Office of Audit Services
Region I
John F. Kennedy Federal Building
Boston, MA 02203
(617) 565-2684

JAN 2 2 2004

Report Number: A-01-03-00013

John A. Stephen
Commissioner
New Hampshire Department of Health & Human Services
129 Pleasant Street
Concord, New Hampshire 03301-3857

Dear Mr. Stephen:

Enclosed are two copies of the U.S. Department of Health and Human Services (HHS), Office of Inspector General report entitled, "Review of the Medicaid Drug Rebate Program – State of New Hampshire 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.

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

To facilitate identification, please refer to Report Number A-01-03-00013 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:

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 THE MEDICAID DRUG REBATE PROGRAM STATE OF NEW HAMPSHIRE AS OF JUNE 30, 2002

JANUARY 2004
A-01-03-00013

Office of Inspector General

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

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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 the information 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 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 & Medicaid Services (CMS) and individual states. The legislation was effective January 1, 1991. In New Hampshire, the state Department of Health and Human Services (State agency) is responsible for administering the drug rebate program. The State agency contracts much of its drug rebate activities to First Health Services, Inc. (First Health).

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

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.

RESULTS OF REVIEW

Our audit focused on the State agency's drug rebate program account balances and activity as of the quarter ending June 30, 2002. We noted that improvements were needed in two activities. Specifically, the State agency needs to reconcile the amount of rebates reported with the accounts receivable records and establish controls over interest due from manufacturers.

- We found that procedures for reconciling and reporting the pending drug rebate amounts and corresponding ageing of these rebates on the Medicaid Quarterly Expenditure Report submitted to CMS were not established. As a result, the amount reported as the pending balance at June 30, 2002 was understated by about $10.9 million ($5.5 million Federal share).

- The State agency did not have procedures in place to monitor the collection of interest due from manufacturers. The State agency relied upon the manufacturer to compute and submit the proper interest with its overdue rebate payments. Without a system of monitoring interest due from manufacturers, we cannot be assured that this interest was accurately computed nor can we determine if any manufacturers failed to submit interest with their overdue rebate payments.

Subsequent to our audit period, we noted that the State agency is in the process of developing corrective actions to improve its tracking of interest receivable on overdue

drug rebates. We commend the State for their effort to increase their Medicaid revenue collection efforts.

RECOMMENDATIONS

We recommend that the State agency:

- develop a pending drug rebate ageing schedule for use in the proper preparation of the CMS 64.9R report, and

- continue its efforts to develop procedures for the proper monitoring and collection of interest owed by manufacturers for overdue drug rebate amounts.

AUDITEE COMMENTS

In its January 15, 2004 comments to our draft report (see Appendix), the State agency agreed with our recommendations. The State agency stated that it has initiated corrective action to verify the accuracy of the CMS 64.9R with its contractor. In addition, the State agency stated that it has implemented a corrective action plan to insure that interest is properly calculated and collected on overdue drug rebates.

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INTRODUCTION

BACKGROUND

MEDICAID DRUG REBATE PROGRAM

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 manufacturers, CMS, and individual 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 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.

Each State agency is required to maintain a 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.

The manufacturer has 38 days from the day the State agency sends an invoice to pay the rebate to avoid interest. The manufacturers submit to the State agency a Reconciliation 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. 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.

Each State agency reports, on a quarterly basis, outpatient drug rebate collections on 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.

In New Hampshire, the Department of Health & Human Services (State agency) is responsible for administering the drug rebate program. Since January 2002, the State agency has contracted much of its day-to-day drug rebate activities to First Health, the State's Medicaid claim processor. Prior to this time, Electronic Data Systems was contracted for drug rebate activities. For the year ending June 30, 2002, the State agency reported averages of $5.9 million ($2.9 million Federal share) per quarter in billings and

$4.3 million ($2.1 million Federal share) per quarter in collections. Also, as of June 30, 2002, the State agency reported $4.6 million ($2.3 million Federal share) in total pending drug rebate accounts receivable.

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

Our audit was conducted in accordance with generally accepted government auditing standards. We focused our audit on the drug rebate policies, procedures and controls of the State agency and its contractor, First Health, as of the quarter ending June 30, 2002. We also reviewed accounts receivable information related to prior periods and interviewed State agency and First Health staff to understand how the Medicaid drug rebate program has operated since its inception.

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 with the New Hampshire Legislative Budget Assistant (LBA) office,
- interviewed State agency and First Health staff to determine the policies, procedures and controls that existed with regard to the Medicaid drug rebate program,
- evaluated the State agency and First Health's internal controls for processing, recording and reporting drug rebates,
- reconciled the drug rebate offset reported on the June 30, 2002 Form CMS 64 report to supporting documentation, and
- reviewed drug rebate accounts receivable records and compared this data to the Form CMS 64.9R report for 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.

Our fieldwork was conducted during September and October of 2003 at the State agency in Concord, New Hampshire and at the CMS and OIG regional offices in Boston, Massachusetts.

The State agency's comments to our draft report are appended to this report (see Appendix).

