DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General
Office of Audit Services

Region VII
601 East 12th Street
Room 284A
Kansas City, Missouri 64106

May 21, 2003

Report Number A-07-03-04015

Jeffrey Urry
Chief Financial Officer
Wyoming Department of Health
151 Hathaway Building
Cheyenne WY 82002

Dear Mr. Urry:

Enclosed are two copies of the U.S. Department of Health and Human Services (HHS), Office of Inspector General, Office of Audit Service's (OAS) final report entitled *"Audit of the Medicaid Drug Rebate Program in Wyoming."*

The HHS action official named below will make final determination as to actions taken on all matters reported. 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, OAS 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. (See 45 CFR Part 5.) As such, within 10 business days after the final report is issued, it will be posted on the worldwide web at *http://oig.hhs.gov.*

To facilitate identification, please refer to Report Number A-07-03-04015 in all correspondence relating to this report. If you have any questions or need additional information, please contact Randy Parker of our Des Moines office at (515) 284-4674 extension 27 or Patrick Cogley of our Kansas City Office at (816) 426-3591, extension 274.

Sincerely,

James P. Aasmundstad
Regional Inspector General
for Audit Services

Direct Reply to HHS Action Official:

Mr. Alex Trujillo
Centers for Medicare and Medicaid Services
Regional Administrator, Region VIII
1600 Broadway, Suite 700
Denver, CO 80202

Enclosures—As stated

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN WYOMING

JANET REHNQUIST
INSPECTOR GENERAL

MAY 2003
A-07-03-04015

Office of Inspector General

http://oig.hhs.gov/

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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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Report Number A-07-03-04015

Jeffrey Urry
Chief Financial Officer
Wyoming Department of Health
151 Hathaway Building
Cheyenne WY 82002

Dear Mr. Urry:

This final report provides you with the results of our ***Audit of the Medicaid Drug Rebate Program in Wyoming.***

EXECUTIVE SUMMARY

OBJECTIVE

The audit objective was to evaluate whether the Wyoming Department of Health Pharmacy Unit (the State agency) had established adequate accountability and internal controls over the Medicaid drug rebate program.

FINDINGS

We found the State agency lacked sufficient internal controls with regard to the Medicaid drug rebate program as required by federal rules and regulations. Areas that lacked sufficient internal controls included:

Recording accounts receivable.
- Form CMS 64.9R and general ledger reconciliation.
- Interest reporting.
- Tracking amounts related to $0 unit rebate amounts.
- Dispute resolution.

These issues occurred because the State agency did not develop or follow adequate policies and procedures with regard to the drug rebate program and its management by Affiliated Computer Services (ACS), a company the State agency contracted with to administer the drug rebate program. Federal regulations require effective control over and accountability for all funds, property and other assets. In addition, the rebate agreements between the Centers for Medicare and Medicaid Services (CMS) and the drug manufacturers require the use of the State's hearing mechanism to resolve disputes. Also, the State Medicaid Manual requires interest revenue to be reported on the Form CMS 64 Summary Sheet.

Our review showed that the State Agency did not have reasonable assurance that drug rebate balances and collections reported to CMS were accurate. In addition, we believe that the State Agency could increase its drug rebate collections by using the State Agency's hearing mechanism to resolve disputes. Moreover, the lack of sufficient internal controls increased the risk for fraud, waste, or abuse of drug rebate program funds.

RECOMMENDATIONS

We recommend that the State agency develop and follow policies and procedures that include:

- Establishing a general ledger accounts receivable control account for drug rebates.
- Developing a subsidiary accounts receivable system for the drug rebate program.
- Reconciling the general ledger control account to the subsidiary ledgers and to the Form CMS 64.9R.
- Reporting interest collections on the Form CMS 64 Summary Sheet.
- Tracking, billing and accounting for all $0 unit rebate amounts.
- Utilizing the State's hearing mechanism to settle disputes after 60 days.

