Office of Audit Services
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AUG 1 2 2004

Report Number: A-01-04-00005

Ms. Beth Waldman
Director of Medicaid
Office of Medicaid
Executive Office of Health and Human Services
Commonwealth of Massachusetts
One Ashburton Place, 11th Floor
Boston, Massachusetts 02108

Dear Ms. Waldman:

Enclosed are two copies of the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG) report entitled "Review Of Medicaid Drug Rebate Collections Commonwealth Of Massachusetts As of June 30, 2002". A copy of this report will be forwarded to the action official noted below 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 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.

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To facilitate identification, please refer to Report Number A-01-04-00005 in all correspondence relating to this report.

Sincerely yours,

Michael J. Armstrong
Regional Inspector General
for Audit Services

Enclosures - as stated

Direct Reply to HHS Action Official:

Charlotte S. Yeh, M.D.
Regional Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
John F. Kennedy Federal Building, Room 2325
Boston, Massachusetts 02203-0003

cc: Frank McNamara, Director, Internal Control & Audit, Executive Office of Health & Human Services, Commonwealth of Massachusetts

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF MEDICAID DRUG REBATE COLLECTIONS COMMONWEALTH OF MASSACHUSETTS AS OF JUNE 30, 2002

August 2004
A-01-04-00005

Office of Inspector General

http://oig.hhs.gov

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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. Authorized officials of the HHS divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

The Medicaid Drug Rebate Program was established in legislation enacted by Congress in the Omnibus Budget Reconciliation Act of 1990. Responsibility for the rebate program is shared among the drug manufacturers, the Centers for Medicare and Medicaid Services (CMS) and individual states. The legislation was effective January 1, 1991. In Massachusetts, the Division of Medical Assistance (State agency) was responsible for administering the drug rebate program during our audit period covering July 1, 2001 through June 30, 2002.

The Medicaid program requires states to present a complete, accurate, and full disclosure of all pending drug rebates and collections. States are responsible to track collections of interest and report these amounts to CMS. States are also required to offset their Federal drawdown by the Federal share of drug rebates collected.

OBJECTIVES

The objective of our audit was to evaluate whether the State agency had established adequate accountability and internal controls over the Medicaid drug rebate program. We focused our audit on the drug rebate policies, procedures and controls of the State agency in effect during the period from July 1, 2001 through June 30, 2002.

RESULTS OF REVIEW

The State agency had established adequate controls to ensure that cash receipts under the drug rebate program were properly offset from Federal Medicaid reimbursement. However, contrary to Federal rules and regulations, the State agency did not establish accounting procedures and internal controls to:

- reconcile and age drug rebate balances on the Form CMS 64.9R report
- monitor the collection of interest due from manufacturers

Reconcile and Age Drug Rebate Balances on the Form CMS 64.9R Report

According to the CMS State Medicaid Manual §2500.7(B), State agencies are required to submit an ageing schedule for the ending balance of pending drug rebates to CMS at the beginning of each quarter. The State agency had no procedures in place to reconcile and age its pending drug rebate balances on the quarterly Form CMS 64.9R report. The primary cause for the lack of procedures can be attributed to the State agency's computer system which did not have the capability of making adjusting entries for cash receipts and other adjustments. As a result, the reported credit balance of $270 million in pending drug rebates as of June 30, 2002 was incorrect. Furthermore, inaccurate accounts receivable information limits the State agency's ability to accurately measure what is owed from the drug manufacturers.

Monitor the Collection of Interest Due From Manufacturers

According to the rebate agreements between the manufacturers and CMS, manufacturers are required to pay interest on late, disputed, or unpaid rebates. However, the State agency did not have adequate controls to track or verify whether interest payments received from manufacturers were correct. The State agency relied upon the manufacturer to compute and submit the proper interest with its overdue rebate payments. As a result, we could not be assured that all interest due on overdue rebates was being properly collected and offset from Federal Medicaid reimbursement.

RECOMMENDATIONS

We recommend that the State agency:

- establish procedures for reconciling and ageing its pending drug rebate amounts on the Form CMS 64.9R

- establish policies and procedures for the proper monitoring and collection of interest due from manufacturers for late, disputed, and unpaid drug rebate amounts

AUDITEE COMMENTS

The State agency agreed with our recommendations, stating that it had already begun taking steps to improve the accuracy of its quarterly drug rebate reports to CMS beginning in July 2002, the quarter following the end of our audit period. The State agency's comments are included in their entirety in the Appendix.

