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OFFICE OF INSPECTOR GENERAL
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JAN 3 1 2008

Report Number: A-03-07-00218

Patrick W. Finnerty, Director
Department of Medical Assistance Services
Commonwealth of Virginia
600 East Broad Street, Suite 1300
Richmond, Virginia 23219

Dear Mr. Finnerty:

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 Virginia." We will forward a copy of this report to the HHS action official noted below.

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.

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If you have any questions or comments about this report, please do not hesitate to call me, or contact Eugene Berti, Audit Manager, at (215) 861-4474 or through e-mail at Gene.Berti@oig.hhs.gov. Please refer to report number A-03-07-00218 in all correspondence.

Sincerely,

Stephen Virbitsky
Regional Inspector General
for Audit Services

Enclosure

HHS Action Official
Jackie Garner, Consortium Administrator
Consortium for Medicaid and Children's Health Operations
Centers for Medicare & Medicaid Services
233 North Michigan Avenue, Suite 600
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Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

FOLLOW UP AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN VIRGINIA

Daniel R. Levinson
Inspector General

January 2008
A-03-07-00218

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 Virginia, the Department of Medical Assistance Services (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 Virginia drug rebate program, we determined the State agency had established adequate controls over its drug rebate program except that it did not reconcile drug manufacturers' payments at the National Drug Code (NDC) level (A-03-03-00208). We recommended that the State agency ensure that the new system implemented by its fiscal agent reconcile manufacturers' payments at the NDC level.

The State agency agreed with our finding and recommendation.

This current review of Virginia's 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 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 Virginia drug rebate program and (2) established controls over collecting rebates on single source drugs administered by physicians.

SUMMARY OF FINDINGS

The State agency implemented the recommendation from our prior audit that related to reconciling drug manufacturer's accounts at the NDC level when it implemented its new Medicaid Management Information System. However, this new system did not allow it to post to the NDC level, rebates received for periods prior to implementation. The State agency has established controls and accountability for collecting rebates on single source drugs administered by physicians.

RECOMMENDATION

We recommend the State agency implement a policy to ensure that its accounting records reconcile with account receivables reported on the quarterly Form CMS-64.

STATE AGENCY COMMENTS

In its comments on our draft report, the State agency concurred with our recommendation. The State agency indicated that is has implemented steps to reconcile the Form CMS-64.9R with the account receivable reports. The State agency response is included in its entirety in the Appendix.

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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 Virginia, the Department of Medical Assistance Services (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.

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

In 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 Virginia drug rebate program, we determined the State agency had established adequate controls over its drug rebate program except that it did not reconcile drug manufacturers' payments at the NDC level.[3] We recommended that the State agency ensure that the new system implemented by its fiscal agent reconcile manufacturers' payments at the NDC level.

The State agency agreed with our findings and recommendations.

Virginia Drug Rebate Program

The State agency contracts with its fiscal agent, First Health Service Corporation, to perform all drug rebate program functions other than receiving rebate funds. The fiscal agent's responsibilities include accounting for rebates on single source drugs administered by physicians and converting the procedure code billing units to equivalent NDC billing units.

The State agency reported an outstanding drug rebate balance of $15,958,209 on the June 30, 2006, Form CMS-64.9R. However, $7,367,393 of this amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining $8,590,816 that was past due, $7,779,538 was more than 1 year old. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of $173,392,453 and collections of $179,459,601.

[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 the Commonwealth of Virginia's Medicaid Drug Rebate Program" (A-03-03-00208), issued July 29, 2003.

This current review of the 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 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 were located in Richmond, Virginia, in June 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 account receivable records to verify that the fiscal agent reconciled accounts to the NDC level;

- reviewed Form CMS-64 for June 30, 2006, to verify that the State agency made the recommended adjustments;

- 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 performed our audit in accordance with generally accepted government auditing standards.

FINDING AND RECOMMENDATION

The State agency implemented the recommendation from our prior audit that related to reconciling drug manufacturer's accounts at the NDC level when it implemented its new Medicaid Management Information System. However, this new system did not allow it to post to the NDC level, rebates received for periods prior to implementation. The State agency has established controls and accountability for collecting rebates on single source drugs administered by physicians.

IMPLEMENTATION OF PRIOR RECOMMENDATION

In our prior audit of the Virginia Drug Rebate Program, we determined that when the fiscal agent reconciled payments with the manufacturers' Reconciliation of State Invoice (ROSI) it did not reconcile at the NDC level. The State agency did not comply with CMS's Best Practice guide or ensure that the fiscal agent followed its Drug Rebate Policy and Procedure Manual. Both the guide and manual stated, "Make sure that it [the manufacturer's check] is posted to the proper labeler and the proper NDC."

After our prior audit of July 27, 2003, the State agency's fiscal agent implemented "First Rebate," its new Medicaid Management Information System. First Rebate is programmed to reconcile payments to the NDC level.

The fiscal agent stated the Commonwealth of Virginia rebate accounting was not maintained at the NDC level prior to third quarter 2003. As of September 2007, the fiscal agent was still receiving payment adjustments on NDCs invoiced prior to the installation of the new system. When payments were received on these aged accounts, the fiscal agent could only post to the labeler, year and quarter. Because the First Rebate system reports activity only at the NDC level, payments made prior to the third quarter of 2003 would not be captured in the account balance reports. As a result, as of June 30, 2006, the State agency's fiscal agent was not able to reconcile payments of $664,584 reported on Form CMS-64.9R to its aged accounts receivable records.

SINGLE SOURCE PHYSICIAN-ADMINISTERED 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 $6,747,804 in claims for physician-administered drugs during the January through June 2006 time period and billed manufacturers for rebates totaling $1,150,093.

RECOMMENDATION

We recommend the State agency implement a policy to ensure that its accounting records reconcile with account receivables reported on the quarterly Form CMS-64.9R.

STATE AGENCY COMMENTS

In its comments on our draft report, the State agency concurred with our recommendation. The State agency indicated that is has implemented steps to reconcile the Form CMS-64.9R with the account receivable reports. The State agency response is included in its entirety in the Appendix.

APPENDIX

COMMONWEALTH of VIRGINIA
Department of Medical Assistance Services

PATRICK W. FINNERTY
DIRECTOR

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January 16, 2008

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

Dear Mr. Virbitsky,

The Department of Medical Assistance Services is in receipt of your draft report entitled "Follow-up Audit of the Medicaid Drug Rebate Program in Virginia".

In this report, the Office of Inspector General recommended the following:

"We recommend the State agency implement a policy to ensure that its accounting records reconcile with account receivable reported on the quarterly Form CMS-64.9R."

Response to the Office of Inspector General's Recommendation

The Department of Medical Assistance Services concurs with the recommendations of the Office of Inspector General, and has implemented steps so that the 64.9R will be made to reconcile with accounts receivable reports going forward.

Please feel free to contact me should you have any questions or need additional information.

Sincerely,

Patrick W. Finnerty