



Memorandum

Date JUL 2 2003

From Regional Inspector General for Audit Services

Subject Audit Report – REVIEW OF THE COMMONWEALTH OF PENNSYLVANIA
MEDICAID DRUG REBATE PROGRAM (Report Number A-03-03-00201)

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 Commonwealth of Pennsylvania Medicaid Drug Rebate Program." This review was self-initiated and the audit objective was to evaluate whether the Commonwealth of Pennsylvania's Department of Public Welfare 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 phone number 215-861-4474.

To facilitate identification, please refer to Report Number A-03-03-00201 in all correspondence relating to this report.

A handwritten signature in black ink, appearing to read "Stephen Virbitsky".

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 - 2 2003

Report Number: A-03-03-00201

Michael L. Stauffer, Deputy Secretary for Administration
Commonwealth of Pennsylvania
Department of Public Welfare
Office of Administration
Health and Welfare Building, Room 234
P.O. Box 2675
Harrisburg, Pennsylvania 17105-2675

Dear Mr. Stauffer:

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 Commonwealth of Pennsylvania's Medicaid Drug Rebate Program." This review was self-initiated and the audit objective was to evaluate whether Pennsylvania's Department of Public Welfare 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-03-03-00201 in all correspondence relating to this report.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Stephen Virbitsky", with a long horizontal flourish extending to the right.

Stephen Virbitsky
Regional Inspector General
for Audit Services

Enclosure

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

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF THE COMMONWEALTH
OF PENNSYLVANIA'S MEDICAID
DRUG REBATE PROGRAM**



**JULY 2003
A-03-03-00201**

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

JUL - 2 2003

Michael L. Stauffer, Deputy Secretary for Administration
Commonwealth of Pennsylvania
Department of Public Welfare
Office of Administration
Health and Welfare Building, Room 234
P.O. Box 2675
Harrisburg, Pennsylvania 17105-2675

Dear Mr. Stauffer:

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

The objective of our audit was to evaluate whether the Pennsylvania Department of Public Welfare (DPW) had established adequate accountability and internal controls over the Medicaid drug rebate program.

FINDINGS

The DPW needs to establish adequate controls over its Medicaid drug rebate program. The DPW had not:

- Reconciled rebates received from drug manufacturers with the invoices submitted for payment by National Drug Codes (NDC), nor did it age its outstanding drug rebate accounts receivable;
- Kept accurate records of outstanding disputed amounts for each manufacturer;
- Reviewed quarterly payments received from drug manufacturers to determine if interest was owed when payment was received 38 days after the due date and verified the accuracy of interest payments on disputes either when received from or owed to drug manufacturers;

- Reconciled the Center for Medicare and Medicaid Services (CMS) 64.9R outstanding balances in the drug rebate program to DPW's accounting records; and
- Maintained all prior years' information, since the inception of the program that is needed for input into the new PROMISE system.

The lack of sufficient controls occurred because: (1) DPW manually maintained its records at the inception of the program and errors made during this period were not corrected, and (2) the current drug rebate staff has 2 years or less of work experience at DPW and has limited knowledge of the prior years records.

The DPW has contracted with Electronic Data Systems (EDS) to implement a new Medicaid management information system, called PROMISE, scheduled for March 2004. The EDS will be responsible for administrating the drug rebate program as part of the new Medicaid management information system.

RECOMMENDATIONS

We recommend that DPW:

- Ensure that the PROMISE system contains adequate policies, procedures and controls that sufficiently detail accounts receivable to accurately monitor and collect receivables, record disputes, and provide information for the CMS 64.9R prior periods;
- Age the accounts receivable and write-off any amount deemed uncollectable. The DPW should follow CMS guidelines for write-offs;
- Monitor interest accruals and payments for accuracy; and
- Move the transition to the PROMISE system earlier than March 2004 and keep CMS advised periodically of the transition.

