Office of Audit Services
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SEP 19 2003

Report Number – A-01-03-00007

Ms. Christine Zukas-Lessard
Acting Director
Department of Human Services
Bureau of Medical Services
11 State House Station
Augusta, Maine 04333

Dear Ms. Zukas-Lessard:

Enclosed are two copies of the U.S. Department of Human Services, Office of Inspector General, Office of Audit Services, (OIG/OAS), report entitled "Review of Medicaid Drug Rebates at State Medicaid Agencies for the State of Maine." A copy of this report will be forwarded to the action official noted below for her review and action deemed necessary.

The HHS action official named below will make final determination as to actions taken on all matters reported. We request that you respond to the HHS action officials 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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If you have any questions or comments about this report, please do not hesitate to call me at (617) 565-2689 or through email at marmstrong@oig.hhs.gov. To facilitate identification, please refer to report number A-01-03-00007 in all correspondence.

Sincerely yours,

Michael J. Armstrong

Michael J. Armstrong
Regional Inspector General
for Audit Services

Enclosure – as stated

Direct Reply to HHS Action Official:

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

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF MEDICAID DRUG REBATES AT STATE MEDICAID AGENCIES FOR THE STATE OF MAINE

September 2003
A-01-03-00007

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 Maine Department of Human Services, Bureau of Medical Services, (State), administers the State's Medical Assistance Plan that was established under Title XIX of the Social Security Act (Act) to provide medical assistance to needy people. Section 1903(a) of the Act, provides for Federal Financial Participation in State expenditures for prescription drugs. On November 5, 1990, Congress enacted the Omnibus Budget Reconciliation Act of the 1990 legislation, which among other provisions established the Medicaid prescription drug rebate program. Responsibility for the rebate program is shared among the drug manufacturer(s), Centers for Medicare and Medicaid Services (CMS), and the State(s). The legislation was effective January 1, 1991. The State uses the Maine Medicaid Information System (MMIS), to process Medicaid claims and make payments to health care providers for services rendered.

OBJECTIVE

The objectives of the audit were: (1) verify the total reported uncollected drug rebates for the State of Maine as of June 30, 2002, (2) determine whether the State agency has established adequate internal controls with regard to the Medicaid drug rebate program, and (3) evaluate the effectiveness of the actions taken by the State agency to resolve outstanding disputes.

SUMMARY OF FINDINGS

For the period under review, we found that controls were generally in place to record and track the collection of drug rebates. However, we found that the State agency had not established adequate procedures to ensure that:

- Invoiced rebates or accounting adjustments are made to the quarterly CMS 64.9R reports. As a result, the June 30, 2002 pending rebate balance (credit of $98 million) is inaccurate.

- All disputed rebate amounts are followed-up with the manufacturer in a timely manner. As a result, there is a risk the revenue may not be properly recorded or collected.

- All interest on unpaid or late drug rebate amounts is properly assessed. As a result, there is a potential loss of revenue to the Medicaid program.

Without adequate accounting controls, there is a risk that revenue may not be properly recorded or collected.

RECOMMENDATIONS

We recommend that the State agency:

- Ensure procedures are established to provide accurate pending rebate amounts and properly present drug rebate receivables in its quarterly reports to CMS.

- Resolve disputed items in a timely manner in accordance with CMS guidelines.

- Collect interest on any disputed or unpaid drug rebate amounts as well as late payments.

AUDITEE COMMENTS

The auditee concurred with our findings and will take appropriate actions to implement our recommendations.

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INTRODUCTION

BACKGROUND

The Maine Department of Human Services, Bureau of Medical Services, (State), administers the State's Medical Assistance Plan that was established under Title XIX of the Social Security Act (Act) to provide medical assistance to needy people. Section 1903(a) of the Act, provides for Federal Financial Participation in State expenditures for prescription drugs. On November 5, 1990, Congress enacted the Omnibus Budget Reconciliation Act of the 1990 legislation, which among other provisions established the Medicaid prescription drug rebate program. Responsibility for the rebate program is shared among the drug manufacturer(s), Centers for Medicare and Medicaid Services (CMS), and the State(s). The legislation was effective January 1, 1991. The State uses the Maine Medicaid Information System (MMIS), to process Medicaid claims and make payments to health care providers for services rendered.

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 its average manufacturer price (AMP) best price and best price information for each covered outpatient drug to CMS. Approximately 520 pharmaceutical companies participate in the program.

The CMS accumulates the AMP and best price data from the manufacturers, and obtains the Consumer Price Index-Urban (CPI-U) and uses this information to calculate a unit rebate amount (URA) for each drug. The URA is the per unit (i.e. per pill) dollar value that should be paid by the manufacturer to the State for each unit of a specifically dispensed drug. The URA consists of (1) a basic rebate amount for all covered outpatient drugs, and (2) an additional rebate amount, based on the amount by which the increase in the AMP exceeds the increase in the CPI-U from the base period to the month before the calendar quarter of the rebate. The additional rebate applies only to single source and innovator multiple source drugs, and does not apply to a newly marketed drug until it has been on the market for a full calendar quarter.

