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

August 15, 2003

Report Number A-09-03-00033

Mr. Charles Duarte, Administrator
Department of Human Resources
Division of Health Care Financing and Policy
1100 East Williams Street, No. 100
Carson City, Nevada 89701

Dear Mr. Duarte:

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 Nevada."

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.

In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), OIG 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 10 business days after the final report is issued, it will be posted on the Internet at *http://oig.hhs.gov.*

To facilitate identification, please refer to report number A-09-03-00033 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:

Mr. H. Stephen Deering
Acting Regional Administrator, Region IX
Centers for Medicare & Medicaid Services
75 Hawthorne Street, Suite 408
San Francisco, CA 94105

Enclosures – As stated

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN NEVADA

AUGUST 2003
A-09-03-00033

Office of Inspector General

http://oig.hhs.gov/

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

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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.

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

August 15, 2003

Report Number A-09-03-00033

Mr. Charles Duarte, Administrator
Department of Human Resources
Division of Health Care Financing and Policy
1100 East Williams Street, No. 100
Carson City, Nevada 89701

Dear Mr. Duarte:

This report provides you with the results of our "Audit of the Medicaid Drug Rebate Program in Nevada." 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 Nevada Division of Health Care Financing and Policy (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. We identified weaknesses in the following areas:

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

- **Rebate Billings** – The State Agency did not bill manufacturers in a timely manner. In addition, the State Agency overbilled manufacturers for injectable medications for the period June 2001 through June 2002.

- **Interest Accrual and Collection** – The State Agency did not account for interest on disputed, late, and unpaid rebate payments nor verify the accuracy of interest payments received.

- **Dispute Resolution** – The State Agency did not actively work to resolve manufacturer disputes and did not periodically review inactive accounts in its subsidiary ledger system to determine collection status. Further, the State Agency did not have policies and procedures to use the State hearing mechanism, when appropriate.

RECOMMENDATIONS

We recommend that the State Agency establish policies, procedures, and internal controls to:

- create a general ledger accounts receivable control account and a sufficiently detailed subsidiary accounts receivable system to track drug rebate activity;

- ensure that manufacturers are billed timely and accurately, and adjust billing units for inaccurately billed injectable medications;

- account for interest due, and verify the accuracy of interest payments received; and

- actively work to resolve manufacturer disputes, review inactive accounts periodically and write off accounts that are no longer collectible, as allowed by the Centers for Medicare & Medicaid Services (CMS) thresholds and, when appropriate, use the State hearing mechanism to resolve long-standing disputes.

STATE AGENCY COMMENTS

The State Agency concurred with our findings and recommendations. The complete text of the State Agency's comments is included as an appendix to this report.

OTHER MATTERS

During our review, we identified two areas the State Agency should consider for further segregation of duties: (1) receiving mail, and (2) posting rebate collections to the general and subsidiary account receivable ledgers.

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 their 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 $10.9 million in billings and $3.8 million in collections per quarter during the 1-year period ending June 30, 2002, and (2) $78.9 million as the outstanding receivable balance as of June 30, 2002.

The Nevada drug rebate program was established on January 1, 1991. The State Agency performed all of the functions of the drug rebate program including billing, collections, accounting, quarterly reporting, and dispute resolution.

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 for the Medicaid drug rebate program. We also reviewed accounts receivable information related to prior periods and interviewed State employees to gain an understanding of how the Medicaid drug rebate program had operated since the beginning of 2001.

Methodology

Our audit was performed in accordance with generally accepted government auditing standards. To accomplish our objective, we interviewed State officials to determine the policies, procedures and internal controls that existed with regard to the Medicaid drug rebate program. We interviewed State employees who performed functions related to the drug rebate program, including gathering information on their roles in the invoicing, collections, accounting, and dispute resolution processes. In addition, we reviewed the State Agency's documentation relating to manufacturer billings for the quarters ending March 31, 1998 through June 30, 2002, and the drug rebate accounts receivable balance reported in the State Agency's subsidiary ledger system and compared the data to the CMS 64.9R report for the quarter ending June 30, 2002.

