Office Of Inspector General
Office Of Audit Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Region II
Jacob K. Javits Federal Building
26 Federal Plaza
New York, NY 10278

September 8, 2008

Report Number: A-02-07-01055

Richard F. Daines, M.D.
Commissioner
New York State Department of Health
14th Floor, Corning Tower
Empire State Plaza
Albany, New York 12237

Dear Dr. Daines:

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 New York." 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.

Pursuant to the principles of the Freedom of Information Act, 5 U.S.C. § 552, as amended by Public Law 104-231, OIG reports generally are made available to the public to the extent the information is not subject to exemptions in the Act (45 CFR part 5). Accordingly, this report will be posted on the Internet at http://oig.hhs.gov.

If you have any questions or comments about this report, please do not hesitate to call me, or contact Brenda Ryan, Audit Manager, at (212) 264-4677 or through e-mail at Brenda.Ryan@oig.hhs.gov. Please refer to report number A-02-07-01055 in all correspondence.

Sincerely,

James P. Edert

James P. Edert
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
Chicago, Illinois 60601

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

FOLLOW-UP AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN NEW YORK

Daniel R. Levinson
Inspector General

September 2008
A-02-07-01055

Office of Inspector General

http://oig.hhs.gov

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Department of Health and Human Services

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Notices

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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 New York, the Department of Health (the State agency) administers the Medicaid drug rebate program.

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 New York drug rebate program (A-02-03-01009), we determined that the State agency produced timely rebate billings and collections in accordance with sections 1927(b)(1) and 1927(b)(2) of the Act. However, we identified weaknesses in processes and controls for rebate billings, collections, dispute resolutions, and quarterly reporting. We recommended that the State agency:

- work with CMS to consider cost-effective measures that could achieve additional savings of approximately $3.3 million a year ($1.65 million Federal share) from entities entitled to discounts under section 340B of the Public Health Service Act (340B entities) that do not bill the State agency at discounted prices;

- strengthen its processes and controls for rebate billings, cash receipts, and collections in order to properly report the aged outstanding rebate amount to CMS on the "Medicaid Drug Rebate Schedule" (Form CMS-64.9R);

- improve its processes and controls to ensure timely recording, endorsement, and deposit of rebate funds; effective resolution of disputes; and the tracking and verification of interest due on rebate payments;

- ensure that the Federal Government receives the appropriate share of rebates for drugs for family planning services (approximately $730,000 in additional rebates a year); and

- use the estimate of $350.6 million in outstanding rebates ($175.3 million Federal share) as of June 30, 2002, as a starting point for a viable accounts receivable system for the rebate program.

The State agency agreed with our findings and recommendations with the following exceptions: the State agency did not agree with the use of the term "uncollected rebates" when referring to the total rebate balance and did not agree with the amount identified as uncollected rebates.

This current review of New York 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 New York drug rebate program and (2) established controls over collecting rebates on single source drugs administered by physicians.

SUMMARY OF FINDINGS

The State agency implemented the recommendations from our prior audit that related to achieving additional savings from 340B entities; ensuring timely recording, endorsement, and deposit of rebate funds; tracking and verifying interest due on late or disputed rebate payments; and crediting the Federal Government with the appropriate share of rebates for family planning drugs. The State agency partially implemented the recommendations related to properly reporting aged outstanding rebate amounts on its Form CMS-64.9R, effectively resolving disputes, and using the estimated amount of outstanding rebates as a starting point for a viable accounts receivable system. In addition, the State agency established controls over collecting rebates on single source drugs administered by physicians.

The State agency implemented a new accounts receivable system which greatly improved the overall operation of New York's drug rebate program, including its ability to track and identify outstanding rebates and to verify interest due on late or disputed rebates. However, when the State agency developed the system, it did not include any outstanding or disputed rebates for the period January 1, 1991, through March 31, 1999. Although the State agency maintains this information in hard copy files, it does not have a complete accounting of outstanding rebates for this period. As a result, the ending balance reported on the Form CMS-64.9R is understated because it does not reflect outstanding and disputed rebates for the period January 1, 1991, through March 31, 1999. Without a comprehensive accounting, the State agency cannot effectively pursue resolution of all outstanding rebates.

