Office of Audit Services
Region I
John F. Kennedy Federal Building
Boston, MA 02203
(617) 565-2684

March 24, 2009

Report Number: A-01-08-00009

Mr. Gary Alexander
Director
Department of Human Services
Forand Building
600 New London Avenue
Cranston, Rhode Island 02920

Dear Mr. Alexander:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled "Follow-up Audit of the Medicaid Drug Rebate Program in Rhode Island." 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 Curtis Roy, Audit Manager, at (617) 565-9281 or through e-mail at Curtis.Roy@oig.hhs.gov. Please refer to report number A-01-08-00009 in all correspondence.

Sincerely,

Michael J. Armstrong

Michael J. Armstrong
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 and Medicaid Services
233 North Michigan Avenue, Suite 600
Chicago, Illinois 60601

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

FOLLOW-UP AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN RHODE ISLAND

Daniel R. Levinson
Inspector General

March 2009
A-01-08-00009

Office of Inspector General

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at http://oig.hhs.gov

Pursuant to the Freedom of Information Act, 5 U.S.C. § 552, Office of Inspector General reports generally are made available to the public to the extent that information in the report is not subject to exemptions in the Act.

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 Rhode Island, the Department of 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 Rhode Island drug rebate program (A-01-03-00001), we determined that the State agency's controls were generally in place to record and track the collection of drug rebates. In addition, the Federal share of drug rebate amounts was properly offset from Federal Medicaid reimbursement. However, the total uncollected drug rebate amount reported on the Form CMS-64.9R for the quarter that ended June 30, 2002, (1) was overstated by $4.7 million because this amount was not supported by the State agency's records and (2) contained approximately $570,000 in uncollected disputed items for the period January 1994 through December 2001 that the State agency had not resolved. In addition, the State agency had not established written procedures for reporting its pending drug rebate amounts on the Form CMS-64.9R report. We recommended that the State agency (1) reconcile the State records to the amount reported on the CMS-64.9R and make a summary adjustment to account for the overstated amount, (2) resolve disputed items either through the CMS hearing mechanism or the National Dispute Resolution conference, and (3) establish written procedures for recording drug rebate transactions.

The State agency agreed with our findings and recommendations.

This current review of Rhode Island is part of a nationwide series of reviews conducted to determine whether States have addressed the weaknesses found in the previous reviews in accountability for and internal controls over their drug rebate programs. 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 Rhode Island drug rebate program and (2) established controls over collecting rebates on single source drugs administered by physicians.

SUMMARY OF FINDING

The State agency had adjusted its CMS-64.9R by $4.7 million and resolved nearly all outstanding disputed amounts for the period 1994 through 2001. However, the State agency had not fully implemented the recommendation from our prior audit to establish written procedures for recording drug rebate transactions.

Regarding the second objective, the State agency had established controls over collecting rebates on single source drugs administered by physicians.

RECOMMENDATION

We reiterate our recommendation that the State agency establish written procedures for recording drug rebate transactions.

DEPARTMENT OF HUMAN SERVICES COMMENTS

In written comments on our draft report, the State agency agreed with our recommendation.

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) 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 Rhode Island, the Department of 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 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 form 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.

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

In Rhode Island, physician-administered drugs are billed to the State Medicaid program on a physician claim form. The State agency uses the Form CMS-1500 as the physician claim form. The physician claim form uses the procedure codes that are part of the Healthcare Common Procedure Coding (HCPC) system instead of the NDC. The HCPC 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. Rebates are calculated and paid based on NDCs. In addition, 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, procedure codes must be converted to NDCs for single source drugs, and procedure code billing units must be converted into equivalent NDC billing units.

Prior 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 Rhode Island drug rebate program (A-01-03-00001), we determined that the State agency's controls were generally in place to record and track the collection of drug rebates. In addition, the Federal share of drug rebate amounts was properly offset from Federal Medicaid reimbursement. However, the total uncollected drug rebate amount reported on the Form CMS-64.9R for the quarter that ended June 30, 2002, (1) was overstated by $4.7 million because this amount was not supported by the State agency's records and (2) contained approximately $570,000 in uncollected disputed items for the period January 1994 through December 2001 that the State agency had not resolved. In addition, the State agency had not established written procedures for reporting its pending drug rebate amounts on the Form CMS-64.9R report. We recommended that the State agency (1) reconcile the State records to the amount reported on the CMS-64.9R and make a summary adjustment to account for the overstated amount, (2) resolve disputed items either through the CMS hearing mechanism or the National Dispute Resolution conference, and (3) establish written procedures for recording drug rebate transactions.