In a written response to the draft report dated April 28, 2003, DPW provided comments to the draft report. Their complete response is included in Appendix A. The DPW officials generally disagreed with our findings. The DPW feels that its drug rebate program is adequate and the findings cited in the report are inaccurate.

BACKGROUND

The Medicaid program was authorized under Title XIX of the Social Security Act and is a joint federal/state program. The purpose of the Medicaid program is to provide federal financial assistance to states for medical assistance on behalf of eligible cash assistance recipients, children, pregnant women, and the aged who meet income and resource requirements, and other categorically eligible groups. At the federal level, CMS, within

the Department of Health and Human Services, administers the Medicaid program. The CMS oversees the drug rebate program.

Under the Medicaid program, states may provide coverage of prescription drugs as an optional service under section 1905(a)(12) of the Social Security Act. Section 1903(a) of the Act provides for federal financial participation in state expenditure for prescription drugs.

On November 5, 1990, Congress enacted The Omnibus Budget Reconciliation Act of 1990 legislation, which among other provisions established the Medicaid prescription drug rebate program. Responsibility for the rebate program is shared among 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 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 provide 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 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 reports, on a quarterly basis, outpatient drug expenditures and rebate collections on Form CMS 64.9R. This report is part of Form CMS 64 quarterly report, which summarizes actual Medicaid expenditures by quarter and is used by CMS to reimburse the federal share of these expenditures. The DPW reported to CMS \$38.9 million in billings and \$35.8 million in collections for the quarter ended June 30, 2002. Also, DPW reported \$36,672,522 on the CMS 64.9R as the outstanding balance as of June 30, 2002.

OBJECTIVE, SCOPE AND METHODOLOGY

Objective

The audit objective was to evaluate whether DPW 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 limited our review to the current drug rebate program policies, procedures and controls. We also reviewed the drug rebate sections of DPW's CMS 64 and CMS 64.9R for the quarter ended June 30, 2002. For the accounts receivable and disputed drug rebates, we reviewed various reports generated by DPW's drug rebate access system such as the Check report, Distribution report and Comptroller's Worksheet report.

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 DPW's limited written procedures and program reports,
- (3) interviewed DPW employees to gain an understanding of the program,
- (4) reviewed step-by-step DPW's drug rebate process, including a walk through of the drug rebate billing and collection quarterly cycle, and
- (5) obtained and examined the CMS 64, CMS 64.9R, and supporting documentation for the quarter ended June 30, 2002 as it related to the drug rebate program.

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

Fieldwork was performed at DPW's offices in Harrisburg, Pennsylvania (PA) and Chester, PA during October and November 2002 and continued in the Office of Audit Services Philadelphia regional office during January and February 2003.

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

FINDINGS AND RECOMMENDATIONS

FINDINGS

The DPW needs to establish adequate controls over its Medicaid drug rebate program. The DPW had not:

- Reconciled rebates received from drug manufacturers with the invoices submitted for payment by NDC, nor did it age its outstanding drug rebate accounts receivable;
- Kept accurate records of outstanding disputed amounts for each manufacturer;
- Reviewed quarterly payments received from drug manufacturers to determine if interest was owed when the payment was received 38 days after the due date and verified accuracy of interest payments on disputes either when received from or owed to drug manufacturers;
- Reconciled the CMS 64.9R outstanding balances in the drug rebate program to DPW's accounting records; and
- Maintained all prior years' information since the inception of the program that is needed to enter into the new PROMISE system.

DPW'S DRUG REBATE PROCESS

The DPW has operated the drug rebate program since its inception in January 1991. A pharmacist and a Medical Assistance Program Specialist are responsible for monitoring and resolving disputes, researching utilization data to resolve errors, communicating with manufacturers, and monitoring outstanding balances. Staff in other departments deposit funds, post payments to the system, and prepare the CMS 64 reports.