RECOMMENDATIONS

We recommend that the State agency:

- identify outstanding and disputed rebates for the period January 1, 1991, through March 31, 1999, and include these rebates in its accounts receivable system; and

- ensure that the aged rebate amount reported on its Form CMS-64.9R reflects all outstanding and disputed rebates.

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its comments on our draft report, the State agency agreed with our recommendations. The State agency indicated that it has begun developing a model accounts receivable system for tracking rebates for the period January 1, 1991, through March 31, 1999, which will interface with the State agency's existing system. The State agency further indicated that, after the development is complete and data is entered into the system, outstanding and disputed rebates for the period January 1, 1991, through March 31, 1999, will be reflected in the aged rebate amounts reported on the Form CMS-64.9R.

The State agency also indicated that the draft report did not entirely describe its comments on our previous audit. Specifically, the State agency indicated that it did not fully agree with the findings from the previous audit. Rather, the State agency indicated that it had disagreed with the amount identified as uncollected rebates. We revised our report accordingly. The State agency's comments appear in their entirety as the Appendix.

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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.

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 CMS Form-64.9R, "Medicaid Drug Rebate Schedule." This is part of the CMS Form-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.

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

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 New York drug rebate program, we determined that the Department of Health (the State agency) produced timely rebate billings and collections in accordance with sections 1927(b)(1) and 1927(b)(2) of the Act. However, we identified weaknesses in processes and controls for rebate billings, collections, dispute resolutions, and quarterly reporting.[3]

We recommended that the State agency:

- work with CMS to consider cost-effective measures that could achieve additional savings of approximately $3.3 million a year ($1.65 million Federal share) from entities entitled to discounts under section 340B of the Public Health Service Act (340B entities) that do not bill the State agency at discounted prices;

- strengthen its processes and controls for rebate billings, cash receipts, and collections in order to properly report the aged outstanding rebate amount to CMS on the Form CMS-64.9R;

- improve its processes and controls to ensure timely recording, endorsement, and deposit of rebate funds; effective resolution of disputes; and the tracking and verification of interest due on rebate payments;

- ensure that the Federal Government receives the appropriate share of rebates for drugs for family planning services (approximately $730,000 in additional rebates a year); and

- use the estimate of $350.6 million in outstanding rebates ($175.3 million Federal share) as of June 30, 2002, as a starting point for a viable accounts receivable system for the rebate program.

The State agency agreed with our findings and recommendations with the following exceptions: the State agency did not agree with the use of the term "uncollected rebates" when referring to the total rebate balance and did not agree with the amount identified as uncollected rebates.

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[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]"Medicaid Drug Rebate Program in New York State" (A-02-03-01009), issued August 18, 2004.

New York Drug Rebate Program

In New York, two offices within the State agency (the Office of Health Insurance Programs and the Fiscal Management Group) and the State's fiscal agent are responsible for performing all drug rebate program functions. The State agency reported an outstanding drug rebate balance of $278,655,704 on its June 30, 2007, Form CMS-64.9R. However, $229,416,956 of this amount related to quarterly billings and was not past due as of June 30, 2007. For the quarter ending June 30, 2007, the State agency reported rebate billings of approximately $287.8 million and collections of $287.4 million.

Physician-administered drugs are billed to the State Medicaid program on a physician claim form using procedure codes that are part of the Healthcare Common Procedure Coding System. The NDC is not included on the physician claim form. 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.

This current review of the New York State 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 New York 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 its Form CMS-64.9R as of June 30, 2007.