The State agency did not concur with our findings and recommendations. Their response is included as Appendix A.

INTRODUCTION

BACKGROUND

On November 5, 1990, Congress enacted the Omnibus Budget Reconciliation Act (OBRA '90) of 1990 legislation, which established the Medicaid drug rebate program. Responsibility for the rebate program is shared among the drug manufacturer(s), CMS, and the State(s). The legislation was effective January 1, 1991. The CMS also issued release memorandums to State agencies and manufacturers throughout the history of the rebate program to give guidance related to the Medicaid drug rebate program.

A manufacturer is required to have a rebate agreement in effect with CMS in order to have its products covered under the Medicaid program. 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.

The 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 computed URA 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 is required to calculate the URA and remit the appropriate amount to the State agency. In addition, the manufacturers can change any URA based on updated pricing information, and submit this information to the State agency in a Prior Quarter Adjustment Statement (PQAS).

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

The manufacturer has 38 days to remit payment from the date an invoice is postmarked. The manufacturers provide the State agency with a Reconciliation of State Invoice (ROSI) detailing their payment by each NDC. A manufacturer can dispute utilization data that is believed to be erroneous, but they are 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, 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. The State agency reported to CMS an uncollected rebate balance of $1,211,893 on the CMS 64.9R as of June 30, 2002. Of that amount, $1,056,532 was outstanding for 90 days or longer. For the period July 1, 2001 through June 30, 2002, the State agency reported total rebate collections of $6,969,986 or an average of $1,742,497 per quarter.

OBJECTIVE, SCOPE AND METHODOLOGY

Objective

The audit objective was to evaluate whether the Wyoming Department of Health, Pharmacy Unit, had established adequate accountability and internal controls over the Medicaid drug rebate program.

Scope

The drug rebate program became effective January 1, 1991. We concentrated our audit on current policies, procedures and controls that existed with regard to ACS.

Methodology

To achieve our objective, we reviewed the applicable Federal laws, regulations, and requirements including sections 1903 and 1927 of the Social Security Act, the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) and the OMB Circular A-87.

We examined copies of the CMS 64.9R reports for the period July 1, 2001 through June 30, 2002 submitted to CMS by the State of Wyoming. We obtained and reviewed drug rebate accounts receivable records. Finally, we interviewed ACS and Department of Health, Budget Office staff that performed functions related to the drug rebate program.

Our fieldwork was conducted at the ACS office in Cheyenne, Wyoming, the week of November 18, 2002, and continued in the Office of Audit Services field office in Denver, Colorado through March 2003.

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

FINDINGS AND RECOMMENDATIONS

We found that the State agency and its management contractor, ACS, lacked sufficient internal controls with regard to the Medicaid drug rebate program as required by federal rules and regulations. Areas that lacked sufficient internal controls included:

- Recording accounts receivable.
- Form CMS 64.9R and general ledger reconciliation.
- Interest reporting.
- Tracking amounts related to $0 unit rebate amounts.
- Dispute resolution.

INTERNAL CONTROLS

Accounts Receivable

The State agency did not maintain a general ledger accounts receivable control account or a detailed subsidiary ledger to account for uncollected rebate balances as required. Drug rebates are "other assets" to the State that should be accounted for properly.

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. Recipients shall adequately safeguard all such assets and assure they are used solely for authorized purposes." Additionally, generally accepted accounting principles (GAAP) require the use of a general ledger. The National

Council on Governmental Accounting (NCGA)[1] issued *Statement 1, Governmental Accounting and Financial Reporting Principles*. It states in part,

> "A governmental accounting system must make it possible both: (a) to present fairly and with full disclosure the financial position and results of financial operations of the funds and account groups of the governmental unit in conformity with generally accepted accounting principles; and (b) to determine and demonstrate compliance with finance-related legal and contractual provisions."

