



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Office of Inspector General

Office of Audit Services  
1100 Commerce, Room 632  
Dallas, Texas 75242

June 4, 2009

Report Number: A-06-07-00092

Albert Hawkins, Executive Commissioner  
Texas Health and Human Services Commission  
P.O. Box 13247  
Austin, Texas 78711

Dear Mr. Hawkins:

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 Texas 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 Freedom of Information Act, 5 U.S.C. § 552, OIG reports generally are made available to the public to the extent that information in the report is not subject to exemptions in the Act. Accordingly, this report will be posted on the Internet at <http://oig.hhs.gov>.

If you have any questions or comments about this report, please do not hesitate to call me, or contact Ms. Sylvie Witten, Audit Manager, at (512) 339-3071 or through e-mail at [Sylvie.witten@oig.hhs.gov](mailto:Sylvie.witten@oig.hhs.gov). Please refer to report number A-06-07-00092 in all correspondence.

Sincerely,

A handwritten signature in black ink, which appears to read "Gordon L. Sato".

Gordon L. Sato  
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  
TEXAS FOR THE PERIOD  
OCTOBER 1, 2003, THROUGH  
SEPTEMBER 30, 2005**



Daniel R. Levinson  
Inspector General

June 2009  
A-06-07-00092

# ***Office of Inspector General***

<http://oig.hhs.gov>

---

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

## ***Office of Audit Services***

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

## ***Office of Evaluation and Inspections***

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

## ***Office of Investigations***

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

## ***Office of Counsel to the Inspector General***

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

# *Notices*

---

## **THIS REPORT IS AVAILABLE TO THE PUBLIC**

at <http://oig.hhs.gov>

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

## **OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS**

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

## **EXECUTIVE SUMMARY**

### **BACKGROUND**

Pursuant to Title XIX of the Social Security Act, the Medicaid program provides medical assistance to low-income individuals and individuals with disabilities. The Federal and State Governments jointly fund and administer the Medicaid program. At the Federal level, the Centers for Medicare & Medicaid Services (CMS) administers the program. Each State administers its Medicaid program in accordance with a CMS-approved State plan. Although the State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements. In Texas, the Texas Health and Human Services Commission (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 Texas, 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 Texas, 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 expenditures, including 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 \$4.6 billion (\$2.9 billion Federal share) claimed, \$324,908 (Federal share) represented expenditures for drug products that were not eligible for Medicaid coverage because they were (1) terminated drugs for which the termination dates were listed on the CMS quarterly drug tape before the drugs were dispensed, (2) drugs listed on the CMS quarterly drug tape as less than effective, or (3) inadequately supported with documentation.

An additional \$52,986 (Federal share) represented expenditures for drug products that were not listed on the quarterly drug tapes. Because the State agency did not provide support to indicate whether or not it had verified if 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 \$4.6 billion (\$2.9 billion Federal share) claimed, we identified no other errors with respect to whether the drugs were (a) terminated, (b) less than effective, (c) supported with adequate documentation, 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 \$324,908 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;
- work with CMS to resolve \$52,986 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 drug tapes,
  - do not claim expenditures for drugs that are listed as less than effective on the quarterly drug tapes,
  - maintain documentation that supports the expenditures reported on the CMS-64, and
  - verify whether drugs not listed on the quarterly drug tapes are covered under the Medicaid program and notify CMS when drugs are missing from the tapes.

## **STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, the State agency addressed our first two recommendations by agreeing to work with CMS to ensure that Federal reimbursement is appropriate and to refund the Federal share of any drug expenditures that were not eligible for Medicaid coverage. Regarding the third recommendation, the State agency maintains that it has management controls in place that provide strong assurance that drugs are eligible for Medicaid reimbursement. The State agency's comments are included in their entirety as the Appendix.

We continue to recommend that the State agency strengthen its internal controls. The State agency claimed \$324,908 for drugs that were not eligible for Medicaid coverage and \$52,986 for drugs that may not have been eligible for Medicaid coverage.

