



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-05-03-00042

Tom Hayes, Director
Ohio Department of Job and Family Services
30 East Broad Street, 32nd Floor
Columbus, Ohio 432 15-3414

Dear Mr. Hayes:

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 Ohio." 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-05-03-00042 in all correspondence.

Sincerely yours,

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

Paul Swanson
Regional Inspector General
for Audit Services

Attachments - as stated

Page 2 - Mr. Hayes

Direct Reply to HHS Action Official:

Cheryl Hams, 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 MEDICAID
DRUG REBATE PROGRAM
STATE OF OHIO**

**OHIO DEPARTMENT OF JOB
AND FAMILY SERVICES
COLUMBUS, OHIO**



**SEPTEMBER 2003
A-05-03-00042**

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 Ohio Department of Job 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 drug rebate program, as required by Federal rules and regulations. It had extensive policies and procedures in place that enabled it to keep detailed and accurate records and properly segregate duties and safeguard rebate program funds. However, we identified two areas where the Agency could improve accountability over drug rebates. Specifically, the Agency could improve its policies regarding the collection of interest for unpaid, late, and disputed drug rebates and the use of a hearing mechanism to resolve drug rebate disputes with the manufacturers. In that regard, Federal Regulations at 45 CFR 74.21(b)(3) requires that financial management systems provide for effective control over and accountability for all funds, property, and other assets.

The Agency did not have adequate controls to follow-up and collect interest for unpaid, late, or disputed drug rebate payments. Although the Agency sends a second demand invoice letter to manufacturers requesting interest payments for unpaid, late, and disputed drug rebates, the Agency does not follow-up with manufacturers to ensure that drug rebate interest is properly remitted to the Agency. On a test basis, we examined drug rebate payment records for 383 manufacturers for the drug rebate schedule period ended March 31, 2002 and determined that 70 of 383 manufacturers were late forwarding drug rebate payments. Fifty-nine of the 70 or 84% of manufacturer records reviewed did not remit interest for the late drug rebate payments. The Agency did not establish adequate follow-up procedures and controls to collect interest for unpaid, late, or disputed drug rebate payments.

The Agency did not have adequate controls to monitor outstanding drug rebate disputes and provide a hearing mechanism to resolve disputes as prescribed in the rebate agreement between CMS and the manufacturers. This occurred because the Agency did not develop adequate policies and procedures for resolving disputes with manufacturers including appropriate use of the hearing mechanism. Due to the complexity of the program, disputes occur frequently and a resolution mechanism is needed.

RECOMMENDATIONS

We recommend the Agency develop formal policies, procedures, and controls to:

- Follow-up and collect interest for unpaid, late, or disputed drug rebate payments.

- Monitor disputed rebate amounts, including appropriate use of the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturers.

AGENCY COMMENTS

In written comments to our draft report, the Agency disagreed with our findings. The Agency cites CMS release No. 65 that states: “It is the State’s responsibility to track the collection of interest due, and report those amounts...”, therefore, the Agency believes it is in compliance by tracking and reporting all interest submitted from manufacturers. The Agency also believes that they have a mechanism that fully supports the reconciliation of disputes. The complete text of the Agency’s comments is included as an appendix to this report.

OFFICE OF INSPECTOR GENERAL RESPONSE

We believe that 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.

In addition, Governmental Accounting and Financial Reporting standards require the States to accrue revenue (interest) when it is measurable (a reasonable estimate) and available. As such, the Agency should not assume that it is in compliance by simply collecting and accounting interest for unpaid, late, or disputed drug rebate payments and should develop policies, procedures, and controls to verify that the correct amounts were paid.

We recognize that the Agency resolves many of their disputes with the manufacturers, however, there are unresolved disputes dating back to 1999 and continuing to 2002. The rebate agreement states that, “in the event that the State and the manufacturer are not able to resolve a discrepancy within 60 days, CMS shall require the State to make available to the manufacturer the State’s hearing mechanism available under the Medicaid Program.” The Agency did not have written policies and procedures in place to utilize the State hearing mechanism to resolve disputes with manufacturers. Therefore, we believe, that the Agency shall develop formal policies, procedures and controls to monitor disputed amounts, including appropriate use of the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturers.

