DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
OFFICE OF AUDIT SERVICES
150 S. INDEPENDENCE MALL WEST
SUITE 316
PHILADELPHIA, PENNSYLVANIA 19106-3499

JAN 4 2008

Report Number: A-03-07-00216

Robert T. Maruca, Senior Deputy Director
Medical Assistance Administration
Department of Health
825 N. Capitol Street, NE Suite 5200
Washington, DC 20002

Dear M. Maruca:

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 the District of Columbia." 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 Public Law 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 part 5). Accordingly, within 10 business day after this report is issued, it 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 Eugene Berti, Audit Manager, at (215) 861-4474 or through e-mail at Gene.Berti@oig.hhs.gov. Please refer to report number A-03-07-00216 in all correspondence.

Sincerely,

Stephen Virbitsky
Regional Inspector General
for Audit Services

Enclosure

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 AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN THE DISTRICT OF COLUMBIA

Daniel R. Levinson
Inspector General

January 2008
A-03-07-00216

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 all 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. Specifically, these evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness in departmental programs. To promote impact, the reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, 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 in OIG's internal operations. OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within HHS. OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops compliance program guidances, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

Notices

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

In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), Office of Inspector General, Office of Audit Services reports are made available to members of the public to the extent the information is not subject to exemptions in the act. (See 45 CFR Part 5.)

OAS FINDINGS AND OPINIONS

The designation of financial or management practices as questionable or a recommendation for the disallowance of costs incurred or claimed, as well as other conclusions and recommendations in this report, represent the findings and opinions of the HHS/OIG/OAS. Authorized officials of the HHS 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 the District of Columbia (the District), the Medical Assistance Administration (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 (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 District drug rebate program, we determined that the State agency had adequate controls over its drug rebate program, with two exceptions: the Fiscal Year 2002 Form CMS-64.9R reports were not accurate and included incomplete data, and the endorsement stamp used by the fiscal agent on drug rebate checks was too generic and did not provide for proper security over the checks (A-03-03-00205). We recommended that the State agency:

- accurately report outstanding rebates receivable and rebates collected, and include rebates invoiced and adjustments on the Form CMS-64.9R and

- include on the endorsement stamp either the District's name or the District's bank account number to ensure greater security of drug rebate checks on behalf of the District.

The State agency agreed with our findings and recommendations.

This current review of the District 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 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 District's 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 prior audit. The District's Form CMS-64.9R reports were accurate and included complete data. The fiscal agent endorsed all checks "For Deposit Only" with the specific bank account number identified. However, the State agency did not collect rebates on single source drugs administered by physicians or establish controls over and accountability for their collection.

RECOMMENDATIONS

We recommend that the State agency:

- implement policies and procedures to collect and submit utilization for single source drugs administered by physicians so that the District may obtain rebates for the drugs and

- collect rebates for single source drugs, retroactive to January 1, 2006, when it implements its single source drug rebate program.

STATE AGENCY'S COMMENTS

In its comments on our draft report, the State agency concurred with our findings and stated that it plans to adhere to our recommendations. The Appendix presents the State agency's comments.

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 manufacturers 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 the District of Columbia (the District), the Medical Assistance Administration (the State agency) is responsible for the 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.

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

Generally, physician-administered drugs are billed to States' Medicaid programs 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.

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.[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 District's drug rebate program, we determined that the State agency had adequate controls over its drug rebate program, with two exceptions: the Fiscal Year 2002 Form CMS-64.9R reports were not accurate and included incomplete data, and the endorsement stamp used by the fiscal agent on drug rebate checks was too generic and did not provide for proper security over the checks.[3] We recommended that the State agency:

- accurately report outstanding rebates receivable and rebates collected, and include rebates invoiced and adjustments on the Form CMS-64.9R and

- include on the endorsement stamp either the District's name or the District's bank account number to ensure greater security of drug rebate checks on behalf of the District.

The State agency agreed with our findings and recommendations.

The District Drug Rebate Program

The State agency contracts with its fiscal agent, Affiliated Computer Services, to perform all drug rebate program functions, other than receiving rebate funds. The fiscal agent's responsibilities included comparing CMS data to other sources so that discrepancies can be identified and resolved.