We performed our fieldwork at the State agency in Albany, New York, and at its fiscal agent in Rensselaer, New York, from October 2007 through March 2008.

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 State agency's drug rebate accounts receivable system;

- interviewed State agency officials 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 October 1, 2006, through June 30, 2007;

- reviewed accounts receivable records as of June 30, 2007;

- reviewed State agency invoices for 340B entities that do not bill Medicaid at discounted prices;

- interviewed State agency staff to obtain an understanding of the process for tracking and verifying interest due on late or disputed rebates;

- determined if the Federal Government received the appropriate share of rebates for family planning drugs;

- interviewed State agency 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 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 achieving additional savings from 340B entities; ensuring timely recording, endorsement, and deposit of rebate funds; tracking and verifying interest due on late or disputed rebate payments;

and crediting the Federal Government with the appropriate share of rebates for family planning drugs. The State agency partially implemented the recommendations related to properly reporting aged outstanding rebate amounts on its Form CMS-64.9R, effectively resolving disputes, and using the estimated amount of outstanding rebates as a starting point for a viable accounts receivable system. In addition, the State agency established controls over collecting rebates on single source drugs administered by physicians.

IMPLEMENTATION OF PRIOR RECOMMENDATIONS

In our prior audit of the New York drug rebate program, we determined that the State agency did not:

- have procedures in place to determine whether 340B providers had billed Medicaid at discounted prices;
- properly report aged outstanding rebate amounts on its Form CMS-64.9R;
- have adequate procedures to ensure timely recording, endorsement, and deposit of rebate funds;
- have an efficient system to monitor and resolve outstanding disputes;
- implement procedures to accrue or verify interest due on late rebates;
- credit the Federal Government with the appropriate share of rebate collections on family planning drugs; and
- maintain an effective accounts receivable system for its rebate program.

Since our prior audit, we determined that the State agency has (1) developed procedures to identify and invoice 340B entities that had not billed Medicaid at discounted prices, (2) improved procedures for recording, endorsing, and depositing rebate funds, (3) implemented procedures to track and verify interest due from manufacturers on late or disputed rebates, (4) revised existing procedures to ensure that the Federal Government is credited with the appropriate share of rebate collections on family planning drugs, and (5) redesigned its drug rebates accounts receivable system. However, the State agency cannot readily identify all rebates requiring resolution. In addition, the aged outstanding rebate amount reported on its Form CMS-64.9R does not account for all outstanding and disputed rebates.

Pursuant to 42 CFR § 433.32(a), States are required to maintain an accounting system and supporting fiscal records to assure that claims for Federal funds are in accordance with applicable Federal requirements. The State agency implemented a new accounts receivable system which greatly improved the overall operation of New York's drug rebate program, including its ability to track and identify outstanding rebates and to verify interest due on late or disputed rebates. However, when the State agency developed the system, it did not include any outstanding or disputed rebates for the period January 1, 1991, through March 31, 1999.

Although the State agency maintains this information in hard copy files, it does not have a complete accounting of outstanding rebates for this period. As a result, the ending balance reported on the Form CMS-64.9R is understated because it does not reflect outstanding and disputed rebates for the period January 1, 1991, through March 31, 1999. Without a comprehensive accounting, the State agency cannot effectively pursue resolution of all outstanding rebates.

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. The State agency paid $31,198,779 in claims for physician-administered drugs during the period January 1 through June 30, 2006, and billed manufacturers for rebates totaling $5,828,282.

RECOMMENDATIONS

We recommend that the State agency:

- identify the amount of outstanding and disputed rebates for the period January 1, 1991, through March 31, 1999, and include these rebates in its accounts receivable system; and

- ensure that the aged rebate amount reported on its Form CMS-64.9R reflects all outstanding and disputed rebates.