Reconciliation Process

Quarterly, DPW generates two copies of the invoices that contain detail at the NDC level. One copy is sent to the manufacturer, the other is filed in a box according to DPW personnel. When a check is received, it is split between state and federal shares before the aggregate total is entered and verified into the drug rebate access system. After the payment received is entered into the system, it is reconciled at the aggregate amount and not at the NDC level. If the payment received plus any noted disputes do not equal the invoice, the difference is then investigated by the Medical Assistance Program Specialist.

The Code of Federal Regulations at 45 CFR Section 74.21 requires that the states' financial management system provide for "effective control over and accountability for all funds, property and other assets."

Since the drug rebate access system does not reconcile payments received at the NDC level, DPW is unable to verify the accuracy of all payments. Also, the drug rebate access system does not allow DPW to age its accounts receivable and disputes. Thus, DPW has not written off uncollectable receivables. In addition, the system cannot verify the accuracy of interest paid to or received from manufacturers since it does not track the timing of payments to determine when interest is payable.

Disputes

We requested a listing of unresolved disputes as of June 30, 2002. According to DPW personnel, they were unable to provide information by disputes only. They did, however, provided us with a schedule showing disputes for 10 manufacturers that contained corrections and adjustments. This schedule totaled \$14.6 million and accounted for about 75 percent of the outstanding balances per DPW personnel. The DPW personnel stated they could not give an exact dollar amount for total disputes, either as an aggregate total of all manufacturers or for just one manufacturer, without reviewing the old ROSI reports. However, DPW did say that the total outstanding disputed rebate balance is approximately \$19 million. This number is consistent with an extrapolated total of \$19.5 million based on \$14.6 million equaling 75 percent.

The DPW personnel expressed concerns that some manufacturers continue to change the URAs back to 1991. Currently, there is no time limit for these changes. Because of this situation, DPW's accounts would have to be repeatedly reconciled since the dollar amounts can continually change. To resolve the issue of ongoing changes that affect the program back to its inception, DPW believes that CMS should limit the amount of time a manufacturer can change the unit rebate amount rates to 12 quarters.

Interest

The DPW had not reviewed drug manufacturers' quarterly rebate payments that were received 38 days or more after the due date to determine if interest was owed. When interest was paid, DPW relied on and accepted the manufacturers' calculations. Similarly, DPW also accepted the manufacturers' calculations of the amount of interest DPW owed a manufacturer. They had not verified the accuracy of interest paid to or owed by manufacturers, which is a prudent business practice.

The CMS Program Releases - Numbers 15 and 29 addressed to State Medicaid Directors, provide for detailed instruction on interest payments for dispute resolution and late rebate payments as follows:

"A manufacturer or State must pay or credit a reasonable rate of interest on a disputed rebate amount after the dispute is resolved. ... Interest accrues on the disputed portion of the rebate amount or on the total amount of the late rebate payment for all quarters beginning January 1, 1991 and only stops accruing on the date the check is disbursed.... Interest must be collected and may not be disregarded as part of the dispute resolution process by the State or manufacturer... Interest will begin accruing on disputed or unpaid amounts 38 calendar days from the date the State mails the State utilization data [to the manufacturer], as evidenced by the postmark by the United States Postal Service or other common mail carrier on the envelope (not a postage meter stamp)."

Moreover, CMS indicated that states are accountable for the federal share of any interest earned on recoupments or refunds pending their return to the Federal Government.

CMS 64 REPORTING

Medicaid drug rebate program current quarter collections are shown on Line 7A of the CMS 64 report and also on the CMS 64.9R (Medicaid Drug Rebate Schedule). The CMS 64.9R is an attachment to the CMS 64 that is updated on a quarterly basis to reflect the drug rebate program activity for that quarter.

In addition to the current quarter's drug rebate information, the CMS 64.9R contains information for each of the last three quarters along with the combined totals of all prior quarters beyond the most recent four quarters. The CMS 64.9R prior quarters are not reconciled to DPW accounting records because of problems with record keeping in the early years of the program. As a result, the DPW has not been able to verify that all numbers from the beginning of the program are accurate.