TABLE OF CONTENTS

	Page
INTRODUCTION	1
BACKGROUND	1
OBJECTIVE, SCOPE AND METHODOLOGY	2
Objective	2
Scope	2
Methodology	2
FINDINGS AND RECOMMENDATIONS.....	3
Interest Collections	3
Dispute Resolution.....	4
RECOMMENDATIONS	4
AGENCY COMMENTS	4
OFFICE OF INSPECTOR GENERAL RESPONSE	5

APPENDIX - OHIO DEPARTMENT OF JOB AND FAMILY SERVICES COMMENTS

Glossary of Abbreviations and Acronyms

Agency Ohio Department of Job and Family Services

CFR Code of Federal Regulations

CMS Centers for Medicare & Medicaid Services

HHS Department of Health and Human Services

OIG Office of Inspector General

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 (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 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 its average manufacturer price and best price information for each covered outpatient drug to CMS. 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. In addition, 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 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. 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 codes. 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 resolve the dispute. 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 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 Ohio Department of Job and Family Services (Agency) reported to CMS an average of \$63,260,817 in billings per quarter and collections of \$63,871,031 per quarter during the 1-year period ending June 30, 2002. As of June 30, 2002, the Agency reported an outstanding balance of \$72,829,528 on the CMS 64.9R. Only \$1,942,256 of the uncollected receivables were outstanding over 90 days.

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

Methodology

To accomplish our objectives, we interviewed Agency 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 Agency office and our field office in Columbus, Ohio, during the months of April 2003 through June 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 drug rebate program, as required by Federal rules and regulations. It had extensive policies and procedures in place that enabled it to keep detailed and accurate records, properly segregate duties, and safeguard rebate program funds. However, we identified two areas where the Agency could improve accountability over drug rebates. Specifically, the Agency could improve its policies regarding the collection of drug rebate interest for unpaid, late, and disputed drug rebates and the use of a hearing mechanism to resolve drug rebate disputes with the manufacturers.

Interest Collections

The Agency did not have adequate controls to follow-up and collect interest for unpaid, late, or disputed drug rebate payments. Although the Agency sends a second demand invoice letter to manufacturers; requesting interest payments for unpaid, late, and disputed drug rebates; the Agency does not follow-up with manufacturers to ensure that drug rebate interest is properly remitted to the Agency.

Federal Regulations at 45 CFR 74.21 (b)(3) requires that financial management systems provide for effective control over and accountability for all funds, property, and other assets. In addition, the Medicaid Drug Rebate Program Release Number 65 requires the payment of interest on all disputed, late, and unpaid drug rebates. The rebate agreements between CMS and the drug manufacturer(s) require the use of a hearing mechanism to resolve disputes between the State and the drug manufacturers. Section 1927 of the Social Security Act states that manufacturers are required to pay interest on late, disputed, or unpaid rebates. Section V, Paragraph (b), of the rebate agreements 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.

The Agency did not establish adequate follow-up procedures and controls to collect interest for unpaid, late, or disputed drug rebate payments. On a test basis, we examined drug rebate payment records for 383 manufacturers, as reported on the Rebate Schedule for the period ended March 31, 2002. We determined that 70 of 383 manufacturers were late forwarding drug rebate payments and that 59 of these did not remit interest for the late drug rebate payments.

In addition, the State of Ohio single audits for the 5-year period July 1, 1997 through June 30, 2002 disclosed the Agency was not pursuing interest for late payments from the manufacturers and questioned costs in the amount of \$50,034.

Dispute Resolution

The Agency did not have adequate controls to monitor outstanding drug rebate disputes and provide a hearing mechanism to resolve disputes as prescribed in the rebate agreement between CMS and the manufacturers.

The 45 CFR 74.21(b)(3) requires that financial management systems provide for effective control over and accountability for all funds, property, and other assets. Section V (c) of the rebate agreement states:

“(c) The State and the Manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of such notification. In the event that the State and the Manufacturer are not able to resolve the discrepancy within 60 days, CMS shall require the State to make available to the Manufacturer the State hearing mechanism available under the Medicaid Program.”

The Agency did not develop adequate policies and procedures for resolving disputes with manufacturers including appropriate use of the hearing mechanism. Due to the complexity of the program, the large numbers of manufacturers and drugs, and the large volume of dispensed drugs, disputes frequently occur and a resolution mechanism is needed.

RECOMMENDATIONS

We recommend the Agency develop formal policies, procedures, and controls to:

- Follow-up and collect interest for unpaid, late, or disputed drug rebate payments.
- Monitor disputed rebate amounts, including appropriate use of the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturers.

