DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

NOV 15 2006

**TO:** Leslie V. Norwalk, Esq.
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 Nebraska for the Period October 1, 1997, Through September 30, 2004 (A-07-05-04056)

Attached is an advance copy of our final report on Medicaid outpatient drug expenditures in Nebraska for the period October 1, 1997, through September 30, 2004. We will issue this report to the Nebraska Department of Health and Human Services, Finance and Support (the State agency) within 5 business days.

All States offer outpatient prescription drugs to eligible Medicaid beneficiaries. Most States, including Nebraska, 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. 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.

Not all of the State agency's claims for reimbursement of Medicaid outpatient drug expenditures complied with Federal requirements.

- For Federal fiscal years (FY) 1998 through 2004, the State agency claimed duplicate expenditures ($13,079,059 Federal share) at the enhanced reimbursement rate for State Children's Health Insurance Program, optional breast and cervical cancer, and family planning drugs and at the regular reimbursement rate for drugs under the Medicaid program. During our fieldwork, the State agency refunded $12,783,710 of this overpayment. However, the State agency had not refunded the remaining $295,349 by the end of our fieldwork.

- For FYs 2003 and 2004, the State agency claimed unallowable expenditures ($266,752 Federal share) for drugs that were terminated, less than effective, or inadequately supported. The State agency also claimed expenditures ($608,624 Federal share) 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.

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

We recommend that the State agency:

- refund $562,101 to the Federal Government, including:
    - $295,349 for duplicate Medicaid outpatient expenditures associated with family planning drugs and
    - $266,752 for drug expenditures that were not eligible for coverage;
- work with CMS to resolve $608,624 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:
    - reconcile actual expenditures to the expenditures claimed on the CMS-64s to avoid duplicate expenditures,
    - claim expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes,
    - claim expenditures only for drugs that are not listed as less than effective on the quarterly drug tapes,
    - maintain readily reviewable documentation that identifies the actual drugs used,
    - 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, and
    - report accurate drug utilization data to CMS.

In its comments on our draft report, the State agency concurred with our recommendations and provided comments on our characterization of two findings.

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 or Patrick J. Cogley, Regional Inspector General for Audit Services, Region VII, at (816) 426-3591, extension 274, or through e-mail at Patrick.Cogley@oig.hhs.gov. Please refer to report number A-07-05-04056.

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

NOV 16 2006

Report Number: A-07-05-04056

Ms. Mary Steiner
Medicaid Director
Nebraska Health and Human Services System
Department of Finance and Support
P.O. Box 95026
Lincoln, Nebraska 68509-5026

Dear Ms. Steiner:

Enclosed are two copies of 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 Nebraska for the Period October 1, 1997, 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 the HHS action official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

In accordance with the principles of the Freedom of Information Act (5 U.S.C. § 552, as amended by Public Law 104-231), OIG reports issued to the Department's grantees and contractors are made available to the public to the extent the information is not subject to exemptions in the Act that the Department chooses to exercise (see 45 CFR part 5).

Please refer to report number A-07-05-04056 in all correspondence.

Sincerely,

Patrick J. Cogley
Regional Inspector General
for Audit Services

Enclosures

**Direct Reply to HHS Action Official:**

Mr. Thomas Lenz
Regional Administrator, Region VII
Centers for Medicare & Medicaid Services
Richard Bolling Federal Building
601 East 12th Street, Room 235
Kansas City, Missouri 64106

Department of Health and Human Services

**OFFICE OF INSPECTOR GENERAL**

# REVIEW OF MEDICAID OUTPATIENT DRUG EXPENDITURES IN NEBRASKA FOR THE PERIOD OCTOBER 1, 1997, THROUGH SEPTEMBER 30, 2004


Daniel R. Levinson
Inspector General

November 2006
A-07-05-04056

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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

The Medicaid program, a jointly funded Federal and State program, provides medical assistance to eligible needy people. At the Federal level, the Centers for Medicare & Medicaid Services (CMS) administers Medicaid. In Nebraska, the Nebraska Department of Health and Human Services, Finance and Support (the State agency) administers Medicaid.

In addition to providing mandatory Medicaid services, States may offer certain optional services, such as outpatient prescription drugs. States also may offer optional services to individuals who ordinarily would not qualify for Medicaid, including uninsured women under the age of 65 who need treatment for breast or cervical cancer and uninsured low-income children who qualify for the State Children's Health Insurance Program (SCHIP).

