Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

RESULTS OF OUR SELF-INITIATED AUDITS OF MEDICAID DRUG REBATE PROGRAMS OPERATED BY THE STATE AGENCIES OF ARKANSAS, LOUISIANA, NEW MEXICO, AND OKLAHOMA, AS WELL AS THE TEXAS STATE AUDITOR'S REPORT ON THE TEXAS MEDICAID DRUG REBATE PROGRAM

Inspector General

JANUARY 2004
A-06-03-00043

Office of Inspector General

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

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

January 30, 2004

TO: Dr. James R. Farris, M.D
Regional Administrator
Centers for Medicare & Medicaid Services

FROM: Regional Inspector General for Audit Services, Region VI

SUBJECT: Region VI Rollup Report for 5-State Review of Medicaid Drug Rebate Collections Report Number A-06-03-00043

Attached is a copy of our final report providing the results of our rollup report on Medicaid drug rebate collections in the five States in Region VI. The objective of the audit was to determine whether the State Agencies in Region VI had established adequate accountability and controls over their respective Medicaid drug rebate programs.

In written comments, the Centers for Medicare & Medicaid Services (CMS) agreed with the content of the report and indicated that they would follow up on the specific recommendations to the State Agencies. The CMS comments are included as an appendix to our report.

Please send us your final management decision, including any action plan, as appropriate, within 60 days. If you have any questions or comments about this report please do not hesitate to call me or George M. Reeb, Assistant Inspector General for Centers for Medicare and Medicare Services Audits at (410) 786-7104 or through e-mail at greeb@oig.hhs.gov. To facilitate identification, please refer to report number A-06-03-00043 in all correspondence.

Sincerely,

Gordon L. Sato

Gordon L. Sato
Regional Inspector General
for Audit Services

EXECUTIVE SUMMARY

OBJECTIVE

The audit objective was to determine whether the five State Agencies in Region VI (Arkansas, Louisiana, New Mexico, Oklahoma, and Texas) had established adequate accountability and controls over their respective Medicaid drug rebate program. Individual reports were issued to each State Agency, and this report summarizes the issues identified in the five reports.

FINDINGS

Three of the five State Agencies (New Mexico, Oklahoma, and Texas) had not established adequate accountability and controls over their Medicaid drug rebate programs. As a result, there was no assurance that all drug rebates due the State Agencies were collected.

Title 45 Sec. 74.21 paragraph (b)(3) of the Code of Federal Regulations requires that financial management systems provide for effective control over and accountability for all funds, property, and other assets.

Additionally, weaknesses were identified in the drug rebate program for each State Agency. Specifically, the weaknesses related to:

- Accounts receivable systems for the State Agencies of New Mexico and Oklahoma;
- Accounting for interest on late drug rebates for the State Agencies of Arkansas, New Mexico, and Texas;
- Dispute resolution and collection for the State Agencies of New Mexico and Texas;
- Segregation of duties for the State Agencies of New Mexico and Texas;
- Accuracy of reporting accounts receivable information on the Centers for Medicare & Medicaid Services (CMS) Form 64.9R for the State Agencies of Arkansas, Louisiana, and New Mexico.

Specific recommendations were made to each of the State Agencies that addressed the weaknesses described above. Each State Agency generally agreed with the findings and recommendations and indicated that corrective action had been enacted or was planned.

RECOMMENDATION

The Medicaid drug rebate program produces millions of dollars each quarter for each State Agency and is a very complex program. Thus, the State Agencies should ensure that proper policies, procedures, and controls exist to safeguard program funds. We believe the corrective action recommended in the prior reports will provide State Agencies the opportunity to increase drug rebate revenue and report more reliable

accounts receivable information to CMS. Therefore, we recommend that CMS follow up on each of the recommendations and ensure that corrective action is implemented by each State Agency.

The CMS responded to our draft report in a memorandum dated January 20, 2004. The CMS agreed with the content of the report and indicated that they would follow up on the specific recommendations to the State Agencies. The complete text of CMS' comments is included in Appendix 1.

INTRODUCTION

BACKGROUND

On November 5, 1990, Congress enacted the Omnibus Budget Reconciliation Act of 1990 legislation, which among other provisions established the Medicaid drug rebate program. Responsibility for the rebate program is shared among the drug manufacturer(s), the Centers for Medicare & Medicaid Services (CMS), and the State(s). The legislation was effective January 1, 1991. CMS also issued release memorandums to State Agencies and manufacturers throughout the history of the rebate program to give guidance on numerous issues related to the Medicaid drug rebate program.

