DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
OFFICE OF AUDIT SERVICES
150 S. INDEPENDENCE MALL WEST
SUITE 316
PHILADELPHIA, PENNSYLVANIA 19106-3499

JUN 10 2003

Report Number: A-03-03-00203

Vincent P. Meconi, Secretary
Department of Health and Social Services
State of Delaware
The Herman M. Holloway, Sr. Campus
1901 North Dupont Highway
Main Building
New Castle, Delaware 19720

Dear Mr. Meconi:

Enclosed are two copies of the U.S. Department of Health and Human Services (HHS), Office of Inspector General, Office of Audit Services' report entitled "Review of the State of Delaware's Medicaid Drug Rebate Program." This review was self-initiated and the audit objective was to evaluate whether the State of Delaware's Department of Health and Social Services had established adequate accountability and internal controls over the Medicaid drug rebate program. Should you have any questions or comments concerning the matters commented on in this report, please direct them to the HHS official named on page 2 of this letter.

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To facilitate identification, please refer to Report Number A-03-03-00203 in all correspondence relating to this report.

Sincerely yours,

Stephen Virbitsky
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:
Ms. Sonia Madison
Regional Administrator
Centers for Medicare and Medicaid Services, Region III
Public Ledger Building, Suite 216
150 S. Independence Mall West
Philadelphia, PA 19106-3499

Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

REVIEW OF THE STATE OF DELAWARE'S MEDICAID DRUG REBATE PROGRAM

JUNE 2003
A-03-03-00203

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.

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Vincent P. Meconi, Secretary
Department of Health and Social Services
State of Delaware
The Herman M. Holloway, Sr. Campus
1901 North Dupont Highway
Main Building
New Castle, Delaware 19720

Dear Mr. Meconi:

This final report presents the results of the Office of Inspector General, Office of Audit Services REVIEW OF THE STATE OF DELAWARE'S MEDICAID DRUG REBATE PROGRAM.

The objective of our review was to determine whether the Delaware Department of Health and Social Services (DHSS) had established adequate accountability and internal controls over rebate billings to drug manufacturers, the resulting rebate collections, and the resolution of disputes. In 1992, DHSS contracted with Electronic Data Systems (EDS) to operate its drug rebate program.

FINDINGS

Generally, DHSS had established adequate accountability and internal controls over the Medicaid drug rebate program. However, we found that:

- DHSS personnel had not routinely backed-up spreadsheets that contain the state's Medicaid drug rebate program information reported to the Centers for Medicare and Medicaid Services (CMS); and

- DHSS overstated its outstanding rebate receivables, and had not reported rebates invoiced and adjustments on the CMS 64.9R (Drug Rebate Schedule).

RECOMMENDATIONS

We recommend that DHSS:

- Backup its drug rebate program spreadsheets on a regular basis;
- Develop procedures and reconcile the CMS 64.9R to accounting control totals reported to DHSS by its fiscal agent, EDS; and
- Accurately report billings, collections and outstanding rebate receivables on the CMS 64.9R.

The DHSS responded to our draft report in a letter dated May 23, 2003. Their complete response is included in Appendix A. The DHSS officials agreed with our findings. Based on their experience, DHSS officials discussed what they believe are the shortcomings of the CMS 64.9R reporting form. In addition, DHSS officials requested additional clarification on the requirements for level of detail and length of time records must be maintained.

INTRODUCTION

BACKGROUND

On November 5, 1990, Congress enacted the Omnibus Budget Reconciliation Act of 1990 legislation that, among other provisions, established the Medicaid drug rebate program. Responsibility for the rebate program is shared among the drug manufacturer(s), CMS, and the state(s). 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 on numerous issues 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 its average manufacturer price and best price information for each covered outpatient drug to CMS. Approximately 520 pharmaceutical companies participate in the program.

The CMS provides the unit rebate amount (URA) information to the state agency on a quarterly computer tape. However, the CMS tape may contain a $0 URA if the pricing information was not provided timely or if the pricing information has a 50 percent variance from the previous quarter. In instances of $0 URAs, the state agency is instructed to invoice the units, and the manufacturer should pay the rebate, based on the manufacturer's information. In addition, the manufacturers often change the URA based on updated pricing information, and submit this information to the state agency in the Prior Quarter Adjustment Statement.

In Delaware, the DHSS personnel expressed concern that some manufacturers continue to retroactively change the URAs on drugs back to the inception of the program in 1991. Currently there is no time limit for these changes. They recommended that prior period adjustments should be limited to 12 quarters – sufficient time for manufacturers to make adjustments and have CMS approve those adjustments.

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. Each state agency uses the URA from CMS and the utilization for 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 manufacturer has 38 days, from the day a state agency sends an invoice, to pay the rebate and avoid interest. 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 manufacturer and the state agency 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 under the Medicaid program to the manufacturer in order to resolve the dispute.

Each state agency is required to report, on a quarterly basis, outpatient drug expenditures and rebate collections on Forms CMS 64 (Medicaid Program Expenditure Report) and CMS 64.9R. The CMS 64.9R is part of the Form CMS 64 report that summarizes actual Medicaid expenditures for each quarter and is used by CMS to reimburse the federal share of these expenditures.