All States offer outpatient prescription drugs to eligible Medicaid beneficiaries. Most States, including Nebraska, 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, indicates a drug's termination date if applicable, and specifies whether the Food and Drug Administration has determined the drug to be less than effective. CMS guidance instructs the States to use the tape to verify coverage of the drugs for which they claim reimbursement.

In Nebraska, the State agency claims Medicaid and SCHIP 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 (regular reimbursement rate) for the majority of claimed Medicaid outpatient drug expenditures. However, CMS applies an enhanced reimbursement rate to some Medicaid outpatient drug expenditures, such as those for optional breast and cervical cancer services and family planning services, as well as to SCHIP 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

Not all of the State agency's claims for reimbursement of Medicaid outpatient drug expenditures complied with Federal requirements.

- For Federal fiscal years (FY) 1998 through 2004, the State agency claimed duplicate expenditures ($13,079,059 Federal share) at the enhanced reimbursement rate for SCHIP, optional breast and cervical cancer, and family planning drugs and at the regular

reimbursement rate for drugs under the Medicaid program. During our fieldwork, the State agency refunded $12,783,710 of this overpayment. However, the State agency had not refunded the remaining $295,349 by the end of our fieldwork.

- For FYs 2003 and 2004, the State agency claimed unallowable expenditures ($266,752 Federal share) for drugs that were terminated, less than effective, or inadequately supported. The State agency also claimed expenditures ($608,624 Federal share) 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.

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

## RECOMMENDATIONS

We recommend that the State agency:

- refund $562,101 to the Federal Government, including:
  - $295,349 for duplicate Medicaid outpatient expenditures associated with family planning drugs and
  - $266,752 for drug expenditures that were not eligible for coverage;
- work with CMS to resolve $608,624 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:
  - reconcile actual expenditures to the expenditures claimed on the CMS-64s to avoid duplicate expenditures,
  - claim expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes,
  - claim expenditures only for drugs that are not listed as less than effective on the quarterly drug tapes,
  - maintain readily reviewable documentation that identifies the actual drugs used,
  - 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, and
  - report accurate drug utilization data to CMS.

## STATE AGENCY'S COMMENTS

In its comments on our draft report, the State agency concurred with our recommendations and provided comments on our characterization of two findings. The State agency's comments are included in their entirety as the Appendix.

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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 eligible needy people. Medicaid is a jointly funded Federal and State program that the States administer in accordance with State plans approved by the Centers for Medicare & Medicaid Services (CMS). In Nebraska, the Nebraska Department of Health and Human Services, Finance and Support (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. In addition, States may provide optional services to individuals who ordinarily would not qualify for Medicaid, including uninsured women under the age of 65 who need treatment for breast or cervical cancer.

### Medicaid Outpatient Prescription Drug Program

All States offer outpatient prescription drugs to eligible Medicaid beneficiaries. Most States, including Nebraska, 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.

Section 1927(b)(2) of the Act requires each State to report drug utilization data to CMS quarterly. CMS compares the utilization data with the information on the quarterly drug tape and identifies any drugs classified as less than effective or drugs not listed on the tape. CMS reports

[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.

the discrepancies to each State on the quarterly Utilization Discrepancy Report, which is CMS's mechanism for notifying the States of potential problems with their utilization data.

### State Children's Health Insurance Program

Pursuant to Title XXI of the Act, the State Children's Health Insurance Program (SCHIP) provides uninsured low-income children with health care coverage, including outpatient prescription drugs. Like Medicaid, SCHIP is a jointly funded Federal and State program that the States administer in accordance with CMS-approved State plans.

States have three SCHIP coverage options: a separate children's health insurance program, expanded Medicaid eligibility, or a combination of the two. Nebraska expanded Medicaid coverage for children with family incomes up to 185 percent of the Federal poverty level.

### Reimbursement of Medicaid and State Children's Health Insurance Program Expenditures

The Federal Government pays its share of Medicaid and SCHIP expenditures to States according to a defined formula.

In Nebraska, the State agency claims Medicaid and SCHIP 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 (regular reimbursement rate) for the majority of claimed Medicaid expenditures, including outpatient drug expenditures. However, CMS applies an enhanced reimbursement rate to some Medicaid expenditures, such as those for optional breast and cervical cancer services and family planning services. CMS also applies an enhanced reimbursement rate to SCHIP expenditures.

