DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

JUN 27 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 Illinois for the Period October 1, 2003, Through September 30, 2005 (A-05-07-00019)

Attached is an advance copy of our final report on Medicaid outpatient drug expenditures in Illinois for the period October 1, 2003, through September 30, 2005. We will issue this report to the Illinois Department of Healthcare and Family Services (the State agency) within 5 business days.

All States offer outpatient prescription drugs to eligible Medicaid beneficiaries. Most States, including Illinois, 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 for fiscal years (FY) 2004 and 2005 complied with Federal requirements.

The State agency's claims for reimbursement of Medicaid outpatient drug expenditures for FYs 2004 and 2005 did not always comply with Federal requirements. The State agency claimed $207,454 ($108,331 Federal share) for terminated drug products that were not eligible for Medicaid coverage because the termination dates were listed on the CMS quarterly drug tape before the drugs were dispensed. The State agency also claimed $6,849,395 ($3,485,893 Federal share) for drug products that were not listed on the quarterly drug tapes. Because the State agency did not verify with CMS whether the drugs not listed on the tapes were eligible for Medicaid coverage, these drug expenditures may not have been allowable for Medicaid reimbursement.

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

We recommend that the State agency:

- refund $108,331 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;

- work with CMS to resolve $3,485,893 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 by:

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

    - verifying with CMS whether drugs not listed on the quarterly drug tapes are covered under the Medicaid program and notifying CMS when drugs are missing from the tapes.

In written comments on our draft report, the State agency concurred with our first two recommendations. For the third recommendation, the State agency said that it maintains sufficient internal controls to comply with Federal requirements and does not intend to change its processes.

We continue to recommend that the State agency strengthen its internal controls to ensure that its outpatient drug expenditures comply with Federal requirements.

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 Marc Gustafson, Regional Inspector General for Audit Services, Region V, at (312) 353-2621 or through e-mail at Marc.Gustafson@oig.hhs.gov. Please refer to report number A-05-07-00019.

Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF AUDIT SERVICES
233 NORTH MICHIGAN AVENUE
CHICAGO, ILLINOIS 60601

REGION V
OFFICE OF
INSPECTOR GENERAL

JUL - 2 2008

Report Number: A-05-07-00019

Mr. Barry S. Maram
Director, Department of Healthcare and Family Services
201 South Grand Avenue East
Springfield, Illinois 62763-0002

Dear Mr. Maram:

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 Illinois for the Period October 1, 2003, Through September 30, 2005." 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, the final 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, or contact David Markulin, Audit Manager, at (312) 353-1644 or through email at david.markulin@oig.hhs.gov. Please refer to report number A-05-07-00019 in all correspondence.

Sincerely,

Marc Gustafson
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 ILLINOIS FOR THE PERIOD OCTOBER 1, 2003, THROUGH SEPTEMBER 30, 2005

Daniel R. Levinson
Inspector General

July 2008
A-05-07-00019

Office of Inspector General

http://oig.hhs.gov

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The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

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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 Illinois, the Department of Healthcare and Family Services (the State agency) administers the Medicaid program.

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 Illinois, 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 Illinois, 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 claimed Medicaid outpatient drug expenditures. The State agency claimed $3.6 billion ($1.9 billion Federal share) for reimbursement of Medicaid outpatient drug expenditures during fiscal years (FY) 2004 and 2005.

OBJECTIVE

Our objective was to determine whether the State agency's claims for reimbursement of Medicaid outpatient drug expenditures for FYs 2004 and 2005 complied with Federal requirements.

