



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

REGION V
OFFICE OF
INSPECTOR GENERAL

September 22, 2003

Report Number: A-05-03-00046

Peggy Handrich, Acting Administrator
Wisconsin Department of Health and Family Services
Division of Health Care Financing
1 West Wilson Street, Room 350
Madison, WI 53701-0309

Dear Ms. Handrich:

Enclosed are two copies of the Department of Health and Human Services, Office of Inspector General (OIG) final report entitled, "Review of Medicaid Drug Rebates Program - State of Wisconsin." 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-05-03-00046 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

Page 2 – Ms. Handrich

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 WISCONSIN**

**WISCONSIN DEPARTMENT OF
HEALTH AND FAMILY SERVICES
MADISON, WISCONSIN**



**SEPTEMBER 2003
A-05-03-00046**

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

FINDINGS

Generally, the Agency had established adequate controls over the Medicaid drug rebate program, as required by Federal rules and regulations. The State Medicaid Program Fiscal Agent, EDS Federal Corporation (founded as Electronic Data Systems), had extensive policies and procedures in place that enabled it to keep detailed and accurate records. However, improvement in two areas could enhance accountability over drug rebates. Specifically, the Agency and EDS had not: (1) reconciled the outstanding balance of drug rebate accounts receivable, reported on the Centers for Medicare and Medicaid Services (CMS) Form CMS 64.9R, to the supporting record and (2) established adequate procedures to accrue interest for late or disputed rebate payments.

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. In addition, the rebate agreements between CMS and the drug manufacturers require the payment of interest on all late, disputed, and unpaid drug rebates.

Our review showed that without routine reconciliations, the Agency did not have reasonable assurance that drug rebate information reported to CMS was accurate. In addition, it is likely that the Agency did not receive interest on late or disputed rebate payments due from manufacturers.

RECOMMENDATIONS

We recommend that the Agency:

- 1) Develop policies, procedures, and controls to ensure that the reported outstanding rebate amount is reconciled to the supporting records,
- 2) Correct the outstanding balance on the quarter-ending June 30, 2001 Form CMS 64.9R for an understatement of \$3,329,034 for the period prior to June 30, 2000, and
- 3) Develop policies, procedures, and controls to account for the interest related to late, disputed, or unpaid rebate payments.

AGENCY COMMENTS

In written comments to our draft report, the Agency generally agreed with our findings. The Agency implemented a new report, to reconcile the outstanding rebate amount reported on Form CMS 64.9R with the supporting records, corrected the error in the outstanding balance, and completed an adjustment to the Form CMS 64.9R. The Agency will review its existing policies, procedures and controls to identify any additional actions to enhance their current activities to account for the interest related to late, disputed or unpaid rebate payments. 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, to correct the Form CMS 64.9R balance and implement procedures to reconcile reported amounts to supporting records. With regards to developing procedures to account for the interest related to late or disputed rebate payments, we believe that the Agency should not accept an interest payment from a manufacturer as payment in full without determining the accuracy of the payment. We recognize that the drug rebate interest calculation is complex due to the weekly changes in interest rates. In fact, due to the complexity of the calculation, it is important for the Agency to verify the accuracy of the manufacturer's payments. Without comparing the interest paid by the manufacturer to the interest owed by the manufacturer, the Agency does not have reasonable assurance that the manufacturer has complied with the terms of the rebate agreement, i.e., no assurance that the Agency collected all of the interest owed on disputed, late, and unpaid rebates.

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Glossary of Abbreviations and Acronyms

Agency	Wisconsin Department of Health and Family Services
CFR	Code of Federal Regulations
CMS	Centers for Medicare and Medicaid Services
EDS	Electronic Data Systems Federal Corporation
Form CMS 64.9R	Medicaid Drug Rebate Schedule
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 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. 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 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 national drug code. 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, 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. Tracking interest owed to the State agency is 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 Form CMS 64.9R.

The Wisconsin Department of Health and Family Services (Agency) reported an average of \$26 million in billings and \$22 million in collections per quarter during the 1-year period ending June 30, 2002. On Form CMS 64.9R as of June 30, 2002, the Agency reported an outstanding balance amounting to \$37 million, with approximately \$10 million of the uncollected rebates outstanding over 90-days.

