DEPARTMENT OF HEALTH & HUMAN SERVICES REGION III

Memorandum

Date JAN 30 2004

From Regional Inspector General for Audit Services

Subject Audit Report – Summary Report on Reviews of Medicaid Drug Rebate Programs in Five States and the District of Columbia (Report Number A-03-04-00200)

To Sonia A. Madison
Regional Administrator
Centers for Medicare and Medicaid Services

Attached are two copies of the Department of Health and Human Services, Office of Inspector General's report entitled "Summary Report on Reviews of Medicaid Drug Rebate Programs in Five States and the District of Columbia." These self-initiated reviews evaluated whether Delaware, the District of Columbia, Maryland, Pennsylvania, Virginia and West Virginia had established adequate accountability and internal controls over the Medicaid drug rebate program.

Officials in your office have concurred with the attached report and have agreed to take corrective action. We would appreciate your views and the status of any further action taken or contemplated on our recommendations within the next 60 days. Should you have any questions or comments concerning the matters commented on in this report, please contact me or have your staff contact Eugene G. Berti, Jr., Audit Manager at 215-861-4474.

To facilitate identification, please refer to Report Number A-03-04-00200 in all correspondence relating to this report.

Stephen Virbitsky

Attachment

Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

SUMMARY REPORT ON REVIEWS OF MEDICAID DRUG REBATE PROGRAMS IN FIVE STATES AND THE DISTRICT OF COLUMBIA

January 2004
A-03-04-00200

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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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 awarding agency will make final determination on these matters.

DEPARTMENT OF HEALTH & HUMAN SERVICES REGION III

Memorandum

Date JAN 30 2004

From Regional Inspector General for Audit Services

Subject Final Audit Report - Summary Report on Reviews of Medicaid Drug Rebate Programs in Five States and the District of Columbia (Report Number: A-03-04-00200)

To Sonia A. Madison
Regional Administrator
Centers for Medicare & Medicaid Services

This final report summarizes the results of the Office of Inspector General self-initiated audits of Medicaid drug rebate programs in Delaware, the District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia.

The objective of our audit was to determine whether State Agencies in Region III had established adequate accountability and internal controls over their respective Medicaid drug rebate programs. We issued individual reports to each State Agency, and this report summarizes the issues identified in the six reports.

We found that:

- ✓ Four State Agencies (Delaware, the District of Columbia, Pennsylvania, and West Virginia) had not reported accurate or complete information on the Centers for Medicare & Medicaid Services (CMS) Form 64.9R.

- ✓ One State Agency (Virginia) had not reconciled drug rebates received with the invoices submitted by National Drug Code (NDC).

- ✓ One State Agency (Pennsylvania) had not kept accurate records of outstanding disputed amounts for each manufacturer and another State Agency (West Virginia) had not resolved disputes timely.

- ✓ One State Agency (Pennsylvania) had not reviewed quarterly rebates received from drug manufacturers to determine if interest was owed when rebates were received after the due date, nor had it verified the accuracy of interest on disputes either due to or due from drug manufacturers.

Title 45 Section 74.21 paragraph (b)(3) of the Code of Federal Regulations requires that financial management systems provide for effective control over and accountability for all funds, property, and other assets.

RECOMMENDATION

The Medicaid drug rebate program generates millions of dollars each quarter for each State Agency and is a very complex program. Thus, the State Agencies should ensure that proper policies, procedures, and controls exist to safeguard program funds. We believe the corrective action that we recommended in each of the individual reports, which we issued to the States and the District of Columbia, will provide opportunities to increase drug rebate revenues and to report more reliable accounts receivable information to CMS. Therefore, we recommend that CMS ensure that appropriate clearance documents are prepared to resolve each individual state report findings and recommendations.

CMS agreed with the content of the audit report but suggested that we modify our draft recommendation. We agreed with CMS and revised our recommendation.

INTRODUCTION

BACKGROUND

On November 5, 1990, Congress enacted the Omnibus Budget Reconciliation Act of 1990 legislation, which 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. 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.

CMS requires drug manufacturers to have a rebate agreement in order to have its products covered under the Medicaid program. The agreement requires the manufacturer to submit to CMS a listing of all covered outpatient drugs, and to report its average manufacturer price and best price information for each covered outpatient drug. Approximately 520 pharmaceutical companies participate in the program.

CMS calculates the unit rebate amount (URA) for each covered drug using pricing data submitted by the drug manufacturers. Each quarter, CMS provides the URA information to State Agencies on a computer file. However, the CMS file 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, CMS instructs State Agencies to invoice the manufacturer for the units dispensed and the manufacturer to pay the rebate based on the manufacturer's information. In addition, manufacturers often change the URA based on updated pricing information, and submit this information to the State Agency in the Prior Quarter Adjustment Statement.

