



July 22, 2003

Report Number: A-04-03-06006

Mr. Mike Robinson, Commissioner  
Kentucky Department for Medicaid Services  
275 East Main Street, 6W-A  
Frankfort, Kentucky 40621

Dear Mr. Robinson:

Enclosed are two copies of the U.S. Department of Health and Human Services (HHS), Office of Inspector General report providing the results of our *Audit of the Medicaid Drug Rebate Program in the State of Kentucky*. The audit objective was to evaluate whether the Kentucky Department for Medicaid Services (DMS) had established adequate accountability and internal controls over the Medicaid drug rebate program. Our audit covered Medicaid drug rebates through June 30, 2002.

We found that DMS had not provided effective control and accountability for drug rebate collections. Specifically, we found the amounts reported to the Centers for Medicare and Medicaid Services (CMS) were not supported by the accounting records. In our opinion, the inaccurate reporting occurred because DMS did not maintain a general ledger accounts receivable control account for drug rebates which could be balanced to subsidiary receivable accounts maintained by Unisys, their fiscal agent. Thus, there was no audit trail to support the drug rebate activities reported to CMS. As a result, there is no assurance that the program has provided CMS with an accurate picture of the drug rebate program. Additionally, there was a material amount of uncollected rebate dollars outstanding.

To correct these weaknesses, we recommend that DMS:

- verify all amounts reported on the CMS-64.9R, to ensure that those amounts tie directly back to the aged accounts receivable listing;
- maintain a general ledger accounts receivable control account for drug rebates, which could be balanced to subsidiary receivable accounts maintained by Unisys; and
- continue their efforts to collect the older outstanding drug rebates.

DMS officials agreed with our findings and have taken steps to correct the identified weaknesses.

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

Page 2 – Mike Robinson

In accordance with the principles of the Freedom of Information Act, 5 United States Code 552, as amended by Public Law 104-231, Office of Inspector General reports are made available to members of the public to the extent information contained therein is not subject to exemptions in the Act which the Department chooses to exercise (see 45 Code of Federal Regulations, Part 5).

To facilitate identification, please refer to report number A-04-03-06006 in all correspondence relating to this report.

Sincerely,

A handwritten signature in cursive script that reads "Charles J. Curtis".

Charles J. Curtis  
Regional Inspector General  
for Audit Services, Region IV

Enclosures – as stated

**HHS Action Official:**

Associate Regional Administrator  
Centers for Medicare and Medicaid Services, Region IV  
Division of Medicaid and State Operations  
61 Forsyth Street, S.W., Suite 4T20  
Atlanta, Georgia 30303

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**AUDIT OF THE MEDICAID  
DRUG REBATE PROGRAM IN THE  
STATE OF KENTUCKY**



**July 2003  
A-04-03-06006**

# **Notices**

**THIS REPORT IS AVAILABLE TO THE PUBLIC  
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In accordance with the principles of the Freedom of Information Act, 5 U.S.C. 552, as amended by Public Law 104-231, Office of Inspector General, Office of Audit Services, reports are made available to members of the public to the extent information contained therein is not subject to exemptions in the Act. (See 45 CFR Part 5.)

## **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. Authorized officials of the awarding agency will make final determination on these matters.





July 22, 2003

Report Number: A-04-03-06006

Mr. Mike Robinson, Commissioner  
Kentucky Department for Medicaid Services  
275 East Main Street, 6W-A  
Frankfort, Kentucky 40621

Dear Mr. Robinson:

This final report provides you with the results of an Office of Inspector General, Office of Audit Services' review entitled, *Audit of the Medicaid Drug Rebate Program in the State of Kentucky*.

## EXECUTIVE SUMMARY

The audit objective was to evaluate whether the Kentucky Department for Medicaid Services (DMS) had established adequate accountability and internal controls over the Medicaid drug rebate program. Our audit covered Medicaid drug rebates ending June 30, 2002.

We found that DMS had not provided effective control and accountability for drug rebate collections. Specifically, we found the amounts reported to the Centers for Medicare and Medicaid Services (CMS) were not supported by the accounting records. In our opinion, the inaccurate reporting occurred because DMS did not maintain a general ledger accounts receivable control account for drug rebates which could be balanced to subsidiary receivable accounts maintained by Unisys, their fiscal agent (FA). Thus, there was no audit trail to support the drug rebate activities reported to CMS. As a result, there is no assurance that the program has provided CMS with an accurate picture of the drug rebate program. Additionally, there was a material amount of uncollected rebate dollars outstanding.

