DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General

Region IX
Office of Audit Services
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

OCT - 8 2008

Report Number: A-09-08-00026

Mr. Charles Duarte
Administrator
Nevada Department of Health and Human Services
Division of Health Care Financing and Policy
1100 East Williams Street, Suite 101
Carson City, Nevada 89701

Dear Mr. Duarte:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled "Follow-Up Audit of the Medicaid Drug Rebate Program in Nevada." We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

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If you have any questions or comments about this report, please do not hesitate to contact me at (415) 437-8360 or through e-mail at Lori.Ahlstrand@oig.hhs.gov, or contact Doug Preussler, Audit Manager, at (415) 437-8309 or through e-mail at Doug.Preussler@oig.hhs.gov. Please refer to report number A-09-08-00026 in all correspondence.

Sincerely,

Lori A. Ahlstrand
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Ms. Jackie Garner, Consortium Administrator
Consortium for Medicaid and Children's Health Operations
Centers for Medicare & Medicaid Services
233 North Michigan Avenue, Suite 600
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Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

FOLLOW-UP AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN NEVADA

Daniel R. Levinson
Inspector General

October 2008
A-09-08-00026

Office of Inspector General

http://oig.hhs.gov

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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

EXECUTIVE SUMMARY

BACKGROUND

The Medicaid drug rebate program, which began in 1991, is set forth in section 1927 of the Social Security Act (the Act). For a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the program, the manufacturer must enter into a rebate agreement with the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each undertake certain functions in connection with the drug rebate program. In Nevada, the Department of Health and Human Services (the State agency) administers the Medicaid drug rebate program.

Section 1927(b)(2)(A) of the Act requires States to maintain drug utilization data that identifies, by National Drug Code (NDC), the number of units of each covered outpatient drug for which the States reimbursed providers. The number of units is applied to the unit rebate amount to determine the actual rebate amount due from each manufacturer. Section 1927(b)(2) of the Act requires States to provide the drug utilization data to CMS and the manufacturer. States also report drug rebate accounts receivable data on Form CMS-64.9R, "Medicaid Drug Rebate Schedule."

In 2005, we issued a report on the results of audits of the Medicaid drug rebate programs in 49 States and the District of Columbia (A-06-03-00048). Those audits found that only four States had no weaknesses in accountability for and internal controls over their drug rebate programs. As a result of the weaknesses, we concluded that States lacked adequate assurance that all of the drug rebates due to the States were properly recorded and collected. Additionally, CMS did not have reliable information from the States to properly monitor the drug rebate program.

In our previous audit of the Nevada drug rebate program, we determined that the State agency had not established adequate policies, procedures, and internal controls over the Medicaid drug rebate program (A-09-03-00033). Specifically, we identified weaknesses in the following areas: (1) accounts receivable system, (2) rebate billings, (3) interest accrual and collection, and (4) dispute resolution. We recommended that the State agency establish policies, procedures, and internal controls to:

- create a general ledger accounts receivable control account and a sufficiently detailed subsidiary accounts receivable system to track drug rebate activity;
- ensure that manufacturers are billed timely and accurately, and adjust billing units for inaccurately billed injectable medications;
- account for interest due and verify the accuracy of interest payments received; and
- actively work to resolve manufacturer disputes, review inactive accounts periodically and write off accounts that are no longer collectible, as allowed by CMS thresholds, and when appropriate, use the State hearing mechanism to resolve longstanding disputes.

The State agency concurred with our findings and recommendations.

This current review of Nevada is part of a nationwide series of reviews conducted to determine whether States have addressed the weaknesses in accountability for and internal controls over their drug rebate programs found in the previous reviews. Additionally, because the Deficit Reduction Act of 2005 required States as of January 2006 to begin collecting rebates on single source drugs administered by physicians, this series of reviews will also determine whether States have complied with the new requirement.

