MEDICAID OUTPATIENT DRUG EXPENDITURES IN MONTANA FOR THE PERIOD OCTOBER 1, 2001, THROUGH SEPTEMBER 30, 2004

Daniel R. Levinson
Inspector General

January 2008
A-07-07-04103

Office of Inspector General

http://oig.hhs.gov

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OAS FINDINGS AND OPINIONS

The designation of financial or management practices as questionable or a recommendation for the disallowance of costs incurred or claimed, as well as other conclusions and recommendations in this report, represent the findings and opinions of the HHS/OIG/OAS. Authorized officials of the HHS 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 Montana, the Montana Department of Public Health and Human Services (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 Montana, 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 Montana, 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 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 2002 through 2004 did not fully comply with Federal requirements. Of the $266 million ($198 million Federal share) claimed, $992,440 (Federal share) represents expenditures for drug products that were not eligible for Medicaid coverage because they were either (1) terminated drugs for which the termination dates were listed on the CMS quarterly drug tape before the drugs were dispensed or (2) inadequately supported compound drug expenditures. An additional $363,210 (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 $266 million ($198 million Federal share) claimed, we identified no other errors with respect to whether the drugs were (a) terminated, (b) supported with adequate documentation, or (c) 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 $992,440 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;

- work with CMS to resolve $363,210 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:

    - claim expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes,

    - maintain readily reviewable documentation that identifies the actual drugs used, and

    - 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 all of the recommendations.

In addition, the State agency raised a concern that the CMS quarterly drug tapes are not "real-time data." The State agency offered to work with CMS to update the quarterly drug tapes with timely, accurate information to "ensure that claimed Medicaid drug expenditures comply with Federal requirements." The State agency also stated that it would continue to allow reimbursement for new drug products that are not included on the quarterly drug tapes in a timely manner because "[a]llowing reimbursement for a potential life saving medication should not wait for the process delay of adding a data element to the CMS quarterly tape." 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 notify CMS of the missing drugs. While we acknowledge the State agency's concerns about the potential for time delays in the update process for CMS's quarterly drug tapes, the set-aside amount of $363,210 includes only those drug products that were never listed on a quarterly drug tape for the period the drug was claimed. Had the State agency notified CMS that these drug products were missing from the quarterly drug tape, CMS could have adjusted subsequent quarterly drug tapes to include the missing drugs eligible for Medicaid coverage for the periods claimed. However, the State agency did not provide any documentation showing that it had checked with CMS to assure that the drug products were eligible for Medicaid coverage. Therefore, we continue to recommend that the State agency 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.

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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 Montana, the Montana Department of Public Health and Human Services (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 Montana, administer their Medicaid prescription drug programs in accordance with the Medicaid drug rebate program.[1] 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,[2] if applicable, specifies whether the drug is less than effective,[3] 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.

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[1]The 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.

[2]The 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.

[3]The 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 Montana, 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) 2002 through 2004, Montana's Federal reimbursement rate for Medicaid expenditures varied from 72.83 percent to 75.91 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 $266 million ($198 million Federal share) in Medicaid outpatient drug expenditures that the State agency claimed for FYs 2002 through 2004. We limited our testing of these expenditures to determining compliance with specific Federal requirements related to whether the drugs were (a) terminated, (b) supported with adequate documentation, and (c) 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 Helena, Montana.

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. If the drugs were compound drugs, we requested supporting documentation that identified the individual drug components.[4]

We calculated the Federal share of the expenditures using the lowest percentage (72.83 percent to 75.91 percent) applicable for each quarter. We did not reduce the questioned drug expenditures by the rebate amounts that the State received.

We conducted our review in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

The State agency's claims for reimbursement of Medicaid outpatient drug expenditures for FYs 2002 through 2004 did not fully comply with Federal requirements. Of the $266 million ($198 million Federal share) claimed, $992,440 (Federal share) represents expenditures for drug products that were not eligible for Medicaid coverage because they were either (1) terminated drugs for which the termination dates were listed on the CMS quarterly drug tape before the drugs were dispensed or (2) inadequately supported compound drug expenditures. An additional $363,210 (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 $266 million ($198 million Federal share) claimed, we identified no other errors with respect to whether the drugs were (a) terminated, (b) supported with adequate documentation, or (c) 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.