The State agency did not have a general ledger accounts receivable control account or subsidiary ledgers to provide a sufficient audit trail. Specifically, ACS recorded and tracked uncollected rebates as running balances in a system known as the Drug Rebate Analysis and Management System (DRAMS). The system was also used to prepare quarterly invoices that were sent to manufacturers and to track payments received. However, DRAMS did not retain the original billed amount or any adjustments that were made. Furthermore, the DRAMS included incorrect balances. As of June 2002, the State agency reported on the Form CMS 64.9R that manufacturers owed the State $1,211,893 in unpaid rebates. However, the DRAMS showed a credit balance (i.e., the State owed manufacturers) of $378 million.[2]

Because there were no general or subsidiary accounts receivable ledgers, the State agency did not have reasonable assurance that receivable and collection balances reported to CMS were accurate. Furthermore, without sufficient ledgers, the State agency did not recognize that balances recorded in the DRAMS system were incorrect. As a result of these accounting weaknesses, rebate funds were subject to potential waste, fraud, and abuse.

CMS 64.9R Reconciliation

The State agency did not perform a reconciliation to verify the accuracy of the uncollected rebate balance or collections reported on the Form CMS 64.9R as required by federal regulations.

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. Recipients shall adequately safeguard all such assets and assure they are used solely for authorized purposes."

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[1] The Governmental Accounting Standards Board (GASB) establishes standards for activities and transactions of State and local governmental entities. Its pronouncements are authoritative for State and local governmental entities. Following the jurisdictional approach discussed in the GASB Codification of Governmental Accounting and Financial Reporting Standards, the hierarchy of GAAP for governmental entities begins with GASB pronouncements and all pronouncements of the NCGA acknowledged as applicable by the GASB.

[2] The large credit balance was primarily due to billing errors on two invoices to a single manufacturer. In addition, DRAMS showed that 140 of 411 manufacturers had credit balances.

The State agency could not reconcile the general ledger account balance to the detailed subsidiary accounts receivable records because they did not maintain a general ledger accounts receivable control account or subsidiary ledgers. Moreover, the State agency did not reconcile the rebate collections on the cash receipts log to the collections reported on the Form 64.9R. The Fiscal Office within the Wyoming Department of Health prepared the Form CMS 64.9R. The Fiscal Office calculated the uncollected rebate balance by using figures from a report generated by ACS. However, the Fiscal Office did not properly allocate collections to the proper quarters on the CMS Form 64.9R, and improperly applied disputed rebates as adjustments to prior quarter uncollected rebate balances on the Form CMS 64.9R.

Without a general ledger control account and adequate subsidiary ledgers, routine reconciliations could not be performed to verify the accuracy of the reported uncollected rebate balances and collections on the Form 64.9R. As a result, the State agency did not have reasonable assurance that drug rebate program activity reported to CMS was accurate.

Interest Reporting

The State agency did not establish procedures to report interest received as required by Federal rules and regulations, but instead, included interest as a rebate collection on the Form CMS 64.9R. According to the State Medicaid Manual, interest should be reported separately on the Form 64 summary sheet. Reporting interest revenue on Form 64.9R caused the drug rebate receivables to be understated. Due to the lack of internal controls over the drug rebate program, we were unable to determine the amount of the understatement.

As a result, drug rebate collections reported by the State agency on the Form 64.9R were overstated and the receivable balance was understated.

$0 URA's

The State agency did not adequately track and bill $0 URA line items as required. The Code of Federal Regulations, Title 45 Sec. 74.21 paragraph (b)(3) requires states to adequately safeguard assets. In addition, the CMS Medicaid Drug Rebate Program Release #33 requires states to include $0 URA's on the quarterly invoices sent to the manufacturers. Manufacturers are required to calculate the correct URA and remit the appropriate rebate to the State agency. In some cases, the manufacturer may not comply, requiring the State agency to track those amounts until payment is made in order to adequately safeguard assets.