OBJECTIVES

Our objectives were to determine whether the State agency had (1) implemented the recommendations made in our previous audit of the Nevada drug rebate program and (2) established controls over collecting rebates on single source drugs administered by physicians.

SUMMARY OF FINDINGS

Regarding the first objective, the State agency implemented the recommendations from our prior audit that related to rebate billings and dispute resolution. The State agency partly implemented the recommendations related to the accounts receivable system and interest accrual and collection.

- **Accounts Receivable System.** Although the State agency did not create a general ledger accounts receivable control account, it notified upper management of the drug rebate receivable balance by providing a report to the State Controller's office at the end of each fiscal year. However, the State agency did not create a sufficiently detailed subsidiary accounts receivable system to track drug rebate activity before 2003 by NDC. As a result, the State agency cannot actively work to resolve any remaining pre-2003 drug rebate balances.

- **Interest Accrual and Collection.** The State agency accounted for interest due on disputed, late, and unpaid rebate payments. However, it did not verify the accuracy of interest payments received. As a result, the State agency could not assure that it collected all of the interest owed on disputed, late, and unpaid balances.

Regarding the second objective, the State agency established controls over collecting rebates on single source drugs administered by physicians.

RECOMMENDATIONS

We recommend that the State agency implement policies, procedures, and internal controls to:

- create a sufficiently detailed subsidiary accounts receivable system to track drug rebate activity by NDC for all drug rebate balances and

- verify the accuracy of interest payments received.

STATE AGENCY COMMENTS

In comments on the draft report (included as the Appendix), the State agency did not concur fully with our findings and recommendations. Regarding the first recommendation, the State agency commented that it was not feasible to track pre-2003 drug rebate activity by NDC because of limitations in the accounts receivable system used for that period. The State agency did not concur with our statement that the State agency could not actively work to resolve the pre-2003 drug rebate balances and commented that its fiscal agency has actively pursued collection of pre-2003 balances. For the remaining pre-2003 balances, the State agency commented that most of them were uncollectible and that it would work with its fiscal agent to identify the uncollectible balances so that they can be properly written off. The State agency questioned whether attempting to implement a system to track pre-2003 drug rebate activity by NDC was cost effective.

Regarding the second recommendation, the State agency did not fully concur with our statement that neither the State agency nor its fiscal agent verified the accuracy of interest collected. However, the State agency commented that its fiscal agent had developed a methodology to manually verify the interest paid by manufacturers against the actual amount of interest due.

OFFICE OF INSPECTOR GENERAL RESPONSE

Based on the State agency's comment, we modified our statement that the State could not actively work to resolve the pre-2003 drug rebate balances. We continue to recommend that the State agency create a sufficiently detailed subsidiary accounts receivable system to track drug rebate activity by NDC for all drug rebate balances, unless CMS agrees that the remaining pre-2003 balances are uncollectible and can be written off.

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INTRODUCTION

BACKGROUND

Pursuant to Title XIX of the Social Security Act (the Act), the Medicaid program provides medical assistance to certain low-income individuals and individuals with disabilities. The Federal and State Governments jointly fund and administer the Medicaid program. At the Federal level, the Centers for Medicare & Medicaid Services (CMS) administers the program. Each State administers its Medicaid program in accordance with a CMS-approved State plan. Although the State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements.

Drug Rebate Program

The Medicaid drug rebate program, which began in 1991, is set forth in section 1927 of the Act. For a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the program, the manufacturer must enter into a rebate agreement with CMS and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each undertake certain functions in connection with the drug rebate program. In Nevada, the Department of Health and Human Services (the State agency) is responsible for the drug rebate program.

Pursuant to section II of the rebate agreement and section 1927(b) of the Act, manufacturers are required to submit a list to CMS of all covered outpatient drugs and to report each drug's average manufacturer price and, where applicable, best price. Based on this information, CMS calculates a unit rebate amount for each covered outpatient drug and provides the amounts to States quarterly.