To correct these weaknesses, we recommend that DMS:

- verify all amounts reported on the CMS-64.9R, to ensure that those amounts tie directly back to the aged accounts receivable listing;
- maintain a general ledger accounts receivable control account for drug rebates, which could be balanced to subsidiary receivable accounts maintained by Unisys; and
- continue their efforts to collect the older outstanding drug rebates.

DMS responded to our draft report in a letter dated June 27, 2003. Their complete response is included in the Appendix. DMS officials agreed with our findings and have taken steps to correct the identified weaknesses. Based on their experience, DMS officials also discussed what they believe are the shortcomings of the Medicaid drug rebate reporting system.

## INTRODUCTION

### BACKGROUND

On November 5, 1990, Congress enacted the Omnibus Budget Reconciliation Act of 1990, which among other provisions established the Medicaid drug rebate program. Responsibility for the rebate program is shared among the drug manufacturer(s), CMS, and the State(s). The legislation was effective January 1, 1991. CMS also issued release memorandums to State agencies and manufacturers to give guidance on numerous issues related to the Medicaid drug rebate program.

A drug manufacturer is required to enter into, and have in effect, a rebate agreement 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.

CMS provides the unit rebate amount (URA) information to the State agency on a quarterly computer tape. However, 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 (PQAS).

Each State agency is required to maintain the number of units dispensed, by manufacturer, for each covered drug. Approximately 56,000 National Drug Codes (NDC) are available under the program. Each State agency multiplies the URA by the drug utilization 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.

The manufacturer has 38 days from the day a State agency sends an invoice to pay the rebate. The manufacturer submits to the State agency a Reconciliation of State Invoice (ROSI) that details the NDC by current quarter's payment. A manufacturer can dispute utilization data that it believes is erroneous, but the manufacturer 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 may consider using a hearing mechanism, available to the manufacturer under the Medicaid program, in order to resolve the dispute.

Each State agency reports, on a quarterly basis, 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 DMS reported to CMS an average of \$32.1 million in billings per quarter and collections of \$32.5 million per quarter during the 1-year period ending June 30, 2002. DMS reported \$34,914,588 on the Form CMS 64.9R, as the outstanding balance as of June 30, 2002, with \$27,547,372 of the billed rebates being reported as outstanding for over 90 days.

DMS contracts with Unisys Corporation, which they refer to as their FA, to perform the daily operations of the drug rebate program, including billing, collection, accounting, and dispute resolution. Employees of DMS perform the functions of transferring funds, posting payments to the general ledger, and preparing the Form HCFA-64 reports. On March 1, 1997, DMS entered into a contract with an outside subcontractor, Claim Traq, to resolve drug rebate disputes for 1991 through 1996. This was DMS' first comprehensive effort at resolving disputes. In March 2000, DMS entered into a second agreement with another outside subcontractor, First Health, to resolve drug rebate disputes for 1997 and 1998 and renewed this contract through June 30, 2003.

## **OBJECTIVE, SCOPE, AND METHODOLOGY**

### ***Objective***

The objective of our audit was to evaluate whether DMS had established adequate accountability and internal controls over the Medicaid drug rebate program.

### ***Scope***

Our audit was performed in accordance with generally accepted government auditing standards. We reviewed DMS and Unisys policies, procedures, and controls with regard to manufacturer's drug rebates ending June 30, 2002. Our review of internal controls was limited to the controls concerning drug rebate billings, collections, and dispute resolution. This was accomplished through interviews and testing pertaining exclusively to the drug rebate program. We limited the scope of our review of internal controls because our audit objective did not require a full assessment or understanding of DMS and Unisys internal control structure.

### ***Methodology***

To accomplish our audit objective, we obtained the State's Medicaid Drug Rebate Schedule (Form CMS-64.9R) for the period ending June 30, 2002 and reviewed supporting documentation to assess the reliability of the outpatient drug rebate information reported to CMS. We reviewed accounts receivable and subsidiary records and compared the information with the data presented in the Form CMS-64.9R report. We interviewed DMS personnel who performed functions

related to the drug rebate program to determine existing policies, procedures, and controls as of June 30, 2002.

Fieldwork was performed at DMS Offices in Frankfort, Kentucky and at our field office in Jacksonville, Florida from March through May 2003.

## FINDINGS AND RECOMMENDATIONS

We found that DMS had not provided effective control and accountability for drug rebate collections. Specifically, we found the amounts reported to CMS were not supported by the accounting records. Additionally, there was a material amount of uncollected rebate dollars outstanding.

