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

APR 11 2008

Report Number: A-04-07-07022

Ms. Holly Benson, Secretary
Agency for Health Care Administration
2727 Mahan Drive
Tallahassee, Florida 32308

Dear Ms. Benson:

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 Florida." 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 to the public to the extent the information is not subject to exemptions in the Act (45 CFR part 5). Accordingly, within 10 business days 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 direct them to the HHS action official. Please refer to report number A-04-07-07022 in all correspondence.

Sincerely,

Peter J. Barbera

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
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 FLORIDA

Daniel R. Levinson
Inspector General

April 2008
A-04-07-07022

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 principles of the Freedom of Information Act, 5 U.S.C. § 552, as amended by Public Law 104-231, Office of Inspector General 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).

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 Florida, the Agency for Health Care 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 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 Florida drug rebate program, we determined that the State agency had adequate controls over its drug rebate program, with three exceptions. It did not: (1) track or verify the accuracy of interest payments received from manufacturers and provide certainty that all interest due on late, unpaid or disputed rebates was accrued and collected; (2) have adequate policies and procedures for resolving disputes with manufacturers; and (3) provide reasonable assurance that rebates reported to CMS on Form CMS-64.9R were accurate (A-04-03-06016). We recommended that the State agency:

- make it a priority to program the existing computer system to calculate interest and verify that interest payments are accurate and

- develop policies and procedures that establish 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).

We did not make any recommendation relative to the reconciliation of Form CMS-64.9R because at the time of our review, the State agency was in the process of implementing a computerized reporting system for processing drug rebates.

The State agency agreed with our findings and recommendations.

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

SUMMARY OF FINDINGS

The State agency had implemented the recommendations from our prior audit related to calculating and verifying the accuracy of interest payments and developing policies and procedures that establish write-off criteria, within CMS guidelines, for dispute resolution. The State agency established controls over collecting rebates on single source drugs administered by physicians. Therefore, we do not offer any recommendations.

STATE AGENCY'S COMMENTS

The State agency agreed with our report. Its comments are attached 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 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 Florida, the Agency for Health Care Administration (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 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 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.

In Florida, 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. Because the form is used as an outpatient pharmacy claim form, the physician claim form can accommodate all three codes: the Current Procedural Terminology, the Healthcare Common Procedure Coding System, and the NDC. The NDC may not be 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 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 Florida drug rebate program, we determined that the State agency had adequate controls over its drug rebate program, with three exceptions. It did not: (1) track or verify the accuracy of interest payments received from manufacturers and provide certainty that all interest due on late, unpaid, or disputed rebates was accrued and collected; (2) have adequate policies and procedures for resolving disputes with manufacturers; and (3) provide reasonable assurance that rebates reported to CMS on Form CMS-64.9R were accurate.[3] We recommended that the State agency:

- make it a priority to program the existing computer system to calculate interest and verify that interest payments are accurate and

- develop policies and procedures that establish 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).

We did not make any recommendation relative to the reconciliation of Form CMS-64.9R because, at the time of our review, the State agency was in the process of implementing a computerized reporting system for processing drug rebates.

[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 Drug Rebate Program in the State of Florida" (A-04-03-06016), issued August 29, 2003.

The State agency agreed with our findings and recommendations.

Florida Drug Rebate Program

The State agency contracts with Unisys to perform all drug rebate program functions other than receiving rebate funds. The State agency reported an outstanding drug rebate balance of $208,741,390 on the June 30, 2006, Form CMS-64.9R. However, $55,823,321 of this amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining $152,918,069 that was past due, $118,001,498 was more than 1 year old. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately $110.1 million and collections of $263.1 million.

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

Scope

We reviewed the State agency's 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. Florida's Medicaid drug rebate program's new fiscal agent, Unisys, became operational November 2005. However, Unisys's drug rebate collection efforts actually began during the quarter ended June 30, 2006. Therefore, we extended our review through the quarter ended June 30, 2007, to determine the progress Unisys had made with its rebate collection efforts.

We did not include a reported weakness from the prior report related to the use of the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturers for resolving disputes over rebate amounts owed to the State. The State agency was not required to use the hearing mechanism, and our recommendation, which related to its use, was a suggestion for the State agency to consider.