Our fieldwork was conducted during the period March through the middle of June 2003, and included site visits to State offices in Carson City, Nevada.

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. We identified weaknesses in the following areas:

- Accounts Receivable System
- Rebate Billings
- Interest Accrual and Collection
- Dispute Resolution

INTERNAL CONTROLS AND ACCOUNTABILITY

Accounts Receivable System

The State Agency did not maintain a general ledger accounts receivable control account nor a subsidiary accounts receivable system designed to provide sufficiently detailed information of its drug rebate activity. The State Agency general ledger system, Integrated Financial System (IFS), only maintained drug rebate collections in the aggregate, whereas the State Agency's subsidiary ledger system, Accounting Plus (A+), tracked drug rebate activity by quarter and year for each labeler number but was not set up to track activity by NDC. In addition, A+ was overloaded and started to drop detail from manufacturer accounts. As a result, the outstanding rebate balance reported on the State Agency's CMS 64.9R could not be reconciled to the A+ system. Lastly, the manufacturer of A+ was no longer in business so the software was no longer supported or updated.

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 State was 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, 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 the State, the receivable balance was inaccurate. Since the State Agency

did not maintain a general ledger accounts receivable control account nor a subsidiary accounts receivable system set up to track rebate activity to the NDC level, the State Agency could not reconcile the amount of uncollected rebates between the two systems, IFS and A+. In addition, the State Agency's subsidiary system was overloaded, had started to drop account detail, and was no longer supported by its manufacturer. Therefore, there was no assurance as to the accuracy of the outstanding receivable balances reported to CMS.

Rebate Billings

The State Agency did not bill manufacturers in a timely manner as required by CMS guidelines. The CMS guidelines specify that invoices should be mailed out within 60 days after quarter end or within 15 days after receipt of the CMS tape containing unit rebate amounts. For the 14 quarters ending March 31, 1998 through June 30, 2002, the State Agency was late in mailing out drug rebate invoices for 11 of the 14 quarters. Furthermore, for 7 of the 11 quarters, the State Agency mailed manufacturer invoices over 100 days after quarter end.

In addition, the State Agency overbilled manufacturers for injectable medications from June 2001 through June 2002. The State Agency billed units for injectable medications by the milligram instead of by the vial. The State Agency instructed providers to bill units for injectable medications based on volume rather than on the number of vials dispensed and the employee responsible for adjusting billing units prior to invoicing resigned in May 2001. The State Agency indicated that this function was assigned to an employee in December 2002.

Since the State Agency did not mail rebate invoices to drug manufacturers in a timely manner, the State Agency was at a higher risk for delayed collection of drug rebate funds and the potential loss of interest that could have been collected. In addition, because the State Agency did not accurately bill manufacturers for injectable medications from June 2001 through June 2002, the outstanding receivable balances reported by the State Agency to CMS may have been overstated.

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. Since the State Agency did not account for interest due, nor verify that the interest voluntarily paid by manufacturers was accurate, there was no assurance that the State Agency collected all of the interest owed on disputed, late, and unpaid rebates.

According to the rebate agreement between drug 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 A+ subsidiary system did not calculate or accrue interest on its labeler accounts receivable for disputed, late, and unpaid rebates. When a manufacturer made a late rebate payment, a State employee calculated interest for the purpose of determining whether to send the manufacturer an interest due letter. Interest due letters were only sent in instances where interest of at least $10 was due but the letters did not specify how much interest was to be paid. The State Agency did not verify the accuracy of the interest payments received from the manufacturers. Since the State Agency did not account for interest due, nor verify that 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 actively work to resolve manufacturer disputes and did not periodically review inactive accounts in its subsidiary ledger system to determine collection status. In addition, the State Agency did not have policies and procedures in place to utilize the State hearing mechanism to resolve long-standing disputes with manufacturers.

