DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

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

November 27, 2007

Report Number: A-06-07-00015

Mr. John Selig
Director
Arkansas Department of Human Services
Donaghey Plaza South, Slot S201
P. O. Box 1437
Little Rock, Arkansas 72203-1437

Dear Mr. Selig:

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 Drug Rebate Program in Arkansas." 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.

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If you have any questions or comments about this report, please direct them to the HHS action official. Please refer to report number A-06-07-00015 in all correspondence.

Sincerely,

for Gordon L. Sato
Regional Inspector General
for Audit Services

Enclosure

HHS Action Official:

Jackie Garner, Consortium Administrator
Consortium for Medicaid and Children's Health Operations
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233 North Michigan Avenue, Suite 600
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cc: Mr. Roy Jeffus
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Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

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

Daniel R. Levinson
Inspector General

November 2007
A-06-07-00015

Office of Inspector General

http://oig.hhs.gov

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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 Arkansas, the Department of Human 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 Arkansas drug rebate program, we determined that the State agency had adequate controls over its drug rebate program, with one exception: interest payments received from drug manufacturers (A-06-03-00042). We recommended that the State agency:

- adjust the outstanding drug rebate balance to account for the interest received and correctly report (1) the interest on Form CMS-64, line 5, and (2) the outstanding balance on the Form CMS-64.9R on the next quarterly report; and

- implement a procedure to verify that interest payments are accurate.

The State agency agreed with our findings and recommendations.

This current review of Arkansas 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 Arkansas 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 recommendations from our prior audit that related to interest payments received from manufacturers, with one exception: It did not implement a procedure for verifying the accuracy of interest payments received from manufacturers. The State agency established controls over collecting rebates on single source drugs administered by physicians.

The State agency's fiscal agent did not verify the accuracy of interest payments received from manufacturers during the quarter ending June 30, 2006, and attributed the error to staff turnover. The accounts receivable system had a program to verify the accuracy of interest payments, but the State agency did not have a procedure in place to ensure that interest payments were verified. As a result, the State agency could not have been assured that it had collected all of the interest due from manufacturers.

RECOMMENDATION

We reiterate our recommendation that the State agency implement a procedure to ensure that interest payments are verified for accuracy.

STATE AGENCY'S COMMENTS

The State agency agreed with our finding and said that it would put procedures for verifying interest in writing. The State agency also said that it was verifying current and past interest payments. The full text of the State agency's comments is included 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 Arkansas, the Department of Human 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 Arkansas, 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 Arkansas drug rebate program, we determined that the State agency had adequate controls over its drug rebate program, with one exception: interest payments received from drug manufacturers.[3] We recommended that the State agency:

- adjust the outstanding drug rebate balance to account for the interest received and correctly report (1) the interest on Form CMS-64, line 5, and (2) the outstanding balance on the Form CMS-64.9R on the next quarterly report; and

- implement a procedure to verify that interest payments are accurate.[4]

The State agency agreed with our findings and recommendations.

Arkansas Drug Rebate Program

The State agency contracts with its fiscal agent, Electronic Data Systems, 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 converted the procedure code billing units into equivalent NDC billing units.

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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 Arkansas" (A-06-03-00042), issued May 13, 2003.

[4]Verification here means that interest payments are mathematically accurate and in accordance with CMS guidance concerning interest payment calculations.

The State agency reported an outstanding drug rebate balance of $38,268,825 on the June 30, 2006, Form CMS-64.9R. However, $24,625,060 of this amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining $13,643,765 that was past due, $10,516,396 was more than 1 year old. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately $124.7 million and collections of $119.1 million.

This current review of the Arkansas 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 Arkansas 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 Little Rock, Arkansas, from November 2006 through May 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;

- reviewed Form CMS-64 for June 30, 2003, 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.

FINDINGS AND RECOMMENDATION

The State agency implemented the recommendations from our prior audit that related to interest payments received from manufacturers, with one exception: It did not implement a procedure for verifying the accuracy of interest payments received from manufacturers. 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 Arkansas drug rebate program, we determined that the State agency had understated its outstanding drug rebate balance on Form CMS-64.9R because it had recorded interest it had received without entering a corresponding rebate amount as a receivable. The State agency also failed to report the interest on the proper line of the Form CMS-64. Further, the State agency did not verify that the interest payments were accurate.

Since our prior audit, the State agency has (1) corrected the understatement of the accounts receivable balance, (2) modified its accounts receivable system to enable it to properly record interest payments received from manufacturers, and (3) reported interest received on the proper line of the Form CMS-64. However, as of the end of our fieldwork, the State agency had not implemented a procedure to verify the accuracy of interest payments.

Pursuant to 45 CFR § 92.20(b)(3), States are required to provide for effective control over and accountability for all funds, property, and other assets. Section (V)(b) of the rebate agreement between CMS and manufacturers requires manufacturers to pay interest on late rebate payments, and CMS program release 29 requires interest to be collected.[5] The fiscal agent did not verify the accuracy of interest payments received from manufacturers during the quarter ending June 30, 2006, and attributed the error to staff turnover. The accounts receivable system had a program to verify the accuracy of interest payments, but the State agency did not have a procedure in place to ensure that interest payments were verified. As a result, the State agency

[5]CMS has issued guidance to State Medicaid directors pertaining to the drug rebate program and posts the program releases on its Web site at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/02_StateReleases.asp.

could not have been assured that all interest due had been collected. The fiscal agent stated that it planned to review interest payments from prior quarters for accuracy and send collection letters to manufacturers for any unpaid interest identified by this review.

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 $6,785,767 in claims for physician-administered drugs during the January through June 2006 time period and billed manufacturers for rebates totaling $2,331,297.

RECOMMENDATION

We reiterate our recommendation that the State agency implement a procedure to ensure that interest payments are verified for accuracy.

STATE AGENCY'S COMMENTS

The State agency agreed with our finding and said that it would put procedures for verifying interest in writing. The State agency also said that it was verifying current and past interest payments. The full text of the State agency's comments is included as the Appendix.

APPENDIX

Arkansas Department of Human Services
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November 19, 2007

Report Number: A-06-07-00015

Gordon L. Sato
Regional Inspector General
for Audit Services
Office of Inspector General
Office of Audit Services
1100 Commerce, Room 632
Dallas, TX 75242

Dear Mr. Sato:

We have received the copies of the Department of Health and Human Services, Office of Inspector General, Office of Audit Services' draft report entitled "Follow-Up Audit of the Medicaid Drug Rebate Program in Arkansas."

I have had the opportunity to review the report and discuss the findings with our fiscal agent. We are in agreement with the findings of the report.

In response to the recommendations within the report to the Arkansas Department of Human Services, review has already begun to assure the verification of interest payments. Based on the findings in the prior report, A-06-03-00042, a system had been developed to verify the accuracy of the interest collected from drug rebate. Due to a turnover in staff, current rebate analysts were not fully knowledgeable of the process, but have since gained that knowledge and are currently reviewing past interest for verification, as well as current interest. A goal has been established for having the majority of the interest reviewed and billed by May 2008. Also, to prevent any misunderstanding of the interest verification process for the future, the current rebate analysts are putting the procedures in writing to be included in the rebate process.

If you have further questions please feel free to contact me at (501) 683-4120.

Sincerely,

Suzette Bridges

Suzette Bridges, PD
Director, Pharmacy Program
Arkansas Medicaid

Cc: John Selig, Director Arkansas Department of Human Services
Roy Jeffus, Director Arkanasas DHS/DMS

CIN: A-06-07-00015

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