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OCT 6 2008

Report Number: A-03-08-00200

Ms. Marsha K. Morris, Commissioner
Department of Health and Human Resources
350 Capital Street, Room 251
Charleston, West Virginia 25301-3706

Dear Ms. Marsha:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled "Follow-Up Audit of the Medicaid Drug Rebate Program in West Virginia." We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this 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.

Pursuant to the principles of the Freedom of Information Act, 5 U.S.C. § 552, as amended by Public Law 104-231, OIG reports generally are made available to the public to the extent the information is not subject to exemptions in the Act (45 CFR part 5). Accordingly, this report will be posted on the Internet at <http://oig.hhs.gov>.

If you have any questions or comments about this report, please do not hesitate to call me, or contact Mr. Eugene G. Berti, Jr., Audit Manager, at (215) 861-4474 or through e-mail at Gene.Berti@oig.hhs.gov. Please refer to report number A-03-08-00200 in all correspondence.

Sincerely,


Stephen Virbitsky
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Ms. Jackie Garner, Consortium Administrator
Consortium for Medicaid and Children's Health Operations
Centers for Medicare & Medicaid Services
233 North Michigan Avenue, Suite 600
Chicago, Illinois 60601

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**FOLLOW-UP AUDIT OF THE
MEDICAID DRUG REBATE
PROGRAM IN WEST VIRGINIA**



Daniel R. Levinson
Inspector General

October 2008
A-03-08-00200

Office of Inspector General

<http://oig.hhs.gov>

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

The Medicaid drug rebate program, which began in 1991, is set forth in section 1927 of the Social Security Act. For a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the program, the manufacturer must enter into a rebate agreement with the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each undertake certain functions in connection with the drug rebate program. In West Virginia, the Department of Health and Human Resources (the State agency) administers the Medicaid drug rebate program.

In 2005, we issued a report on the results of audits of the Medicaid drug rebate programs in 49 States and the District of Columbia (A-06-03-00048). Those audits found that only four States had no weaknesses in accountability for and internal controls over their drug rebate programs. As a result of the weaknesses, we concluded that States lacked adequate assurance that all of the drug rebates due to the States were properly recorded and collected. Additionally, CMS did not have reliable information from the States to properly monitor the drug rebate program.

In our previous audit of the West Virginia drug rebate program, we determined that the State agency did not have adequate controls over certain aspects of its Medicaid drug rebate program. We found that: 1) outstanding rebates reported on the Form CMS-64.9R did not agree with the accounting records, 2) drug rebate disputes were not resolved in a timely manner, 3) the rebate billing department and accounts receivable department maintained separate accounting records of rebate transactions and did not reconcile their records to one another, and 4) the State agency used an outdated policies and procedures manual for the Medicaid drug rebate program that was not approved by management (A-03-03-00207).

We recommended that the State agency:

- reconcile the outstanding rebates reported on the Form 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.

The State agency agreed with our findings and stated that it had taken action to correct them.

This current review of West Virginia is part of a nationwide series of reviews conducted to determine whether States have addressed the weaknesses in accountability for and internal

controls over their drug rebate programs found in the previous reviews. Additionally, because the Deficit Reduction Act of 2005 required States, as of January 2006, to begin collecting rebates on single source drugs administered by physicians, this series of reviews will also determine whether States have complied with the new requirement.

OBJECTIVES

Our objectives were to determine whether the State agency had (1) implemented the recommendations made in our previous audit of the West Virginia drug rebate program and (2) established controls over collecting rebates on single source drugs administered by physicians.

SUMMARY OF FINDINGS

The State agency initiated corrective measures to address all of our recommendations except one. The State agency did not resolve disputes in a timely manner. The State agency established controls over collecting rebates on single source drugs administered by physicians.

Since our prior audit, the State agency has resolved some rebate disputes. However, the State agency did not comply with the requirements of the rebate agreement or its own policies and procedures for the timely resolution of disputes due to insufficient staffing. As a result, the aggregate unresolved disputes grew from \$561,088 in 2002 to \$5,779,790 on June 30, 2006 as disputed items aged and new disputes remained unresolved.

RECOMMENDATION

We recommend that the State agency resolve \$5,779,790 in disputes in a timely manner.

STATE AGENCY COMMENTS

In its comments to our draft report, the State agency concurred with our recommendation. The Appendix presents the State agency comments.

