DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Memorandum

Date JUL 29 2003

From Regional Inspector General for Audit Services

Subject Audit Report – REVIEW OF THE COMMONWEALTH OF VIRGINIA'S MEDICAID DRUG REBATE PROGRAM (Report Number A-03-03-00208)

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 Commonwealth of Virginia's Medicaid Drug Rebate Program." This review was self-initiated and the audit objective was to evaluate whether the Commonwealth of Virginia's Department of Medical Assistance Services 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-03-03-0208 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

JUL 29 2003

Report Number: A-03-03-00208

Patrick W. Finnerty, Director
Department of Medical Assistance Services
Commonwealth of Virginia
600 East Broad Street, Suite 1300
Richmond, Virginia 23219

Dear Mr. Finnerty:

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 Commonwealth of Virginia's Medicaid Drug Rebate Program." This review was self-initiated and the audit objective was to evaluate whether Virginia's Department of Medical Assistance Services 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 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-03-03-00208 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 COMMONWEALTH OF VIRGINIA'S MEDICAID DRUG REBATE PROGRAM

JULY 2003
A-03-03-00208

Office of Inspector General

http://oig.hhs.gov

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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. Authorized officials of the HHS divisions will make final determination on these matters.

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150 S. INDEPENDENCE MALL WEST
SUITE 316
PHILADELPHIA, PENNSYLVANIA 19106-3499

JUL 29 2003

Report Number: A-03-03-00208

Patrick W. Finnerty, Director
Department of Medical Assistance Services
Commonwealth of Virginia
600 East Broad Street, Suite 1300
Richmond, Virginia 23219

Dear Mr. Finnerty:

This final report presents the results of the Office of Inspector General REVIEW OF THE COMMONWEALTH OF VIRGINIA'S MEDICAID DRUG REBATE PROGRAM.

The audit objective was to evaluate whether the Commonwealth of Virginia's Department of Medical Assistance Services (DMAS) established adequate accountability and internal controls over the Medicaid drug rebate program.

FINDING

Generally, DMAS, along with its fiscal agent First Health Services Corporation (FHSC) had established adequate accountability and internal controls over the Medicaid drug rebate program. However, we found that FHSC had not reconciled payments to the National Drug Codes (NDC) level.

FHSC will be implementing a new Medicaid management information system as of June 27, 2003. The new system will be called First Rebate and is FHSC proprietary rebate program, which it currently uses in several other states.

RECOMMENDATION

We recommend that DMAS ensure that the new system reconcile manufacturers' payments to the NDC level.

In a written response to the draft report dated July 17,2003, DMAS provided comments to the draft report. Their complete response is included in Appendix A. DMAS concurred with our finding and identified the step being taken to resolve the finding.

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, 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 fiom 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.

Each state agency is required to maintain the number of units dispensed, by manufacturer, for each drug covered. Approximately 56,000 NDCs are available under the program. Each state agency uses the URA fiom 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 fiom 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 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.

DMAS reported to CMS average billings of $21,400,244 and average collections of $22,037,036 per quarter during the 1-year period ending June 30, 2002. DMAS also reported $35,040,262 on the CMS 64.9R as the outstanding balance as of June 30,2002, with $32,327,411 over 90 days old.

On June 30,2002, the outstanding rebate balance was $35,040,262. DMAS and FHSC personnel expressed concerns that some manufacturers continue to change the URA on drugs back to 1991. Currently there is no time limit for these changes. To resolve this issue, DMAS and FHSC suggested 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.

OBJECTIVE, SCOPE AND METHODOLOGY

Objectives

The audit objective was to evaluate whether the Commonwealth of Virginia's DMAS 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 the current policies, procedures and controls of the DMAS as of June 30, 2002. We also reviewed the aging schedule of accounts receivable and interviewed DMAS staff to understand how the Medicaid drug rebate program has operated since 1991.

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 DMAS and FHSC written procedures and program reports,

(3) Interviewed DMAS and FHSC employees to gain an understanding of the program,

(4) Reviewed step-by-step FHSC drug rebate process, including a walk through of the drug rebate billing and collection quarterly cycle,

(5) Obtained and examined outstanding, uncollected and aged drug rebates; and

(6) Obtained and examined the CMS 64, CMS 64.9R,and supporting documentation for the fiscal year ended June 30, 2002 as it related to the drug rebate program.

