DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF INSPECTOR GENERAL

Region IX
Office of Audit Services
50 United Nations Plaza, Room 171
San Francisco, CA 94102

July 23, 2003

Report Number A-10-03-00006

Mr. John Gaisford, Director
Alaska Department of Health and Social Services
Division of Medical Assistance
P.O. Box 110660
Juneau, Alaska 99811-0660

Dear Mr. Gaisford:

Enclosed are two copies of the Department of Health and Human Services (HHS), Office of Inspector General (OIG) Report entitled, "Audit of the Medicaid Drug Rebate Program in Alaska."

Final determination as to actions taken on all matters reported will be made by the HHS action official named on page 2 of this transmittal letter. 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.

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To facilitate identification, please refer to report number A-10-03-00006 in all correspondence relating to this report. If you have any questions or need additional information, please contact Doug Preussler at (415) 437-8309 or Juliet Lo at (415) 437-8350.

Sincerely,

Lori A. Ahlstrand
Regional Inspector General
for Audit Services

Direct Reply to HHS Action Official:

Ms. Linda A. Ruiz
Centers for Medicare and Medicaid Services
Regional Administrator, Region X
2201 Sixth Avenue, MS-40
Seattle, WA 98121

Enclosures – As stated

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN ALASKA

JULY 2003
A-10-03-00006

Office of Inspector General

http://oig.hhs.gov/

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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, Office of Audit Services, reports are made available to members of the public to the extent information contained therein is not subject to exemptions in the Act. (See 45 CFR Part 5.)

OAS FINDINGS AND OPINIONS

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

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Mr. John Gaisford, Director
Alaska Department of Health and Social Services
Division of Medical Assistance
P.O. Box 110660
Juneau, Alaska 99811-0660

Dear Mr. Gaisford:

This report provides you with the results of our "Audit of the Medicaid Drug Rebate Program in Alaska." The Medicaid drug rebate program was established to allow Medicaid to receive pricing benefits commensurate with its position as a high-volume purchaser of prescription drugs.

EXECUTIVE SUMMARY

OBJECTIVE

The objective of our review was to evaluate whether the State of Alaska Department of Health and Social Services (the State Agency) had established adequate accountability and internal controls over the Medicaid drug rebate program.

SUMMARY OF FINDINGS

The State Agency had not established adequate policies, procedures, and internal controls over the Medicaid drug rebate program as required by Federal rules and regulations. As a result, the State Agency did not properly report drug rebate information to the Centers for Medicare & Medicaid Services (CMS), nor adequately establish policies, procedures, and internal controls to account for drug rebate program transactions. We identified weaknesses in the following areas:

- **Quarterly Reporting** – The State Agency understated by $3.3 million the June 30, 2002 balance of uncollected rebates reported to CMS. One reason for the understatement was that the State Agency did not reconcile its CMS quarterly reports to its subsidiary ledger system and it did not identify that prior quarter adjustments were not reflected in some of its CMS quarterly reports.

- **Accounts Receivable System -** The State Agency did not maintain a general ledger accounts receivable control account nor a sufficiently detailed subsidiary accounts receivable system to provide adequate accountability over its drug rebate activity.

- **Segregation of Duties -** The State Agency did not properly segregate duties within and between the rebate billing, collection and accounting functions.

- **Interest Accrual and Collection -** The State Agency did not calculate simple interest due on disputed, late, and unpaid rebate amounts. Also, the State Agency did not verify the accuracy of interest payments received.

- **Dispute Resolution** - The State Agency did not have policies and procedures in place to use the State hearing mechanism.

RECOMMENDATIONS

We recommend that the State Agency correct the reported balance of uncollected rebates to accurately reflect the State Agency's drug rebate activity and ending balance. In addition, we recommend that the State Agency establish policies, procedures, and internal controls to:

- Reconcile the ending balance of uncollected rebates to the State Agency's supporting receivable account, and ensure the accuracy of the data reported to CMS.

- Create a general ledger accounts receivable control account and a sufficiently detailed subsidiary accounts receivable system.

- Provide for the proper segregation of duties within and between the rebate billing, collection, and accounting functions.

- Calculate simple interest on disputed, late, and unpaid rebate payments, and verify the accuracy of interest payments received.

- Make use of the State hearing mechanism when appropriate.

STATE AGENCY COMMENTS

The State Agency generally concurred with our findings and recommendations. However, the State Agency expressed concerns regarding the use of the State hearing mechanism. The complete text of the State Agency's comments is included as an appendix to this report.

