DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

MAY 2 0 2009

TO: Charlene Frizzera
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 the State of New York for the Period October 1, 2003, Through September 30, 2005 (A-02-07-01028)

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

Under the Medicaid drug rebate program, the Centers for Medicare & Medicaid Services (CMS) provides the States with a quarterly Medicaid drug tape, which lists all covered outpatient drugs, indicates a drug's termination date if applicable, and specifies whether the Food and Drug Administration has determined the drug to be less than effective. CMS guidance instructs the States to use the tape to verify coverage of the drugs for which they claim reimbursement.

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

The State agency's claims for reimbursement of Medicaid outpatient drug expenditures for fiscal years 2004 and 2005 did not fully comply with Federal requirements. Of the $10.1 billion ($5.2 billion Federal share) in claimed Medicaid reimbursement, $1,236,302 (Federal share) represented expenditures for drug products that were not eligible for Medicaid coverage because they were (1) terminated drugs for which the termination dates were listed on the CMS quarterly drug tape before the drugs were dispensed, (2) drugs listed on the CMS quarterly drug tape as less than effective, or (3) inadequately supported with documentation. In addition, $16,189,125 (Federal share) represented expenditures for drug products that were not listed on the quarterly drug tapes. Because the State agency did not verify whether the drugs missing from the tapes were eligible for Medicaid coverage, these drug expenditures may not be allowable for Medicaid reimbursement. For the remainder of the $10.1 billion ($5.2 billion Federal share) claimed, we identified no other errors with respect to whether the drugs were terminated, less than effective, supported with adequate documentation, or included on the CMS quarterly drug tapes.

The improper claims were submitted for Medicaid reimbursement because the State agency did not have controls to adequately ensure that outpatient drug expenditures complied with Federal requirements.

We are recommending that the State agency:

- refund $1,236,302 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;

- work with CMS to resolve $16,189,125 in payments for drugs that were not listed on the quarterly drug tapes and, therefore, may not have been eligible for Medicaid reimbursement; 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 tapes,

    - claim expenditures only for drugs that are not listed as less than effective on the quarterly drug tapes,

    - maintain documentation that supports the expenditures reported on the Form CMS-64, and

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

The State agency generally agreed with our first and second recommendations and agreed with our third recommendation. The State agency said that rebates credited to the Federal Government should have been taken into account in determining the appropriate refund amounts. The State agency also disputed the disallowance of claims for less-than-effective drugs in situations where expenditures were incurred before the State agency received notification from CMS that the drugs were not eligible for Federal reimbursement. Nothing in the State agency's comments has given us cause to change our findings and recommendations.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact George M. Reeb, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through e-mail at George.Reeb@oig.hhs.gov or James P. Edert, Regional Inspector General for Audit Services, at (212) 264-4620 or through e-mail at James.Edert@oig.hhs.gov. Please refer to report number A-02-07-01028.

Attachment

Office Of Inspector General
Office Of Audit Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Region II
Jacob K. Javits Federal Building
26 Federal Plaza
New York, NY 10278

MAY 26 2009

Report Number: A-02-07-01028

Richard F. Daines, M.D.
Commissioner
New York State Department of Health
14th Floor, Corning Tower
Empire State Plaza
Albany, New York 12237

Dear Dr. Daines:

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 the State of New York for the Period October 1, 2003, Through September 30, 2005." We will forward a copy of this report to the 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 Freedom of Information Act, 5 U.S.C. § 552, OIG reports generally are made available to the public to the extent that information in the report is not subject to exemptions in the Act. Accordingly, this report will be posted on the Internet at http://oig.hhs.gov.

If you have any questions or comments about this report, please do not hesitate to call me, or contact Richard Schlitt, Audit Manager, at (212) 264-4817 or through e-mail at Richard.Schlitt@oig.hhs.gov. Please refer to report number A-02-07-01028 in all correspondence.

Sincerely,

James P. Edert

James P. Edert
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 THE STATE OF NEW YORK FOR THE PERIOD OCTOBER 1, 2003, THROUGH SEPTEMBER 30, 2005

Daniel R. Levinson
Inspector General

May 2009
A-02-07-01028

Office of Inspector General

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

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.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at http://oig.hhs.gov

Pursuant to the Freedom of Information Act, 5 U.S.C. § 552, Office of Inspector General reports generally are made available to the public to the extent that information in the report is not subject to exemptions in the Act.