The State agency was not tracking and billing $0 URA's adequately. ACS used DRAMS to create the invoices that were sent to the manufacturers and the invoices included the $0 URAs as required. However, the State agency considered an invoice paid in full when the amount billed was paid, regardless of how many $0 URA's were included on the invoice.

The State agency's position was that they could only dispute units, not URA amounts. Since the units were billed at $0, they were considered "paid." Therefore, they did not re-bill for the unpaid $0 URAs and did not adequately track them in the DRAMS system.

As a result, some drug rebate receivables may remain uncollected. Moreover, the lack of sufficient internal controls resulted in a potential risk for fraud, waste, or abuse of drug rebate program funds.

Dispute Resolution

The State agency did not utilize state hearings to resolve disputes as required by the rebate agreement. Specifically, the rebate agreement requires that the State and the manufacturers resolve rebate discrepancies within 60 days of receipt of notification of a dispute. It further states, "In the event that the State and the manufacturer are not able to resolve a discrepancy within 60 days, CMS shall require the State to make available to the manufacturer the State's hearing mechanism available under the Medicaid program."

Instead, the State agency contacted manufacturers directly and utilized Dispute Resolution Program (DRP) meetings for those manufacturers who attended. Furthermore, they did not actively pursue disputes that were not adjudicated during DRP meetings or through direct contact. Direct contact generally consisted of a notification letter and perhaps a follow-up letter.

Because manufacturers were not required to attend DRP meetings, there were no incentives for them to resolve claims and there were no other sanctions provided in the regulations. Therefore, we believe the State agency could increase its drug rebate collections by utilizing the State's hearing mechanism.

RECOMMENDATIONS

We recommend that the State agency develop and follow policies and procedures that include:

- Establishing a general ledger accounts receivable control account for drug rebates.
- Developing a subsidiary accounts receivable system for the drug rebate program.
- Reconciling the general ledger control account to the subsidiary ledgers and to the Form CMS 64.9R.
- Reporting interest collections on the Form CMS 64 Summary Sheet.
- Tracking, billing and accounting for all $0 unit rebate amounts.
- Utilizing the State's hearing mechanism to settle disputes after 60 days.

AUDITEE'S RESPONSE AND OIG COMMENTS

The State agency did not concur with our findings and recommendations. "The state believes that the recommendations of the OIG do reflect processes that the state currently has in place to safeguard these assets and that no changes are necessary in the Wyoming program at this time." Their comments are summarized below and included in their entirety as Appendix A.

1) **Maintain a general ledger control account for drug rebate receivables.**

Auditee Response:

The State agency did not agree that a general ledger control account was necessary to record and maintain drug rebate accounts receivable because they posted amounts billed, collected and disputed to the Form CMS 64.9R from the DRAMS tracking system. They further stated that the State "operates on a cash basis" and that they "would only record an accrual if the value was certain, material and collectible. Moreover, the State agency responded that the amount in question by the OIG audit is only about $260,000 over the course of eight years with the major potion of the amount in dispute, and therefore, is questionable as to its collections. This amount represents about 0.17% of the state's net pharmacy payments over the same eight-year period and is not considered by the State to be a material issue.

OIG Comments:

The State agency did not dispute the fact that a general ledger control account was not maintained. They implied that the various sources they used to compile the Form CMS 64.9R were sufficient in the absence of a general ledger control account. As we reported in our finding, the use of a general ledger is required by GAAP.

Without a general ledger control account for the rebate accounts receivable, the State agency had no assurance that balances in the subsidiary ledgers and the rebate balances reported to CMS were correct. For example, a simple posting error to the subsidiary ledger would not be detected. Moreover, an authorized write-off of an account balance could be processed without detection.

While the State responded with an analysis on why the receivable balance is immaterial, we disagree with the analysis on several key points.

1) We did not question $260,000 in our audit, and we do not know where the State arrived at the $260,000 figure as the starting point of its materiality analysis.

2) The State made a calculation over an eight-year period to determine that the receivable balance was immaterial. Because a receivable is a balance sheet line item, it is calculated as of a specific date in time, not over a time period.

