



JUN 1 0 2003

Office of Audit Services
Region I
John F. Kennedy Federal Building
Boston, MA 02203
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Report Number – A-01-03-0001

Mr. John Young, CPM
Director, RI Department of Human Services
Division of Health Care Quality,
Financing and Purchasing for the State of
Rhode Island
600 New London Avenue
Cranston, Rhode Island 02920

Dear Mr. Young:

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 Rhode Island."

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.

In accordance with the principles of the Freedom of Information Act (U.S.C.552, as amended by Public Law 104-231), OIG, OAS reports issued to the department's grantees and contractors are made available to members of the press and general public to extent information contained therein is not subject to exemptions in the Act which the department chooses to exercise. (See 45 CFR Part 5.)

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-01-03-00001 in all correspondence.

Sincerely yours,


Michael J. Armstrong
Regional Inspector General
for Audit Services

Enclosure – as stated

Direct Reply to HHS Action Official:

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 RHODE ISLAND**



**JUNE 2003
A-01-03-00001**

Office of Inspector General

<http://oig.hhs.gov>

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EXECUTIVE SUMMARY

BACKGROUND

The Rhode Island Department of Human 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. States may provide coverage of prescription drugs as an optional service under section 1905(a)(12) of the Act. 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, and the State(s). The legislation was effective January 1, 1991. The State uses the RMB System (Medicaid claims processing system), to process Medicaid claims and make payments to health care providers for services rendered.

OBJECTIVE

The objectives of this audit are to (1) verify the total reported uncollected drug rebates for the State of Rhode Island as of June 30, 2002, and (2) determine whether the State agency has established adequate internal controls with regard to the reported drug rebates uncollected balance and disputed items.

SUMMARY OF FINDINGS

Based on the results of our review, we found that:

- Quarterly reports could not be reconciled to State records that resulted in a difference of \$4.7 million for the total uncollected drug rebate amount.
- State records show that there is approximately \$570,000 of uncollected disputed items for the period January 1994 through December 2001 that has not been resolved in accordance with CMS guidelines.

RECOMMENDATIONS

We recommend that the State agency: (1) reconcile State records to the amount reported on the CMS 64.9R make one summary adjustment for the period from 1991 through 2000 to account for lost records and adjustments not previously made, (2) establish written procedures for recording drug rebate transactions and (3) resolve disputed items either by means of the CMS hearing mechanism or consider participating in the National Dispute Resolution conference.

AUDITEE COMMENTS

The Rhode Island Department of Human Services concurred with our findings and will take appropriate actions to implement our recommendations.

TABLE OF CONTENTS

	Page
INTRODUCTION	1
Background	1
Objective, Scope and Methodology	2
FINDINGS AND RECOMMENDATIONS	3
Evaluation of Quarterly Reports	3
Disputed Items	4
Recommendations	5
APPENDIX A	
Auditee's Response	

INTRODUCTION

BACKGROUND

The Rhode Island Department of Human 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. States may provide coverage of prescription drugs as an optional service under section 1905(a)(12) of the Act. 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 RMB System (Medicaid claims processing system), 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) 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, and the States use the URAs to calculate the rebate amounts owed by the manufacturer. The States maintain the number of units dispensed, by manufacturer, for each covered drug. The States multiply the URA by the drug utilization for each drug to determine the actual rebate amounts due from the manufacturer. The CMS requires the States to provide drug utilization data to the manufacturer.

Each state agency is required to maintain a number of units dispensed by manufacturer, for each covered drug. Approximately 56,000 National Drug Codes (NDCs) are available under the program. Each 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.

The Electronic Data Center (EDS) has been processing the drug rebate invoices for the State of Rhode Island from January 1, 1995 to present. CMS sends a tape to EDS that lists all the manufacturers enrolled in the drug rebate program. The CMS tape is merged with the paid claim information, which produces invoices to each manufacturer for reimbursement. Individual accounts for manufacturers are created each quarter. Invoices are sent twice a month. A summary report of these rebates along with copies of checks received, invoices, deposit slips, Reconciliation of State Invoice (ROSI) report and transmittal memo are then sent to the State for posting. EDS provides the State drug rebate deposits.

The State posts the deposited amounts to their drug rebate account. A clerk posts the deposited amounts in the appropriate account; the financial staff person verifies these deposits. Also, adjustments made from depositing errors, i.e., deposit to another department in error or mathematical errors when making deposits, are done by the State. The amounts are then posted to the appropriate line/column on the CMS 64.9R form. The form generates the totals for that quarter and the report is then sent to CMS electronically.

