DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General
Office of Audit Services

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

MAY 22 2003

Report Number: A-04-03-06009

Ms. Nina M. Yeager, Director
North Carolina Division of Medical Assistance
2517 Mail Service Center
Raleigh, North Carolina 27699-2517

Dear Ms. Yeager:

Enclosed are two copies of our final report providing the results of our ***Audit of the Medicaid Drug Rebate Program in the State of North Carolina.*** Our audit covered a 1-year period ending June 30, 2002. A copy of this report will be forwarded to the Department of Health and Human Services (HHS) action official noted below for review and any action deemed necessary.

In written comments, the North Carolina Division of Medical Assistance (DMA) concurred with our assessment. The DMA comments are included as an appendix to our report.

Final determination as to actions taken on all matters reported will be made by the HHS action official. We request that you respond to the HHS action 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. If you have any questions, please contact me or your staff may call Mary Ann Moreno, Audit Manager, at (305) 536-5309, extension 24 or e-mail at mmoreno@oig.hhs.gov.

To facilitate identification, please refer to report number A-04-03-06009 in all correspondence relating to this report.

Sincerely,

John J. Drake Jr. /for

Charles J. Curtis
Regional Inspector General
for Audit Services, Region IV

Enclosures – as stated

HHS Action Official

Associate Regional Administrator
Centers for Medicare and Medicaid Services
Division of Financial Management and Program Initiatives
61 Forsyth Street, S.W., Suite 4T20
Atlanta, Georgia 30303

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN THE STATE OF NORTH CAROLINA

JANET REHNQUIST
Inspector General

MAY 2003
A-04-03-06009

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OAS FINDINGS AND OPINIONS

The designation of financial or management practices as questionable or a recommendation for the disallowance of costs incurred or claimed as well as other conclusions and recommendations in this report represent the findings and opinions of the HHS/OIG/OAS. Authorized officials of the awarding agency will make final determination on these matters.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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61 Forsyth Street, S.W., Suite 3T41
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May 22, 2003

Report Number: A-04-03-06009

Ms. Nina M. Yeager, Director
North Carolina Division of Medical Assistance
2517 Mail Service Center
Raleigh, North Carolina 27699-2517

Dear Ms. Yeager:

This final report provides you with the results of an Office of Inspector General, Office of Audit Services' review entitled, ***Audit of the Medicaid Drug Rebate Program in the State of North Carolina***.

EXECUTIVE SUMMARY

The objective of our review was to evaluate whether the North Carolina Division of Medical Assistance (DMA) had established adequate accountability and internal controls over the Medicaid drug rebate program. Our audit covered Medicaid drug rebates through June 30, 2002.

We found that the North Carolina DMA appeared to have adequate accounting procedures and internal controls with regard to the Medicaid drug rebate program, as required by federal regulations. The DMA reported to the Centers for Medicare and Medicaid Services (CMS) approximately $18.6 million in uncollected drug rebates as of June 30, 2002, but only about $3.9 million were rebates outstanding over 90 days. We found that DMA, through its contractor Electronic Data System (EDS), actively pursued drug rebate collections and the resolution of disputes. Because of the nature of our findings, we are not addressing recommendations to the DMA in this report. In written comments, the DMA agreed with our findings. The DMA comments are enclosed in their entirety as an Appendix to this report.

INTRODUCTION

BACKGROUND

On November 5, 1990, Congress enacted the Omnibus Budget Reconciliation Act of 1990, which among other provisions established the Medicaid drug rebate program. Responsibility for the rebate program is shared among the drug manufacturer(s), CMS, and the state(s). The legislation was effective January 1, 1991. The CMS also issued release memorandums to state agencies and manufacturers to give guidance on numerous issues related to the Medicaid drug rebate program.

A drug manufacturer is required to enter into, and have in effect, a rebate agreement with CMS in order to have its products covered under the Medicaid program. After a rebate agreement is signed, the manufacturer is required to submit a listing to CMS of all covered outpatient drugs, and to report its average manufacturer price and best price information for each covered outpatient drug to CMS. Approximately 520 pharmaceutical companies participate in the program.