The CMS provides the URAs to the States. The States use the URAs to calculate the rebate amounts owed by the manufacturer. Each state agency is required to maintain a number of units dispensed by manufacturers for covered drugs. Approximately 56,000 National Drug Codes (NDCs) are available under the program. The state agency uses the URA from CMS and the utilization of each drug to determine the actual rebate amounts due from the manufacturer. The CMS requires each state agency to provide drug utilization data to the manufacturer.

Goold Health Services, (GHS) has processed the drug rebate invoices for the State of Maine from 1996 to present. Approximately six weeks after each quarter, GHS receives the quarterly Medicaid rebate labeler and NDC pricing data from CMS. The labeler data contains manufacturer identification and status within the rebate program. The NDC file contains current and historical corrected NDC pricing. The GHS then matches the CMS

tape with claim information from labelers -- this creates a list of invoices. A copy of this tape along with a summary of invoices is then given to the State for processing. GHS also submits a copy to CMS for internal studies as well as a mandated annual report to the State Congress. When disputed items are cleared, the State will contact GHS and a "reversal" will be done to the invoice in question.

The State's drug rebate staff generates electronic invoices from the tape created by GHS. Invoices are sent to the manufacturers by email or diskettes. A paper copy is then mailed to the manufacturers. The Third Party Liability Accounting Unit (TPL) receives checks and supporting documentation, Reconciliation of State Invoice and Prior quarter Adjustment Statement – from manufacturer. TPL applies the summary of the payment (interest and adjustment) by labeler and quarter in the database and forwards a paper backup of transactions with a copy of the check to the Drug Rebate staff.

At the end of each month, the Drug Rebate staff generates a query for management of total dollar amount of rebates collected for that month.

OBJECTIVE, SCOPE AND METHODOLOGY

Our review was conducted in accordance with generally accepted government auditing standards. The objectives of the audit were: (1) verify the total reported uncollected drug rebates for the State of Maine as of June 30, 2002, (2) determine whether the State agency has established adequate internal controls with regard to the Medicaid drug rebate program, and (3) evaluate the effectiveness of the actions taken by the State agency to resolve outstanding disputes.

Scope and Methodology:

To accomplish our objectives, we:

- Evaluated the State's internal controls and system of processing, recording and reporting the drug rebate amount.
- Tested the State's accounting system by reviewing quarterly reports, deposits and adjustments made during those quarters.
- Reviewed GHS' internal controls and invoice processing system for the State.
- Reviewed the State process for settling disputed invoices.
- Reviewed procedures for billing and collecting interest due for late rebate payments.

We limited the consideration of the internal control structure to those controls relating to the State's accumulation of drug utilization data, drug rebate billing and collection procedures, and the reporting of drug rebate payments to CMS. Our fieldwork was

conducted from March 10, 2003 through June 4, 2003 at the State, GHS processing center, CMS and the Boston Regional Office.

FINDINGS AND RECOMMENDATIONS

For the period under review, we found that controls were generally in place to record and track the collection of drug rebates. However, we found that the State agency had not established adequate procedures to ensure that:

- Invoiced rebates or accounting adjustments are made to the quarterly CMS 64.9R reports. As a result, the June 30, 2002 pending rebate balance (credit of $98 million) is inaccurate.

- All disputed rebate amounts are followed-up with the manufacturer in a timely manner. As a result, there is a risk the revenue may not be properly recorded or collected.

- All interest on unpaid or late drug rebate amounts is properly assessed. As a result, there is a potential loss of revenue to the Medicaid program.

Without adequate accounting controls, there is a risk that revenue may not be properly recorded or collected.

Evaluation of Quarterly Reports

The State's CMS 64.9R form for quarter ending June 30, 2002, shows a credit balance of $98 million. This amount appears to represent cumulative collections for all quarters from March 31, 2000 through June 30, 2002. A review of State agency records shows that the State does not record either the rebates invoiced or adjustments to prior quarters on the CMS 64.9R.

Section 2500.7 of the State Medicaid Manual requires states to: "maintain in a formal system of records, in readily reviewable form, supporting documentation that provides detailed information on pending drug rebates at the beginning of the quarter, the amounts of drug rebates computed for each labeler, amounts written off, other adjustments made, amounts collected and remaining pending drug rebates at the end of the quarter. This information must be made available to Federal reviewers upon request."

The State was unable to provide us with documentation supporting the outstanding balance of rebates due under the drug rebate program. There are gaps in the sequence of CMS 64.9R reports filed by the State and the CMS 64.9R is not completed in compliance with CMS instructions.

