Memorandum

Date  JUL 15 2003

From  Regional Inspector General for Audit Services

Subject  Audit Report – REVIEW OF THE DISTRICT OF COLUMBIA’S MEDICAID DRUG REBATE PROGRAM (Report Number A-03-03-00205)

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's report entitled "Review of the District of Columbia's Medicaid Drug Rebate Program." This review was self-initiated and the audit objective was to evaluate whether the District of Columbia's Medical Assistance Administration 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-03-03-00205 in all correspondence relating to this report.

Attachment
Dear Ms. Tucker:

Enclosed are two copies of the U.S. Department of Health and Human Services (HHS), Office of Inspector General's report entitled "Review of the District of Columbia's Medicaid Drug Rebate Program." This review was self-initiated and the audit objective was to evaluate whether the District of Columbia's Medical Assistance Administration 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's 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-03-03-00205 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
150S. Independence Mall West
Philadelphia, PA 19106-3499
Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

REVIEW OF THE DISTRICT OF COLUMBIA'S MEDICAID DRUG REBATE PROGRAM

JULY 2003
A-03-03-00205
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.
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's 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 HHSIOIG. Authorized officials of the HHS divisions will make final determination on these matters.
Dear Ms. Tucker:

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

The audit objective was to evaluate whether the District of Columbia's (the District) Medical Assistance Administration (MAA) had established adequate accountability and internal controls over the Medicaid drug rebate program.

FINDINGS

Generally, MAA had established adequate accountability and internal controls over the Medicaid drug rebate program using Affiliated Computer Services (ACS), as its fiscal agent. However, we found that the:

- Fiscal Year 2002 CMS 64.9R reports were not accurate and included incomplete data; and
- endorsement stamp used by ACS on drug rebate checks was too generic and did not provide for proper security over the checks.
RECOMMENDATIONS

We recommend that MAA:

- accurately report outstanding rebates receivable and rebates collected, and include rebates invoiced and adjustments on the CMS 64.9R; and

- include on the endorsement stamp either the District's name or the District's bank account number to ensure greater security of drug rebate checks on behalf of the District.

In a written response to the draft report dated July 3, 2003, MAA provided comments to the draft report. Their complete response is included in Appendix A. MAA concurred with our findings and identified actions taken to resolve the findings.

BACKGROUND

On November 5, 1990, Congress enacted The Omnibus Budget Reconciliation Act of 1990 legislation, which among other provisions established the Medicaid drug rebate program. Responsibility for the rebate program is shared among drug manufacturer(s), the Centers for Medicare and Medicaid Services (CMS), and the state(s). The legislation was effective January 1, 1991. 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 the best price for each covered outpatient drug to CMS. Approximately 520 pharmaceutical companies participate in the program.

CMS provides the unit rebate amount (URA) information to the State Agency on a quarterly computer tape. However, 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 variance. 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.

Each State Agency is required to maintain the number of units dispensed, by manufacturer, for each drug covered. 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. 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 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 is required to report, on a quarterly basis, outpatient drug expenditures and rebate collections on Forms CMS 64 Medicaid Program Expenditure Report and CMS 64.9R. 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. MAA reported to CMS average collections of $2.8 million per quarter during the 1-year period ended June 30,2002. MAA reported $4.1 million in outstanding disputes as of June 30,2002. MAA and ACS personnel expressed concerns that some manufacturers continue to change URAs on drugs back to 1991. Currently there is no time limit for these changes. To resolve this issue, MAA and ACS suggest that CMS limit the amount of time a manufacturer can change the URA rates to 12 quarters, or use a 12-month rolling average for the unit rebate amount.

Prior to April 2002, MAA was completely responsible for administering the Medicaid drug rebate program. However, ACS signed a 5-year contract with MAA to handle all aspects of the drug rebate program from billing, collection, reconciliation and dispute resolution from April 1, 2002 forward. MAA also hired First Health Services Corporation (FHSC) to resolve disputes that pre-date the ACS contract.