A drug manufacturer is required to enter into, and have in effect, a rebate agreement with CMS in order to have its products covered under the Medicaid program. After a rebate agreement is signed, the manufacturer is required to submit a listing to CMS of all covered outpatient drugs, and to report its average manufacturer price and best price information for each covered outpatient drug to CMS. Approximately 520 pharmaceutical companies participate in the program.

CMS calculates the unit rebate amount for each covered drug from the pricing data submitted by the drug manufacturers. CMS provides the unit rebate amount information to the State Agency on a quarterly computer tape. However, the CMS tape may contain a $0 unit rebate amount if the pricing information was not provided timely or if the pricing information has a 50 percent variance from the previous quarter. In instances of $0 unit rebate amounts, the State Agency is instructed to invoice the units and the manufacturer should pay the rebate based on the manufacturer's information. In addition, the manufacturers often change unit rebate amounts based on updated pricing information, and submit this information to the State Agency in the Prior Quarter Adjustment Statement.

Each State Agency is required to maintain a record of the units dispensed, by manufacturer, for each covered drug. Approximately 56,000 National Drug Codes (NDCs) are available under the program. Each State Agency uses the unit rebate amount from CMS and the utilization for each drug to determine the actual rebate amount due from the manufacturer. CMS requires each State Agency to provide drug utilization data to the manufacturer.

The manufacturer has 38 days from the day a State Agency sends an invoice to pay the rebate to avoid interest. The manufacturers submit to the State Agency a Reconciliation of State Invoice that details the current quarter's payment by NDC. A manufacturer can dispute utilization data that it believes is erroneous, but the manufacturer is required to pay the undisputed portion by the due date. If the manufacturer and the State Agency cannot in good faith resolve the discrepancy, the manufacturer must provide written notification to the State Agency by the due date. If the State Agency and the manufacturer are not able to resolve the discrepancy within 60 days, the State Agency

must make a hearing mechanism available under the Medicaid program to the manufacturer in order to resolve the dispute.

Each State Agency reports, on a quarterly basis, accounts receivable and rebate collection information for the drug rebate program on the Form CMS 64.9R. This report is part of the Form CMS 64 report, which summarizes actual Medicaid expenditures for each quarter and is used by CMS to reimburse the Federal share of these expenditures. Together, the five States in Region VI reported to CMS an average of $134.0 million in billings per quarter and collections of $131.4 million per quarter for the drug rebate program during the 1-year period ending June 30, 2002. These five States also reported a total of $181,098,176 of outstanding drug rebate program accounts receivable as of June 30, 2002 on the CMS 64.9R.

The five State Agencies responsible for the drug rebate program in Region VI are:

- Arkansas-Department of Human Services
- Louisiana-Department of Health and Hospitals
- New Mexico-Human Services Department
- Oklahoma-Oklahoma Health Care Authority
- Texas-Health and Human Services Commission

OBJECTIVE, SCOPE AND METHODOLOGY

Objective

The audit objective was to determine whether the five State Agencies in Region VI had established adequate accountability and controls over their respective Medicaid drug rebate program. Individual reports were issued to each State Agency, and this report summarizes the issues identified in the five reports.

Scope

The drug rebate program was effective January 1, 1991. We concentrated our review on the current policies, procedures and controls of each State Agency. We also reviewed accounts receivable information related to prior periods and interviewed staff from each State Agency to understand how the Medicaid drug rebate program had operated in each State.

We focused our review of the Oklahoma State Agency primarily on the controls over cash receipts because of an accounts receivable system conversion that occurred in December 2002.

We did not perform an audit of the Texas drug rebate program. The State Auditor issued a report in April 2003 on the Texas program, which had a timeframe that was comparable to our other States. We reviewed the State Auditor's report, but we did not conduct any tests of the underlying work. Also, the State Auditor's report addressed some issues that were not part of our review in the other States. Thus, we did not include all of the

findings and recommendations of the State Auditor in this report. A copy of the report is available at http://www.sao.state.tx.us/reports/2003/03-029.pdf.

