



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General
Office of Audit Services

AUG 21 2008

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

Report Number: A-04-07-07024

Lynn Abrell
Alabama Medicaid Agency
P.O. Box 5624
Montgomery, Alabama 36103

Dear Ms. Abrell:

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 Alabama." 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 P.L. No. 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 pt. 5). 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-04-07-07024 in all correspondence.

Sincerely,

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
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Chicago, Illinois 60601

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**FOLLOW-UP REVIEW OF THE
MEDICAID DRUG REBATE
PROGRAM IN ALABAMA**



Daniel R. Levinson
Inspector General

August 2008
A-04-07-07024

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 manufacturers each undertake certain functions in connection with the drug rebate program. In Alabama, the Alabama Medicaid Agency (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. Because 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 Alabama drug rebate program (A-04-03-06005), we determined that the State agency had generally followed accounting procedures and had controls over the drug rebate program. However, the State agency did not account for the collection of interest or utilize write-off criteria, within CMS guidelines, for dispute resolution including appropriate use of the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturer(s). State agency officials agreed with our finding and recommendation on the collection of interest and planned to upgrade their computer system to calculate interest due. The State agency disagreed with our finding on dispute resolution, however, and stated that it had a formal resolution process in place and was making every effort to resolve the outstanding disputes. We found no evidence that the State had utilized the write-off criteria, within CMS guidelines, for dispute resolution.

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

SUMMARY OF RESULTS

The State agency implemented the recommendations from our previous audit related to the collection of interest and the utilization of write-off criteria for dispute resolution. In addition, 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) administer 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 Alabama, the Alabama Medicaid Agency (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 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.

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

In Alabama, physician-administered drugs are billed to the State Medicaid program on the professional claim form (CMS-1500) using procedure codes that are part of the Healthcare Common Procedure Coding System. Some physician-administered drugs are billed to the State Medicaid program on the institutional claim form (UB-92) using procedure codes that are part of the Healthcare Common Procedure Coding System. The NDC is not included on either one of the claim forms. 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 via a crosswalk, 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 Alabama drug rebate program (A-04-03-06005), we determined that the State agency had generally followed accounting procedures and had controls over the drug rebate program. However, the State agency did not account for the collection of interest or utilize write-off criteria, within CMS guidelines, for dispute resolution including appropriate use of the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturer(s). State agency officials agreed with our finding and recommendation on the collection of interest and planned to upgrade their computer system to calculate interest due. The State agency disagreed with our finding on dispute resolution, however, and stated that it had a formal resolution process in place and was making every effort to resolve the outstanding disputes. We found no evidence that the State had utilized the write-off criteria, within CMS guidelines, for dispute resolution.

Alabama Drug Rebate Program

The State agency contracts with Electronic Data Systems (EDS) to perform all drug rebate program functions. The State agency reported an outstanding drug rebate balance of \$35,279,364 on the June 30, 2006, Form CMS-64.9R. However, \$29,067,308 of this amount

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.

related to quarterly billings and was not past due as of June 30, 2006. Of the remaining \$6,212,056 that was past due, \$6,717,452 was more than 1 year old.³

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	29,067,308	571,109	228,614	(1,305,119)	6,717,452	35,279,364

For the fiscal year ended June 30, 2006, the State agency reported rebate billings of \$144,655,633 and collections of \$160,650,469.

This current review of the Alabama 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 Alabama 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 address the recommendation from our previous report regarding the dispute resolutions and the use of the hearing mechanism. The State agency was not required to use the hearing mechanism; our recommendation, which related to its use, was a suggestion for the State agency to consider.

We performed our fieldwork at the State agency in Montgomery, Alabama, in July 2007.

³The total past balance of \$6,212,056 (Columns B-E) was impacted by the credit balance (Column D), thus causing the past due balance to appear smaller than the 1 year and older balance (Column E \$6,717,452).

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;
- 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 objective.

RESULTS OF AUDIT

The State agency implemented the recommendations from our previous audit related to the collection of interest and the utilization of write-off criteria for dispute resolution. In addition, the State agency 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 Alabama drug rebate program, we determined that the State agency had generally followed accounting procedures and had controls over the drug rebate program. However, the State agency did not account for the collection of interest or utilize write-off criteria for dispute resolution.

Since our previous audit, EDS has provided the State agency with a comprehensive package of information technology services for the drug rebate program. EDS has set up programs to calculate the interest due on late payments and can identify outstanding amounts due from manufacturers.

Additionally, the State agency has criteria, which it is now implementing, for write-off and dispute resolution.

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 \$2,096,436 in claims for physician-administered drugs during the January through June 2006 period and billed manufacturers for rebates totaling \$758,865.