DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF AUDIT SERVICES
233 NORTH MICHIGAN AVENUE
CHICAGO, ILLINOIS 60601

REGION V
OFFICE OF
INSPECTOR GENERAL

March 31, 2008

Report Number: A-05-08-00015

Mr. Shawn Crouch
Commissioner
Kentucky Department for Medicaid Services
275 East Main Street, 6W-A
Frankfort, Kentucky 40621

Dear Mr. Crouch:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled "Follow-Up Review of the Medicaid Drug Rebate Program in Kentucky." 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-05-08-00015 in all correspondence.

Sincerely,

Marc Gustafson
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
Chicago, Illinois 60601

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

FOLLOW-UP REVIEW OF THE MEDICAID DRUG REBATE PROGRAM IN KENTUCKY

Daniel R. Levinson
Inspector General

March 2008
A-05-08-00015

Office of Inspector General

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Department of Health and Human Services

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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 Kentucky, the Department for Medicaid 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 Kentucky drug rebate program, we determined that the State agency did not have adequate controls and accountability over its drug rebate program (A-04-03-06006). Specifically, we found the accounts receivable amounts reported to the CMS were understated and not supported by accounting records. Additionally, there was a material amount of uncollected rebate dollars outstanding. We recommended that the State agency:

- verify all amounts reported on the Form CMS-64.9R, to ensure that those amounts tie directly back to the aged accounts receivable listing;

- maintain a general ledger accounts receivable control account for drug rebates, which could be balanced to subsidiary receivable accounts; and

- continue their efforts to collect the older outstanding drug rebates.

The State agency agreed with our findings and recommendations.

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

RESULTS OF REVIEW

The State agency implemented the recommendations from our prior audit that related to verifying amounts reported on the Form CMS-64.9R, reconciling accounts receivable amounts to subsidiary records and collecting older outstanding drug rebates. Additionally, the State agency established controls over collecting 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 Kentucky, the Department for Medicaid 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) 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 requirement to certain multiple source drugs administered by physicians after January 1, 2008.

In Kentucky, 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 Kentucky drug rebate program, we determined that the State agency did not have adequate controls and accountability over its drug rebate program. Specifically, we found the amounts reported to the CMS were not supported by the accounting records. Additionally, there was a material amount of uncollected rebate dollars outstanding.[3]

We recommended that the State agency:

- verify all amounts reported on the Form CMS-64.9R, to ensure that those amounts tie directly back to the aged accounts receivable listing;

- maintain a general ledger accounts receivable control account for drug rebates, which could be balanced to subsidiary receivable accounts; and

- continue their efforts to collect the older outstanding drug rebates.

The State agency agreed with our findings and recommendations.

Kentucky Drug Rebate Program

The State agency contracts with its fiscal agent, First Health Services Corporation (First Health) to perform all drug rebate program functions other than receiving rebate funds. The fiscal

[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]"Audit of the Medicaid Drug Rebate Program in the State of Kentucky" (A-04-03-06006), issued July 22, 2003.

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.

The State agency had an outstanding drug rebate balance of $27,869,200 on the June 30, 2006, Form CMS-64.9R. However, $10,980,403 of this amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining $16,888,797 that was past due, $15,899,777 was more than 1 year old. For the fiscal year ended June 30, 2006, the State agency had rebate billings of approximately $185.5 million and collections of $216.2 million.[4]

The current review of the Kentucky 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 Kentucky 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, which is located in Frankfort, Kentucky, from December 2007 through January 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;

[4]The amounts reported to CMS were $217 million in total billings for the fiscal year and $59,430,002 for outstanding drug rebate balance with $42,541,205 in current quarter billings for the quarter ended June 30, 2006. The difference in the reported amounts, which was corrected in the following quarter, was due to an error made by First Health.

- reviewed the policies and procedures related to the fiscal agent'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 and compared to subsidiary schedules;

- compared subsidiary schedules to accounts receivable detail for the quarters ending March 31, 2006 and June 30, 2006;

- traced accounts receivable balance on the CMS-64.9R back to the aged accounts receivable listing;

- reviewed Form CMS-64 for the quarters ending June 30th for fiscal years 2002, 2003, 2004, 2005 and 2006 to determine efforts of collecting older outstanding drug rebates;

- reviewed adjustment support to verify that the State agency made the recommended adjustment;

- interviewed State agency officials 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 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 verifying amounts reported on the Form CMS-64.9R, reconciling accounts receivable amounts to subsidiary records and collecting older outstanding drug rebates. Additionally, the State agency established controls over collecting rebates on single source drugs administered by physicians. Therefore, we do not offer any recommendations.

IMPLEMENTATION OF PRIOR RECOMMENDATIONS

In our previous audit of the Kentucky drug rebate program, we determined that the State agency did not have adequate controls and accountability over its drug rebate program. Specifically, the State agency (1) had understated its outstanding drug rebate balance on the Form CMS-64.9R due to inaccurate reporting; (2) could not verify all amounts reported on the Form CMS-64.9R, to ensure that those amounts tied directly back to the aged accounts receivable listing; (3) did not maintain a general ledger accounts receivable control account for drug rebates, which could be balanced to subsidiary receivable accounts; and (4) had $37.2 million in outstanding drug rebates.

Since our prior audit, the State agency:

- corrected the accounts receivable balance as of the quarter ending December, 2004;
- ensured that the amounts reported on the CMS-64.9R tied directly back to the aged accounts receivable listing;
- maintained a system to ensure that accounts receivable amounts are properly reconciled to subsidiary receivable accounts maintained by its contractor; and
- continued its efforts to collect the older outstanding drug rebates. Accounts receivable balance greater than 90 days has decreased from $37.2 million to $16.9 million from June 2002 to June 2006.

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 $7,856,149 in claims for physician-administered drugs during the January through June 2006 time period and billed manufacturers for rebates totaling $922,990.