Section 1927(b)(2)(A) of the Act requires States to maintain drug utilization data that identifies, by National Drug Code (NDC), the number of units of each covered outpatient drug for which the States reimbursed providers. The number of units is applied to the unit rebate amount to determine the actual rebate amount due from each manufacturer. Section 1927(b)(2) of the Act requires States to provide the drug utilization data to CMS and the manufacturer. States also report drug rebate accounts receivable data on Form CMS-64.9R, "Medicaid Drug Rebate Schedule." This is part of Form CMS-64, "Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program," which summarizes actual Medicaid expenditures for each quarter and is used by CMS to reimburse States for the Federal share of Medicaid expenditures.

Physician-Administered Drugs

Section 6002(a) of the Deficit Reduction Act of 2005 (DRA) amends section 1927 of the Act and requires States, as of January 1, 2006, to collect and submit utilization data for single source drugs administered by physicians so that States may obtain rebates for the drugs.[1] Single source drugs are commonly referred to as "brand name drugs" and do not have generic equivalents.

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[1]This provision of the DRA expands the requirement to certain multiple source drugs administered by physicians after January 1, 2008.

In Nevada, physician-administered drugs are billed to the State Medicaid program on either a physician claim form or an outpatient hospital claim form. Before January 1, 2008, physician-administered drugs were billed on the claim forms using procedure codes that are part of the Healthcare Common Procedure Coding System. The procedure code identifies a drug by its active ingredient(s) and identifies the number of drug units (billing units) allowed per reimbursement for that procedure code. Because rebates are calculated and paid based on NDCs, each procedure code must be converted to an NDC. Additionally, the billing units for a procedure code may differ from the units used for rebate purposes (e.g., grams versus liters). Therefore, to determine rebates, the procedure codes must be converted into NDCs for single source drugs, and procedure code billing units must be converted into equivalent NDC billing units.

Effective January 1, 2008, the State agency required claim forms to include the NDCs (and NDC billing units) for all physician-administered drugs.

Prior Office of Inspector General Reports

In 2005, we issued a report on the results of audits of the Medicaid drug rebate programs in 49 States and the District of Columbia.[2] Those audits found that only four States had no weaknesses in accountability for and internal controls over their drug rebate programs. As a result of the weaknesses, we concluded that States lacked adequate assurance that all of the drug rebates due to the States were properly recorded and collected. Additionally, CMS did not have reliable information from the States to properly monitor the drug rebate program.

In our previous audit of the Nevada drug rebate program, we determined that the State agency had not established adequate policies, procedures, and internal controls over the Medicaid drug rebate program.[3] Specifically, we identified weaknesses in the following areas: (1) accounts receivable system, (2) rebate billings, (3) interest accrual and collection, and (4) dispute resolution. We recommended that the State agency establish policies, procedures, and internal controls to:

- create a general ledger accounts receivable control account and a sufficiently detailed subsidiary accounts receivable system to track drug rebate activity;[4]

- ensure that manufacturers are billed timely and accurately, and adjust billing units for inaccurately billed injectable medications;

- account for interest due and verify the accuracy of interest payments received; and

[2]"Multistate Review of Medicaid Drug Rebate Programs" (A-06-03-00048), issued July 6, 2005; Arizona was not included because it did not operate a drug rebate program.

[3]"Audit of Medicaid Drug Rebate Program in Nevada" (A-09-03-00033), issued August 15, 2003.

[4]A sufficiently detailed system is one that tracks drug rebate activity by NDC.

- actively work to resolve manufacturer disputes, review inactive accounts periodically and write off accounts that are no longer collectible, as allowed by CMS thresholds, and when appropriate, use the State hearing mechanism to resolve longstanding disputes.

The State agency concurred with our findings and recommendations.