For the quarter ended June 30, 2002, EDS accounting records showed $5.4 million in billings. Based on its CMS 64.9Rs, DHSS averaged quarterly collections of $5.2 million for fiscal year 2002. The DHSS schedule of disputed rebates totaled $472,766, with the oldest dispute dated 1998.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

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

Scope

The drug rebate program was effective January 1, 1991. We concentrated our review on DHSS's policies, procedures and controls as of June 30, 2002. We also reviewed the aging schedule of accounts receivable and interviewed DHSS staff to understand how the Medicaid drug rebate program has operated since 1991.

Methodology

To accomplish our objectives, we interviewed DHSS officials to determine the policies, procedures and controls that existed with regard to the Medicaid drug rebate program. Also, we interviewed staff members that performed functions related to the drug rebate program, and we interviewed EDS staff to determine its role in the process. For disputed drug rebates, we reviewed reports generated by EDS. We also reviewed the drug rebate sections of DHSS's CMS 64 and CMS 64.9R for the fiscal year ended June 30, 2002.

Fieldwork was performed at the DHSS's office in New Castle, Delaware. The fieldwork was conducted during December 2002 and continued in the Office of Audit Services' Philadelphia regional office through February 2003.

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

FINDINGS AND RECOMMENDATIONS

FINDINGS

Generally, DHSS had established adequate accountability and internal controls over the Medicaid drug rebate program. However, we found that:

- DHSS personnel had not routinely backed-up spreadsheets that contain the state's Medicaid drug rebate program information reported to CMS; and

- DHSS overstated its outstanding rebate receivables, and had not reported rebates invoiced and adjustments on the CMS 64.9R.

DHSS'S DRUG REBATE PROGRAM

In 1992, Delaware contracted with EDS to prepare and mail invoices to manufacturers, collect drug rebates, resolve disputes, research utilization data to resolve errors, communicate with manufacturers, and monitor outstanding balances. In addition, EDS reconciled the drug rebate accounts, and reported rebate collections and outstanding receivables to DHSS. The DHSS staff posted payments to the general ledger, and prepared the CMS 64 reports.

The EDS staff stated that they collected 90 percent of manufacturers' rebates within 38 days. For the year ended June 30, 2002, the DHSS collected approximately $21 million in manufacturers' rebates; of that amount, half is the federal share. In our opinion, except as noted below, DHSS had established adequate internal controls over the Medicaid drug rebate program.

Data Backup

The DHSS had not routinely backed-up spreadsheets that contain the state's Medicaid drug rebate program data. According to DHSS personnel, there were no policies and procedures in place to indicate how often the accumulated data should be backed-up. At the time we interviewed DHSS personnel, they acknowledged that the data was last backed-up in 1999.

The EDS reported amounts invoiced and collected to DHSS, which accumulated data on rebates and allocated the state and federal share. To do this, DHSS personnel manually entered rebate information data into Excel spreadsheets on a stand-alone system. While it would not be impossible to recreate these spreadsheets, we think that the amount of time and effort would be extraordinary and that backing up electronic data on a regular basis is a prudent business practice.

DHSS'S CMS 64.9R Report Contained Incomplete and Inaccurate Data

For the quarter ended June 30, 2002, DHSS reported $30.4 million as the outstanding rebates receivable on line 6, column F of the CMS 64.9R. However, EDS reported, on its quarterly report to DHSS, $3.7 million as the outstanding balance of rebates receivable.

We asked both DHSS and EDS staff to explain the difference between the $30.4 million reported to CMS and the $3.7 million reported by EDS. The EDS records supported the $3.7 million of drug rebate receivables as the actual rebates receivable. The EDS personnel initially told us that they could not identify the $30.4 million. However, in a later conversation EDS personnel identified the $30.4 million as cash equal to 5 quarters of rebates collected.

The DHSS personnel stated that the $30.4 million was computer generated and they had not reconciled the CMS 64.9R report to EDS's cumulative totals for more than 1 year. The DHSS only reported cash collected on the CMS 64.9R. It did not include amounts invoiced and adjustments. The DHSS stated that it could not use EDS's quarterly reports because they are produced after the CMS reporting deadline.

The Code of Federal Regulations at 45 CFR Section 74.21 requires that the states' financial management system provide for "effective control over and accountability for all funds, property and other assets." Reconciling the quarterly reports from EDS to the CMS 64.9R report would create an effective control.

RECOMMENDATIONS

We recommend that DHSS:

- Backup its drug rebate program spreadsheets on a regular basis;
- Develop procedures and reconcile the CMS 64.9R to accounting control totals reported to DHSS by EDS; and
- Accurately report billings, collections and outstanding rebate receivables on the CMS 64.9R.

STATE AGENCY RESPONSE AND OIG COMMENTS

The DHSS responded to our draft report in a letter dated May 23, 2003. The complete response is included in Appendix A. Generally, DHSS officials agree with our findings. The DHSS response and OIG comments are summarized below.

