DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

JUL 17 2007

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 Iowa for the Period October 1, 2002, Through September 30, 2004 (A-07-06-04062)

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

All States offer outpatient prescription drugs to eligible Medicaid beneficiaries. Most States, including Iowa, 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. Of the $709 million ($466 million Federal share) in Medicaid outpatient drug expenditures that the State agency claimed for fiscal years 2003 and 2004, $154,245 (Federal share) represents expenditures for drug products that were not eligible for Medicaid coverage because they were terminated drugs for which the termination dates were listed on the CMS quarterly drug tape before the drugs were dispensed. An additional $1,079,386 (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, the expenditures may not be allowable for Medicaid reimbursement. 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 $154,245 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;

- work with CMS to resolve $1,079,386 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 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 did not concur with part of our first recommendation, which the State agency estimated to be approximately $109,000 Federal share. This represented expenditures for drugs whose termination dates were listed for the first time on the quarterly drug tapes after the drugs were dispensed. The State agency contended that it was unaware of the termination dates at the time the drugs were dispensed. The State agency concurred with the remaining portion of our first recommendation, which the State agency estimated to be approximately $300,000 (Federal share).

The State agency concurred with our second recommendation. The State agency concurred with our third recommendation but stated that it cannot prevent payment for terminated drugs on claims whose termination dates are "retroactive to the date received by the State."

After reviewing the State agency's comments, we revised this report to exclude from our findings and recommendations the $254,524 (Federal share) of expenditures for terminated drugs whose termination dates were listed on the quarterly drug tape after the drugs were dispensed. We continue to recommend a refund of the $154,245 for terminated drugs whose termination dates were listed on the quarterly drug tapes before the drugs were dispensed.

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 or through e-mail at Patrick.Cogley@oig.hhs.gov. Please refer to report number A-07-06-04062.

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General
Office of Audit Services

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

JUL 19 2007

Report Number: A-07-06-04062

Mr. Kevin W. Concannon
Director, Department of Human Services
Hoover State Office Building
1305 East Walnut Street
Des Moines, Iowa 50319-0114

Dear Mr. Concannon:

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 Iowa for the Period October 1, 2002, Through September 30, 2004." A copy of this report will be forwarded to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make the 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).

If you have any questions or comments about this report, please do not hesitate to call me at (816) 426-3591, or your staff may 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-07-06-04062 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 IOWA FOR THE PERIOD OCTOBER 1, 2002, THROUGH SEPTEMBER 30, 2004

Daniel R. Levinson
Inspector General

July 2007
A-07-06-04062

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

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

OBJECTIVE

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

SUMMARY OF FINDINGS

Not all of the State agency's claims for reimbursement of Medicaid outpatient drug expenditures complied with Federal requirements. Of the $709 million ($466 million Federal share) in Medicaid outpatient drug expenditures that the State agency claimed for fiscal years 2003 and 2004, $154,245 (Federal share) represents expenditures for drug products that were not eligible for Medicaid coverage because they were terminated drugs for which the termination dates were listed on the CMS quarterly drug tape before the drugs were dispensed. An additional $1,079,386 (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, the expenditures may not be allowable for Medicaid reimbursement.

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 $154,245 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;

- work with CMS to resolve $1,079,386 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 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 did not concur with part of our first recommendation, which the State agency estimated to be approximately $109,000 Federal share. This represented expenditures for drugs whose termination dates were listed for the first time on the quarterly drug tapes after the drugs were dispensed. The State agency contended that it was unaware of the termination dates at the time the drugs were dispensed. The State agency concurred with the remaining portion of our first recommendation, which the State agency estimated to be approximately $300,000 (Federal share).

The State agency concurred with our second recommendation. The State agency concurred with our third recommendation but stated that it cannot prevent payment for terminated drugs on claims whose termination dates are "retroactive to the date received by the State."

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 revised this report to exclude from our findings and recommendations the $254,524 (Federal share) of expenditures for terminated drugs whose termination dates were listed on the quarterly drug tape after the drugs were dispensed. We continue to recommend a refund of the $154,245 for terminated drugs whose termination dates were listed on the quarterly drug tapes before the drugs were dispensed.

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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 Iowa, the Department of 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 Iowa, 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.

