DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF AUDIT SERVICES
233 NORTH MICHIGAN AVENUE
CHICAGO, ILLINOIS 60601

REGION V
OFFICE OF
INSPECTOR GENERAL

July 7, 2003

Report Number. A-05-03-00045

Kevin Goodno, Commissioner
Minnesota Department of Human Services
444 Lafayette Road North
St. Paul, Minnesota 55155

Dear Mr. Goodno:

Enclosed are two copies of the U.S. Department of Health and Human Services, Office of Inspector General (OIG), Office of Audit Services (OAS)' final report entitled "Review of Medicaid Drug Rebates Program - State of Minnesota." This audit was conducted as part of a nationwide review of Medicaid drug rebate collections in various states. Should you have any questions or comments concerning the matters commented on in this report, please direct them to the HHS action official named below.

In accordance with the principles of the Freedom of Information Act, 5 U.S.C. 552, as amended by Public Law 104-231, OIG, OAS reports issued to the department's grantees and contractors are made available, if requested, 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.)

Should you have any questions or comments concerning the matters contained in this report, please do not hesitate to contact Ross Anderson, Audit Manager, call me at (312)-353-8663 or through e-mail at RANDERSON@OIG.HHS.GOV. To facilitate identification, please refer to report number A-05-03-00045 in all correspondence.

Sincerely yours,

Paul Swanson

Paul Swanson
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Cheryl Harris, Associate Regional Administrator
Division of Medicaid and Children's Health
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
233 North Michigan Avenue, Suite 600
Chicago, Illinois 60601-5519

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF THE MEDICAID DRUG REBATE PROGRAM STATE OF MINNESOTA

MINNESOTA DEPARTMENT OF HUMAN SERVICES ST. PAUL, MINNESOTA

JUNE 2003
A-05-03-00045

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:

Office of Audit Services

The OIG's Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout the department.

Office of Evaluation and Inspections

The OIG's Office of Evaluation and Inspections (OEI) conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the department, the Congress, and the public. The findings and recommendations contained in the inspections reports generate rapid, accurate, and up-to-date information on the efficiency, vulnerability, and effectiveness of departmental programs.

Office of Investigations

The OIG's Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil monetary penalties. The OI also oversees state Medicaid fraud control units, which investigate and prosecute fraud and patient abuse in the Medicaid program.

Office of Counsel to the Inspector General

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.

EXECUTIVE SUMMARY

OBJECTIVE

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

RESULTS OF REVIEW

The DHS had established adequate accountability and internal controls over the drug rebate program, as required by federal rules and regulations.

Federal regulations require that financial management systems provide for 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 manufacturer(s) require the payment of interest on all disputed, late, and unpaid drug rebates.

Specific areas reviewed that were determined to incorporate sufficient accountability and controls included:

- accounts receivable system,
- segregation of duties,
- Form CMS 64.9R reconciliation,
- billing for interest, and
- dispute resolution.

In our opinion, DHS established adequate accountability and internal control over its Medicaid drug rebate program. The financial management system used by DHS provided the necessary information to comply with Federal regulations.

TABLE OF CONTENTS

Glossary of Abbreviations and Acronyms

ARC	Automated Receipts Center
CFR	Code of Federal Regulations
CMS	Centers for Medicare and Medicaid Services
Consultec	Formerly know as Affiliate Computer Services
DHS	Minnesota Department of Human Services
DRAMS	Drug Rebate Analysis and Management System
MAPS	Minnesota Accounting and Procurement System
NDC	National Drug Code
OBRA	Omnibus Budget Reconciliation Act
PQAS	Prior Quarter Adjustment Statement
ROSI	Reconciliation of State Invoice
URA	Unit rebate amount

INTRODUCTION

BACKGROUND

On November 5, 1990, Congress enacted the Omnibus Budget Reconciliation Act (OBRA) of 1990 legislation, which established the Medicaid drug rebate program. Responsibility for the rebate program is shared among the drug manufacturers, the Centers for Medicare and Medicaid Services (CMS), and the states. 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 on numerous issues related to the Medicaid drug rebate program.