Nevada Drug Rebate Program

The State agency contracted with its fiscal agent, First Health Services Corporation, to perform all drug rebate program functions other than receiving rebate funds and quarterly reporting. The fiscal agent's responsibilities included preparing and mailing invoices to manufacturers, managing dispute resolution procedures, and accounting for rebates on single source drugs administered by physicians. Before January 1, 2008, the fiscal agent also converted procedure code billing units into equivalent NDC billing units.

The State agency reported an outstanding drug rebate balance of $4,831,437 on the June 30, 2006, Form CMS-64.9R. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately $32.1 million and collections of approximately $34.7 million.[5]

This current review of the Nevada drug rebate program is part of a nationwide series of reviews conducted to determine whether States have addressed the weaknesses in accountability for and internal controls over their drug rebate programs found in the previous reviews. Additionally, because the DRA required States as of January 2006 to begin collecting rebates on single source drugs administered by physicians, this series of reviews will also determine whether States have complied with the new requirement.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

Our objectives were to determine whether the State agency had (1) implemented the recommendations made in our previous audit of the Nevada drug rebate program and (2) established controls over collecting rebates on single source drugs administered by physicians.

Scope

We reviewed the State agency's current policies, procedures, and controls over the drug rebate program and the accounts receivable data reported on Form CMS-64.9R as of June 30, 2006.

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[5]The State agency originally reported rebate billings of approximately $16.6 million because it did not report rebate billings for two of the four quarters. However, the fiscal agent's records showed rebate billings of approximately $15.5 million for those quarters. To correct the understatement, the State agency made adjustments on the Form CMS-64.9Rs for September 30, 2006, and December 31, 2006.

We performed our fieldwork at the State agency in Carson City, Nevada, from January through May 2008. We also performed fieldwork at the fiscal agent's office in Richmond, Virginia.

Methodology

To accomplish our objectives, we

- reviewed section 1927 of the Act , section 6002(a) of the DRA, CMS guidance issued to State Medicaid directors, and other information pertaining to the Medicaid drug rebate program;

- reviewed the policies and procedures related to the fiscal agent's drug rebate accounts receivable system;

- interviewed State agency officials and fiscal agent staff to determine the policies, procedures, and controls that related to the Medicaid drug rebate program;

- reviewed copies of Form CMS-64.9R for the period July 1, 2005, through June 30, 2006;

- reviewed supporting documentation for rebates invoiced, adjustments, and rebate and interest payments received for the quarter ended June 30, 2006;

- interviewed fiscal agent staff to determine the processes used in converting physician services claims data into drug rebate data related to single source drugs administered by physicians; and

- reviewed rebate listings of billings and reimbursements for procedure codes related to single source drugs administered by physicians for the period January 1 through June 30, 2006.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

FINDINGS AND RECOMMENDATIONS

The State agency implemented the recommendations from our prior audit that related to rebate billings and dispute resolution. The State agency partly implemented the recommendations related to the accounts receivable system and interest accrual and collection. In addition, the State agency established controls over collecting rebates on single source drugs administered by physicians.

IMPLEMENTATION OF PRIOR RECOMMENDATIONS

The State agency partly implemented the recommendations from our prior audit that related to the accounts receivable system and interest accrual and collection.

Federal Regulations

Pursuant to 42 CFR § 433.32(a), States are required to "[m]aintain an accounting system and supporting fiscal records to assure that claims for Federal funds are in accord with applicable Federal requirements."

Accounts Receivable System

In our prior audit, we determined that the State agency did not maintain a general ledger accounts receivable control account nor maintain its subsidiary accounts receivable system at a sufficiently detailed level to accurately account for drug rebate activity. Although the State agency had not created a general ledger accounts receivable control account, it notified upper management of the drug rebate receivable balance by providing a report to the State Controller's office at the end of each fiscal year. However, as of the end of our fieldwork, the State agency had not created a sufficiently detailed subsidiary accounts receivable system to track drug rebate activity for drug rebate balances before 2003.