Reimbursement of Medicaid Expenditures

In Iowa, the State agency claims Medicaid expenditures on Form CMS-64, "Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program" (CMS-64). CMS reimburses

[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 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, Iowa's Federal reimbursement rate for Medicaid expenditures varied from 63.50 percent to 66.88 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 $709 million ($466 million Federal share) in Medicaid outpatient drug expenditures that the State agency claimed for FYs 2003 and 2004.

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. In addition, we did not review compound drugs because the total expenditure was immaterial, but we will continue to include these expenditures with the expenditures for drugs not listed on the quarterly drug tapes.[4]

We conducted fieldwork from February through June 2006 at the State agency's offices in Des Moines, Iowa.

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

[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.

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 States retroactively.

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

We calculated the Federal share of the expenditures using the lowest percentage (63.50 percent to 66.88 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

Not all of the State agency's claims for reimbursement of Medicaid outpatient drug expenditures complied with Federal requirements. Of the $709 million ($466 million Federal share) in Medicaid outpatient drug expenditures that the State agency claimed for FYs 2003 and 2004, $154,245 (Federal share) represents expenditures for drug products that were not eligible for Medicaid coverage because they were terminated drugs for which the termination dates were listed on the CMS quarterly drug tape before the drugs were dispensed. An additional $1,079,386 (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, the expenditures may not be allowable for Medicaid reimbursement.

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

CLAIMS FOR TERMINATED DRUGS

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

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

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

For FYs 2003 and 2004, the State agency claimed $235,779 ($154,245 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 Zocor, which was dispensed on September 15, 2004. However, the drug's termination date was May 31, 2004, according to the tapes beginning with the quarter that ended March 31, 2002. The claimed expenditure was unallowable because it occurred after the drug's termination date, which was listed on the quarterly drug tape at the time the State agency made the expenditures.

CLAIMS FOR DRUGS NOT LISTED ON QUARTERLY DRUG TAPES

Section 1927(a)(1) of the Act generally conditions Medicaid reimbursement for covered outpatient drugs on a requirement that manufacturers of those products enter into rebate agreements with CMS under which they pay rebates to the States.[5] 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 $1,646,030 ($1,079,386 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 check the quarterly drug tapes to ensure that the drugs were eligible for Medicaid coverage.

[5]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.

REIMBURSEMENT OF UNALLOWABLE AND POTENTIALLY UNALLOWABLE CLAIMS FOR DRUG EXPENDITURES

The State agency claimed Federal reimbursement for certain drugs that were not eligible for Medicaid coverage because they were terminated. As a result, for FYs 2003 and 2004, the State agency claimed unallowable expenditures totaling $235,779 ($154,245 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 $1,646,030 ($1,079,386 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 $154,245 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;

- work with CMS to resolve $1,079,386 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 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 our draft report, we recommended that the State agency refund $408,769 in drug expenditures that were dispensed after the termination date shown on the quarterly drug tape. The State concurred with $300,000 of the recommendation. However, the State agency did not concur with the remaining portion, which the State agency estimated to be approximately $109,000 Federal share. This represented expenditures for drugs whose termination dates were listed for the first time on the quarterly drug tapes after the drugs were dispensed. The State agency contended that it was unaware of the termination dates at the time the drugs were dispensed.

The State agency concurred with our second recommendation. The State agency concurred with our third recommendation but stated that it cannot prevent payment for terminated drugs on claims whose termination dates are "retroactive to the date received by the State."

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 revised this report to exclude from our first finding, and its corresponding recommendation ($408,769 Federal share), the expenditures for terminated drugs whose termination dates were listed on the quarterly drug tape after the drugs were dispensed. The State agency had estimated this amount to be approximately $109,000 (Federal share). However, we calculated this amount to be $254,524 (Federal share). Thus, we are recommending that the State agency refund $154,245 ($408,769 less $254,524).

APPENDIX

Fields of Opportunities

STATE OF IOWA

THOMAS J. VILSACK, GOVERNOR
SALLY J. PEDERSON, LT. GOVERNOR

DEPARTMENT OF HUMAN SERVICES
KEVIN W. CONCANNON, DIRECTOR

JAN 1 6 2007

Patrick J. Cogley
Regional Inspector General for Audit Services
Department of Health & Human Services
Office of Inspector General - Offices of Audit Services
Region VII
601 East 12th Street
Kansas City, Missouri 64106

Re: Report Number A-07-06-04062

Dear Mr. Cogley:

The enclosed comments are in response to the Department of Health and Human Services, Office of Inspector General (OIG) draft report entitled "Review of Medicaid Outpatient Drug Expenditures in Iowa for the Period October 1, 2002 Through September 30, 2004" as requested.