According to CMS, the amounts reported on the CMS 64 and its attachments must be actual expenditures for which all supporting documentation, in readily reviewable form, has been compiled and is available immediately at the time the claim is filed. In our opinion, an adequate drug rebate accounting system would provide the necessary information to update the reported information accurately.

PROMISe SYSTEM

The DPW has contracted with EDS for a new Medicaid management information system. Implementation of the new system is scheduled for March 2004. While we support DPW's upgrade to a new system, we are concerned about the transfer of historical drug rebate program information to the new system (to be started in March 2004). According to a DPW employee, it could take up to one year to enter everything that has to be done manually, which will put completion of the data entry to March 2005.

According to DPW, four EDS employees will manually enter all information accumulated since the inception of the program that cannot be electronically transferred (e.g., PQAS and disputed amounts). To help the process along, DPW has contacted some drug manufacturers to obtain the old ROSIs, however, at least one manufacturer stated that it would not be able to provide this data.

We reviewed rebate histories for two drug manufacturers. In both instances, DPW was unable to provide all past history. The missing information included corrections and adjustments as well as eight ROSI reports, which are necessary to reconcile monthly payments. In our opinion, it will be a difficult task to transition the entire history of the drug rebate program to the new PROMISe system, since we were unable to verify the balances of two manufacturers.

RECOMMENDATIONS

We recommend that DPW:

- Ensure that the PROMISe system contains adequate policies, procedures and controls that sufficiently detail its accounts receivable system to accurately monitor and collect receivables, report disputes, and provide information for the CMS 64.9R prior periods;
- Age the accounts receivable and write-off any amount deemed uncollectable. The DPW should follow CMS guidelines for write-offs;
- Monitor interest accruals and payments for accuracy; and
- Move the transition to the PROMISe system earlier than March 2004 and keep CMS advised periodically of the transition.

Pennsylvania's Response and OIG Comments

The DPW responded to our draft report in a letter dated April 28, 2003. In its response, DPW generally disagreed with our findings. The DPW's response and our comments on each finding are summarized below. The DPW response is included in its entirety as Appendix A.

Finding 1 - The DPW had not maintained records by NDC as required by CMS.

DPW's Response

The DPW does not concur. The DPW stated that, while not maintaining a fully automated drug rebate program, it does maintain manual NDC records (since 1991). In addition, DPW stated that it meets CMS requirements for NDC maintenance, as Pennsylvania NDC utilization data is maintained in (1) Labeler files with the ROSI correspondence and payment history; (2) an electronic NDC file in the Pennsylvania Drug Rebate System; and (3) on microfiche and electronically for Pennsylvania invoices with NDC detail.

OIG Comment

We agree DPW maintains records at the NDC level and have adjusted our report.

Finding 2A - The DPW had not reconciled rebates received from drug manufacturers with the invoices submitted for payment.

DPW's Response

The DPW does not agree. Currently, the DPW reconciles aggregate payments from the manufacturers to invoices in the Pennsylvania Drug Rebate Access System.

OIG Comment

We agree that DPW reconciles aggregate payments from the manufacturers to invoices in the Pennsylvania Drug Rebate Access System. In fact, we said the same thing on page 6 of the report. However, the report goes on to point out that by not reconciling payments received to the NDC level, DPW is unable to verify the accuracy of the payments.

Finding 2B -- The DPW did not age its outstanding drug rebate accounts receivable.

DPW's Response

The DPW does not concur. Since manufacturers, at any time, are able to affect prior periods back to first quarter 1991, "aging" out claims does not appear appropriate or practical. The DPW has taken the position that all outstanding drug rebate amounts are potentially collectable and intends to collect all disputes; and accrues interest on unpaid disputes until resolution.