[4]Pharmacists create compound drugs by combining two or more prescription or nonprescription drug products and then repackaging them into a new capsule or other dosage form.

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 2002 through 2004, the State agency claimed $15,270 ($11,454 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 Dilaudid, which was dispensed on April 28, 2004. However, the drug's termination date was November 1, 2003, according to the tapes beginning with the quarter that ended June 30, 2003. 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 INADEQUATELY SUPPORTED DRUG EXPENDITURES

Section 1927 of the Act generally defines which covered outpatient drugs are allowable for Federal reimbursement under the Medicaid program. To receive reimbursement for covered drugs, States must maintain documentation identifying the specific drugs used. According to the CMS "State Medicaid Manual," section 2497.1: "Expenditures are allowable only to the extent that, when a claim is filed, you have adequate supporting documentation in readily reviewable form to assure that all applicable Federal requirements have been met."

For FYs 2002 through 2004, the State agency claimed $1,322,006 ($980,986 Federal share) in drug expenditures for which it did not have any supporting documentation to indicate that the drugs met Federal requirements. The drugs were compound drugs made up of two or more prescription or nonprescription drug products. The State agency created its own drug codes for the compound drugs, but it could not identify the individual drugs that were included. The claimed expenditures were unallowable because the State agency did not have documentation showing that the drugs complied with Federal requirements.[5]

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.[6] The rebate agreements

[5]In addition, Montana did not receive rebates owed for covered outpatient drugs that may have been used in making compound drugs. The State did not invoice the drug manufacturers for such drugs because it could not identify the individual components of the compound drugs.

[6]Pursuant 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.

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 2002 through 2004, the State agency claimed $488,978 ($363,210 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.

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 maintain documentation of its compound drug claims at a level of detail to demonstrate that the drugs for which it claimed reimbursement were covered under the Medicaid program. The State agency also 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 or were inadequately supported. As a result, for FYs 2002 through 2004, the State agency claimed unallowable expenditures totaling $1,337,276 ($992,440 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 $488,978 ($363,210 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 $992,440 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;

- work with CMS to resolve $363,210 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:

    - claim expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes,

    - maintain readily reviewable documentation that identifies the actual drugs used, and

    - 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 all of the recommendations.

In addition, the State agency raised a concern that the CMS quarterly drug tapes are not "real-time data." The State agency offered to work with CMS to update the quarterly drug tapes with timely, accurate information to "ensure that claimed Medicaid drug expenditures comply with Federal requirements." The State agency also stated that it would continue to allow reimbursement for new drug products that are not included on the quarterly drug tapes in a timely manner because "[a]llowing reimbursement for a potential life saving medication should not wait for the process delay of adding a data element to the CMS quarterly tape." 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 notify CMS of the missing drugs. While we acknowledge the State agency's concerns about the potential for time delays in the update process for CMS's quarterly drug tapes, the set-aside amount of $363,210 includes only those drug products that were never listed on a quarterly drug tape for the period the drug was claimed.

Had the State agency notified CMS that these drug products were missing from the quarterly drug tape, CMS could have adjusted subsequent quarterly drug tapes to include the missing drugs eligible for Medicaid coverage for the periods claimed. However, the State agency did not provide any documentation showing that it had checked with CMS to assure that the drug products were eligible for Medicaid coverage. Therefore, we continue to recommend that the State agency 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.

APPENDIX

DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES

BRIAN SCHWEITZER
GOVERNOR

JOAN MILES
DIRECTOR

STATE OF MONTANA

www.dphhs.mt.gov

PO Box 4210
HELENA, MT 59604-4210

November 30, 2007

Department of Health & Human Services
Office of Inspector General, Offices of Audit Services
Region VII
Attn: Patrick J. Cogley
601 East 12th St, Room 284A
Kansas City, MO 64106

Re: Report Number (A-07-07-04130)

Dear Mr. Cogley:

Thank you for your letter dated November 2, 2007, regarding the audit of the Department's Medicaid Outpatient Drug Program reimbursements and expenditures. The Department is confident in the management of the Medicaid Outpatient Drug Program and of the controls that are in place to ensure effective accountability of funds. There have been many innovative cost saving measures put into effect over the past several years saving both federal and state taxpayers millions of dollars. Department personnel have worked diligently to complete administrative rules and system changes to strengthen the internal control weaknesses identified in the audit.