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INTRODUCTION

BACKGROUND

Pursuant to Title XIX of the Social Security Act (the Act), the Medicaid program provides medical assistance to certain low-income individuals and individuals with disabilities. The Federal and State Governments jointly fund and administer the Medicaid program. At the Federal level, the Centers for Medicare & Medicaid Services (CMS) administers the program. Each State administers its Medicaid program in accordance with a CMS-approved State plan. Although the State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements.

Drug Rebate Program

The Medicaid drug rebate program, which began in 1991, is set forth in section 1927 of the Act. For a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the program, the manufacturer must enter into a rebate agreement with CMS and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each undertake certain functions in connection with the drug rebate program. In West Virginia, the Department of Health and Human Resources (the State agency) is responsible for the drug rebate program.

Pursuant to section II of the rebate agreement and section 1927(b) of the Act, manufacturers are required to submit a list to CMS of all covered outpatient drugs and to report each drug's average manufacturer price and, where applicable, best price. Based on this information, CMS calculates a unit rebate amount for each covered outpatient drug and provides the amounts to States quarterly.

Section 1927(b)(2)(A) of the Act requires States to maintain drug utilization data that identifies, by National Drug Code (NDC), the number of units of each covered outpatient drug for which the States reimbursed providers. The number of units is applied to the unit rebate amount to determine the actual rebate amount due from each manufacturer. Section 1927(b)(2) of the Act requires States to provide the drug utilization data to CMS and the manufacturer. States also report drug rebate accounts receivable data on Form CMS-64.9R. This is part of Form CMS-64, "Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program," which summarizes actual Medicaid expenditures for each quarter and is used by CMS to reimburse States for the Federal share of Medicaid expenditures.

Physician-Administered Drugs

Section 6002(a) of the Deficit Reduction Act of 2005 (DRA) amends section 1927 of the Act and requires States, as of January 1, 2006, to collect and submit utilization data for single source drugs administered by physicians so that States may obtain rebates for the drugs.¹ Single source drugs are commonly referred to as "brand name drugs" and do not have generic equivalents.

¹This provision of the DRA expands the requirement to certain multiple source drugs administered by physicians after January 1, 2008.

In West Virginia, physician-administered drugs are billed to the State Medicaid program on a physician claim form using procedure codes that are part of the Healthcare Common Procedure Coding System. The NDC is not included on the physician claim form. The procedure code identifies a drug by its active ingredient(s) and identifies the number of drug units (billing units) allowed per reimbursement for that procedure code. Because rebates are calculated and paid based on NDCs, each procedure code must be converted to an NDC. Additionally, the billing units for a procedure code may differ from the units used for rebate purposes (e.g., grams versus liters). Therefore, to determine rebates, the procedure codes must be converted into NDCs for single source drugs, and procedure code billing units must be converted into equivalent NDC billing units.

Prior Office of Inspector General Reports

In 2005, we issued a report on the results of audits of the Medicaid drug rebate programs in 49 States and the District of Columbia.² Those audits found that only four States had no weaknesses in accountability for and internal controls over their drug rebate programs. As a result of the weaknesses, we concluded that States lacked adequate assurance that all of the drug rebates due to the States were properly recorded and collected. Additionally, CMS did not have reliable information from the States to properly monitor the drug rebate program.

In our previous audit of the West Virginia drug rebate program, we determined that the State agency did not have adequate controls over certain aspects of its Medicaid drug rebate program. We found that: 1) outstanding rebates reported on the Form CMS-64.9R did not agree with the accounting records, 2) drug rebate disputes were not resolved in a timely manner, 3) the rebate billing department and accounts receivable department maintained separate accounting records of rebate transactions and did not reconcile their records to one another, and 4) the State agency used an outdated policies and procedures manual for the Medicaid drug rebate program that was not approved by management.³

We recommended that the State agency:

- reconcile the outstanding rebates reported on the Form 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.

²“Multistate Review of Medicaid Drug Rebate Programs” (A-06-03-00048), issued July 6, 2005; Arizona was not included because it did not operate a drug rebate program.

³“Review of West Virginia’s Medicaid Drug Rebate Program” (A-03-03-00207), issued October 15, 2003.

The State agency agreed with our findings and stated that it had taken action to correct them.

West Virginia Drug Rebate Program

The State agency contracts with its fiscal agent, Unisys, to perform all drug rebate program functions other than receiving rebate funds. The fiscal agent's responsibilities included verifying interest payments and accounting for rebates on single source drugs administered by physicians. The fiscal agent also converts the procedure code billing units into equivalent NDC billing units.

The State agency reported an outstanding drug rebate balance of \$36,802,938 on the June 30, 2006, Form CMS-64.9R. However, none of this amount related to the June 30, 2006, quarterly billings. Of the \$36,802,938 that was past due, \$7,527,153 was more than 1 year old. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately \$142,551,410 million and collections of \$142,407,504 million.

