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

REGION V
OFFICE OF
INSPECTOR GENERAL

April 14, 2008

Report Number: A-05-08-00010

Mr. Cal Ludeman
Commissioner
Department of Human Services
PO Box 64998
St. Paul, Minnesota 55164-0998

Dear Mr. Ludeman:

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 Minnesota." 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-05-08-00010 in all correspondence.

Sincerely,

Marc Gustafson
Regional Inspector General
for Audit Services

Enclosure

HHS Action Official:

Ms. 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

REVIEW OF THE MEDICAID DRUG REBATE PROGRAM IN MINNESOTA

Daniel R. Levinson
Inspector General

April 2008
A-05-08-00010

Office of Inspector General

http://oig.hhs.gov

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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 Minnesota, 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 Minnesota 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 Minnesota'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 Minnesota drug rebate program, we determined that the State agency had adequate controls over its drug rebate program (A-05-03-00045). Therefore, the nationwide objective to determine whether the states have addressed prior findings is irrelevant to and 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.

RESULTS OF REVIEW

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

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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 Minnesota, 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, its 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 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 expanded the requirement to certain multiple source drugs administered by physicians after January 1, 2008.

In Minnesota, 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.

Minnesota Drug Rebate Program

The State agency performs all drug rebate program functions with one exception. The State agency contracts with First Health Services Corporation to support the development of the Preferred Drug List, generate and forward supplemental rebate invoices, conduct dispute resolution, and update and maintain a labeler accounts receivable file.

The State agency's accounting records showed an outstanding drug rebate balance of $21,153,637[2] as of June 30, 2006. However, $16,951,897 of this amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining $4,201,740 that was past due, $1,551,396 was more than 1 year old. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately $123.1 million and collections of $139.5 million.

The current review of the Minnesota 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.[3] Those audits found that only Minnesota 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.

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[2]The outstanding drug rebate balance reported on the Form CMS-64.9R was negative $10,210,990. The understatement of approximately $31.4 million was due to data entry errors and the State agency not implementing procedures to reconcile the reported accounts receivable balance to supporting records. We will issue a separate report (A-05-08-00058) to the State agency regarding this matter.

[3]"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.

Additionally, CMS did not have reliable information from the States to properly monitor the drug rebate program.

In our previous audit of the Minnesota drug rebate program, we determined that the State agency had adequate controls over its drug rebate program.[4] Therefore, the nationwide objective to determine whether the states have addressed prior findings is irrelevant to and 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 St. Paul, Minnesota, from October 2007 through January 2008.

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 State agency's drug rebate accounts receivable system;

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

- reviewed the State agency's accounting records and copies of Form CMS-64.9R for the period July 1, 2005, through June 30, 2006;

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

[4] "Review of Medicaid Drug Rebate Program State of Minnesota" (A-05-03-00045), issued July 7, 2003.

- 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 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.

RESULTS OF REVIEW

The State agency established controls over collecting rebates for single source drugs administered by physicians as required by the DRA. The State agency paid $7,636,105 in claims for physician-administered drugs during the January through June 2006 time period and billed manufacturers $1,871,208 for rebates. Therefore, we do not offer any recommendations.