The State agency agreed with our findings and recommendations.

Rhode Island Drug Rebate Program

Since January 1, 1995, the State agency has contracted with its fiscal agent, Electronic Data Systems, to perform all drug rebate program functions other than preparing and submitting the Form CMS-64.9R. The fiscal agent's responsibilities include preparing and mailing invoices to manufacturers, receiving and posting payments, resolving disputes, and accounting for rebates on

[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.

single source drugs administered by physicians. The fiscal agent also converts the procedure code billing units into equivalent NDC billing units.

For the fiscal year ending June 30, 2006, the State agency reported rebate billings of approximately $36.9 million and collections of approximately $49.3 million on its Forms CMS-64.9R.

This current review of the Rhode Island drug rebate program is part of a nationwide series of reviews conducted to determine whether States have addressed the weaknesses found in the previous reviews in accountability for and internal controls over their drug rebate programs. 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 Rhode Island 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 that it reported on Form CMS-64.9R as of June 30, 2006.

We conducted our fieldwork at the State agency in Cranston, Rhode Island, and Electronic Data Systems in Warwick, Rhode Island, from July through September 2008.

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;

- reviewed the previous Office of Inspector General audit report on the drug rebate program in Rhode Island;

- 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 supporting documentation for rebates invoiced, adjustments, and rebates collected for the four quarters that ended June 30, 2006 (July 1, 2005, through June 30, 2006); and

- interviewed fiscal agent staff to determine the processes used in (1) resolving claims disputed by the drug manufacturers and (2) converting physician services claims data into drug rebate data related to single source drugs administered by physicians.

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 finding and conclusion based on our audit objectives.

FINDING AND RECOMMENDATION

The State agency had adjusted its CMS-64.9R by $4.7 million and resolved nearly all outstanding disputed amounts for the period 1994 through 2001. However, the State agency had not fully implemented the recommendation from our prior audit to establish written procedures for recording drug rebate transactions.

Regarding the second objective, the State agency had established controls over collecting rebates on single source drugs administered by physicians.

IMPLEMENTATION OF PRIOR RECOMMENDATIONS

In our prior audit of the Rhode Island drug rebate program, we determined that the State agency had overstated its total uncollected drug rebate amount by $4.7 million, had not resolved claims disputed by drug manufacturers, and had not established written procedures for recording drug rebate transactions.

Federal regulations at 45 CFR § 92.20(a) require that " . . . Fiscal control and accounting procedures of the State . . . must be sufficient to . . . establish that such [Medicaid] funds have not been used in violation of the restrictions and prohibitions of applicable statutes."

Our current review found that the State agency had adjusted its CMS-64.9R by $4.7 million and that, as a result, the total uncollected drug rebate amount reported on the CMS-64.9R reconciled to the State agency's records. In addition, the State agency, through its own resolution process, had successfully resolved nearly all disputed items as of June 30, 2006, and had resolved all items by the end of our fieldwork.

However, the State agency had not developed adequate written procedures for recording drug rebate transactions, as we had recommended and as Federal regulations require. Specifically, the State agency produced a document with six bullet points of one sentence each, entitled "Procedures to Record, Reconcile and Report Drug Rebates." However, four of these bullets were for functions performed by the State agency's fiscal agent, who maintains its own procedures. The remaining two bullets did not comprehensively describe the State agency's procedures for recording drug rebate transactions.

PHYSICIAN-ADMINISTERED SINGLE SOURCE DRUGS

The State agency had established controls over collecting rebates on single source drugs administered by physicians, as the DRA requires. The State agency paid $458,490 in claims for physician-administered drugs from January through June 2006 and billed manufacturers for rebates totaling $81,833.

RECOMMENDATION

We reiterate our recommendation that the State agency establish written procedures for recording drug rebate transactions.

DEPARTMENT OF HUMAN SERVICES COMMENTS

In written comments on our draft report, the State agency agreed with our recommendation.

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

APPENDIX

State of Rhode Island and Providence Plantations

DEPARTMENT OF HUMAN SERVICES
Office of the Director

February 2, 2009

Mr. Michael J. Armstrong
Regional Inspector General for Audit Services
Office of Inspector General
Region I
John F. Kennedy Federal Building
Boston, MA 02203

Re: Report Number: A-01-08-00009

Dear Mr. Armstrong:

In response to your recommendation, the Rhode Island Department of Human Services, Office of Financial Management, is revising the written procedures relating to the recording of drug rebate transactions.

Sincerely,

Gary D. Alexander
Director

Cc: Ralph Racca
Paula Avarista
Robert Farley
Richard Piscopiello