The Agency contracted with EDS Federal Corporation (founded as Electronic Data Systems), the State Medicaid Program Fiscal Agent, to administer most of the daily operations of the drug rebate program. The EDS staff 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. Agency staff prepare the Form CMS 64 reports and authorize 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 EDS. We also reviewed accounts receivable information related to the quarter ending June 30, 2002 and interviewed Agency and EDS staff to understand how the Medicaid drug rebate program has operated since 1991.

Methodology

To accomplish our objectives, we interviewed Agency and EDS officials to determine the policies, procedures, and controls that existed with regard to the Medicaid drug rebate program. We also interviewed Agency and EDS 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 and EDS offices and in our field office in Madison, Wisconsin, during the months February through April 2003.

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

FINDINGS AND RECOMMENDATIONS

Generally, the Agency had established adequate controls over the Medicaid drug rebate program, as required by Federal rules and regulations. EDS had extensive policies and procedures in place that enabled it to keep detailed and accurate records. However, improvement in two areas could enhance accountability over drug rebates. Specifically, the Agency and EDS had not: (1) reconciled the outstanding balance of drug rebate accounts receivable, reported on the Form CMS 64.9R report, to the supporting records, and (2) established adequate procedures to accrue interest for late or disputed rebate payments.

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. In addition, the rebate agreements between CMS and the drug manufacturers require the payment of interest on all late, disputed, and unpaid drug rebates.

Adequate Controls Established

As part of the Agency's controls over the Medicaid drug rebate program, the EDS contract employees kept detailed and accurate records by: (1) recording all transactions at the national drug code level, (2) reconciling units and payments to the original invoices, (3) responding to every payment received, and (4) recording contact with the manufacturers. By keeping such a detailed information system, the Agency and EDS can accurately monitor accounts receivable and effectively pursue collection of outstanding balances from drug manufacturers.

The Agency and EDS have policies and procedures in place to resolve disputes with manufacturers. Before invoices are sent, EDS staff review the number of units and reimbursement amount for reasonableness. After invoices are sent and payment received, EDS staff identify disputed units during the posting of payments. Once disputes are identified, EDS staff verify provider data and work to resolve the dispute.

Form CMS 64.9R Reconciliation

The Agency did not perform a reconciliation to verify the accuracy of the uncollected rebate balance reported on Form CMS 64.9R. Form CMS 64.9R was prepared by the Agency based on EDS reported totals of invoiced amounts and cash receipts. 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, adjustments were applied, and payments received during the current quarter were subtracted to calculate the ending balance. However, the Agency did not reconcile the rebate figures reported to CMS to the supporting records.

The Agency staff prepared the Form CMS 64.9R report without comparing the ending balances to the detailed data maintained by EDS staff. As a result, the Agency understated the Medicaid

drug account receivable balance on Form CMS 64.9R by \$3,329,034 as of June 30, 2001. The error occurred and was not discovered because the Agency had not developed a procedure to reconcile the outstanding balance reported to CMS to the supporting records.

During the course of our audit, the Agency identified the error that led to the understatement. The Agency official stated that they intended to contact CMS to determine the proper way to correct the understatement.

Interest on Late, Disputed, and Unpaid Rebates

The Agency and EDS did not have procedures to accrue interest for late or disputed rebate payments. Furthermore, the Agency did not accrue, track, or verify whether interest payments received from manufacturers were correct.

According to the rebate agreements between the manufacturers and CMS, required by Section 1927 of the Social Security Act, manufacturers are required to pay interest on late, disputed, or unpaid rebates. Section V, paragraph (b) of the rebate agreement states:

...(b) If the Manufacturer in good faith believes the State Medicaid Agency's Medicaid Utilization Information is erroneous, the Manufacturer shall pay the State Medicaid Agency that portion of the rebate amount claimed which is not disputed within the required due date in II (b). The balance due, if any, plus a reasonable rate of interest as set forth in section 1903(d)(5) of the Act, will be paid or credited by the Manufacturer or the State by the due date of the next quarterly payment in II(b) after resolution of the dispute....

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 collections and report those amounts to CMS. In addition, 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. As the methodology is prescribed in the regulations, a reasonable estimate could have been made for late rebates and interest payments received could have been verified.

The Agency did not calculate interest for late or disputed payments, nor did they recalculate interest voluntarily paid by manufacturers to verify that the correct amounts were paid. Since the Agency was not calculating or verifying interest, there was no assurance that the Agency was collecting all of the interest payments for late, disputed, or unpaid rebates.