INTRODUCTION

BACKGROUND

On November 5, 1990, Congress enacted the Omnibus Budget Reconciliation Act of 1990 legislation (OBRA '90), which established the Medicaid drug rebate program that became effective January 1, 1991. The Medicaid drug rebate program was established to allow Medicaid to receive pricing benefits commensurate with its position as a high-volume purchaser of prescription drugs. Responsibility for the rebate program was shared among the drug manufacturers, CMS, and participating States. Throughout the program, CMS issued memoranda to State agencies and manufacturers to provide guidance on numerous issues related to the Medicaid drug rebate program.

The OBRA '90 required a drug manufacturer 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 was signed, the manufacturer was required to submit to CMS a listing of all covered outpatient drugs, including the average manufacturer price and best price information for each drug. Approximately 550 pharmaceutical companies participated in the program.

Based on the information received from the manufacturers, CMS calculated and provided the unit rebate amount (URA) for each covered drug to States quarterly on a computer tape. However, the CMS tape may have contained a $0 URA if the pricing information was not provided timely by a manufacturer or if the computed URA had a 50 percent variance from the previous quarter. In instances of $0 URAs, States were instructed to invoice the units and the manufacturers were required to calculate the URAs and remit the appropriate amounts to the State. In addition, the manufacturers could change any URA based on updated pricing information, and submit this information to States.

Each State was required to maintain, by manufacturer, the number of units dispensed for each covered drug. That number was applied to the URA to determine the actual rebate amount due from each manufacturer. States were required to provide drug utilization data to the manufacturers and CMS on a quarterly basis. Approximately 56,000 National Drug Codes (NDC) were covered under the Medicaid drug rebate program.

From the date an invoice was postmarked, each manufacturer had 38 days to remit the drug rebate amount owed to the State. The manufacturers were to provide the State with a Reconciliation of State Invoice detailing its rebate payment by NDC. A manufacturer could dispute utilization data it believed to be erroneous, but was required to pay the undisputed portion of the rebate by the due date. If the manufacturer and the State could not, in good faith, resolve the discrepancy, the manufacturer was required to provide written notification of the dispute to the State by the due date. The manufacturer was required to calculate and remit interest for disputed rebates when settlement was made in favor of the State. If the State and manufacturer were not able to resolve the discrepancy within 60 days, the State was required to make available a hearing mechanism under the State's Medicaid program for the manufacturer to resolve the dispute.

States were required to report, on a quarterly basis, rebate collections on the CMS 64.9R report. Specifically, States were required to report rebates invoiced in the current quarter, adjustments and rebates received during the current quarter, and uncollected rebate balances for the current and prior quarters. The CMS 64.9R report was part of the CMS 64 report, which summarized actual Medicaid expenditures for each quarter and was used by CMS to reimburse the Federal share of these expenditures.

The State Agency reported (1) an average of $3.5 million in billings and $3.2 million in collections per quarter during the 1-year period ending June 30, 2002, and (2) $(642,610) as the outstanding receivable balance as of June 30, 2002. According to its accounting records, the State Agency's outstanding receivable balance as of June 30, 2002 was $2.7 million. Of this $2.7 million, $138,828 had been outstanding for 90 days or longer.

The Alaska drug rebate program became effective January 1, 1991. From January 1991 through January 1997, the State Agency was responsible for all of the functions of the drug rebate program. The State Agency contracted with First Health Services Corporation (FH) to perform the day-to-day management of the rebate program effective February 1997. The contracted services with FH included the invoicing, rebate collections, adjustment, dispute resolution and record keeping processes. The State Agency continued to perform the quarterly reporting function.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The objective of our review was to evaluate whether the State Agency had established adequate accountability and internal controls over the Medicaid drug rebate program.

Scope

We focused our audit on the current policies, procedures, and internal controls established by the State Agency and FH for the Medicaid drug rebate program. We also reviewed accounts receivable information related to prior periods and interviewed the State Agency and FH staff to gain an understanding of how the Medicaid drug rebate program had operated since the State Agency contracted with FH in February 1997.

Methodology

Our audit was performed in accordance with generally accepted government auditing standards. To accomplish our objective, we interviewed State Agency and FH officials to determine the policies, procedures, and internal controls that existed with regard to the Medicaid drug rebate program. We also interviewed individuals who performed functions related to the drug rebate program, including gathering information on their roles in the invoicing, collections, and dispute resolution processes. In addition, we reviewed the State Agency's drug rebate activity summaries and compared (1) the data on the summaries to the CMS 64.9R report for the

quarters ending March 31, 2001 through June 30, 2002 and (2) the data on the June 30, 2002 summary to the State Agency's subsidiary ledger system.