Although the State Agency had a backlog of long-standing manufacturer disputes, it had not actively worked to resolve identified disputes since May 2001 when the last employee responsible for the dispute resolution process resigned. In January 2003, the State Agency resumed working on manufacturer disputes for a limited number of manufacturers but had not resumed the dispute resolution process for the remainder of its manufacturers. The drug rebate agreement between CMS and manufacturers required the State and manufacturers to use their best efforts to resolve rebate discrepancies within 60 days of receipt of a dispute notification. By not actively working to resolve manufacturer disputes, the State Agency was at a higher risk for delayed collection of drug rebate funds and the potential loss of interest that could have been collected.

Also, the State Agency maintained inactive accounts in its subsidiary ledger system. The State Agency's subsidiary ledger system listed 594 labeler accounts as of February 18, 2003. According to a State employee, only 300-350 of those accounts were still active and the inactive accounts should have been written off as uncollectible. We did not perform any testing, however, to determine the collectibility of the inactive accounts. We believe the State Agency should review its inactive accounts periodically to determine whether it can still collect on them; if not, the State Agency should write off these accounts as allowed by CMS thresholds.

In addition, the State Agency did not have written 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 disputes in the event that it is unable to reach satisfactory resolution with drug manufacturers once it resumes its dispute resolution process.

RECOMMENDATIONS

We recommend that the State Agency establish policies, procedures, and internal controls to:

- create a general ledger accounts receivable control account and a sufficiently detailed subsidiary accounts receivable system to track drug rebate activity;

- ensure that manufacturers are billed timely and accurately, and adjust billing units for inaccurately billed injectable medications;

- account for interest due, and verify the accuracy of interest payments received; and

- actively work to resolve manufacturer disputes, review inactive accounts periodically and write off accounts that are no longer collectible as allowed by CMS thresholds, and, when appropriate, use the State hearing mechanism to resolve long-standing disputes.

STATE AGENCY COMMENTS

In written response to our draft report, the State Agency concurred with our findings and recommendations. The State Agency also provided comments relating to the segregation of duties information contained in the Other Matters section of this report. The enclosed Appendix includes the complete text of the State Agency's comments.

OTHER MATTERS

Segregation of Duties

At the time of our review, there was only one individual responsible for the receipt and restrictive endorsement of rebate checks, and entering these checks into a check log. In addition, there was only one individual responsible for posting rebate collections to both the general and subsidiary ledger systems. We believe that having more than one individual involved in the mail receipt process would reduce the potential risk for misappropriation of rebate funds. Also, segregating the duties for posting to the general and subsidiary ledgers would provide greater control over rebate collections.

* * * * * * *

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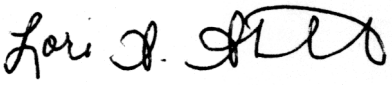
To facilitate identification, please refer to report number A-09-03-00033 in all correspondence relating to this report.

Sincerely,



Lori A. Ahlstrand
Regional Inspector General
for Audit Services

Enclosure

APPENDIX

STATE OF NEVADA
DEPARTMENT OF HUMAN RESOURCES
DIVISION OF HEALTH CARE FINANCING AND POLICY
1100 E. William Street, Suite 116
Carson City, Nevada 89701

KENNY C. GUINN
Governor

MICHAEL J. WILLDEN
Director

CHARLES DUARTE
Administrator

August 1, 2003

Ms. Lori A. Ahlstrand
Regional Inspector General for Audit Services
U.S. Department of Health and Human Services
50 United Nations Plaza, Room 171
San Francisco, CA 94102

RE: Report Number A-09-03-00033

Dear Ms. Ahlstrand:

In response to your report on the Medicaid Drug Rebate Program in Nevada, we concur with the majority of your findings. Appropriate actions have already been taken to implement your recommendations. The Division of Health Care Financing and Policy (DHCFP) has contracted with First Health Services Corporation (FHSC) to administer the Medicaid Drug Rebate Program beginning with the second quarter of 2003. First Health's rebate procedures comply with all OBRA 1990 requirements. The following is our response to each of the Office of Inspector General's (OIG) findings and recommendations:

1. Create a general ledger accounts receivable control account and a sufficiently detailed subsidiary accounts receivable system to track drug rebate activity.