The draft has been reviewed and prior to responding to the specific recommendations in the draft report, the Iowa Department of Human Services (DHS) would like to provide a summary of some outstanding Drug Rebate Program issues that we would like to discuss and clarify with the Centers for Medicare and Medicaid Services (CMS). In identifying these issues, we will refer to a review of the most recent CMS NDC tape (Q20063) compared to the previous quarter CMS NDC tape (Q20062), however the issues identified are not limited to these specific quarters and are representative of outstanding problems.

1. Non-reported NDCs

Issue	# of NDCs Impacted	Problem
A. The NDC is reported on the CMS NDC tape in Q20062 and not termed, but not reported on the CMS NDC tape in Q20063.	For this period there were 2140 NDCs that dropped off.	The State is unable to determine the exact "end date" applied to the NDC due to the total drop-off of the NDC from the CMS NDC tape. If one is to assume that the "end date" is the last day of the previous reported quarter, approximately 135 days will elapse between this date and the date the next CMS NDC tape is received. This lag time will cause payments for non-rebatable products. There needs to be a process to report "end dates" for non-terminated drugs that drop off the CMS file and the time lag issue needs to be addressed.
B. The NDC is reported on the CMS NDC tape in Q20062 and termed, but not reported on the CMS NDC tape in Q20063.	For this period there were 2797 NDCs that dropped off.	There is no issue with these dropped NDCs as the CMS NDC tape carried a termination date four quarters in a row and then the NDC dropped off in the fifth quarter. These would be legitimate drop-offs as compared to Item A. Other legitimate drop-off issues would include terminated labelers and items no longer considered to meet the definition of an outpatient drug. Still, these products need clearly defined end dates.

2. Termination Date Change/Retroactive

Issue	# of NDCs Impacted	Problem
The NDC is reported on the CMS NDC tape in Q20062 and a termination date is reported, but on the CMS NDC tape in Q20063 a different termination date is reported which may be several years different from the original termination date and/or retroactive to the date received.	For this period there were 1105 NDCs that had a termination date change.	A. If the termination date by the labeler truly reflects the date the drug was withdrawn from the market or shelf-life of the last lot sold, this should not be provided to the States as a retroactive date as this information should be available well in advance of that date if it represents the shelf-life of the last lot sold. B. The State is uncertain as to the exact date of termination due to the change in termination date provided by CMS. i.e. Oramorph SR 15mg; NDC 00054479025; Q20062 tape had a termination date of 12/31/9999; Q20063 tape, received by Iowa on 10/15/06, had a termination date of 03/31/06. There are other examples of retroactive termination dates on this tape.

3. Addition of New Drugs to the CMS Tape

Issue	Problem
A. The delay in the addition of new drugs to the CMS NDC tape can cause payment of claims when a product is not on the tape. The reason could be due to either or both of the following: 1. Labeler non-reporting or delay in reporting to CMS. 2. The labeler confirms the information was provided to CMS but the information is not on the CMS NDC tape provided to the State.	A. Reporting Delay 1. There seems to be issues with enforcement of the labeler reporting requirements by CMS. 2. New products recently entering the market present problems and may not be included on the CMS NDC tape. As we understand it, any new drug coming on to the market, which is under a participating labeler, should be eligible for rebate as of its market date. There are many examples where there is a delay of new products being listed on the CMS NDC Tape. i.e. Levemir, a new product by Novo Nordisk, has not been listed on any of the CMS tapes since its market date of 03/06/06 and we know that Novo Nordisk is a participating labeler.

4. Zero RPUs

Issue	Problem
The CMS Rebate tape shows a $0.00 RPU for a number of consecutive quarters.	It is unclear what CMS's procedure is with labelers who have products that continue to be reported with zero RPUs quarter after quarter. i.e. Remeron, NDC 00052011090, has been on the CMS drug file since Q20014 and there has never been an RPU reported.

In regard to the recommendations contained within the draft report, comments to each recommendation are in the concurrence or non-concurrence format as requested.