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 New York, the Department of Health (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 New York, administer their Medicaid prescription drug programs in accordance with the Medicaid drug rebate program. The program generally pays for covered outpatient drugs if the drug manufacturers have rebate agreements with CMS and pay rebates to the States. Under the drug rebate program, CMS provides the States with a quarterly Medicaid drug tape, which lists all covered outpatient drugs, indicates a drug's termination date if applicable, and specifies whether the Food and Drug Administration has determined the drug to be less than effective. CMS guidance instructs the States to use the tape to verify coverage of the drugs for which they claim reimbursement.

In New York, 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

The State agency's claims for reimbursement of Medicaid outpatient drug expenditures for fiscal years 2004 and 2005 did not fully comply with Federal requirements. Of the $10.1 billion ($5.2 billion Federal share) in claimed Medicaid reimbursement, $1,236,302 (Federal share) represented expenditures for drug products that were not eligible for Medicaid coverage because they were (1) terminated drugs for which the termination dates were listed on the CMS quarterly drug tape before the drugs were dispensed, (2) drugs listed on the CMS quarterly drug tape as less than effective, or (3) inadequately supported with documentation. An additional $16,189,125 (Federal share) represented expenditures for drug products that were not listed on the quarterly drug tapes. Because the State agency did not verify whether the drugs missing from the tapes were eligible for Medicaid coverage, these drug expenditures may not be

allowable for Medicaid reimbursement. For the remainder of the $10.1 billion ($5.2 billion Federal share) claimed, we identified no other errors with respect to whether the drugs were terminated, less than effective, supported with adequate documentation, or included on the CMS quarterly drug tapes.

The improper claims were submitted for Medicaid reimbursement because the State agency did not have controls to adequately ensure that outpatient drug expenditures complied with Federal requirements.

RECOMMENDATIONS

We recommend that the State agency:

- refund $1,236,302 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;

- work with CMS to resolve $16,189,125 in payments for drugs that were not listed on the quarterly drug tapes and, therefore, may not have been eligible for Medicaid reimbursement; 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 tapes,

    - claim expenditures only for drugs that are not listed as less than effective on the quarterly drug tapes,

    - maintain documentation that supports the expenditures reported on the Form CMS-64, and

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

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the State agency did not agree to refund $1,236,302 to the Federal Government but did agree to refund reimbursement for ineligible claims. The State agency said that rebates credited to the Federal Government should have been taken into account in determining the appropriate refund amounts. The State agency disagreed with the disallowance of claims for less-than-effective drugs in situations where expenditures were incurred before the State agency received notification from CMS that the drugs were not eligible for Federal reimbursement. The State agency agreed to work with CMS to resolve payments for drugs not listed on the quarterly drug tapes but stated its belief that the amount would be less

than $16,189,125. The State agency also agreed with the third recommendation. The State agency's comments appear in their entirety as the Appendix.

We indicated in the methodology section of our report that we did not reduce the questioned drug expenditures by rebates that the State received. The State agency may not claim rebates on drug expenditures not eligible for Federal reimbursement. If the State agency had collected rebates for these expenditures, it should have refunded the rebates (including the portion paid to the Federal Government) to the manufacturers. Therefore, these rebates would have no dollar effect on our recommended disallowance. Regarding the State agency's concerns about claims for less-than-effective drugs, we did not question expenditures incurred before the State agency received notification from CMS that the drugs were not eligible for Federal reimbursement. Rather, we used the first day of the quarter after the State agency received the tape as the date the drug was classified as less than effective. Nothing in the State agency's comments has given us cause to change our findings and recommendations.

TABLE OF CONTENTS

Page

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 New York, the Department of Health (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 New York, 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, P.L. No. 101-508, 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 New York, the State agency claims Medicaid expenditures on Form CMS-64, "Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program" (Form CMS-64). CMS reimburses the State agency based on the Federal medical assistance percentage (reimbursement rate) for the majority of claimed Medicaid expenditures, including outpatient drug expenditures.