   The DHCFP concurs with the OIG finding. In response to the recommendation, First Health Services will utilize FirstRebate, a proprietary accounting system. The FirstRebate system is an accounts receivable process that facilitates posting of labeler rebate and interest payments, dispute resolution transactions and quarterly reconciliation activity. The various accounting activities are assigned transaction codes. The system automatically updates the accounting file for certain types of transactions. These transactions include quarterly invoice billing, prior period adjustments, and interest billing. Other transactions are input manually, including principal and interest payment remittance, dispute resolution adjustments, and adjustments made by labelers. FirstRebate tracks rebate activity by labeler, NDC code, year and quarter, batch (or deposit ticket) number and deposit date. The State of Nevada receives and deposits rebate account checks. FHSC then receives copies of the checks and accompanying paperwork which are entered into FirstRebate.

FirstRebate is a self-reconciliatory system that requires payment to be allocated to the labeler, year/quarter and NDC level, thus providing the same back up functionality as a subsidiary system.

2. Ensure that manufacturers are billed timely and accurately, and adjust billing units for inaccurately billed injectable medications.

   The DHCFP agrees with the OIG finding. In accordance with the recommendation, the DHCFP, through FHSC, will bill timely and accurately. Per CMS guidelines, the Nevada CSA requires FHSC to invoice within 60 days after the end of the quarter. FHSC currently provides rebate services for several clients that are obliged to adhere to CMS guidelines in terms of timeliness of billing. FHSC has historically produced invoices within the CMS defined time frame and there should be no obstacles for FHSC to provide this same punctual service for Nevada. Prior to invoicing, FHSC uses weekly variance reports (Claims Level Detail Reports for quantity greater than 4,000 and unit cost less than $0.01) and quarterly pre-invoice edits (Rebate Amount Exceeds Reimbursement Amount report and a review of NDC's with unit discrepancies between FirstDataBank and CMS) to make appropriate unit adjustments prior to invoicing labelers. This will ensure that non-unit of use items (i.e. injectables, opthalmics, otics and compounds) are billed in the appropriate manner.

3. Account for interest due and verify the accuracy of interest payments received.

   The DHCFP concurs with the OIG finding. FHSC's FirstRebate system provides for the accrual and collection of interest, as recommended by the OIG. Interest applied to unpaid rebate amounts and to late rebate payments (those payments received 38 days after invoice postmarked or electronically transmitted) is calculated in accordance with CMS guidelines and invoiced quarterly as an effort to remind the labelers of unpaid interest due. In addition, FHSC has begun the process of enhancing the FirstRebate system to allow for automatic verification of the accuracy of interest payment.

4. Actively work to resolve manufacturer disputes, review inactive accounts periodically and write off accounts that are no longer collectible, as allowed by CMS thresholds and, when appropriate, use the state hearing mechanism to resolve longstanding disputes.

   The DHCFP concurs with this finding. Since FHSC dispute resolution procedures are based on the official CMS "Best Practices for Dispute Resolution under the Medicaid Drug Rebate Program", the DHCFP's dispute resolution process should be consistent with the OIG recommendation. This includes using FirstRebate to catalog and track disputes. Provider level drug claim detail reports can be produced to aid in resolving disputes. FHSC will respond to the labeler within 15 days of receiving the dispute. If repeated attempts to resolve a dispute with a labeler remain unsuccessful after 240

days, FHSC will forward the complaint and detailed pattern of non-responsiveness to the State for discussion and further action.

Regarding the other matter related to the segregation of duties for the proper handling of rebate checks and deposits, the DHCFP is in compliance with the State of Nevada Department of Administration, Internal Audit Division guidelines. In conclusion, with the implementation of the aforementioned drug rebate procedures, the DHCFP will now be able to fully comply with the OBRA 1990 requirements.

Sincerely,

Charles Duarte
Administrator, DHCFP

pc: Michael J. Willden, Director, Nevada Department of Human Resources
Mary Wherry, Deputy Administrator DHCFP
Deb King, Deputy Administrator DHCFP
Signe Davis, Region IX, Office of Audit Services