DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

OCT - 6 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 Pennsylvania for the Period October 1, 2003, Through September 30, 2005 (A-03-07-00203)

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

The Federal and State Governments jointly fund and administer the Medicaid program. 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 $1.96 billion ($1.1 billion Federal share) claimed, $4.4 million (Federal share) represented expenditures for drug products that were not eligible for Medicaid coverage because they were either (1) terminated drugs for which the termination dates were listed on the CMS quarterly drug tape before the drugs were dispensed, (2) inadequately supported drug expenditures, or (3) drugs listed on the CMS quarterly drug tape as less than effective.

An additional $5.9 million (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 $1.96 billion ($1.1 billion Federal share) claimed, we identified no other errors with respect to whether the

drugs were (a) terminated, (b) supported with adequate documentation, (c) less than effective, or (d) 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.

We recommend that the State agency:

- refund $4,397,728 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;

- work with CMS to resolve $5,900,935 in payments for drugs that were not listed on the quarterly drug tapes and that may not have been eligible for Medicaid coverage; and

- strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements, specifically:

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

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

    - maintain readily reviewable documentation that identifies the actual drugs used,

    - do not claim expenditures for drugs that are 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.

In comments on our draft report, the State agency generally agreed with our recommendations and provided additional documentation to support $957,999 (Federal share) of its claim. However, we were unable to reconcile the documentation we received to the CMS-64 or to other documentation previously provided during the audit. We modified our finding accordingly, and continue to support our 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 Stephen Virbitsky, Regional Inspector General for Audit Services, at (215) 861-4470 or through e-mail at Stephen.Virbitsky@oig.hhs.gov. Please refer to report number A-03-07-00203.

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

Office of Audit Services, Region III
Public Ledger Building, Suite 316
150 S. Independence Mall West
Philadelphia, PA 19106-3499

OCT 10 2008

Report Number: A-03-07-00203

Mr. Theodore Dallas
Executive Deputy Secretary
Pennsylvania Department of Public Welfare
P.O. Box 2675
Harrisburg, Pennsylvania 17105-2675

Dear Mr. Dallas:

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 Pennsylvania 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. Robert Baiocco, Audit Manager, at 215-861-4486 or through e-mail at Robert.Baiocco@oig.hhs.gov. Please refer to report number A-03-07-00203 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

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF MEDICAID OUTPATIENT DRUG EXPENDITURES IN PENNSYLVANIA FOR THE PERIOD OCTOBER 1, 2003, THROUGH SEPTEMBER 30, 2005

Daniel R. Levinson
Inspector General

October 2008
A-03-07-00203

Office of Inspector General

http://oig.hhs.gov

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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 Pennsylvania, the Department of Public Welfare (the State agency) administers Medicaid.

In addition to providing mandatory Medicaid services, States may offer certain optional services, such as outpatient prescription drugs, to eligible Medicaid beneficiaries. Most States, including Pennsylvania, 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 Pennsylvania, 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 $1.96 billion ($1.1 billion Federal share) claimed, $4,397,728 (Federal share) represented expenditures for drug products that were not eligible for Medicaid coverage because they were either (1) terminated drugs for which the termination dates were listed on the CMS quarterly drug tape before the drugs were dispensed, (2) inadequately supported drug expenditures, or (3) drugs listed on the CMS quarterly drug tape as less than effective.

An additional $5,900,935 (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 $1.96 billion ($1.1 billion Federal share) claimed, we identified no other errors with respect to whether the drugs were (a) terminated, (b) supported with adequate documentation, (c) less than effective, or (d) 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 $4,397,728 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;

- work with CMS to resolve $5,900,935 in payments for drugs that were not listed on the quarterly drug tapes and that may not have been eligible for Medicaid coverage; and

- strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements, specifically:

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

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

    - maintain readily reviewable documentation that identifies the actual drugs used,

    - do not claim expenditures for drugs that are 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 AND OFFICE OF INSPECTOR GENERAL RESPONSE

In comments on our draft report, the State agency generally agreed with our recommendations and provided additional documentation to support $957,999 (Federal share) of its claim. However, we were unable to reconcile the documentation we received to the CMS-64 or to other documentation previously provided during the audit. We modified our finding accordingly and continue to support our recommendation.

