



JUN - 9 2008

**TO:** Kerry Weems  
Acting Administrator  
Centers for Medicare & Medicaid Services

**FROM:**   
Joseph E. Vengrin  
Deputy Inspector General for Audit Services

**SUBJECT:** Review of Medicaid Outpatient Drug Expenditures in Missouri for the Period October 1, 2002, Through September 30, 2004 (A-07-06-04063)

Attached is an advance copy of our final report on Medicaid outpatient drug expenditures in Missouri for the period October 1, 2002, through September 30, 2004. We will issue this report to the Missouri Department of Social Services (the State agency) within 5 business days.

All States offer outpatient prescription drugs to eligible Medicaid beneficiaries. Most States, including Missouri, 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 the Centers for Medicare & Medicaid Services (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.

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

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 \$2.09 billion (\$1.33 billion Federal share) claimed, \$2,937,056 (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 with documentation. An additional \$1,887,845 (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 have been allowable for Medicaid reimbursement. For the remainder of the \$2.09 billion (\$1.33 billion 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.

We recommend that the State agency:

- refund \$2,937,056 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;
- work with CMS to resolve \$1,887,845 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 documentation that supports the expenditures reported on the Form CMS-64, 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.

In written comments on our draft report, the State agency disagreed with our findings and recommendations. After reviewing the State agency's comments, we continue to support our findings and recommendations.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact George M. Reeb, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through e-mail at [George.Reeb@oig.hhs.gov](mailto:George.Reeb@oig.hhs.gov) or Patrick J. Cogley, Regional Inspector General for Audit Services, Region VII, at (816) 426-3591 or through e-mail at [Patrick.Cogley@oig.hhs.gov](mailto:Patrick.Cogley@oig.hhs.gov). Please refer to report number A-07-06-04063 in all correspondence.

Attachment



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

JUN 13 2008

Report Number: A-07-06-04063

Ms. Deborah E. Scott  
Director  
Missouri Department of Social Services  
Broadway State Office Building  
P.O. Box 1527  
Jefferson City, Missouri 65102

Dear Ms. Scott:

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 Missouri for the Period October 1, 2002, Through September 30, 2004." 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.

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, this report 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](mailto:Raylene.Mason@oig.hhs.gov). Please refer to report number A-07-06-04063 in all correspondence.

Sincerely,

A handwritten signature in black ink, appearing to read "Patrick J. Cogley", written over a horizontal line.

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 MISSOURI  
FOR THE PERIOD  
OCTOBER 1, 2002, THROUGH  
SEPTEMBER 30, 2004**



Daniel R. Levinson  
Inspector General

June 2008  
A-07-06-04063

# *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 Missouri, the Department of Social 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 Missouri, 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 Missouri, the State agency claims Medicaid expenditures on Form CMS-64, "Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program" (Form 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 2003 and 2004 did not fully comply with Federal requirements. Of the \$2.09 billion (\$1.33 billion Federal share) claimed, \$2,937,056 (Federal share) represented 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 with documentation. An additional \$1,887,845 (Federal share) represented 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 have been allowable for Medicaid reimbursement. For the remainder of the \$2.09 billion (\$1.33 billion 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 \$2,937,056 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;
- work with CMS to resolve \$1,887,845 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 documentation that supports the expenditures reported on the Form CMS-64, 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 COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, the State agency disagreed with our findings and recommendations. After reviewing the State agency's comments, we continue to support our findings and recommendations.

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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 Missouri, the Department of Social 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 Missouri, administer their Medicaid prescription drug programs in accordance with the Medicaid drug rebate program.<sup>1</sup> 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,<sup>2</sup> if applicable; specifies whether the drug is less than effective;<sup>3</sup> 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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<sup>1</sup>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.

<sup>2</sup>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.

<sup>3</sup>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 Missouri, the State agency claims Medicaid expenditures on Form CMS-64, “Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program” (Form 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, Missouri’s Federal reimbursement rate for Medicaid expenditures varied from 61.23 percent to 64.42 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 \$2.09 billion (\$1.33 billion 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 and guidance 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 Jefferson City, Missouri.

### **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 Forms CMS-64 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 obtained supporting documentation that identified the individual drug components.<sup>4</sup>

We calculated the Federal share of the expenditures using the lowest percentage (61.23 percent to 64.42 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 objective.

