July 15, 2003

Common Identification Number: A-06-03-00044

Mr. Mike Fogarty  
Chief Executive Officer  
Oklahoma Health Care Authority  
4545 North Lincoln Boulevard, Suite 124  
Oklahoma City, OK 73105-3413

Dear Mr. Fogarty:

The attached final report provides the results of our self-initiated audit of Medicaid drug rebate collections for the State of Oklahoma. A copy of this report will be forwarded to the action official noted below for his/her review and any action deemed necessary.

The objective of the audit was to determine whether the State had established adequate accountability and controls over the Medicaid drug rebate program. Our audit covered Medicaid drug rebates through June 30, 2002. Because of an information system conversion that occurred in December 2002, we focused our review primarily on the controls over cash receipts.

The State had established adequate controls over cash receipts, as required by Title 45 Sec. 74.21 paragraph (b)(3) of the Code of Federal Regulations, which states that financial management systems provide for effective control over and accountability for all funds, property, and other assets. However, inaccurate data was transferred into the new accounts receivable system from the old system, and the State cannot be assured that all rebates have been collected until records are adjusted to accurately reflect the billing and payment history.

Final determination as to actions taken on all matters reported will be made by the HHS action official named below. We request that you respond to the HHS action 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.

In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), Office of Inspector General Reports issued to the Department's grantees and contractors are made available to members of the press and general public to the extent information contained therein is not subject to exemptions in the Act which the Department chooses to exercise. (See 45 CFR Part 5.) As such, within ten business days after the final report is issued, it will be posted on the OIG web site at http://oig.hhs.gov.
To facilitate identification, please refer to Common Identification Number A-06-03-00044 in all correspondence relating to this report.

Sincerely yours,

Gordon L. Sato
Regional Inspector General for Audit Services

Enclosures - as stated

Direct Reply to HHS Action Official:
Dr. James R. Farris, M.D.
Regional Administrator
Centers for Medicare and Medicaid Services
1301 Young Street, Suite 714
Dallas, TX 75202
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**

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EXECUTIVE SUMMARY

OBJECTIVE

The audit objective was to evaluate whether the Oklahoma Health Care Authority (OHCA) had established adequate accountability and internal controls over the Medicaid drug rebate program. Our audit covered Medicaid drug rebates through June 30, 2002. However, the OHCA completed an information system conversion in December 2002, which resulted in a new accounts receivable system. Because of this change, we focused our review primarily on the controls over cash receipts. Additionally, we reviewed controls that were not directly related to the old accounts receivable system.

FINDINGS

OHCA had established adequate controls over cash receipts related to the drug rebate program, as required by federal rules and regulations. Although the policies and procedures were not official OHCA policy, procedures and controls were effectively used by OHCA staff for cash receipts. However, inaccurate data was transferred into the new accounts receivable system from the old system.

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.

According to the OHCA drug rebate program manager, accounts receivable data in the previous system was inaccurate for a number of reasons. OHCA was not always able to adjust account balances for changes in unit rebate amounts. Also, settled disputes were not always entered into the system. Additionally, from 1991 through 1998, the OHCA did not post payments in sufficient detail to adequately monitor unpaid rebates. OHCA plans to reconstruct the payment records for this time period in order to identify any unpaid amounts.

As a result of the problems associated with the previous accounts receivable system, the accounts receivable balances in the new system are inaccurate. Until the records in the new accounts receivable system are adjusted to accurately reflect the billing and payment history, the OHCA cannot be assured that all rebates have been collected.

RECOMMENDATIONS

We recommend that OHCA review and adjust the accounts receivable balances in the new system and pursue collection of any unpaid balances. We recognize that such an effort would require considerable resources so we also recommend that the OHCA consider devoting more resources to the drug rebate program.

OHCA responded to our draft report in a letter dated July 3, 2003. OHCA agreed with our finding in the report, and indicated that it plans for the new accounts receivable
system to be adjusted to reflect the correct billing and payment history. OHCA also noted that $11 million of the $15.3 million of uncollected drug rebates reported on the CMS 64.9R for June 30, 2002 was for current quarter billings. In addition, the OHCA stated that much of the remaining $4.3 million was not truly receivable due to adjustments that were not made in the books for settlements and other billing errors. The complete text of OHCA’s response is included as 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 and 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 provides the unit rebate amount (URA) information to the state agency on a quarterly computer tape. However, the CMS tape may contain a $0 URA 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 URAs, 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 the URA based on updated pricing information, and submit this information to the state agency in the Previous Quarter Adjustment Statement.