For Federal fiscal years (FY) 2004 and 2005, New York's Federal reimbursement rate for Medicaid expenditures varied from 50 percent to 52.95 percent, and its enhanced reimbursement rates varied from 65 percent to 90 percent.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

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

Scope

The audit scope included $10.1 billion ($5.2 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 and guidance related to whether the drugs were terminated, less than effective, supported with adequate documentation, and included on the CMS quarterly tapes.

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

We conducted fieldwork at the State agency's offices in Albany, New York.

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 June 30, 2006. We reconciled the amounts that the State agency reported on its Forms CMS-64 to a detailed list of the State agency's outpatient drug expenditures. We also used the detailed list of drug expenditures to determine whether the expenditures complied with Federal requirements. Specifically, we determined whether the drugs for which the State agency claimed

reimbursement were dispensed after the termination dates listed on the quarterly drug tape or were listed as less than effective on the tape. In addition, we determined whether CMS had included the termination dates on the quarterly drug tape in a timely manner—that is, before terminated drugs could be dispensed. To account for reasonable delays in processing data for terminated drugs, we used the first day of the quarter after the State received the tape as the termination date if the termination dates were provided to the 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. If the drugs were compound drugs, we requested supporting documentation that identified the individual drug components.[4]

We obtained the Federal share of the expenditures from the Medicaid Management Information System, which the State agency uses to process Medicaid claims.[5] 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 fully comply with Federal requirements. Of the $10.1 billion ($5.2 billion Federal share) claimed, $2,409,985 ($1,236,302 Federal share) represented expenditures for drug products that were not eligible for Medicaid coverage because they were (1) terminated drugs for which the termination dates were listed on the CMS quarterly drug tape before the drugs were dispensed, (2) drugs listed on the CMS quarterly drug tape as less than effective, or (3) inadequately supported with documentation. An additional $31,952,653 ($16,189,125 Federal share) represented expenditures for drug products that were not listed on the quarterly drug tapes. Because the State agency did not verify whether the drugs missing from the tapes were eligible for Medicaid coverage, these drug expenditures may not have been allowable for Medicaid reimbursement. For the remainder of the $10.1 billion ($5.2 billion Federal share) claimed, we identified no other errors with respect to whether the drugs were terminated, less than effective, supported with adequate documentation, or included on the CMS quarterly drug tapes.

[4]Compound drugs are created by combining two or more prescription or nonprescription drug products and repackaging them into a new capsule or other dosage form.

[5]We calculated the Federal share of New York's Medicaid expenditures during the period from October 1, 2003, through June 30, 2004, when its Federal reimbursement rate was 52.95 percent. During the remainder of the audit period, we were able to obtain the Federal share from the Medicaid Management Information System because New York's Federal reimbursement rate was equal to its normal Federal share amount (i.e., 50 percent).

The State agency had inadequate controls to ensure that 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 release 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." (Emphasis in the original.)

In addition, the CMS Medicaid drug rebate program release 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 $1,106,367 ($578,321 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 Zocor, which was dispensed on August 22, 2004. However, according to the tapes beginning with the quarter ended March 31, 2002, the drug's termination date was May 31, 2004. Therefore, 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 LESS-THAN-EFFECTIVE DRUGS

Section 1903(i)(5) of the Act prohibits Federal Medicaid funding for drug products that are ineligible for Medicare payment pursuant to section 1862(c) of the Act. Section 1862(c) prohibits Federal funding for drug products determined to be less than effective for all conditions prescribed, recommended, or suggested on the product's label. According to the CMS Medicaid drug rebate program release to State Medicaid directors, number 130: ". . . the CMS [quarterly drug tape] is the one to use for ALL data when you are dealing with the drug rebate program . . . ." The quarterly drug tapes identify drugs that have been determined to be less than effective.

For FYs 2004 and 2005, the State agency claimed $173,467 ($89,650 Federal share) in expenditures for drugs classified as less than effective on the quarterly drug tapes. For example, the State paid for the drug Estratest, which was dispensed on September 23, 2004. However, CMS reported the drug as less than effective on the tapes beginning with the quarter that ended September 30, 2003. The claimed expenditure was unallowable because the drug was dispensed after CMS reported it as less than effective.

