



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office Of Inspector General
Office Of Audit Services

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

June 12, 2008

Report Number: A-02-07-01056

Ms. Jennifer Velez
Commissioner
New Jersey Department of Human Services
Division of Medical Assistance and Health Services
222 South Warren Street
P.O. Box 700
Trenton, New Jersey 08625-0700

Dear Ms. Velez:

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 Jersey." 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 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-02-07-01056 in all correspondence.

Sincerely,

A handwritten signature in cursive script that reads "James P. Edert".

James P. Edert
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

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 NEW JERSEY**



Daniel R. Levinson
Inspector General

June 2008
A-02-07-01056

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. 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 Jersey, the Department of Human Services (the State agency), Division of Medical Assistance and Health Services, 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 Jersey drug rebate program (A-02-03-01024), we determined that the State agency had adequate controls over its drug rebate program, with the exceptions of reporting rebate activity on its "Medicaid Drug Rebate Schedule" (Form CMS-64.9R), offsetting rebate collections against Federal expenditures, resolving disputes timely, estimating and accruing interest on late or disputed rebates, and reporting interest collected on late rebate payments to CMS. We recommended that the State agency:

- revise its reporting procedures to ensure that Form CMS-64.9R is accurate and complete;
- reduce its drawdowns of Federal funds through timely consideration of the drug rebates it has collected;
- implement procedures to offer a hearing mechanism when dispute resolution procedures are not successful within 60 days;
- estimate and accrue interest on overdue rebate balances; and
- report \$1,134,372 (\$567,186 Federal share) of interest collected on late rebate payments as of June 30, 2002, and update its procedures to ensure that interest earned on late rebate payments in subsequent periods is reported on the "Quarterly Statement of Medicaid Expenditures" (Form CMS-64).

The State agency agreed with our findings and recommendations with one exception: the State agency did not agree with our recommendation to estimate and accrue interest on overdue rebate balances. The State agency stated that it would not be feasible to invoice manufacturers for

interest on overdue rebates because invoicing interest is complex and subject to continual rate adjustments or changes in units.

This current review of New Jersey 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 Jersey 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 drawing down Federal funds, offering a hearing mechanism for resolving disputes, and reporting interest on late rebate payments on its Form CMS-64. Although the State agency agreed to revise its procedures for the preparation of its Form CMS-64.9R, no revisions have been made. The State agency also did not implement our recommendation to estimate and accrue interest on overdue rebate balances. The State agency established controls over collecting rebates on single source drugs administered by physicians.

The State agency did not report current-quarter drug rebate activity on its Form CMS-64.9R. Rather, the State agency reported the current quarter's drug rebate activity as prior period adjustments in the quarter that the service was provided instead of the quarter the rebate was invoiced. Without accurate information on the State agency's rebate activity, CMS cannot provide adequate oversight of the Medicaid drug rebate program.

In addition, the State agency did not have adequate procedures to ensure that the entire amount of interest due from manufacturers on late or disputed rebates was collected. The State agency relied upon manufacturers to compute and submit the proper amount of interest with overdue rebate payments. As a result, the State agency could not assure that all interest due on overdue rebates was paid.

RECOMMENDATIONS

We recommend that the State agency:

- revise its reporting procedures to ensure that its Form CMS-64.9R is accurate, and

- improve its procedures to ensure the entire amount of interest due from manufacturers on late or disputed rebates is collected.

STATE AGENCY COMMENTS

In its June 10, 2008, written comments on the draft report, the State agency concurred with our recommendations. 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 the 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.

¹This 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 Jersey drug rebate program, we determined that the Department of Human Services (the State agency) had adequate controls over its drug rebate program, with the exceptions of reporting rebate activity on its Form CMS-64.9R, offsetting rebate collections against Federal expenditures, resolving disputes timely, estimating and accruing interest on late or disputed rebates, and reporting interest collected on late rebate payments to CMS.³

We recommended that the State agency:

- revise its reporting procedures to ensure that Form CMS-64.9R is accurate and complete;
- reduce its drawdowns of Federal funds through timely consideration of the drug rebates it has collected;
- implement procedures to offer a hearing mechanism when dispute resolution procedures are not successful within 60 days;
- estimate and accrue interest on overdue rebate balances; and
- report \$1,134,372 (\$567,186 Federal share) of interest collected on late rebate payments as of June 30, 2002, and update its procedures to ensure that interest earned on late rebate payments in subsequent periods is reported on its Form CMS-64.

The State agency agreed with our findings and recommendations with one exception: the State agency did not agree with our recommendation to estimate and accrue interest on overdue rebate balances. The State agency stated that invoicing interest is complex and subject to continual rate adjustments or changes in units.

