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-04-07-07027

Mr. Jerry Dubberly, Chief
Division of Medical Assistance Plans
Georgia Department of Community Health
2 Peachtree, NW, 36th Floor
Atlanta, Georgia 30303

Dear Mr. Dubberly:

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 Georgia." 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-04-07-07027 in all correspondence.

Sincerely,

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 GEORGIA

Daniel R. Levinson
Inspector General

July 2009
A-04-07-07027

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 Georgia, the Department of Community Health (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 Georgia drug rebate program (A-04-03-06010), we determined that the State agency had weaknesses over its drug rebate program in the areas of billing procedures, reconciliation of records, dispute resolution, and write-offs. We recommended that the State agency:

- more closely monitor fiscal agent activities,
- accurately report drug rebate activities on the Form CMS-64.9R,
- follow CMS guidelines in the collection process, and
- determine and document the amount of the rebate write-offs that occurred during the 1998 transition to First Health Services (FHS).

The State agency agreed that they would review the Drug Rebate Program by taking into account the recommendations in our report.

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

SUMMARY OF FINDINGS

The State agency implemented the recommendations from our previous audit relating to (1) monitoring fiscal agent activities and (2) accurately reporting drug rebate activities on the Form CMS-64.9R. However, the State agency did not implement the two recommendations relating to (3) the collection process and (4) write-offs.

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

The Collection Process

The State agency reported an outstanding drug rebate receivables balance of $67,237,892 that was more than 1 year old on its June 30, 2006, Form CMS-64.9R. However, the State agency did not have a report showing the age of the receivables for the amount reported as over 1 year old.

The State agency's reporting process continues to be affected by inadequate record keeping and missing documentation from the period covered by its previous fiscal agent, Electronic Data Systems (EDS). As a result, the State agency could not determine exactly what amount in uncollected drug rebates to pursue from the manufacturers.

Furthermore, as stated in our previous report, the State agency had never used the hearing mechanism in its collection process. According to a State agency official, the hearing mechanism still has not been used because no manufacturers have absolutely refused to pay.

Write-offs

The State agency did not implement our recommendation from the previous report because they were unable to determine an accurate accounts receivable balance as of the 1998 transition from EDS to FHS. During the transition, EDS did not provide FHS with accurate accounts receivable data because of EDS's inadequate recordkeeping. As a result, the State agency is unable to correctly identify drug rebate amounts due to the State agency from the various manufacturers.

RECOMMENDATIONS

We recommend that the State agency actively pursue collection of aged accounts receivable and use the hearing mechanism in its collection process to resolve disputed and outstanding drug

rebate accounts receivable. We also recommend that the State agency work with the manufacturers and FHS to determine accurate drug rebate accounts receivable that existed during the transition to FHS and resolve outstanding balances.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency described its plans to respond to our recommendations. Specifically, it is making efforts to reconcile rebates from the 1991–1998 undocumented transition period and to recover the approximately $67 million in outstanding drug rebate receivables identified above. The State agency's comments are included in their entirety as the Appendix.

TABLE OF CONTENTS

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 Georgia, the Department of Community Health (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.

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

In Georgia, physician-administered drugs are billed to the State Medicaid program on a physician services claim form (CMS 1500) using procedure codes that are part of the Healthcare Common Procedure Coding System. The NDC and J-Codes are both included on the claim form.

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 Georgia drug rebate program, we determined that the State agency had weaknesses over its drug rebate program, in the areas of billing procedures, reconciliation of records, dispute resolution, and write-offs.[3] We recommended that the State agency:

- more closely monitor fiscal agent activities,
- accurately report drug rebate activities on the Form CMS-64.9R,
- follow CMS guidelines in the collection process, and
- determine and document the amount of the rebate write-offs that occurred during the 1998 transition to First Health Services (FHS).

The State agency agreed that they would review the drug rebate program by taking into account the recommendations in our report.

Georgia Drug Rebate Program

The State agency contracts with its fiscal agent, FHS, to perform all drug rebate program functions other than receiving rebate funds and handling disputes in the second phase of the dispute resolution process. FHS's responsibilities included posting payments and producing quarterly rebate invoices. The State agency reported an outstanding drug rebate balance of $160,933,695 on the June 30, 2006, Form CMS-64.9R. However, $74,437,609 of this amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining $86,496,086 that was past due, $67,237,892 was more than 1 year old. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately $269 million and collections of $272.3 million.[4]

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[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 Georgia" (A-04-03-06010), issued August 29, 2003.

