



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General
Office of Audit Services

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REGION IV
61 Forsyth Street, S.W., Suite 3T41
Atlanta, Georgia 30303

Report Number: A-04-07-07026

Mr. Darin Gordon
Deputy Commissioner
Bureau of TennCare
310 Great Circle Road
Nashville, Tennessee 37243

Dear Mr. Pierce:

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 Tennessee." 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-04-07-07026 in all correspondence.

Sincerely,

A handwritten signature in cursive script that reads "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

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cc:

Mr. Scott Pierce

Chief Financial Officer

Bureau of TennCare

310 Great Circle Road

Nashville, Tennessee 37243

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**FOLLOW-UP AUDIT OF THE
MEDICAID DRUG REBATE
PROGRAM IN TENNESSEE**



Daniel R. Levinson
Inspector General

May 2008
A-04-07-07026

Office of Inspector General

<http://oig.hhs.gov>

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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 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 Tennessee, the Bureau of TennCare (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 Tennessee drug rebate program, we determined that the State agency had adequate controls over its drug rebate program, with one exception: reported amounts to CMS did not agree with amounts supported by accounting records (A-04-03-06012). We recommended that the State agency verify all amounts reported on the CMS 64.9R to ensure that those amounts tie directly back to the amounts recorded in the accounting records. The State agency agreed with our findings and recommendation.

This current review of Tennessee 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 Tennessee 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 previous audit that related to the verification of all amounts reported on the Form CMS-64.9R to ensure that those amounts tie directly back to the amounts recorded in the accounting records. The State agency established controls over 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 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) administer 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 quarterly rebates to the States. CMS, the States, and drug manufacturers each undertake certain functions in connection with the drug rebate program. In Tennessee, the Bureau of TennCare (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 of 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.

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

In Tennessee, 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 usually 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 claim with only a 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.

Previous 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 Tennessee drug rebate program (A-04-03-06012), we determined that the State agency had adequate controls over its drug rebate program, with one exception: reported amounts to CMS did not agree with amounts supported by accounting records.³ We recommended that the State agency verify all amounts reported on the Form CMS-64.9R to ensure that those amounts tie directly back to the amounts recorded in the accounting records.⁴ The State agency agreed with our findings and recommendation.

Tennessee Drug Rebate Program

The State agency contracts with its fiscal agent, Electronic Data Systems, to perform a portion of the drug rebate program functions. The fiscal agent's responsibilities included generating drug rebate invoices and mailing them to manufacturers for all drug rebates, and accounting for rebates on single source drugs administered by physicians. The fiscal agent also enters check detail information into the State's accounting system.

The State agency reported an outstanding drug rebate balance of \$73,064,036 on the June 30, 2006, Form CMS-64.9R. However, \$41,383,701 of this amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining \$31,680,335 that was past due, \$28,056,617 was more than 1 year old. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately \$455.3 million and collections of \$611 million.

²Multistate 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 Medicaid Drug Rebate Program in the State of Tennessee" (A-04-03-06012), issued August 15, 2003.

⁴Verification here means that accounting records fully supported and tie to the amount as reported on the CMS 64.9R.

This current review of the Tennessee 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 Tennessee 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 conducted our fieldwork from August through November 2007 by working with the State agency located in Nashville, Tennessee.

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 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 supporting CMS-64.9R for the period July 1, 2005, through June 30, 2006;

- interviewed State agency's 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 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 previous audit that related to the verification of all amounts reported on the CMS 64.9R to ensure that those amounts are reflected in the accounting 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 PREVIOUS RECOMMENDATIONS

In our previous audit of the Tennessee drug rebate program, we determined that the State agency did not have sufficient control and accountability over its reporting of drug rebate activities. We found the amounts reported to CMS did not agree with the amounts supported by the accounting records.

Since our previous audit, the State agency has (1) corrected the accounts receivable balance on the Form CMS-64.9R and (2) ensured the reports submitted to CMS agreed to the accounting records.

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 \$42,928,193 in claims for physician-administered drugs during the January through June 2006 period and billed manufacturers for rebates totaling \$2,045,170.