



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General
Office of Audit Services

REGION IV
61 Forsyth Street, S.W., Suite 3T41
Atlanta, Georgia 30303

October 9, 2008

Report Number: A-04-07-07023

Lynda Dutton, CPA
Deputy Administrator for Administrative Services
Division of Medicaid, Office of the Governor
550 High Street, Suite 1000
Jackson, Mississippi 39201

Dear Ms. Dutton:

Enclosed is the U.S. Department of Health and Human Services, Office of Inspector General (OIG), final report entitled "Follow-Up Review of the Medicaid Drug Rebate Program in Mississippi." 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 do not hesitate to call me, or contact Andrew Funtal, Audit Manager, at (404) 562-7762 or through e-mail at Andrew.Funtal@oig.hhs.gov. Please refer to report number A-04-07-07023 in all correspondence.

Sincerely,

A handwritten signature in cursive script that reads "Peter Barbera".

Peter Barbera
Regional Inspector General
for Audit Services

Enclosure

Page 2 – Lynda Dutton

HHS Action Official:

Jackie Garner, Consortium Administrator
Consortium for Medicaid and Children's Health Operations
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 MISSISSIPPI**



Daniel R. Levinson
Inspector General

October 2008
A-04-07-07023

Office of Inspector General

<http://oig.hhs.gov>

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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 (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 the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. CMS, the States, and drug manufactures each undertake certain function in connection with the drug rebate program. In Mississippi, the Division of Medicaid (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 Mississippi drug rebate program (A-04-03-06015), we determined that the State agency had adequate controls over its drug rebate program with one exception: it did not verify the accuracy of the accrual and collection of interest.

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

SUMMARY OF FINDINGS

The State agency had corrected the previous weakness by upgrading its computer system to verify the accuracy of the accrual and collection of interest. However, it had not established controls over collecting rebates on single source drugs administered by physicians.

RECOMMENDATION

We recommend that the State agency establish controls over collecting rebates for single source drugs administered by physicians and ensure that the invoiced amounts are collected and/or resolved.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency's fiscal agent began implementing our recommendation to start collecting rebates from pharmaceutical manufacturers for single source drugs administered by physicians on August 1, 2007.

The State agency's comments are included in their entirety 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 Mississippi, the Division of Medicaid (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 identify, 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. In Mississippi, physician-administered drugs are billed to the State Medicaid program on a physician claim form. The State agency had not completed preparations for collecting the rebates associated with these drugs by NDC. To capture the NDCs from the claims, the State agency requested additional time from CMS and contracted with Affiliated Computer Services (ACS) to computerize the drug rebate program.

The State agency had not yet billed for rebates on single source drugs administered by physicians. However, they anticipated being able to bill for rebates on single source drugs soon and on multiple source drugs by January 1, 2008.

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 Mississippi drug rebate program (A-04-03-06015), we determined that the State agency had adequate controls over its drug rebate program with one exception: it did not verify the accuracy of the accrual and collection of interest.

Mississippi Drug Rebate Program

The State agency contracted with ACS to perform all drug rebate program functions other than receiving rebate funds. The State agency had not completed preparations for collecting the rebates associated with these drugs by NDC. To capture the NDCs from the claims, the State agency requested additional time from CMS. The State agency had not yet billed for rebates on single source physician-administered drugs. However, they anticipated being able to bill for rebates on single source drugs soon and multiple source drugs by January 1, 2008.

The State agency reported an outstanding drug rebate balance of \$20,414,893 on its June 30, 2006, Form CMS-64.9R. However, \$12,217,194 of that amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining \$8,197,699 that was past due,

¹This provision of the DRA expands the requirement to certain multiple source drugs administered by physicians after January 1, 2008.

²“Multistate Review of Medicaid Drug Rebate Programs” (A-06-03-00048), issued July 6, 2005.

\$8,350,354³ was more than 1 year old. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately \$114.3 million and collections of \$146.2 million.

Drug Rebate	Quarter Ending 06/30/2006 (A)	Quarter Ending 03/31/2006 (B)	Quarter Ending 12/31/2005 (C)	Quarter Ending 09/30/2005 (D)	Quarter Ending 06/30/2005 And Prior (E)	Total (F)
Balance	12,217,194	109,084	(184,646)	(77,093)	8,350,354	20,414,893

The current review of the Mississippi 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, which were found in 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 Mississippi 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 in Jackson, Mississippi, in July 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;

³The total past balance of \$8,197,699. (Columns B-E) was affected by the credit balance (Columns C & D), thus causing the past due balance to appear smaller than the one year balance (Column E \$8,350,354).

- interviewed State agency officials and ACS 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;
- interviewed ACS 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.

FINDINGS AND RECOMMENDATION

The State agency corrected the previous weakness by upgrading its computer system to verify the accuracy of the accrual and collection of interest. However, it had not established controls over collecting rebates on single source drugs administered by physicians.

PREVIOUS WEAKNESS CORRECTION

In our previous audit of the Mississippi drug rebate program, we determined that the State agency was not able to verify the accuracy of the accrual and collection of interest. Subsequently, the State agency corrected this weakness by using a new computer system, the Drug Rebate Analysis and Management System.

ACS had set up programs to calculate the interest due on late payments and to identify outstanding amounts due from manufacturers. ACS stated that it reviews interest payments from prior quarters for accuracy and sends collection letters to manufacturers for any unpaid interest identified by this review.

As a result of the implementation and upgrade of the new computer system, the State agency could verify the accuracy of interest payments and had increased its collections of interest, current and outstanding, in each quarter of our review.

PHYSICIAN-ADMINISTERED SINGLE SOURCE DRUGS

The State agency had not established controls over collecting rebates for single source drugs administered by physicians, as required by the DRA. During our fieldwork, the State agency had not started invoicing drug manufacturers for single source drugs. After the completion of our fieldwork, in August 2007, the State agency began invoicing them.

RECOMMENDATION

We recommend that the State agency establish controls over collecting rebates for single source drugs administered by physicians and ensure that the invoiced amounts are collected and/or resolved.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency's fiscal agent began implementing our recommendation to start collecting rebates from pharmaceutical manufacturers for single source drugs administered by physicians on August 1, 2007. The State agency had established controls over collecting rebates and claimed to have collected over \$21 million in rebates as of September 2008.

The State agency's comments are included in their entirety as the Appendix.

APPENDIX

APPENDIX



STATE OF MISSISSIPPI
OFFICE OF THE GOVERNOR
DIVISION OF MEDICAID

Dr. Robert L. Robinson
Executive Director

September 16, 2008

Peter J. Barbera
Regional Inspector General for Audit Services
Office of the Inspector General – Region IV
61 Forsyth Street, S.W., Suite 3T41
Atlanta, GA 30303

Report Number: A-04-07-07023

Dear Mr. Barbera:

I write in response to the draft report of August 15, 2008 entitled "Follow-Up Review of the Medicaid Drug Rebate Program in Mississippi." I am pleased to note your conclusion that overall the accrual and collection of drug rebates and interest is adequate.

With respect to your specific recommendation regarding establishing controls over collecting rebates for single source drugs administered by physicians, I am pleased to inform you that the agency's fiscal agent, ACS, began billing pharmaceutical manufacturers for single source drugs administered by physicians on August 1, 2007. Since that time the agency has collected over \$21,517,824.01. The same process/controls and computer system, the Drug Rebate Analysis and Management System, is used for the collection of physician administered drug rebates as is used with the current Mississippi Drug Rebate Program.

We appreciate the opportunity to review this draft report and provide comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert L. Robinson", written over a horizontal line.

Robert L. Robinson

pc: Maritza Hawrey, OIG