Report Number: A-03-07-00220

Ms. Marsha K. Morris
Commissioner
Bureau of Medical Services
Department of Health and Human Resources
350 Capitol Street, Room 251
Charleston, West Virginia 25301-3706

Dear Ms. Morris:

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 West Virginia 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, 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 Mr. Eugene G. Berti, Jr., Audit Manager, at 215-861-4474 or through e-mail at Gene.Berti@oig.hhs.gov. Please refer to report number A-03-07-00220 in all correspondence.

Sincerely,

Stephen Virbitsky
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
REVIEW OF MEDICAID OUTPATIENT DRUG EXPENDITURES IN WEST VIRGINIA FOR THE PERIOD OCTOBER 1, 2003, THROUGH SEPTEMBER 30, 2005
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 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 West Virginia, the Department of Health and Human Resources (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 West Virginia, 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 West Virginia, 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 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 $808 million ($615 million Federal share) claimed, $175,252 (Federal share) represented a duplicate prior period adjustment claimed by the State agency and $111,142 (Federal share) represents 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) inadequately supported, or (3) drugs listed on the CMS quarterly drug tape as less than effective.
An additional $2,147,510 (Federal share) represents expenditures for drug products that were not listed on the quarterly drug tapes. Because the State agency did not verify whether the drugs missing from the tapes were eligible for Medicaid coverage, these drug expenditures may not be allowable for Medicaid reimbursement. For the remainder of the $808 million ($615 million Federal share) claimed, we identified no other errors with respect to whether the drugs were terminated, supported with adequate documentation, less than effective, or included on the CMS quarterly drug tapes.

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

**RECOMMENDATIONS**

We recommend that the State agency:

- refund $286,394 to the Federal Government, including:
  - $175,252 for a duplicate prior period adjustment, and
  - $111,142 for drug expenditures that were not eligible for Medicaid coverage,
- work with CMS to resolve $2,147,510 in payments for drugs that were not listed on the quarterly drug tapes and that may not have been eligible for Medicaid coverage, and
- strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements, specifically:
  - reconcile actual expenditures to the expenditures claimed on the CMS-64s to avoid duplicate expenditures,
  - claim expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes,
  - maintain readily reviewable documentation that identifies the actual drugs used,
  - claim expenditures only for drugs that are not listed as less than effective on the quarterly drug tapes, and
  - verify whether drugs not listed on the quarterly drug tapes are covered under the Medicaid program and notify CMS when drugs are missing from the tapes.

**STATE AGENCY COMMENTS**

In a letter dated June 13, 2008, the State agency concurred with our recommendations. The Appendix presents the State agency comments.
TABLE OF CONTENTS

INTRODUCTION.................................................................................................................................1

BACKGROUND ........................................................................................................................................1
Medicaid Program..............................................................................................................................1
Medicaid Outpatient Prescription Drug Program ..............................................................1
Reimbursement of Medicaid Expenditures...........................................................................2

OBJECTIVE, SCOPE, AND METHODOLOGY ...............................................................................2
Objective..............................................................................................................................................2
Scope....................................................................................................................................................2
Methodology.....................................................................................................................................2

FINDINGS AND RECOMMENDATIONS ....................................................................................3
DUPLICATE PRIOR PERIOD ADJUSTMENT....................................................................................4
CLAIMS FOR TERMINATED DRUGS ..............................................................................................4
CLAIMS FOR INADEQUATELY SUPPORTED DRUG EXPENDITURES ....................................5
CLAIMS FOR LESS-THAN-EFFECTIVE DRUGS..........................................................................5
CLAIMS FOR DRUGS NOT LISTED ON QUARTERLY DRUG TAPES.......................................5
INADEQUATE CONTROLS TO DETECT UNALLOWABLE AND POTENTIALLY UNALLOWABLE CLAIMS FOR DRUG EXPENDITURES.................................................................6
REIMBURSEMENT OF UNALLOWABLE AND POTENTIALLY UNALLOWABLE CLAIMS FOR DRUG EXPENDITURES........................................................................................................6
RECOMMENDATIONS..................................................................................................................7
STATE AGENCY COMMENTS..........................................................................................................7

APPENDIX

STATE AGENCY COMMENTS
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 West Virginia, the Department of Health and Human Resources (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 West Virginia, 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. 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, if applicable, specifies whether the drug is less than effective, 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.

---

1The 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.

2The 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.

3The 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 West Virginia, 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 Federal fiscal years (FY) 2004 and 2005, West Virginia’s Federal reimbursement rate for Medicaid expenditures varied from 74.65 percent to 78.14 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 was $808 million ($615 million 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, supported with adequate documentation, less than effective, 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 at the State agency’s offices in Charleston, West Virginia.

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 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 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 State retroactively.

