DEPARTMENT OF HEALTH & HUMAN SERVICES



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Region VII 601 East 12th Street Room 284A Kansas City, Missouri 64106

Report Number: A-07-08-03102

Andrew Allison, PhD.
State Medicaid Director
Kansas Health Policy Authority
Landon State Office Building
900 SW. Jackson St.
Topeka, Kansas 66612

Dear Dr. Allison:

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

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, within 10 business days after this report is issued, it will be posted on the Internet at http://oig.hhs.gov.

If you have any questions or comments about this report, please direct them to the HHS action official. Please refer to report number A-07-08-03102 in all correspondence.

Sincerely,

Patrick J. Cogley

Regional Inspector General for Audit Services

Enclosure

HHS Action Official:

Ms. Jackie Garner Consortium Administrator 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 KANSAS



Daniel R. Levinson Inspector General

> December 2007 A-07-08-03102

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 HHS 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 drug rebate agreement with 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 Kansas, the Kansas Health Policy Authority (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 Kansas drug rebate program (A-07-03-04017), we determined that the State agency had adequate controls over its drug rebate program, with the exceptions of recording accounts receivable, reconciliation of Form CMS-64.9R and the General Ledger, interest accrual, interest reporting, and invoice verification.

We recommended that the State agency:

- ensure that the Form CMS-64.9R report is adjusted for the additional rebates billed for the first quarter 2002 and the invalid receivables that were included in the receivable balance reported on June 30, 2002;
- establish a general ledger control account for drug rebate receivables;
- reconcile quarterly the general ledger control account to the Form CMS-64.9R and subsidiary ledgers;
- reconcile quarterly the drug rebate collections on the cash receipts log to collections on the Form CMS-64.9R;
- estimate and accrue interest on all overdue rebate balances;
- report drug rebate interest revenue on the Form CMS-64 Summary Sheet; and
- verify that drug rebate invoices include total units dispensed for each quarter.

The State agency agreed with our findings and recommendations with one exception: the State agency did not agree to estimate and accrue interest due to the complexity of the calculation.

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

RESULTS OF REVIEW

Since our prior audit, the State agency implemented the recommendations made in our previous audit of the Kansas drug rebate program. Specifically, the State agency has:

- adjusted the Form CMS-64.9R for additional rebates billed during the first quarter 2002, and adjusted the accounts receivable balance for the invalid receivables reported on the June 30, 2002 Form CMS-64.9R;
- established general ledger controls in the form of reports to account for drug rebate receivables:
- developed policies and procedures to perform quarterly reconciliations of the general ledger control account to the Form CMS-64.9R and the drug rebate receivables report;
- developed procedures to perform quarterly reconciliations of the cash collections recorded on the cash receipts log to the collections reported on the Form CMS-64.9R;
- developed policies and procedures to estimate and accrue interest on all overdue rebate balances:
- developed procedures to accurately report drug rebate interest revenue on the Form CMS-64 Summary Sheet; and
- developed policies and procedures to verify that drug rebate invoices include total units dispensed for each quarter.

Additionally, the State agency established controls over collecting rebates on single source drugs administered by physicians.

This report contains no recommendations.

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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 drug 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 Kansas, the Kansas Health Policy Authority (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, its best price. Based on this information, CMS calculates a unit rebate amount for each covered outpatient drug and provides the amounts to States on a quarterly basis.

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 have 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. 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 Kansas, 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 Kansas drug rebate program, we determined that the State agency had adequate controls over its drug rebate program, with the exceptions of recording accounts receivable, reconciliation of Form CMS-64.9R and the General Ledger, interest accrual, interest reporting, and invoice verification.³

We recommended that the State agency:

- ensure that the Form CMS-64.9R report is adjusted for the additional rebates billed for the first quarter 2002 and the invalid receivables that were included in the receivable balance reported on June 30, 2002;
- establish a general ledger control account for drug rebate receivables;
- reconcile quarterly the general ledger control account to the Form CMS-64.9R and subsidiary ledgers;
- reconcile quarterly the drug rebate collections on the cash receipts log to collections on the Form CMS-64.9R;
- estimate and accrue interest on all overdue rebate balances;
- report drug rebate interest revenue on the Form CMS-64 Summary Sheet; and

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 Medicaid Drug Rebate Collections State of Kansas" (A-07-03-04017), issued May 8, 2003.