SUMMARY OF FINDINGS

The State agency's claims for reimbursement of Medicaid outpatient drug expenditures for FYs 2004 and 2005 did not always comply with Federal requirements. The State agency claimed $207,454 ($108,331 Federal share) for terminated drug products that were not eligible for Medicaid coverage because the termination dates were listed on the CMS quarterly drug tape before the drugs were dispensed. The State agency also claimed $6,849,395 ($3,485,893 Federal share) for drug products that were not listed on the quarterly drug tapes. Because the State agency did not verify with CMS whether the drugs not listed on the tapes were eligible for Medicaid coverage, these drug expenditures may not have been allowable for Medicaid

reimbursement. For the remainder of the $1.9 billion (Federal share) claimed, we identified no other errors with respect to whether the drugs were either terminated or included on the CMS quarterly drug tapes.

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

RECOMMENDATIONS

We recommend that the State agency:

- refund $108,331 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;

- work with CMS to resolve $3,485,893 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 by:

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

    - verifying with CMS whether drugs not listed on the quarterly drug tapes are covered under the Medicaid program and notifying 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 concurred with our first two recommendations. Regarding the third recommendation, the State agency said that it maintains sufficient internal controls to comply with Federal requirements and does not intend to change its processes.

We continue to recommend that the State agency strengthen its internal controls to ensure that its outpatient drug expenditures comply with Federal requirements.

The State agency 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 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 Illinois, the Department of Healthcare and Family 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 Illinois, 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.

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

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

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

Reimbursement of Medicaid Expenditures

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

For fiscal years (FY) 2004 and 2005, Illinois's reimbursement rate for Medicaid drug expenditures varied from 50.00 percent to 52.95 percent.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether the State agency's claims for reimbursement of Medicaid outpatient drug expenditures for FYs 2004 and 2005 complied with Federal requirements.

Scope

The audit scope included $3.6 billion ($1.9 billion Federal share) in Medicaid outpatient drug expenditures that the State agency claimed for FYs 2004 and 2005. We limited our testing of these expenditures to determining compliance with specific Federal requirements related to whether the drugs were terminated and included on the CMS quarterly drug tapes.

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

We conducted fieldwork from February through December 2007 at the State agency's offices in Springfield, Illinois.

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 CMS quarterly drug tapes for the period October 1, 1999, through June 30, 2006. 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 included the termination dates on the quarterly drug tape in a timely manner (i.e., before terminated drugs were 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 if the State agency had verified with CMS whether the drugs were eligible for Medicaid coverage.

We calculated the Federal share of the expenditures using the reimbursement rate (50.00 to 52.95 percent for Medicaid) 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 2004 and 2005 did not always comply with Federal requirements. The State agency claimed $207,454 ($108,331 Federal share) for terminated drug products that were not eligible for Medicaid coverage because the termination dates were listed on the CMS quarterly drug tape before the drugs were dispensed. The State agency also claimed $6,849,395 ($3,485,893 Federal share) for drug products that were not listed on the quarterly drug tapes. Because the State agency did not verify with CMS whether the drugs not listed on the tapes were eligible for Medicaid coverage, these drug expenditures may not have been allowable for Medicaid reimbursement. For the remainder of the $1.9 billion (Federal share) claimed, we identified no other errors with respect to whether the drugs were either terminated or included on the CMS quarterly drug tapes.

The State agency had inadequate controls to ensure that all of its claims for 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 2004 and 2005, the State agency claimed $207,454 ($108,331 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 Soriatane, which was dispensed on May 20, 2004. However, the drug's termination date was February 29, 2004, according to the tapes beginning with the quarter that ended June 30, 2003. The claimed expenditure was unallowable because it occurred after the drug's termination date, which was listed on the quarterly drug tape at the time the State agency made the expenditures.

CLAIMS FOR 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.[4] 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 2004 and 2005, the State agency claimed $6,849,395 ($3,485,893 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.

[4]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.

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

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

REIMBURSEMENT OF UNALLOWABLE AND POTENTIALLY UNALLOWABLE CLAIMS FOR DRUG EXPENDITURES

The State agency claimed Federal reimbursement for certain drugs that were not eligible for Medicaid coverage because they were terminated. As a result, for FYs 2004 and 2005, the State agency claimed unallowable expenditures totaling $207,454 ($108,331 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 $6,849,395 ($3,485,893 Federal share) for CMS adjudication because the State agency did not verify with CMS whether the drugs were covered by Medicaid.