For each covered drug, CMS requires State Agencies to maintain the number of units dispensed by manufacturer. Approximately 56,000 NDCs are available under the drug rebate program. Each State Agency uses the URA from CMS and the units dispensed for

each drug to determine the actual rebate amounts due from the manufacturer. CMS requires each State Agency to provide drug utilization data to the manufacturer when billing for rebates.

The manufacturer has 38 days from the day a State Agency sends an invoice to pay the rebate and avoid interest charges. The manufacturers submit to the State Agency a Reconciliation of State Invoice (ROSI) that details the current quarter's rebate 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 reports, on a quarterly basis, accounts receivable and rebate collection information for the drug rebate program on the 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.

The following schedule shows the average billings, collections, and outstanding rebates receivable for the 1-year period ending June 30, 2002.

State Agency	**Average Billings / Quarter (in millions $)**	**Average Collections / Quarter (in millions $)**	**Average Outstanding Balance (in millions $)**
Delaware	5.40	5.20	0.47
District of Columbia	Not Reported	2.80	4.10
Maryland	15.70	14.50	4.80
Pennsylvania	38.90	35.80	36.67
Virginia	21.40	22.00	35.04
West Virginia	Not Reported	12.80	15.50
Totals	81.40	93.10	96.58

The six State Agencies responsible for the drug rebate program in Region III are:

- ✓ Delaware – Health and Social Services
- ✓ District of Columbia – Medical Assistance Administration
- ✓ Maryland – Department of Health and Human Services
- ✓ Pennsylvania – Department of Public Welfare
- ✓ Virginia – Department of Medical Assistance Services
- ✓ West Virginia – Department of Health and Human Resources

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The audit objective was to evaluate whether the State Agencies in Region III had established adequate accountability and internal controls over their respective Medicaid drug rebate program. Individual reports were issued to each State Agency, and this report summarizes the issues identified in the six reports.

Scope

The drug rebate program was effective January 1, 1991. We concentrated our review on current policies, procedures, and controls as of June 30, 2002 for each State Agency. We also reviewed the aging schedule of accounts receivable and interviewed personnel from each State Agency or its fiscal agents to understand how the Medicaid drug rebate program has operated since 1991.

Methodology

To accomplish our objective we:

- ✓ Reviewed criteria for the drug rebate program including Federal regulations and CMS Program Releases;
- ✓ Reviewed States' written procedures and program reports;
- ✓ Interviewed State Agency personnel to gain an understanding of the program;
- ✓ Reviewed step-by-step the drug rebate process, including the drug rebate billing and collection quarterly cycle;
- ✓ Examined outstanding, uncollected and aged drug rebates; and
- ✓ Examined the CMS 64 and CMS 64.9R, and supporting documentation for the fiscal year ended June 30, 2002 as it related to the drug rebate program.

Fieldwork for this review was performed in our Philadelphia, Pennsylvania regional office. Fieldwork for each of the State reviews was performed at the State Agency offices in New Castle, Delaware; Washington, D.C.; Baltimore, Maryland; Harrisburg, Pennsylvania; Richmond, Virginia; and Charleston, West Virginia from October 2002 through November 2003.

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

FINDINGS AND RECOMMENDATIONS

Our audits showed that:

- ✓ Four State Agencies (Delaware, the District of Columbia, Pennsylvania, and West Virginia) had not reported accurate or complete information on the Centers for Medicare & Medicaid Services (CMS) Form 64.9R.

- ✓ One State Agency (Virginia) had not reconciled drug rebates received with the invoices submitted by National Drug Code (NDC).

- ✓ One State Agency (Pennsylvania) had not kept accurate records of outstanding disputed amounts for each manufacturer and another State Agency (West Virginia) had not resolved disputes timely.

- ✓ One State Agency (Pennsylvania) had not reviewed quarterly rebates received from drug manufacturers to determine if interest was owed when rebates were received after the due date, nor had it verified the accuracy of interest on disputes either due to or due from drug manufacturers.

CMS 64.9R Reports Not Accurate or Complete

The State Agencies in Delaware, the District of Columbia, Pennsylvania, and West Virginia submitted CMS 64.9R reports that were not accurate or complete.

