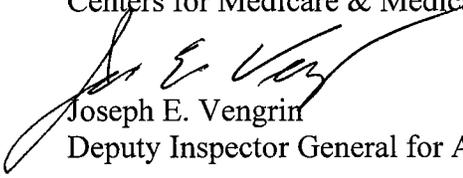




APR 27 2009

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 California for Fiscal Years 2004 and 2005 (A-09-07-00039)

Attached is an advance copy of our final report on Medicaid outpatient drug expenditures in California for fiscal years (FY) 2004 and 2005. We will issue this report to the California Department of Health Care Services (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 related to adequacy of support for the Federal share claimed, and whether the drugs were terminated, included on the CMS quarterly drug tapes, or less than effective.

The State agency's claims for reimbursement of Medicaid outpatient drug expenditures for FYs 2004 and 2005 did not fully comply with Federal requirements. The State agency claimed \$24,082,193 (Federal share) for unallowable Medicaid expenditures, which included \$21,024,264 in unsupported drug expenditures and \$3,057,929 in drug expenditures that were not eligible for Medicaid coverage because the drugs were terminated. In addition, the State agency claimed \$10,926,099 (Federal share) for drug products not listed on the quarterly drug tapes for which the State agency did not provide conclusive evidence that the drugs were eligible for Medicaid coverage. The State agency had inadequate controls to ensure that all of its outpatient drug expenditures complied with the Federal requirements described in our objective.

We recommend that the State agency:

- refund \$24,082,193 (Federal share) to the Federal Government for (1) claims for unsupported drug expenditures and (2) drug expenditures that were not eligible for Medicaid coverage;
- work with CMS to resolve \$10,926,099 (Federal share) in expenditures for drug products that were not listed on the quarterly tapes and that may not have been eligible for Medicaid coverage; and
- strengthen and establish internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements, specifically:
 - maintain documentation supporting all expenditures claimed on the CMS-64 in an easily retrievable and readily reviewable form,
 - retain funding codes to identify the Medicaid program and reimbursement rate for each claim when the claims are initially processed,
 - claim expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes,
 - prevent claims with prior authorizations from overriding drug termination dates, 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 its comments on our draft report, the State agency agreed to work with CMS to resolve the issues regarding drugs not listed on the quarterly drug tapes and disagreed with our internal control recommendations related to maintaining documentation and retaining funding codes. However, the State agency did not explicitly address our remaining recommendations. The State agency's comments did not provide any new information to cause us to modify 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 Lori A. Ahlstrand, Region Inspector General for Audit Services, at (415) 437-4360 or through e-mail at Lori.Ahlstrand@oig.hhs.gov. Please refer to report number A-09-07-00039.

Attachment



Region IX
Office of Audit Services
90 - 7th Street, Suite 3-650
San Francisco, CA 94103

APR 29 2009

Report Number: A-09-07-00039

David Maxwell-Jolly, Ph.D.
Director
Department of Health Care Services
1501 Capitol Avenue, MS 0000
P.O. Box 997413
Sacramento, California 95899-7413

Dear Dr. Maxwell-Jolly:

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 California for Fiscal Years 2004 and 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 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 at (415) 437-8360, or contact Jerry McGee, Audit Manager, at (323) 261-7218 or through e-mail at Jerry.McGee@oig.hhs.gov. Please refer to report number A-09-07-00039 in all correspondence.

Sincerely,

Lori A. Ahlstrand
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 CALIFORNIA
FOR FISCAL YEARS
2004 AND 2005**



Daniel R. Levinson
Inspector General

April 2009
A-09-07-00039

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:

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

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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.

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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 California, the Department of Health Care Services (the State agency) administers the Medicaid program.

In addition to providing mandatory Medicaid services, States may offer certain optional services, such as outpatient prescription drugs, to eligible Medicaid beneficiaries. Most States, including California, 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 California, 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 outpatient drug expenditures.

For fiscal years (FY) 2004 and 2005, the State agency claimed approximately \$10.1 billion (\$5.2 billion Federal share) in Medicaid outpatient drug expenditures. We reviewed this amount for compliance with Federal requirements related to adequacy of support for the Federal share claimed. Of the \$10.1 billion, we reviewed approximately \$9.3 billion (\$4.8 billion Federal share) for compliance with Federal requirements related to whether the drugs were terminated, included on the CMS quarterly drug tapes, or less than effective. The remaining \$756.1 million represented certain Medicaid outpatient drug expenditures that we excluded from our review, as described in the "Scope" section of this report.