### Reporting

We found that the DMS contractor, Unisys, maintained sufficient detailed billing records, by drug manufacturer, to effectively pursue outstanding receivables from the manufacturers. Billing and accounting responsibilities were properly segregated. Also, there were adequate internal controls in place to ensure that manufacturers were billed each quarter, bills were maintained as a basis for collections, and rebates and interest were recorded timely and reconciled with accounting records. We determined that subsidiary records at the manufacturers' level included reconciliation of payments with ROSI and PQAS and that the information was recorded at NDC levels. Also, invoices to manufacturers included the drug utilization units for \$0 URAs and interest on late payments, which were verified and recorded upon receipt.

However, the amounts reported on the CMS-64.9R did not reconcile to the accounting records.

As of June 30, 2002	Reported on CMS-64-9.R	Supported by Accounting Records	Difference
Billed	\$35.9 m	\$35.9 m	\$0.0 m
Collected	\$41.0 m	\$41.0 m	\$0.0 m
Outstanding	\$34.9 m	\$44.6 m	\$9.7 m
Outstanding Over 90 days	\$27.5 m	\$37.2 m	\$9.7 m

DMS was not able to explain these discrepancies. In our opinion, the inaccurate reporting occurred because DMS did not maintain a general ledger accounts receivable control account for drug rebates, which could be balanced to subsidiary receivable accounts maintained by Unisys. Thus, there was no audit trail to support the drug rebate activities reported to CMS. As a result, there is no assurance that the program has provided CMS with an accurate picture of the drug rebate program.

## **Outstanding Collections**

Based on the accounting records, DMS has \$37.2 million in outstanding drug rebates, which were over 90 days old. DMS is attempting to reduce this number. DMS has contracted with collection agencies to collect the outstanding rebates. Additionally, DMS sent a representative to the federally sponsored Dispute Resolution Program to learn more about resolving outstanding disputes.

## **RECOMMENDATIONS**

As a result of our audit findings, we recommend that DMS:

- verify all amounts reported on the CMS-64.9R, to ensure that those amounts tie directly back to the aged accounts receivable listing;
- maintain a general ledger accounts receivable control account for drug rebates, which could be balanced to subsidiary receivable accounts maintained by Unisys; and
- continue their efforts to collect the older outstanding drug rebates.

## **DMS RESPONSE AND OIG COMMENTS**

DMS officials agreed with our findings and have taken steps to correct the identified weaknesses. Based on their experience, DMS officials also discussed what they believe are the shortcomings of the Medicaid drug rebate reporting system. DMS' response and OIG's comments are summarized below.

### **DMS Response**

DMS concurred with the recommendation to verify amounts reported on the CMS-64.9R. They have identified the source of past discrepancies and will make corrections on the June 30, 2003 report. In regard to the recommendation to maintain a general ledger accounts receivable control account, DMS stated that they have made changes to enhance the accuracy of the reporting process and would study the feasibility of the general ledger control account. DMS reported that they are working with their FA to increase and improve resources devoted to drug rebate recovery.

Also, DMS commented that the program could be further enhanced with "improved and more frequent URA tapes from CMS and the elimination of the open-ended nature of collection where manufacturers at any time can re-open disputed amounts back to the beginning of the program (1991).

**OIG Comments**

We commend DMS' efforts to improve their drug rebate program. We agree that multiple prior period adjustments add to the complexity of rebate reporting.

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To facilitate identification, please refer to report number A-04-03-06006 in all correspondence relating to this report.

Sincerely,



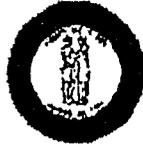
Charles J. Curtis  
Regional Inspector General  
for Audit Services, Region IV

Enclosure – as stated

**Direct Reply to HHS Action Official:**

Associate Regional Administrator  
Centers for Medicare and Medicaid Services  
Division of Medicaid and State Operations  
61 Forsyth Street, S.W., Suite 4T20  
Atlanta, Georgia 30303

# APPENDIX



The Secretary for Health Services  
COMMONWEALTH OF KENTUCKY  
275 EAST MAIN STREET  
FRANKFORT 40621-0001  
(502) 564-7042

PAUL E. PATTON  
GOVERNOR

MARCIA R. MORGAN  
SECRETARY

June 27, 2008

Report Number: A-04-03-06006

Mr. Charles J. Curtis  
Regional Inspector General for Audit Services, Region IV  
Department for Health and Human Services  
Office of Inspector General  
Office of Audit Services  
81 Forsyth Street, S.W., Suite 3T41  
Atlanta, Georgia 30303

Dear Mr. Curtis:

Attached, please find our response to the draft report entitled, *Audit of the Medicaid Drug Rebate Program in the State of Kentucky.*

If you have any questions concerning this document, please contact Commissioner Robinson at 502-564-4321.