Delaware

The Delaware State Agency reported $30.4 million as the outstanding rebates receivable on line 6, column F of the CMS 64.9R for the quarter ending June 30, 2002. However, Electronic Data Systems (EDS) (the State's drug rebate program contractor) reported $3.7 million as the outstanding balance of rebate receivables on its quarterly report to the State. EDS records supported the $3.7 million of drug rebate receivables as the actual rebates received. EDS personnel identified the $30.4 million as rebates collected for 5 quarters. State Agency personnel stated that the $30.4 million was computer generated and they had not reconciled the CMS 64.9R to EDS's cumulative totals for more than 1 year. State Agency personnel stated that they could not use EDS's quarterly reports because they were produced after the CMS reporting deadline.

District of Columbia

The District of Columbia State Agency reported the same outstanding balance ($4,129,033) each quarter of the fiscal year ending June 30, 2002. The $4.1 million represented disputes its fiscal agent was tasked with resolving. The State Agency reported rebates received during the quarter on line 5(b) of the CMS 64.9R and on line 2(b) of the CMS 64.9R to zero out the balance at the end of the quarter.

In addition, the State Agency had not allocated reported rebate information to the proper quarter. Technically, prior quarter rebate activity such as payments and receivables should be allocated to the quarters in which the transactions originated. The CMS 64.9R provides space to report the current quarter, the last 3 quarters, and a cumulative column for all other prior quarters receivables.

Finally, the State Agency had not reported the amount invoiced, corrections, adjustments, or disputes not paid during the quarter. In the narrative section of the CMS 64.9Rs for fiscal year ending June 30, 2002, State Agency personnel noted that, "Invoice information was not available at the time of submission. It will be provided as soon as possible." However, the subsequent CMS 64.9Rs did not contain the information. As a result, the State Agency was not providing CMS with accurate information regarding its drug rebate program.

According to a State Agency official, the main reasons the CMS 64.9Rs were not completed accurately and completely were the lack of personnel and time. The official also commented that the addition of Affiliated Computer Services and First Health Service Corporation (FHSC) has helped greatly in administering the drug rebate program.

Pennsylvania

The Pennsylvania State Agency had not reconciled the CMS 64.9R prior quarters to its accounting records because of problems with record keeping in the early years of the program. As a result, the State Agency has not been able to verify that all numbers from the beginning of the program are accurate; therefore causing the CMS 64.9R to be inaccurate when reporting amounts to CMS.

West Virginia

The West Virginia State Agency accounts receivable department, which prepared the CMS 64.9R, had not reconciled the outstanding rebate balance reported on the CMS 64.9R to its accounting records. As of June 30, 2002, the accounts receivable department reported an outstanding rebate balance of $15.5 million on the CMS 64.9R, however its accounting records indicated that the outstanding rebate balance was $20.7 million. According to the accounts receivable staff it would be difficult to reconcile the CMS 64.9R outstanding rebate balance to the accounting records because the process would have to be done manually and it would be time consuming to complete. As a result, the outstanding rebate balance reported on the CMS 64.9R did not agree with supporting accounting records.

We made the following recommendations to each State Agency:

- The Delaware State Agency should develop procedures and reconcile the CMS 64.9R to accounting control totals reported to the State Agency by the fiscal

agent, and accurately report billings, collections and outstanding receivables on the CMS 64.9R.

- ❖ The District of Columbia State Agency should accurately report outstanding rebates receivable and rebates collected, and include rebates invoiced and adjustments on the CMS 64.9R.

- ❖ The Pennsylvania State Agency should ensure that its new accounting system (PROMISe system), expected to be implemented in 2004, contain adequate policies, procedures and controls that sufficiently detail accounts receivable to accurately monitor and collect receivables, record disputes, and provide information for the CMS 64.9R prior periods.

- ❖ The West Virginia State Agency should reconcile the outstanding rebates reported on the CMS 64.9R to its accounting records, and instruct its rebate billing department and accounts receivable department to reconcile duplicate records, and total amount invoiced, collected, disputed and outstanding.

Rebates not Reconciled to National Drug Codes

The Virginia State Agency used a fiscal agent, FHSC to administer its drug rebate program since the third quarter of State fiscal year 1998. However, when reconciling rebates with the manufacturers' ROSIs, FHSC had not reconciled to the NDC level. This practice did not follow CMS's Best Practice Guide nor FHSC's Drug Rebate Policy and Procedures Manual. Both the guide and the manual state, "Make sure that it [the manufacturer's check] is posted to the proper labeler and the proper NDC."

According to FHSC personnel, when a rebate is received, it is reconciled to the labeler level on each account. In our opinion, reconciling to the NDC level provides a greater depth of detail that increases the accuracy of the records.

FHSC implemented a new Medicaid management information system on June 27, 2003. It is our understanding that the new system will reconcile the records to the NDC level.

- ❖ We recommended that the Virginia State Agency ensure that the new system reconcile manufacturers' rebates to the NDC level.