CLAIMS FOR INADEQUATELY SUPPORTED DRUG EXPENDITURES

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

For FYs 2004 and 2005, the State agency claimed $1,130,151 ($568,331 Federal share) in drug expenditures on its quarterly Forms CMS-64 for which it did not have any supporting documentation that identified which drugs were claimed. The drugs were compound drugs made up of two or more prescription or nonprescription drug products. The State agency created its own drug codes for the compound drugs, but it could not identify the individual drugs that were included. Without this supporting documentation, the State agency could not demonstrate that its claims for reimbursement were covered under the Medicaid program. These claims were therefore unallowable.[6]

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.[7] 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 release 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 release to State Medicaid directors, number 44, provides that: "States must check the [quarterly drug tape] to ensure the continued presence of a drug product . . . ."

In addition, page S13 of CMS's "Medicaid Drug Rebate Operational Training Guide," 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."

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

[7]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.

For FYs 2004 and 2005, the State agency claimed $31,952,653 ($16,189,125 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 indicating that these payments were allowable Medicaid expenditures.

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

The State agency did not have adequate controls to ensure that all Medicaid drug expenditures complied with Federal requirements or to detect unallowable and potentially unallowable claims for reimbursement. For some of its drug claims, the State agency did not maintain supporting documentation that identified which drugs it claimed and, therefore, could not demonstrate that the claims were covered under the Medicaid program. The State agency also did not check the quarterly drug tapes to ensure that the drugs were eligible for Medicaid coverage.

REIMBURSEMENT OF UNALLOWABLE AND POTENTIALLY UNALLOWABLE CLAIMS FOR DRUG EXPENDITURES

The State agency claimed Federal reimbursement for certain drugs that were not eligible for Medicaid coverage because they were terminated, less than effective, or inadequately documented. As a result, for FYs 2004 and 2005, the State agency claimed unallowable expenditures totaling $2,409,985 ($1,236,302 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 $31,952,653 ($16,189,125 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 $1,236,302 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;

- work with CMS to resolve $16,189,125 in payments for drugs that were not listed on the quarterly drug tapes and, therefore, may not have been eligible for Medicaid reimbursement; 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 tapes,

- claim expenditures only for drugs that are not listed as less than effective on the quarterly drug tapes,

- maintain documentation that supports the expenditures reported on the Form CMS-64, and

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

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency did not agree to refund $1,236,302 to the Federal Government but did agree to refund the net Federal funds reimbursed for ineligible claims. The State agency said that rebates credited to the Federal Government should have been taken into account in determining the appropriate refund amounts. The State agency disagreed with the disallowance of claims for less-than-effective drugs in situations where expenditures were incurred before the State agency received notification from CMS that the drugs were not eligible for Federal reimbursement. The State agency agreed to work with CMS to resolve payments for drugs not listed on the quarterly drug tapes but stated its belief that the amount would be less than $16,189,125. The State agency also agreed with the third recommendation. The State agency's comments appear in their entirety as the Appendix.

OFFICE OF INSPECTOR GENERAL RESPONSE

We indicated in the methodology section of our report that we did not reduce the questioned drug expenditures by the rebates that the State had received. The State agency may not claim rebates on drug expenditures not eligible for Federal reimbursement. If the State agency had collected rebates for these expenditures, it should have refunded the rebates (including the portion paid to the Federal Government, if any) to the manufacturers. Therefore, these rebates would have no dollar effect on our recommended disallowance. Regarding the State agency's concerns about claims for less-than-effective drugs, we did not question expenditures incurred before the State agency received notification from CMS that the drugs were not eligible for Federal reimbursement. Rather, we used the first day of the quarter after the State agency received the tape as the date the drug was classified as less than effective. Nothing in the State agency's comments has given us cause to change our findings and recommendations.

APPENDIX

STATE OF NEW YORK
DEPARTMENT OF HEALTH
Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Richard F. Daines, M.D.
Commissioner

Wendy E. Saunders
Executive Deputy Commissioner

January 5, 2009

James P. Edert
Regional Inspector General for Audit Services
Department of Health and Human Services
Region II
Jacob Javitz Federal Building
26 Federal Plaza
New York, New York 10278

Ref. No. A-02-07-01028

Dear Mr. Edert:

Enclosed are the New York State Department of Health's comments on the Department of Health and Human Services, Office of Inspector General's draft audit report A-02-07-01028 on "Review of Medicaid Outpatient Drug Expenditures in the State of New York for the Period October 1, 2003, Through September 30, 2005."