**OBJECTIVE, SCOPE AND METHODOLOGY**

**Objectives**

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

**Scope**

Although the drug rebate program was established in January 1991, we concentrated our review on the current policies, procedures and controls of MAA as of June 30,2002, except for some procedures that were dated after June 30,2002. This was necessary because prior to MAA contracting with ACS, the drug rebate program was administered by MAA under its own procedures.
In addition to contracting with ACS to administer the drug rebate program, the District contracted with FHSC to resolve all outstanding disputes that pre-date the beginning of the ACS contract. ACS is responsible for resolving disputes occurring during its contract with the District.

We also reviewed the drug rebate sections of MAA’s CMS 64 and CMS 64.9R for the fiscal year ending June 30, 2002. For the accounts receivable and disputed drug rebates, we reviewed various reports (i.e., check, batch total and disputed amounts reports) generated by ACS.

**Methodology**

To accomplish our objectives we:

1. obtained and reviewed criteria for the drug rebate program including Federal regulations and CMS Program Releases,
2. obtained and reviewed MAA’s, ACS and FHSC written procedures and program reports,
3. interviewed MAA and ACS employees to gain an understanding of the program,
4. reviewed step-by-step ACS drug rebate process, including a walk through of the drug rebate billing and collection quarterly cycle,
5. obtained and examined outstanding, uncollected, aged drug rebates for the quarter ending June 30, 2002, and
6. obtained and examined the CMS 64, CMS 64.9R, and supporting documentation for the quarter ending June 30, 2002 as it related to the drug rebate program.

The audit did not require an evaluation of MAA’s entire internal control system. Instead, we evaluated only those controls that relate to MAA’s accumulation of drug rebate billing and collection procedures and the reporting of drug rebate payments to CMS.

Fieldwork was performed at MAA’s offices in Washington, D.C. The fieldwork was conducted during February 2003 and continued in the Office of Audit Services’ Philadelphia regional office through April 2003.

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

Generally, MAA had established adequate accountability and internal controls over the Medicaid drug rebate program. However, we found that the (1) Fiscal Year 2002 CMS 64.9R reports were not accurate and included incomplete data; and (2) the endorsement stamp used by ACS on drug rebate checks was too generic and did not provide for proper security over the checks.

MAA'S DRUG REBATE PROGRAM

Since April 1, 2002, MAA has used a fiscal agent, ACS to administer its drug rebate program. ACS performs the billing, collections, account reconciliation, and dispute resolution functions. ACS reports rebate collection to MAA on a daily basis. MAA deposits the rebate checks daily and reports quarterly to CMS. In our opinion, ACS had adequate billing, account receivables and dispute resolution controls in place.

MAA's CMS 64.9R Report Contained Inaccurate and Incomplete Data

The Fiscal Year 2002 CMS 64.9R reports were not accurate and included incomplete data. MAA reported the same outstanding balance ($4,129,033) each quarter of the fiscal year ending June 30, 2002. The $4.1 million represented disputes FHSC was tasked with resolving. MAA reported rebates received during the quarter on line 5(b) of the CMS 64.9R. MAA also reported this same amount on line 2(b) of the CMS 64.9R to zero out the balance at the end of the quarter.

MAA did not allocate reported rebate information to the proper quarter. Technically, prior quarter rebate activity such as payments and receivables should be allocated to the quarters in which the transactions originated. CMS 64.9R provides space to report the current quarter, the last 3 quarters and a cumulative column for all other prior quarters receivables.

Finally, the MAA did not report the amount invoiced, corrections, adjustments or disputes not paid during the quarter. In the narrative section of the CMS 64.9Rs for fiscal year ending June 30, 2002, MAA noted that, "Invoice information was not available at the time of submission. It will be provided as soon as possible." However, the subsequent CMS 64.9Rs did not contain the information. As a result, MAA was not providing CMS with accurate information regarding its drug rebate program.