3) The State indicated that much of the receivable balance is questionable as to collection. However, the State collected, on average $1.7 million per quarter. The State agency reported to CMS as of June 30, 2002, a drug rebate receivable balance of $1.2 million. We believe that much of the $1.2 million receivable that was reported to CMS as of June 30, 2002 consisted of recently billed receivables that were likely to be collected.

We would also point out that by not following the Governmental Accounting Standards, GAAP and CMS Medicaid drug rebate program requirements, the State agency has exposed the drug rebate program funds to an unnecessary level of risk for fraud, waste and abuse. We believe that the State agency should properly safeguard its assets to ensure that collections are maximized.

2) Develop a subsidiary accounts receivable ledger system for the drug rebate program. And

3) Reconcile the general ledger control account to the subsidiary ledgers and to the Form CMS 64.9R.

Auditee Response:

The State agency implied that the DRAMS program was sufficient to be considered as a subsidiary ledger. They went on to cite the $378 million credit balance we reported as evidence that we lacked understanding and were simply being arbitrary, capricious and inflammatory.

The State agency did not agree that they should reconcile amounts reported between the general ledger, subsidiary ledgers and the Form CMS 64.9R. They asserted that they reconciled collections with a deposit database maintained by their Fiscal Office and used the "Rebate Summary Report" produced by the DRAMS to properly report disputes and to allocate collections to prior quarters.

OIG Comments:

The DRAMS created invoices and tracked payments from manufacturers. We believe that it could not be considered an adequate subsidiary ledger because it contained only amounts billed and collected, but not details of all adjustments made to the individual accounts. A complete audit trail is needed to verify that the amounts billed and adjusted are properly supported by source documentation.

The State Agency uses selected data from the DRAMS to report rebate activity to CMS on the Form CMS 64.9R. However, as we reported, the DRAMS balance for accounts receivable, was negative $378 million while the accounts receivable balance reported to CMS as of June 30, 2002 was positive $1.2 million. The State agency was unaware of

this discrepancy even though the incorrect balances caused by the error existed in DRAMS for several years. Only after being notified by the auditors was the error corrected.

We completely agree with the State agency's response that a programming error caused this significant dollar discrepancy. However, our issue is not with the error itself, but our concern is the failure of the State agency's internal control system to detect the error in a timely manner. We believe that this clearly demonstrates that their internal controls are not adequate to prevent or detect significant errors.

Accordingly, we believe corrective action is necessary. Specifically, the existence of a general ledger and routine reconciliations between the general ledger and the subsidiary ledger would have detected the $378 million dollar programming error. Therefore, routine reconciliations would provide the State agency reasonable assurance that assets are adequately safeguarded and rebate activity reported to CMS is accurate. In addition, the State agency needs to develop a subsidiary accounts receivable system for the drug rebate program that maintains a complete audit trail of all rebate activity.

4) Reporting interest collections on the Form CMS 64 Summary Sheet.

Auditee Response:

The State agency did not agree with our recommendation. They contend that interest related to drug rebates is "immaterial" and that is sufficient justification to include interest as part of the drug rebate collections.

OIG Comments:

The State Medicaid Manual requires the State to report interest on the Form 64 Summary Sheet because the Form CMS 64.9R does not have a separate line to capture interest. The State agency reported interest received as "rebates reported" on the Form CMS 64.9R. Because CMS designed the form to subtract rebates reported from the rebate balance to arrive at the ending rebate receivable balance, the State agency's treatment of interest results in an understatement of rebates receivable reported to CMS.

While the State agency believes the amount of interest collections is immaterial, we believe that the State's current treatment of interest will hinder a proper reconciliation. To properly safeguard the rebate receivables and ensure that the information reported to CMS is accurate, we believe a reconciliation of the Form CMS 64.9R to the underlying accounting information at the State agency is necessary. However, the incorrect reporting of interest creates an out of balance condition and will undermine the State's ability to safeguard the assets and ensure reported figures are accurate.