As a result, the CMS94.9R report submitted to CMS shows only drug rebates collected during the period and does not accurately reflect the outstanding drug rebate balance as of the end of the quarter.

Disputed Items

The State provided an automated report supporting disputed balances of approximately $4.6 million reported on or after October 1, 2001. Even though the State negotiates payment of these disputed items with the manufacturer, if no payment is made, follow-up is not always done timely.

The Drug Rebate Agreement states "the State and 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 a discrepancy within 60 days, CMS shall require the State to make available to the manufacturer the State hearing mechanism available under the Medicaid Program. Also, Section 2500.7 D of the State Medicaid Manual instructs the State to file page 2 of the CMS 64.9R form to explain significant problems in resolving disputed that are over 12 months old.

Although the State has policies in place to collect and follow-up on disputed items, they are not always implemented in every case. As a result, there is a risk that the State will not collect the money for the aged disputed items.

Interest Due for Late Rebate Payments

The State has no mechanism in place to calculate and bill or check whether interest payments are received on drug rebates to the Medical Assistance Program are correct. Also, the State does not calculate or assess any interest penalties on unpaid amounts.

Section V(b) of the National Drug Rebate Agreement mandates that drug manufacturer pay interest on any disputed or unpaid drug rebate amounts as well as on any late payments. The State must collect interest and may not disregard it as part of the dispute resolution process.

In this regard, there was a concern written in a Management Letter for fiscal year ended June 30, 2000, from the Maine State Auditor's Office regarding calculation of interest payments that are received from labelers. The State agreed with the finding and stated that it was continuing to work on developing a solution as part of the MMIS database that will calculate interest payments automatically.

To date, the database is still in the developmental phase, therefore, interest is not being collected in accordance to CMS policies. As a result, there is a potential loss of revenue to the Medicaid program.

RECOMMENDATIONS

We recommend that the State agency:

- Ensure procedures are established to provide accurate pending rebate amounts and properly present drug rebate receivables in its quarterly reports to CMS.

Auditee Comment

Maine currently captures this information and will immediately begin sending it to the Department of Human Services' Division of Finance on a quarterly basis for inclusion on the HCFA 64 report.

- Resolve disputed items in a timely manner in accordance with CMS guidelines.

Auditee Comment

The staff of the Bureau of Medical Services responsible for drug rebates will continue to create claim level detail reports and forward the information to appropriate drug labelers within the timeframe required by CMS.

- Collect interest on any disputed or unpaid drug rebate amounts as well as late payments.

Auditee Comment

The Maine Claims Management System, Drug Rebate Subsystem will have the functionality to calculate interest due for both disputed and late rebates. The new system is scheduled to go live in early 2004. We recognize that the State cannot invoice the manufacturer for interest, however the State will know what is owed.

APPENDIX

John Elias Baldacci
Governor

State of Maine
DEPARTMENT OF HUMAN SERVICES
11 State House Station
Augusta, Maine 04333-0011

September 8, 2003

Mr. Michael J. Armstrong
Regional Inspector General for Audit Services
Office of Audit Services
JFK Federal Building
Boston, MA 02203

Re: Report No. A-01-03-00007

Dear Mr. Armstrong:

Thank you for providing me with copies of your draft report entitled, "Review of Medicaid Drug Rebates at State Medicaid Agencies for the State of Maine." We offer the following comments in relation to the recommendations on Page 5 of this report.

- **Ensure procedures are established to provide accurate pending rebate amounts and properly present drug rebate receivables in its quarterly reports to CMS.**
  Maine currently captures this information and will immediately begin sending it to the Department of Human Services' Division of Finance on a quarterly basis for inclusion on the HCFA 64 report.

- **Resolve disputed items in a timely manner in accordance with CMS guidelines.**
  The staff of the Bureau of Medical Services responsible for drug rebates will continue to create claim level detail reports and forward the information to appropriate drug labelers within the timeframe required by CMS.

- **Collect interest on any disputed or unpaid drug rebate amounts as well as late payments.**
  The Maine Claims Management System, Drug Rebate Subsystem will have the functionality to calculate interest due for both disputed and late rebates. The new system is scheduled to go live in early 2004. We recognize that the State cannot invoice the manufacturer for interest, however the State will know what is owed.

We sincerely appreciate the time spent in Maine by OIG staff reviewing Maine's drug rebate processes. We believe this effort will enable us to perform this function more accurately in the future.

Sincerely,

Christine Zukas-Lessard

Christine Zukas-Lessard
Acting Director , Bureau of Medical Services

cc Peter Walsh, Acting Commissioner, Department of Human Services
Craig Hitchings, Acting Director, Division of Reimbursement and Financial Services, BMS
Rossi Rowe, Third Party Liability Unit