OBJECTIVE

Our objective was to determine whether the State agency's claims for reimbursement of Medicaid outpatient drug expenditures complied with Federal requirements related to adequacy of support for the Federal share claimed, and whether the drugs were terminated, included on the CMS quarterly drug tapes, or less than effective.

SUMMARY OF FINDINGS

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) we reviewed for adequacy of support, \$21,024,264 (Federal share) represented expenditures for which the State agency's accounting system did not provide supporting claim documentation. The remainder of the Federal share claimed met Federal requirements related to adequacy of support.

Of the \$9.3 billion (\$4.8 billion Federal share) we reviewed for compliance with Federal requirements related to whether the drugs were terminated, included on the CMS quarterly drug tapes, or less than effective:

- \$3,057,929 (Federal share) represented expenditures for drug products that were not eligible for Medicaid coverage because they were terminated drugs for which the termination dates were listed on the CMS quarterly drug tapes before the drugs were dispensed and
- \$10,926,099 (Federal share) represented expenditures for drug products not listed on the quarterly drug tapes for which the State agency did not provide conclusive evidence that the drugs were eligible for Medicaid coverage.

The remainder of the \$9.3 billion reviewed met Federal requirements related to whether the drugs were terminated, included on the CMS quarterly drug tapes, or less than effective.

In total, the State agency claimed \$24,082,193 (Federal share) for unallowable drug expenditures and \$10,926,099 (Federal share) for drug expenditures that may have been unallowable for Medicaid reimbursement.

The State agency had inadequate controls to ensure that all of its outpatient drug expenditures complied with the Federal requirements described in our objective. Specifically, the State agency did not maintain documentation supporting all expenditures claimed on the CMS-64 in an easily retrievable and readily reviewable form, did not retain funding codes to identify the Medicaid program and reimbursement rate for each claim when the claims were initially processed, allowed claims with prior authorizations to override drug termination dates, and did not verify whether drugs missing from the quarterly drug tapes were eligible for Medicaid coverage.

RECOMMENDATIONS

We recommend that the State agency:

- refund \$24,082,193 (Federal share) to the Federal Government for (1) claims for unsupported drug expenditures and (2) drug expenditures that were not eligible for Medicaid coverage;

- work with CMS to resolve \$10,926,099 (Federal share) in expenditures for drug products that were not listed on the quarterly tapes and that may not have been eligible for Medicaid coverage; and
- strengthen and establish internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements, specifically:
 - maintain documentation supporting all expenditures claimed on the CMS-64 in an easily retrievable and readily reviewable form,
 - retain funding codes to identify the Medicaid program and reimbursement rate for each claim when the claims are initially processed,
 - claim expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes,
 - prevent claims with prior authorizations from overriding drug termination dates, 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 its comments on our draft report (included in their entirety as the Appendix), the State agency did not specifically agree with our first recommendation to refund \$24,082,193 (Federal share) to the Federal Government. The State agency agreed with our second recommendation to work with CMS to resolve \$10,926,099 (Federal share) for drugs not listed on the quarterly drug tapes. The State agency did not explicitly address all elements of our third recommendation.

The State agency's comments did not provide any new information to cause us to modify our recommendations.

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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 California, the Department of Health Care Services (the State agency) administers the Medicaid program.

State Medicaid programs must provide certain medical services, including inpatient and outpatient hospital, physician, and family planning services. States also may offer certain optional services, such as outpatient prescription drugs, as long as the services are included in their approved State plans.

Medicaid Outpatient Prescription Drug Program

All States offer outpatient prescription drugs to eligible Medicaid beneficiaries. Most States, including California, 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.

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 California, 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 some outpatient drug expenditures.

For Federal fiscal years (FY) 2004 and 2005, California’s reimbursement rate for Medicaid expenditures varied from 50 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 related to adequacy of support for the Federal share claimed and whether the drugs were terminated, included on the CMS quarterly drug tapes, or less than effective.

