



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

REGION V
OFFICE OF
INSPECTOR GENERAL

September 19, 2003

Report Number: A-05-03-00047

Janet Olszewski, Director
Michigan Department of Community Health
Lewis Cass Building, Sixth Floor
320 South Walnut Street
Lansing, Michigan 48913

Dear Ms. Olszewski:

Enclosed are two copies of the Department of Health and Human Services, Office of Inspector General (OIG) final report entitled, "Review of Medicaid Drug Rebate Program - State of Michigan." This audit was conducted as part of a nationwide review of Medicaid drug rebate collections in various states. A copy of the report will be forwarded to the action official noted on page 2 for her review and any action deemed necessary.

Final determination as to actions taken on all matters reported will be made by the HHS action official named on page 2. 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.

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Should you have any questions or comments concerning the matters contained in this 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-05-03-00047 in all correspondence.

Sincerely yours,

A handwritten signature in cursive script that reads "Paul Swanson".

Paul Swanson
Regional Inspector General
for Audit Services

Attachments – as stated

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 MICHIGAN**

**MICHIGAN DEPARTMENT OF
COMMUNITY HEALTH
LANSING, MICHIGAN**



**SEPTEMBER 2003
A-05-03-00047**

Office of Inspector General

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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 Michigan Department of Community Health (Agency) had established adequate accountability and internal controls over the Medicaid drug rebate program.

FINDING

Generally, the Agency had established adequate controls over the Medicaid drug rebate program as required by Federal rules and regulations. First Health Services Corporation, the State contractor (Contractor) had policies and procedures in place that enabled it to keep detailed and accurate records. However, improvement in one area could enhance accountability over drug rebates. Specifically, the Agency had not reconciled the outstanding balance of drug rebate accounts receivable reported on the Centers for Medicare & Medicaid Services (CMS) 64.9R report to the supporting books and records.

Federal regulations at 45 CFR 74.21 require that financial management systems provide for effective control over and accountability for all funds, property, and other assets. Without routine reconciliations, the Agency did not have reasonable assurance that drug rebate information reported to CMS was accurate.

RECOMMENDATION

We recommend the Agency develop policies, procedures, and controls to ensure that the outstanding rebate amount reported to CMS is reconciled with the supporting records.

AGENCY COMMENTS

The Agency agrees with the finding and recommendation and has implemented policies, procedures and controls to ensure that the outstanding rebate amount reported to CMS is reconciled with the supporting records. The complete text of the Agency's comments is included as an appendix to this report.

OFFICE OF INSPECTOR GENERAL RESPONSE

We agree with the corrective action taken, to date, in response to the procedural recommendation.

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Glossary of Abbreviations and Acronyms

Agency Michigan Department of Community Health

CFR Code of Federal Regulations

CMS Centers for Medicare & Medicaid Services

Contractor First Health Services Corporation

NDC National Drug Code

URA Unit rebate amount

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 manufacturers, the Centers for Medicare & Medicaid Services (CMS), and the States. The legislation was effective January 1, 1991. 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 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. 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.

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.

Each State agency is required to maintain drug utilization data for total units dispensed, by manufacturer, for each covered drug. State agencies use the URA from CMS and the utilization data to determine the actual rebate amounts due from the manufacturer. CMS requires each State agency to provide drug utilization data to the manufacturer. Approximately 56,000 national drug codes (NDC) 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 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. The manufacturer is required to calculate and remit interest for any late payments or disputed rebates when settlement is made. It is the State agency's responsibility to track interest owed to the program as required by CMS.

On a quarterly basis, each State agency reports rebates invoiced and collected on the Medicaid Drug Rebate Schedule (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, 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.

The Michigan Department of Community Health (Agency) reported an average of \$38.3 million in billings and \$37.9 million of collections per quarter during the 1-year period ending June 30, 2002. The Agency reported an outstanding balance of \$53.7 million on Form CMS 64.9R as of June 30, 2002 with approximately \$9 million of the uncollected rebates outstanding over 90-days.

The Agency contracted with First Health Services Corporation (Contractor) to administer most of the daily operations of the drug rebate program. The Contractor is responsible for invoicing, posting payments to accounts receivable, reconciling units reported on the Reconciliation of State Invoice to the units invoiced, identifying disputes, researching utilization data to resolve disputes and communicating with drug manufacturers to resolve disputes. The Agency prepares the Form CMS 64 reports and authorizes accounts receivable write-off adjustments and final dispute resolution.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The audit objective was to evaluate whether the Agency 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 Agency and the Contractor. We also reviewed accounts receivable information related to the quarter ending June 30, 2002.

Methodology

To accomplish our objectives, we interviewed Agency and Contractor 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.

Our fieldwork was performed at the Agency offices in Lansing, Michigan during March and April 2003, and continued in the Madison field office in May 2003.

