



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-04-07-07028

William Lawrence, MD, Acting Director
North Carolina Division of Medical Assistance
2501 Mail Service Center
Raleigh, North Carolina 27699-2501

Dear Dr. Lawrence:

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 North Carolina." 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, 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-04-07-07028 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
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 REVIEW OF THE
MEDICAID DRUG REBATE
PROGRAM IN NORTH CAROLINA**



Daniel R. Levinson
Inspector General

June 2008
A-04-07-07028

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 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 North Carolina, the Division of Medical Assistance (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, including North Carolina, 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.

This current review of North Carolina 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. Since North Carolina did not have any weaknesses in accountability for and internal controls over their drug rebate programs in the previous review, this review is limited to single source drugs administered by physicians.

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 FINDINGS

The State agency had 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 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 North Carolina, the Division of Medical Assistance (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.

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

In North Carolina, physician-administered drugs are billed to the State Medicaid program on the professional claim form (CMS-1500) using procedure codes that are part of the Healthcare Common Procedure Coding System. Some physician-administered drugs are billed to the State Medicaid program on the institutional claim form (UB-92) using procedure codes that are part of the Healthcare Common Procedure Coding System. The NDC is not included on either one of the claim forms. 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 via a crosswalk, 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, including North Carolina,³ 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.

North Carolina Drug Rebate Program

The State agency contracts with its fiscal agent, Electronic Data Systems, to perform all drug rebate program functions including the accounting for rebates on single source drugs administered by physicians. The fiscal agent also converted the procedure code billing units into equivalent NDC billing units.

The State agency reported an outstanding drug rebate credit balance of (\$64,749,512) on the June 30, 2006, Form CMS-64.9R. Of this amount, \$40,548,055 related to quarterly billings and was not past due as of June 30, 2006. The past due amount was a credit balance of (\$105,297,567). However, of the past due amount, \$2,858,546 was more than 1 year old.⁴ The following table is an excerpt from the State agency's Form CMS 64.9R for the Quarter Ending June 30, 2006.

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 Medicaid Drug Rebate Program in the State of North Carolina" (A-04-03-06009), issued May 22, 2003.

⁴Due to a previous reporting error, the balances for columns B and F [(\$109,479,626) and (\$64,749,512)] on the Form CMS-64.9R were reported incorrectly. These errors did not impact our review and are disclosed for informational purposes only. The State agency reported an adjustment to correct these errors on the Form CMS 64.9R for the Quarter Ended September 30, 2007.

Drug Rebate	Quarter Ending 06/30/2006 (A)	Quarter Ending 03/31/2006 (B)	Quarter Ending 12/31/2005 (C)	Quarter Ending 09/30/2005 (D)	Quarter Ending 06/30/2005 and Prior (E)	Total (F)
Balance	40,548,055	(109,479,626)	729,346	594,167	2,858,546	(64,749,512)

For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately \$76.7 million and collections of \$122.8 million.

This current review of the North Carolina 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.

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 and its fiscal agent, both of which are located in Raleigh, North Carolina in July 2007.

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 fiscal agent's drug rebate accounts receivable system;
- interviewed State agency officials and fiscal agent 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 fiscal agent 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 objective.

RESULTS OF AUDIT

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

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 \$10,922,428 in claims for physician-administered drugs during the January through June 2006 period and billed manufacturers for rebates totaling \$5,216,672.