Although the subsidiary accounts receivable system tracked drug rebate activity for 2003 and later years by NDC, it did not track the pre-2003 activity by NDC. The 2002 activity was tracked only by quarter and year for each manufacturer. The pre-2002 activity was tracked only by manufacturer. As a result, the State agency cannot work to resolve any remaining pre-2003 drug rebate balances.

Interest Accrual and Collection

In our prior audit, we determined that the State agency did not have adequate controls to accurately account for interest due on disputed, late, and unpaid rebate payments nor to ensure that interest payments received from manufacturers were accurate. Since our prior audit, the State agency has accounted for interest due on disputed, late, and unpaid rebate payments. However, as of the end of our fieldwork, the State agency had not implemented a procedure to verify the accuracy of interest payments received from manufacturers.

Section(V)(b) of the rebate agreement between CMS and manufacturers requires manufacturers to pay interest on late rebate payments, and CMS program release 29 requires interest to be collected.[6] Neither the State agency nor its fiscal agent verified the accuracy of interest payments received from manufacturers. The fiscal agent believed that it was the manufacturers' responsibility to accurately calculate and pay the interest owed. However, without verification that interest paid by manufacturers was accurate, the State agency could not assure that it

[6]CMS has issued guidance to State Medicaid directors pertaining to the drug rebate program and posts the program releases on its Web site at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/02_StateReleases.asp. Accessed April 22, 2008.

collected all of the interest owed on disputed, late, and unpaid balances. The State agency indicated that it planned to work with its fiscal agent on the verification of interest payments received.

PHYSICIAN-ADMINISTERED SINGLE SOURCE DRUGS

The State agency established controls over collecting rebates for single source drugs administered by physicians as required by the DRA. For the procedure codes on the crosswalk, the State agency paid $1,042,893 in claims for physician-administered drugs from January through June 2006 and billed manufacturers for rebates totaling $144,567.

RECOMMENDATIONS

We recommend that the State agency implement policies, procedures, and internal controls to:

- create a sufficiently detailed subsidiary accounts receivable system to track drug rebate activity by NDC for all drug rebate balances and

- verify the accuracy of interest payments received.

STATE AGENCY COMMENTS

In comments on the draft report (included as the Appendix), the State agency did not concur fully with our findings and recommendations. Regarding the first recommendation, the State agency commented that it was not feasible to track pre-2003 drug rebate activity by NDC because of limitations in the accounts receivable system used for that period. The State agency did not concur with our statement that the State agency could not actively work to resolve the pre-2003 drug rebate balances and commented that its fiscal agency has actively pursued collection of pre-2003 balances. For the remaining pre-2003 balances, the State agency commented that most of them were uncollectible and that it would work with its fiscal agent to identify the uncollectible balances so that they can be properly written off. The State agency questioned whether attempting to implement a system to track pre-2003 drug rebate activity by NDC was cost effective.

Regarding the second recommendation, the State agency did not fully concur with our statement that neither the State agency nor its fiscal agent verified the accuracy of interest collected. However, the State agency commented that its fiscal agent had developed a methodology to manually verify the interest paid by manufacturers against the actual amount of interest due.

OFFICE OF INSPECTOR GENERAL RESPONSE

Based on the State agency's comment, we modified our statement that the State could not actively work to resolve the pre-2003 drug rebate balances. We continue to recommend that the State agency create a sufficiently detailed subsidiary accounts receivable system to track drug rebate activity by NDC for all drug rebate balances, unless CMS agrees that the remaining pre-2003 balances are uncollectible and can be written off.

APPENDIX

STATE OF NEVADA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH CARE FINANCING AND POLICY
1100 E. William Street, Suite 101
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(775) 684-3600

JIM GIBBONS
Governor

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Director

CHARLES DUARTE
Administrator

July 10, 2008

Lori A. Ahlstrand
Regional Inspector General for Audit Services
Region IX Audit Services
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

Subject: Report Number A-09-08-00026
State of Nevada Division of Health Care Financing and Policy
Drug Rebate Audit
State Response to Draft OIG Audit Report

Dear Ms: Ahlstrand:

In response to your report on the Medicaid Drug Rebate Program in Nevada, we concur with your findings that the state has implemented recommendations from the 2003 audit regarding rebate billings and dispute resolution. The Division of Health Care Financing and Policy (DHCFP) does not concur fully with your findings and recommendations regarding the accounts receivable system and interest accrual and collection.