We are cognizant of costs associated with implementing recommendations. However, we believe that the State agency can implement this recommendation at virtually no cost. The amount of interest received can be identified in DRAMS each quarter and reported to

CMS on the correct form. By doing so, the State agency will be compliant with the State Medicaid Manual requirement. Also, proper classification of the interest will facilitate the reconciliation process.

5) Tracking, billing and accounting for all $0 unit rebate amounts.

Auditee Response:

The State agency believes that the OIG is mistaken about the $0 URA process. They asserted that it is the responsibility of the manufacturers to calculate and remit the proper amount for unit rebate amounts billed at $0. They contend that they must wait for a "revised CMS URA list" to provide an amount, then they apply the revised unit rebate amount to the utilization figures and offset that amount by the payment received.

OIG Comments:

While the State agency believes that it is effectively processing $0 URAs, we believe that they need to improve the internal controls over $0 URAs. Specifically, our finding relates to situations in which the manufacturer remits a partial payment on an invoice, but fails to calculate a rebate amount and include a payment for a $0 URA item.

We understand that the current process for invoicing numerous $0 URAs causes accounting problems for the States. We intend to use the results of our statewide rebate audits and make recommendations to CMS to improve this process. In the meantime, because of problems associated with $0 URAs caused by the current process mandated by CMS, we believe that the State agency needs to do a better job tracking the unpaid $0 URAs. At a minimum, the State agency should be able to identify how many unpaid URA's are in the system and identify the corresponding NDC's by manufacturer. While it is the manufacturers' responsibility to calculate the rebate amount and submit a payment, we believe that the State needs to track these items, and re-bill them if necessary, to ensure payments are made. Waiting to see if the URA is "revised" on next quarter's CMS tape is not sufficient.

6) Utilizing the State's hearing mechanism to settle disputes after 60 days.

Auditee Response:

The State agency believed we were mistaken about the dispute resolution process. They explained that they contact manufacturers directly and participate in the Dispute Resolution Program. They continued with the prospect that drug manufacturers would not request such a hearing since Wyoming represents such a small percentage of the national drug rebate program.

OIG Comments:

The State agency indicated that they have not received any requests for a hearing from a manufacturer. However, there is no provision in the rebate agreement that requires a manufacturer to request a hearing. Instead, the manufacturer is required to notify the State, in writing, of any unresolved discrepancies prior to the due date. Furthermore, the rebate agreement states that: "In the event that the State and the manufacturer are not able to resolve a discrepancy within 60 days, CMS shall require the State to make available to the manufacturer the State's hearing mechanism available under the Medicaid Program."

Some manufacturers interpret these provisions to mean the disputes are automatically resolved in their favor if the states do not formally respond to their written disputes within 60 days offering a hearing. Therefore, we believe, at a minimum, the State agency should offer the State hearing mechanism to settle disputes when the State has received a written notice of dispute from a manufacturer.

OIG REFERRAL

As reported above, we believe that the State agency does not have effective internal controls to monitor the Medicaid drug rebate program. Specifically, the State agency did not comply with provisions of GAAP, the State Medicaid Manual, and the rebate agreement. Averaging more than $1.7 million per quarter in rebate collections and reporting a balance of $1.2 million in outstanding receivables, we believe the rebate program needs better internal controls.

Therefore, we have referred this matter to Pam Robinson, Administrator, Wyoming Department of Audit, Public Funds Division for a follow-up audit.