OIG Comment

The OIG commends DPW for intending to collect all outstanding rebates. However, this does not change the fact that DPW does not age its receivables. Identifying receivables by age would help DPW monitor manufacturer adjustments and also make it easier to determine when interest should be collected.

Finding 3 - The DPW had not kept accurate records of outstanding disputed amounts for each manufacturer.

DPW's Response

The DPW does not agree. The DPW's major issue with this finding is the implication that drug rebate information is not available. The DPW maintains accurate manual records of outstanding disputes. Since 1999, the DPW has maintained a separate filing of worksheets that contain the ROSI information, which identifies accurate NDC level disputes. The DPW also verifies dispute units from the ROSI; reviews accounts for disputes prior to the dispute resolution process; and has the capability of calculating outstanding dispute amounts through the manual process.

OIG Comment

During the audit, OIG staff attempted to reconcile the total outstanding disputes, adjustments and corrections to the supporting documentation for 2 of the top 10 drug manufacturers. The DPW was not able to provide documentation to support the outstanding balances, and therefore, the outstanding balances could not be verified. The DPW officials told us that they had requested drug rebate payment histories from the manufacturers for use in establishing their new PROMISe system. The DPW drug rebate staff offered this as the solution to the issue of not having all the documentation available for review.

Finding 4 - The DPW had not reviewed quarterly payments received from drug manufacturers' to determine if interest was owed when the payment was received 38 days after the due date. The DPW had not verified accuracy of interest payments on disputes either when received from or owed to drug manufacturers.

DPW's Response

The DPW does not concur with these findings. They stated that labelers calculate the interest for dispute resolution. To support this position, DPW referred to a directive contained in CMS Release 65, which indicates that the states are responsible to report interest and CMS Release 26, which indicates that manufacturers are responsible to calculate the interest.

OIG Comment

The DPW is correct that it is the manufacturers' responsibility to calculate and report interest; OIG never stated otherwise. The OIG was aware of the CMS Releases and took them into consideration when formulating the finding. With that understood, our report stated that DPW did not systematically review and verify the interest calculated by the manufacturers. We believe that DPW should verify the accuracy of the interest paid as a prudent business practice.

Finding 5 - The DPW had not reconciled the CMS 64.9R outstanding balances in the drug rebate program to DPW's accounting records.

DPW's Response

The DPW has attempted, and continues to attempt, to perform reconciliations between the CMS 64.9R and the DPW's Drug Rebate Program accounting records. The concurrence with this finding is that a successful reconciliation has not been accomplished, not a concurrence that a reconciliation has not been attempted.

OIG Comment

Our report stated that the CMS 64.9R prior quarters are not reconciled to DPW accounting records because of problems with record keeping in the early years of the program. We did not imply that an attempted reconciliation has not been made. We stated that because DPW had not reconciled its accounting records they were not able to verify that all numbers from the beginning of the program are accurate. If DPW's record keeping, back to 1991, is as good as DPW officials claim they should not have a problem reconciling their records.

Finding 6 - The DPW had not maintained all prior years' information since the inception of the program that is needed to enter into the new PROMISE system.

DPW's Response

The DPW does not concur. While the DPW is aware that all drug rebate manufacturer information will need to be input with the implementation of the PROMISE system, the DPW has maintained all prior-year information since the inception of the program in the Drug Rebate Access System. The contractor will utilize the electronic information from the Drug Rebate Access System for input into the PROMISE system. Also, the Drug Rebate Access System contains information identifying the invoices, payments, and NDC level data. The contractor will input the information into the new PROMISE system. The DPW will make available to the contractor the maintained worksheets, which contain the ROSI information. Lastly, the DPW intends to have available to the contractor any correspondence received from Labelers with regard to drug rebate issues such as settled dispute units.

OIG Comment

We attempted to reconcile the outstanding disputes, adjustments and corrections for two manufacturers. We requested all ROSIs for the two manufacturers, however, DPW officials could not locate eight ROSIs. The missing ROSIs were discussed with DPW officials while the audit was ongoing and again at the exit conference. The officials acknowledged that the documents were not available.

