Office of Audit Services
Region I
John F. Kennedy Federal Building
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AUG 13 2008

Report Number: A-01-08-00004

Mr. Joshua Slen, Director
Office of Vermont Health Access
State of Vermont
312 Hurricane Lane, Suite 201
Williston, Vermont 05495

Dear Mr. Slen:

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 Vermont." 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 Curtis Roy, Audit Manager, at (617) 565-9281 or through e-mail at Curtis.Roy@oig.hhs.gov. Please refer to report number A-01-08-00004 in all correspondence.

Sincerely,

Michael J. Armstrong

Michael J. Armstrong
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to 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
Chicago, Illinois 60601

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

FOLLOW-UP AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN VERMONT

Daniel R. Levinson
Inspector General

August 2008
A-01-08-00004

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 Vermont, the Agency of Human Services, Office of Vermont Health Access (the State agency) is responsible for the 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 Vermont drug rebate program, we determined that the State agency generally had adequate controls over its drug rebate program. However, we noted that the State agency needed to improve its monitoring of overdue drug rebate payments to ensure that all applicable interest was collected and reported properly. In addition, we found that the State agency needed to improve its procedures for reconciling and reporting its pending drug rebate amounts on the Form CMS 64.9R report. Accordingly, we recommended that the State agency:

- establish policies and procedures for the proper monitoring and collection of interest owed by manufacturers for late, disputed, and unpaid drug rebate amounts; and

- develop a pending drug rebate aging schedule for use in the proper preparation of the CMS 64.9R report.

The State agency agreed with our findings and recommendations.

This current review of the Vermont drug rebate program is part of a nationwide series of reviews conducted to determine whether States have addressed the weaknesses found in the previous reviews in accountability for and internal controls over their drug rebate programs. 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 Vermont drug rebate program and

(2) established controls over collecting rebates on single source drugs administered by physicians.

SUMMARY OF FINDINGS

The State agency had not implemented the recommendations from our prior audit. Specifically, the State agency had neither established policies and procedures for verifying the accuracy of interest payments received from manufacturers nor developed a pending drug rebate aging schedule for use in the proper preparation of the CMS 64.9R report. We also found that the State agency did not have adequate policies and procedures for reconciling and reporting its pending drug rebate amounts on Form CMS 64.9R to ensure the accuracy of pending drug rebate amounts reported to CMS.

Regarding the second objective, the State agency had established controls over collecting rebates on single source drugs administered by physicians.

RECOMMENDATIONS

We reiterate our recommendation that the State agency implement policies and procedures for properly monitoring and collecting interest owed by manufacturers for late, disputed, and unpaid drug rebate amounts. We also reiterate our recommendation that the State agency develop a pending drug rebate aging schedule for use in the proper preparation of the CMS 64.9R report. Furthermore, we recommend that the State agency improve its policies and procedures for reconciling the receivable balance on Form CMS 64.9R to the amount reported on the accounts receivable system to ensure the accuracy of pending drug rebate amounts reported to CMS.

OFFICE OF VERMONT HEALTH ACCESS COMMENTS

In comments on our draft report, the State agency agreed with our findings and recommendations.

The State agency's comments are included in their entirety as 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 Vermont, the Agency of Human Services, Office of Vermont Health Access (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 identify, 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.

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

In Vermont, 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. During our audit period, the NDC was not included on the physician claim form.[2] 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. Rebates are calculated and paid based on NDCs rather than on procedure codes. In addition, the billing units for a procedure code may differ from the units used for rebate purposes (e.g., grams versus liters). Thus, before rebates can be determined, 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.[3] 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 Vermont drug rebate program, we determined that the State agency generally had adequate controls over its drug rebate program.[4] However, we noted that the State agency needed to improve its monitoring of overdue drug rebate payments to ensure that all applicable interest was collected and reported properly. In addition, we also found that the State agency needed to improve its procedures for reconciling and reporting its pending drug rebate amounts on the Form CMS 64.9R report. Accordingly, we recommended that the State agency:

- establish policies and procedures for the proper monitoring and collection of interest owed by manufacturers for late, disputed, and unpaid drug rebate amounts; and

- develop a pending drug rebate aging schedule for use in the proper preparation of the CMS 64.9R report.