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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. The legislation was effective January 1, 1991. To supplement legislative requirements, the CMS also issued release memorandums to State agencies and manufacturers throughout the history of the rebate program to give guidance related to the Medicaid drug rebate program. In Massachusetts, the Division of Medical Assistance was responsible for administering the drug rebate program during our audit period. For the year ending June 30, 2002, the State agency reported averages of $48 million ($24 million Federal share) per quarter in billings and $50.1 million ($25 million Federal share) per quarter in collections.

The following paragraphs describe the flow of drug rebate information which the State agencies must monitor effectively in order to submit accurate quarterly reports to CMS.

Participating Drug Manufacturers Requirements

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 to CMS a listing of all covered outpatient drugs, and to report to CMS its average manufacturer price and best price information for each covered outpatient drug.

State Agency Drug Rebate Invoicing

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. The CMS requires each State agency to provide drug utilization data to the manufacturer. This information is used to determine the actual rebate amounts due from the manufacturer.

Payment of Drug Rebate Invoices

The manufacturer has 38 days from the day the State agency sends an invoice to pay the rebate. The manufacturers submit to the State agency a Reconciliation of State Invoice that details the current quarter's payment by NDC. 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. Furthermore, the manufacturer is required to pay interest on late, disputed, or unpaid rebates. If the State agency and the manufacturer 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 to the manufacturer under the Medicaid program in order to resolve the dispute.

State Agency Submission of Quarterly Form 64.9R Reports

Each State agency reports, on a quarterly basis, outpatient drug 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 report also includes aged summary information on the balance of pending rebates.

OBJECTIVE, SCOPE AND METHODOLOGY

Objective

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

Scope

We focused our audit on the drug rebate policies, procedures and controls of the State agency in effect during the period from July 1, 2001 through June 30, 2002. We limited consideration of the internal control structure to those controls concerning drug rebate reporting because the objective of our review did not require an understanding or assessment of the complete internal control structure at the State agency.

Methodology

To accomplish our objective, we:

- reviewed criteria related to the billing, collection, and reporting of the Medicaid drug rebate program
- discussed prior audit work of the drug rebate program with the Massachusetts State Auditor's office
- interviewed State agency officials to determine the policies, procedures and controls that existed with regard to the Medicaid drug rebate program
- reconciled the drug rebate collections reported on the four quarterly Form CMS 64.9R reports for fiscal year 2002 to supporting documentation
- reconciled the total of drug rebate invoices to the total reported on the Form CMS 64.9R report for the quarter ended June 30, 2002

We performed our fieldwork during the period from February through June 2004 at the State agency in Boston, Massachusetts.

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

FINDINGS AND RECOMMENDATIONS

The State agency had established adequate controls to ensure that cash receipts under the drug rebate program were properly offset from Federal Medicaid reimbursement. However, contrary to Federal rules and regulations, the State agency did not establish accounting procedures and internal controls to:

- reconcile and age drug rebate balances on the Form CMS 64.9R report
- monitor the collection of interest due from manufacturers

RECONCILE AND AGE DRUG REBATE BALANCES ON THE CMS 64.9R REPORT

Criteria – Requirements to Reconcile and Age Pending Rebate Balances

The State agency is required to report aged summary information on its drug rebate program. Such information is to be included quarterly on the Form CMS 64.9R report. The CMS State Medicaid Manual §2500.7(B), requires the State agency to:

> …submit to HCFA [CMS] summary information on pending drug rebates at the beginning of the quarter, the amounts of drug rebates computed for all drug labelers, amounts written off, other adjustments, remaining pending drug rebates and amounts collected, and reduce your claim for Federal reimbursement by the Federal share of amounts received. All pending drug rebates must be aged by comparing the dates the pending rebate was established with the ending date of the period shown on the Quarterly Expenditure Report, Form HCFA [CMS] 64….

Condition – State Agency Did Not Reconcile and Age Pending Rebate Balances

The State agency had no procedures in place to reconcile and age its pending drug rebate balances on the Form CMS 64.9R report. For the quarter ended June 30, 2002, the State agency reported the ending balance of pending drug rebates as a $270.4 million credit on the Form CMS 64.9R report. Since the normal balance of pending drug rebates is a debit, the reported $270.4 million credit balance was inaccurate and provides no useful information to CMS regarding the actual balance of pending drug rebates as of that date.

Cause – Limited Capabilities of State Agency's Computer System

The computer system in place at the State agency during our audit period was only capable of calculating, preparing, and submitting drug rebate invoices to the manufacturers. However, once these invoices were submitted to the manufacturers, the system did not have the capability of subsequently adjusting invoice balances for cash receipts or other adjustment transactions. The computer system was incapable of providing the State agency with either the balance of pending rebates at the end of each quarter or the age of the various rebates included in that balance.