RECOMMENDATIONS

We recommend that the State agency:

- refund $108,331 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;

- work with CMS to resolve $3,485,893 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 by:

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

    - verifying with CMS whether drugs not listed on the quarterly drug tapes are covered under the Medicaid program and notifying 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 concurred with our first two recommendations. Regarding the third recommendation, the State agency said that it maintains sufficient internal controls to comply with Federal requirements and does not intend to change its

processes. In addition, the State agency included suggestions to improve the Medicaid drug rebate program.

We continue to recommend that the State agency strengthen its internal controls. Because the State agency did not follow Medicaid guidance, CMS reimbursed the State agency $108,331 for drugs not eligible for Medicaid coverage and $3,485,893 for drugs that may not be eligible for Medicaid coverage because the drugs were not listed on the CMS quarterly drug tapes.

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

APPENDIX

ILLINOIS DEPARTMENT OF
Healthcare and
Family Services

Rod R. Blagojevich, Governor
Barry S. Maram, Director

201 South Grand Avenue East
Springfield, Illinois 62763-0002

Telephone: 1-877-782-5565
TTY: (800) 526-5812

May 2, 2008

Marc Gustafson
Regional Inspector General for Audit Services
U.S. Department of Health and Human Services
233 North Michigan Avenue
Chicago, IL 60601

Re: Report Number A-05-07-00019

Dear Mr. Gustafson:

We have reviewed the draft report, "Review of Medicaid Outpatient Drug Expenditures in Illinois for the period October 1, 2003 through September 30, 2005" and the recommendations made by your office. We appreciate the opportunity to review this draft report and provide responses. Additionally, we appreciate the cooperation and assistance of the auditors in addressing the various issues that arose during the audit.

The Illinois Department of Healthcare and Family Services (HFS) Medicaid program strives to be one of the finest administered Medicaid programs in the nation. In fact, two years ago, a United States Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) review of the Illinois Drug Rebate program resulted in high praise for the staff and operation of this program. In 2005, a review conducted of all the drug rebate programs in the United States found that Illinois was one of five states that were in compliance with the program requirements.

Since the inception of the Drug Rebate Program, the partnership between HFS and CMS has been excellent. In order to improve the drug rebate program we are interested in building on this relationship so that CMS and all states benefit from a program that runs more smoothly. We believe that the findings cited in the audit report highlight various issues that are not specific to the state of Illinois but are national issues and should be addressed in further detail. We further believe that the issues are not an indication that the states have inadequate internal controls, but rather, they are an indication that CMS lacks adequate internal controls related to the integrity, reliability, and completeness of the drug rebate data transmitted to the states. We believe that addressing these issues will not only benefit CMS and Illinois, but also all state Medicaid agencies.

Therefore, our response to the draft audit report will not only address the findings and recommendations contained in the report, but will also address issues that have a significant impact on the operational component of the drug rebate program. Attached to this letter is the detailed response that addresses the recommendations and below is our discussion of these other issues.

Background

Section 1927 of the Social Security Act requires state Medicaid programs to cover all drugs manufactured by companies participating in the federal rebate program, with a few specified exceptions. Drugs manufactured by companies not participating in the federal rebate program are not eligible for coverage under the Medicaid program. CMS provides notification to states of which drug manufacturers participate in the federal rebate program.

Each drug product contains a National Drug Code (NDC). Each quarter, CMS provides each state Medicaid agency with a tape that includes various NDC-specific data elements, including the rebate rate for that quarter, and a termination date for the NDC, if applicable. The termination date is the shelf-life expiration date of the last batch sold of a particular drug code. If a product is removed from the market, the termination date is the date the drug was pulled from the market. After the termination date, any product with that NDC is expired.