[2] "Multistate Review of Medicaid Drug Rebate Programs" (A-06-03-00048), issued July 6, 2005; Arizona was not included as it did not operate a drug rebate program.

[3] "Review of the District of Columbia's Medicaid Drug Rebate Program" (A-03-03-00205), issued July 15, 2003.

The State agency reported an outstanding drug rebate balance of $10,834,034 on the June 30, 2006, Form CMS-64.9R. However, $210,507 of this amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining $10,623,527 that was past due, $9,301,730 was more than 1 year old. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately $4.1 million and collections of $5.1 million.

This current review of the District 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 District's 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 and its fiscal agent, both of which are located in the District, in June 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 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;

- obtained and reviewed rebate checks to determine whether the District corrected the findings from the prior audit; and

- interviewed fiscal agent staff to determine whether the District collects rebates on single source drugs administered by physicians.

We performed our audit in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

The State agency implemented the recommendations from our prior audit. The District's Form CMS-64.9R reports were accurate and included complete data. The fiscal agent endorsed all checks "For Deposit Only" with the specific bank account number identified. However, the State agency did not collect rebates on single source drugs administered by physicians or establish controls over and accountability for their collection.

IMPLEMENTATION OF PRIOR RECOMMENDATIONS

In our prior audit of the District, we determined that the State agency's Fiscal Year 2002 Form CMS-64.9R reports were not accurate and included incomplete data. Also, the State agency's endorsement stamp used by its fiscal agent on drug rebate checks was too generic and did not provide for proper security over the checks.

Since our prior audit, the State agency modified its policies to require that the fiscal agent (1) report rebate collections on a daily basis to ensure that the Form CMS-64.9R are accurate and include completed data and (2) modify its rebate check endorsement by stamping checks "For Deposit Only" to the specific account.

PHYSICIAN-ADMINISTERED SINGLE SOURCE DRUGS

The State agency has not established a program to collect and submit utilization for single source drugs administered by physicians and consequently has made no claims for these drugs. However, the State agency requested a cost/price proposal from its fiscal agent to include single-source drugs administered by physicians in the District's Medicaid Management Information System. The fiscal agent has prepared a proposal in draft form that includes controls that will be required when the State agency does collect rebates on single source drugs administered by physicians.

RECOMMENDATIONS

We recommend that the State agency:

- implement policies and procedures to collect and submit utilization for single source drugs administered by physicians so that the District may obtain rebates for the drugs and

- collect rebates for single source drugs, retroactive to January 1, 2006, when it implements its single source drug rebate program.

STATE AGENCY'S COMMENTS

In its comments on our draft report, the State agency concurred with our findings and stated that it plans to adhere to our recommendations. The Appendix presents the State agency's comments.

APPENDIX

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Department of Health
Medical Assistance Administration

Office of the Senior Deputy Director

December 6, 2007

Mr. Stephen Virbitsky
Regional Inspector General for Audit Service
Office of the Inspector General
Department of Health and Human Services
150 S. Independence Mall West
Suite 316
Philadelphia, PA 10906-3499

Dear Mr. Virbitsky:

The District of Columbia Department of Health, Medical Assistance Administration (MAA) is in receipt of your letter dated November 16, 2007 requesting our comments on the draft report entitled "Follow-up Audit of the Medicaid Drug Rebate Program in Washington, DC.

I have read the draft report and I concur with the summary of findings as written in the document. MAA plans to adhere to the proposed recommendations as follows:

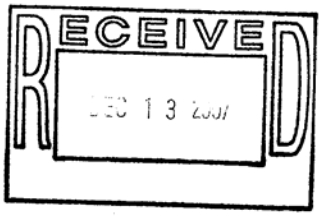
- We are currently developing policies and procedures to collect and submit utilization for single source drugs administered by physicians.

- The collection of rebates for single source, physician administered drugs will be retroactive to January 1, 2006.

If you have any questions or need additional information, please contact me on (202) 442-5988.

Sincerely,

Robert T. Maruca
Senior Deputy Director



825 North Capitol Street, N.E., Washington, D.C. 20002 (202) 442-5988 Fax (202) 442-4790