DEPARTMENT OF HEALTH & HUMAN SERVICES REGION III

Memorandum

Date MAY 8 2003

From Regional Inspector General for Audit Services

Subject Audit Report – REVIEW OF THE STATE OF MARYLAND'S MEDICAID DRUG REBATE PROGRAM (Report Number A-03-03-00204)

To Sonia A. Madison
Regional Administrator
Centers for Medicare and Medicaid Services

Attached are two copies of the U. S. Department of Health and Human Services (HHS), Office of Inspector General, Office of Audit Services' (OAS) report entitled "Review of the State of Maryland's Medicaid Drug Rebate Program." This review was self-initiated and the audit objective was to evaluate whether Maryland's Department of Health and Mental Hygiene had established adequate accountability and internal controls over the Medicaid drug rebate program. Should you have any questions or comments concerning the matters commented on in this report, please contact me or have your staff contact Eugene Berti, Audit Manager at 215-861-4474.

To facilitate identification, please refer to Report Number A-03-03-00204 in all correspondence relating to this report.

Stephen Virbitsky

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
OFFICE OF AUDIT SERVICES
150 S. INDEPENDENCE MALL WEST
SUITE 316
PHILADELPHIA, PENNSYLVANIA 19106-3499

MAY 8 2003

Report Number: A-03-03-00204

Nelson J. Sabatini, Secretary
Department of Health and Mental Hygiene
Executive Suite, 5th Floor
201 West Preston Street
Baltimore, Maryland 21201-2399

Dear Mr. Sabatini:

Enclosed are two copies of the U.S. Department of Health and Human Services (HHS), Office of Inspector General, Office of Audit Services' report entitled "Review of the State of Maryland's Medicaid Drug Rebate Program." This review was self-initiated and the audit objective was to evaluate whether Maryland's Department of Health and Mental Hygiene had established adequate accountability and internal controls over the Medicaid drug rebate program. Should you have any questions or comments concerning the matters commented on in this report, please direct them to the HHS official named below.

In accordance with the principles of the Freedom of Information Act, 5 U.S.C. 552, as amended by Public Law 104-231, Office of Inspector General, Office of Audit Services reports issued to the Department's grantees and contractors are made available to members of the press and general public to the extent information contained therein is not subject to exemptions in the Act which the Department chooses to exercise (see 45 CFR Part 5).

To facilitate identification, please refer to Report Number A-03-03-00204 in all correspondence relating to this report.

Sincerely yours,

Stephen Virbitsky
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:
Ms. Sonia Madison
Regional Administrator
Centers for Medicare and Medicaid Services, Region III
Public Ledger Building, Suite 216
150 S. Independence Mall West
Philadelphia, PA 19106-3499

Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

REVIEW OF THE STATE OF MARYLAND'S MEDICAID DRUG REBATE PROGRAM

JANET REHNQUIST
Inspector General

MAY 2003
A-03-03-00204

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:

Office of Audit Services

The OIG's Office of Audit Services (OAS) provides all 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 in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout the department.

Office of Evaluation and Inspections

The OIG's Office of Evaluation and Inspections (OEI) conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the department, the Congress, and the public. The findings and recommendations contained in the inspections reports generate rapid, accurate, and up-to-date information on the efficiency, vulnerability, and effectiveness of departmental programs.

Office of Investigations

The OIG's Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil monetary penalties. The OI also oversees state Medicaid fraud control units, which investigate and prosecute fraud and patient abuse in the Medicaid program.

Office of Counsel to the Inspector General

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 in OIG's internal operations. The OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within the department. The OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops model compliance plans, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at http://oig.hhs.gov

In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), Office of Inspector General, Office of Audit Services reports are made available to members of the public to the extent the information is not subject to exemptions in the act. (See 45 CFR Part 5.)

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 HHS divisions will make final determination on these matters.

DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
OFFICE OF AUDIT SERVICES
150 S. INDEPENDENCE MALL WEST
SUITE 316
PHILADELPHIA, PENNSYLVANIA 19106-3499

MAY 8 2003

Nelson J. Sabatini, Secretary
Department of Health and Mental Hygiene
Executive Suite, 5th Floor
201 West Preston Street
Baltimore, Maryland 21201-2399

Dear Mr. Sabatini:

This final report presents the results of the Office of Inspector General, Office of Audit Services REVIEW OF THE STATE OF MARYLAND'S MEDICAID DRUG REBATE PROGRAM.

The audit objective was to evaluate whether the Department of Health and Mental Hygiene (DHMH) had established adequate accountability and internal controls over the Medicaid drug rebate program.

Our review showed that DHMH had established accountability and controls over its Medicaid Drug Rebate program. We have no recommendations to make at this time.