We also determined whether the drugs claimed for reimbursement were listed on the applicable quarterly drug tape. If the drugs were not listed on the tape, we determined whether the State agency had verified whether the drugs were eligible for Medicaid coverage. If the drugs were compound drugs, we requested supporting documentation that identified the individual drug components.4

We calculated the Federal share of the expenditures using the lowest percentage (74.65 percent to 78.14 percent) applicable for each quarter. We did not reduce the questioned drug expenditures by the rebate amounts that the State received.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

**FINDINGS AND RECOMMENDATIONS**

The State agency’s claims for reimbursement of Medicaid outpatient drug expenditures for FYs 2004 and 2005 did not fully comply with Federal requirements. Of the $808 million ($615 million Federal share) claimed, $175,252 (Federal share) represented a duplicate prior period adjustment claimed by the State agency and $111,142 (Federal share) represents 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) inadequately supported, or (3) drugs listed on the CMS quarterly tape as less than effective.

An additional $2,147,510 (Federal share) represents expenditures for drug products that were not listed on the quarterly drug tapes. Because the State agency did not verify whether the drugs missing from the tapes were eligible for Medicaid coverage, these drug expenditures may not be allowable for Medicaid reimbursement. For the remainder of the $808 million ($615 million Federal share) claimed, we identified no other errors with respect to whether the drugs were terminated, supported with adequate documentation, less than effective, or included on the CMS quarterly drug tapes.

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

---

4Pharmacists create compound drugs by combining two or more prescription or nonprescription drug products and then repackaging them into a new capsule or other dosage form.
DUPLICATE PRIOR PERIOD ADJUSTMENT

CMS State Medicaid Manual, section 2497.1 states that “Federal financial participation (FFP) is available only for allowable actual expenditures made on behalf of eligible recipients for covered services rendered by certified providers.”

Office of Management and Budget (OMB) Circular A-87, section C(1)(a), states that to be allowable under Federal awards, costs must “[b]e necessary and reasonable for proper and efficient performance and administration of Federal awards.”

Contrary to these requirements, the State agency claimed a prior period adjustment twice on the CMS-64 for the quarter ending March 31, 2004. The State agency did not have adequate controls in place to prevent such duplication and ensure that its Medicaid drug expenditures complied with Federal requirements. As a result, the State agency claimed a duplicate prior period adjustment totaling $224,279 ($175,252 Federal share). We discussed this finding with State agency officials, who agreed that the adjustment was duplicated.

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 $124,560 ($94,133 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 Dipyridamole, which was dispensed on September 6, 2005. However, the drug’s termination date was April 1, 2005, according to the tapes beginning with the quarter that ended December 31, 2004. 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.

5Federal regulations (45 CFR § 95.507) make OMB Circular A-87 applicable.
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 $21,704 ($16,539 Federal share) in drug expenditures for which it did not have any supporting documentation to indicate that the drugs met Federal requirements. The drugs were compound drugs made up of two or more prescription or nonprescription drug products. The State agency created its own drug codes for the compound drugs, but it could not identify the individual drugs that were included. The claimed expenditures were unallowable because the State agency did not have documentation showing that the drugs complied with Federal requirements.6

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 memorandum to State Medicaid directors, number 130: “. . . the CMS [quarterly drug tape] is the one to use for ALL data when you are dealing with the drug rebate program . . . .” The quarterly drug tapes identify drugs that have been determined to be less than effective.

For FYs 2004 and 2005, the State agency claimed $603 ($470 Federal share) in expenditures for drugs classified as less than effective. For example, the State paid for a Hemorrhoidal suppository, which was dispensed on March 22, 2004. However, CMS reported the drug as less than effective on the tapes beginning with the quarter that ended June 30, 2000. The claimed expenditure was unallowable because the drug was dispensed after CMS reported it as less than effective.

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

6West Virginia 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.

7Pursuant 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.
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 S-S5, 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 $2,850,722 ($2,147,510 Federal share) in expenditures for drug products that were not listed on the quarterly drug tapes. The State agency did not contact CMS to ensure that these drugs were eligible for Medicaid coverage under the Act. As a result, the State agency did not have conclusive evidence that these payments were allowable Medicaid expenditures.