1. OIG Recommendation: We recommend that the State agency refund $408,769 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage.

   Response: The State concurs with this recommendation in the amount of approximately $300,000 and would non-concur with the remainder, as this amount represents retroactive termination dates, as discussed previously. The State would like to work with CMS on the claims totaling approximately $109,000 on the issue of retroactive termination dates.

2. OIG Recommendation: We recommend that the State agency work with CMS to resolve $1,079,386 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 State concurs with this recommendation and would welcome the opportunity to work with CMS to resolve programmatic issues that would strengthen the Medicaid Rebate Program.

3. OIG Recommendation: We recommend that the State agency 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

     Response: When given termination dates on the CMS NDC tape the State can assure CMS that an NDC with a terminated date will be rejected by the POS system thus resulting in a rejected claim. The claim date of service is always compared to the NDC termination date by the POS system. If the date of service is before the termination date, the claim will pay. If the date of service is after the termination date, the pharmacy will receive NCPDP reject 77 "DISCONTINUED PRODUCT/SERVICE ID NUMBER". NOTE: This cannot be applied to claims where the termination date is retroactive to the date received by the State.

   - 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: With the receipt of each new quarterly CMS NDC tape, a comparison will be done with the previous tape. The comparison will identify NDC's that have been "dropped off". Each labeler will be contacted to verify that the NDC in question should have been excluded from the tape. The State will then forward their findings by certified mail to the Regional CMS office.

Thank you for the opportunity to respond to the draft report and provide additional information regarding the State's experience with the Medicaid Drug Rebate Program and how it reflects the State's outpatient drug expenditure claims. DHS would welcome the opportunity to work with OIG to resolve areas of disagreement or other concerns before the final report is issued.

Questions about the DHS response can be addressed to:

Ken Tigges
Iowa Department of Human Services
Division of Fiscal Management
Hoover State Office Building, 1st Floor South
Des Moines, IA 50319-0114
Phone: (515) 281-6027
Fax: (515) 281-6237

Sincerely,

Kevin W. Concannon
Director

KWC/slp

Fields of Opportunities

STATE OF IOWA

CHESTER J. CULVER, GOVERNOR
PATTY JUDGE, LT. GOVERNOR

DEPARTMENT OF HUMAN SERVICES
KEVIN W. CONCANNON, DIRECTOR

JAN 3 0 2007

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

Re: Report Number: A-07-06-04062 -- Review of Medicaid Outpatient Drug Expenditures in Iowa for the Period October 1, 2002 through September 30, 2004

Dear Mr. Cogley:

This is to clarify the Iowa Department of Human Services (DHS) response to the Office of Inspector General (OIG) draft report A-07-06-04062. This clarification should be included as part of the formal DHS response, dated January 16, 2007, to the draft report.

The State concurs with the OIG recommendation number three. These internal controls have already been implemented at the Iowa Medicaid Enterprise.

OIG Recommendation: We recommend that the State agency 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

  Response: The State concurs that when given termination dates on the CMS NDC tape the State can assure CMS that an NDC with a terminated date will be rejected by the POS system thus resulting in a rejected claim. The claim date of service is always compared to the NDC termination date by the POS system. If the date of service is before the termination date, the claim will pay. If the date of service is after the termination date, the pharmacy will receive NCPDP reject 77 "DISCONTINUED PRODUCT/SERVICE ID NUMBER." NOTE: This cannot be applied to claims where the termination date is retroactive to the date received by the State.

- 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.

Patrick J. Cogley
Office of Inspector General
Re: Report Number A-07-06-04062

Response: The state concurs that with the receipt of each new quarterly CMS NDC tape, a comparison will be done with the previous tape. The comparison will identify NDCs that have been "dropped off." Each labeler will be contacted to verify that the NDC in question should have been excluded from the tape. The State will then forward their findings by certified mail to the Regional CMS office.

Thank you for the opportunity to clarify the information regarding the State's experience with the Medicaid Drug Rebate Program and how it reflects the State's outpatient drug expenditure claims. DHS would welcome the opportunity to work with OIG to resolve areas of disagreement or other concerns before the final report is issued.

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Phone: (515)-281-6027

Sincerely,

Kevin W. Concannon

Kevin W. Concannon
Director

KWC/sp

cc: Dustin Litwiler, OIG