## **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 \$2.09 billion (\$1.33 billion Federal share) claimed, \$2,937,056 (Federal share) represented 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 with documentation. An additional \$1,887,845 (Federal share) represented 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 have been allowable for Medicaid reimbursement. For the remainder of the \$2.09 billion (\$1.33 billion 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.

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<sup>4</sup>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.

## **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 \$3,138,734 (\$1,985,938 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 Lorabid, which was dispensed on April 27, 2004. However, the drug’s termination date was May 1, 2003, according to the tapes beginning with the quarter that ended December 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 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 2003 and 2004, the State agency claimed \$1,487,566 (\$951,118 Federal share) in drug expenditures on its quarterly Forms CMS-64 for which it did not have any supporting documentation that identified which drugs were claimed. Without this supporting documentation, the State agency could not demonstrate that its claims for reimbursement were covered under the Medicaid program. These claims were therefore unallowable.

## **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.<sup>5</sup> 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 \$2,990,561 (\$1,887,845 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. For some of its drug claims, the State agency did not maintain supporting documentation that identified which drugs it claimed and therefore could not demonstrate that its claims for 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 2003 and 2004, the State agency claimed unallowable expenditures totaling \$4,626,300 (\$2,937,056 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 \$2,990,561 (\$1,887,845 Federal share) for CMS adjudication because the State agency did not determine whether the drugs were covered by Medicaid.

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<sup>5</sup>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 and if certain other conditions are met.

## RECOMMENDATIONS

We recommend that the State agency:

- refund \$2,937,056 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;
- work with CMS to resolve \$1,887,845 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 documentation that supports the expenditures reported on the Form CMS-64, 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 COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the State agency disagreed with our findings and recommendations. The State agency's comments appear in their entirety as the Appendix.

After reviewing the State agency's comments, we disagree with the State agency and continue to support our findings and recommendations.

### Claims for Terminated Drugs

#### *State Agency Comments*

The State agency said that we did not provide additional detail on the terminated drugs. According to the State agency, it reviewed the initial list of terminated drugs totaling approximately \$4 million and determined "that payments are not being made for terminated drugs." Specifically, the State agency said some of the claims that it reviewed were "recouped in subsequent quarters and were not accounted for by OIG [Office of Inspector General]." In addition, the State agency said that it disagreed with us on the termination dates for the majority of the claims it reviewed, stating that it received notification of unit rebate amounts for these drugs and "has collected rebate on these [drugs] for these quarters." Elsewhere in its written comments, the State agency said that it "began using the CMS termination date from the CMS quarterly tape to update the system prior to the review being done by OIG."

## *Office of Inspector General Response*

During the exit conference, the State agency requested detail for our finding on the terminated drugs, and on December 21, 2006, we provided the State agency with detailed data supporting this finding. We subsequently reduced the finding by \$629,141 to account for retroactive termination dates as described in our Methodology section.

For the claims that the State agency said were recouped in subsequent quarters and not accounted for by OIG, we informed the State agency at the exit conference that we had made adjustments to account for these claims. Therefore, these claims were not included in the finding cited in our draft report.

The State agency also said that it received unit rebate amount information for some of the terminated drugs and had received drug rebates for these drugs. However, receiving unit rebate amount information and drug rebates does not, in and of itself, prove that the drugs were not terminated. CMS continues to list all terminated drugs and their pricing data—including unit rebate amounts—on the quarterly drug tapes for 4 quarters beyond the termination dates because pharmacies have up to 1 year to submit reimbursement claims to the States. Therefore, if the State agency paid for drugs that were dispensed before the termination date, it should have received drug rebates for those drugs. However, our review demonstrated that, according to the State's records, the questioned drugs were dispensed after the drugs' termination dates.

Furthermore, the State agency acknowledged that, before our review, it began using the CMS termination dates from the CMS quarterly tape to update its system. However, our review demonstrated that the State agency was claiming reimbursement for drugs that CMS had identified as terminated on its quarterly drug tape.

CMS guidance instructs States to reject claims for drugs dispensed after the termination date because such claims are invalid. We continue to support our finding that the State agency made payments for terminated drugs. Accordingly, we continue to recommend that the State agency refund the \$1,985,938 Federal share of drug expenditures that were not eligible for Medicaid coverage because they were terminated drugs.