• verify that drug rebate invoices include total units dispensed for each quarter.

The State agency agreed with our findings and recommendations with one exception: the State agency did not agree to estimate and accrue interest due to the complexity of the calculation.

Kansas Drug Rebate Program

The State agency contracted with its fiscal agent, Electronic Data Systems, to perform all drug rebate program functions other than receiving rebate funds and preparing and submitting the Form CMS-64.9R. The fiscal agent's responsibilities included invoicing, resolving disputes, verifying interest payments and accounting for rebates on single source drugs administered by physicians. The fiscal agent also converted the procedure code billing units into equivalent NDC billing units.

The State agency reported an outstanding drug rebate balance of \$4,800,355 on the June 30, 2006, Form CMS-64.9R. However, \$5,479,053 of this amount related to quarterly billings and was not past due as of June 30, 2006. The State agency thus had a negative \$678,698 accounts receivable balance which was due to manufacturers for prior period unit rebate adjustments as of June 30, 2006. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately \$74.7 million and collections of approximately \$91.9 million.

This current review of the Kansas 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 Kansas 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 conducted fieldwork at the State agency and its fiscal agent, both of which are located in Topeka, Kansas, during October and November 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 the previous Office of Inspector General audit report over the drug rebate program in Kansas;
- 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;
- reviewed Form CMS-64 for the quarters ended June 30, 2002 and September 30, 2002 to verify that the State agency made the recommended adjustments;
- reviewed drug rebate invoices to determine whether the invoices identified the total units dispensed;
- 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.

RESULTS OF REVIEW

The State agency implemented the recommendations from our prior audit. Additionally, the State agency established controls over collecting rebates on single source drugs administered by physicians.

IMPLEMENTATION OF PRIOR RECOMMENDATIONS

In our prior audit of the Kansas drug rebate program, we determined that the State agency:

- did not maintain a general ledger accounts receivable control account to account for uncollected rebate balances;
- did not perform reconciliations to verify the accuracy of the uncollected rebate balance or collection report on the Form CMS-64.9R;
- did not accrue interest for late or disputed payments;
- reported interest on the Form CMS-64.9R instead of the Form CMS-64 Summary Sheet, which caused receivables to be understated by \$31,531.94 for the two-year period ending June 30, 2002; and
- sent inaccurate drug rebate invoices to manufacturers for the first quarter 2002, resulting in an understatement of the rebate balance of approximately \$2.3 million on the June 30, 2002 Form CMS-64.9R.

Since our prior audit, the State agency has:

- adjusted the Form CMS-64.9R for additional rebates billed during the first quarter 2002, and adjusted the accounts receivable balance for the invalid receivables reported on the June 30, 2002 Form CMS-64.9R;
- established general ledger controls in the form of reports to account for drug rebate receivables;
- developed policies and procedures to perform quarterly reconciliations of the general ledger control account to the Form CMS-64.9R and the drug rebate receivables report;
- developed procedures to perform quarterly reconciliations of the cash collections recorded on the cash receipts log to the collections reported on the Form CMS-64.9R;
- developed policies and procedures to estimate and accrue interest on all overdue rebate balances;
- developed procedures to accurately report drug rebate interest revenue on the Form CMS-64 Summary Sheet; and
- developed policies and procedures to verify that drug rebate invoices include total units dispensed for each quarter.

Additionally, the State agency established controls over collecting rebates on single source drugs administered by physicians.

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 \$2,818,943 in claims for physician-administered drugs during the January through June 2006 time period and billed manufacturers for rebates totaling \$993,561.

This report contains no recommendations.