Sincerely,

Jack Morman

for James P. Aasmundstad
Regional Inspector General
for Audit Services

Wyoming Department of Health

Dave Freudenthal, Governor
Deborah K. Fleming, Ph.D., Director

April 30, 2003

James P. Aasmundstad
Regional Inspector General for Audit Services
Department of Health and Human Services
Region VII
601 East 12th Street
Room 284A
Kansas City, Missouri 64106

Dear Mr. Aasmundstad:

We have reviewed the copy of the U.S. Department of Health and Human Services, Office of Inspector General, Office of Audit Service's draft report entitled "Audit of the Medicaid Drug Rebate Program in Wyoming." We also reviewed the findings contained in the report with our fiscal agent (ACS Healthcare or ACS) and the fiscal staff of the Wyoming Department of Health (WDH). We disagree with the OIG findings.

We believe that the OIG findings are arbitrary and capricious. We also believe that:

- The report indicates a complete lack of understanding of the Wyoming system for managing drug rebates,
- The OIG has misstated the facts surrounding the state's drug rebate program, and
- Those misstatements may lead the reader to incorrect conclusions regarding the state's management of the drug rebate program and the national drug rebate program as a whole.

The OIG report states that WDH/ACS "...lacked sufficient internal controls with regard to the Medicaid drug rebate program as required by federal rules and regulation." The OIG report goes on to state that the following specific areas lacked sufficient internal controls:

- Recording accounts receivable.
- Form CMS 64.9R and general ledger reconciliation.
- Interest reporting.
- Tracking amounts related to $0 unit rebate amounts.
- Dispute resolution.

Our response below will discuss each finding in the order presented by the OIG audit report.

Recording accounts receivable

The OIG report states that WDH/ACS did not maintain applicable general and subsidiary ledgers necessary to properly safeguard assets. The state disagrees.

ACS maintains the Drug Rebate Analysis and Management System (DRAMS) that is, in general, the subsidiary ledger. DRAMS is used to prepare invoices to drug manufactures for drug rebates and to track payments received. Invoices are prepared quarterly based on the amount of prescription drug units paid on claims processed through the ACS point-of-sale system (i.e. on-line claims submission). The drug units are multiplied by the drug unit rebate amount (URA) provided quarterly by the Center for Medicare and Medicaid Services (CMS). The information submitted by CMS reflects the current nationally negotiated URA for each drug (or NDC) and may change from fiscal quarter to fiscal quarter. Current balances due from each manufacturer can be determined by running a query against the DRAMS database.

As far as a general ledger is concerned, ACS uses the DRAMS system to produce a quarterly report that summarizes billings, collections and disputed amounts. The collections stated on the report are reconciled with the deposit database maintained in the WDH Fiscal Office. The reconciled collections, as well as the reported billed and disputed amounts, are posted to the form CMS 64.9R.

The OIG report suggests that since DRAMS did not retain the original billed amount or adjustments, that the system lacked an audit trail. However, the drug manufacturers set the per URA. Since it is the final per unit drug rebate amount that is relevant to the receivable value, it is irrelevant to maintain the history of URAs. Since the value of the receivable is the number of units multiplied by the current URA, then DRAMS does show the appropriate value of the receivables, reports that value to the WDH Fiscal Division, and is included in the form CMS 64.9R.

It should be stated at this point that the state operates on a cash basis and credits the collection of drug rebates against the pharmacy claim expenditures. The state records accruals at year-end in order to present receivables and payables on the statewide financial report. Additionally, the state would only record an accrual if the value was certain, material and collectible. The amount in question by the OIG audit is only about $260,000 over the course of eight years with the major portion of that amount in dispute, and therefore, is questionable as to its collection. This amount represents about 0.17% of the state's net pharmacy payments over the same eight-year period and is not considered by the state to be a material issue.

The OIG report states that DRAMS showed an accounts payable of $378 million due at the end of state fiscal year 2000. The report footnotes this issue stating that "The large credit balance was primarily due to billing errors on two invoices to a single manufacturer." This statement shows a lack of understanding by OIG and the arbitrary and capricious nature of the report. As explained to the auditors, the credit balance was related to one drug (Novo Nordisk NDC 00169706201) that is invoiced in DRAMS with one vial equal to one unit. However, Wyoming pharmacies are instructed to bill 4,800 units per vial. This 4,800 to 1 conversion error caused the overstated payable. The net affect is that the overstated payable of $378 million is a more

reasonable $78,000 ($378 million divided by 4,800). This problem has been fixed in the system and was communicated to the OIG audit staff. Its inclusion in the findings is inflammatory and provides nothing constructive to report.