The CMS provides the unit rebate amount (URA) information to the state agency on a quarterly computer tape. However, the CMS tape may contain a $0 URA if the pricing information was not provided timely, or if the pricing information has a 50 percent variance from the previous quarter. In instances of $0 URAs, the state agency is instructed to invoice the units and the manufacturer should pay the rebate based on the manufacturer's information. In addition, the manufacturers often change the URA, based on updated pricing information, and submit this information to the state agency in the Prior Quarter Adjustment Statement (PQAS).

Each state agency is required to maintain the number of units dispensed, by manufacturer, for each covered drug. Approximately 56,000 National Drug Codes (NDC) are available under the program. Each state agency multiplies the URA by the drug utilization for each drug to determine the actual rebate amounts due from the manufacturer. The CMS requires each state agency to provide drug utilization data to the manufacturer.

The manufacturer has 38 days from the day a state agency sends an invoice to pay the rebate. The manufacturer submits to the state agency, by NDC, a Reconciliation of State Invoice (ROSI) that details the current quarter's payment. A manufacturer can dispute utilization data that it believes is erroneous, but the manufacturer is required to pay the undisputed portion by the due date. If the manufacturer and the state agency cannot in good faith resolve the discrepancy, the manufacturer must provide written notification to the state agency by the due date. If the state agency and the manufacturer are not able to resolve the discrepancy within 60 days, the state agency must make a hearing mechanism available to the manufacturer under the Medicaid program, in order to resolve the dispute.

Each state agency reports, on a quarterly basis, outpatient drug expenditures and rebate collections on the Form CMS 64.9R. This report is part of the Form CMS 64 report, which summarizes actual Medicaid expenditures for each quarter and is used by CMS to reimburse the federal share of these expenditures.

The DMA administers the Medicaid program in the State of North Carolina. The DMA reported to CMS approximately $81.6 million in Medicaid drug rebates from drug manufacturers during the 1-year period ending June 30, 2002. The DMA also reported uncollected drug rebates of $18,680,825 as of June 30, 2002, but only $3,887,146 of the uncollected receivables were outstanding over 90 days.

The DMA contracts with its Medicaid fiscal intermediary, EDS, to perform the daily operations of the drug rebate program, including billings, collections, accounting, and dispute resolutions. Employees in other departments of the State Controller's Office separately perform the functions of transferring funds, posting payments to the general ledger, and preparing the Form CMS 64 reports.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The objective of our audit was to evaluate whether the DMA had established adequate accountability and internal controls over the Medicaid drug rebate program.

Scope

Our audit was performed in accordance with generally accepted government auditing standards. We reviewed DMA and EDS' policies, procedures, and controls with regard to manufacturer's drug rebates for the period ending June 30, 2002. Our review of internal controls was limited to the controls concerning drug rebate billings, collections, and dispute resolutions. This was accomplished through interviews and testing pertaining exclusively to the drug rebate program. We limited the scope of our review of internal controls because our audit objectives did not require a full assessment or understanding of the DMA and EDS internal control structure.

Methodology

To accomplish our audit objectives, we obtained the state's Medicaid Drug Rebate Schedule (Form CMS 64.9R) for the 1-year period ending June 30, 2002 and reviewed supporting documentation to assess the reliability of the outpatient drug rebates information reported to CMS. We reviewed accounts receivable and subsidiary records and compared the information with the data presented in the Form CMS 64.9R report. We interviewed DMA, EDS, and the State Controllers' Office staff who performed functions related to the drug rebate program to determine existing policies, procedures, and controls as of June 30, 2002.

Fieldwork was performed at the DMA, EDS, and the State Controller's Offices in Raleigh, North Carolina and at our field office in Miami, Florida from January through March 2003.

FINDINGS AND RECOMMENDATIONS

The North Carolina DMA, through its contractor EDS, appeared to have adequate accounting procedure and internal controls with regard to the Medicaid drug rebate program.