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

FINDING AND RECOMMENDATION

Generally, the Agency had established adequate controls over the Medicaid drug rebate program as required by Federal rules and regulations. The Contractor had policies and procedures in place that enabled it to keep detailed and accurate records. However, improvement in one area could enhance accountability over drug rebates. Specifically, the Agency had not completely reconciled the outstanding balance of drug rebate accounts receivable reported on Form CMS 64.9R report to the Contractor's supporting books and records.

Federal Regulations at 45 CFR 74.21 (b)(3) require that financial management systems provide effective control over and accountability for all funds, property, and other assets.

Controls Established

As part of the Agency's controls over the Medicaid drug rebate program, the Contractor kept detailed and accurate records by: (1) recording all transactions at the NDC level, (2) reconciling units and payments to the original invoices, and (3) recording contacts with the manufacturers. By keeping such a detailed information system, the Agency and Contractor can accurately monitor accounts receivable and effectively pursue collection of outstanding balances from drug manufacturers.

The Agency and Contractor have policies and procedures in place to resolve disputes with manufacturers. Before invoices are sent, the Contractor reviews the number of units and reimbursement amount for reasonableness. After invoices are sent and payments received, the Contractor identifies disputed units during the posting of payments. Once disputes are identified, the Contractor verifies provider data and works to resolve the dispute.

CMS 64.9R Reconciliation

The Agency did not perform a complete reconciliation to verify the accuracy of the uncollected rebate balance reported on the Form CMS 64.9R. The Form CMS 64.9R was prepared by the Agency based on reported totals of invoiced amounts and cash receipts from the Contractor. The ending balance of the prior quarter was rolled forward to become the beginning balance for the current quarter. New rebates invoiced during the current quarter were added, net adjustments to previously reported rebates were applied, and rebate payments received during the current quarter were subtracted to calculate the ending balance. The Agency verified that the ending balance from the previous quarter was the beginning balance for the current quarter. They also reconciled rebates received as reported by the Contractor to actual cash recoveries recorded on the Agency's accounting records. However, they did not reconcile the final accounts receivable outstanding balance, as reported to CMS, to the Contractor's supporting detail records. As a result, the Agency did not have reasonable assurance that the outstanding balance reported to CMS was accurate.

RECOMMENDATION

We recommend the Agency develop policies, procedures, and controls to ensure that the outstanding rebate amount reported to CMS is reconciled with the supporting records.

AGENCY COMMENTS

The Agency agrees with the finding and recommendation and has implemented policies, procedures and controls to ensure that the outstanding rebate amount reported to CMS is reconciled with the supporting records. The complete text of the Agency's comments is included as an appendix to this report.

OFFICE OF INSPECTOR GENERAL RESPONSE

We agree with the corrective action taken, to date, in response to the procedural recommendation.

APPENDIX



JENNIFER M. GRANHOLM
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
LANSING

JANET OLSZEWSKI
DIRECTOR

August 27, 2003

Mr. Paul Swanson
Regional Inspector General for Audit Services
Department of Health and Human Services
Office of Audit Services
233 North Michigan Avenue
Chicago, Illinois 60601

Re: Report Number (A-05-03-00047)

Dear Mr. Swanson:

Enclosed is the Michigan Department of Community Health's response to the draft report entitled "Review of Medicaid Drug Rebate Program State of Michigan". A formal response to the first finding was not prepared because the audit found that the Agency had established adequate controls over the Medicaid Drug Rebate Program. The audit confirmed that the Contractor kept detailed and accurate records, and that policies and procedures were in place to resolve disputes from drug manufacturers.

We appreciate the opportunity to review and comment on the report before it is released. If you have any questions regarding this response, please refer them to Jim Hennessey at (517) 335-5323.

Sincerely,

A handwritten signature in black ink that reads "Paul Reinhart".

Paul Reinhart, Director
Medical Services Administration

PR:jh/kk

Enclosure

cc: Janet Olszewski
Michael Ezzo
Doris Gellert
Jim Hennessey

Review of Medicaid Drug Rebate Program

State of Michigan

MDCH Response

Finding Title: CMS 64.9R RECONCILIATION

Recommendation:

We recommend the Agency develop policies, procedures, and controls to ensure that the outstanding rebate amount reported to CMS is reconciled with supporting records.

Response:

MDCH agrees with the finding and recommendation and has implemented policies, procedures, and controls to ensure that the outstanding rebate amount reported to CMS is reconciled to the supporting records. When this issue was first raised during the audit, MDCH and the Contractor immediately initiated software modifications to the rebate system to ensure that outstanding rebate amounts reported to CMS could be reconciled with the supporting records. The software modifications have been developed, tested, implemented, and the outstanding rebate amounts reported to CMS are reconciled with the supporting records quarterly.



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*

Donna Kern, *Senior Auditor*

Michael Carr, *Auditor*

Ken Joosse, *Auditor*

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