The DPW officials also added that DPW contacted manufacturers to obtain previously submitted ROSIs in order to include the entire drug rebate program history in the new PROMISE system. If DPW maintained accurate manual records as stated in their response to finding number 1 there would be no need to request copies from the manufacturers. The DPW officials added that at least one manufacturer was willing to send the information but would not do so until just before the PROMISE system was put into operation because the manufacturer did not want to send the information more than once.

DPW provided the following additional comments:

- The DPW's contractor is obligated to complete the data entry into the PROMISE system for the March 2004 deadline. The contractor is obligated to provide personnel necessary to achieve the objective.
- The DPW supports a CMS adoption to limit rate changes for product rebates, regardless of the origin, to within a 2-year prior period only.
- The DPW supports the adoption of guidance in the form of regulations, as applicable to the Drug Rebate Program.
- The DPW supports a CMS adoption to limit rate changes for product rebates, regardless of the origin, to within a 2-year period only.

OIG Comment

The DPW made some good points, which will be shared with CMS.

To facilitate identification, please refer to report number A-03-03-00201 in all correspondence relating to this report.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Stephen Virbitsky", with a long horizontal flourish extending to the right.

Stephen Virbitsky
Regional Inspector General
for Audit Services

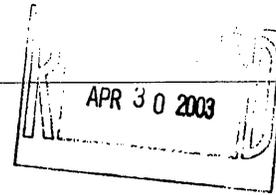
Direct Reply to HHS Action Official:

Sonia A. Madison, Regional Administrator
Centers for Medicare and Medicaid Services, Region III
Public Ledger Building, Suite 216
150 S. Independence Mall West
Philadelphia, Pennsylvania 19106-3499

APPENDIX



COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF PUBLIC WELFARE
P.O. BOX 2675
HARRISBURG, PENNSYLVANIA 17105-2675



APR 28 2003

Michael Stauffer
Deputy Secretary for Administration

(717) 787-3422
Email: MikeS@dpw.state.pa.us

Mr. Stephen Virbitsky
Regional Inspector General for Audit
Services
Office of Inspector General
Department of Health & Human Services
Suite 316
150 South Independence Mall West
Philadelphia, Pennsylvania 19106-3499

Dear Mr. Virbitsky:

Thank you for your March 17, 2003, letter in which you transmitted the draft report entitled "Review of the Commonwealth of Pennsylvania's Medicaid Drug Rebate Program" (Report No. A-03-03-00201). The response developed by the Department of Public Welfare (DPW) is presented below.

While a completely automated Drug Rebate Program (DRP) does not currently exist in Pennsylvania, the DPW has established adequate accountability and internal controls over the Medicaid DRP, and is capable of providing DRP data within a reasonable timeframe. It must also be noted that there is no federal requirement for automation.

Please note that Pennsylvania has contracted for complete automation of the DRP. With the advent of the PROMISE system, Pennsylvania's accountability of the current DRP will be enhanced.

In the meantime, the DPW offers the following responses to the findings contained in the draft report.

Finding 1 – The DPW had not maintained records by the National Drug Codes (NDC) as required by the Centers for Medicare and Medicaid Services (CMS).

DPW Response – The DPW does not concur. The DPW, while not maintaining a fully automated DRP, does:

1. Maintain manual NDC records (since 1991). The CMS does not prohibit NDC manual maintenance through any federal regulation.

Mr. Stephen Virbitsky

- 2 -

2. Meet CMS requirements for NDC maintenance, as Pennsylvania NDC utilization data is:
 - a. maintained in Labeler files with the Reconciliation of State Invoice (RSI) correspondence and payment history;
 - b. maintained in an electronic NDC file in the Pennsylvania Drug Rebate System;
 - c. maintained on microfiche and electronically for Pennsylvania invoices, with the following NDC detail:
 - Period Covered
 - Labeler Code
 - Product Code
 - Package Size Code
 - Product FDA Registration Name
 - Rebate Amount per Unit
 - Total Units Reimbursed
 - Total Rebate Amount Claimed
 - Number of Prescriptions
 - Total Amount Reimbursed by the State
 - Prior Period Adjustments (PPA)

DPW Future Enhancements – The DPW will enhance the NDC maintenance to a fully automated electronic system with the start of the PROMISE system, which is scheduled for March 2004.