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

Fieldwork was performed at DMAS's and FHSC's offices in Richmond, Virginia. The fieldwork was conducted during March 2003 and continued in the Office of Audit Services' Philadelphia regional office through May 2003.

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

FINDING AND RECOMMENDATION

FINDING

Generally, DMAS, along with FHSC had established adequate accountability and intemal controls over the Medicaid drug rebate program. However, we found that FHSC had not reconciled payments down to the NDC level.

DMAS' DRUG REBATE PROGRAM

DMAS had established adequate intemal controls over the Medicaid drug rebate program except as noted. DMAS has been using a fiscal agent, FHSC to administer its drug rebate program since the third quarter of State fiscal year 1998.

FHSC performs the billing, account reconciliation, and dispute resolution functions. DMAS deposits the rebate checks on a daily basis, which are copied and forwarded to FHSC with all supporting documentation. DMAS also reports quarterly figures to CMS. We found that FHSC had adequate billing and dispute resolution controls in place.

However, when reconciling payments with the manufacturers' ROSI, FHSC had not reconciled to the NDC level. This practice did not comply with CMS's Best Practice Guide nor FHSC's Drug Rebate Policy and Procedures Manual. Both the guide and the manual state, "Make sure that it [the manufacturer's check] is posted to the proper labeler and the proper NDC."

According to FHSC personnel, when payment is received, it is reconciled to the labeler level on each account. In our opinion, reconciling to the NDC level provides a greater depth of detail that increases the accuracy of the records.

FHSC will be implementing a new Medicaid management information system as of June 27,2003. It is our understanding that the new system will reconcile the records to the NDC level.

RECOMMENDATION

We recommend that DMAS ensure that the new system reconcile manufacturers' payments to the NDC level.

Commonwealth of Virginia's Response and OIG Comments

DMAS responded to our draft report in a letter dated July 17,2003. In its response, DMAS officials concurred with our finding. DMAS response and our comment on the finding are summarized below. DMAS response is included in its entirety as Appendix A.

DMAS stated they would have their new drug rebate system operational no later then September 2003. This system will track and reconcile payments to the NDC level.

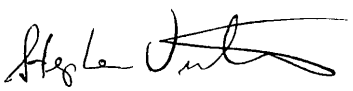
OIG Comment

The OIG believes that the new drug rebate system, when implemented, should address the audit finding.

*** *** ***

To facilitate identification, please refer to report number A-03-03-00208 in all correspondence relating to this report.

Sincerely yours,



Stephen Virbitsky
Regional Inspector General
for Audit Services

Direct Reply to HHS Action Official:

Sonia A. Madison, Regional Administrator
Centers for Medicare and Medicaid Services, Region III
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Philadelphia, Pennsylvania 19106-3499

APPENDIX

COMMONWEALTH of VIRGINIA

Department of Medical Assistance Services

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DIRECTOR

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July 17, 2003

Mr. Stephen Virvitsky
Regional Inspector General for Audit Services
U.S. Department of Health and Human Services
Office of Inspector General
Office of Audit Services
Suite 316, the Public Ledger Building
150 S. Independence Mall West
Philadelphia PA 19106-3499

Dear Mr. Virvitsky:

The Virginia Department of Medical Assistance Services ("DMAS") has received the Department of Health and Human Services' draft audit report #A-03-03-00208, and DMAS concurs with the report's findings. This audit is a review of Virginia's Medicaid Drug Rebate Program.

Virginia shall have the new drug rebate system operational no later than September 2003. This system tracks and reconciles payments to the NDC level. Therefore, Virginia shall be in compliance with the NDC tracking requirement if and when the federal government promulgates final rules for the program.

It was truly a pleasure to have the opportunity to work with Mr. Lieberman. If you have any further questions regarding this audit or DMAS' response to the draft, please contact me at 804-786-5592.

Sincerely,

D. Doyle Earhart
Controller

J;csa;dde;OIG Audit Draft Response 7 2003

Cc: Michael Lieberman, Auditor, OIG
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ACKNOWLEDGMENTS

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

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