Additionally, OIG's concern relating to this overstated payable defies any reasonableness tests that could be applied to the amount. Wyoming's entire Medicaid budget is only about $320 million per year. In the past 8 years, the Prescription Drug Program in Medicaid has paid out about $150 million in drug claims net of drug rebate. Obviously, reasonableness tests on the $378 million payable and the discussion with ACS staff should have proved to OIG that the issue was a programming error that ACS had corrected.

Form CMS 64.9R and general ledger reconciliation

The OIG report states that the WDH Fiscal Office did not:

1) Reconcile the rebate collections on the cash receipts log to the collections reported on the form CMS 64.9R,
2) Properly allocate collections to the proper quarters on the form CMS 64.9R, and
3) Improperly applied disputed rebates as adjustments to prior quarter uncollected rebate balances on the form CMS 64.9R.

We believe that OIG is mistaken as to the process. As previously stated, the WDH Fiscal Office does reconcile collections reported on the DRAMS "Rebate Summary Report" to our deposit database prior to reporting them on the form CMS 64.9R. The state also uses the DRAMS "Rebate Summary Report" to post collections related to prior quarters to the form CMS 64.9R. The state also uses the DRAMS "Rebate Summary Report" to properly report disputed rebates as adjustments to prior quarters.

Therefore, we disagree with the OIG findings stated above and the OIG statement that "...routine reconciliations could not be performed to verify the accuracy of the reported uncollected rebate balances and collections on the Form 64.9R..." and that the state "...did not have reasonable assurance that drug rebate program activity reported to CMS was accurate."

Interest Reporting

Interest revenue from the drug rebate program is minimal, running less than $1,000 per quarter. The state believes that this amount is immaterial compared to overall collections in the Wyoming drug rebate program, and therefore, we include the interest revenue as part of drug rebate collections reported on form CMS 64.9R.

$0 URA's

The state believes that OIG is mistaken about the $0 URA process.

OIG states clearly in their report that "...Manufacturers are required to calculate the correct URA and remit the appropriate rebate to the state agency." ACS follows just such a principle and requires manufacturers to submit their payments for $0 URAs with the corrected URAs. In essence, the federal

system allows the manufacturers to value those rebates and submit payment. The state and ACS must accept the value as correct until CMS provides an updated list of URA's. DRAMS would then show the corrected URA offset by the manufacturers payment.

We believe that OIG feels that since ACS waits for the revised CMS URA list, that ACS does not pursue payment on items originally invoiced with a $0 URA. The opposite is true in that no value can be established until a URA is posted in DRAMS. Once the URA is posted, the value is then computed and offset by payments received.

Dispute Resolutions

The state believes that OIG is mistaken about the dispute resolution process.

ACS does contact manufacturers directly, works through the Dispute Resolution Program (DRP) with CMS and manufacturers, and contacts CMS directly for assistance with dispute resolution. These methods have worked well for Wyoming since our "hearing mechanisms" are geared to deal with Medicaid provider and/or recipient disputes, not disputes with drug manufacturers. It is not reasonable to assume that drug manufacturers would even request a hearing in Wyoming since the volume and value of the rebates received by Wyoming represent such a small percentage of the national drug rebate program.

Summary

In Conclusion, the state disagrees with the findings reported by the OIG, believes that several of the findings are misleading and/or inflammatory. The state believes that the recommendations of the OIG do reflect processes that the state currently has in place to safeguard these assets and that no changes are necessary in the Wyoming program at this time.

Sincerely,

Jeff Urry

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Audit of the Medicaid Drug Rebate Program in Wyoming

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