Finding 2A – The DPW had not reconciled rebates received from drug manufacturers with the invoices submitted for payment.

DPW Response: The DPW does not agree. Currently, the DPW reconciles aggregate payments from the manufacturers to invoices in the Pennsylvania Drug Rebate Access System.

DPW Future Enhancements: The DPW will enhance the reconciliation of drug rebate receivables to a fully automated electronic system with the start of the PROMISE system, which is scheduled for March 2004.

Mr. Stephen Virbitsky

- 3 -

Finding 2B – The DPW did not age its outstanding drug rebate amounts receivable.

DPW Response: The DPW does not concur. Since manufacturers, at any time, are able to affect prior periods back to the first quarter of 1991, "aging" out claims does not appear appropriate or practical. The DPW has taken the position that all outstanding drug rebate amounts are potentially collectable and:

1. Intends to collect all disputes.
2. Accrues interest on unpaid disputes until resolution.

A recommendation from the Commonwealth of Pennsylvania would be for the CMS to provide guidelines to limit manufacturers from affecting account issues to prior periods (back to the first quarter of 1991).

DPW Future Enhancements: The DPW will enhance the receivable aging process, regarding interest, to a fully automated electronic system with the start of the PROMISE system scheduled for March 2004.

Finding 3 – The DPW had not kept accurate records of outstanding disputed amounts for each manufacturer.

DPW Response: The DPW does not agree. The DPW's major issue with this finding is the implication that drug rebate information is not available. The DPW:

1. Maintains accurate manual records of outstanding disputes. Since 1999, the DPW has maintained a separate filing of worksheets that contain the Reconciliation of State Invoice (ROSI) information, which identifies accurate NDC level disputes.
2. Verifies dispute units from the ROSI.
3. Reviews accounts for disputes prior to the dispute resolution process.
4. Has the capability of calculating outstanding dispute amounts through the manual process.

DPW Future Enhancements: The DPW will enhance the record keeping for disputed amounts in a fully automated electronic system with the start of the PROMISE system scheduled for March 2004.

Mr. Stephen Virbitsky

- 4 -

Finding 4A – The DPW had not reviewed quarterly payments received from drug manufacturers' to determine if interest was owed when payment was received 38 days after the due date.

DPW Response: The DPW disagrees with this finding as:

1. The DPW collects and reports interest due.
2. The DPW considers that the interest calculation responsibility lies with the manufacturer. To support this position:
 - a. CMS Release #65 to States indicates that the responsibility of interest calculation lies with the manufacturer. The State responsibility is to report the interest calculated to CMS.
 - b. CMS Release #26 to Drug Manufactures indicates that the responsibility for calculating interest due lies with the manufactures. The States responsibility is to report the interest to CMS.

DPW Future Enhancements: The DPW will enhance the 38-day interest determination with the start of the PROMISe system in March 2004.

Finding 4B – The DPW had not verified the accuracy of interest payments on disputes either when received from or owed to drug manufacturers.

DPW Response: The DPW does not concur with this finding as:

1. Labelers calculate the interest for dispute resolution. To support this position:
 - a. CMS Release #65 to States indicates that the responsibility of interest calculation lies with the manufacturer. The State responsibility is to report the interest calculated to CMS.
 - b. CMS Release #26 to Drug Manufactures indicates that the responsibility for calculating interest due lies with the manufactures. The States responsibility is to report the interest to CMS.
2. The DPW reviews and verifies the interest calculations for disputes from the Labelers when dispute settlement occurs or soon thereafter.