According to an MAA official, the main reasons the CMS 64.9Rs were not completed accurately and completely were the lack of personnel and time. The official also commented that the addition of ACS and FHSC has helped greatly in administering the drug rebate program.
Cash Receipt Controls

The endorsement stamp used to restrict deposits on incoming drug rebate checks is a generic "For Deposit Only" stamp that does not contain any District information, and therefore is not as restrictive and secure as possible.

After ACS collects the checks from its lockbox, or from Federal Express, they enter the checks into the system, photocopy them, and then place the endorsement on the back of each check. ACS seals the checks in an envelope, and then has a courier pick up and deliver the endorsed check to MAA for deposit.

Although the overall accounts receivable procedures are adequate, we believe a restrictive endorsement including either the District's name or the District's bank account number should be placed on the checks sent for deposit. In our opinion, this change would help to better secure incoming rebate checks received from the drug manufacturers.

RECOMMENDATIONS

We recommend that MAA:

- accurately report outstanding rebates receivables and rebates collected, and include rebates invoiced and adjustments on the CMS 64.9R; and

- include on the endorsement stamp either the District's name or the District's bank account number to ensure greater security of drug rebate checks on behalf of the District.

District of Columbia's Response and OIG Comments

MAA responded to our draft report in a letter dated July 3, 2003. In its response, MAA officials concurred with our findings. MAA's response and our comments on each finding are summarized below. MAA's response is included in its entirety as Appendix A.

MAA agrees the FY 2002 CMS 64.9R reports were not accurate and included incomplete data. MAA has taken action to provide accurate information on the CMS 64.9R report by (1) conducting dispute resolution with historical manufacturer payments and (2) reconciling current adjustments and posting the results to the current quarter of the CMS 64.9R.
MAA concurs with our recommendation to include a "For Deposit Only" stamp with D.C. Government identified as the agency. At the last step, when the Finance and Audit team prepares the 64.9R for submission, the specific bank account number will be identified and entered on the stamp, as this number can change.

**OIG Comment**

The OIG believe that the corrective actions proposed by MAA, when implemented, should address the audit findings.
APPENDIX
Stephen Virbitsky  
Regional Inspector General for Audit Services  
Office of Inspector General  
150 S. Independence Mall West  
Suite 316  
Philadelphia, PA 19106-3499  

RE: Report Number A-03-03-00205  

Dear Mr. Virbitsky:  

The Medical Assistance Administration (MAA) is in receipt of your draft report evaluating whether MAA has established adequate accountability and internal controls over the Medicaid drug rebate program. Please find our response to each of your recommendations below.

**Accurately report outstanding rebates receivables and rebates collected, and include rebates invoiced and adjustments on the CMS 64.9R**

MAA concurs with your findings, and we have taken the necessary steps to accurately reflect the adjustments on the 64.9R. By conducting dispute resolution with historical manufacturer payments, as well as continuing to reconcile current adjustments and posting these resolutions to the correct quarter, ongoing correct adjustments to the 64.9R are reflected.

**Include on the endorsement stamp either the District’s name or the District’s bank account number to ensure greater security of drug rebate checks on behalf of the District.**

MAA concurs with your findings and we have purchased a "For Deposit Only" stamp with DC Government identified as the agency. At the last step, when our Finance and Audit team prepares the 64.9R for submission, the specific bank account number will be identified and entered on the stamp, as this number can change.
Stephen Virbitsky  
July 3, 2003  
Page 2

If you have any questions or need additional information, please contact Donna Bovell, Acting Chief, Office of Quality Assurance, MAA, on (202) 442-9078.

Sincerely,

Wanda R. Tucker  
Interim Senior Deputy Director  
Medical Assistance Administration

Cc: Donna Bovell
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*
Daniel Malis, *Auditor*

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