We found that EDS maintains sufficient detailed collection and subsidiary accounts receivable records to effectively pursue outstanding receivables from drug manufacturers. Billing, collection, and accounting responsibilities are properly segregated and there were adequate

internal controls in place to ensure that manufacturers are billed each quarter, that the bills are maintained as a basis for collections, and that rebates and interest due for late rebate payments are timely recorded and reconciled with accounting records. We determined that subsidiary records, at the manufacturers' level, included reconciliation of payments with the ROSI and the PQAS and that the information was recorded at the NDC levels. Also, invoices to manufacturers included the drug utilization units for $0 URAs and interest on late payments, which were verified and recorded upon receipt.

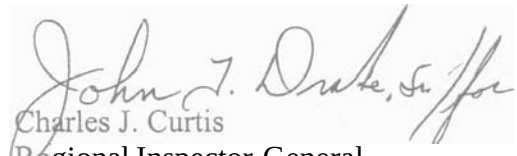
As a result, it appears that the DMA, through EDS, is able to actively pursue outstanding receivables from drug manufacturers. On their Form CMS 64.9R, as of June 30,2002, the DMA reported to CMS approximately $81.6 million in Medicaid drug rebates from drug manufacturers and $18.6 million in uncollected rebates. However, of the $18.6 million uncollected rebates, only about $3.9 million were rebates outstanding over 90 days.

We discussed our results with DMA and EDS officials who indicated that CMS has no time limitations for URA adjustments based on manufacturers' updated pricing data. The manufacturers frequently request refunds on their rebates as far back as 1991. In their opinion, it is in the manufacturers' best interest to devote considerable resources to URA adjustments. Although the state strives to research and resolve the manufacturers' disputes timely, their staff and resources are limited. As a result, they carry forward millions of dollars in rebates outstanding over 90 days. Also, the state's budgetary constraints preclude them from participating in the national dispute resolution conferences organized by CMS.

RECOMMENDATION

Because of the nature of our findings, we are not addressing recommendations to the state.

Sincerely,



Charles J. Curtis
Regional Inspector General
for Audit Services, Region IV

Enclosure

APPENDIX

North Carolina Department of Health and Human Services
2001 Mail Service Center • Raleigh, North Carolina 27699-2001
Tel 919-733-4534 • Fax 919-715-4645

Michael F. Easley, Governor

Carmen Hooker Odom, Secretary

May 14, 2003

Transmit via fax:
404-562-7795

Reference: A-04-03-06009

Mr. Charles J. Curtis
Regional Inspector General for Audit Services, Region IV
Room 3T41, Atlanta Federal Center
61 Forsyth Street, S.W.
Atlanta, Georgia 30303-8909

Dear Mr. Curtis:

The North Carolina Department of Health and Human Services is in receipt of your March 28, 2003 letter regarding the draft audit report entitled, *Audit of the Medicaid Drug Rebate Program in the State of North Carolina*. DHHS appreciates the opportunity to review and comment on this report.

We are pleased that the OIG audit found sufficient accounting, billing and collection procedures as well as adequate internal controls for the North Carolina Medicaid drug rebate program. DHHS and DMA have worked diligently with our Medicaid fiscal agent – Electronic Data Systems (EDS) – to establish an accurate and reliable rebate system.

While we are pleased with the N.C. Drug Rebate Program, DHHS looks forward to the publishing of other State audits on their respective rebate programs. More specifically, we are interested in finding "best practices" from the other states to determine if other practices exist that would further improve North Carolina's drug rebate system.

Again, thank you for this opportunity to comment on the draft report. If you should have any further questions regarding our drug rebate program, please contact Debbie Barnes or Kyle Fay of the Division of Medical Assistance at (919) 857-4015.

Sincerely,

Carmen Hooker Odom

Carmen Hooker Odom

CHO:ds

cc: Lanier Cansler, Gary Fuquay, Dan Stewart, Nina Yeager, Gé Brogden, Allyn Guffey, Honorable Ralph Campbell

ACKNOWLEDGMENTS

This report was prepared under the direction of Charles J. Curtis, Regional Inspector General for Audit Services, Region IV. Other principal Office of Audit Services staff who contributed include:

Mary Ann Moreno, *Audit Manager*
Lourdes Puntonet, *Senior Auditor*
Lynn Stevens, *Auditor*

For information or copies of this report, please contact the Office of Inspector General's Public Affairs office at (202) 619-1343.