Methodology

Our audit was performed in accordance with generally accepted government auditing standards. To accomplish our objective for each of the State reviews, we interviewed State Agency officials to determine the policies, procedures and controls that existed with regard to the Medicaid drug rebate program. We also interviewed staff that performed functions related to the drug rebate program of each State. In addition, we obtained and reviewed drug rebate accounts receivable records for each State and compared this data to Form CMS 64.9R report for June 30, 2002.

Fieldwork for this review was performed in the Little Rock, Arkansas field office from June through September 2003. Fieldwork for each of the State reviews was performed at the State Agency offices in Little Rock, Arkansas; Baton Rouge, Louisiana; Santa Fe, New Mexico; and Oklahoma City, Oklahoma.

FINDINGS AND RECOMMENDATION

Three of the five State Agencies (New Mexico, Oklahoma, and Texas) had not established adequate accountability and controls over their Medicaid drug rebate programs. As a result, there was no assurance that all drug rebates due the State Agencies were collected.

Additionally, weaknesses were identified in the drug rebate program for each State Agency. Specifically, the weaknesses related to:

- Accounts receivable systems for the State Agencies of New Mexico and Oklahoma;
- Accounting for interest on late drug rebates for the State Agencies of Arkansas, New Mexico, and Texas;
- Dispute resolution and collection for the State Agencies of New Mexico and Texas;
- Segregation of duties for the State Agencies of New Mexico and Texas;
- Accuracy of reporting accounts receivable information on the CMS Form 64.9R for the State Agencies of Arkansas, Louisiana, and New Mexico.

Criteria

Title 45 Sec. 74.21 paragraph (b)(3) of the Code of Federal Regulations requires that financial management systems provide for effective control over and accountability for all funds, property, and other assets.

Accounts Receivable Systems

The State Agencies of New Mexico and Oklahoma had weaknesses in their accounts receivable systems that resulted in inaccurate and/or insufficiently detailed information to properly monitor uncollected drug rebates. Specifically:

- The New Mexico State Agency did not maintain a general ledger control account nor were the subsidiary accounts receivable maintained at a sufficiently detailed level to accurately account for drug rebate collections; and
- The Oklahoma State Agency did not always have the ability to adjust unit rebate amounts, and from 1991 through 1998, payments were not posted to NDC-level.
- However, the new information system implemented in December 2002 should resolve many of the accounts receivable limitations, according to the State Agency officials.

The following recommendations were made to each State Agency:

- The New Mexico State Agency should create a sufficiently detailed subsidiary accounts receivable with a corresponding control account for accounts receivable; and
- The Oklahoma State Agency should review and adjust the accounts receivable balances in the new system and pursue collection of any unpaid balances.

Accounting for Interest on Late Rebate Payments

The State Agencies of Arkansas, New Mexico, and Texas had weaknesses in accounting of interest for late drug rebates. The rebate agreement between CMS and drug manufacturers requires interest to be paid for late rebates. Additional guidance from CMS stated that it is the manufacturer's responsibility to calculate and pay interest for applicable rebate invoices and the State's responsibility to track collections and report these amounts to CMS.

The State Agencies of Arkansas, New Mexico and Texas did not verify that interest payments received were accurate. Also, the New Mexico State Agency did not accrue or track interest, and the Texas State Agency only informed drug manufacturers of an unspecified amount of interest due on late rebate payments. Although CMS guidance states that it is the manufacturers' responsibility to calculate and pay interest for late rebates, we believe it is a prudent business practice to calculate interest due, invoice manufacturers, and verify the accuracy of interest payments to ensure that all interest amounts due to the State Agencies are collected.

The following recommendations were made to each State Agency:

- The Arkansas State Agency should implement a procedure to verify that interest payments are accurate;
- The New Mexico State Agency should account for interest related to late or disputed rebate payments; and
- The Texas State Agency should accurately calculate and track interest owed, actively pursue and collect outstanding interest, and determine the accuracy of past interest payments.

Dispute Resolution and Collection

The State Agencies of New Mexico and Texas had weaknesses in dispute resolution and collection. The New Mexico State Agency did not have a formal system for monitoring outstanding disputes. Additionally, the one staff member who was responsible for resolving disputes estimated only 30 percent of her time was related to drug rebates during the past 2 years. The Texas State Agency had inefficient processes to resolve disputes, which included manual reviews and entering data on separate spreadsheets outside of the information system. Also, uncollected balances were not aged to prioritize staff workloads. As a result, due to the complexity and large volume of records in the drug rebate program, disputes were not always resolved in a timely manner.