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

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

**REIMBURSEMENT OF UNALLOWABLE AND POTENTIALLY UNALLOWABLE CLAIMS FOR DRUG EXPENDITURES**

The State agency claimed Federal reimbursement for certain drugs that were not eligible for Medicaid coverage because they were terminated, inadequately supported, or less than effective. As a result, for FYs 2004 and 2005, the State agency claimed unallowable expenditures totaling $371,146 ($286,394 Federal share) for these drugs. The State agency also claimed Federal reimbursement for drug products that were not listed on the quarterly drug tapes. For these drugs, we set aside potentially unallowable expenditures totaling $2,850,722 ($2,147,510 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 $286,394 to the Federal Government, including:
  o $175,252 for a duplicate prior period adjustment, and
  o $111,142 for drug expenditures that were not eligible for Medicaid coverage,

• work with CMS to resolve $2,147,510 in payments for drugs that were not listed on the quarterly drug tapes and that may not have been eligible for Medicaid coverage, and

• strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements, specifically:
  o reconcile actual expenditures to the expenditures claimed on the CMS-64s to avoid duplicate expenditures,
  o claim expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes,
  o maintain readily reviewable documentation that identifies the actual drugs used,
  o claim expenditures only for drugs that are not listed as less than effective on the quarterly drug tapes, and
  o 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 its comments on our draft report, the State agency concurred with our findings and recommendations and advised us of the corrective actions it was taking to implement our recommendations. The State agency stated that it has in place a reconciliation process that reconciles actual expenditures to the expenditures claimed on the CMS-64. The duplicate claiming of the prior period adjustment appears to have been an isolated incident and attributable to clerical oversight or error.
APPENDIX

Dear Mr. Virbisky:

The West Virginia Department of Health and Human Resources and the Bureau for Medical Services (Bureau), the single state agency, offers the following response to the draft report entitled “Review of Medicaid Outpatient Drug Expenditures in West Virginia for the period October 1, 2003, through September 30, 2005.” We will address specifically the following recommendations submitted by the OIG in their report:

Recommendation 1: Refund $286,394 to the Federal Government

West Virginia’s Response and Proposed Corrective Action:

The State concurs with the OIG’s finding to refund $286,394 to the Federal Government.

The overpayment resulted from the duplication of a prior period adjustment filed on the CM36G in Q2 FYT 2004 in the amount of $175,252 (FFP) and $111,142 (FFP) for drug expenditures found ineligible for Medicaid coverage during the review. The ineligible drug expenditures are categorized into the following three categories: 1.) Terminated Drugs - $94,132.95; 2.) Compound Drugs - $16,539.03; and 3.) Less than Effective Drugs (DES1) - $470.34.

In response to the OIG findings, the Bureau has implemented a reconciliation process that occurs in conjunction with drug rebate invoicing that identifies ineligible payments for drugs listed as terminated per the CMS quarterly drug tape. However, due to timing differences of when the expenditure report is filed and drug rebate invoicing occurs, corrective measures will not be reflected until the following quarters CMS 64 report is filed. Additional steps will be taken to assure that the drug files used in claims processing will be updated to reflect the termination date submitted on the CMS quarterly drug tape to prevent any future payment of ineligible drugs.

With the transition to the State’s current claim fiscal agent, the Bureau has resolved the finding for unsupported or undocumented claims. All drug ingredients are required to be
submitted with the claim for compound drugs; therefore bringing the Bureau into compliance with section 2497.1 of the State Medicaid Manual.

The State has implemented an additional reconciliation process in regard to Less Than Effective (DESI) drugs which are ineligible for FFP, by comparing the information available from First Data Bank to the CMS quarterly drug file data. When differences occur, the DESI information is reset according to the CMS tape information for future claims processing. Because there is a lag between real-time processing and the delivery of the CMS tape, claims can potentially be paid in error. The State will work with CMS to explore ways of obtaining this information on a timelier basis.

Recommendation 2: Work with CMS to resolve $2,147,510 in payments for drugs that were not listed on the quarterly drug tapes and that may not have been eligible for Medicaid coverage.

West Virginia’s Response and Proposed Corrective Action:

The State concurs with the OIG’s recommendation to resolve with CMS $2,147,510 in payments for drugs that were not found on the CMS quarterly drug tape. Based on these discussions, the State will implement a corrective action plan, including a review of drugs paid that are not listed on the CMS file. However, the State would like to remind the OIG that the CMS quarterly drug file lags behind changes in the market place. New drug entities are routinely marketed and should be made available to Medicaid members even though they may not appear until a later time period on the CMS file. The State will work with CMS to explore ways to make more current data available to the State.

Recommendation 3: Strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements.

West Virginia’s Response and Proposed Corrective Action:

The State concurs that the review identified additional opportunities for the Bureau to strengthen and improve internal controls. However, the State has in place a reconciliation process that reconciles actual expenditures to the expenditures claimed on the CMS64. The duplicate claiming of the prior period adjustment appears to have been an isolated incident and attributable to clerical oversight or error. The remaining recommendations and the Bureau’s response have been addressed in previous sections.

Should you have any further questions, please contact Tina Bailes at 304-558-1526.

Sincerely,

[Signature]

Marsha K. Morris
Commissioner

MKM/jd

c: Nora M. Antlake, Counsel
Tina Bailes, Chief Financial Officer
Peggy King, Pharmacy Director