[4]Billing amounts represent current quarter billings. Collection amounts represent current quarter and prior quarter collections.

This current review of the Georgia 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 Georgia 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 July through October 2007 at the offices of the State agency and its fiscal agent in Atlanta, Georgia.

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, in addition to June 30, 2002, and September 30, 2007;

- reviewed supporting documentation for the outstanding accounts receivable balances on Form CMS-64.9R as of September 30, 2007;

- interviewed fiscal agent staff and reviewed documentation to determine whether inaccurate drug rebate amounts had been adjusted accordingly;

- 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.

FINDINGS AND RECOMMENDATIONS

The State agency implemented the recommendations from our previous audit relating to (1) monitoring fiscal agent activities and (2) accurately reporting drug rebate activities on the Form CMS-64.9R. However, the State agency did not implement the two recommendations relating to (3) the collection process and (4) write-offs.

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 Georgia drug rebate program, we determined that the State agency's billing system procedures were inefficient, supporting records and reports were not accurate, and the dispute resolution process did not conform to CMS's guidelines. Also, an undetermined amount of rebate accounts receivables adjustments occurred during the transition to a new fiscal agent in 1998.

Since our previous audit, the State agency has improved its monitoring of fiscal agent activities by (1) implementing edits in FHS's billing system to detect unreasonable or aberrant error conditions, and (2) ensuring that supporting records and reports are accurate. However, we noted issues that still existed relating to the collection process and adjustments.

Rebate Collection Requirements

State agencies are required to maintain adequate supporting records to account for drug rebates. Pursuant to 42 CFR § 433.32(a), States are required to "[m]aintain an accounting system and supporting fiscal records to assure that claims for Federal funds are in accord with applicable Federal requirements . . . ."

Furthermore, collection process procedures have been established in the event that the State and the manufacturer are unable to resolve a drug rebate discrepancy. According to the Rebate

Agreement (V)(c), "The State and the Manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of such notification. In the event that the State and the Manufacturer are not able to resolve a discrepancy within 60 days, CMS shall require the State to make available to the Manufacturer the State hearing mechanism available under the Medicaid Program . . . ." In addition, 42 CFR § 447.253(e), which pertains to provider appeals, states that "[t]he Medicaid agency must provide an appeals or exception procedure that allows individual providers an opportunity to submit additional evidence and receive prompt administrative review, with respect to such issues as the agency determines appropriate, of payment rates."

The Collection Process

The State agency reported an outstanding drug rebate receivables balance of $67,237,892 that was more than 1 year old on its June 30, 2006, Form CMS-64.9R. However, the State agency did not have a report showing the age of the receivables for the amount reported as over 1 year old. The State agency produced an aging report for the quarter ended September 30, 2007, but it was not accurate.

The State agency's reporting process continues to be affected by inadequate record keeping and missing documentation from the period covered by its previous fiscal agent, Electronic Data Systems (EDS). Because of this previously reported condition, which has yet to be resolved, FHS, the current fiscal agent, was unable to accurately support the receivables balance more than 1 year old. As a result, the State agency could not determine exactly what amount in uncollected drug rebates to pursue from the manufacturers.

Furthermore, as previously reported, the State agency had never used the hearing mechanism in its collection process. During our current review, a State agency official informed us that the State agency still has not used the hearing mechanism in its collection process. The official stated that this procedure has not been necessary because no manufacturers have absolutely refused to pay. However, making the hearing mechanism available to the manufacturer may help the State agency resolve disputed drug rebates.

Write-offs

The State agency did not implement our recommendation from the previous report because they were unable to determine an accurate accounts receivable balance as of the 1998 transition from EDS to FHS. During the transition, EDS did not provide FHS with accurate accounts receivable data because of EDS's inadequate recordkeeping. According to a State official, it was not possible to recreate a history of what was paid by manufacturer under the previous fiscal agent. As a result, the State agency is unable to identify the amount of rebate payments that is still due to the State agency from the various manufacturers.

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 $57,297,480 in claims for physician-administered drugs during the January through June 2006 period and billed manufacturers for rebates totaling $23,841,056.

RECOMMENDATIONS

We recommend that the State agency actively pursue collection of aged accounts receivable and use the hearing mechanism in its collection process to resolve disputed and outstanding drug rebate accounts receivable. We also recommend that the State agency work with the manufacturers and FHS to determine accurate drug rebate accounts receivable that existed during the transition to FHS and resolve outstanding balances.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency described its plans to respond to our recommendations. Specifically, it is making efforts to reconcile rebates from the 1991–1998 undocumented transition period and to recover the approximately $67 million in outstanding drug rebate receivables identified above. The State agency's comments are included in their entirety as the Appendix.