Scope

To determine compliance with Federal requirements related to adequacy of support for the Federal share claimed, we reviewed approximately \$10.1 billion (\$5.2 billion Federal share) in Medicaid outpatient drug expenditures that the State agency claimed for FYs 2004 and 2005 (October 1, 2003, through September 30, 2005).

To determine compliance with Federal requirements related to whether the drugs were terminated, included on the CMS quarterly drug tapes, or less than effective, we reviewed approximately \$9.3 billion (\$4.8 billion Federal share). We excluded from our review the following \$756.1 million in expenditures claimed on the CMS-64s as outpatient drug expenditures:

- approximately \$468.9 million for medical procedures, durable medical equipment, medical supplies, enteral nutritional products, vaccines, over-the-counter vitamins and minerals, and nondrug products that were incorrectly reported as outpatient drug expenditures;
- approximately \$212.2 million for products with Healthcare Common Procedure Coding System codes that were not national drug codes (NDC); and
- approximately \$75 million for compound drugs for which the State agency did not have readily available supporting documentation that identified the individual drug components.⁴ We will review compound drug expenditures in a separate audit.

⁴Pharmacists create compound drugs by combining two or more prescription or nonprescription drugs and repackaging them into a new capsule or other dosage form.

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 performed our audit from January 2007 through February 2008 and conducted fieldwork at the State agency's offices in Sacramento, California.

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 obtained from the State agency a detailed list of outpatient drug claims by quarter, which included the following: (1) claim number, (2) product, (3) date provided, (4) amount paid, and (5) funding code.⁵ The information provided agreed with the paid claim amounts of weekly disbursements recorded by the State controller. We judgmentally selected and obtained 30 sample claims (1 claim was voided) and compared these claims to the claims data provided by the State agency.

We used the funding codes identified by the State agency to determine support for total Medicaid drug expenditures claimed on the CMS-64s. To calculate the Federal share of total Medicaid drug expenditures, we used the Federal reimbursement rates identified by the State agency. We compared the amounts claimed on the CMS-64s to amounts that we determined from the supporting documentation. We also reviewed summary expenditures and adjustments and compared the summary amounts with the amounts reported on the CMS-64s.

We used the quarterly drug tapes for the period October 1, 1999, through June 30, 2006. We determined whether the drugs for which the State agency claimed reimbursement were dispensed after the termination or less-than-effective dates listed on the quarterly drug tape. In addition, we determined whether CMS had included the termination dates on the quarterly drug tape in a timely manner—that is, before terminated drugs could be dispensed. To account for reasonable delays in processing data for terminated drugs, we used the first day of the quarter after the State agency received the tape as the termination date if the termination dates were provided to the State agency 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 provided a list of the nonmatching drugs to the State agency for additional information to determine whether the drugs were eligible for Medicaid coverage.

⁵The funding code identified the Medicaid or non-Medicaid program for each claim and the program's reimbursement rate. For example, during the audit period, funding code 061 represented State Children's Health Insurance Program claims with a Federal reimbursement rate of 65 percent, and funding code 100 represented claims with the standard Federal reimbursement rate of 50 percent.

We calculated the Federal shares of the questioned expenditures for terminated drugs and the set-aside expenditures for drugs not listed on the quarterly drug tapes using the lowest reimbursement rate applicable for each quarter. We did not reduce the questioned drug expenditures by any rebate credits that the State agency 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) we reviewed for adequacy of support, \$21,024,264 (Federal share) represented expenditures for which the State agency's accounting system did not provide supporting claim documentation. The remainder of the Federal share claimed met Federal requirements related to adequacy of support.

Of the \$9.3 billion (\$4.8 billion Federal share) we reviewed for compliance with Federal requirements related to whether the drugs were terminated, included on the CMS quarterly drug tapes, or less than effective:

- \$3,057,929 (Federal share) represented expenditures for drug products that were not eligible for Medicaid coverage because they were terminated drugs for which the termination dates were listed on the CMS quarterly drug tapes before the drugs were dispensed and
- \$10,926,099 (Federal share) represented expenditures for drug products not listed on the quarterly drug tapes for which the State agency did not provide conclusive evidence that the drugs were eligible for Medicaid coverage.

The remainder of the \$9.3 billion reviewed met Federal requirements related to whether the drugs were terminated, included on the CMS quarterly drug tapes, or less than effective.