AGENCY COMMENTS

In written comments to our draft report, the Agency disagreed with our findings. The Agency cites CMS release No. 65 that states: “It is the State’s responsibility to track the collection of interest due, and report those amounts...”, therefore, the Agency believes it is in compliance by tracking and reporting all interest submitted from manufacturers. The Agency also believes that they have a mechanism that fully supports the reconciliation of disputes. The complete text of the Agency’s comments is included as an appendix to this report.

OFFICE OF INSPECTOR GENERAL RESPONSE

We believe that 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.

In addition, Governmental Accounting and Financial Reporting standards require the States to accrue revenue (interest) when it is measurable (a reasonable estimate) and available. As such, the Agency should not assume that is in compliance by simply collecting and accounting interest for unpaid, late, or disputed drug rebate payments and should develop policies, procedures, and controls to verify that the correct amounts were paid.

We recognize that the Agency resolves many of their disputes with the manufacturers, however, there are unresolved disputes dating back to 1999 and continuing to 2002. The rebate agreement states that, "in the event that the State and the manufacturer are not able to resolve a discrepancy within 60 days, CMS shall require the State to make available to the manufacturer the State's hearing mechanism available under the Medicaid Program." The Agency did not have written policies and procedures in place to utilize the State hearing mechanism to resolve disputes with manufacturers. Therefore, we believe that the Agency shall develop formal policies, procedures and controls to monitor disputed amounts, including appropriate use of the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturers.

APPENDIX

Bob Taft
Governor



Tom Hayes
Director

APPENDIX
Page 1 of 2

30 East Broad Street • Columbus, Ohio 43215
www.state.oh.us/odjfs

September 2, 2003

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

RE: A-05-03-00042

Dear Mr. Swanson:

Thank you for the opportunity to respond to the U.S. Department of Health and Human Services, Office of Inspector General (OIG), Office of Audit Services (OAS)' draft report entitled "Review of Medicaid Drug Rebate Program-State of Ohio from the period July 1, 2001 through June 30, 2002."

We were pleased that the auditor found that Ohio had established adequate controls over the drug rebate program as required by federal rules and regulations. Further, we were happy that the auditor acknowledged our extensive policies and procedures that are in place that enables us to keep detailed and accurate records, properly segregate duties, and safeguard rebate program funds.

At this time we would like to respond to the two recommendations identified in the draft report.

Follow-up and collect interest for unpaid, late or disputed drug rebate payments.

The Centers for Medicare and Medicaid Services (CMS) continues to place the responsibility for interest calculation and payment on the manufacturers, not the states. Even while maintaining this position, the state did implement a late payment notice process whereby we remind manufacturers of their interest obligations. CMS release No. 26 clearly says that "whether or not a state invoices for interest has no bearing on the manufacturers' responsibilities to calculate and pay the amount(s) of interest due." From this statement it is clear that CMS has no expectation that states invoice manufacturers for interest. We do agree that if manufacturers send the interest payment, it is up to states to accept it as part of the rebate payments and furthermore, report it to CMS.

The auditor sites CMS release No.65 as a requirement for interest to be paid. However, again in No. 65 CMS explicitly refrains from saying it is the state's responsibility to invoice for the interest. "The obligation for calculating interest due to the States on late rebate payments rests with the manufacturer. It is the State's responsibility to track the collection of interest due , and report those amounts to HCFA. However, whether or not a State invoices for interest has no bearing on the manufacturers' responsibilities to calculate and pay the amount(s) of interest due." Ohio has tracked and reported all interest submitted from manufacturers and therefore believes we are in compliance. Because of Ohio's extremely high record of rebate collection, we believe that the administrative costs of pursuing interest beyond what we currently do, is not cost effective. We also believe that because the agreements are between CMS and the manufacturers, that it is the responsibility of CMS to audit/monitor contract compliance.

Monitor disputed rebate amounts, including appropriate use of the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturers.

Ohio has demonstrated consistently high collection of invoiced rebates. We have successfully negotiated disputes with manufacturers, averaging over a 99% collection rate since the beginning of the program. In the event that a dispute cannot be reconciled at the program level, there is a reconsideration process before the Deputy Director of the Ohio Department of Job and Family Services that complies with the hearing mechanism required by the federal rebate agreement. Ultimately, if rebates are not paid at the end of the reconciliation process, they can be certified to the Attorney General for collection. Thus Ohio believes that we have a mechanism that fully supports the reconciliation of disputes.

If you have any questions regarding this response, please contact Robert Reid at (614) 466-6420.

Sincerely,



Tom Hayes, Director
Ohio Department of Job and Family Services

C: Barbara Coulter Edwards, Deputy Director
Office of Ohio Health Plans