DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General

Memorandum

Date OCT 15 2003

From Regional Inspector General for Audit Services

Subject Audit Report – REVIEW OF WEST VIRGINIA'S MEDICAID DRUG REBATE PROGRAM (Report Number A-03-03-00207)

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

Attached are two copies of the U. S. Department of Health and Human Services (HHS), Office of Inspector General report entitled "Review of West Virgnia's Medicaid Drug Rebate Program." This review was self-initiated and the audit objective was to evaluate whether the West Virginia's Department of Health and Human Resources (DHHR) 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 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-03-03-00207 in all correspondence relating to this report.

Stephen Virbitsky

Attachment

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

OCT 15 2003

Report Number: A-03-03-00207

Paul M. Nusbaum, Secretary
West Virginia Department of Health and Human Resources
State Capital Complex, Building 3, Room 206
Charleston, West Virginia 25305

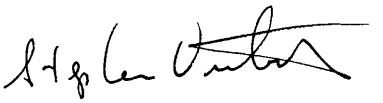
Dear Mr. Nusbaum:

Enclosed are two copies of the Department of Health and Human Services (HHS), Office of Inspector General report entitled "Review of West Virginia's Medicaid Drug Rebate Program." This review was self-initiated and the audit objective was to evaluate whether West Virginia's Department of Health and Human Resources 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 below.

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 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-03-03-00207 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 WEST VIRGINIA'S MEDICAID DRUG REBATE PROGRAM

OCTOBER 2003
A-03-03-00207

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 awarding agency will make final determination on these matters.

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

OCT 15 2003

Paul L. Nusbaum, Secretary
West Virginia Department of Health and Human Resources
State Capitol Complex, Building 3, Room 206
Charleston, West Virginia 25305

Dear Mr. Nusbaum:

This final report presents the results of the Office of Inspector General "Review of West Virginia's Medicaid Drug Rebate Program."

Our audit objective was to evaluate whether the West Virginia Department of Health and Human Resources (DHHR) had established adequate accountability and internal controls over the Medicaid drug rebate program.

FINDINGS AND RECOMMENDATIONS

FINDINGS

DHHR needs to establish better controls over certain aspects of its Medicaid drug rebate program. We found that:

- Outstanding rebates reported on the CMS 64.9R did not agree with the accounting records;
- DHHR had not resolved disputes timely;
- The rebate billing department and accounts receivable department maintained separate accounting records of rebate transactions without reconciling their records to one another; and
- DHHR used an outdated policies and procedures manual for the Medicaid drug rebate program that was not approved by management.

RECOMMENDATIONS

We recommend that DHHR:

- Reconcile the outstanding rebates reported on the CMS 64.9R to its accounting records;
- Resolve disputes as expeditiously as possible;
- Instruct its rebate billing department and accounts receivable department to reconcile duplicate records, and total amount invoiced, collected, disputed and outstanding; and
- Update its written policies and procedures manual and have the manual approved by management.

In a written response dated September 16, 2003, DHHR provided comments to our draft report. DHHR officials concurred with our recommendations and identified actions being taken to resolve the audit findings. Their complete response is included in Appendix A.

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), Centers for Medicare & Medicaid Services (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.

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.

CMS provides the unit rebate amount (URA) information to the state agency on a quarterly computer tape. However, 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.

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. 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 to 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.

In West Virginia, DHHR 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 reports, on a quarterly basis, outpatient drug expenditures and rebate collections on Forms CMS 64 and CMS 64.9R. Form CMS 64.9R is part of the CMS 64 report that summarizes actual Medicaid expenditures for each quarter and is used by CMS to reimburse the federal share of these expenditures. Specifically, on the Form CMS 64.9R, the states report rebates invoiced in the current quarter, rebates received, and uncollected rebate balances. For the year ended June 30, 2002, DHHR reported an average of $12.8 million in rebates received per quarter and an outstanding rebate balance of $15.5 million. About $1.8 million of this amount is over 90 days old per the CMS-64.9R.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

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

Scope

Although the drug rebate program was established in January 1991, we limited our review to the current drug rebate program policies, procedures and controls. We also reviewed the drug rebate sections of DHHR's CMS 64 and CMS 64.9R for the fiscal year ended June 30, 2002. We also reviewed the aging schedule of accounts receivable and interviewed DHHR staff to understand how the Medicaid drug rebate program has operated since 1991.

Methodology

To accomplish our objectives we:

1) Obtained and reviewed criteria for the drug rebate program including federal regulations and CMS Program Releases;

2) Obtained and reviewed DHHR's written policies and procedures;

3) Interviewed DHHR employees to gain an understanding of the program;

4) Reviewed step-by-step DHHR's drug rebate process, including a walk through of the drug rebate billing and collection quarterly cycle; and

5) Obtained and examined Forms CMS 64 and CMS 64.9R, and supporting documentation for the year ended June 30, 2002 as it related to the drug rebate program.