The Department programs its claims processing system, based on the notification documentation received from CMS, so that it only reimburses for drugs manufactured by those entities identified by CMS as rebating manufacturers. In addition, the claims processing system is coded so that NDCs added to the system that are manufactured by a rebating manufacturer, as identified by CMS, are reimbursable. NDCs added to our system that are manufactured by non-rebating manufacturers are not reimbursable, and will reject with the following message: "Manufacturer Not on File For Rebate Quarter." The claims processing system also rejects all claims when the NDC is billed after the termination date, with the following message: "NDC Has Termination Date of (DATE)."

Overview

During the testing performed, the auditors compared our claims data to the quarterly federal rebate tapes for the quarters being audited. The findings represent the products with NDCs not found on the quarterly rebate tape for the quarter the Department reimbursed for the product, or NDCs found on the rebate tape but with termination dates prior to the date on which the product was reimbursed.

Initially, the auditors identified $63,285,516 in expenditures for products not found on the quarterly rebate tapes provided by the CMS during the audit period. The auditors did not find that the Department paid inappropriately for Drug Efficacy Study Implementation (DESI) drugs, and did not find any other problems with payments made by the Department. After thorough review and analysis, the Department provided documentation to demonstrate that $56,228,667of the above amount was justified, supported by one of the following reasons:

- The items were non-drug items, and therefore, not subject to the federal rebate requirements.
- The items were covered under Supplemental Rebate Agreements and therefore, the auditors determined that the Department had verification from the manufacturers that the NDCs were valid prior to reimbursing for them.
- Although the NDCs were terminated at the time the Department reimbursed for them, CMS did not provide the termination date to the Department in a timely manner.

Of the remaining amount of $7,056,849, the Department received federal rebates during the quarters in question on NDCs that account for $5,826,382. Since the manufacturer paid a federal rebate for the quarter during which the product was reimbursed, the manufacturer has confirmed that the product was a valid product. However, the auditors included these NDCs in their findings because the Department did not have documentation from CMS or the manufacturer prior to reimbursing for the products. Nevertheless, the Department believes we are in compliance with federal law, Section 1927 of the Social Security Act, which requires Medicaid programs to reimburse for products manufactured by rebating manufacturers, allowing only certain specific exceptions. The Department does not believe that it should be held accountable for the manufacturers' failure to report these NDCs to CMS in a timely manner, as required under the federal rebate agreement, Section II (a).

Of the remaining amount of $1,230,467, $486,052 was spent on non-drug products that were identified as such. Of that amount, according to detail reports provided to the Department in December 2007, the auditors acknowledged that NDCs representing $462,702 in spend were for non-drug items. In a December 2007 response to the auditors, the Department provided detail identifying additional non-drug NDCs representing $23,350 in spend.

Non-drug products are not subject to the rebate requirements under Section 1927 of the Social Security Act. The Department believes the inclusion of these products in the audit findings was inadvertent, and that claims for these products should have been removed from the total identified in the audit findings.

After taking into account federal rebates and non-drug products, the Department paid a total of $744,415 for products during FFY04 and FFY05 that were not on the federal rebate tapes, and on which the Department did not receive a federal rebate. This amount accounts for 0.02% of the Department's FFY04 and FFY05 total drug spend of $3,591,885,287. The total amount that the auditors seek to set aside, $6,849,395, represents only 0.19% of the Department's FFY04 and FFY05 total drug spend. This demonstrates that the Department has adequate controls in place to ensure that only those products that are eligible for coverage under the Medicaid drug program are reimbursed.

Conclusion

There are several issues, outside of the Department's control, which have an affect on ensuring that only products eligible for coverage under the Medicaid drug program are reimbursed. These include, the manufacturer not providing termination dates to CMS in a timely manner; manufacturers that do not continue to report an NDC after its termination date, as required; manufacturers' failure to report NDCs timely when they become available in the marketplace; over the counter products that contain only the UPC on the product package, but the UPC is not reported to CMS; and timely and adequate responses from CMS.