The following response will provide you with a level of confidence that the Department has made the appropriate corrective actions since the start of this audit on May 10, 2005. As requested, the following information is provided on: Claims for Terminated Drugs; Claims for Inadequately Supported Drug Expenditures; Claims for Drugs Not Listed on Quarterly Drug Tapes; Inadequate Controls to Detect Unallowable and Potentially Unallowable Claims for Drug Expenditures; Reimbursement of Unallowable Claims for Drug Expenditures.

Claims For Terminated Drugs:

The Department concurs with the audit findings regarding claims for terminated drugs. Historically, the Department has relied upon its Fiscal Agent, Affiliated Computer Systems, Inc. (ACS), to load a drug's termination date into the prescription drug claims system (PDCS). ACS obtained this information from First DataBank through a contractual relationship. The Department submitted a work order on 7/14/05 to have ACS pull its drug termination date information directly from the CMS quarterly tape vs. from First DataBank. This work order moved into production 11/01/07.

This change will bring the Department into compliance with State Release number 130, dated April 30, 2004.

Claims for Inadequately Supported Drug Expenditures:

The Department concurs with the audit findings regarding Claims for Inadequately Supported Drug Expenditures. The Department had allowed providers to bill compound medications using locally established drug codes. This practice has been terminated through a change to the Administrative Rules of Montana which only allows reimbursement of compound ingredients considered to be "covered" under 42USC1396r-8. The effective date of this rule change is January 1, 2008.

Claims for Drugs Not Listed on CMS Quarterly Drug Tapes:

The Department concurs with the audit findings regarding claims for drugs not listed on the CMS quarterly drug tapes. The Department will work with CMS on this issue as recommended but would like to put the issue into perspective. If a new drug were introduced into the marketplace on November 1st, 2007, the drug would not appear on the CMS tape sooner than April 15th, 2008. Allowing reimbursement for a potential life saving medication should not wait for the process delay of adding a data element to the CMS quarterly tape. The Department therefore will continue to allow reimbursement for any new drug products from rebateable labelers. The Department urges CMS to streamline the process of introducing new medications as covered drugs allowing Medicaid clients access to state of the art treatments within the guidelines of 42USC1396r-8.

Inadequate Controls to Detect Unallowable and Potentially Unallowable Claims for Drug Expenditures:

The Department concurs with the audit findings regarding inadequate controls to detect unallowable and potentially unallowable claims for drug expenditures. The Department's change in compound medication reimbursement, as stated previously, will correct this finding.

Reimbursement of Unallowable and Potentially Unallowable Claims for Drug Expenditures:

The Department concurs with the audit findings regarding reimbursement of unallowable claims for drug expenditures. The Department has addressed this issue in the response to "Claims for Inadequately Supported Drug Expenditures."

OIG Recommendations:

- Refund $992,440 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage.
- Work with CMS to resolve $363,210 in payments for drugs that were not listed on the CMS 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:
  - claim expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes,
  - maintain readily reviewable documentation that identifies the actual drugs used, and
  - 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.

The Department concurs with the recommendations. As stated previously, the necessary internal controls have been put in place to correct the audit findings.

Summary:
The OIG audit revealed two items in the Department's outpatient prescription drug program. These are reimbursement for compounds with locally established drug codes and not editing directly from the CMS quarterly tape. Since Montana citizens who utilize Medicaid need access to pharmaceuticals these practices were initially put in place for the sole purpose of increasing access to needed drug therapies. CMS does not provide real-time data nor is there significant guidance regarding compounded medications so workarounds were necessary. The pharmaceutical marketplace is dynamic. Considering this, the Department would like to work with CMS to develop methods to deliver real-time drug information to State Medicaid programs. A real time or near real time system would more accurately reflect the constant changes in the marketplace and in itself, strengthen the internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements.

The Department is committed to providing an outpatient prescription drug program that offers a best value to our clients and the taxpayers. I look forward to your final report on this issue. Should you have any questions regarding this response please contact Dan Peterson at (406) 444-4144.

Sincerely,

Joan Miles
Director

Cc: John Chappuis
Mary Dalton
Marie Matthews
Dan Peterson
Beckie Beckert-Graham
Duane Preshinger

1.6.3