The audit did not require an evaluation of DHHR's entire internal control system. Instead, we evaluated only those controls that relate to DHHR's accumulation of drug rebate billing and collection procedures and the reporting of drug rebate payments to CMS.

Fieldwork was performed at the DHHR's office in Charleston, West Virginia. The fieldwork was conducted during March 2003 and continued in the Office of Audit Services' Philadelphia regional office through June 2003.

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

FINDINGS AND RECOMMENDATIONS

FINDINGS

DHHR needs to establish better controls over certain aspects of its Medicaid drug rebate program. We found that:

- Outstanding rebates reported on the CMS 64.9R did not agree with the accounting records;

- DHHR had not resolved disputes timely;

- The rebate billing department and accounts receivable department maintained separate accounting records of rebate transactions without reconciling their records to one another; and

- DHHR used an outdated policies and procedures manual for the Medicaid drug rebate program that was not approved by management.

DHHR'S DRUG REBATE PROGRAM

Two departments within DHHR handle the Medicaid drug rebate program, except for the preparation of the rebate invoices. The two departments are the accounts receivable department and the Bureau for Medical Services, Office of Pharmacy Services (rebate billing department).

The accounts receivable department collected and endorsed checks, bundled them with other checks for deposit by Treasury staff. The rebate billing department mailed invoices to manufacturers, resolved disputes, calculated interest due, and communicated with manufacturers. Affiliated Computer Services, the State's claim processor, is responsible for creating the quarterly invoices while the State's Information Services and Communication office is responsible for printing the invoices.

CMS 64.9R Report Not Accurate

The accounts receivable department, which prepares the CMS 64.9R did not reconcile 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.

Dispute Resolution

DHHR 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, DHHR's rebate billing department was not resolving rebate discrepancies as expeditiously as would be expected.

DHHR's Billing Department and Accounts Receivable Department

DHHR's rebate billing department and accounts receivable department maintained separate accounting records that contain the same transactions, thus duplicating efforts by manually inputting the information into their own stand-alone systems.

For example, each department inputs the date invoices are mailed, invoiced amount, date payment was received, amount received, adjustments, corrections, interest due or interest paid into the accounting records. Both departments used this information to maintain individual accounting records of the cumulative receivable balances for all drug manufacturers. Also, the two departments did not reconcile totals, thus missing an important control to ensure the accuracy of both departments' records.

Policies and Procedures Manual

DHHR did not have a current policies and procedures manual for the Medicaid drug rebate program. In 1994, DHHR staff developed a procedures manual that was not reviewed or approved by management. Since 1994 there had been additions to staff and changes in operating procedures; however, the manual had not been updated. An updated manual would provide guidance to current staff as well as make the transition of a new employee easier while maintaining continuity in the program.

RECOMMENDATIONS

We recommend that DHHR:

- Reconcile the outstanding rebates reported on the CMS 64.9R to accounting records;

- Resolve disputes as expeditiously as possible;

- Instruct its rebate billing department and accounts receivable department to reconcile duplicate records, and total amount invoiced, collected, disputed and outstanding rebates; and

- Update its written policies and procedures manual, and have the manual reviewed by management.

DHHR Response and OIG Comments

DHHR responded to our draft report in a letter dated September 16, 2003 (Appendix A). In its response DHHR officials concurred with our recommendations. DHHR's response and our comments are summarized below.

DHHR contracted with Unisys to be its new fiscal agent and will use Unisys' Pharmaceutical Rebate Information Management System (PRIMS) to manage the drug rebate program. The PRIMS is expected to be functional in February 2004. DHHR stated that once PRIMS is loaded and functioning, rebate payments will be reconciled on a National Drug Code level for the first time in West Virginia. In addition, PRIMS includes a CMS 64 report function, which will provide information, in the proper format to complete the CMS 64.

DHHR stated that the accounting position for the rebate program will be moved from the Office of Accounting to the Bureau for Medical Services' Drug Rebate program. This staff person will be trained on PRIMS and duties will only include rebate related activities such as: evaluating the rebate accounting records for completeness; developing and conducting internal audit schedules for assuring accuracy of the data; maintain rebate historical documents as well as the new rebate computer system; and overseeing all accounting processes within the Rebate Program.

Currently, DHHR resolves disputes as best as possible using available resources. DHHR plans to change the workflow and responsibilities within the rebate program to aid in the dispute resolution process and hire additional staff to support the new PRIMS system.

DHHR agreed it needed to update its current policies and procedures manual. DHHR is currently drafting a new policies and procedures manual. Appropriate sections will be written and added as the new rebate program is put into place and procedures are defined. Once the manual is completed, it will be presented to management for review and approval.

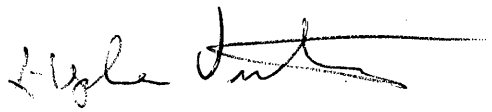
OIG Comment

The OIG believe that the corrective actions proposed by DHHR and the PRIMS, when implemented, should address the audit findings.