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its July 24, 2008, written comments on our draft report, the State agency agreed with our recommendations. The State agency indicated that it has begun developing a model accounts receivable system for tracking rebates for the period January 1, 1991, through March 31, 1999, which will interface with the State agency's existing system. The State agency further indicated that, after the development is complete and data is entered into the system, outstanding and disputed rebates for the period January 1, 1991, through March 31, 1999, will be reflected in the aged rebate amounts reported on the Form CMS-64.9R.

The State agency also indicated that the draft report did not entirely describe its comments on our previous audit. Specifically, the State agency indicated that it did not fully agree with the findings from the previous audit. Rather, the State agency indicated that it had disagreed with the amount identified as uncollected rebates. We revised our report accordingly. The State agency's comments appear in their entirety as the Appendix.

APPENDIX

STATE OF NEW YORK
DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Richard F. Daines, M.D.
Commissioner

Wendy E. Saunders
Chief of Staff

July 24, 2008

James P. Edert
Regional Inspector General for Audit Services
Department of Health and Human Services
Region II
Jacob Javitz Federal Building
26 Federal Plaza
New York, New York 10278

Ref. No. A-02-07-01055

Dear Mr. Edert:

Enclosed are the New York State Department of Health's comments on the Department of Health and Human Services, Office of Inspector General's draft audit report A-02-07-01055 on "Follow-Up Audit of the Medicaid Drug Rebate Program in New York State."

Thank you for the opportunity to comment.

Sincerely,

Wendy Saunders

Wendy E. Saunders
Chief of Staff

Enclosure

cc: Stephen Abbott
Deborah Bachrach
Homer Charbonneau
Ronald Farrell
Gail Kerker
Sandra Pettinato
Robert W. Reed

New York State Department of Health Comments on the Department of Health and Human Services Office of Inspector General Draft Audit Report A-02-07-01055 on "Follow-Up Audit of the Medicaid Drug Rebate Program in New York"

The following are the New York State Department of Health's (Department) comments in response to the Department of Health and Human Services, Office of Inspector General's (OIG) draft audit report A-02-07-01055 on "Follow-Up Audit of the Medicaid Drug Rebate Program in New York" (A-02-03-01009), including a general comment followed by the Department's response to the specific recommendation contained in the report.

General Comment:

The audit report twice states (on pages ii and 2) that the Department agreed with the OIG findings from the earlier audit (A-02-03-01009), which is not entirely accurate. The Department's significant disagreement with the amount identified for uncollected rebates should be addressed and clarified in the latest report. Specifically, Department comments forwarded October 22, 2004 in response to the earlier audit state:

> "The Department agrees that it must identify a starting point for a viable accounts receivable system. However, the OIG audit report seriously overstates the amount uncollected. As discussed below, the Department believes that a more accurate estimate of uncollected rebates is $31.6 million.
>
> OIG's recommendation that there is '$350.6 million in uncollected rebates' is misleading. At the time of the audit, the estimated dispute balance of uncollected rebates was $31.6 million, which is the total amount outstanding since the inception of the program in 1991. The report estimate mischaracterizes rebate amounts due and owing for a current quarter as an 'uncollected rebate.' In fact, most of this amount is included in the federally prescribed collection process that affords manufacturers a set amount of time to review their invoices and remit the rebate and, therefore, is not 'uncollected.'"

OIG Recommendation:

OIG recommends that the State agency:

- identify the amount of outstanding and disputed rebates for the period January 1, 1991 through March 31, 1999, and include these rebates in its accounts receivable system; and

- ensure that the aged rebate amount reported on its Form CMS-64.9R reflects all outstanding and disputed rebates.

Department Response:

The Department has initiated development of a model accounts receivable system for tracking drug rebates during the period January 1, 1991 through March 31,1999, which will interface with the existing system. Hiring and training of additional staff will be required to complete this task. Upon completion and data-entry of accounts receivable data into the new accounting system, outstanding and disputed rebates for the period January 1, 1991 through March 31, 1999 will be reflected in the Form CMS-64.9R rebate aging amounts.