INTRODUCTION

BACKGROUND

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

The DHMH expressed concern that some manufacturers continue to retroactively change the URA on drugs back to the inception of the program in 1991. Currently there is no time limit for these changes. The DHMH recommended that prior period adjustments should be limited to 12 quarters – sufficient time for manufacturers to make adjustments and have CMS approve those adjustments.

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 uses the URA from CMS and the 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 to avoid interest. The manufacturers submit to the state agency a Reconciliation of State Invoice (ROSI) that details the current quarter's payment by NDC. 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 under the Medicaid program to the manufacturer in order to resolve the dispute.

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

For fiscal year 2002, the DHMH reported to CMS an average of $15.7 million in billings per quarter and collections of $14.5 million per quarter. On its subsidiary accounting records, DHMH documented $20.9 million in rebates receivable dating back to the inception of the program in 1991, $4.8 million of which were outstanding more than 12 months.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

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

Scope

The drug rebate program was effective January 1, 1991. We concentrated our review on DHMH policies, procedures and controls as of June 30, 2002. We also reviewed the aging schedule of accounts receivable and interviewed DHMH personnel and the staff of Maryland's fiscal agent, First Health Services Corporation (FHSC), to understand how the Medicaid drug rebate program has operated since 1991.

Methodology

To accomplish our objectives, we interviewed DHMH officials to determine the policies, procedures and controls that existed with regard to the Medicaid drug rebate program. We interviewed DHMH staff members that performed functions related to the drug rebate program and we interviewed the staff of FHSC to determine its role in the process. For invoiced, collected and disputed drug rebates, we reviewed reports generated by FHSC, and by DHMH. We also reviewed the drug rebate sections of DHMH's CMS 64 Medicaid Program Expenditure Report and CMS 64.9R Drug Rebate Schedule for the state fiscal year ended June 30, 2002.

Fieldwork was performed at the DHMH's office in Baltimore, Maryland. The fieldwork was conducted during January 2003 and continued in the Office of Audit Services' Philadelphia regional office through March 2003.

Our audit was performed in accordance with generally accepted government auditing standards.

RESULTS OF AUDIT

Our review showed that DHMH had established adequate accountability and controls over its Medicaid Drug Rebate program. There were no exceptions noted.

In 1995, DHMH hired FHSC to administer its drug rebate program. The FHSC prepared and sent invoices to manufacturers, resolved disputes, and tracked invoices by cumulative and individual manufacturers' balances and by NDC code. Also, FHSC aged outstanding rebate receivables.

The DHMH staff were responsible for collecting rebates and maintaining control totals for aggregate billing. Rebate checks from the manufacturers were mailed directly to

DHMH for deposit. The DHMH completed the CMS 64 report, which included the CMS 64.9R and reconciled it to FHSC's accounting records.

The DHMH and FHSC have implemented several detailed policies and procedures that we believe enhance the control and administration of the drug rebate process. For example, as part of the invoice preparation process, FHSC employees used a detailed checklist that, when completed, ensured that the invoices were properly prepared for mailing.

Also, the DHMH 's Manufacturers' Drug Rebate Program Policies and Procedures Manual provided detailed instructions for payment posting. In addition to describing the task, the manual indicated the frequency each task is to be performed, i.e. weekly, monthly or quarterly.

The FHSC organized the outstanding drug rebate receivables quarterly by manufacturer with detailed information on invoices submitted and remittances received from manufacturers. The records included remittance credits, prior period adjustments, interest payments, and dispute adjustments. By keeping detailed records, DHMH was in a position to effectively and accurately negotiate billing issues with manufacturers.

For drug rebate disputes, DHMH and FHSC had implemented a proactive approach. When a dispute arose, FHSC sent a letter to the manufacturer acknowledging the dispute. The FHSC then sent a second letter to the manufacturer with the information confirming the dispute requesting a response from the manufacturer. Finally, FHSC will open the lines of communication via the phone and start discussing the dispute with the manufacturer.

Conclusion

Based on our review, we believe that DHMH established adequate accountability and internal controls over the Medicaid drug rebate program. We have no recommendations to make at this time.

***** ***** *****

To facilitate identification, please refer to report number A-03-03-00204 in all correspondence relating to this report.

Sincerely yours,

Stephen Virbitsky
Regional Inspector General
for Audit Services

ACKNOWLEDGMENTS

This report was prepared under the direction of Stephen Virbitsky, Regional Inspector General for Audit Services. Other principal Office of Audit Services staff who contributed include:

Eugene Berti, *Audit Manager*
Carolyn Hoffman, *Senior Auditor*
Michael Lieberman, *Auditor*
Linda Millares, *Auditor*
David Mackay, *Auditor*

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