Our field work was conducted during the period February through April 2003, and included site visits to the FH office in Salem, Oregon.

FINDINGS AND RECOMMENDATIONS

We found that the State Agency had not established adequate policies, procedures, and internal controls over the Medicaid drug rebate program as required by Federal rules and regulations. As a result, the State Agency did not properly report drug rebate information to CMS nor adequately establish policies, procedures, and internal controls to account for drug rebate program transactions. We identified weaknesses in the following areas:

- Quarterly Reporting
- Accounts Receivable System
- Segregation of Duties
- Interest Accrual and Collection
- Dispute Resolution

QUARTERLY REPORTING

The State Agency understated by $3.3 million the June 30, 2002 balance of uncollected rebates reported to CMS. The June 30, 2002 balance of uncollected rebates reported to CMS was $(642,610). However, the State Agency's subsidiary ledger system supported an outstanding receivable balance of $2,662,301. One reason for the understatement was that the State Agency did not reconcile its CMS quarterly reports to its subsidiary ledger system. Therefore, the State Agency did not identify that prior quarter adjustments were not reflected in some of its CMS quarterly reports.

Based on a review of the State Agency's CMS 64.9R reports from quarters ending March 31, 2001 through June 30, 2002, the State Agency's prior quarter adjustments were not reflected on three of these six reports. By omitting adjustments on quarterly reports, incorrect ending balances were carried forward to subsequent reporting periods. Since CMS 64.9R reports were not available for the entire history of the program, the cumulative effect over time could not be determined.

ACCOUNTS RECEIVABLE SYSTEM

The State Agency did not maintain a general ledger accounts receivable control account nor maintain its subsidiary accounts receivable system at a sufficiently detailed level to accurately account for drug rebate activity. The State Agency's general ledger system, the Alaska Statewide Accounting System (AKSAS), only maintained drug rebate collections in the aggregate, whereas the State Agency's subsidiary accounts receivable system, the Medicaid

Management Information System (MMIS), tracked drug rebate activity by quarter and year for each labeler number but did not track activity by NDC. In addition, MMIS was limited to the number of transactions maintained on-line and drug rebate activities beyond this limit were tracked manually.

For the complex drug rebate program, rebates were calculated quarterly by CMS for approximately 56,000 NDCs. The complexity was increased by $0 URAs and URA adjustments.

The quarterly URA tapes provided by CMS contained many $0 URAs. In those instances, the States were instructed to prepare an invoice for the manufacturer to calculate the URA and remit the appropriate rebate to the State. As a result of $0 URAs, the original invoiced amount recorded as a receivable was understated and should have been adjusted when the manufacturer remitted payment.

Additionally, because of updated pricing information, manufacturers were required by CMS to adjust URAs for updated pricing information. Adjustments in URAs were common and, if not posted or otherwise accounted for by States, the receivable balance was inaccurate.

Since the State Agency did not maintain a general ledger accounts receivable control account nor a sufficiently detailed subsidiary accounts receivable system, the State Agency could not reconcile the amount of uncollected rebates between the two systems, AKSAS and MMIS, nor adequately account for the complex NDC-level transactions that made up the drug rebate program.

SEGREGATION OF DUTIES

The State Agency did not properly segregate duties for rebate billings, collections, and accounting for drug rebates in the subsidiary ledger system. Only one individual was involved in the billing process. Also, this individual (1) prepared rebate checks for deposit, (2) restrictively endorsed the checks, (3) made deposits, (4) posted rebate collections and adjustments to the subsidiary ledger system, and (5) handled manufacturer disputes. The lack of segregation of duties within and between the rebate billing, collection, and accounting functions increased the potential risk for fraud, waste, and abuse of drug rebate program funds.

INTEREST ACCRUAL AND COLLECTION

The State Agency did not have adequate controls in place to accurately account for interest on disputed, late, and unpaid rebate payments nor to ensure that interest collections received from manufacturers were accurate.