In total, the State agency claimed \$24,082,193 (Federal share) for unallowable drug expenditures and \$10,926,099 (Federal share) for drug expenditures that may not have been allowable for Medicaid reimbursement.

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

CLAIMS FOR UNSUPPORTED DRUG EXPENDITURES

To receive reimbursement for Medicaid claims, States must maintain records identifying the individual claims reported on the CMS-64. Pursuant to 42 CFR § 433.32(a), States are required to “[m]aintain an accounting system and supporting fiscal records to assure that claims for Federal funds are in accord with applicable Federal requirements” According to the CMS “State Medicaid Manual,” section 2497.3, States “. . . must have a record-keeping system which assures that documentation supporting a claim is regularly maintained, easily retrieved, and in readily reviewable form.”

Furthermore, pursuant to 42 CFR § 430.30(c)(2), the CMS-64 is “. . . the State’s accounting of actual recorded expenditures.” In addition, section 2500 A.1 of the “State Medicaid Manual” states that amounts reported on the CMS-64 “. . . must be actual expenditures for which all supporting documentation, in readily reviewable form, has been compiled and is available immediately at the time the claim is filed.”

The State agency claimed approximately \$5.2 billion (Federal share) in outpatient drug expenditures for FYs 2004 and 2005. Of the \$5.2 billion, the State agency did not provide supporting claim documentation for \$21,024,264 (Federal share) in drug expenditures claimed on its CMS-64s. According to State agency documentation, the State agency’s accounting system did not retain funding codes identifying the Medicaid program for each claim when the claims were initially processed and reported on the CMS-64s. To provide the claims information required for our audit, the State agency reconstructed the support for the claimed amounts. The support included the following information: claim number, product, date provided, amount paid, and funding code.⁶ The process took 7 months to complete and resulted in these differences:

Differences Between Amounts Reported on Form CMS-64s and Amounts Shown in Supporting Documentation for Fiscal Years 2004 and 2005

	<u>Total Medicaid Expenditures</u>	<u>Federal Share</u>
Amounts Claimed on CMS-64s ⁷	\$10,095,209,447	\$5,198,163,492
Amounts Shown in Supporting Documentation	<u>\$10,126,757,892</u>	<u>\$5,177,139,228⁸</u>
Difference: Amounts Claimed on CMS-64s Less Amounts Shown in Supporting Documentation	<u>(\$31,548,445)</u>	<u>\$21,024,264</u>

⁶We selected 30 individual claims and requested source documentation. The State agency furnished source documentation for 29 claims and indicated that 1 claim was voided.

⁷Specifically, line 7 on CMS-64.9 Base and CMS-64.9 Waivers and line 8 on CMS-64.21 and CMS-64.21U.

⁸To calculate the Federal share of total Medicaid drug expenditures, we used the Federal reimbursement rates identified by the State agency.

The State agency's accounting system and records did not fully support its claims for Federal reimbursement. Based on the records that the State agency provided to us, we could not reconcile the Federal share of the supporting claims to the Federal share claimed on the CMS-64s.

We informed the State agency of discrepancies between amounts claimed on the CMS-64s and the supporting documentation provided. In May 2007, we informed the State agency of an approximately \$1.5 million (Federal share) difference for the quarter ended December 31, 2003. We then informed the State agency in January 2008 of the approximately \$21 million (Federal share) that was unsupported for FYs 2004 and 2005. The State agency pointed out that (1) the difference was less than 1 percent of the claimed expenditures and (2) the accounting system's inability to retain funding codes identifying the Medicaid program for each claim had come up in prior State audits but had not been a concern for the State agency.

At the State agency's request in February 2008, we provided an explanation of our methodology for comparing claimed amounts on the CMS-64s to the supporting documentation. The State agency's written response indicated that our methodology did not account for changes to the claims processing system, retroactive funding adjustments, and family planning claims identified at the 90-percent reimbursement rate. However, the State agency's response did not provide us with any additional claim information that we had not already considered in our reconciliation. The State agency could not provide supporting documentation for the approximately \$21 million (Federal share) difference.

CLAIMS FOR TERMINATED DRUGS

States are prohibited from claiming expenditures for drugs dispensed after the termination date. 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 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 \$5,992,396 (\$3,057,929 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 meclizine, which was dispensed on November 5, 2003. However, the drug's termination date

was June 30, 2002, according to the tapes beginning with the quarter that ended December 31, 2001. 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 expenditure.