Dispute Resolution

The Pennsylvania State Agency was unable to provide information by disputes only. The State Agency, however, provided us a schedule showing disputes for 10 manufacturers that may contain corrections and adjustments. This schedule totaled $14.6 million and accounted for about 75 percent of the outstanding balances per State Agency personnel. State Agency personnel stated they could not give an exact dollar amount for total disputes, either as an aggregate total of all manufacturers or for just one manufacturer, without reviewing the old ROSI reports. However, State Agency personnel stated that

the total outstanding disputed rebate balance was approximately $19 million. This number was consistent with an extrapolated total of $19.5 million based on $14.6 million equaling 75 percent.

The West Virginia State Agency had not resolved rebate discrepancies timely. The rebate billing department provided a list of disputed amounts, by manufacturer and by year, totaling $561,088. The rebate billing department staff stated that, while they kept files and spreadsheets that track disputes by manufacturer, they had not had time to work on resolving disputes for a year. The rebate coordinator, whose responsibilities include resolving disputes, stated she was able to spend only about 40 percent of her time on the rebate program, which was not sufficient time to complete the tasks. Consequently, West Virginia's rebate billing department was not resolving rebate discrepancies in a timely manner.

We made the following recommendations to each State Agency:

- The Pennsylvania State Agency ensure that its new accounting system age the accounts receivable and write-off any amount deemed uncollectible.

- The West Virginia State Agency should resolve disputes as expeditiously as possible.

Accounting for Interest on Late Rebate Payments

The Pennsylvania State Agency had not reviewed drug manufacturers' quarterly rebates that were received 38 days or more after the due date to determine if interest was owed. When a manufacturer paid interest, the State Agency relied on and accepted the manufacturers' calculations. The State Agency also accepted the manufacturers' calculations of the amount of interest Pennsylvania owed a manufacturer. State Agency officials had not verified the accuracy of interest paid to or owed by manufacturers.

Although CMS guidance states that it is the manufacturers' responsibility to calculate and pay interest for late rebates, we believe it would be a prudent business practice on the part of the State Agency to verify the accuracy of the manufacturers' interest calculations.

- We recommended that the Pennsylvania State Agency monitor interest accruals and payments for accuracy.

Conclusion

With the exception of Pennsylvania, the State Agencies generally agreed with the findings and recommendations summarized in this report, and indicated that corrective action had been enacted or was planned. Copies of our reports, including State Agency comments, are available at http://oig.hhs.gov.

Recommendation

The Medicaid drug rebate program generates millions of dollars each quarter for each State Agency and is a very complex program. Thus, the State Agencies should ensure that proper policies, procedures, and controls exist to safeguard program funds. We believe the corrective action that we recommended in each of the individual reports, which we issued to the States and the District of Columbia, will provide opportunities to increase drug rebate revenues and to report more reliable accounts receivable information to CMS. Therefore, we recommend that CMS ensure that appropriate clearance documents are prepared to resolve each individual State report findings and recommendations.

CMS Comments and OIG Response

On December 24, 2003, CMS responded to our draft report. CMS agreed with the content of the report but felt the recommendation was redundant since it called for CMS to follow up on each of the recommendations in the individual State reports, which it does as part of the clearance process for the individual reports. CMS suggested a better recommendation would be to recommend that CMS ensure that the appropriate clearance documents are prepared to resolve the individual State report findings and recommendations. CMS's response is contained in its entirety as an Appendix to this report.

We agreed with CMS's comments and revised our recommendation.

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To facilitate identification, please refer to report number A-03-04-00200 in all correspondence relating to this report.

Stephen Virbitsky

APPENDIX

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Memorandum

Centers for Medicare & Medicaid Services
Region III
Suite 216, The Public Ledger Bldg
150 S. Independence Mall West
Philadelphia, PA 19106-3499

Date: DEC 2 4 2003

To: Regional Inspector General for Audit Services

From: Manager, Financial Review Branch
Division of Medicaid and Children's Health

Subject: Region III Roll up Report for 6-State Review of Medicaid Drug Rebate Program (A-03-04-00200)

We reviewed the subject report and agree with the content of the report. However, the one recommendation in the report would appear to be redundant since the recommendation calls for CMS to follow up on each of the recommendations contained in the individual state reports.

As part of the audit clearance process for the individual state reports, we follow up on the specific recommendations and if the states have taken the appropriate corrective action, then we prepare the proper audit clearance documents. Perhaps a better recommendation would be that CMS ensure that appropriate clearance documents are prepared to resolve the individual state report findings and recommendations.

If you should have any questions regarding this matter, contact Thomas Zlakowski of my staff at (215) 861-4242.

Ted Gallagher