DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General
Office of Audit Services

REGION IV
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Atlanta, Georgia 30303

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Report Number: A-04-08-07005

Helen E. Jones-Kelly, Director
Ohio Department of Job and Family Services
30 East Broad Street, 32nd Floor
Columbus, Ohio 43215-3414

Dear Ms. Jones-Kelly:

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

Pursuant to the Freedom of Information Act, 5 U.S.C. § 552, OIG reports generally are made available to the public to the extent that information in the report is not subject to exemptions in the Act. 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 direct them to the HHS action official. Please refer to report number A-04-08-07005 in all correspondence.

Sincerely,

Peter J. Barbera

Peter J. Barbera
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
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Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

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

Daniel R. Levinson
Inspector General

February 2009
A-04-08-07005

Office of Inspector General

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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.

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

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

Daniel R. Levinson
Inspector General

February 2009
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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 the drug manufacturers each undertake certain functions in connection with the drug rebate program. In Ohio, the Ohio Department of Job and Family 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 Ohio drug rebate program (A-05-03-00042), we determined that the State agency had generally established controls over the drug rebate program with two exceptions: (1) it needed to improve its policies regarding the collection of interest for unpaid, late, and disputed drug rebates and (2) it did not have adequate controls to monitor outstanding drug rebate disputes and provide a hearing mechanism to resolve disputes. We recommended that the State agency develop formal policies, procedures, and controls to: (1) follow up and collect interest for unpaid, late, or disputed drug rebates and (2) monitor disputed rebate amounts, including appropriate use of the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturers.

This current review of the Ohio 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 Deficit Reduction Act of 2005 required States, as of January 1, 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 Ohio drug rebate program and (2) established controls over collecting rebates on single source drugs administered by physicians.

SUMMARY OF RESULTS

The State agency had implemented the recommendations from our previous audit related to interest collection and dispute resolution. In addition, the State agency had 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 the drug manufacturers each undertake certain functions in connection with the drug rebate program. In Ohio, the Ohio Department of Job and Family Services (the State agency) administers the Medicaid 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(a) 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 Ohio, physician-administered drugs are billed to the State Medicaid program on physician claim forms 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.

Previous 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 Ohio drug rebate program (A-05-03-00042), we determined that the State agency had generally established controls over the drug rebate program with two exceptions: (1) it needed to improve its policies regarding the collection of interest for unpaid, late, and disputed drug rebates and (2) it did not have adequate controls to monitor outstanding drug rebate disputes and provide a hearing mechanism to resolve disputes. We recommended that the State agency develop formal policies, procedures, and controls to: (1) follow up and collect interest for unpaid, late, or disputed drug rebates and (2) monitor disputed rebate amounts, including appropriate use of the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturers.

Ohio Drug Rebate Program

The State agency contracts with its fiscal agent, Affiliated Computer Services, Inc., to perform all drug rebate program functions including the 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 $140,375,073 on the June 30, 2006, Form CMS-64.9R. However, $105,026,349 of this amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining $35,348,724 that was past due, $12,208,436 was more than 1 year old. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of $621,209,574 and collections of $701,294,868.

[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.

This current review of the Ohio 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 1, 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 Ohio 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 did not include a weakness identified in the previous report related to the use of the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturers for resolving disputes over rebate amounts owed to the State. The State agency was not required to use the hearing mechanism, and our previous recommendation, which related to its use, was a suggestion for the State agency to consider.

We performed our fieldwork at the State agency's fiscal agent in Atlanta, Georgia, in September 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 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;

- 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 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 AUDIT

The State agency had implemented the recommendations from our previous audit related to interest collection and dispute resolution. In addition, the State agency had established controls over collecting rebates on single source drugs administered by physicians. Therefore, we do not offer any recommendations.

IMPLEMENTATION OF PREVIOUS RECOMMENDATIONS

In our previous audit of the Ohio drug rebate program, we determined that the State agency needed to improve its policies regarding the collection of interest for unpaid, late, and disputed drug rebates and that the State agency did not have adequate controls to monitor outstanding drug rebate disputes and provide a hearing mechanism to resolve disputes.

Since our previous audit, the State agency and its fiscal agent had implemented our recommendations related to interest collection and dispute resolution.

PHYSICIAN-ADMINISTERED SINGLE SOURCE DRUGS

The State agency had established controls over collecting rebates for single source drugs administered by physicians as required by the DRA. The State agency paid $10,550,257 in claims for physician-administered drugs during the January through June 2006 period and billed manufacturers for rebates totaling $1,572,204.