



DEC 26 2003

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

Report Number: A-01-03-00012

Mr. Joshua Slen, Director  
Office of Vermont Health Access  
State of Vermont  
103 South Main Street  
Waterbury, Vermont 05671-1201

Dear Mr. Slen:

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 - State of Vermont Office of Vermont Health Access 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-01-03-00012 in all correspondence relating to this report.

Sincerely yours,

A handwritten signature in black ink that reads "Michael J. Armstrong".

Michael J. Armstrong  
Regional Inspector General  
for Audit Services

Enclosures – as stated

Page 2 – Mr. Joshua Slon

**Direct Reply to HHS Action Official:**

Charlotte Yeh, M.D.  
Regional Administrator  
Centers for Medicare and Medicaid Services – Region I  
Department of Health and Human Services  
Room 2325, JFK Federal Building  
Boston, Massachusetts 02203

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**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**REVIEW OF MEDICAID  
DRUG REBATE COLLECTIONS  
STATE OF VERMONT  
OFFICE OF  
VERMONT HEALTH ACCESS  
AS OF JUNE 30, 2002**



**December 2003  
A-01-03-00012**

# *Office of Inspector General*

<http://oig.hhs.gov>

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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 Vermont, the Office of Vermont Health Access (State agency) is responsible for administering the drug rebate program. The State agency contracts much of its drug rebate activities to the Electronic Data Systems (EDS) Corporation.

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.

### **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.

### **RESULTS OF REVIEW**

We found that the State agency generally followed adequate accounting procedures and had sufficient controls over the drug rebate program as required by Federal rules and regulations. In addition, we noted that the Federal share of drug rebate amounts, for the most part, was properly offset from Federal Medicaid reimbursement. In this regard, we noted that the State agency needs to improve its monitoring on overdue drug rebate receivables to ensure that all interest applicable to these receivables is collected and reported properly. We also found that the State agency needs to improve its procedures for reconciling and reporting its pending drug rebate amounts on the Form CMS 64.9R report.

### **RECOMMENDATIONS**

We recommend that the State agency:

- establish policies and procedures for the proper monitoring and collection of interest owed by manufacturers for late, disputed, and unpaid drug rebate amounts; and
- develop a pending drug rebate ageing schedule for use in the proper preparation of the CMS 64.9R report.

## **AUDITEE COMMENTS**

In its December 11, 2003 comments to our draft report (see Appendix), the State agency agreed to work with EDS, its contractor, in implementing our audit recommendations.

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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. 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 the number of units dispensed, by manufacturer, for each covered drug. Approximately 56,000 National Drug Codes (NDC) are available under the program. 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. 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. 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 Vermont, the Office of Vermont Health Access (State agency) is responsible for administering the drug rebate program. The State agency contracts much of its day-to-day drug rebate activities to the EDS Corporation, the State agency's Medicaid claim processor. For the year ending June 30, 2002, the State agency reported averages of \$6.9 million (\$4.3 million Federal share) per quarter in billings and \$6.2 million (\$3.9 million Federal share) per quarter in collections. Also, as of June 30, 2002, the State agency reported \$7.6 million (\$4.8 million Federal share) in total pending drug rebate accounts

receivable. Approximately \$847,000 (\$534,000 Federal share) of this amount was outstanding over 90 days.

## **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 and its contractor, EDS, as of the quarter ending June 30, 2002. We also reviewed accounts receivable information related to prior periods and interviewed State agency and EDS staff to understand how the Medicaid drug rebate program has operated since its inception.

### **METHODOLOGY**

Our audit was conducted in accordance with generally accepted government auditing standards. 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 Vermont State Auditor's office;
- interviewed State agency and EDS staff to determine the policies, procedures, and controls that existed with regard to the Medicaid drug rebate program;
- 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 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 performed during August and September of 2003 at the State agency in Waterbury, Vermont and at EDS's offices in Williston, Vermont.

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

## **FINDINGS AND RECOMMENDATIONS**

We found that the State agency generally followed adequate accounting procedures and had sufficient controls over the drug rebate program as required by Federal rules and regulations. In addition, we noted that the Federal share of drug rebate amounts, for the most part, was properly offset from Federal Medicaid reimbursement. In this regard, we noted that the State agency needs to improve its monitoring on overdue drug rebate receivables to ensure that all interest applicable to these receivables is collected and reported properly. We also found that the State agency needs to improve its procedures for reconciling and reporting its pending drug rebate amounts on the Form CMS 64.9R report.