For Federal fiscal years (FY) 2003 and 2004, Nebraska's regular reimbursement rate for Medicaid expenditures varied from 59.52 percent to 62.84 percent, and its enhanced reimbursement rate varied from 71.66 percent to 90 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 initial audit scope included $459.1 million ($285.6 million Federal share) in Medicaid outpatient drug expenditures that the State agency claimed for FYs 2003 and 2004. Based on the results of our review, we expanded the scope to include duplicate drug expenditures for FYs 1998 through 2004. During this period, the State agency reported $1.2 billion ($738.9 million Federal share) in outpatient drug expenditures.

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 from June through November 2005 at the State agency's offices in Lincoln, Nebraska.

**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 compared the detailed expenditures reported on the CMS-64s with the drug utilization data reported to CMS to verify the accuracy of the drug utilization data, and we reviewed CMS's Utilization Discrepancy Reports to the State agency. We also used the detailed list of outpatient 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 or listed as less than effective on the tape.

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 (59.52 percent to 62.84 percent) applicable for each quarter. We did not reduce the questioned drug expenditures by any credits that the State agency reported, including rebates.

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

## FINDINGS AND RECOMMENDATIONS

Not all of the State agency's claims for reimbursement of Medicaid outpatient drug expenditures complied with Federal requirements.

- For FYs 1998 through 2004, the State agency claimed duplicate expenditures ($13,079,059 Federal share) at the enhanced reimbursement rate for SCHIP, optional

[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.

breast and cervical cancer, and family planning drugs and at the regular reimbursement rate for drugs under the Medicaid program. During our fieldwork, the State agency refunded $12,783,710 of this overpayment. However, the State agency had not refunded the remaining $295,349 by the end of our fieldwork.

- For FYs 2003 and 2004, the State agency claimed unallowable expenditures ($266,752 Federal share) for drugs that were terminated, less than effective, or inadequately supported. The State agency also claimed expenditures ($608,624 Federal share) 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.

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

## DUPLICATE CLAIMS FOR DRUG EXPENDITURES

The CMS "State Medicaid Manual," section 2497.1, states that "Federal financial participation (FFP) is available only for allowable actual expenditures made on behalf of eligible beneficiaries for covered services rendered by certified providers." Office of Management and Budget (OMB) Circular A-87, section C(1)(a), states that to be allowable under Federal awards, costs must "Be necessary and reasonable for proper and efficient performance and administration of Federal awards."[5] Additionally, section C(1)(h) provides that costs claimed under one Federal program may not be claimed under another Federal program.

Contrary to these requirements, the State agency claimed duplicate drug expenditures on the CMS-64s. The State agency correctly claimed allowable expenditures at the enhanced reimbursement rate for SCHIP, optional breast and cervical cancer, and family planning drugs but incorrectly claimed the same drug expenditures at the regular reimbursement rate under the Medicaid program. The State agency did not have adequate controls to prevent such duplication and ensure that its Medicaid drug expenditures complied with Federal requirements. Specifically, the State agency did not reconcile actual expenditures to the expenditures claimed on the CMS-64s. As a result, the State agency claimed duplicate expenditures totaling $21,285,277 ($13,079,059 Federal share) for the quarters that ended September 30, 1998, through June 30, 2004. The table on the following page presents the duplicate claimed drug expenditures.

[5]Federal regulations (45 CFR § 95.507) make OMB Circular A-87 applicable.

**Duplicate Claims for Drug Expenditures**

| | Period (by Quarter Ending Date) | Total Drug Expenditures Claimed | Federal Reimbursement Claimed |
|---|---|---|---|
| SCHIP | September 30, 1998–June 30, 2004 | $20,568,307 | $12,632,386 |
| Optional breast and cervical cancer | December 31, 2001–June 30, 2004 | 246,968 | 151,324 |
| Family planning | December 31, 2003 | 470,002 | 295,349 |
| **Total** | | **$21,285,277** | **$13,079,059** |

We discussed our findings with State agency officials, who agreed that the reported amounts on the CMS-64s were duplicated. During our fieldwork, the State agency made a $12,783,710 adjustment on its CMS-64 for the quarter that ended June 30, 2005, for duplicate expenditures associated with SCHIP and optional breast and cervical cancer drugs.[6] CMS received the adjustment in August 2005, and we verified that the adjusted amount was correct. However, the State agency had not refunded the $295,349 overpayment for family planning drugs by the end of our fieldwork.