The State agency indicated that the CMS quarterly drug tapes do not provide timely information on drug termination dates. The State agency commented that it "often receives notification from a drug manufacturer years after the drug has been removed from the market and is obsolete, yet there is nothing on the CMS [quarterly drug tape] denoting any change in the drug status." The State agency also indicated that its electronic formulary file allowed payments for some terminated drugs. This file lists both Medicaid-covered and non-Medicaid-covered drugs and is used to process all pharmacy claims.

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.⁹ 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 S13, states: "If you have paid for [a drug code] that is NOT on [the quarterly drug tape] you should have checked to make sure it was correct. If you paid a pharmacy for utilization on an invalid [drug code], you may have to . . . recoup your funds."

For FYs 2004 and 2005, the State agency claimed \$21,496,496¹⁰ (\$10,926,099 Federal share) in expenditures for drug products that were not listed on the quarterly drug tapes.¹¹ According to State agency documentation, the claims processing system did not identify which drugs in the formulary file were eligible for Federal reimbursement. In addition, the State agency did not

⁹Pursuant 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.

¹⁰The State agency indicated that NDCs representing \$8,469,990 (\$4,278,370 Federal share) of the \$21,496,496 related to generic drugs without rebate agreements.

¹¹During our audit, the State agency made adjustments to the CMS-64s of \$3,787,921 (\$1,935,005 Federal share) related to our audit period. The State agency said that it had determined that these expenditures were not covered by Medicaid.

contact CMS to ensure that these drugs were eligible for Medicaid coverage under the Act. As a result, the State agency did not provide conclusive evidence that these payments were allowable Medicaid expenditures.

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

The State agency had inadequate controls to ensure that all of its outpatient drug expenditures complied with the Federal requirements described in our objective. Specifically, the claims processing system did not maintain documentation supporting all expenditures claimed on the CMS-64 in an easily retrievable and readily reviewable form. In addition, the claims processing system did not retain funding codes identifying the Medicaid program and reimbursement rate for each claim when the claims were initially processed. Furthermore, the State agency commented that the electronic formulary file within the claims processing system allowed claims with prior authorizations to override drug termination dates. Finally, the State agency did not verify whether drugs not listed on the quarterly drug tapes were covered under the Medicaid program.

REIMBURSEMENT OF UNALLOWABLE AND POTENTIALLY UNALLOWABLE CLAIMS FOR DRUG EXPENDITURES

The State agency claimed Federal reimbursement for unsupported drug expenditures and drugs that were not eligible for Medicaid coverage because they were terminated. As a result, for FYs 2004 and 2005, the State agency claimed unallowable expenditures totaling \$24,082,193 (Federal share). The State agency also claimed Federal reimbursement for drug products that may not have been allowable because they were not listed on the quarterly drug tapes. For these expenditures, we set aside \$10,926,099 (Federal share) for CMS adjudication because the State agency did not provide conclusive evidence that these payments were allowable Medicaid expenditures.

RECOMMENDATIONS

We recommend that the State agency:

- refund \$24,082,193 (Federal share) to the Federal Government for (1) claims for unsupported drug expenditures and (2) drug expenditures that were not eligible for Medicaid coverage;
- work with CMS to resolve \$10,926,099 (Federal share) in expenditures for drug products that were not listed on the quarterly tapes and that may not have been eligible for Medicaid coverage; and
- strengthen and establish internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements, specifically:

- maintain documentation supporting all expenditures claimed on the CMS-64 in an easily retrievable and readily reviewable form,
- retain funding codes to identify the Medicaid program and reimbursement rate for each claim when the claims are initially processed,
- claim expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes,
- prevent claims with prior authorizations from overriding drug termination dates, 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 its comments on our draft report (included in their entirety as the Appendix), the State agency did not specifically agree with our first recommendation to refund \$24,082,193 (Federal share) to the Federal Government. The State agency agreed with our second recommendation to work with CMS to resolve \$10,926,099 (Federal share) for drugs not listed on the quarterly drug tapes.

