DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General
Offices of Audit Services

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

October 8, 2003

Report Number A-07-03-04019

Mr. Dave Zetner,
Director, Medical Services
North Dakota Department of Human Services
600 E. Boulevard Ave.
Bismarck, ND 58505-0250

Dear Mr. Zetner:

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) report entitled *"Audit of the Medicaid Drug Rebate Program in North Dakota."*

The audit objective was to evaluate whether the North Dakota Department of Human Services (DHS) had established adequate accountability and internal controls over the Medicaid drug rebate program.

We determined the DHS had adequate controls over the drug rebate program as required by Federal regulations except for billing and tracking $0 unit rebate amount(s) (URA's). Specifically, Federal regulations require effective control over and accountability for all funds, property and other assets. This issue occurred because the DHS did not develop or follow adequate policies and procedures with regard to $0 URAs. As a result of the $0 URA issue, drug rebate receivables were perpetually understated and the DHS may not have received all possible drug rebates due from manufacturers.

We recommend that at a minimum, the DHS should develop and follow policies and procedures that include controls designed to track $0 URA line items and generate notifications to manufacturers when they fail to compute the proper URA amount and remit payment. Such controls should allow for the DHS to identify the outstanding $0 URA's by manufacturer and to distinguish between those that represent disputed amounts or that were not paid when due.

The Department concurred with our finding and agreed to take appropriate corrective actions.

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-07-03-04019 in all correspondence relating to this report.

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 VII
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 NORTH DAKOTA

OCTOBER 2003
A-07-03-04019

Office of Inspector General

http://oig.hhs.gov/

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The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. The OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within the Department. The OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops model compliance plans, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

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THIS REPORT IS AVAILABLE TO THE PUBLIC
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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.

EXECUTIVE SUMMARY

OBJECTIVE

The audit objective was to evaluate whether the North Dakota Department of Human Services (DHS) had established adequate accountability and internal controls over the Medicaid drug rebate program.

FINDINGS

We determined that the DHS generally had sufficient internal controls with regard to the Medicaid drug rebate program as required by Federal rules and regulations except for tracking and pursuing $0 unit rebate amount(s) (URA's).

This issue occurred because the DHS did not develop or follow adequate policies and procedures with regard to $0 URA's. Federal regulations require effective control over and accountability for all funds, property and other assets. Several other minor control issues were discussed with DHS officials who agreed to take corrective actions. Therefore, we did not consider those issues to be material to our review and did not report them.

As a result of the $0 URA issue, the drug rebate receivables were perpetually understated and DHS may not have received all possible drug rebates due from manufacturers.

RECOMMENDATIONS

We recommend that at a minimum, the DHS should develop and follow policies and procedures that include controls designed to track $0 URA line items and generate notifications to manufacturers when they fail to compute the proper URA amount and remit payment. Such controls should allow for the DHS to identify the outstanding $0 URA's by manufacturer and to distinguish between those that represent disputed amounts or that were not paid when due.

The DHS officials concurred with our finding. Their written response to our draft report is included as Appendix A.

INTRODUCTION

BACKGROUND

On November 5, 1990, Congress enacted the Omnibus Budget Reconciliation Act 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 URA's, the State agency is instructed to invoice the units and the manufacturer is required to calculate the URA and remit the appropriate rebate to the State agency. In addition, the manufacturers are allowed to change any URA based on updated pricing information, and submit this information to the State agency in a Prior Quarter Adjustment Statement.

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 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.

The manufacturer is required to calculate and remit interest for late payments or disputed rebates when settlement is made in favor of the State. Governmental Accounting and Financial Reporting Standards require states to calculate and accrue a reasonable estimate of the interest owed. Tracking interest owed to the State agency is required by CMS.

Each State agency reports, on a quarterly basis, drug rebate program activity 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. Specifically, states report rebates invoiced in the current quarter, rebates received during the current quarter, and uncollected rebate balances for the current and prior quarters on the Form CMS 64.9R.

The DHS reported an uncollected rebate balance of $3,541,180 on the Form CMS 64.9R dated June 30, 2002. That report also disclosed that $795,185 represented uncollected rebate balances over 90 days old. The average collections per quarter during our audit period were $2,415,790.