FINDINGS AND RECOMMENDATIONS

Our audit focused on the State agency's drug rebate program account balances and activity as of the quarter ending June 30, 2002. We noted that improvements were needed in two activities. Specifically, the State agency needs to reconcile the amount of rebates reported with the accounts receivable records and establish controls over interest due from manufacturers.

- We found that procedures for reconciling and reporting the pending drug rebate amounts and corresponding ageing of these rebates on the Medicaid Quarterly Expenditure Report submitted to CMS were not established. As a result, the amount reported as the pending balance at June 30, 2002 was understated by about $10.9 million ($5.5 million Federal share).

- The State agency did not have procedures in place to monitor the collection of interest due from manufacturers. The State agency relied upon the manufacturer to compute and submit the proper interest with its overdue rebate payments. Without a system of monitoring interest due from manufacturers, we cannot be assured that this interest was accurately computed nor can we determine if any manufacturers failed to submit interest with their overdue rebate payments.

Subsequent to our audit period, we noted that the State agency is in the process of developing corrective actions to improve its tracking of interest receivable on overdue drug rebates. We commend the State for their effort to increase their Medicaid revenue collection efforts.

The results of our review are described in detail below.

CMS 64.9R RECONCILIATION AND AGEING OF DRUG REBATE RECEIVABLES

We found that the State agency had not established procedures to fully identify and age its pending drug rebate receivable amounts on the Form CMS 64.9R report. As part of its quarterly reporting process to CMS, the State agency is required to report summary

information on its drug rebate program. Such information is to be included quarterly on the CMS 64.9R Medicaid Drug Rebate Schedule report. Instructions for this report, per CMS State Medicaid Manual §2500.7(B), require 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…."*

As of June 30, 2002, the State agency reported a credit balance of about $6.3 million in total pending drug rebates on its CMS 64.9R report. However, supporting documentation provided by the State agency and First Health showed a total pending drug rebate balance of $4.6 million. As such, the pending drug rebate balance was understated by $10.9 million. Further, the State agency did not properly age its pending drug rebates on the CMS 64.9R report. While the State agency was able to track outstanding balances by individual manufacturer, it did not maintain a mechanism to age its total pending drug rebates and report such information on the June 30, 2002 CMS 64.9R report. Therefore, we were unable to determine the age of the State agency's drug rebate receivables as of June 30, 2002.[1] The State agency attributed this problem, in part, to its change in contractors for the drug rebate program.

COLLECTION OF INTEREST ON LATE, DISPUTED AND UNPAID REBATES

The State agency did not have adequate controls to track or verify whether interest payments received from manufacturers were correct. According to the rebate agreements between the manufacturers and CMS, required by Section 1927 of the Social Security Act, 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…."*

According to CMS Medicaid Drug Rebate Program Release No. 65, it is the manufacturers' responsibility to calculate and pay interest for applicable rebate invoices

[1] While no ageing schedule was available for our audit period, the nearest ageing schedule, as of January 2, 2002, showed a pending drug rebate balance of $5.3 million, of which $5.0 million (94 percent) was related to billings made within the last three months of that run date.

and the State'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.

For the period of our audit, the State agency did not have procedures in place monitor the collection of interest due from manufacturers. The State agency relied upon the manufacturer to compute and submit the proper interest with its overdue rebate payments. Without a system of monitoring interest due from manufacturers, we cannot be assured that this interest was accurately computed nor can we determine if any manufacturers failed to submit interest with their overdue rebate payments. Accordingly, we could not be assured that all interest due on overdue rebates was being properly collected and offset from Federal Medicaid reimbursement.

We discussed this issue with the State agency and found that the State agency had begun developing a system in April 2003 to track interest due from manufacturers. According to the State agency, interest due is now computed by First Health and included in overdue notices to manufacturers. We commend the State agency for initiating this corrective action.

RECOMMENDATIONS

We recommend that the State agency:

- develop a pending drug rebate ageing schedule for use in the proper preparation of the CMS 64.9R report, and

- continue its efforts to develop procedures for the proper monitoring and collection of interest owed by manufacturers for overdue drug rebate amounts.

AUDITEE COMMENTS

In its January 15, 2004 comments to our draft report (see Appendix), the State agency agreed with our recommendations.

In response to our first recommendation, the State agency stated that it has initiated corrective action to verify the accuracy of the CMS 64.9R with First Health. Specifically, the State agency has implemented quarterly internal audits of First Health's submitted CMS 64.9R. The audit verifies reported amounts for drug rebate invoices, ageing of pending drug rebate collections and drug rebate collections received.

With regard to our second recommendation, the State agency responded that it has implemented a corrective action plan to insure that interest is correctly calculated, interest collections are received, drug rebate disputes are resolved and overdue drug rebates are collected. Under this plan, the State agency monitors drug rebate collection activity and collaborates with First Health to generate drug rebate revenue due to the State and CMS.