1. **Recommendation 1: Create a sufficiently detailed subsidiary accounts receivable system to track drug rebate activity by NDC for all drug rebate balances.**

   DHCFP does not accept the recommendation. In 2003 the OIG performed an audit of Nevada's drug rebate program and recommended that DHCFP "create a general ledger receivable control account and a sufficiently detailed subsidiary accounts receivable system to track drug rebate activity." DHCFP accepted this recommendation and responded that it would utilize FirstRebate on a prospective basis to track rebate activity by labeler, NDC code, year and quarter, batch number, and deposit date. DHCFP fully implemented the response to this recommendation and, since implementation, can track all rebate activity by NDC. The 2003 audit did not recommend that DHCFP create a system to account for rebate activities before 2003, nor did DHCFP agree to do this. In fact, it is not feasible for DHCFP to track pre-2003 rebate activity to the NDC level because the system used prior to FirstRebate stored at the labeler level and did not include NDC. When FirstRebate took over the contract, outstanding balances were rolled into a single quarter in the new system, but payment information was not transferred, so there is no way to match any remaining outstanding balances with NDC.

   In spite of this, FirstRebate has actively pursued collection of pre-2003 drug rebate balances. DHCFP, thus, takes issue with the statement that "the State agency could not actively work to resolve the pre-2003 drug rebate balances." In fact, more than $16 million dollars has been collected on the pre-2003 balances since the FirstRebate

program was implemented in Nevada. Of the remaining outstanding balances, both DHCFP and FirstRebate are of the opinion that most are uncollectible because of documentation and accounting issues inherent in the system previously used. DHCFP will be working with FirstRebate to identify the uncollectible balances so they can be properly written off.

2. **Recommendation 2: Verify the accuracy of interest payments received.**

   DHCFP does not fully concur with the statement, "Neither the state nor its fiscal agent verified the accuracy of interest collected." Currently, the FirstRebate system does an interest calculation on the date of invoice preparation that takes the average weekly t-bill rate and the outstanding balance to a daily level and calculates interest owed based on the days late of the payment. The application allows for interest received to be allocated against that figure and for the interest payment to be accepted as paid in full or not. Since the interest calculated is ahead of the payment, the interest paid by the manufacturer usually exceeds the amount due. The system then allows for an adjustment to be made to account for the interest in the days since mailing. Where interest paid is less than calculated, the system will continue to show interest due on prior quarter statements until the interest is paid or adjusted. In addition, FirstRebate staff has developed a methodology to manually verify the interest paid against the actual amount due. This methodology will be used check the amount of rebate due against the automated calculation on drug rebate payments that include interest payments.

DHCFP has fully complied with the recommendations in the 2003 OIG Drug Rebates audit report. DHCFP's response to those recommendations was implemented precisely as outlined in the response letter dated August 1, 2003. DHCFP lacks the capacity to go beyond what was agreed to do in 2003 and implement a system to track pre-2003 drug rebate activity by NDC. Given the likelihood that little or no rebate monies would be collected as a result of such an effort, DHCFP questions whether attempting to do this would be a wise use of the State General Funds and federal matching dollars that would be invested to accomplish it.

Sincerely,

Charles Duarte, Administrator,
Division of Health Care Financing and Policy

cc: Michael J. Willden, Director, Department of Health and Human Services
Elizabeth Aiello, Deputy Administrator DHCFP
Lynn Carrigan, Chief Financial Officer DHCFP
Doug Preussler, Audit Manager, OIG