APPENDIX

GEORGIA DEPARTMENT OF
COMMUNITY HEALTH

Rhonda M. Medows, MD, Commissioner

Sonny Perdue, Governor

2 Peachtree Street, NW
Atlanta, GA 30303-3159
www.dch.georgia.gov

May 26, 2009

Report Number A-04-07-07027

Mr. Peter J. Barbera
Regional Inspector General for Audit Services
Region IV
61 Forsyth Street, S. W. Suite 3141
Atlanta, GA 30303

Dear Mr. Barbera:

The Georgia Department of Community Health (DCH) has reviewed the draft report entitled "Follow-up Review of the Medicaid Drug Rebate Program in Georgia" from the U. S. Department of Health and Human Services, Office of Inspector General (OIG) regarding the audit, findings and recommendations contained in report number A-04-07-07027.

DCH's response to the findings as well as OIG recommendations as stated on page six (6) in the draft report are detailed below.

"We recommend that the state agency actively pursue collection of aged accounts receivable and use the hearing mechanism in its collection process to resolve disputed and outstanding drug rebate accounts receivable. We also recommend that the State agency work with the manufacturers and FHS to determine accurate drug rebate accounts receivable that existed during the transition to FHS and resolve outstanding balances."

DCH Response:

- In December 2008, after a thorough review and evaluation of the undocumented rebate period of 1991 - 1998 and available supporting documents, DCH decided that a direct written communication plan was needed instead of the reliance on the Prior Period Adjustment (PPA) notification. First Health Services Company, Inc. (FHS) sent letters to labelers and received a 66% (10 of 15) response. The reconciliation process is complete for five (5) labelers, and the others are in process with completion targeted for September 1, 2009. Additional outreach will be made to the non-responders by July 1, 2009.
- The Dunning process has been used routinely to remind labelers and request payments of outstanding balances. This process has been enhanced through the use of a Standard Operating Procedure (SOP) for Late Payments and Uncooperative Labelers which was implemented in December 2008. This process alters the activities required for greater efficiency in collections and labeler communications.
- Implementing and applying CMS thresholds for 1998Q2 and forward is currently under review to ensure compliance with State regulations and procedures for write offs.
- Prior Period Adjustment notices have been sent routinely each quarter since 1998Q3 to remind labelers of outstanding balances.
- Progress has been documented in the reduction of the audited balance of $67,237,892. This figure has been reduced by $24,550,991 as of May 1, 2009. The aged receivables will continue to be monitored to complete reconciliation in accordance with the Statement of Understanding (SOU) initiated in December 2008.

- DCH has not used the hearing mechanism to collect outstanding balances from uncooperative labelers. However, DCH is addressing this based on the CMS guidelines and through the process established in the SOP revising the Dunning notification process and timeline.

To prevent aging of current outstanding balances the Late Payments and Uncooperative Labelers Standard Operating Procedures (SOP) focuses on actions that will be taken to address current labelers that are unresponsive. This includes those that do not follow up after being contacted and those agreeing to payment of balances but fail to do so. The process will provide documentation of reasons given for non-payment. Included in the SOP is the process for notifying CMS after two Dunning notices have been sent at 45 days and again at 75 days with a subsequent phone call to the non-responders. At 90 days, a review is done to determine if a payment has been received by the date promised or if the labeler is still non-compliant. A report of these labelers as uncooperative is sent to DCH at 90 days after the review is completed. Upon notice, DCH will send a letter endorsed by its legal department prior to proceeding to a hearing as a final measure to obtain the outstanding balances.

DCH recognizes that the cost of pursuing and collecting very low balances is expensive financially and requires a large number of man hours to resolve. Previously, DCH had a zero threshold for write-offs. However, consideration to a process consistent with both federal and state requirements is underway.

It is anticipated that with the actions planned and currently being executed as mentioned above for the rebate program, the recommendations and findings will satisfy the auditor's requirements. If there are additional questions or clarifications needed, please do not hesitate to call me at 404-657-7793 or by email at jdubberly@dch.ga.gov.

Sincerely,

Jerry Dubberly, Chief
Medical Assistance Plans

cc: Rhonda Medows
Adrian Washington