This current review of the West Virginia drug rebate program is part of a nationwide series of reviews conducted to determine whether States have addressed the weaknesses in accountability for and internal controls over their drug rebate programs found in the previous reviews. Additionally, because the DRA required States, as of January 2006, to begin collecting rebates on single source drugs administered by physicians, this series of reviews will also determine whether States have complied with the new requirement.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

Our objectives were to determine whether the State agency had (1) implemented the recommendations made in our previous audit of the West Virginia drug rebate program and (2) established controls over collecting rebates on single source drugs administered by physicians.

Scope

We reviewed the State agency's current policies, procedures, and controls over the drug rebate program and the accounts receivable data reported on Form CMS-64.9R as of June 30, 2006.

We performed our fieldwork at the State agency and its fiscal agent, both of which are located in Charleston, West Virginia, in October 2007.

Methodology

To accomplish our objectives, we:

- reviewed section 1927 of the Act, section 6002(a) of the DRA, CMS guidance issued to State Medicaid directors and other information pertaining to the Medicaid drug rebate program;
- reviewed the policies and procedures related to the fiscal agent's drug rebate accounts receivable system;
- interviewed State agency officials and fiscal agent staff to determine the policies, procedures, and controls that related to the Medicaid drug rebate program;
- reviewed copies of Form CMS-64.9R for the period July 1, 2005, through June 30, 2006;
- reviewed accounts receivable records as of June 30, 2006, and interest payments received for the quarter ended June 30, 2006;
- interviewed fiscal agent staff to determine the processes used in converting physician services claims data into drug rebate data related to single source drugs administered by physicians; and
- reviewed rebate billings and reimbursements for procedure codes related to single source drugs administered by physicians for the period January 1 through June 30, 2006.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

FINDINGS AND RECOMMENDATION

The State agency initiated corrective measures to address all of our recommendations except one. The State agency did not resolve disputes in a timely manner. The State agency established controls over collecting rebates on single source drugs administered by physicians.

Since our prior audit, the State agency has resolved some rebate disputes. However, the State agency did not comply with the requirements of the rebate agreement or its own policies and procedures for the timely resolution of disputes due to insufficient staffing. As a result, the aggregate unresolved disputes grew from \$561,088 in 2002 to \$5,779,790 on June 30, 2006, as disputed items aged and new disputes remained unresolved.

IMPLEMENTATION OF PRIOR RECOMMENDATIONS

In our prior audit of the West Virginia drug rebate program, we determined that the State agency did not have adequate controls over certain aspects of its Medicaid drug rebate program. We found that: 1) outstanding rebates reported on the Form CMS-64.9R did not agree with the accounting records, 2) drug rebate disputes were not resolved in a timely manner, 3) the rebate

billing department and accounts receivable department maintained separate accounting records of rebate transactions and did not reconcile their records to one another, and 4) the State agency used an outdated policies and procedures manual for the Medicaid drug rebate program that was not approved by management.

Since our prior audit, the State agency has reconciled the outstanding rebates reported on the Form CMS-64.9R to its accounting records. To address our recommendation to reconcile duplicate records of the billing and accounts receivable departments, the State agency merged the two functions under the Rebate program, eliminating the duplicate recordkeeping. The State agency has also begun to address the control issues that resulted in our prior findings. The State agency is implementing a new computer rebate system that will assist in strengthening accounting controls and has established a new position to evaluate the rebate accounting records and maintain internal controls over the accounting data. The State agency updated its policies and procedures manual to reflect changes in staff responsibilities and to address functions of the new computer rebate system. However, at the time of our fieldwork the computer rebate system was not fully functional and the position was not filled.

RESOLUTION OF DISPUTES

Section V(c) of the standard Rebate Agreement states that “the State and the Manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of such notification. In the event that the State and the Manufacturer are not able to resolve a discrepancy within 60 days, CMS shall require the State to make available to the Manufacturer the State hearing mechanism available under the Medicaid program.” The updated State agency’s Policies and Procedures Manual requires that disputes are to be resolved on a timely basis with the newest and largest disputes resolved first.

Since our prior audit, the State agency has resolved some rebate disputes. However, the total amount of unresolved rebates increased as the items in dispute aged and new disputes remained unresolved. The State agency acknowledged that the current staffing, one staff member responsible for resolving disputes in addition to other duties, was not sufficient. As of June 30, 2006, the aggregate unresolved disputes had grown from \$561,088 in 2002 to \$5,779,790.