### **Claims for Inadequately Supported Drug Expenditures**

#### *State Agency Comments*

The State agency said that “OIG requested an adhoc file of drug expenditures . . . and was attempting to reconcile the totals of this adhoc to the CMS 64 report.” According to the State agency, “The adhoc is a special request report and, therefore, it is difficult to match the expenditures reported on the CMS 64 report.” The State agency also said that “there are adequate checks and balances to validate the amounts reported on the CMS 64 report.”

### *Office of Inspector General Response*

We requested that the State agency provide detailed support for its claim for Federal matching funds for Medicaid drug expenditures on the Forms CMS-64. The State agency ultimately provided an “ad hoc report” that supported \$2,087,720,199 out of the total of \$2,089,207,765 claimed. We then made repeated requests that the State agency provide detailed data to support the remaining \$1,487,566 (\$951,118 Federal share), but the State agency did not do so. Without this supporting documentation, the State agency could not demonstrate that its claims for reimbursement were covered under the Medicaid program or that it had adequate checks and balances in place to validate the amounts reported on the Forms CMS-64. Therefore, we continue to recommend that the State agency refund the \$951,118 (Federal share) of drug expenditures that were not supported.

### **Claims for Drugs Not Listed on Quarterly Drug Tapes**

#### *State Agency Comments*

The State agency said that OIG did not provide “any detail between [the] initial finding and the current amount [cited in the draft report]” and that it “feels that the sampling that was done was adequate to show that there were no expenditures for non-matching drugs.” The State agency noted that \$10,177,082 of the initial \$13,291,119 amount included diabetic supplies and vaccines. Of the remaining \$3,114,037 of expenditures, the State agency said that it reviewed the top 30 drugs, representing almost half the drug expenditures, and determined that drug rebates had been received for these drugs.

#### *Office of Inspector General Response*

During the exit conference, the State agency requested detail for this finding, and on December 21, 2006, we provided the State agency with detailed data supporting the finding cited in the draft report. As discussed during the exit conference, and contrary to the State agency’s comments, OIG had removed expenditures for the diabetic supplies and vaccines from the finding cited in the draft report.

In addition, although the State agency said that it received rebates for some of the drugs, receiving drug rebates does not, in and of itself, prove that the drugs are eligible for Federal Medicaid reimbursement. It remains the State agency’s responsibility to comply with CMS’s guidance, which advises the State agency to check with CMS to ensure that the drugs are correctly listed on the quarterly drug tapes. Therefore, we continue to recommend that the State agency work with CMS to resolve the \$1,887,845 Federal share of payments for drugs that were not listed on the quarterly drug tapes and that may not have been eligible for Medicaid coverage.

## **Recommendation That the State Agency Strengthen Internal Controls**

### *State Agency Comments*

The State agency said that it began using the CMS termination dates from the quarterly tapes before our review began. The State agency also said that it “feels that it is unfeasible to verify coverage using the quarterly tapes” because the tapes “are provided to the State about two months after the end of the quarter, so the data is somewhere between 3 – 6 months in arrears.” Further, the State agency said that “there is adequate documentation to support the expenditures on the CMS-64 report.”

### *Office of Inspector General Response*

We disagree with the State agency’s comments.

- CMS guidance instructs States to reject as invalid claims for drugs dispensed after the drugs’ termination dates. Given the fact that the State agency claimed drug expenditures on the Form CMS-64 for drugs dispensed after it should have known the drugs were terminated, we continue to recommend that the State agency strengthen internal controls to ensure that it does not claim expenditures for terminated drugs.
- CMS guidance requires adequate supporting documentation to support claims for Federal reimbursement. Without supporting documentation, we cannot be sure that claimed Medicaid drug expenditures comply with Federal requirements. Therefore, we continue to recommend that the State agency maintain documentation that supports the expenditures reported on the Form CMS-64.
- CMS guidance instructs States 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. The amount we set aside (\$1,887,845 Federal share) 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 tape, CMS could have determined that the drugs were Medicaid-eligible and could have adjusted the subsequent quarterly tapes to include the missing drugs for the period claimed. However, because the State agency was unable to provide any documentation that it had checked with CMS to assure that the drug products were eligible, we cannot be sure the expenditures claimed for Federal reimbursement were covered by Medicaid. 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**



**MISSOURI**  
**DEPARTMENT OF SOCIAL SERVICES**

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December 5, 2007

Patrick J. Cogley  
Regional Inspector General for Audit Services  
Department of Health and Human Services  
Region VII  
601 East 12<sup>th</sup> Street, Room 284A  
Kansas City, MO 64106

Dear Mr. Cogley:

This is in response to your October 30, 2007 request for comment on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) draft report entitled "Review of Medicaid Outpatient Drug Expenditures in Missouri for the Period October 1, 2002 through September 30, 2004." For ease of reference the recommendations have been repeated along with the Department of Social Services response.