Sincerely,

A handwritten signature in black ink, appearing to read "M R Morgan".

Marcia R. Morgan  
Secretary

c: Commissioner Robinson

Enclosure

*"...promoting and safeguarding the health and wellness of all Kentuckians."*



EQUAL OPPORTUNITY EMPLOYER M/F/D

Commonwealth of Kentucky  
 Cabinet for Health Services  
 Department for Medicaid Services  
 Response to Draft

**Audit of the Medicaid Drug Rebate Program in the State of Kentucky**  
 (Report Number A-04-03-06006)

Performed by  
 Department of Health and Human Services  
 Office of Inspector General  
 Office of Audit Services

Auditors Findings and Recommendations	Kentucky Department for Medicaid Services Response
<p>We found that the DMS had not provided effective control and accountability for drug rebate collections. Specifically, we found the amounts reported to the Centers for Medicare and Medicaid Services (CMS) were not supported by the accounting records. In our opinion, the inaccurate reporting occurred because DMS did not maintain a general ledger accounts receivable control account for drug rebates which could be balanced to subsidiary receivable accounts maintained by Unisys, their fiscal agent. Thus, there was no audit trail to support the drug rebate activities reported to CMS. As a result, there is no assurance that the program has provided CMS with an accurate picture of the drug rebate program. Additionally, there was a material amount of uncollected rebate dollars outstanding.</p>	<p>While we do not currently maintain a general ledger accounts receivable control account for drug rebates, we do have and did supply documentation that was generated by our MMIS which supported the amounts reported to CMS.</p> <p>Discrepancies occurred when the changes in historical reports were not carried forward to the CMS-64.9R.</p> <p>These discrepancies have been identified and corrections will be reflected in the June 30, 2003 CMS-64 Report.</p>
<p>To correct these weaknesses, we recommend that DMS:</p> <ul style="list-style-type: none"> <li>• verify all amounts reported on the CMS-64.9R, to ensure that those amounts tie directly back to the aged account receivable listing;</li> <li>• maintain a general ledger accounts receivable control account for drug rebates, which could be balanced to subsidiary receivable accounts maintained by Unisys; and</li> </ul>	<p>We concur with the recommendation. As noted above, we have identified the source of past discrepancies and will make the corrections in the June 30, 2003 report. We will also continue to monitor to ensure accuracy and consistency.</p> <p>We have made changes to enhance the accuracy of the reporting process. We will review the requirements for implementation of this recommendation to determine its current feasibility and impact.</p>

Commonwealth of Kentucky  
Cabinet for Health Services  
Department for Medicaid Services  
Response to Draft  
*Audit of the Medicaid Drug Rebate Program in the State of Kentucky*  
(Report Number A-04-03-06006)  
Performed by  
Department of Health and Human Services  
Office of Inspector General  
Office of Audit Services

Auditors Findings and Recommendations	Kentucky Department for Medicaid Services Response
<ul style="list-style-type: none"> <li>continue their efforts to collect the older outstanding drug rebates.</li> </ul>	<p>We are currently working with our fiscal agent to increase and improve resources devoted to drug rebate recovery. Beginning July 1, 2003, the fiscal agent will perform all tasks associated with federal rebates, including dispute resolution, with DMS Program Integrity staff monitoring and supporting the dispute resolution function. This streamlined and augmented function should improve collections as there will no longer be any disconnect among the DMS, its fiscal agent contractor (in possession of the utilization data for rebate calculation) and the separate dispute resolution contractor (charged with mirroring the fiscal agent data). There will be additional staff assigned at the fiscal agent devoted to recovery against outstanding and disputed rebate amounts. The DMS staff person monitoring the dispute recovery function will benefit from the increased efficiency of working only with the fiscal agent, with which we are very familiar. All outstanding rebates will be addressed either for collection or write off through the existing fiscal agent contract, without the sometimes counter-productive financial pressure from a second line fee based contractor charged only with resolving disputes.</p> <p>As we discussed with the auditors, tightened and improved guidance and rules from CMS would assist in the states' efforts, such as improved and more frequent URA tapes from CMS, and the elimination of the open ended nature of collection where manufacturers at any time can re-open disputed amounts back to the beginning of the program (1991). It is our understanding from this audit process that recommendations for improvement will be made to CMS. We look forward to these recommendations.</p>

## ACKNOWLEDGMENTS

This report was prepared under the direction of Charles J. Curtis, Regional Inspector General for Audit Services, Region IV. Other principal Office of Audit Services staff who contributed include:

Mary Ann Moreno, *Audit Manager*

Tim Crye, *Senior Auditor*

Michael Abbott, *Auditor in Charge*

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