The Department believes that unless these issues are resolved, states will continue to have similar audit findings. Four drug rebate program staff spent two weeks printing multiple screen prints out of the MMIS system for each NDC to demonstrate that CMS did not provide termination dates in a timely manner, and to demonstrate that the Department received rebates on NDCs in question. Two of these staff were dedicated to this project exclusively. The other two worked on this project part-time. This time would have been better spent resolving rebate disputes, which generates revenue for both the state and federal government.

In addition, failure to address these issues will result in continued potentially inappropriate reimbursement for products that are terminated, resulting in inappropriate expenditures and loss of rebates, and continued use of CMS and state staffing resources to address these issues that could be more efficiently and cost-effectively resolved by CMS.

As was evidenced by our comprehensive analysis of the problems and recommended solutions, these issues are national and not Illinois-specific. CMS should be the party responsible for leading the rebate program to a successful resolution of these issues. Addressing these issues centrally will prevent problems from occurring, and will be more efficient and cost-effective than requiring all states to address the issues on an individual basis.

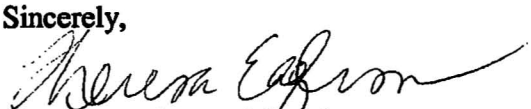
The Department believes that resolution of the issues that resulted in the audit findings can be facilitated by the following: Improved accuracy and completeness of data provided by CMS on quarterly rebate tapes; improved enforcement of provisions of the rebate agreement between CMS and the drug manufacturers; better-defined communication protocols between CMS and the states to ensure timely responses to problems that arise; and facilitation of a working group or advisory group that would allow state Medicaid staff and CMS the opportunity to work together to identify and resolve drug rebate program problems.

The Department believes that improved communications protocols and improvements in the quality and completeness of the federal rebate tape will not only reduce discrepancies, but will improve the effectiveness of the data exchange process and will provide greater efficiencies for both CMS and the states.

In addition, creation of a working group by CMS that would consist of CMS rebate staff and Medicaid staff from each region to identify problems and draft recommendations to resolve these problems would be beneficial. The Department would be happy to participate in such a workgroup, and would take the lead in coordinating meetings, if appropriate.

The Department fully supports any efforts to resolve these issues for the future and is interested in working with CMS, as well as other states, to assist in resolving the issues addressed as expeditiously as possible as all will benefit from a more efficiently run program.

Sincerely,



Theresa Eagleson, Administrator
Division of Medical Programs

Attachment Response
Report Number: A-05-07-00019

Recommendation:

- Refund $108,331 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage.

Response:

The Department concurs with the recommendation. The federal rebate tape is the source that states use to obtain the termination date of drug products. A specific drug's termination date is the date after which the drug is no longer available in the marketplace. Manufacturers provide the termination date to CMS, and CMS includes the date in the quarterly rebate tape. However, oftentimes termination dates are not provided to states in a timely manner. This results in the Department continuing to reimburse for the NDC after the termination date.

For example, NDC 00088102101 had a termination date of 12/31/2000, however, CMS did not provide the termination date to the state until the November 2005 rebate tape. In addition, NDC 60258044216 had a termination date of 12/31/2002, however, CMS did not provide the termination date until the November 2005 rebate tape.

Attachment A is a listing of NDCs for which the Department first received a termination date on the fourth quarter 2007 rebate tape. However, the termination date is prior to the fourth quarter. Please note that the retroactive termination dates for three of the NDCs go back as far as March 1, 2004. There are 37 NDCs with termination dates in 2006 and an additional 67 NDCs which have termination dates in the first two calendar quarters of 2007.

The Department experienced a problem with one file load of one rebate tape during the audit period which caused the Department to pay for some NDCs after the termination date provided by CMS. According to the audit report, this resulted in a spend of $207,454 ($108,331 federal share) on terminated products, which represents 0.01% of the Department's drug spend during the period covered in the audit. This was considered to be an isolated incident. In the future, if any problems are encountered with a load of a federal rebate tape, termination dates will be entered manually to ensure that the Department does not reimburse for products after the termination date.