APPENDIX

STATE OF NEW HAMPSHIRE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF HEALTH PLANNING & MEDICAID

129 PLEASANT STREET, CONCORD, NH 03301-3857
603-271-5254 1-800-852-3345 Ext. 5254
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John A. Stephen
Commissioner

Janice C. Paterson
Acting Director

January 15, 2004

Report Number: A-01-03-00013

Michael J. Armstrong
Office of Audit Services
Region I
John F. Kennedy Federal Building
Boston, MA 02203

Dear Mr. Armstrong:

The Office of Health Planning and Medicaid is pleased to provide the enclosed audit response on behalf of the State of New Hampshire. This response is reference to the U.S. Department of Health and Human Services, Office of Inspector General draft report entitled, "Review of the Medicaid Drug Rebate Program- State of New Hampshire as of June 30. 2002."

The response includes an Auditee Corrective Action Plan that details the State's review of the audit findings and recommendations presented by the Office of Inspector General. The State wants to commend the efforts of Gail Walley regarding the audit of New Hampshire's Drug Rebate Program. Her assistance was invaluable in supporting the State's ongoing efforts to comply with the Centers for Medicare and Medicaid Services regulations.

If you have any questions regarding the enclosed audit response, please feel free to contact Grant Beckman directly at (603) 271-7386.

Sincerely,

Janice C. Paterson
Acting Director
Office of Health Planning
and Medicaid

cc: J.Stephen, J.Fredyma, L.Hodgdon, J.Bonds

Drug rebate collections are mailed directly to the Department with copies sent to the First Health Services Corporation for posting into the contractors First Rebate System. The Department reconciles postings on a quarterly basis for drug rebate checks received to amounts reported to CMS on the HCFA 64.9R.

The Department issued a Pharmacy Benefit Management (PBM) Services Request for Proposal (RFP) on October 10, 2003 for services provided from January 1, 2004 to December 31. 2005. A primary objective of the PBM RFP was to enhance financial reporting of the PBM system. Contractors are required to meet standards established in the Statements on Auditing Standards No. 70. In addition, the PBM RFP Work Statement includes requirements for OBRA Drug Rebate Processing and Reporting that comply with Generally Accepted Accounting Principles.

Finding: "The State agency did not have procedures in place to monitor the collection of interest due from manufacturers. The State agency relied upon the manufacturer to compute and submit the proper interest with its overdue rebate payments. Without a system of monitoring interest due from manufacturers, we cannot be assured that this interest was accurately computed nor can we determine if any manufacturers failed to submit interest with their overdue rebate payments."

Recommendation: " We recommend that the State agency continue its efforts to develop procedures for the proper monitoring and collection of interest owed by manufacturers for overdue drug rebate amounts."

Auditee Corrective Action Plan:

The Department concurs that sufficient state monitoring of interest owed by drug manufacturers was not in place at June 30, 2002. A corrective action plan has been implemented to insure that interest is correctly calculated, interest collections are received, drug rebate disputes are resolved and overdue drug rebates are collected. The Department monitors drug rebate collection activity and collaborates with the contracted vendor to generate drug rebate revenue due to the State and CMS.

The Department contracted with the Electronic Data Systems Corporation (EDS) to operate the Omnibus Budget Reconciliation Act of 1990 (OBRA) Drug Rebate system through 2001. The First Health Services Corporation began processing New Hampshire's OBRA Drug Rebate Invoices and Collections in March of 2002. The OBRA Drug Rebate systems at EDS and First Health Services Corporation calculated manufacturer's interest owed in accordance with Section 1927 of the Social Security Act. Drug Rebate invoicing and collections have occurred un-interrupted from EDS to the First Health Services Corporation. The Department receives ongoing reporting from First Health that details intrest calculated for overdue payments and the amount of interest collected. This reporting includes interest activity from 1991 forward.

State of New Hampshire
Department of Health and Human Services
Office of Health Planning and Medicaid

U.S. Department of Health and Human Services, Office of Inspector General
Draft Report: "Review of the Medicaid Drug Rebate Program-State of New Hampshire as of June 30, 2002."
Report Number A-01-03-00013
Federal Mail Document Date: 12/16/03

Finding:

"We found that procedures for reconciling and reporting the pending drug rebate amounts and corresponding ageing of these rebates on the Medicaid Quarterly Expenditure Report submitted to CMS was not established. As a result, the amount reported as the pending balance at June 30, 2002 was understated by about $10.9 million ($5.5 million Federal share)."

Recommendation:

"We recommend that the State agency: develop a pending drug rebate ageing schedule for use in the proper preparation of the CMS 64.9R report"

Auditee Corrective Action Plan:

The Department concurs that the CMS HCFA 64.9R report for June 2002 was not completed in accordance with CMS guidelines. These reporting issues occurred due to a lack of training for Department staff responsible for CMS quarterly reporting. In addition, reporting issues occurred due to the transition of Drug Rebate reporting between contractors in 2002.

Corrective action has been taken and CMS HCFA 64.9R reports from March 2003 forward have been submitted in accordance with CMS State Medicaid Manual 2500.7(B) instructions. The Department has implemented quarterly internal audits of First Health Services Corporations' HCFA 64.9R. This audit verifies reported amounts for drug rebate invoices, aging of pending drug rebate collections and drug rebate collections received.