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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 Pennsylvania, the Department of Public Welfare (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 Pennsylvania, 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 Pennsylvania, 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, Pennsylvania's Federal reimbursement rate for Medicaid expenditures varied from 53.84 percent to 57.71 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 $1.96 billion ($1.1 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 (a) terminated, (b) supported with adequate documentation, (c) less than effective, and (d) 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 Harrisburg, Pennsylvania.

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 States retroactively.

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

We calculated the Federal share of the expenditures using the lowest percentage (53.84 percent to 57.71 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 $1.96 billion ($1.1 billion Federal share) claimed, $4,397,728 (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) inadequately supported with documentation, or (3) drugs listed on the CMS quarterly drug tape as less than effective.

An additional $5,900,935 (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 $1.96 billion ($1.1 billion Federal share) claimed, we identified no other errors with respect to whether the drugs were (a) terminated, (b) supported with adequate documentation, (c) less than effective, or (d) included on the CMS quarterly drug tapes.

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.)

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 $3,283,294 ($1,800,651 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 May 9, 2005. However, the drug's termination date was April 30, 2004, according to the tapes beginning with the quarter that ended March 31, 2002. The claimed expenditure was unallowable because it occurred after the drug's termination date, which was listed on the quarterly drug tape at the time the State agency made the expenditures.

CLAIMS FOR 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 $2,819,189 ($1,493,284 Federal share) in drug expenditures on its quarterly CMS-64s for which it did not have any supporting documentation that identified which drugs were claimed. 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.

The State agency also claimed $1,663,053 ($957,999 Federal share) in drug expenditures for which it did not provide adequate supporting documentation to indicate that the drugs met Federal requirements. These expenditures contained national drug codes (NDC) that had a labeler code (first five digits of the NDC) with all zeroes, with all nines, or were blank. The claimed expenditures were unallowable because the State agency did not have adequate documentation to show that the drugs complied with Federal requirements.

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 $266,882 ($145,794 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 4, 2004. However, CMS reported the drug as less than effective on the tapes beginning with the quarter that ended March 31, 2004. 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.[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 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 . . . ."

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 $10,840,017 ($5,900,935 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 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. 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 $8,032,418 ($4,397,728 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 $10,840,017 ($5,900,935 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 $4,397,728 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;

- work with CMS to resolve $5,900,935 in payments for drugs that were not listed on the quarterly drug tapes and that may not have been eligible for Medicaid coverage; and

- strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements, specifically:

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

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

    - maintain readily reviewable documentation that identifies the actual drugs used,

    - do not claim expenditures for drugs that are 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 comments on our draft report, the State agency generally agreed with our recommendations but asked us to reconsider our finding that $957,999 was unallowable because the State agency did not have any supporting documentation. On July 30, 2008, the State agency provided additional claims data to support its request.

OFFICE OF INSPECTOR GENERAL RESPONSE

We were unable to reconcile the documentation we received to the CMS-64 or to other documentation previously provided during the audit. We modified our finding accordingly and continue to support our recommendation.

APPENDIX

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF PUBLIC WELFARE
P.O. BOX 2675
HARRISBURG, PENNSYLVANIA 17105-2675

JUN 11 2008

Theodore Dallas
Executive Deputy Secretary

(717) 787-2600
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Mr. Stephen Virbitsky
Regional Inspector General for Audit Services
Department of Health & Human Services
Office of Inspector General
Office of Audit Services, Region III
150 South Independence Mall West, Suite 316
Philadelphia, Pennsylvania 19106-3499

Dear Mr. Virbitsky:

Thank you for your April 2 letter that transmitted the draft report entitled "Review of Medicaid Outpatient Drug Expenditures in Pennsylvania" for the period October 1, 2003 through September 30, 2005.

This audit reviewed Pennsylvania's outpatient prescription drug program which is administered by the Department of Public Welfare (DPW). This program pays for covered outpatient drugs, and also requires that the DPW submit to the participating drug manufacturers for the applicable drug rebates. To assist the States in the identification of the covered outpatient drugs, terminated drugs, less-than effective drugs, and available drug rebates, the Center for Medicare & Medicaid Services (CMS) prepares quarterly drug tapes. The objective of this audit was to determine whether the claims submitted by the DPW for reimbursement complied with these federal regulations. Responses to the identified recommendations are indicated below.

OIG Recommendation: We recommend that the State agency refund $4,397,728 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage.