According to the rebate agreement between the manufacturers and CMS, as stipulated by Section 1927 of the Social Security Act (the Act), manufacturers were required to pay interest on disputed, late, and unpaid rebates. Section V, paragraph (b) of the rebate agreement states:

> *(b) If the Manufacturer in good faith believes the State Medicaid Agency's Medicaid Utilization Information is erroneous, the Manufacturer shall pay the State Medicaid Agency that portion of the rebate amount claimed which is not disputed within the required due date in II (b). The balance due, if any, plus a reasonable rate of interest as set forth in section 1903(d)(5) of the Act, will be paid or credited by the Manufacturer or the State by the due date of the next quarterly payment in II(b) after resolution of the dispute.*

According to CMS Medicaid Drug Rebate Program Release (Program Release) #29 to the State Medicaid Directors, interest must be collected and could not be disregarded as part of the dispute resolution process by either the manufacturer or the State. The calculation of interest, as set forth in section 1903(d)(5) of the Act and Program Release #29 to the State Medicaid Directors, involved applying simple interest to the average yield of the weekly 90-day Treasury bill auction rates during the period in which interest was charged. In addition, Program Release #65 to the State Medicaid Directors stated that it was the manufacturers' responsibility to calculate and pay interest for applicable rebate invoices and the State's responsibility to track collections and report those amounts to CMS.

The State Agency's MMIS subsidiary system did not calculate interest on its labeler accounts receivable for disputed, late, and unpaid rebates. When a manufacturer paid interest, the payment would be posted along with a corresponding adjustment for interest. Interest paid on disputed, late, and unpaid rebates was not verified by either the State Agency or FH because they contended that it was the manufacturer's responsibility to calculate and pay the interest owed. Since the State Agency did not calculate interest nor verify that the interest voluntarily paid by the manufacturers was accurate, there was no assurance that the State Agency collected all of the interest owed on disputed, late, and unpaid rebates.

DISPUTE RESOLUTION

The State Agency did not have policies and procedures in place to utilize the State hearing mechanism to resolve long-standing disputes with manufacturers. We believe that the State Agency would benefit from establishing procedures for use of the State hearing mechanism to resolve future disputes in the event that it is unable to reach satisfactory resolution with drug manufacturers.

RECOMMENDATIONS

We recommend that the State Agency correct the uncollected rebate balance on its CMS 64.9R report to accurately reflect its drug rebate activity and ending balance. In addition, we recommend that the State Agency establish policies, procedures, and internal controls to:

- Reconcile the ending balance of uncollected rebates to the State Agency's supporting receivable account, and ensure the accuracy of the data on the CMS 64.9R report.

- Create a general ledger accounts receivable control account and a sufficiently detailed subsidiary accounts receivable system to account for all drug rebate activity.

- Provide for the proper segregation of duties within and between the rebate billing, collection, and accounting functions.

- Calculate simple interest on disputed, late, and unpaid rebate payments, and verify the accuracy of interest payments received.

  Make use of the State hearing mechanism when appropriate.

STATE AGENCY COMMENTS

In written response to our draft report, the State Agency concurred with our findings and recommendations regarding quarterly reporting, accounts receivable system, segregation of duties, and interest accrual and collection. The State Agency also agreed with our finding that it did not have policies and procedures in place to utilize the State hearing mechanism to resolve long-standing disputes with manufacturers. However, the State Agency questioned whether the State hearing mechanism is the appropriate forum for a hearing requested by the State.

OFFICE OF INSPECTOR GENERAL (OIG) RESPONSE

CMS provided guidance to the State Medicaid Directors in Program Release #44 which indicated that CMS believed that the State hearing process was the appropriate mechanism for both manufacturers and States to resolve disputes. Therefore, the State Agency should work with CMS to determine the appropriate use of the State hearing mechanism.

* * * *

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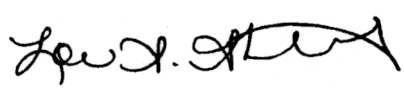
Sincerely,



Lori A. Ahlstrand
Regional Inspector General
for Audit Services

Enclosure

APPENDIX

STATE OF ALASKA
DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF MEDICAL ASSISTANCE

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Anchorage, AK 99503-7167
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June 26, 2003

TO: Lori Ahlstrand
Regional Inspector General for Audit Services
Office of Inspector General, Region IX
Office of Audit Services
50 United Nations Plaza
San Francisco, CA 94102

From: John Gaisford
Director
Alaska Department of Health and Social Services
Division of Medical Assistance

RE: Report Number A-10-03-00006
Audit of the Medicaid Drug Rebate Program in Alaska

Introduction

The State of Alaska currently contracts our fiscal agent services and the drug rebate function to First Health Services Corporation (FHSC). We are currently in the process of implementing a new Medicaid Management Information System (MMIS) for the state. In order to become HIPAA compliant, we have already implemented a new Pharmacy Point of Sale system (First SX) and are in the process of converting to a new Drug Rebate subsystem (First Rebate). As part of the conversion to First Rebate, drug rebate functions which were performed in Oregon by FHSC will soon be performed in Richmond, VA. by FHSC. The transition to the new First Rebate system is scheduled for completion by October 1,2003. Several of the recommendations included in your report will be adopted by the new system. Our response to your audit findings are presented below.