Also, the Texas State Agency lacked standardized procedures and criteria for adjusting unit rebate amounts and drug utilization. As a result, rebate staff members have arbitrarily adjusted disputed rebates because of confusing claims data and the staff's perception of an unmanageable workload.

The following recommendations were made to each State Agency:

- The New Mexico State Agency should develop formal policies, procedures, and controls to monitor disputed rebate amounts, and consider devoting more resources to the program; and
- The Texas State Agency should (1) develop policies and procedures to resolve disputes efficiently and adjust balances consistently for utilization and pricing, and (2) should use an aging schedule as a factor in prioritizing collection activity.

Segregation of Duties

The State Agencies of New Mexico and Texas had weaknesses in segregation of duties. The New Mexico State Agency did not have a proper segregation of duties for cash receipts, and the Texas State Agency did not have proper segregation of duties for billing, collecting, and posting adjustments. The lack of segregation of duties resulted in a potential risk of waste, fraud, and abuse of drug rebate program funds.

The following recommendations were made to each State Agency:

- The New Mexico State Agency should segregate duties for receipt of cash; and
- The Texas State Agency should segregate duties and limit access for transactions related to billing, payment, and adjustment.

Accuracy of CMS 64.9R Reporting

The State Agencies of Arkansas, Louisiana, and New Mexico did not report accurate uncollected balance information to CMS for the quarter ended June 30, 2002. The Arkansas State Agency did not separate interest payments from rebate payments in its accounts receivable system, which caused an understatement of the outstanding balance. The Louisiana State Agency overstated its reported ending balance because it did not have a control in place to reconcile to the supporting books and records. The New Mexico State Agency had numerous errors and inconsistencies in accounts receivable data that occurred throughout the history of the program, and did not perform a reconciliation to verify the accuracy of the uncollected balance reported to CMS.

The following recommendations were made to each State Agency:

- The Arkansas State Agency should adjust the outstanding balance on the next Form CMS 64.9R quarterly report to account for interest received; and
- The Louisiana State Agency should implement a control to reconcile the outstanding balance reported on Form CMS 64.9R to the supporting books and records; and
- The New Mexico State Agency should develop policies, procedures, and controls to accurately report drug rebate collections on Form CMS 64.9R.

Each of the State Agencies generally agreed with the findings and recommendations summarized in this report, and indicated that corrective action had been enacted or was planned. Copies of our reports, including State Agency comments, are available at http://oig.hhs.gov. The report on the Texas State Agency is available at http://www.sao.state.tx.us/reports/2003/03-029.pdf.

RECOMMENDATION

The Medicaid drug rebate program produces millions of dollars each quarter for each State Agency and is a very complex program. Thus, the State Agencies should ensure that proper policies, procedures, and controls exist to safeguard program funds. We believe the corrective action recommended in the prior reports will provide State Agencies the opportunity to increase drug rebate revenue and report more reliable accounts receivable information to CMS. Therefore, we recommend that CMS follow up on each of the recommendations and ensure that corrective action is implemented by each State Agency.

CMS RESPONSE

The CMS responded to our draft report in a memorandum dated January 20, 2004. The CMS agreed with the content of the report and indicated that they would follow up on the specific recommendations to the State Agencies. The complete text of CMS' comments is included in Appendix 1.

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Memorandum

Centers for Medicare & Medicaid Services
Region VI
1301 Young Street Room 827
Dallas, TX 75202
Phone (214) 767-6301
Fax (214) 767-0322

Date: January 20, 2004

To: Regional Inspector General for Audit Services

From: Manager, Financial Review Branch, Division of Medicaid and Children's Health

Subject: Region VI Roll Up Report for 5-State Review of Medicaid Drug Rebate Program (A-06-03-00043)

We reviewed the subject report and agree with the content of the report. However, the one recommendation in the report would appear to be redundant since the recommendation calls for CMS to follow up on each of the recommendations contained in the individual state reports.

As part of the audit clearance process for individual state reports, we follow up on the specific recommendations and, if the state has taken appropriate corrective action, then we prepare the proper audit clearance documents.

If you should have any questions regarding this matter, contact Linda Deramus of my staff at (214) 767-6484.

Bill Brooks

Bill Brooks