DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF AUDIT SERVICES
233 NORTH MICHIGAN AVENUE
CHICAGO, ILLINOIS 60601

REGION V
OFFICE OF
INSPECTOR GENERAL

July 29, 2008

Report Number: A-05-08-00011

Mr. Barry Maram
Director
Illinois Department of Healthcare and Family Services
201 South Grand Avenue East
Springfield, Illinois 62763

Dear Mr. Maram:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled "Review of the Medicaid Drug Rebate Program in Illinois." 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 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, this report will be posted on the Internet at http://oig.hhs.gov.

If you have any questions or comments about this report, please contact Lynn Barker, Audit Manager, at (317) 226-7833 extension 21 or through e-mail at Lynn.Barker@oig.hhs.gov. Please refer to report number A-05-08-00011 in all correspondence.

Sincerely,

Marc Gustafson
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

cc:
Ms. Peggy Edwards
Healthcare and Family Services
Office of Planning
201 South Grand Avenue East, 3rd Floor
Springfield, IL 62763

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF THE MEDICAID DRUG REBATE PROGRAM IN ILLINOIS

Daniel R. Levinson
Inspector General

July 2008
A-05-08-00011

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:

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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.

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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.

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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
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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 Illinois, the Department of Healthcare and Family 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 Illinois and three other States had no weaknesses in accountability for and internal controls over their drug rebate programs. As a result of the weaknesses, we concluded that most 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.

The current review of Illinois's 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.

In our previous audit of the Illinois drug rebate program, we determined that the State agency had adequate controls over its drug rebate program (A-05-03-00044). Therefore, the nationwide objective to determine whether the States have addressed prior findings is not a part of our current review.

OBJECTIVE

Our objective was to determine whether the State agency had established controls over collecting rebates on single source drugs administered by physicians.

SUMMARY OF FINDING

The State agency did not collect rebates on single source drugs administered by physicians or establish controls over and accountability for their collection. The State agency stated that it experienced problems with the billing information provided by its drug rebate contractors, and it planned to bill for rebates, totaling $308,030, for the first quarter of 2006 in June 2008, and subsequent quarters thereafter.

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 drug rebates can be obtained and

- collect rebates totaling $308,030 for the first quarter of 2006, and bill for and collect rebates for subsequent periods for single source drugs administered by physicians.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency agreed with our finding and recommendations. The State agency 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 Illinois, the Department of Healthcare and Family 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 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) amended section 1927 of the Act and required 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 expanded the requirement to certain multiple source drugs administered by physicians after January 1, 2008.

In Illinois, 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.

Illinois Drug Rebate Program

The State agency contracted with Affiliated Computer Services, Inc. (ACS) and Public Consulting Group (PCG) to convert the procedure code billing units to equivalent NDC billing units. ACS is responsible for developing the crosswalks and the conversion factors for claims through 2007. PCG is responsible for approving the crosswalks. The State agency is responsible for all other drug rebate accounts receivable functions.

The State agency reported an outstanding drug rebate balance of $68,024,775 on the June 30, 2006, Form CMS-64.9R. However, $49,009,103 of this amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining $19,015,672 that was past due, $13,932,767 was more than one year old. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately $568.3 million and collections of $633.9 million.

The current review of the Illinois 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.

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 Illinois and three other States had no weaknesses in accountability for and internal controls over their drug rebate programs. As a result of the weaknesses, we concluded that most 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.

[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.

In our previous audit of the Illinois drug rebate program, we determined that the State agency had adequate controls over its Medicaid drug rebate program.[3] Therefore, the nationwide objective to determine whether the States have addressed prior findings is not a part of our current review.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether the State agency had 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 in Springfield, Illinois.

Methodology

To accomplish our objective, 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 drug rebate accounts receivable system;

- interviewed State agency officials to determine the policies, procedures, and controls that related to the Medicaid drug rebate programs;

- reviewed the State agency's accounts receivable records as of June 30, 2006 and copies of Form CMS-64.9R;

- interviewed State agency officials to determine the processes used in converting physician service claims data into drug rebate data related to future billings of single source drugs administered by physicians; and

- traced the State's invoiced amounts for drug rebates to supporting records for the period January 1 through June 30, 2006.

[3] "Review of Medicaid Drug Rebate Program State of Illinois" (A-05-03-00044), issued June 24, 2003.

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 objective.

FINDING AND RECOMMENDATIONS

The State agency did not collect rebates on single source drugs administered by physicians or establish controls over and accountability for their collection.

Section 6002(a) of the Deficit Reduction Act of 2005 amended section 1927 of the Act and required 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.

The State agency paid $12,596,576 for single source, physician-administered drugs during the January through June 2006 time period. However, the State agency did not collect rebates on single source drugs administered by physicians or establish controls over and accountability for their collection. On November 1, 2005**,** the State contracted with ACS and PCG to determine the amount of past rebates due for physician-administered single source drugs. The State agency stated that it experienced problems with the billing information provided by its drug rebate contractors, and it planned to bill for rebates, totaling $308,030, for the first quarter of 2006 in June 2008, and subsequent quarters thereafter.

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 drug rebates can be obtained and

- collect rebates totaling $308,030 for the first quarter of 2006, and bill for and collect rebates for subsequent periods for single source drugs administered by physicians.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency agreed with our finding and recommendations. The State agency comments are included in their entirety as the Appendix.

APPENDIX

ILLINOIS DEPARTMENT OF
Healthcare and
Family Services

Rod R. Blagojevich, Governor
Barry S. Maram, Director

201 South Grand Avenue East
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July 15, 2008

Department of Health and Human Services
Office of Audit Services
Attn: Marc Gustafson, Regional Inspector General for Audit Services
233 North Michigan Avenue, Suite 1360
Chicago, Illinois 60601-5502

Re: Draft Audit Report No. A-05-08-00011

Dear Mr. Gustafson:

Thank you for providing an opportunity to comment on your draft audit report entitled "Review of the Medicaid Drug Rebate Program in Illinois." We appreciate the work performed by the Office of Inspector General auditors, especially the opportunity to meet and review with the auditors the individual findings.

The Agency concurs with the findings and has taken the following steps to resolve the findings.

The Agency is in the process of developing policies and procedures for use in obtaining drug rebates for single source drugs administered by physicians.

In addition, the Agency set up a schedule for contractor and Agency use to ensure expectations and timeframes were followed. At this time we have now received and approved the crosswalks supplied by Affiliated Computer Services, Inc. (ACS) for calendar years 2006 and 2007.

The Agency has also received from ACS, the claims files for the single source drugs for all of 2006. The Agency has processed these files through our test billing system to validate the unit conversion process against the results received from a PC based testing process. The files for the first two quarters of 2006 have completed these steps and have been processed through our production billing system. The first quarter was processed June 30, 2008, which met the deadline, and the second quarter was processed July 2, 2008. For these quarters we are billing $308,030 and $1,074,360 respectively. We are scheduled to bill the two remaining quarters of 2006 by 7/21/2008 and are scheduled to bill all four quarters of 2007 in October 2008.

If you have any questions or comments about our response to the audit, please contact Peggy Edwards, External Audit Liaison, at (217) 785-9764 or through e-mail at Peggy.Edwards@illinois.gov.

Sincerely,

Barry S. Maram

Barry S. Maram
Director