Each state agency is required to maintain the number of 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 URA from CMS and the utilization for each drug to determine the actual rebate amounts 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, outpatient drug expenditures and rebate collections 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. Oklahoma Health Care Authority (OHCA) reported to CMS an average of $12.4 million in billings per quarter and collections of $12.0 million per quarter during the 1-year period ending June 30, 2002. OHCA reported $15,335,572 of outstanding drug rebate program accounts receivable as of June 30, 2002 on the CMS 64.9R.

OHCA performed most of the functions of the drug rebate program, including receiving and posting drug rebate payments, researching utilization data for errors, corresponding with manufacturers to resolve disputes, and preparing the CMS 64.9R report. OHCA’s fiscal agent generated and mailed the invoices to manufacturers based on utilization data and the URA information provided by CMS.

**OBJECTIVE, SCOPE AND METHODOLOGY**

**Objective**

The audit objective was to evaluate whether the OHCA had established adequate accountability and internal controls over the Medicaid drug rebate program. Our audit covered Medicaid drug rebates through June 30, 2002. However, the OHCA completed an information system conversion in December 2002, which resulted in a new accounts receivable system. Because of this change, we focused our review primarily on the controls over cash receipts. Additionally, we reviewed controls that were not directly related to the old accounts receivable system.

**Scope**

The drug rebate program was effective January 1, 1991. We concentrated our review on the current policies, procedures and controls of OHCA. We also interviewed OHCA staff to understand how the Medicaid drug rebate program had operated under the previous information system.

**Methodology**

To accomplish our objectives, we obtained procedures used by OHCA staff and interviewed OHCA officials to determine the policies, procedures and controls that existed with regard to the Medicaid drug rebate program. We also interviewed OHCA staff that performed functions related to the drug rebate program. In addition, we obtained and reviewed a detailed drug rebate accounts receivable report and compared this data to the CMS 64.9R report for June 30, 2002.

Our testing was limited to the controls over cash receipts because the OHCA converted to a new information system in December 2002. As of the time of our fieldwork, enough time had not elapsed to properly test the accuracy of the new accounts receivable system.
Fieldwork was performed at the OHCA office in Oklahoma City, Oklahoma office during April 2003, and continued in the Little Rock, Arkansas field office through May 2003.

Our audit was performed in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

OHCA had established adequate controls over cash receipts related to the drug rebate program, as required by federal rules and regulations. Although the policies and procedures were not official OHCA policy, procedures and controls were effectively used by OHCA staff for cash receipts. However, inaccurate data was transferred into the new accounts receivable system from the old system.

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.

Cash Receipt Controls

Although the policies and procedures were not official OHCA policy, OHCA staff utilized adequate procedures and controls for cash receipts. The financial services staff of OHCA received the drug rebate payments. One staff member opened the checks, stamped the restrictive endorsement, and created a calculator tape total each day. A different staff member posted payments to the general ledger, with a cash control number generated for each check, and reconciled the system total to the calculator tape. A daily deposit was then prepared and delivered to the State Treasury. Finally, copies of the check and accompanying documentation were sent to the drug rebate staff, which posted the detailed information on each payment to the NDC-level.

Issues Related to the Previous Accounts Receivable System

According to the OHCA drug rebate program manager, accounts receivable data in the previous system was inaccurate for a number of reasons. OHCA was not always able to adjust account balances for changes in unit rebate amounts. Also, settled disputes were not always entered into the detailed records. The manager identified some of the large URA errors that resulted in overstatements to the accounts receivable balance and adjusted the outstanding balance reported on the CMS 64.9R, but did not make these rate adjustments to the detailed records. For example, the amount reported on the June 30, 2002 CMS 64.9R ($15.3 million) did not agree with the amount shown as the outstanding balance in the detailed records ($16.1 million).
Additionally, from 1991 through 1998, the OHCA did not post payments in sufficient
detail to adequately monitor unpaid rebates. This occurred because the previous
information system did not allow for payment posting to the NDC-level. Without NDC-
level accounts receivable balances, the OHCA could not efficiently pursue unpaid
balances. OHCA drug rebate program manager stated that OHCA plans to proceed
through payment records for these prior years and allocate payments to the NDC-level.

As a result of the problems associated with the previous accounts receivable system, the
accounts receivable balances in the new system were inaccurate. Until the records in the
new accounts receivable system are adjusted to accurately reflect the billing and payment
history, the OHCA cannot be assured that all rebates have been collected.

RECOMMENDATIONS

We recommend that OHCA review and adjust the accounts receivable balances in the
new system and pursue collection of any unpaid balances. We recognize that such an
effort would require considerable resources so we also recommend that the OHCA
consider devoting more resources to the drug rebate program.