A drug manufacturer is required to have a rebate agreement in effect with CMS in order to have its products covered under the Medicaid program. After a rebate agreement is signed, the manufacturer is required to submit a listing to CMS of all covered outpatient drugs and to report to CMS its average manufacturer price and best price information for each covered outpatient drug. 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 pricing information has a 50 percent variance from the previous quarter. In instances of $0 URAs, the state agency is instructed to invoice the units, and the manufacturer should pay the rebate based on the manufacturer's information. The manufacturers often change the URA based on updated pricing information and submit this information to the state agency in the Prior Quarter Adjustment Statement (PQAS).

Each state agency is required to maintain drug utilization data for the number of units dispensed, by manufacturer, for each covered drug. Each state agency uses the URA from CMS and the utilization data for each drug to determine the actual rebate amounts due from the manufacturer. The CMS requires each state agency to provide drug utilization data to the manufacturer. Approximately 56,000 National Drug Codes (NDCs) are available under the program.

To avoid interest, the manufacturer must remit payment within 38 days of the invoice being sent. The manufacturers submit a Reconciliation of State Invoice (ROSI) to the state agency that details the current quarter's payment by NDC. A manufacturer can dispute utilization data that it believes is erroneous but is required to pay the undisputed portion by the due date. If the manufacturer and the state agency cannot in good faith resolve the discrepancy, the manufacturer must provide written notification to the state agency by the due date. If the state agency and the manufacturer are not able to resolve the discrepancy within 60 days, the state agency must make a hearing mechanism available under the Medicaid program to the manufacturer in order to resolve the dispute.

On a quarterly basis, each state agency reports outpatient drug expenditures and rebate

collections on the Form CMS 64.9R. This report is part of the Form CMS 64 report, which summarizes actual Medicaid expenditures for each quarter and is used by CMS to reimburse the federal share of these expenditures. The Minnesota Department of Human Services (DHS) reported to CMS an average of $15 million in billings per quarter and collections of $15.1 million per quarter during the 1-year period ending June 30, 2002. On the CMS 64.9R as of June 30, 2002, the DHS reported $21.7 million as the outstanding balance, with approximately $5 million of the uncollected rebates outstanding over 90-days.

During the year 2000, the DHS changed the financial system used to administer the Medicaid drug rebate program to a new software system, Drug Rebate Analysis and Management System (DRAMS). It was the result of a joint effort between Consultec (formerly known as Affiliate Computer Services) and the States of Minnesota and Montana. This software allocated revenue over units of specific NDCs in specific quarters. Thus, the number of units billed, paid, and disputed for a given NDC in any quarter were easily identifiable and recorded.

OBJECTIVE, SCOPE AND METHODOLOGY

Objective

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 as of June 30, 2002. We also reviewed accounts receivable information related to prior periods and interviewed DHS staff to understand how the Medicaid drug rebate program has operated since 1991.

Methodology

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

Field work was performed at the DHS office in St. Paul, Minnesota, and continued in our field office in Madison, Wisconsin, during March and April 2003. Our audit was performed in accordance with generally accepted government auditing standards.

RESULTS OF REVIEW

The DHS had established adequate accountability and internal controls over the drug rebate program, as required by federal rules and regulations. Significant areas reviewed that were determined to incorporate sufficient accountability controls included:

- accounts receivable system,
- segregation of duties,
- Form CMS 64.9R reconciliation,
- billing for interest, and
- dispute resolution.

Title 45, Sec. 74.21, paragraph (b)(3), of the Code of Federal Regulations requires that financial management systems provide effective control over and accountability for all funds, property, and other assets. In addition, the rebate agreements between CMS and the drug manufacturers require the payment of interest on all disputed, late, and unpaid drug rebates.

Accounts Receivables

The DHS accounts receivable system was sufficiently detailed to accurately monitor rebate collections. The DHS maintained a general ledger including control accounts for its medical assistance programs. Medicaid rebate drug program receipts were recorded as credits to these general ledger control accounts. The Drug Rebate Analysis and Management System (DRAMS) maintained subsidiary accounts receivable information that was reconciled on a monthly basis to the rebate receipts recorded in the general ledger control accounts. The subsidiary receivable information in DRAMS allowed analysis at various levels of detail including the total for: a manufacturer, a NDC, or a specific originating invoice. The availability of such detailed information, along with the monthly reconciliation process, confirmed that DHS had established adequate accountability and internal controls over the drug rebate program as required by federal rules and regulations.