RECOMMENDATIONS

We recommend that the Agency:

- 1) Develop policies, procedures, and controls to ensure that the reported outstanding rebate amount is reconciled with the supporting records,

- 2) Correct the outstanding balance on the quarter-ending June 30, 2001 Form CMS 64.9R for an understatement of \$3,329,034 during the period prior to June 30, 2000, and
- 3) Develop policies, procedures, and controls to account for the interest related to late, disputed, or unpaid rebate payments.

AGENCY COMMENTS

In written comments to our draft report, the Agency generally agreed with our findings. The Agency implemented a new report, to reconcile the outstanding rebate amount reported on Form CMS 64.9R with the supporting records, corrected the error in the outstanding balance, and completed an adjustment to Form CMS 64.9R. The Agency will review its existing policies, procedures and controls to identify any additional actions to enhance their current activities to account for the interest related to late, disputed or unpaid rebate payments. 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, to correct the Form CMS 64.9R balance and implement procedures to reconcile reported amounts to supporting records. With regards to developing procedures to account for the interest related to late or disputed rebate payments, we believe that the Agency should not accept an interest payment from a manufacturer as payment in full without determining the accuracy of the payment. We recognize that the drug rebate interest calculation is complex due to the weekly changes in interest rates. In fact, due to the complexity of the calculation, it is important for the Agency to verify the accuracy of the manufacturer's payments. Without comparing the interest paid by the manufacturer to the interest owed by the manufacturer, the Agency does not have reasonable assurance that the manufacturer has complied with the terms of the rebate agreement, i.e., no assurance that the Agency collected all of the interest owed on disputed, late, and unpaid rebates.

APPENDIX

Jim Doyle
GovernorHelene Nelson
Secretary

State of Wisconsin

Department of Health and Family Services

August 11, 2003

APPENDIX
Page 1 of 2Paul Swanson
Regional Inspector General
Office of Audit Services
233 North Michigan Avenue
Chicago, IL 60601

Re: Report Number A-05-03-00046

Dear Mr. Swanson:

This letter is in response to the draft audit report recently completed by your office entitled "Review of the Medicaid Drug Rebate Program – State of Wisconsin."

We have reviewed your findings and recommendations and submit the following responses to the areas you indicate the Wisconsin Department of Health and Family Services (DHFS) needs improvement to enhance accountability over drug rebates: (1) Develop policies, procedure, and controls to ensure that the reported outstanding rebate amount is reconciled to the supporting records; (2) Correct the understated outstanding balance on the quarter-ending June 30, 2001, Form Centers for Medicare and Medicaid Services (CMS) 64.9r for the period prior to June 30, 2000; and (3) Account for interest related to late, disputed, or unpaid rebate payments.

Recommendation 1 – Ensure Accuracy of Outstanding Rebate Amounts on 64.9r

DHFS has been generating reports of the outstanding rebate amounts by labeler number on an on-going basis. Beginning with quarter ending March 31, 2003, DHFS implemented a new report to reconcile the outstanding rebate amount reported on the CMS 64.9r with the supporting records.

Recommendation 2 – CMS 64.9r Reconciliation

The understated outstanding balance of \$3,329,034 on the drug rebate accounts receivable line on Form CMS 64.9r on the quarter ending June 30, 2001, was the result of a data entry keying error. Reports and data received from our fiscal agent to complete the CMS 64.9r were correct, however, the amount entered into the federal reporting system Medicaid Benefits Expenditures System was keyed in error by DHFS and a review performed by DHFS prior to transmission of the report did not identify this error. DHFS staff corrected the error and completed an adjustment to the CMS 64.9r.

Recommendation 3 – Interest for Late or Disputed Rebate Payments

DHFS has policies, procedures and controls to account for the interest related to late, disputed or unpaid rebate payments. Letters that accompany each rebate invoice and letters in response to disputes request interest on late, disputed or unpaid rebate payments. DHFS tracks collections of interest payments and reports these amounts to CMS on the appropriate federal reports. DHFS does not calculate interest amounts, or invoice interest amounts because it is the manufacturers' responsibility to calculate and pay interest in accordance with CMS Medicaid Drug Rebate Program Release number 65 and additional direction received in telephone call with CMS in November 1997. DHFS will review its existing policies, procedures and controls to identify any additional actions to enhance our current activities in light of the findings from your review.

Thank you for the opportunity to comment on your draft report. If you have any questions, please contact Ken Dybevik at (608) 267-7118.

Sincerely,



Mark B. Moody
Administrator

MBM:my
CB08027.EO
G-11-01-03

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*

Donna Kern, *Senior Auditor*

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