AUDITEE RESPONSE

OHCA responded to our draft report in a letter dated July 3, 2003. OHCA agreed with
our finding in the report, and indicated that it plans for the new accounts receivable
system to be adjusted to reflect the correct billing and payment history. OHCA also
noted that $11 million of the $15.3 million of uncollected drug rebates reported on the
CMS 64.9R for June 30, 2002 was for current quarter billings. In addition, the OHCA
stated that much of the remaining $4.3 million was not truly receivable due to
adjustments that were not made in the books for settlements and other billing errors. The
complete text of OHCA’s response is included as Appendix 1.
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July 3, 2003

Common Identification Number: A-06-03-00044

Mr. Gordon Sato
Regional Inspector General for Audit Services
Department of Health and Human Services
Office of Inspector General – Office of Audit Services
1100 Commerce, Room 632
Dallas, Texas 75242

Dear Mr. Sato,

The Oklahoma Health Care Authority (OHCA) appreciates the opportunity to respond to the recent audit on the Oklahoma's drug rebate program.

**OIG recommendations:** We recommend that OHCA review and adjust the accounts receivable balances in the new system and pursue collection of any unpaid balances. We recognize that such an effort would require considerable resources so we also recommend that the OHCA consider devoting more resources to the drug rebate program.

OHCA concurs that the accounts receivable data contained in its new information system, converted in December 2002, is not completely accurate. OHCA’s previous fiscal agent did a relatively good job of accounting for the invoicing component of the drug rebate accounts receivable system; however, the collection component was not as effective. OHCA was able to capture receipts at the labeler/quarter level, but at the NDC/quarter level, the receipts were not easily posted to the information system.

For this reason, from 1991 to 1998, in addition to the mainframe information system, OHCA operated a PC-based database system, utilizing the same invoicing and collection information as that used by the mainframe system, the only difference being the numbers of units reported. In the PC-based system, units adjusted through dispute resolution were able to be recorded correctly, thus creating differences in net rebates invoiced between the mainframe and the PC-based systems. The PC-based database system was augmented by the use of Excel worksheets. On these worksheets, for over 130 manufacturers who represented the bulk of rebates dollars collected, the true accounts receivable information was maintained at the NDC/quarter level. Information created from the PC-based system was used to complete the quarterly CMS 64.9R accounts receivable reports. OHCA believes that these reports were relatively accurate, other than for NDCs which had zero rebate per unit amounts received from CMS. For NDCs whose rebates per unit were other than zero, the PC-based system captured the correct rebates per unit received from CMS.
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Plans are for the new accounts receivable system, operated by the new fiscal agent, to be adjusted to reflect the correct billing and payment history. The units should be adjusted to reflect those to which both the manufacturer and the state have previously agreed. Any zero rebate per unit amounts should be adjusted to those provided by the manufacturers, and then compared to CMS' records. Also, from 1991 through 1998, the payment history at the NDC/quarter level should be posted to agree with the postings at the labeler/quarter level.

OHCA's new system has the on-line capability to adjust both the units and the rebates per unit to reflect the correct numbers. Many unit adjustments previously made in OHCA's PC-based system have already been posted to the new system. Next, the OHCA will attempt to identify zero rebates per unit in the system, and insert the amounts provided by the labelers. This will give the OHCA a new starting point from which it will begin its review of accounts receivable balances per its books. Then, OHCA should be able to determine the proper course of action to take.

While OHCA recognizes the importance of the audit recommendations, the agency also recognizes that such efforts will require considerable staffing resources. In this time of tight resources, OHCA must carefully consider all functions and requirements, assess priorities, and balance resources accordingly. The OIG recommendations will be included in our future resource planning.

Before closing, OHCA would like to provide clarification to a statement made on page two of the background section. The draft audit report states, "The OHCA reported $15,335,572 of outstanding drug rebate program accounts receivable as of June 30, 2002 of the CMS $4.3M.” While this is a true statement, it should be noted that, of the $15.3 million reported as outstanding, $11 million was not due from the manufacturers until after June 30, 2002, and of the remaining $4.3 million, much of the balance was not truly receivable. For example, as CMS noted, many old balances had been settled, but the results not entered on the books. Also, many large balances were the result of over-billing of units for compounded drugs, and the OHCA has acknowledged to several labelers that the majority of these disputes will require adjustments downward. OHCA is eager to begin the process of adjusting its books to reflect accurate accounts receivable.

In conclusion, OHCA's new drug rebate information system has excellent capabilities. OHCA is encouraged that it will be able to operate a modern efficient drug rebate accounts receivable system that will provide effective control and accountability for rebates and interest receivable.

Sincerely,

[Signature]
Mike Fogarty
Chief Executive Officer