The State agency did not address all elements of our third recommendation. The State agency disagreed that it did not maintain documentation supporting expenditures. It stated that its Rebate Accounting Information System (RAIS) currently retains all drug claims dating back to the beginning of the drug rebate program and contains funding indicators for all drug claims when the claims were initially processed. It acknowledged that “there have been issues related to terminated drugs and the need to improve the system.” The State agency commented that it would set up a process to verify whether drugs listed in the formulary file, not the CMS quarterly tapes, are covered under the Medicaid program by using information from the Food and Drug Administration and manufacturers. The State agency also commented that it will communicate formulary file discrepancies to CMS.

OFFICE OF INSPECTOR GENERAL RESPONSE

Although we made multiple requests for the information that the State agency said was available in the RAIS, the State agency did not provide the information to us during our audit. To our knowledge, the RAIS was not the source of the claims data that the State agency provided to support drug expenditures on the CMS-64, and State agency personnel did not identify the RAIS as a possible source of data for resolving unsupported expenditures.

If the State agency shows that RAIS documentation related to our audit can be reconciled to the Federal share claimed on the CMS-64, CMS can consider this information during the audit resolution process. The State agency’s comments did not provide any new information to cause us to modify our recommendations.

APPENDIX



State of California—Health and Human Services Agency
Department of Health Care Services



ARNOLD SCHWARZENEGGER
Governor

JAN 08 2009

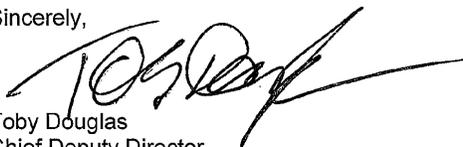
Ms. Lori A. Ahlstrand
Regional Inspector General for Audit Services
Office of Inspector General
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

Dear Ms. Ahlstrand:

The California Department of Health Care Services (DHCS) has prepared its revised response to the U.S. Department of Health and Human Services, Office of Inspector General (OIG), draft report entitled "Review of Medicaid Outpatient Drug Expenditures in California for Fiscal Years 2004 and 2005" (Report A-09-07-00039). As requested, DHCS has revised its original response to address the \$3,057,929 (Federal share) finding related to expenditures for terminated drugs. DHCS appreciates the work performed by the OIG and the opportunity to clarify its response.

Please contact Ms. Lauren Gomez, Acting Chief, Fiscal Intermediary and Contracts Oversight Division, at (916) 319-8000 if you have any questions.

Sincerely,



Toby Douglas
Chief Deputy Director
Health Care Programs

Enclosure

Ms. Lori A. Ahlstrand
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cc: Ms. Pilar Williams, Chief
Pharmacy Benefits Division
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Sacramento, CA 95899-7413

Ms. Lauren Gomez
Acting Chief
Fiscal Intermediary and Contracts Oversight Division
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**California Department of Health Care Services' Response to the
U.S. Department of Health and Human Services
Office of Inspector General Draft Report Entitled
*Review of Medicaid Outpatient Drug Expenditures in California for
Fiscal Years 2004 and 2005***

Recommendation: Refund \$24,082,193 (Federal share) to the Federal Government for (1) claims for unsupported drug expenditures and (2) drug expenditures that were not eligible for Medicaid coverage.

Response: Item (1): The Office of Inspector General (OIG) compared the amounts claimed on the CMS-64 report to the supporting drug claims (amounts that the OIG determined from the claims/funding information provided by the Department of Health Care Services). Looking at the detail provided by the OIG for the October-December 2003 quarter comparison, \$8,569,531 (Federal share) was claimed as family planning on the CMS-64; however, on the claims/funding information to which it is being compared, there are no claims identified as family planning (90 percent Federal share). This clearly indicates a problem. The Department of Health Care Services (DHCS) is in the process of determining if this is a problem in the claims/funding information provided by DHCS, a problem with the OIG's analysis, or some other unforeseen problem or interpretation of the data.

It is unclear whether claims were paid for drug expenditures in error. DHCS would like to note that in some instances manufacturers fail to report all of the National Drug Code (NDC) numbers for all of their Food and Drug Administration (FDA) approved drugs that are covered outpatient drugs pursuant to Section 1927(k) of the Social Security Act. Additionally, some of the items claimed as drugs may be non-drug items that were inadvertently claimed as a drug, but should be claimed as medically necessary products or services in a different category. Though the Centers for Medicare and Medicaid Services (CMS) indicates that states should use the quarterly tape as the guide, it also admits that mistakes and omissions do occur. DHCS will continue to research this item.

