DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Office of Audit Services
1100 Commerce, Room 632
Dallas, TX 75242

November 27, 2007

Report Number: A-06-07-00067

Jerry Phillips
Medicaid Director
Louisiana Department of Health and Hospitals
Attention: M.J. Terrebonne
628 North 4th Street
Seventh Floor
Baton Rouge, Louisiana 70802

Dear Mr. Phillips:

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 Drug Rebate Program in Louisiana." 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 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-06-07-00067 in all correspondence.

Sincerely,

for Gordon L. Sato
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 LOUISIANA

Daniel R. Levinson
Inspector General

November 2007
A-06-07-00067

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.

EXECUTIVE SUMMARY

BACKGROUND

The Medicaid drug rebate program, which began in 1991, is set forth in section 1927 of the Social Security Act (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 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 Louisiana, the Department of Health and Hospitals (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 Louisiana drug rebate program, we determined that the State agency had adequate controls over its drug rebate program, with one exception: It did not reconcile the outstanding drug rebate balance reported to CMS to its accounts receivable records (A-06-03-00011). We recommended that the State agency implement a control requiring that the outstanding rebate amount reported to CMS be reconciled with the accounts receivable records. The State agency agreed with our finding and recommendation.

The current review of Louisiana 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 Louisiana 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 recommendation from our prior audit related to reconciling the outstanding balance reported on the Form CMS-64.9R to its accounts receivable records.

The State agency established controls over collecting rebates on single source drugs administered by physicians. Therefore, we do not offer any recommendations.

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 Louisiana, the Department of Health and Hospitals (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 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.

In Louisiana, physician-administered drugs are billed to the State Medicaid program on a physician claim form using procedure codes that are part of the Healthcare Common Procedure Coding System. The NDC is not included on the physician claim form. The procedure code identifies a drug by its active ingredient(s) and identifies the number of drug units (billing units) allowed per reimbursement for that procedure code. Because rebates are calculated and paid based on NDCs, each procedure code must be converted to an NDC. Additionally, the billing units for a procedure code may differ from the units used for rebate purposes (e.g., grams versus liters). Therefore, to determine rebates, the procedure codes must be converted into NDCs for single source drugs, and procedure code billing units must be converted into equivalent NDC billing units.

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 Louisiana drug rebate program, we determined that the State agency had adequate controls over its drug rebate program, with one exception: It did not reconcile the outstanding drug rebate balance reported to CMS to its accounts receivable records.[3] We recommended that the State agency implement a control requiring that the outstanding rebate amount reported to CMS be reconciled with the accounts receivable records. The State agency agreed with our finding and recommendation.

Louisiana Drug Rebate Program

The State agency contracts with the University of New Orleans (UNO) to perform all drug rebate program functions other than receiving rebate funds and preparing Form CMS-64. The State agency reported an outstanding drug rebate balance of $45,467,115 on the June 30, 2006, Form CMS-64.9R. However, $41,381,268 of this amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining $4,085,847 that was past due, $3,467,826 was more than 1 year old. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately $249.2 million and collections of $260.5 million.

The current review of the Louisiana 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

[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]"Review of Medicaid Drug Rebate Collections–State of Louisiana" (A-06-03-00011), issued April 7, 2003.

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 recommendation made in our previous audit of the Louisiana 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 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 at the State agency in Baton Rouge, Louisiana, from January through July 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 State agency's drug rebate accounts receivable system;

- interviewed State agency officials and UNO 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 UNO 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 performed our audit in accordance with generally accepted government auditing standards.

FINDINGS

The State agency implemented the recommendation from our prior audit related to reconciling the outstanding balance reported on the Form CMS-64.9R to its accounts receivable records. 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 RECOMMENDATION

In our prior audit of the Louisiana drug rebate program, we determined that the State agency had not reconciled the outstanding drug rebate balance reported to CMS to its accounts receivable records. Since our prior audit, the State agency has implemented a procedure to reconcile the drug rebate data reported to CMS to its accounts receivable records. It also has maintained detailed records that supported the amounts of the rebates invoiced and collected and the outstanding balance that was reported on the June 30, 2006, CMS Form-64.9R.

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 $1,983,648 in claims for physician-administered drugs during the January through June 2006 time period and billed manufacturers for rebates totaling $1,871,560.

CIN: A-06-07-00067

REPORT DISTRIBUTION SCHEDULE

HHS ACTION OFFICIAL	**No. of Copies**
Jackie Gardner Consortium Administrator Consortium for Medicaid and Children's Health Operations Centers for Medicare & Medicaid Services cms rochiora@cms.hhs.gov	2

HHS AUDIT LIAISON	
Wynethea Walker Director, Division of Audit Liaison Centers for Medicare & Medicaid Services U.S. Department of Health and Human Services Room C5-15-12 7500 Security Boulevard Baltimore, Maryland 21244-1850 CMS KC_OIG_Audit@CMS.HHS.GOV	2

AUDITEE	
Mr. Jerry Phillips Medicaid Director Louisiana Department of Health and Hospitals 628 North 4th Street Seventh Floor Baton Rouge, LA 70802	2

OFFICE OF AUDIT SERVICES	
Director, Audit Planning and Implementation	1
Centers for Medicare & Medicaid Services Audits	1
Regional Office	2
Little Rock Field Office	2

POSTED ON THE WEB? Yes