The State agency agreed with our findings and recommendations.

Vermont Drug Rebate Program

The State agency contracted with its Medicaid claim processor, Electronic Data Systems (EDS), to perform all drug rebate program functions other than preparing and submitting the Form

[2]Beginning July 1, 2008, the State agency is requiring claim forms to include not only procedure codes but also the corresponding NDCs for single source physician-administered drugs.

[3]"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.

[4]"Review of Medicaid Drug Rebate Collections - State of Vermont Office of Vermont Health Access as of June 30,2002" (A-01-03-00012), issued December 26, 2003.

CMS-64.9R. EDS's responsibilities included processing the drug rebate tape with the unit rebate amounts from CMS, preparing and mailing invoices to manufacturers, and collecting and depositing drug rebate payments. EDS also accounted for rebates on single source drugs administered by physicians and converted the procedure code billing units into equivalent NDC billing units.

For the fiscal year ending June 30, 2006, the State agency reported rebate billings of approximately $32.9 million and collections of approximately $11.9 million on its Forms CMS-64.9R.

This current review of the Vermont 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 Vermont 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's and EDS's offices in Williston, Vermont during February and March 2008.

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 previous Office of Inspector General audit report on the drug rebate program in Vermont;

- reviewed the policies and procedures related to the drug rebate accounts receivable system;

- interviewed State agency officials and EDS staff to determine the policies, procedures, and controls related to the Medicaid drug rebate program;

- reviewed Form CMS-64.9R for the period July 1, 2005, through June 30, 2006;

- reviewed drug rebate accounts receivable records and compared these data to Form CMS 64.9R for June 30, 2006;

- interviewed EDS 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, 2006, 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 RECOMMENDATIONS

The State agency had not implemented the recommendations from our prior audit. Specifically, the State agency had neither implemented policies and procedures for verifying the accuracy of interest payments received from manufacturers nor developed a pending drug rebate aging schedule for use in the proper preparation of the CMS 64.9R report. We also found that the State agency did not have adequate policies and procedures for reconciling and reporting its pending drug rebate amounts on Form CMS 64.9R to ensure the accuracy of pending drug rebate amounts reported to CMS.

Regarding the second objective, the State agency had established controls over collecting rebates on single source drugs administered by physicians.

IMPLEMENTATION OF PRIOR RECOMMENDATIONS

In our prior audit of the Vermont drug rebate program, we determined that the State agency did not have adequate controls to track or verify whether interest payments received from manufacturers were correct. We also found that the State agency had not established procedures to fully identify and age its pending drug rebate receivable amounts on Form CMS 64.9R.

Interest Verification

Section (V)(b) of the rebate agreement between CMS and manufacturers requires manufacturers to pay interest on late rebate payments, and CMS Medicaid Drug Rebate Program Release No. 29 requires States to collect interest. In addition, CMS Medicaid Drug Rebate Program Release No. 65 states that it is the manufacturer's responsibility to calculate and pay interest for applicable rebate invoices and the State's responsibility to track collections.

Our current review found that the State agency had not established adequate controls to verify interest payments received on disputed, late, and unpaid drug rebate amounts. Thus, EDS did not verify the accuracy of interest payments received from manufacturers. Instead, EDS relied upon the manufacturer to compute and submit the proper interest with its overdue drug rebate payments.

As a result, we have no assurance that all interest due on overdue rebates was properly collected and offset from Federal Medicaid reimbursement.

Reporting of Drug Rebate Receivables

Section 2500.6(B) of the CMS State Medicaid Manual requires the State agency to " . . . submit to HCFA [CMS] summary information on pending drug rebates at the beginning of the quarter, the amounts of drug rebates computed for all drug labelers, amounts written off, other adjustments, remaining pending drug rebates and amounts collected, and reduce your claim for Federal reimbursement by the Federal share of amounts received. All pending drug rebates must be aged by comparing the dates the pending rebate was established with the ending date of the period shown on the . . . . Form [CMS]-64 . . . . "

Our current review found that the State agency had not developed policies and procedures to properly present an aging schedule, as we had recommended and as CMS requires. Instead, the State agency reported all collected drug rebates as having been invoiced during the most current quarter rather than in the quarters in which they were actually invoiced.