Thank you for the opportunity to comment.

Sincerely,

Wendy E. Saunders
Executive Deputy Commissioner

Enclosure

cc: Stephen Abbott
Deborah Bachrach
Homer Charbonneau
Ronald Farrell
Gail Kerker
Sandra Pettinato
Robert W. Reed
James Sheehan

New York State Department of Health Comments on the Department of Health and Human Services Office of Inspector General's Draft Audit Report A-02-07-01028 on "Review of Medicaid Outpatient Drug Expenditures in the State of New York for the Period October 1, 2003, Through September 30, 2005"

The following are the New York State Department of Health's (Department) comments in response to the Department of Health and Human Services, Office of Inspector General's (OIG) draft audit report A-02-07-01028 on "Review of Medicaid Outpatient Drug Expenditures in the State of York State for the Period October 1, 2003, Through September 30, 2005" (A-02-07-01028).

Recommendation #1:

The State agency should refund $1,236,302 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage.

Response #1:

The Department will refund the net federal funds reimbursed for any claims determined ineligible for reimbursement, although it does not agree with the $1,236,302 refund amount identified in the report. According to the report, the auditors "did not reduce the questioned drug expenditures by the rebate amounts that the State received." Since the Department credited the Federal government for the Federal share of the rebates received for the disallowed claims, these credits should have been taken into account in determining the appropriate refund amount. Additionally, the Department disputes the disallowance of reimbursement associated with claims for less-than-effective ("DESI") drugs in situations where the expenditures were incurred prior to the Department receiving notification of the DESI classification from CMS. The Department contends that such claims are appropriate and should be reimbursed.

Recommendation #2:

The State agency should work with CMS to resolve $16,189,125 in payments for drugs that were not listed on the quarterly drug tapes and, therefore, may not have been eligible for Medicaid reimbursement.

Response #2:

The Department will work with CMS to resolve the reimbursement status of the payments identified for drugs not listed on the quarterly drug tape. However, the Department will continue its practice of updating the formulary for new FDA-approved products of participating manufacturers, even if the new products haven't been included

on the quarterly CMS tape. This will ensure patient access to medically necessary, and perhaps life saving, medications. Additionally, similar to the above response, since the auditors did not take the rebate offset into account, the net federal reimbursement associated with these claims is considerably less than the $16,189,125 identified in the report.

Recommendation #3:

The State agency should strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements; specifically, the State agency should:

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

Response #3:

The Department agrees with the recommendation and has already initiated changes to strengthen internal controls to ensure claiming activities comply with Federal requirements; specifically:

- The Department routinely monitors CMS reports and other relevant data to detect terminated products, then takes swift action to discontinue their coverage. Terminated products are timely removed from the formulary whenever information verifying the termination is obtained from either CMS, the Department's drug information contractor, drug manufacturers or through the rebate resolution process. The Department has additionally initiated development of a process to identify and recover payments where the date-of-service falls on or after the product's termination date but prior to the date the Department received notification of the termination.
- The Department's fiscal agent contractor routinely prescreens drug products in an effort to ensure DESI drugs are not added to the formulary. In addition, the Department implemented monthly reviews of all formulary drugs to identify changes in non-reimbursable DESI identifiers, with product coverage promptly discontinued when such changes are identified. It has additionally implemented operational changes to address revised CMS procedures for notifying States of

DESI classification changes (Release 148 for State Medicaid Directors), permitting the most timely updates possible to the formulary.

- The audit identified an anomaly with the Department's claims documentation relative to compounds. The Department agrees that it should maintain documentation supporting the expenditures reported on Form CMS-64, and has initiated a systems evolution project (EP0624) which will allow drugs billed as compounds to be properly identified.

- Prior to modifying the formulary for drugs not listed on the CMS tape, the Department will verify that only products manufactured by participating labelers are added to the formulary, and will subsequently confirm such changes via review of the next CMS tape received. In addition, the Department will note when products are missing from the CMS tape as part of the data sent back to CMS.