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

REGION V
OFFICE OF
INSPECTOR GENERAL

June 24, 2003

Report Number A-05-03-00044

Barry S. Maram, Director
Illinois Department of Public Aid
201 South Grand Avenue East
Springfield, Illinois 62763

Dear Mr. Maram:

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 Rebate Program - State of Illinois." This review 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 noted 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 the report, please do not hesitate to contact Ross Anderson, Audit Manager, at (312) 353-8663 or through e-mail at RANDERSON@OIG.HHS.GOV. To facilitate identification, please refer to report number A-05-03-00044 in all correspondence.

Sincerely yours,

Paul Swanson

Paul Swanson
Regional Inspector General
for Audit Services

Enclosures – as stated

Direct Reply to HHS Action Official:
Cheryl Harris, Associate Regional Administrator
Division of Medicaid and Children's Health
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
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Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

REVIEW OF MEDICAID DRUG REBATE PROGRAM STATE OF ILLINOIS

ILLINOIS DEPARTMENT OF PUBLIC AID SPRINGFIELD, ILLINOIS

JUNE 2003
A-05-03-00044

Notices

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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. Final determination on these matters will be made by authorized officials of the HHS divisions.

EXECUTIVE SUMMARY

OBJECTIVE

The audit objective was to evaluate whether the Illinois Department of Public Aid (IDPA) had established adequate accountability and internal controls over the Medicaid drug rebate program.

RESULTS OF REVIEW

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

TABLE OF CONTENTS

Glossary of Abbreviations and Acronyms

BFF	Bureau of Federal Finance
CFR	Code of Federal Regulations
CMS	Centers for Medicare and Medicaid Services
CMU	Cash Management Unit
FMAP	Federal Medical Assistance Percentage
GOV	Government
HHS	Health and Human Services, Department of
IDPA	Illinois Department of Public Aid
MRAS	Manufacturers Rebate Accounting System
NDC	National Drug Codes
OBRA 90	Omnibus Budget Reconciliation Act of 1990
OIG	Office of Inspector General
PAAS	Public Aid Accounting System
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 IDPA reported to CMS an average of $49 million in billings per quarter and collections of $50 million per quarter during the 1-year period ending June 30, 2002. On the CMS 64.9R as of June 30, 2002, the IDPA reported $68.1 million as the outstanding balance, with approximately $23.1 million of the uncollected rebates outstanding over 90-days.

The IDPA modified the financial system used to administer the Medicaid drug rebate program during the year 2000. The system improvements 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 IDPA 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 IDPA as of June 30, 2002. We also reviewed accounts receivable information related to prior periods and interviewed IDPA staff to understand how the Medicaid drug rebate program has operated since 1991.

Methodology

To accomplish our objectives, we interviewed IDPA 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 IDPA office in Springfield, Illinois, during February 2003 through April 2003. Our audit was performed in accordance with generally accepted government auditing standards.

RESULTS OF REVIEW

The IDPA 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 Receivable System

The IDPA accounts receivable system was sufficiently detailed to accurately monitor rebate collections. The IDPA 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 IDPA Manufactuers Rebate Accounting System (MRAS) maintained subsidiary accounts receivable information that was reconciled weekly to the rebate receipts recorded in the general ledger control accounts. The subsidiary receivable information in MRAS allowed analysis at various levels of detail including: total for a manufacturer; total for a NDC; or total for a specific originating invoice. The availability of such detailed information, along with the weekly reconciliation process, confirmed that IDPA had established adequate accountability and internal controls over the drug rebate program, as required by federal rules and regulations.

Segregation Of Duties

The IDPA 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 IDPA Cash Management Unit (CMU). The CMU included multiple, cross-trained individuals. The CMU prepared a daily report listing checks making up the days deposit for each area. The Medicaid drug rebate portion of this list and related manufacturer support were forwarded from CMU to the IDPA Drug Rebate Unit area, where drug rebate staff would make the appropriate entries into MRAS.

General ledger accounts were segregated from subsidiary account data. General ledger accounts were maintained in the Public Aid Accounting System (PAAS). The PAAS is interfaced with the MRAS and identifies the amount of money MRAS applies to the paying manufacturer by year and quarter. The IDPA Drug Rebate Unit maintained subsidiary account information in MRAS, allowing invoicing and recording of rebate payments received at the NRC detail level.

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

CMS 64.9R Reconciliation

IDPA 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 state reports 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.

Drug Rebate Unit staff reviewed MRAS subsidiary summary account data for each quarter. After determining what MRAS deposits related to the quarter, they forwarded the MRAS summary reports to the IDPA Bureau of Federal Finance (BFF), which prepares the Form CMS 64.9R. The BFF was responsible for ensuring that reported rebates, received on the MRAS summary reports, agreed to rebate revenue, recorded in the PAAS general ledger control accounts, and for verifying that the quarter's collected rebates, reported on the 64.9R, agreed to the rebates, recorded on line 7A1 of the Form CMS 64.9 report.

As an added control, IDPA pharmacy claim data was loaded into MRAS, which incorporated pre-set parameters for identifying claims that should be researched by IDPA Drug Rebate Unit staff. The rebate staff compared paid pharmacy claims data used by MRAS to a separate database of all IDPA paid claims. This check ensured that MRAS did not miss any paid pharmacy claims.

Interest on Late, Disputed, and Unpaid Rebates

The IDPA had implemented adequate controls to accrue interest for late, disputed and unpaid rebate payments, in accordance with federal rules and regulations. 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 disregarded by either the manufacturer or the State, as part of the dispute resolution process.

To address its collection responsibility, IDPA generates a report, which identifies manufacturers that have not remitted drug rebates 45 days after invoices are mailed. The IDPA compares the elapsed time between payment postmark dates to the invoice date and sends an interest demand letter to manufacturers that have not remitted payments within 38 days of the invoice. The process also generates a demand letter requesting payment of any unpaid amount plus interest. The IDPA has follow-up procedures to ensure that interest for late, disputed, or unpaid amounts collected. The IDPA also has a procedure in place to verify that manufacturers paid interest correctly, as disputes were resolved.

Dispute Resolution

The level of detail maintained by the MRAS database makes it possible to determine how many units were billed, paid, and disputed. MRAS reports show manufactures disputed units, amounts by NDC, and total disputed dollars by manufacturers.

When manufacturers questioned an invoice, the rebate staff attempted to avoid a dispute by investigating the NDC and answering the manufacturer's questions. They send the Proposal Packet to the manufacturer, supported by claim detail. If units were actually placed in dispute, the IDPA policy includes the following steps:

- Involve the manufacturer 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 Resolution Proposal Packet with the claim data; as well as, the resolution worksheet.

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

ACKNOWLEDGMENTS

This report was prepared under the direction of Paul Swanson (RIGA). Other principal Office of Audit Services staff who contributed include:

Ross Anderson, *Audit Manager*
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For information or copies of this report, please contact the Office of Inspector General's Public Affairs office at (202) 619-1343.