Effect – Information Reported on CMS 64.9R Report Was Inaccurate

As a result, the reported credit balance of $270 million in pending drug rebates as of June 30, 2002 was incorrect. Furthermore, inaccurate accounts receivable information limits the State agency's ability to accurately measure what is owed from the drug manufacturers.

MONITOR THE COLLECTION OF INTEREST DUE FROM MANUFACTURERS

Criteria – Interest Collection Requirements

According to the rebate agreements between the manufacturers and CMS, 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…. 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…after resolution of the dispute….

The CMS Medicaid Drug Rebate Program Release No. 65 states that it is the manufacturers' responsibility to calculate and pay interest for applicable rebate invoices and the State agency's responsibility to track collections and report those amounts to CMS. In addition, Program Release No. 29 requires that interest must be collected and not disregarded by either the manufacturer or the State, as part of the dispute resolution process.

Condition – Lack of Procedures to Effectively Monitor Interest Collection

The State agency had no procedures in place to monitor the collection of interest due from manufacturers for late, disputed, and unpaid rebates. The State agency relied on the manufacturers to compute and submit the proper interest with its overdue rebate payments.

Cause – Limited Capabilities of State Agency's Computer System

The computer system in place at the State agency during our audit period was only capable of calculating, preparing, and submitting drug rebate invoices to the manufacturers. However, once these invoices were submitted to the manufacturers, the system did not have the capability of subsequently adjusting invoice balances for cash receipts or other adjustment transactions. With no capability to age drug rebate invoices, the State agency could not identify situations where interest was due from the manufacturers.

Effect – State Agency May Not Have Collected All Interest Due

As a result, we cannot be assured that all interest due on overdue rebates was properly collected and offset from Federal Medicaid reimbursement.

RECOMMENDATIONS

We recommend that the State agency:

- establish procedures for reconciling and ageing its pending drug rebate amounts on the Form CMS 64.9R

- establish policies and procedures for the proper monitoring and collection of interest owed by manufacturers for late, disputed, and unpaid drug rebate amounts

STATE AGENCY COMMENTS

The State agency agreed with our recommendations, stating that it had already begun taking steps to improve the accuracy of its quarterly drug rebate reports to CMS beginning in July 2002, the quarter following the end of our audit period. The State agency's comments are included in their entirety in the Appendix.

APPENDIX

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Office of Medicaid
One Ashburton Place
Boston, MA 02108

MITT ROMNEY
Governor
KERRY HEALEY
Lieutenant Governor

RONALD PRESTON
Secretary
BETH WALDMAN
Director

August 9, 2004

Mr. Joseph Kwiatanowski, Audit Manager
Office of Inspector General
Office of Audit Services, Region I
John F. Kennedy Federal Building
Boston, Massachusetts 02203

RE: US Department of Health and Human Services, Office of the Inspector General Draft Report on Review of Medicaid Drug Rebate Collections Commonwealth of Massachusetts as of June 30, 2002 A-01-04-00005

Dear Mr. Kwiatanowski:

Thank you for the opportunity to comment on the United States Department of Health and Human Services, Office of the Inspector General Draft Report on Review of Medicaid Drug Rebate Collections Commonwealth of Massachusetts as of June 30, 2002 A-01-04-00005.

As you know, prior to your audit, the MassHealth program made substantial changes to its processes for monitoring Medicaid drug rebate collections. Our own reviews of our processes had led us to similar conclusions as you've found in your review. MassHealth is in agreement with the results of the review and the report recommendations.

During the review period ending June 30, 2002, the Division had used its Medicaid Management Information System (MMIS) to monitor drug rebate collection. The MMIS did not have the ability to systematically calculate and monitor interest on past due manufacturers and did not reconcile the drug rebate balances reported on the CMS 64.9R to accounts receivable reports. This latter issue resulted in mathematical errors reflected in the drug rebate balances reported in the CMS 64 9R for the quarter ending June 30, 2002. The CMS 64 reporting errors were corrected in subsequent quarterly reports.

Beginning in July 2002 (just after the end of the audit period), MassHealth has been using a new system called Drug Rebate Analysis and Management System (DRAMS). The DRAMS system is a fully functioning billing and accounts receivable system. Consistent with your recommendations, DRAMS provides MassHealth with the ability to calculate and monitor the collection of interest due from manufacturers. In addition, it provides the required CMS 64.9R

and accounts receivable reports to ensure that amounts reported can be reconciled to subsidiary reports.

Thank you for your continued interest in the MassHealth program. We believe the audit provided a useful forum for us to address issues of common concern with the objective of improving overall performance.

Sincerely,

Beth Waldman
Medicaid Director

Cc: Frank McNamara, Director
Internal Control & External Audit Unit