DPW Response: The Department of Health and Human Services (HHS) and the Office of the Inspector General identified the following categories for the drug expenditures that are deemed not eligible for Medicaid coverage: Terminated Drugs, Inadequately Supported Drug Expenditures, and Less-Than-Effective Drugs. For these categories, the DPW plans to remit $1,800,651 (federal share), $1,493,284 (federal share), and $145,794 (federal share), respectively.

With regard to those drugs for which no supporting documentation was present; however, the DPW would like HHS to reconsider expenditures resulting in $957,999 (federal share). The supporting drug specific documentation is available for paper-submitted, compound claims, and program exceptions, but was not requested within this audit.

OIG Recommendation: We recommend that the State agency work with CMS to resolve the $5,900,935 in payments made for drugs that were not listed on the quarterly drug tapes and that may not have been eligible for Medicaid coverage.

DPW Response: The DPW will work with CMS to resolve any discrepancies in payment. However, the DPW would like consideration to be granted for the states that use the CMS quarterly tapes and communications in good faith.

OIG Recommendation: We recommend that the State agency strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements, specifically:

- Claim expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes,
- Maintain documentation that supports the expenditures reported on the CMS-64,
- Maintain readily reviewable documentation that identifies the actual drugs used,
- Claim expenditures 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.

DPW Response: The DPW has taken appropriate measures effective November 29, 2007 to ensure that the Provider Reimbursement and Operations Management Information System (PROMISe) online claims adjudication system is updated with the information from the CMS quarterly tape for the purpose of identifying all terminated National Drug Codes (NDCs). Although this was not an issue identified in previous audits, this will prevent future payment for terminated drugs.

The DPW's Medical Assistance Management Information System (MAMIS), the original MAMIS approved by CMS, did not have the capacity to process claims for compound drugs submitted online. Therefore, in order to assure access to compound drugs, the Department allowed providers to use non-specific NDCs and to submit paper claims for compound prescriptions. Non-specific NDCs included the claims referenced in the findings report where the first five digits of the NDC were found to be all zero's, all nines, or were blank. In these cases, the drug ingredient specific information was converted from the MAMIS claims processing system to the DPW's new claims processing system called PROMISe, where these claims are archived electronically.

Since the conversion from MAMIS to PROMISe, all pharmacy claims must be submitted with accurate NDCs corresponding to the outpatient covered medication dispensed. This includes compound claims which allows for each NDC used in the compound to be captured for the purpose of maximizing federal rebates for all outpatient covered medications.

The DPW will remit for drugs classified as less than effective on the quarterly drug tapes. CMS assigns a code of '5' or '6' to drug products which are less than effective or identical, similar, or related products. Pennsylvania Code of Regulations, Title 55, Chapter 1121, Section 1121.54 (20), states that drugs deemed less-than-effective are noncompensable items. Therefore, the DPW has taken appropriate measures within the PROMISe claims adjudication system on June 28 in order to ensure that pharmacy claims are processed consistently with the CMS tape.

Even with this corrective action, there will be instances when a labeler reports that its product is safe and effective, but it is later determined by CMS that a product has a Desi code of "5" or "6". The State Agency will have already begun coverage and paid claims for a Desi product that technically should not have been paid. The state is hopeful that at some point CMS will help states by addressing this issue. Ideally, CMS should require the manufacturer to submit both safety and efficiency supporting Food and Drug Administration (FDA) documentation; also, CMS should delay the mandatory coverage date until the safety and effectiveness can be confirmed through the FDA.

Despite the fact that CMS has issued guidance, it is neither practical nor realistic to expect Pennsylvania (PA), with the volume of claims processed on a daily basis, to do a manual review of the CMS quarterly drug tape and compare that information to the First Data Bank drug file containing hundreds of thousands of NDCs on either a real time or retroactive basis. The emphasis should be on a valid and accurate CMS quarterly drug tape, which states can rely upon, rather than expecting states to monitor and report discrepancies to CMS.

Currently, CMS has entered into rebate agreements with manufacturers of both products that are and are not FDA approved. Not only does this result in compromised quality of drug coverage, but it also places PA in an untenable position of choosing between conflicting requirements—covering both FDA-approved drugs, and drugs for which the manufacturer has an agreement in place to provide a rebate.

Thank you for the opportunity to respond to this report. If you need any further information, please contact Maranatha E. Earling, Bureau of Financial Operations, Audit Resolution Section, at (717) 772-4911, or via e-mail at mearling@state.pa.us.

Sincerely,

Theodore Dallas