DPW Future Enhancements: The DPW will enhance the verification of Labeler interest calculation issues to a fully automated process with the start of the PROMISe system in March 2004.

Mr. Stephen Virbitsky

- 5 -

Finding 5 – The DPW had not reconciled the CMS-64.9R outstanding balances in the drug rebate program to DPW's accounting records.

DPW Response: The DPW has attempted, and continues to attempt, to perform reconciliations between the CMS-64.9R and the DPW's DRP accounting records. The concurrence with this finding is that a successful reconciliation has not been accomplished, not a concurrence that a reconciliation has not been attempted. It is recognized that there is a difference between the Total Balance on the CMS-64.9R [Col (F), Line 6] and the outstanding balances in the DPW drug rebate system's outstanding/disputed items. As identified in the review, the DPW manually maintained its records at the inception of the program and errors made during this period were not corrected. In May 2001, the DPW performed a comparison of the check entries on the Pennsylvania Drug Rebate Invoices and Labeler Payments. As a result of this review, the Total Balance on the CMS-64.9R for the Quarter Ending June 30, 2001, was reduced by \$20 million. This process and action, with supporting documentation, was communicated to the CMS, Region III, in a letter dated June 13, 2001. The DPW has contracted with EDS for a new Medical Assistance management information system, and the DPW is currently in the process of designing the new PROMISe system, which will be responsible for administering the drug rebate program. On an ongoing basis, the DPW's DRP staff continues to resolve disputes with the drug manufactures and to reduce outstanding/disputed rebate claims; these resolutions, when recognized on the CMS-64.9R, will bring the CMS-64.9R and the DPW's accounting records into closer agreement.

Finding 6 – The DPW had not maintained all prior years' information, since the inception of the program that is needed for input into the new PROMISe™ system.

DPW Response: The DPW does not concur. While the DPW is aware that all drug rebate manufacturer information will need to be inputted with the implementation of the PROMISe system:

1. The DPW has maintained all prior-year information since the inception of the program (first quarter of 1991) in the Drug Rebate Access System. The contractor will utilize the electronic information from the Drug Rebate Access System for input into the PROMISe system.
2. The Drug Rebate Access System contains information identifying the invoices, payments, and NDC level data. The contractor will input the information into the new PROMISe system.
3. The DPW will make available to the contractor the maintained worksheets, which contain the ROSI information. The ROSI information will provide additional concurrence for input into the PROMISe system.

Mr. Stephen Virbitsky

- 6 -

4. The DPW intends to have available to the contractor any correspondence received from Labelers with regard to drug rebate issues such as settled dispute units.

DPW Supportive Documentation: The DPW and Labelers mutually verify and concur on information prior to the dispute resolution process and document the resolutions. The documentation correspondence will be available to the contractor for input into the PROMISe system.

ADDITIONAL COMMENTS

PROMISe Transition:

1. The DPW's contractor is obligated to complete the data entry into the PROMISe system for the March 2004 deadline.
2. The contractor is obligated to provide personnel necessary to achieve the objective.

Manufacturers' Rate Changes:

The DPW supports a CMS adoption to limit rate changes for product rebates, regardless of the origin, to within a two-year prior period only.

Drug Rebate Regulations:

The DPW supports the adoption of guidance in the form of regulations, as applicable to the Drug Rebate Program.

CMS-64.9R:

The DPW supports the CMS adoption of a more appropriate reporting form for the Drug Rebate Program.

Thank you for the opportunity to respond to this audit report. Please contact Andrew Johnson, Bureau of Financial Operations, Audit Resolution Section, at 783-6329 if you should need any further assistance.

Sincerely,



Michael Stauffer

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 G. Berti, Jr., *Audit Manager*
Carolyn Hoffman, *Senior Auditor*
Michael Lieberman, *Auditor-in-Charge*
Hilda Mercado, *Auditor*

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