Item (2): For those drugs which the OIG notes claims were paid after the drugs' termination dates and those termination

dates were communicated on the CMS quarterly rebate tape prior to claim payment, DHCS will work to recover payments from providers. DHCS agrees that payment should not have occurred and the provider likely did not dispense that specific National Drug Code (NDC). The pharmacy providers may want to resubmit claims using their purchase invoices to ascertain the appropriate NDC number dispensed on that date of service, which would decrease the amount found by the OIG to be not eligible for Medicaid coverage.

As noted below, DHCS has taken action to make changes to the claims processing system Formulary File to reduce the incidence of paying claims after a drug's termination date. These changes have improved DHCS' ability to deny claims for terminated drugs.

Recommendation: Work with CMS to resolve \$10,926,099 (Federal share) in expenditures for drug products that were not listed on the quarterly tapes and that may not have been eligible for Medicaid coverage.

Response: DHCS looks forward to working with the CMS to resolve the issue regarding drugs that were not listed on the quarterly tapes. DHCS would like to note that the CMS quarterly tape is not always complete. In some instances manufacturers fail to report all of the NDC numbers for all of their FDA approved drugs that are covered outpatient drugs pursuant to Section 1927(k) of the Social Security Act.

Additionally, some of the items claimed as drugs may be non-drug items that were inadvertently claimed as a drug, but should be claimed as medically necessary products or services in a different category.

Though CMS indicates that states should use the quarterly tape as the guide, it also admits that mistakes and omissions do occur. Also, the guide for what is or isn't rebatable is the definition held in Section 1927(k) for a covered outpatient drug and not what CMS lists on the quarterly rebate tape. California has a long standing opinion that drug rebates should be based on the 9-digit level of the NDC to avoid inadvertent omission of a package size by a manufacturer.

Recommendation: Strengthen and establish internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements, specifically:

- Maintain documentation supporting all expenditures claimed on the CMS-64 in an easily retrievable and readily reviewable form.
- Retain funding codes to identify the Medicaid program and reimbursement rate for each claim when the claims are initially processed.
- Claim expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes.
- 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: DHCS agrees that internal controls can be strengthened to ensure proper payment and claiming for medically necessary therapies. To this end, DHCS' current procurement effort for a new Medicaid Management Information System (MMIS) will include an improved pharmacy claims processing system. In response to the specific issues:

- DHCS disagrees that it does not maintain documentation to support drug expenditures claimed on the CMS-64 report. DHCS' Rebate Accounting Information System (RAIS) currently retains all pharmacy drug claims dating back to the beginning of the federal rebate program. The claims can be retrieved and reviewed quite readily through the use of the RAIS reporting tools. In addition to paid claims, the RAIS system also contains quarterly CMS rebate information that can also be used in the reporting process.
- The data in the previously mentioned RAIS system contains funding indicators on all drug claims, as well as the provider billed amount, the calculated allowed amount, and the amount paid to the provider for each claim when the claim was initially processed. Therefore, DHCS believes it is already in compliance with the OIG's recommendation on these points.

- DHCS recognizes that there have been issues related to terminated drugs and the need to improve the system. More recently (i.e. after the audit time frame of 2004 and 2005), DHCS has taken action to make changes to the claims processing system Formulary File to reduce the incidence of paying claims after a drug's termination date. These changes have improved DHCS' ability to deny claims for terminated drugs. DHCS also uses the obsolete date from First Data Bank (the date a product was last shipped by a manufacturer) plus two years to establish a termination date when one is not available from CMS.

DHCS would like to note that drug termination dates are not always readily available or correct on the quarterly tapes supplied by CMS. DHCS rebate analysts have obtained termination dates from manufacturers for drugs that do not have termination dates on the CMS quarterly tape.

- DHCS will set-up a process to regularly identify drugs on its Formulary file, but not on the CMS quarterly tapes. This process will include verification using available information from the FDA, as well as contact with the manufacturer to validate a specific NDC. DHCS will communicate discrepancies to the CMS. DHCS will be dependent on CMS to take appropriate action with manufacturers to update the rebate drug files sent to states.