On page four of the draft audit report, the auditors provide an example of the aforementioned problem, the drug Soriatane. This drug, however, was not affected by the aforementioned problem. It demonstrates yet another problem with CMS rebate tapes. This drug had a termination date of 2/29/2004, which was received in 2003, but there was no termination date for this NDC on CMS federal rebate tapes from 2/21/04 through 2/27/05. When CMS removes a termination date from the quarterly rate tape, the Department also removes the termination date. The Department is unclear as to whether the termination date was a mistake made by the manufacturer, as often occurs, or a mistake made by CMS. It is clear, however, that it was not a

mistake on the part of the Department. As this error was noted in the draft audit report, the Department believes that there may be others, and the total amount of $207,454 in ineligible drug expenditures may be overstated and the actual amount affected by the file load error may be lower.

The Department suggests that CMS require manufacturers to report termination dates in a timely manner. Upon review of the federal rebate agreement, the Department was unable to find a requirement to report termination dates. Therefore, CMS should revise the federal rebate agreement to require timely reporting of termination dates, and should hold manufacturers accountable for this reporting. Further, CMS should clearly define "termination date." The Department has found that manufacturers are not clear on the definition of termination date, and, thus, do not accurately report the termination date timely.

The Department believes that adequate controls are in place to ensure that we do not reimburse for products after the termination date. If a claim is processed for a drug after the termination date provided by CMS on the quarterly rebate tape, the claim rejects. CMS should require manufacturers to report termination dates timely and this requirement should be explicit in the federal rebate agreement. The Department does not plan to make any changes to their process and believes this problem must be addressed by CMS.

However, as to the refund of expenditures claimed, the Department would like to resolve this matter with CMS as quickly as possible. Please provide the name and contact information for the responsible party at CMS so that the Department can contact that individual and resolve these issues promptly.

Recommendation:

- Work with CMS to resolve $3,485,893 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 concurs with the recommendation. There are several issues, which cause these problems to occur as discussed below:

NDC's previously on the federal rebate tape are no longer found on subsequent rebate tapes. Although the federal rebate agreement requires manufacturers to continue reporting NDCs, even after they discontinue sale of that NDC, it appears that manufacturers do not always do so. NDCs on previous rebate tapes sometimes will "fall off" of the rebate tape. If CMS never included a termination date for that NDC on a quarterly federal rebate tape, state Medicaid agencies will never receive a termination date, and will not know that the NDC is no longer valid. The termination date from CMS is the data element that the Department uses to confirm that a product is no longer valid.

The audit report states that expenditures were claimed for drug products that were not listed on the quarterly drug tapes and since the Department did not verify with CMS whether the drugs missing from the tapes were eligible for Medicaid coverage, these drug expenditures may not be allowable for Medicaid reimbursements. This has been an ongoing issue for the Department's drug rebate administrators and staff. Although information from CMS states the drug rebate tape is to be the only source used in the preparation and submission of drug rebate expenditures for federal claiming, the data contained on the CMS data base that is forwarded to the states in not current.

For example, NDC 51479043101 was dropped from the Federal Rebate tape starting with the February 2002 tape. According to the manufacturer, the product was sold to another labeler in 2001, but the Department never received a termination date from CMS. Dropped NDCs continue to be an issue as several products for labeler 00034 were dropped from the November 2007 rebate tape, yet no termination date was sent.

Attachment B is a listing of NDCs that were on the third quarter 2007 rebate tape but were not on the fourth quarter 2007 rebate tape, and for which CMS has never provided a termination date.

The Department suggests that CMS should compare the manufacturers' reported NDCs each quarter. If an NDC that was previously reported by a manufacturer is no longer being reported, CMS should follow up with the manufacturer, since Section II (a) of the Federal Rebate Agreement requires that manufacturers report all NDCs, even after they are discontinued. If the manufacturer reports that the NDC is no longer valid, they should be required to provide CMS with a termination date, and CMS should include such date in the quarterly rebate tape. Of course, if a manufacturer has failed to provide a termination date in a timely manner, the Medicaid agencies may still end up reimbursing for the NDC after it was no longer valid.