**TABLE OF CONTENTS**

	<b><u>Page</u></b>
<b>INTRODUCTION</b> .....	1
<b>BACKGROUND</b> .....	1
Medicaid Program.....	1
Medicaid Outpatient Prescription Drug Program .....	1
Reimbursement of Medicaid Expenditures.....	2
<b>OBJECTIVE, SCOPE, AND METHODOLOGY</b> .....	2
Objective.....	2
Scope.....	2
Methodology.....	2
<b>FINDINGS AND RECOMMENDATIONS</b> .....	3
<b>CLAIMS FOR TERMINATED DRUGS</b> .....	4
<b>CLAIMS FOR LESS-THAN-EFFECTIVE DRUGS</b> .....	4
<b>CLAIMS FOR INADEQUATELY SUPPORTED DRUG EXPENDITURES</b> .....	5
<b>CLAIMS FOR DRUGS NOT LISTED ON QUARTERLY DRUG TAPES</b> .....	5
<b>INADEQUATE CONTROLS TO DETECT UNALLOWABLE AND         POTENTIALLY UNALLOWABLE CLAIMS FOR DRUG EXPENDITURES</b> .....	6
<b>REIMBURSEMENT OF UNALLOWABLE AND POTENTIALLY         UNALLOWABLE CLAIMS FOR DRUG EXPENDITURES</b> .....	6
<b>RECOMMENDATIONS</b> .....	6
<b>STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL         RESPONSE</b> .....	7
<b>APPENDIX</b>	
<b>STATE AGENCY COMMENTS</b>	

# 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 Texas, the Texas Health and Human Services Commission (the State agency) administers Medicaid.

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 Texas, administer their Medicaid prescription drug programs in accordance with the Medicaid drug rebate program.<sup>1</sup> 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,<sup>2</sup> if applicable, specifies whether the drug is less than effective,<sup>3</sup> 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.

---

<sup>1</sup>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.

<sup>2</sup>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.

<sup>3</sup>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 Texas, 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, Texas’s Federal reimbursement rate for Medicaid expenditures varied from 60.22 percent to 63.17 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 \$4.6 billion (\$2.9 billion Federal share) in Medicaid outpatient drug expenditures that the State agency claimed for FYs 2004 and 2005. We limited our testing of these expenditures to determining compliance with specific Federal requirements related to whether the drugs were (a) terminated, (b) less than effective, (c) supported with adequate documentation, and (d) 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 Austin, Texas.

### **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, 2001, through September 30, 2005. 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 tapes 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 tapes in a timely manner—that is, before terminated drugs could be dispensed. To account for reasonable delays in processing data for terminated drugs, we used the first day of the quarter after the State received the tape as the termination date if the termination dates were provided to the States retroactively.

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

We calculated the Federal share of the expenditures using the lowest percentage (60.22 percent to 63.17 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 \$4.6 billion (\$2.9 billion Federal share) claimed, \$324,908 (Federal share) represented expenditures for drug products that were not eligible for Medicaid coverage because they were (1) terminated drugs for which the termination dates were listed on the CMS quarterly drug tape before the drugs were dispensed, (2) drugs listed on the CMS quarterly drug tape as less than effective, or (3) inadequately supported with documentation.

An additional \$52,986 (Federal share) represented expenditures for drug products that were not listed on the quarterly drug tapes. Because the State agency did not provide support to indicate whether or not it had verified if 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 \$4.6 billion (\$2.9 billion Federal share) claimed, we identified no other errors with respect to whether the drugs were (a) terminated, (b) less than effective, (c) supported with adequate documentation, 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.

---

<sup>4</sup>Pharmacists 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.

## **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 \$392,866 (\$242,726 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 Indomethacin, which was dispensed on May 14, 2004. However, the drug’s termination date was October 1, 2001, 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 expenditures.

