



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

JUL 31 2009

Report Number: A-04-08-07004

Donna Parker
South Carolina Department of Health and Human Services
1801 Main Street
Columbia, South Carolina 29202

Dear Ms. Parker:

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 South Carolina." 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.

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 do not hesitate to call me, or contact Denise Rivera Novak, Audit Manager, at (305) 536-5309, extension 10, or through email at Denise.Novak@oig.hhs.gov. Please refer to report number A-04-08-07004 in all correspondence.

Sincerely,

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

Peter J. Barbera
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to 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 SOUTH CAROLINA**



Daniel R. Levinson
Inspector General

July 2009
A-04-08-07004

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. 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 South Carolina, the Department of Health and 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 South Carolina drug rebate program (A-04-03-06011), we determined that the State agency needed improvement over drug rebate accountability in the following areas: (1) interest accrual and collection and (2) data integrity, including records retention. We recommended that the State agency:

- implement adequate procedures and controls that would enable the State agency to account for the accrual and collection of interest on late, disputed, or unpaid rebate payments and
- review existing procedures and implement strict controls to safeguard drug rebate data.

The State agency agreed with our findings and recommendations.

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

SUMMARY OF FINDINGS

The State agency, through its fiscal agent First Health Services, had implemented the recommendations from our previous audit related to data integrity, including record retention. However, the State agency had partially implemented the recommendation related to interest accrual and collection.

The State agency had not established procedures to validate the accuracy of interest paid by the manufacturers and had not actively pursued the outstanding interest due. As a result, there was no assurance that interest paid by the manufacturers was accurate or that the State agency had collected all of the interest due.

The State agency had established controls over collecting rebates on single source drugs administered by physicians.

RECOMMENDATIONS

We recommend that the State agency implement adequate procedures to ensure that interest payments are verified as accurate and that it more actively pursue outstanding interest due.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency concurred with our findings and recommendations. The complete text of the State agency's comments is included in its 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 South Carolina, the Department of Health and 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(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.

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

In South Carolina, 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.

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 South Carolina drug rebate program (A-04-03-06011), we determined that the State agency needed improvement over drug rebate accountability in the following areas: (1) interest accrual and collection and (2) data integrity, including records retention. We recommended that the State agency:

- implement adequate procedures and controls that would enable the State agency to account for the accrual and collection of interest on late, disputed, or unpaid rebate payments and
- review existing procedures and implement strict controls to safeguard drug rebate data.

The State agency agreed with our findings and recommendations.

South Carolina Drug Rebate Program

The State agency contracts with its fiscal agent, First Health Services (FHS), to perform all drug rebate program functions other than receiving rebate funds. FHS's responsibilities include generating and forwarding rebate invoices, conducting dispute resolution, and updating and maintaining a labeler's accounts receivable file.

The State agency reported an outstanding drug rebate balance of \$31,705,144 on the June 30, 2006, Form CMS-64.9R. However, \$28,378,284 of this amount related to quarterly billings and

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.

was not past due as of June 30, 2006. Of the remaining \$3,326,860 that was past due, none of that amount was more than 1 year old. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately \$213.9 million and collections of \$224.4 million.

This current review of the South Carolina 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 South Carolina 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 from June through October 2007, at the offices of FHS, located in Glenn Allen, Virginia.

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 FHS's drug rebate accounts receivable system;
- interviewed FHS 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 FHS 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 RECOMMENDATIONS

The State agency, through its fiscal agent FHS, had implemented the recommendations from our previous audit related to data integrity, including records retention. However, the State agency had partially implemented the recommendation related to interest accrual and collection.

The State agency had established controls over collecting rebates on single source drugs administered by physicians.

IMPLEMENTATION OF PREVIOUS RECOMMENDATIONS

In our previous audit of the South Carolina drug rebate program, we determined that the State agency had not: (1) accrued or tracked interest from drug manufacturers and did not have adequate controls to validate whether interest payments received from manufacturers were correct and (2) maintained adequate controls over data processing records under its care.

Since our previous audit, the State agency had (1) accrued and tracked the interest payments received from manufacturers and (2) implemented strict controls to safeguard drug rebate data. However, the State agency did not have adequate controls to validate whether interest payments received from manufacturers were correct.

Interest Collection

The State agency had accrued the interest due from the manufacturers. The interest was calculated using published yield rates of Treasury bills. In addition, the State agency had tracked the interest payments received from the manufacturers. However, the State agency had not established procedures to validate the accuracy of interest paid by the manufacturers and had not actively pursued the outstanding interest due. Although an FHS official had stated that unpaid interest amounts were communicated to the manufacturers on their Prior Period Adjustment statement, this was the extent of FHS's efforts to collect interest due the State agency. As a result, there was no assurance that interest paid by the manufacturers was accurate or that the State agency had collected all of the interest due.

According to CMS Medicaid Drug Rebate Program Release No. 65, it is the manufacturers' responsibility to calculate and pay interest for applicable rebate invoices. In addition, CMS Medicaid Drug Rebate Program Release No. 29 states that interest must be collected and 45 CFR § 92.20(b)(3) requires that States provide for effective control over and accountability of all

funds, property, and other assets. Furthermore, FHS policies and procedures state that “[t]he Rebate Program provides for the application, accrual and collection of interest.”

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 \$52,057,890 in claims for physician-administered drugs during the January through June 2006 period and billed manufacturers for rebates totaling \$5,980,575.

RECOMMENDATIONS

We recommend that the State agency implement adequate procedures to ensure that interest payments are verified as accurate and that it more actively pursue outstanding interest due.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency concurred with our findings and recommendations. The complete text of the State agency’s comments is included in its entirety as the Appendix.

APPENDIX



State of South Carolina
Department of Health and Human Services

Mark Sanford
Governor

Emma Forkner
Director

July 2, 2009

Mr. Peter J. Barbera
Regional Inspector General for Audit Services
Office of Inspector General
61 Forysth Street, S.W., Suite 3T41
Atlanta, Georgia 30303

Dear Mr. Barbera:

The South Carolina Department of Health and Human Services (SCDHHS) received your draft report entitled "Follow-Up Review of the Medicaid Drug Rebate Program in South Carolina." The findings have been reviewed and SCDHHS concurs with the findings. SCDHHS will establish procedures for our internal audit staff to perform yearly audits of the rebate interest calculations and payments to ensure accuracy. SCDHHS will also be actively pursuing outstanding interest due by referral to our legal department and collections. Please let me know if there are questions.

Sincerely,

A handwritten signature in black ink, appearing to read "William L. Wells".

William L. Wells, CPA
Deputy Director

WW/bfh