OBJECTIVE, SCOPE AND METHODOLOGY

Our review was conducted in accordance with generally accepted government auditing standards. The objectives of the audit are to (1) verify the total reported uncollected drug rebates for the State of Rhode Island as of June 30, 2002, and (2) determine whether the State agency have established adequate internal controls with regard to the reported drug rebates uncollected balances and disputed items.

Scope and Methodology:

To accomplish our objectives, we:

- Reviewed EDS' internal controls and invoice processing system for the State.
- 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 the disputed invoices process done by EDS and the State.

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. In this regard, the RI State Auditor's reported findings were cleared.

Our fieldwork was conducted from October 7, 2002 through January 28, 2003 at the State, EDS processing center, CMS and the Boston Regional Office.

FINDINGS AND RECOMMENDATIONS

Based on the results of our review, we found that:

- Quarterly reports could not be reconciled to State records that resulted in a difference of \$4.7 million for the total uncollected drug rebate amount.
- State records show that there is approximately \$570,000 of uncollected disputed items for the period January 1994 through December 2001 that has not been resolved in accordance with CMS guidelines.

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

Evaluation of Quarterly Reports

We were unable to reconcile the balance of outstanding drug rebates reported on the CMS 64.9R to records maintained at EDS as of June 30, 2002. Review of State Agency records reflect uncollected drug rebates of about \$8.2 million where the amount reported to CMS was approximately \$12.9 million, a difference of \$4.7 million.

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."

Review of State agency records and discussion with responsible personnel show the following causes for the \$4.7 million difference:

- During the period January 1, 1991 through December 31, 1993, the State calculated drug rebate amounts on a manual accounting system. These records could not be found to check the drug rebate balance. From January 1, 1994 to present, an electronic account system was put in place to track the drug rebate dollars.
- During the years 1994 through 2001, the State did not make any adjustments to the drug rebate total that was provided to them by EDS. EDS provides the State with Drug Rebate Status reports showing the amount of invoices mailed each quarter. This amount may be adjusted over time to reflect additional mailings or

reductions for changes to a labeler's URA price. These instances should result in adjustments to previously reported rebates to account for the changes.

In addition, the State does not have written procedures on the drug rebate posting process. The current process involves review of a variety of documents and bank account records, and would be difficult to reconstruct without formal documentation of the process.

Without adequate accounting controls, there is the risk that revenue may not be collected.

Disputed Items

State records show that included in the uncollected drug rebate balance, there is approximately \$570,000 of uncollected disputed items for the period January 1994 through December 2001 for which the State has taken no action on.

When manufacturers notify EDS that invoices are being disputed, EDS copies disputed invoices onto another spreadsheet for further evaluation based on the list of approved NDCs and claim detail. These results are sent back to the labeler with a transmittal indicating whether or not a correction was made. All disputed invoices are based on number of units. A report of all disputed invoices is sent to the State for its pharmacist to review. In accordance with the Drug Rebate Agreement "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.

Discussion with responsible State personnel revealed that disputed items are not resolved in accordance with CMS guidelines. The State does have the opportunity to attend the national disputed invoice meeting hosted by CMS to discuss disputed items that are non-negotiable.

As a result, uncollected disputed items for the period January 1994 through December 2001 are reflected in the uncollected drug rebate total. Moreover, there is a risk that the State will not collect the money for disputed items.

RECOMMENDATIONS

We will recommend that the State Agency (1) reconcile State records to the amount reported on the CMS 64.9R make one summary adjustment for the period from 1991 through 2000 to account for lost records and adjustments not previously made, (2) establish written procedures for recording drug rebate transactions and (3) resolve disputed items either by means of the CMS hearing mechanism or consider participating in the National Dispute Resolution conference.

AUDITEE COMMENTS

The auditee concurred with our findings and will take appropriate actions to implement our recommendations (see Appendix A).

APPENDIX



STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

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DIVISION OF HEALTH CARE QUALITY,
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June 5, 2003

Mr. Michael J. Armstrong
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VIA FACSIMILE
(617)565-3750

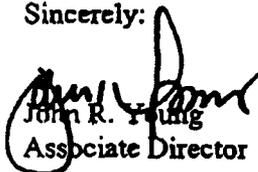
RE: Report No. A-01-03-00001

Dear Mr. Armstrong:

With apology for its lateness, I am writing in response to your report reviewing drug rebates in the Rhode Island Medicaid program.

We concur with your findings, and will take the appropriate actions to implement your recommendations at the first available opportunity.

Sincerely:


John R. Young
Associate Director

Cc: James L. FitzGerald
Ronald Gaskin
Ronald A. Lebel
Frank A. Spinelli