Our current review also found an additional inaccuracy on the State agency's Forms CMS-64.9R for the four quarters that ended June 30, 2006 (July 1, 2005, through June 30, 2006). Specifically, the State agency reported an outstanding drug rebate balance of $63,928,896 for the quarter that ended June 30, 2006, which was overstated by $63,690,466. This erroneous presentation of pending drug rebates occurred in large part because the State agency did not reconcile the receivable balance on Form CMS 64.9R to the amount reported on the accounts receivable system.

As a result, we have no assurance that the Form 64.9R provides CMS with an accurate measure of the rebate amounts that need to be collected by the State agency and the likelihood that these rebates will be collected.

PHYSICIAN-ADMINISTERED SINGLE SOURCE DRUGS

The State agency had established controls over collecting rebates on single source drugs administered by physicians, as the DRA requires. The State agency paid $560,250 in claims for physician-administered drugs during January through June 2006 and billed manufacturers for rebates totaling $155,094.

RECOMMENDATIONS

We reiterate our recommendation that the State agency implement policies and procedures for properly monitoring and collecting interest owed by manufacturers for late, disputed, and unpaid drug rebate amounts. We also reiterate our recommendation that the State agency develop a pending drug rebate aging schedule for use in the proper preparation of the CMS 64.9R report. Furthermore, we recommend that the State agency improve its policies and procedures for reconciling the receivable balance on Form CMS 64.9R to the amount reported on the accounts receivable system to ensure the accuracy of pending drug rebate amounts reported to CMS.

OFFICE OF VERMONT HEALTH ACCESS COMMENTS

In comments on our draft report, the State agency agreed with our findings and recommendations.

The State agency's comments are included in their entirety as the Appendix.

APPENDIX

APPENDIX

State of Vermont
Office of Vermont Health Access
312 Hurricane Lane, Suite 201
Williston, VT 05495-2807
www.ovha.state.vt.us

Agency of Human Services

[Phone] 802-879-5900

August 6, 2008

Mr. Michael J. Armstrong
Office of Audit Services,
Region I
John F. Kennedy Federal Building
Room 2425
Boston, MA 02203

Re: Report Number A-01-08-00004

Dear Mr. Armstrong:

EDS has reviewed the OIG draft report entitled "Follow-Up Audit of the Medicaid Drug Rebate Program in Vermont. EDS would like to provide you with the status of the EDS actions taken in response to the draft recommendations.

"We reiterate our recommendation that the State agency implement policies and procedures for property monitoring and collection interest owed by manufacturers for late, disputed, and unpaid drug rebate amounts."

The EDS CSR to implement the drug rebate interest calculation (DR0035) is currently in test and is expected to be in production by the next drug rebate quarterly cycle (quarter ending 09/30/2008).

"We also reiterate our recommendations that the State agency develop a pending drug rebate aging schedule for use in the preparation of the CMS 64.9R report. Furthermore, we recommend that the State agency improve its policies and procedures for reconciling the receivable balance on Form CMS 64.9R to the amount reported on the accounts receivable system to ensure the accuracy of pending drug rebate amounts reported to CMS."

On July 8th, 2008, representatives from EDS, OVHA and AHS met for the purpose of discussing these draft recommendations. At this meeting EDS agreed to provide, on a quarterly basis, beginning quarter ending 09/30/2008, a drug rebate reconciliation with a breakdown of recoveries and other activity by quarter billed to the OVHA for both the Traditional and the VScript drug rebate program to be used by AHS for the preparation of an aging schedule. The drug rebate reconciliations for the Traditional and VScript programs will continue to contain the account receivable balance ending each quarter to ensure the accuracy of the pending drug rebate amounts reported by CMS. EDS will continue to meet with OVHA and AHS to discuss any further measures required to meet this recommendation as needed.

If I can be of any additional assistance in this matter please let me know.

Sincerely,

Joshua Slen
Director

VERMONT