## OTHER UNALLOWABLE AND POTENTIALLY UNALLOWABLE CLAIMS FOR DRUG EXPENDITURES

### Unallowable Claims for Drug Expenditures

The State agency claimed $266,752 in unallowable Federal reimbursement for terminated, less-than-effective, and inadequately supported drugs.

*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."

[6]The State agency submitted duplicate claims totaling $108,932,236 ($66,858,662 Federal share) for all medical expenditures associated with SCHIP and optional breast and cervical cancer services. The State agency refunded not only the $12,783,710 Federal share for outpatient drug expenditures but also the remaining $54,074,952 Federal share for services other than outpatient drugs.

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 $243,117 ($149,457 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 paid for the drug Lorabid, which was dispensed on August 1, 2003. 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.

*Less-Than-Effective Drugs*

Section 1903(i)(5) of the Act prohibits Federal Medicaid funding for drug products that are ineligible for Medicare payment pursuant to section 1862(c) of the Act. Section 1862(c) prohibits Federal funding for drug products determined to be less than effective for all conditions prescribed, recommended, or suggested on the product's label. 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 . . . ." The quarterly drug tapes identify drugs that have been determined to be less than effective.

For FYs 2003 and 2004, the State agency claimed $43,361 ($26,635 Federal share) in expenditures for drugs classified as less than effective on the quarterly drug tapes. For example, the State paid for the drug Quintex HC, which was dispensed on January 13, 2003. However, CMS reported the drug as less than effective on the tapes beginning with the quarter that ended March 31, 2002. The claimed expenditure was unallowable because the drug was dispensed after CMS reported it as less than effective.

*Inadequately Supported Drugs*

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 drug costs of $148,791 ($90,660 Federal share) 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.[7]

**Potentially Unallowable Claims for Drug Expenditures**

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.[8] 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 $987,632 ($608,624 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 drug payments 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 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. In addition, in reporting its utilization data to CMS, the State agency excluded drugs that were not on the quarterly drug tapes, which compromised the usefulness of CMS's Utilization Discrepancy Reports in identifying potential problems with utilization data.

[7]In addition, Nebraska 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.

[8]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.

**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, less than effective, or inadequately supported. As a result, for FYs 2003 and 2004, the State agency claimed unallowable expenditures totaling $435,269 ($266,752 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 $987,632 ($608,624 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 $562,101 to the Federal Government, including:
    - $295,349 for duplicate Medicaid outpatient expenditures associated with family planning drugs and
    - $266,752 for drug expenditures that were not eligible for coverage;
- work with CMS to resolve $608,624 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:
    - reconcile actual expenditures to the expenditures claimed on the CMS-64s to avoid duplicate expenditures,
    - claim expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes,
    - claim expenditures only for drugs that are not listed as less than effective on the quarterly drug tape,
    - maintain readily reviewable documentation that identifies the actual drugs used,
    - 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, and
    - report accurate drug utilization data to CMS.

## STATE AGENCY'S COMMENTS

In its written comments on our draft report, the State agency concurred with all of our recommendations. However, the State agency did not concur that it had made duplicate payments to providers or that it had drawn Federal funds more than once. The State agency said that only the amounts claimed on the CMS-64 were doubled. The State agency also did not concur that it had inadequate controls to ensure that its outpatient expenditures complied with Federal requirements.

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

## OFFICE OF INSPECTOR GENERAL'S RESPONSE

Our report does not state or imply that the State agency made duplicate payments to providers, nor does it state or imply that the State agency drew Federal funds twice. Instead, the report documents that the State agency made duplicate claims for Federal reimbursement. In addition, we continue to believe that the State agency had inadequate controls to ensure that its outpatient expenditures complied with Federal requirements. We consider findings in excess of $1.1 million in unallowable and potentially unallowable claims to be material amounts and believe that many of these claims would have been detected if controls had been adequate.