Quarterly Reporting

We concur that the June 30, 2002 balance for uncollected rebates was understated on the CMS 64.9R report. The state will ensure that the

correct balance for uncollected rebates will appear on the June 30, 2003 CMS 64.9R report. In addition, the state will implement a process to ensure final review and reconciliation of the 64.9R prior to submission to CMS.

Accounts Receivable

We agree that current system limitations do not permit adequately detailed tracking within our subsidiary accounts receivable system. Findings related to the accounts receivable system will be addressed with the conversion First Rebate.

With First Rebate, all invoices and checks can be reconciled at the National Drug Code (NDC)/Quarter/Year level. First Rebate can also make unit rebate amount (URA) adjustments upon receipt of a reconciliation of State invoice throughout the quarter. These adjustments will create an adjusted invoice amount to which the proper payment is applied, eliminating any understated receivable. In addition, First Rebate applies all URA adjustments from previous quarters based on the quarterly CMS tape. This automated quarterly process produces an accurate and up-to-date accounts receivable file.

In the current system, adjustments are made to each invoice when payments are made on $0 URAs. Posting is to the Alaska subsidiary ledger system.

When the conversion is made to First Rebate, the state will maintain an accurate and sufficiently detailed accounts receivable system, capable of tracking activity by NDC. The new system will also permit an unlimited number of transactions to be maintained on-line with no manual tracking necessary.

Maintaining an accurate accounts receivable for the drug rebate program in general, is exacerbated by the ability for manufacturers to make adjustments to the unit rebate amounts going back to the beginning of the drug rebate program. Some reasonable limitation on the amount of time the manufacturers have to make adjustments would permit some periods to eventually be closed and relieve some of the accounting burden on the States.

Segregation of Duties

We agree with your finding regarding a lack of segregation of duties under our current drug rebate program. FHSC staff working on the Alaska rebate program are co-located with the FHSC staff working on the Oregon rebate program. Due to the limited size of the Alaska account, additional staff to ensure proper segregation was not maintained.

Upon conversion to First Rebate, Alaska will either use a lock-box at a designated bank, or will process the receipt and deposit of checks from rebate manufacturers. Then these daily reports will be reconciled by the First Health rebate analyst in Richmond. First Rebate will not allow a user to complete posting payments to the manufacturers account balance unless the posting balances to the daily report.

First Rebate tracks all data entry with a user/date/time stamp, as well as records the receipt and check number down to the NDC/Quarter/Year level. First Rebate has an extensive package of reports available to Alaska to balance with any other subsidiary accounts receivable system.

In the current system, rebate billing is calculated in the Richmond office, where invoices are produced, then invoices are forwarded to the Salem office, where invoices are randomly checked and mailed. Collections are logged-in by one individual, then posted by another individual in the Salem office. Posting is currently done by the Salem office and several reports are provided to the Division of Medical Assistance in Anchorage. Reporting functions are performed by the State of Alaska.

Interest

We agree that our current system has limitations regarding verifying the accuracy of interest paid to the state. Given current system constraints, and due to the materiality of amounts involved, a cumbersome manual process of verifying the accuracy of interest payments was not performed. Interest is still collected and posted in our current system.

Our new system, First Rebate, calculates interest on disputed, late, and unpaid rebate payments, and verifies accuracy of interest payments.

Dispute Resolution

We agree that the state does not have policies and procedures in place to utilize the state hearing mechanism to resolve long standing disputes with Manufacturers.

The state of Alaska does not currently have any long standing disputes with manufacturers. In accordance with the *Best Practices for Dispute resolution under the Medicaid Drug Rebate Program*, published by CMS, our contractor attends the CMS sponsored Dispute

Resolution Project Meetings. These meetings, attended by the State representative, the Manufacturers and CMS provide for a convenient and cost effective method to handle disputes. In the event these meetings do not resolve the dispute, the *Best practices for dispute resolution* encourages contacting CMS regional and if necessary, the Central office for assistance. If a Hearing becomes necessary the State may request a hearing as a last resort.

We question whether the State hearing mechanism is the appropriate forum for a hearing requested by the state. In addition, there are no manufacturers located in the State of Alaska, and manufacturers would be required to travel to Alaska to attend such a hearing. *The Best practices for dispute resolution* guide makes no mention of utilizing a state hearing mechanism for dispute resolution.