Segregation Of Duties

The DHS sufficiently segregated duties between the cash receipts, general ledger, and subsidiary ledger accounting functions.

Medicaid drug rebate receipts and related supporting documents from manufacturers were received by the DHS Automated Receipts Center (ARC). The ARC included multiple, cross-trained individuals, who prepared a daily report listing checks making up the daily deposit. The Medicaid drug rebate portion of this list and related manufacturer support were forwarded to the DHS Pharmacy Services area, where drug rebate staff make the appropriate entries into DRAMS.

General ledger accounts were segregated from subsidiary account data. General ledger accounts were maintained in the Minnesota Accounting and Procurement System (MAPS), which integrates accounting with procurement activities. The Pharmacy Services area

maintained subsidiary account information in DRAMS, thus, allowing invoicing and recording of rebate payments received by NDC.

The DHS segregation of duties reduced the potential risk for waste, fraud, or abuse of the drug rebate program funds.

CMS 64.9R Reconciliation

The DHS reconciled reported rebates from Form CMS 64.9R to general ledger and subsidiary accounting records. The CMS 64.9R report is used by the states to report the results of the Medicaid drug rebate program. 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, the 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.

Pharmacy Services rebate staff reviewed the DRAMS subsidiary account data for each quarter. After determining what the deposits related to the quarter, they prepared the Form CMS 64.9R and provided it to DHS Financial Management staff. This staff was responsible for ensuring that reported rebate receipts on the Form CMS 64.9R agreed with rebate revenue recorded in the general ledger control accounts. This unit also verified that the quarter's collected and reported rebates on the 64.9R agreed with the sum of rebates recorded on lines 7A1 and 7A2 of Form CMS 64.9.

The DHS pharmacy claim data is loaded into DRAMS, which incorporated pre-set parameters for identifying claims that should be researched by DHS rebate staff. The rebate staff then compared paid pharmacy claims data used by DRAMS to a separate database of all DHS paid claims. This check ensured that DRAMS did not miss any paid pharmacy claims.

Interest on Late, Disputed, and Unpaid Rebates

The DHS had adequate controls to accrue interest for late, disputed, and unpaid rebate payments.

According to CMS Medicaid Drug Rebate Program Release #65, it is the manufacturers' responsibility to calculate and pay interest for applicable rebate invoices and the state's responsibility to track and report collection amounts to CMS. Program Release #29 requires that interest be collected and not be disregarded by either the manufacturer or the state, as part of the dispute resolution process.

The DHS drug rebate staff elects whether to have DRAMS compute, and include interest. They usually recognize a $10 threshold, which was published in the Minnesota Drug Rebate Operational Manual. By contrast, CMS Medicaid Drug Rebate Program Release #48 allows each state to exclude interest calculations on any unpaid rebate amount up to $50. The DRAMS can compute interest for late payments for each NDC. If any interest is computed for a manufacturer, it would be included on the next invoice to that manufacturer. The Drug

Rebate group highlights the interest due on the invoice, and any continuing unpaid interest will be included on future invoices. The DHS had a procedure in place to verify that manufacturers paid interest correctly, as disputes were resolved.

Dispute Resolution

The level of detail maintained by the DRAMS database made it possible to determine how many units were billed, paid, and disputed. The DRAMS reports showed manufacturer's disputed units, dollars by NDC, and total disputed dollars by manufacturer.

When manufacturers questioned an invoice, the rebate staff attempted to avoid a dispute by investigating the NDC and answering the manufacturer's questions within 2 days. They would send the manufacturer a State Adjustment Statement, supported by claim detail. If units were actually placed in dispute, DHS policy included the following steps:

- Involve the manufacturers in the resolution process;
- Exchange data;
- Prepare spreadsheets of NDC claim history;
- Review claim history for errors and contact providers, as necessary;
- Prepare a dispute resolution worksheet; and
- Provide a CD with the audited claim data; as well as, the resolution worksheet.

Conclusion: The DHS established adequate accountability and internal control over its Medicaid rebate drug rebate program. The financial management system used by DHS provides the necessary information to comply with Federal regulations. Therefore, we do not offer any recommendations for improving the DHS Medicaid Drug rebate program.