We performed our fieldwork from June 11 through June 22, 2007, at the offices of the State agency and Unisys in Tallahassee, Florida.

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 State agency's drug rebate accounts receivable system;

- interviewed State agency officials and Unisys 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 Unisys staff to determine the processes used in converting physician services claims data into drug rebate data related to single source drugs administered by physicians;

- 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; and

- reviewed supporting documentation for the reported amounts on Form CMS-64.9R as of June 30, 2007.

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.

RESULTS OF AUDIT

The State agency implemented the recommendations from our prior audit related to calculating and verifying the accuracy of interest payments and developing policies and procedures that establish write-off criteria, within CMS guidelines, for dispute resolution. The State agency established controls over collecting rebates on single source drugs administered by physicians. Therefore, we do not offer any recommendations.

IMPLEMENTATION OF PRIOR RECOMMENDATIONS

In our prior audit of the Florida drug rebate program, we determined that the State agency had not: (1) tracked or verified the accuracy of interest payments received from manufacturers and provided certainty that all interest due on late, unpaid, or disputed rebates was accrued and collected; (2) developed adequate policies and procedures for resolving disputes with

manufacturers, including write-off criteria within CMS guidelines for dispute resolution; or (3) provided reasonable assurance that rebates reported to CMS on Form CMS-64.9R were accurate.

Since our prior audit, the State agency has established a computerized drug rebate reporting system that has enabled it to: (1) track and verify the accuracy of interest payments received from manufacturers and provide certainty that all interest due on late, unpaid, or disputed rebates is accrued and collected; (2) improve its policies and procedures related to the dispute resolution process, including write-off criteria within CMS guidelines; and (3) ensure the accuracy of rebates reported to CMS on Form CMS-64.9R.

Since Unisys became the State's new fiscal agent for the drug rebate program, Unisys has made considerable progress with its rebate collection efforts. From the end of the prior audit report period, quarter ended June 30, 2002, through the quarter ended June 30, 2006, the disputed total outstanding balance had increased 121.1 percent from $94.4 million to $208.7 million, and the over-1-year outstanding balance had increased 695 percent from $14.8 million to $118 million. Conversely, after initiating its collection efforts, Unisys achieved significant decreases in these outstanding balances by June 30, 2007. Unisys's efforts resulted in a decrease of 47.7 percent in the total outstanding balance from $208.7 million to $109.2 million and a decrease of 88.4 percent in the over-1-year outstanding balance from $118 million to $13.6 million.

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 $16,380,949 in claims for physician-administered drugs during the January through June 2006 period and billed manufacturers for rebates totaling $8,824,955.

STATE AGENCY'S COMMENTS

The State agency agreed with our report. Its comments are enclosed in their entirety as the Appendix.

APPENDIX

FLORIDA MEDICAID

CHARLIE CRIST
GOVERNOR

HOLLY BENSON
SECRETARY

March 20, 2008

Maritza Hawrey, Audit Manager
Office of Inspector General
Office of Audit Services
51st SW 1st Avenue, Room 504
Federal Building, Box 20
Miami, Florida 33130-1631

Re: Report Number A-04-07-07022

Dear Ms. Hawrey,

Per your request, we are providing our comments in response to your letter of February 22, 2008. The State of Florida Agency for Health Care Administration is in agreement with the findings and recommendations that were issued by the U.S. Department of Health and Human Services, Office of the Inspector General (OIG), draft report entitled "Follow-up Review of the Medicaid Drug Rebate Program in Florida".

The report states that the Florida Agency for Health Care Administration has implemented the recommendations from the prior audit of 2005 and established controls over collecting single source drugs administered by physicians. The report also does not offer any additional or new recommendations. The recommendations from the prior audit were related to calculating and verifying the accuracy of interest payments and developing policies and procedures that established write-off criteria within Centers for Medicare and Medicaid Services (CMS) guidelines for dispute resolutions. In addition, the audit reviewed Florida's compliance with the portion of the Deficit Reduction Act (DRA) related to physician administration drugs which establish controls over collecting rebates on single source drugs administered by physicians.

If you have any questions, or concerns regarding our response, please do not hesitate to contact Linda Barnes or Paula McKnight at (850) 487-4441.

Sincerely,

Carlton D. Snipes
Deputy Secretary for Medicaid