## **CLAIMS FOR LESS-THAN-EFFECTIVE DRUGS**

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

For FYs 2004 and 2005, the State agency claimed \$128,092 (\$77,973 Federal share) in expenditures for drugs classified as less than effective on the quarterly drug tapes. For example, the State paid for the drug Depo-Testadiol Vail, which was dispensed on October 19, 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 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 \$6,680 (\$4,209 Federal share) in drug expenditures on its quarterly CMS-64s 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. As a result, the State agency did not have conclusive evidence that these payments were allowable Medicaid expenditures. These claims were therefore unallowable.

## **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.<sup>5</sup> 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 \$86,697 (\$52,986 Federal share) in expenditures for drug products that were not listed on the quarterly drug tapes. The State agency did not provide support to indicate whether or not it verified if the drugs missing from the tapes were eligible for Medicaid coverage; therefore, these drug expenditures may not have been allowable for Medicaid reimbursement. As a result, the State agency did not have conclusive evidence that these payments were allowable Medicaid expenditures.

---

<sup>5</sup>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. The State agency did not check the quarterly drug tapes to ensure that the drugs were eligible for Medicaid coverage.

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

The State agency claimed Federal reimbursement for certain drugs that were not eligible for Medicaid coverage because they were terminated, less than effective, or inadequately supported. As a result, for FYs 2004 and 2005, the State agency claimed unallowable expenditures totaling \$527,638 (\$324,908 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 \$86,697 (\$52,986 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 \$324,908 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;
- work with CMS to resolve \$52,986 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 drug tapes,
  - do not claim expenditures for drugs that are listed as less than effective on the quarterly drug tapes,
  - maintain documentation that supports the expenditures reported on the CMS-64, and
  - verify whether drugs not listed on the quarterly drug tapes are covered under the Medicaid program and notify CMS when drugs are missing from the tapes.

## **STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, the State agency addressed our first two recommendations by agreeing to work with CMS to ensure that Federal reimbursement is appropriate and to refund the Federal share of any drug expenditures that were not eligible for Medicaid coverage. Regarding the third recommendation, the State agency said that it has management controls in place that provide strong assurance that drugs are eligible for Medicaid reimbursement. In addition, the State agency said that improvements in the CMS notification process for drug coverage, effectiveness, and termination information will further increase the likelihood that the State agency will request Federal reimbursement only for approved drugs.

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

We continue to recommend that the State agency strengthen its internal controls. The State agency claimed \$324,908 for drugs that were not eligible for Medicaid coverage and \$52,986 for drugs that may not have been eligible for Medicaid coverage because the drugs were not listed on the CMS quarterly drug tapes. As discussed in our methodology, we determined whether the drugs for which the State agency claimed reimbursement were dispensed after the termination dates listed on the quarterly drug tapes 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 tapes 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.

# **APPENDIX**



TEXAS HEALTH AND HUMAN SERVICES COMMISSION

ALBERT HAWKINS  
EXECUTIVE COMMISSIONER

May 5, 2009

Mr. Gordon L. Sato  
Regional Inspector General for Audit Services  
Office of Inspector General, Office of Audit Services  
1100 Commerce, Room 632  
Dallas, Texas 75242

Reference Report Number A-06-07-00092

Dear Mr. Sato:

The Texas Health and Human Services Commission (HHSC) received a draft audit report entitled "Review of Medicaid Outpatient Drug Expenditures in Texas for the Period October 1, 2003, Through September 30, 2005" from the Department of Health and Human Services Office of Inspector General. The cover letter, dated April 8, 2009, requested that HHSC provide written comments, including the status of actions taken or planned in response to the report recommendations.

The report identified three recommendations for HHSC to consider regarding outpatient drug expenditures. These recommendations address: (1) refunding drug expenditures that were not eligible for Medicaid coverage; (2) working with CMS to resolve payments for drugs that were not listed on the quarterly drug tapes; and (3) strengthening internal controls to ensure that claimed Medicaid drug expenditures comply with federal requirements. This management response includes comments related to these recommendations and details related to actions HHSC has completed or planned.