Requiring all states to contact CMS each quarter on all NDCs dropped from the rebate tape is administratively burdensome, unnecessarily time consuming, and unrealistic. CMS could resolve this issue centrally by comparing the current quarter's tape to the prior quarter's, identifying dropped NDCs, and enforcing the rebate agreement by contacting manufacturers to obtain rebate and termination date information for those NDCs no longer reported. This would prevent the need for states to do this comparison individually.

Certain Over-the-Counter (OTC) Products have only a UPC and not an NDC on the package. OTC products such as nicotine replacement patches and gum contain only a UPC on the product packaging, not on the outer labeling of the product. However, manufacturers report the NDCs, and not the UPCs, to CMS for purposes of the federal rebate program.

For example, UPC 00766784420, Nicorette 4 mg chewing gum, was included in the audit findings, as it was not found on the federal rebate tape. The Department spent $195,793 on this product during the audit period. The Department worked with the manufacturer and established a crosswalk process, linking this UPC to the appropriate NDC, 00135017107 and received rebates on this product during the audit period.

Although pharmacies bill using the UPC, the Department has worked closely with the manufacturers to develop crosswalks to link the UPCs in the Department's claims history to the appropriate NDCs for purposes of rebate billing. Thus, the Department has received rebates on products that were billed using the UPC. However, this is a time-consuming, manual process. When manufacturers only print the UPC on a product's package, CMS should require the manufacturer to report that UPC on their federal rebate tape. Otherwise, there will always be problems matching those UPCs to the rebate tape. States will be required to continue to crosswalk UPCs to NDCs in order to get rebates, or will simply forego the rebates. This results in lost revenue for both the state and CMS. CMS could resolve this issue centrally, preventing the need for states to do so individually. The Department will continue to crosswalk as necessary because we believe the resultant rebate revenue justifies the time spent.

Timely and adequate responses from CMS. Department staff are instructed to check with CMS on the validity of NDCs not on the rebate tape. The draft audit report references the CMS drug rebate program memorandum #130 which states that if a drug code is billed by a pharmacy that is not on the last rebate tape . . . states should check with CMS to assure that the [drug code] is valid. However, when the Department brings issues to the attention of CMS, they do not receive timely or adequate responses.

For example, in response to an invoice the Department sent to Purdue Frederick, labeler number 00034, the manufacturer reported that 15 NDCs were terminated and the termination date was reported to CMS. However, those termination dates were not reported to states on the quarterly tapes from CMS. The Department checked with another state, and that state also did not receive the termination dates from CMS. Department staff contacted CMS rebate program staff to inquire on these termination dates, the response from CMS was "I don't have an automated means to provide that data. I looked at the first four NDCs and they were terminated on 9/20/2007. So these termination dates should be on your 3Q2007 tape." The Department never received a termination date from CMS for these NDCs, however, and these NDCs were simply dropped from the rebate tape altogether beginning with the 3Q2007 tape.

The Department suggests that CMS consider designating a state or regional liaison to work more closely with the states to collaboratively and collectively address problems and issues. The Department also suggests that CMS consider a question and answer forum, for usage by all states, so that if one state has questions about NDCs that are causing discrepancies, all states have access to the question and CMS response.

Although the total number of claims and the dollar amount of those claims that were included in the auditors' findings was considered negligible by the Department, the problems detailed above consume a disproportionate amount of staff time working with manufacturers and CMS in order to address the issues and work towards resolution. Department Drug Rebate program administrators and staff are frustrated at the lack of reliability of data on the rebate tapes, specifically with regard to accurate and timely reporting of termination dates, and with the lack of continued reporting of NDCs. Other states' pharmacy staff have also expressed the same frustration to the Department.