*** *** ***

To facilitate identification, please refer to report number A-03-03-00207 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 S. Independence Mall West
Philadelphia, PA 19106-3499

APPENDIX

STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
Office of the Secretary
State Capitol Complex - Building 3, Room 206
Charleston, West Virginia 25305
Telephone: (304) 558-0684 Fax: (304) 558-1130

Bob Wise
Governor

Paul L. Nusbaum
Secretary

September 16, 2003

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

Dear Mr. Virbitsky:

We have received the copies of the Department of Health and Human Services, Office of Inspector General's draft report entitled "Review of West Virginia's Medicaid Drug Rebate Program" (Report Number A-03-03-00207). This draft report was the result of the audit of our rebate program that was performed under your direction in March 2003. We have taken note of the findings and recommendations that were outlined in the report and, as requested, we are providing comments on each recommendation.

The West Virginia Medicaid Rebate Program has historically been performed through a manual process using the guidelines set forth by the Centers for Medicare and Medicaid Services (CMS). Just recently, we have contracted the services of a new fiscal agent, Unisys, and we are going to be utilizing their Pharmaceutical Rebate Information Management System (PRIMS) starting in February 2004. We are very excited about this new venture and hope that it will allow us to have more control over our Rebate Program. PRIMS has many features that will help our Program become more efficient. In addition, the accounting position in the Office of Accounting is being moved to the Bureau for Medical Services' Rebate Program unit. The staff person in this position will be trained on PRIMS and be responsible for the accuracy of the rebate accounting. Once PRIMS is loaded and functioning, the rebate payments will be reconciled on a National Drug Code (NDC) level for the first time in West Virginia. This will also increase the efficiency of the Program. As you can see, we are making significant modifications that will establish better accountability in the Rebate Program.

In response to your request for written comments on the draft report, we have listed each of the recommendations along with our comments. They are as follows:

- **Reconcile the outstanding rebates reported on the CMS 64.9R to accounting records.**

  As stated above, the accounting position for the Rebate Program will be moved from the Office of Accounting to the Bureau for Medical Services' Rebate Program. This staff person will be trained on PRIMS and will become knowledgeable of the Medicaid Drug Rebate Program. Also, this person's duties will only include rebate-related activities instead of numerous accounting responsibilities. This action, along with the new rebate system that will be functional in February 2004, will help correct this audit finding. PRIMS includes a CMS64 report function which will provide the information, in the proper format, required to complete the actual CMS64 report that is sent to CMS. We expect these changes to correct the inaccuracy of the reconciliation of the outstanding rebate balances reported on the CMS64.9R to the Rebate Program's accounting records.

- **Resolve disputes as expeditiously as possible.**

  Dispute resolution is a very time consuming and cumbersome process at the present time. The rebate staff resolves disputes as best as possible using the available resources. However, there are plans to change the work flow and responsibilities within the Rebate Program which will aid in the resolution process. In addition, once our new rebate system is loaded with data and is functional, we will have a more efficient and quicker way of reviewing and collecting data for dispute resolution. We also expect to add additional staff to provide support for the new system. Therefore, we anticipate that these changes will result in more expeditious resolution of drug rebate disputes.

- **Instruct its rebate billing department and accounts receivable department to reconcile duplicate records, and total amount invoiced, collected, disputed and outstanding rebates.**

  Once the accounting position is moved to the Rebate Program and an accountant is hired (the position is presently vacant), the accountant's duties will include evaluating the rebate accounting records for completeness, developing and conducting internal audit schedules for assurance of accuracy, maintaining rebate historical documents as well as the new rebate computer system, and to oversee all accounting processes within the Rebate Program. With these controls in place, we will hopefully eliminate the inaccuracy of the records and any duplicated efforts by the staff.

- **Update its written policies and procedures manual, and have the manual reviewed by management.**

  Since the Rebate Program is currently undergoing changes in staffing responsibilities and duties and a new rebate computer system is being acquired, many of the current procedures will be changing. However, staff have begun to work on a draft of a new policy and procedure manual. Appropriate sections will be written and added as the new rebate system is put into place and procedures are defined. Once the manual is completed, it will be presented to management for review and approval. Changes and updates will be made to the manual as required to provide guidance to current staff, as well as to be a transitioning and learning tool for new employees. This should help maintain continuity in the Program.

We understand the audit objective in evaluating the accountability and internal controls of the Medicaid Drug Rebate Program and appreciate your recommendations. We are always open to suggestions to improve the efficiency and effectiveness of our programs and, therefore, concur with your recommendations. If you need additional information regarding the West Virginia Medicaid Rebate Program, please call Gail Goodnight, Rebate Coordinator, Bureau for Medical Services, at (304) 558-5977.

Sincerely,

Paul Nusbaum
Secretary

PLN:lle

cc: Shana Phares
Danny Franco
Nancy V. Atkins
Peggy A. King

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:

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