PHYSICIAN-ADMINISTERED SINGLE SOURCE DRUGS

The State agency established controls over collecting rebates for single source drugs administered by physicians as required by the DRA. The State agency paid \$2,247,557 in claims for physician-administered drugs during the January through June 2006 time period and billed manufacturers for rebates totaling \$1,002,687.

RECOMMENDATION

We recommend that the State agency resolve \$5,779,790 in disputes in a timely manner.

STATE AGENCY COMMENTS

In commenting on our draft report, the State agency concurred with our recommendation and listed the corrective actions it planned to take. The Appendix presents the State agency comments.

OTHER MATTERS

Improper Completion of Form CMS-64.9R

The State Agency's Medicaid drug rebate policies and procedures manual, Chapter VIII, CMS-64 Report, states that: "We must maintain a formal system of records, in readily reviewable form, supporting documentation that provides detailed information on pending drug rebates at the beginning of the quarter, the amounts of drug rebates computed for each labeler, amounts adjustments made, amounts collected and remaining pending drug rebates at the end of the quarter."

The State agency improperly completed the Form CMS-64.9R for the quarter ended June 30, 2006; all rows for column A were blank. Column A includes information for the current quarter as follows: 1) balance as of the beginning of the quarter, 2) adjustments to previously reported rebates, 3) rebates included in the quarter, 4) subtotal, 5) rebates received, and 6) balance as of the end of the quarter. The State agency informed us that it left the amount in column A blank because it believed that it was supposed to post actual billings for the current quarter in the next quarter (June 30 billings are posted on the Form CMS-64.9R for August 31). As a result, the totals posted in column F (Schedule Total) are incorrect because figures applied to column A would be included in the schedule total.

APPENDIX



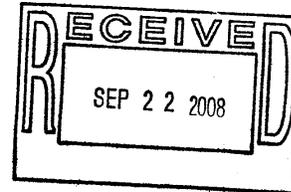
STATE OF WEST VIRGINIA
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Martha Yeager Walker
Secretary

September 15, 2008



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

Re: Report Number A-03-08-00200

Dear Mr. Virbitsky:

The West Virginia Bureau for Medical Service (BMS) received the U.S. Department of Health and Human Services, Office of Inspector General's draft report entitled "Follow-Up Audit of the Medicaid Drug Rebate Program in West Virginia (Report Number A-03-08-00200) dated August 21, 2008. This draft report was the result of the review of our Drug Rebate Program that was performed under your direction in October 2007.

We have taken note of the findings and recommendations that were outlined in the review and, as requested, we are providing written comment on the recommendation.

OIG Recommendation: "We recommend that the State agency resolve \$5,779,790 in disputes in a timely manner."

BMS concurs that the State agency should resolve disputes in a timely manner.

Recently, there has been an increased effort by the rebate staff to resolve disputes. BMS has added two temporary employees to help with the data entry and rebate invoice reconciliation in our new system, Pharmaceutical Rebate Information Management System (PRIMS). This change has allowed the two BMS rebate

Stephen Virbitsky
Office of Inspector General
September 15, 2008
Page 2

employees more time to undertake other necessary rebate functions, such as dispute resolution, implementation of the physician-administered drug rebate program, and transitioning to our new supplemental drug rebate program vendor.

In addition to increased staffing, PRIMS provides the following benefits that will enable staff to respond more timely to manufacturers' disputes:

- Efficient collection and review of data for dispute resolution.
- Electronic viewing of invoices, claims level data, and payment information, as well as provider and manufacturer contact information.
- Electronic submission of claims level data to the manufacturers without having to request the data and wait on paper copies to be delivered from a third party.
- Proactively avoiding disputes by being able to perform functions we were unable to do historically, such as being able to apply conversion factors when the billing unit of a drug differs from the rebate unit.

We plan to continue to focus our attention on working with the manufacturers to resolve our outstanding disputes in a timelier manner and to fine-tune our rebate system to facilitate dispute resolution and to help avoid unnecessary disputes on future drug rebate invoices.

We understand the audit objectives in evaluating the Medicaid Drug Rebate Program and appreciate your recommendation. We are always open to suggestions to improve the effectiveness of our programs. If you need additional information regarding the WV Medicaid Rebate Program, please call Gail Goodnight, Rebate Coordinator, at 304-558-5977.

Sincerely,

Marsha Morris

Marsha Morris
Commissioner

MKM/am

C: Shelley Baston
Nora Antlake
Tina Bailes
Peggy King
Gail Goodnight
Tara Buckner