Valid, active NDCs not listed on the Federal Rebate Tape. Often, although an NDC is valid, is made by a rebating manufacturer, and pharmacies have the product with that NDC in stock, the NDC will not be on the CMS quarterly rebate tape for that quarter. This occurs because when a new NDC is released, it is available in the marketplace prior to being reported to CMS. Because the manufacturer would not have sales data for that NDC, they would not yet have reported the NDC to CMS. Therefore, there will always be NDCs that are reimbursed prior to being reported to state Medicaid agencies on a federal rebate tape. Although the auditors point to the CMS Medicaid drug rebate program memorandum to State Medicaid directors number 130, which 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 Department believes that it is unrealistic for each state to verify with CMS the validity of an NDC missing from the rebate tape prior to paying for that NDC.

Furthermore, NDCs often do not appear on the federal rebate tape for multiple quarters after they are available in the marketplace as manufacturers fail to report NDCs to CMS in a timely manner.

Drug manufacturers are required to provide NDC information to CMS in a timely manner. Clearly, the OIG findings in several states suggest that either drug manufacturers are not submitting the data timely, CMS is not requiring manufacturers to submit the information timely, or, if the manufacturers are providing the information as required in the drug rebate agreements, CMS is not updating the data files to reflect the most current information. This is evidenced by the fact that the Department received rebates on $5,826,382 of the $6,849,395, or 85 percent of the spend for drug products not listed on the quarterly drug tapes.

For example, NDC 00007316418 was included in the auditors' findings because it did not appear on the federal rebate tape for the quarters for which it was reimbursed. However, pharmacies did stock the NDC during the quarters and the Department did receive rebates from the manufacturer for that NDC for those quarters. Thus, the department determined that it was a valid NDC. Although it was added to the database on 9/24/2003, and the Department began to receive claims for it on 10/29/2003, it did not appear on the federal rebate tape until 8/16/2005, seven quarters after the Department received the first claim. When this occurs, the manufacturer pays rebates back to the first quarter during which the Department received claims. Another occurrence of this issue is NDC 49884007269, which is available in the marketplace, and the Department received its first claim for the product on 12/30/2006; however, it is not yet on the federal rebate tape.

Attachment C is a listing of NDCs for which the Department has received claims over the past four quarters, but have not yet been included on the federal rebate tape.

The Department suggests the federal rebate agreement between CMS and the manufacturers require manufacturers to report all NDCs to CMS as soon as the manufacturer is aware of the NDC, even if the manufacturer has no sales data for that NDC. State Medicaid programs obtain their drug data, including NDCs and pricing information, from a source such as First DataBank. This is the mechanism by which NDCs are added to the Department's claims processing system. The Department believes that CMS should obtain update files from a similar source, and should

use those files to ensure that manufacturers report all NDCs that are listed as active, and should resolve problems with reporting of NDCs with manufacturers. This would prevent each state from having to verify the validity of an NDC prior to reimbursing for that NDC when, in almost all cases, the NDC is valid and active.

The Department believes adequate controls are in place to ensure that only those drugs manufactured by rebating manufacturers are reimbursed and does not plan to make any changes to their process. Since manufacturers are the source of information reported to First DataBank, our system is programmed such that we only reimburse for drugs made by rebating manufacturers. Requiring all states to contact CMS each time a claim is paid for an NDC that was not on the prior quarter's rebate tape is administratively burdensome, unnecessarily time consuming, and unrealistic. CMS could resolve most issues centrally by doing data matches against information provided by a pricing source, preventing the need for states to do so individually.

Recommendation:

- Strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements by

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

    - Verifying with CMS whether drugs not listed on the quarterly drug tapes are covered under the Medicaid program and notifying CMS when drugs are missing from the tapes.

Response:

The Department believes that they maintain sufficient internal controls to ensure claimed Medicaid drug expenditures comply with Federal requirements and does not intend to make any changes to their processes.