**Summary Response**

CMS guidance instructs states to utilize the information contained in quarterly Medicaid drug rebate tapes to verify whether drugs are eligible for federal reimbursement. HHSC has processes in place to verify that a drug is listed on the quarterly Medicaid drug rebate tapes before it seeks federal reimbursement. The effectiveness of these processes is supported by the fact that over

Gordon L. Sato  
May 5, 2009  
Page 2

99.99 percent<sup>1</sup> of drug claim amounts for the period covered by the audit were found to be eligible for federal reimbursement.

HHSC is dependent on CMS for notification of drug coverage, effectiveness, and termination information. CMS sends HHSC quarterly Medicaid drug rebate tapes that include drug termination information CMS receives from drug manufacturers. Manufacturers are not always timely in reporting this information to CMS; consequently, the information HHSC receives from CMS in these tapes, and which HHSC uses as the basis for removing terminated drugs from its formulary, is not always current.

For example, the audit report includes exceptions for drugs dispensed in calendar year 2005. CMS did not report some of these drugs as being ineligible for federal reimbursement until February 2007, and did not report others as being ineligible until November 2008. As a result, HHSC was not informed by CMS that these drugs were ineligible for federal reimbursement until over a year after the claims were reimbursed. The receipt of more current drug coverage, effectiveness, and termination information from CMS would increase the likelihood that HHSC would request federal reimbursement only for drugs approved by CMS.

Detailed responses to the OIG recommendations follow.

**DHHS/OIG Recommendation:** *We recommend that the State agency refund \$324,908 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage.*

**HHSC Management Response**

**Actions Planned:** Using the most up-to-date product coverage, effectiveness, and termination information, HHSC will work with CMS to ensure federal reimbursement is appropriate and will refund the federal share for any drug expenditures that were not eligible for Medicaid coverage.

**Estimated Completion Date:** No later than 60 days after agreement is reached with CMS regarding any ineligible expenditures.

**Title of Responsible Person:** Deputy Director, Medicaid-CHIP Vendor Drug Program

**DHHS/OIG Recommendation:** *We recommend that the State agency work with CMS to resolve \$52,986 in payments for drugs that were not listed on the quarterly drug tapes and that may not have been eligible for Medicaid coverage.*

---

<sup>1</sup> The amount questioned (\$324,908) is approximately one hundredth of one percent of the amount associated with claims the auditors reviewed (\$2,900,000,000).

Gordon L. Sato  
May 5, 2009  
Page 3

**HHSC Management Response**

**Actions Planned:** Using the most up-to-date product coverage, effectiveness, and termination information, HHSC will work with CMS to ensure federal reimbursement is appropriate and will refund the federal share for any drug expenditures that were not eligible for Medicaid coverage.

**Estimated Completion Date:** No later than 60 days after agreement is reached with CMS regarding any ineligible expenditures.

**Title of Responsible Person:** Deputy Director, Medicaid-CHIP Vendor Drug Program

**DHHS/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.
- do not claim expenditures for drugs that are listed as less than effective on the quarterly drug tapes,
- maintain documentation that supports the expenditures reported on the CMS-64, and
- verify whether drugs not listed on the quarterly drug tapes are covered under the Medicaid program and notify CMS when drugs are missing from the tapes.

**HHSC Management Response**

HHSC has management controls in place that provide strong assurance that drugs are eligible for federal Medicaid reimbursement. As previously mentioned, over 99.99 percent of drug costs were found to be eligible for federal Medicaid reimbursement during the period covered by the audit. Improvements in the CMS notification process for drug coverage, effectiveness, and termination information will further increase the likelihood that HHSC requests federal reimbursement only for approved drugs.

If you have any questions or require additional information, please contact David M. Griffith, CPA, CIA, CGFM, Internal Audit Director. Mr. Griffith may be reached by telephone at (512) 424-6998 or by e-mail at [David.Griffith@hhsc.state.tx.us](mailto:David.Griffith@hhsc.state.tx.us).

Sincerely,



Albert Hawkins