OBJECTIVE, SCOPE AND METHODOLOGY

Objectives

The audit objective was to evaluate whether the DHS had established adequate accountability and internal controls over the Medicaid drug rebate program.

Scope

The drug rebate program was effective January 1, 1991. We concentrated our review on the current policies, procedures and controls of the DHS. We also interviewed DHS staff to understand how the Medicaid drug rebate program has operated since 1991.

Methodology

To accomplish 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 and the Office of Management and Budget Circular A-87.

We examined copies of the Form CMS 64.9R reports for the period July 1, 2001 through June 30, 2002 submitted to CMS by the State of North Dakota. We also obtained and reviewed drug rebate accounts receivable records. Finally, we interviewed DHS staff that performed functions related to the drug rebate program.

Our fieldwork was conducted at the DHS office in Bismarck, North Dakota during July 2003, and continued in the Office of Audit Services field office in Denver, Colorado through August 2003.

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

FINDINGS AND RECOMMENDATIONS

We determined that the DHS generally had sufficient internal controls with regard to the Medicaid drug rebate program as required by Federal rules and regulations except for tracking and pursuing $0 URA's.

INTERNAL CONTROLS

Tracking $0 URA's

The DHS did not have sufficient controls to track $0 URA's to ensure payment from the manufacturers. Title 45 CFR 74.21 (3) requires "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."

DHS billed the $0 URA's in accordance with CMS regulations and their accounting system properly recorded $0 URA's that were billed. However, no further action was taken until the URA was calculated and paid by the manufacturer, or until the URA was updated by CMS on a subsequent tape. Furthermore, there was no indication of the status of the $0 URA with regard to whether it was disputed or simply not calculated and paid by the manufacturer as required by CMS.

In either case, the manufacturer should be notified to initiate the appropriate action. If the $0 URA was disputed, the DHS should begin the dispute resolution process. If payment was not calculated and submitted on time as required by the rebate agreement, the DHS should notify the manufacturer and begin accruing interest.

As a result of the $0 URA issue, the drug rebate receivables were perpetually understated and DHS may not have received all possible drug rebates due from manufacturers.

RECOMMENDATIONS

We recommend that at a minimum, the DHS should develop and follow policies and procedures that include controls designed to track $0 URA line items and generate notifications to manufacturers when they fail to compute the proper URA amount and remit payment. Such controls should allow for the DHS to identify the outstanding $0 URA's by manufacturer and to distinguish between those that represent disputed amounts or that were not paid when due.

AUDITEE'S RESPONSE

The DHS officials concurred with our finding. Their written response to our draft report is included as Appendix A.

NORTH DAKOTA DEPARTMENT OF HUMAN SERVICES

John Hoeven, Governor
Carol K. Olson, Executive Director

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October 3, 2003

Mr. James P. Aasmundstad
Regional Inspector General for Audit Services
Region VII
601 E 12th St Rm 284A
Kansas City MO 64106

Re: A-07-03-04018

Dear Mr. Aasmundstad:

Below you will find our response to the draft "*Audit of the Medicaid Drug Rebate Program in North Dakota*" dated September 5, 2003. We appreciated the opportunity to interact with your staff and firmly believe that improvements will be made in our drug rebate program as a direct result of this interaction.

Finding

". . . DHS generally had sufficient internal controls . . . except for tracking and pursuing $0 URA's."

Response

North Dakota agrees that $0 URA tracking and pursuing needs to improve. Previously, we had depended on the data received quarterly from CMS to update these URA's appropriately. Thanks to your auditors and the findings in other states, we realize that we cannot depend upon CMS for this information and we must develop a method to track and pursue resolution of these $0 URA's independently.

Our first step will involve developing a process to continually identify all $0 URA's. We will then establish a procedure for contacting manufacturers to establish accurate amounts for the URA's. As the auditors noted, once the URA is no longer a zero dollar amount, our current system functions appropriately to ensure collection of the rebates.

Sincerely,

David J. Zentner
Director, Medical Services