### **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 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.

According to EDS staff, EDS has no procedures in place to compute or otherwise monitor the collection of interest due from manufacturers. EDS relies upon the manufacturer to compute and submit the proper interest with its overdue rebate payments. While we found that the interest that was received from manufacturers was properly included to offset Federal Medicaid reimbursement, 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 cannot be assured

that all interest due on overdue rebates was being properly collected and offset from Federal Medicaid reimbursement.

### **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 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 §2000.7(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 total pending drug rebates of \$7,582,382 (\$4,781,450 Federal share). We found that the State agency did not properly age its drug rebate receivables on its quarterly CMS 64.9R report. Instead, the State agency generally recorded all pending drug rebates as current receivables. While supporting ageing schedules were unavailable as of June 30, 2002, we were able to estimate that approximately \$847,389<sup>1</sup> (\$534,364 Federal share) or 11 percent of pending drug rebates were outstanding for 90 days or more.

### **RECOMMENDATIONS**

We recommend that the State agency:

- establish policies and procedures for the proper monitoring and collection of interest owed by manufacturers for late, disputed, and unpaid drug rebate amounts; and
- develop a pending drug rebate ageing schedule for use in the proper preparation of the CMS 64.9R report.

### **AUDITEE COMMENTS**

In its December 11, 2003 response to our draft report (see Appendix), the State agency agreed to work with EDS, its contractor, in implementing our audit recommendations.

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<sup>1</sup> Based on an EDS August 29, 2002 drug rebate run report, the nearest available to June 30, 2002.

# **APPENDIX**



State of Vermont

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AGENCY OF HUMAN SERVICES

OFFICE OF VERMONT HEALTH ACCESS  
103 South Main Street  
Waterbury, Vermont 05671-1201

Report Number: A-01-03-00012

Telephone: 1-800-250-8427  
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December 11, 2003

Mr. Michael J. Armstrong, Regional Inspector General  
Office of Audit Services  
Region 1  
John F. Kennedy Federal Building  
Boston, MA 02203

Dear Mr. Armstrong:

Thank you for your draft report of November 2003 "Review of Medicaid Drug Rebate Collections-State of Vermont Office of Health Access" as of June 30, 2002. This report found that the Office of Vermont Health Access (OVHA), needed to:

- 1) improve its monitoring on overdue drug rebate receivables to ensure that all interest applicable to these receivables is collected and reported properly and
- 2) improve its procedures for reconciling and reporting its pending drug rebate amounts on Form CMS 64.9R report.

The Office of Audit Services recommended that OVHA:

- 1) establish policies and procedures for proper monitoring and collection of interest owed by manufacturers for late, disputed and unpaid drug rebate amounts, and
- 2) develop a pending drug rebate aging schedule for use in the proper preparation of the CMS 64.9R report.

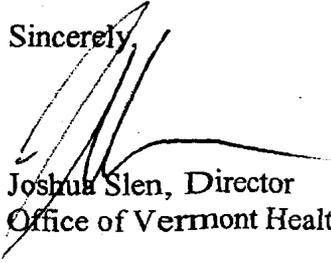
The following is a status report of the actions OVHA has taken in regard to your recommendations.

Representatives from Electronic Data Systems Corporation (EDS), the State agency contractor for Medicaid claim processing and OVHA met for the purpose of discussing the findings of the November 2003 draft report. An outcome of that meeting was the decision by both parties to establish a committee with representation from both OVHA and EDS. This committee is charged with conducting the research and determining the necessary protocols and infrastructure needed within each organization to implement the recommendations made by the Office of Audit Services. Once these protocols are fully defined by the committee, they will be implemented within the OVHA and EDS

operational processes to address the recommendations you have delineated in the OIG draft audit report.

Thank you for the opportunity to provide comments and a status update to your recommendations.

Sincerely,



Joshua Slen, Director  
Office of Vermont Health Access

# ACKNOWLEDGMENTS

This report was prepared under the direction of Michael Armstrong, Regional Inspector General for Audit Services. Other principal Office of Audit Services staff who contributed include:

Robert Champagne, *Audit Manager*

Gregory Pasko, *Senior Auditor*

Michael Willey, *Auditor*

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