DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Office of Audit Services
1100 Commerce, Room 632
Dallas, TX 75242

February 4, 2008

Report Number: A-06-07-00069

Mike Fogarty
Chief Executive Officer
Oklahoma Health Care Authority
4545 North Lincoln Boulevard, Suite 124
Oklahoma City, OK 73105-3413

Dear Mr. Fogarty:

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 Oklahoma." 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-06-07-00069 in all correspondence.

Sincerely,

Gordon L. Sato
Regional Inspector General
for Audit Services

Enclosure

HHS Action Official:

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Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

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

Daniel R. Levinson
Inspector General

February 2008
A-06-07-00069

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 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 Oklahoma, the Oklahoma Health Care 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.

We limited our previous audit of the Oklahoma drug rebate program primarily to the State agency's controls over cash receipts because the State agency had recently converted to a new accounts receivable system. We determined that the State agency had established adequate controls over cash receipts. We also found that the State agency had transferred inaccurate data from the prior accounts receivable system into the new system. We recommended that the State agency:

- review and adjust the accounts receivable balances in the new system and pursue collection of any unpaid balances and

- consider devoting more resources to the drug rebate program.

The State agency agreed with our findings and recommendations.

The current review of Oklahoma 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. Because our previous review of Oklahoma was limited primarily to controls over cash receipts, this review will determine whether the State agency had established controls over the drug rebate program. 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 Oklahoma drug rebate program and (2) established controls over the drug rebate program, including the collection of rebates on single source drugs administered by physicians.

SUMMARY OF FINDINGS

The State agency implemented the recommendations from our prior audit that related to the inaccurate accounts receivable data that was transferred from the prior system to the current system. The State agency established controls over the drug rebate program, including the collection of rebates on single source drugs administered by physicians. Therefore, we do not offer any 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 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 Oklahoma, the Oklahoma Health Care 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, 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) amended 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 expanded the requirements to certain multiple source drugs administered by physicians after January 1, 2008.

In Oklahoma, physician-administered drugs are billed to the State Medicaid program on either a physician or outpatient hospital 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.

We limited our previous audit of the Oklahoma drug rebate program primarily to the State agency's controls over cash receipts because the State agency had recently converted to a new accounts receivable system.[3] We determined that the State agency had established adequate controls over cash receipts. We also found that the State agency had transferred inaccurate data from the prior accounts receivable system into the new system. We recommended that the State agency:

- review and adjust the accounts receivable balances in the new system and pursue collection of any unpaid balances and

- consider devoting more resources to the drug rebate program.[4]

The State agency agreed with our findings and recommendations.

Oklahoma Drug Rebate Program

The State agency contracts with its fiscal agent, Electronic Data Systems, to process claims and create drug rebate invoices and reports. The State agency is responsible for all other drug rebate accounts receivable functions.

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[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 Oklahoma" (A-06-03-00044), issued July 15, 2003.

[4]We made this recommendation because the State agency would require additional personnel to adjust the large volume of accounts receivable records that were transferred from the prior system.

The State agency reported an outstanding drug rebate balance of $24,328,861 on the June 30, 2006, Form CMS-64.9R. However, $20,678,085 of this amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining $3,650,776 that was past due, $3,225,449 was more than 1 year old. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately $114.1 million and collections of $128.1 million.

The current review of the Oklahoma 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. Because our previous review of Oklahoma was limited primarily to controls over cash receipts, this review will determine whether the State agency had established controls over the drug rebate program. 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 Oklahoma drug rebate program and (2) established controls over the drug rebate program, including the collection of 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, which is located in Oklahoma City, Oklahoma, from February through 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 State agency's drug rebate accounts receivable system;

- interviewed State agency officials 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 and tested internal controls that were not reviewed in our prior audit due to the timing of the State agency's conversion from its prior drug rebate accounts receivable system;

- reviewed policies and procedures related to 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.

RESULTS OF REVIEW

The State agency implemented the recommendations from our prior audit that related to the inaccurate accounts receivable data that was transferred from the prior system to the current system. The State agency established controls over the drug rebate program, including the collection of rebates on single source drugs administered by physicians. Therefore, we do not offer any recommendations.

IMPLEMENTATION OF PRIOR RECOMMENDATIONS

In our prior audit of the Oklahoma drug rebate program, we determined that the State agency had established adequate controls over cash receipts. However, inaccurate data had been transferred from the prior accounts receivable system into the new system. Specifically, the State agency (1) did not allocate manufacturer rebate payments to individual NDC balances from 1991 to 1998,[5] (2) did not always update its accounts receivable records after settling disputes with manufacturers, and (3) was not always able to adjust account balances to reflect changes in unit rebate amounts.

Since our prior audit, the State agency has:

- reviewed accounts receivable records for the 1991 through 1998 period to allocate manufacturer rebate payments to individual NDC balances;

- updated accounts receivable records to reflect balance changes resulting from settled rebate disputes with manufacturers;

[5]Without maintaining accurate individual NDC balances, the State agency was unable to effectively pursue unpaid balances.

- developed procedures to adjust unit rebate amounts when necessary; and

- increased its drug rebate program staff from 2.5 to 5 full-time equivalents to handle the additional workload.

ESTABLISHMENT OF CONTROLS OVER THE DRUG REBATE PROGRAM

The State agency established controls over the drug rebate program, including the collection of rebates for single source drugs administered by physicians as required by the DRA. The State agency paid $15,330,375 in claims for physician-administered drugs during the January through June 2006 time period and billed manufacturers $3,887,570 for rebates.