# APPENDIX

NEBRASKA HEALTH AND HUMAN SERVICES SYSTEM
DEPARTMENT OF SERVICES • DEPARTMENT OF REGULATION AND LICENSURE
DEPARTMENT OF FINANCE AND SUPPORT

STATE OF NEBRASKA
DAVE HEINEMAN, GOVERNOR

August 25, 2006

Patrick J. Cogley
Regional Inspector General for Audit Services
Department of Health and Human Services
Region VII
601 East 12th Street
Kansas City, MO 64106

Dear Mr. Cogley:

The following is the Nebraska Health and Human Services, Finance and Support, Medicaid response to the Department of Health and Human Services, Office of the Inspector General draft report entitled "Review of Medicaid Drug Expenditures in Nebraska for the period October 1, 1997 through September 30, 2004."

**Recommendation: The state agency refund $295,349 for duplicate Medicaid outpatient expenditures associated with family planning drugs.**

Response: The Agency concurs with the recommendation. An adjustment in that dollar amount will be made and reflected on the next quarterly claim (CMS-64) for federal financial participation.

**Recommendation: The state agency refund $266,752 for drug expenditures that were "not eligible for coverage".**

Response: The Agency concurs with the recommendation. An adjustment in that dollar amount will be made and reflected on the next quarterly claim (CMS-64) for federal financial participation.

**Recommendation: The state agency work to resolve $608,624 in payment for drugs that were not listed on the quarterly drug tapes and that may not have been eligible for Medicaid coverage.**

Response: The Agency concurs and will work with CMS and manufacturers to determine the amounts, if any, that are not eligible for Medicaid coverage.

**Recommendation: The state agency strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with federal requirements, specifically to reconcile actual expenditures to the expenditures claimed on the CMS 64s to avoid duplicate expenditures.**

Response: The Agency concurs and will reconcile actual to claimed expenditures to avoid future claims for FFP that are duplicative in nature. The State does not concur that it made

duplicate expenditures as payments to providers were not duplicated and federal funds were not drawn more than once. Only the CMS-64 federal claim was doubled

The State does not concur with the statement in the Summary of Findings that it had inadequate controls to ensure that its outpatient expenditures complied with federal requirements, as the findings and recommendations represent less than 0.7 percent of the State's Medicaid drug expenditures.

**Recommendation: The state agency will claim expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes.**

Response: The Agency concurs. In addition to removing the $266,752 claim on the next CMS-64, the Agency is taking steps to identify all current and future claims for drugs dispensed after the termination date on the quarterly drug tapes. That information will be used to a) diagnose potential problems with the point-of-sale system, b) correct any problems with the point-of-sale system, c) reverse the payments to the pharmacies, when appropriate, and d) deal with any other problems discovered. Reversal of payment to the pharmacy will result in correction to the CMS-64.

The Agency urges CMS to work with the State and manufacturers to assure timely and accurate data provision to minimize payment of claims after the termination date and the burden on providers and the State.

**Recommendation: The state agency will claim expenditures only for drugs that are not listed as less than effective on the quarterly tapes.**

Response: The Agency concurs and has taken steps to identify all current and future claims for drugs dispensed that are "less than effective" on the quarterly tapes and will assure that no claim is made for these drugs on the CMS-64.

In this case, the Agency has chosen to cover certain drugs with state funds only, but had failed to remove the claim on the CMS-64. The Agency has determined that the FDA continues to allow these drugs to be marketed, that they have been proven safe, that most are now available generically, are very inexpensive compared to newer brand name drugs with the same uses and indications, and are cost effective for coverage by the Agency using state funds only.

**Recommendation: The state agency will maintain readily reviewable documentation that identifies the actual drugs used.**

Response: The Agency concurs and will maintain readily reviewable documentation that identifies the actual drugs used.

**Recommendation: The state agency will 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 Agency concurs and will verify whether drugs not listed on the quarterly drug tapes are covered under the Medicaid Program and will notify CMS when drugs are missing from the tapes.

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**Recommendation: The state agency will report accurate drug utilization data to CMS.**

Response: The Agency concurs and will report accurate drug utilization data to CMS.

Nebraska Medicaid is proud of the accuracy of claims payment to pharmacies. The findings of this audit only represent a very small part of a large and complicated editing and pricing process.

Let me know if you have any questions or concerns.

Sincerely,

Mary Steiner, Medicaid Director
Medicaid Division

GC:G6235C