**Recommendation:** Refund \$2,937,056 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage.

**Response:** The department disagrees with the finding. This recommendation appears to be two separate issues; terminated drugs and inadequate support.

The OIG report states that unallowable expenditures totaled \$4,626,300 for terminated or inadequately supported drug expenditures. OIG has not provided additional detail on this finding. However, MO HealthNet Division (MHD) reviewed the initial list of terminated drugs provided by OIG, which totaled \$4,049,785. MHD reviewed the top 100 NDC/quarters, which accounted for \$3,266,164 or approximately 81% of the total. The findings are:

- Claims for 19 NDC/quarters have been recouped in subsequent quarters and were not accounted for by OIG. This group totals \$563,789.
- Claims for 5 NDC/quarters have not been recouped. These claims would have been recouped in the normal rebate resolution process. This group totals \$53,330. MHD could recoup the claims and provide the details to OIG or if OIG intends to recoup the funds, MHD will recoup and simply retain all of the funds, instead of 40% (SMAP).

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- MHD disagrees with OIG on the termination date on 76 NDC/quarters. This group totals \$2,649,045. MHD has collected rebate on these NDCs for these quarters. MHD received a Unit Rebate Amount (URA) on 64 of the occurrences. On the other 12 occurrences, the manufacturer provided the URA with their payment.

Based on these findings, MHD feels that an adequate review was completed to verify that payments are not being made for terminated drugs.

**Inadequate Support** - As a part of the review, OIG requested an adhoc file of drug expenditures by NDC/quarter for the two federal fiscal years. OIG was attempting to reconcile the totals of this adhoc to the CMS 64 report. The adhoc is a special request report and, therefore, it is difficult to match the expenditures reported on the CMS 64 report. MHD contends that there are adequate checks and balances to validate the amounts reported on the CMS 64 report.

**Recommendation:** Work with CMS to resolve \$1,887,845 in payments for drugs that were not listed on the quarterly drug tapes and that may not have been eligible for Medicaid coverage.

**Response:** The department disagrees with the recommendation. OIG had not provided any detail between their initial finding and the current amount. However, MHD feels that the sampling that was done was adequate to show that there were no expenditures for non-matching drugs. OIG initially reported expenditures for Non-Matching Drugs for the two federal fiscal years of \$13,291,119. MHD reviewed the list and noted the following:

- \$9,474,340 (71.3%) of the expenditures were related to diabetic supplies. These supplies have been submitted for payment on a drug claim, instead of a medical claim. This has allowed MHD to receive rebate from the diabetic supply manufacturers, which has, in turn, reduced the net cost for the State and CMS.
- \$702,742 (5.3%) of the expenditures were related to vaccines.
- The remainder was \$3,114,037. Of this amount, MHD reviewed the top 30 NDCs/quarter in terms of expenditures. These accounted for approximately \$1.5 million of the remainder. In all 30 instances, MHD received a URA. In 8 occurrences, the URA was provided by the manufacturer and in two occurrences, the URA was provided by CMS. Furthermore, payment has been received on all 30 occurrences.

**Recommendation:** Strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements, specifically:

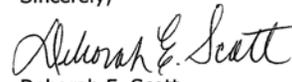
- claim expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes,
- maintain documentation that supports the expenditures reported on the CMS-64, and
- verify whether drugs not listed on the quarterly drug tapes are covered under the Medicaid program and notify CMS when drugs are missing from the tapes.

**Response:** The department disagrees in part with the recommendations:

- MHD began using the CMS termination date from the CMS quarterly tape to update the system prior to the review being done by OIG.
- MHD contends that there is adequate documentation to support the expenditures on the CMS-64 report.
- The CMS quarterly drug tapes are provided to the State about two months after the end of the quarter, so the data is somewhere between 3 – 6 months in arrears. Due to the data being dated, MHD feels that it is unfeasible to verify coverage using the quarterly tapes.

Please contact Ian McCaslin, M.D., Director, MO HealthNet Division at 573-751-6922, if you have additional questions.

Sincerely,



Deborah E. Scott  
Director

DES:rdg