DHSS Response

The DHSS agreed to backup its drug rebate program spreadsheets on a regular basis.

In reference to the recommendations made related to the CMS 64.9R report, DHSS believes that the issues related to the CMS 64.9R involve the definitions for each field on the form. The report has not been modified or changed to reflect the dynamics of the evolving program. In addition, DHSS discussed the effects of multiple prior period adjustments and unit discrepancies on monies collected and in turn the amounts reported on the CMS 64.9R. The DHSS stated that it would be beneficial to have CMS clearly define numbers requested and examples of how prior period adjustments and disputes should be reported when they cross multiple quarters.

Also, the DHSS commented on CMS's requirement that state agencies provide drug utilization data to manufacturers. According to DHSS, Federal regulations and CMS procedures are unclear on this issue. The DHSS requested clarification on how drug utilization data is to be reported to manufacturers, and on the requirements for retaining claim level data.

OIG Comments

We commend DHSS for agreeing to backup its drug rebate program spreadsheets on a regular basis.

We agree that multiple prior period adjustments and unit discrepancies add to the complexity of rebate reporting. Nevertheless, reporting requirements in the *State Medicaid Manual Section 2500.7, Part B requires the complete, accurate and full disclosure " of all drug rebates and collections."* To comply, we believe DHSS needs to

develop procedures and reconcile the CMS 64.9R to accounting control totals reported to DHSS by EDS, and to accurately report billings, collections and outstanding rebate receivables on the CMS 64.9R. In addition, CMS provided instructions for the completion of the CMS 64.9R in the *State Medicaid Manual Section 2500.7, Parts C and D.* The DHSS concerns about the CMS 64.9R will be conveyed to CMS.

Regarding the reporting of drug utilization in the form of claims level data to manufacturers, the requirements are stated in the Omnibus Budget Reconciliation Act of 1990 Section 4401(b)(2)(A), "Each State agency under this title shall report to each manufacturer, in a form consistent with standard reporting format established by the Secretary, information on the total number of dosage units of each covered outpatient drug dispensed under the plan during the quarter..." Therefore, the formats promulgated by CMS are mandatory. The CMS has published reporting formats in the Medicaid Drug Rebate Program State Releases. Release 14, 18, 72 and 73, and Form HCFA-R-144, makes reporting claim utilization data at the NDC level mandatory. Currently, under this program, there is no time limit for the retention of claims data.

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To facilitate identification, please refer to report number A-03-03-00203 in all correspondence relating to this report.

Sincerely yours,

Stephen Virbitsky
Regional Inspector General
for Audit Services

Direct Reply to HHS Action Official:

Sonia A. Madison
Regional Administrator
Centers for Medicare and Medicaid Services, Region III
Public Ledger Building, Suite 216
150 South Independence Mall West
Philadelphia, Pennsylvania 19106-3499

DELAWARE HEALTH
AND SOCIAL SERVICES
OFFICE OF THE SECRETARY

May 23, 2003

Mr. Stephen Virbitsky
Regional Inspector General for Audit Services
Department of Health & Human Services
150 S. Independence Mall West
Suite 316
Philadelphia, PA 19106-3499

Dear Mr. Virbitsky:

Thank you for the opportunity to comment on the draft report of the review of our Medicaid Drug Rebate Program.

My staff has indicated that they appreciate your cooperation and feedback. Specifically, we appreciate the time and effort the auditors from your office put into reviewing our program, especially as it relates to our dispute resolution process and the reporting of funds.

You noted in your discussion notes that CMS requires that each State agency provide drug utilization data to manufacturers. Federal Regulations and CMS procedures are unclear on this issue. As we understand it, the regulations do not require claim level data. It would be helpful if the report would clarify whether states need to provide more than invoice data or if the OIG believes that states should continue to store claim level data forever.

We agree that our financial spreadsheets should be backed up routinely and in the future we will insure that this occurs. As you know, we believe that the issues centered around the CMS 64.9R report involve the definitions for each field on the CMS report. This report was designed before many of the problems related to the rebate process were discovered. The report has not been modified or changed to reflect the dynamics of the evolving program. The multiple prior period adjustments (PPA) and unit discrepancies can radically change the amount of monies collected. It would be beneficial to the states to have CMS clearly define what numbers they are requesting and examples of how PPA and disputes should be reported when they cross multiple quarters. One additional concern that the Delaware Medicaid rebate team has is the disconnect between the NCPDP standards for billing units and the CMS rebate units. This adds to the time and effort needed to resolve disputes that could otherwise be avoided.

Again, I want to thank the OIG Team for its thorough review. We believe the rebate program is key in controlling costs to States in providing pharmacy benefits to their beneficiaries.

Sincerely,

Vincent P. Meconi

Vincent P. Meconi
Secretary

VPM:pam

pc: Elaine Archangelo, DSS Director
Phil Soule, DSS Deputy Director

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ACKNOWLEDGMENTS

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

Eugene Berti, *Audit Manager*
Carolyn Hoffman, *Senior Auditor*
Michael Lieberman, *Auditor*
Linda Millares, *Auditor*

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