New Jersey Drug Rebate Program

In New Jersey, three offices within the State agency's Division of Medical Assistance and Health Services (the Office of Information and Telecommunications, the Office of Utilization Management, and the Bureau of Financial Reporting) are responsible for performing all drug rebate program functions other than receiving rebate funds. The State agency reported an

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"Review of the Medicaid Drug Rebate Program in New Jersey" (A-02-03-01024), issued October 14, 2004.

outstanding drug rebate balance of \$57,768,028 on its June 30, 2006, Form CMS-64.9R. In addition, for the quarter ending June 30, 2006, the State agency reported rebate billings of \$35,024,336 and collections of \$74,636,320.

Physician-administered drugs were billed to the State Medicaid program on a physician claim form using procedure codes that are part of the Healthcare Common Procedure Coding System.⁴ 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 Jersey 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 Jersey 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, 2006.

We performed our fieldwork at the State agency in Trenton, New Jersey, from October 2007 through January 2008.

⁴Beginning August 6, 2007, New Jersey required physicians to use NDCs to bill Medicaid for physician-administered drugs.

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 July 1, 2005, through June 30, 2006;
- reviewed accounts receivable records as of June 30, 2006;
- traced interest collected on late rebate payments to Forms CMS-64 for the period July 1, 2005, through June 30, 2006;
- reviewed State regulations to determine whether a hearing mechanism for dispute resolution was available to drug manufacturers;
- reviewed documentation related to the State agency's drawdown of Federal funds for the period July 1, 2005, through June 30, 2006;
- 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 drawing down Federal funds, offering a hearing mechanism for resolving disputes, and reporting interest on late rebate payments on Form CMS-64. Although the State agency agreed to revise its procedures for the preparation of its Form CMS-64.9R, no revisions have been made. The State

agency also did not implement our recommendation to estimate and accrue interest. The State agency established controls over collecting rebates on single source drugs administered by physicians.

IMPLEMENTATION OF PRIOR RECOMMENDATIONS

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

- accurately report information on its Form CMS-64.9R;
- consider drug rebate collections when determining its needs for drawdown of Federal funds;
- implement a hearing mechanism for dispute resolutions;
- have processes to estimate or accrue interest on late or disputed rebates; and
- report interest collected on late rebate payments to CMS.

Since our prior audit, the State agency has (1) reduced its drawdowns of Federal funds by the amount of drug rebates collected, (2) made available to manufacturers a hearing mechanism when dispute resolution procedures are not successful within 60 days, and (3) reported interest collected on late rebate payments on its Form CMS-64. However, as of the end of our fieldwork, the State agency had not revised its reporting procedures to ensure that its Form CMS-64.9R is accurate or implemented a process to estimate or accrue interest for late or disputed rebates.

To facilitate periodic monitoring of rebate activity by CMS, States are required to report their quarterly rebate invoices and collections on Form CMS-64.9R. Section 2500.6 of the CMS State Medicaid manual instructs States to present a complete, accurate, and full disclosure of all drug rebates and collections. States are also instructed to report rebates and collections in the quarter invoiced. The State agency did not report current-quarter drug rebate activity on its Form CMS-64.9R. Rather, the State agency reported the current quarter's drug rebate activity as prior period adjustments in the quarter that the service was provided instead of the quarter the rebate was invoiced. Without accurate information on the State agency's rebate activity, CMS cannot provide adequate oversight of the Medicaid drug rebate program.

Pursuant to section V(b) of the rebate agreement between manufacturers and CMS, manufacturers are required to pay interest on late or disputed rebates. In this respect, CMS Medicaid Drug Rebate Program Release No. 65 states that it is the manufacturers' responsibility to calculate the amount of interest due States on late rebate payments and the State's responsibility to track the collection of interest due. While the State agency verified some interest payments, its procedures were inadequate to ensure that the entire amount of interest due from manufacturers was collected. The State agency relied upon manufacturers to compute and submit the proper amount of interest with its overdue rebate payments. However, if the amount of total interest due was not received, additional steps were not always taken by the State agency

to collect the correct amount of interest. As a result, the State agency could not assure that all interest due on overdue rebates was paid.

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 \$3,786,640 in claims for physician-administered drugs during the period January through June 2006 and billed manufacturers for rebates for these drugs totaling \$312,660.

RECOMMENDATIONS

We recommend that the State agency:

- revise its reporting procedures to ensure that Form CMS-64.9R is accurate, and
- improve its procedures to ensure the entire amount of interest due from manufacturers on late or disputed rebates is collected.

STATE AGENCY COMMENTS

In its June 10, 2008, written comments on the draft report, the State agency concurred with our recommendations. The State agency's comments appear in their entirety as the Appendix.

APPENDIX



State of New Jersey
DEPARTMENT OF HUMAN SERVICES
DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES
PO Box 712
TRENTON NJ 08625-0712
TELEPHONE 1-800-356-1561

JON S. CORZINE
Governor

JENNIFER VELEZ
Commissioner

JOHN R. GUHL
Director

June 10, 2008

James P. Edert
Regional Inspector General for Audit Services
Department of Health and Human Services
Office of Inspector General
Office of Audit Services
Region II
Jacob K. Javits Federal Building – Room 3900
New York, NY 10278

Report Number A-02-07-01056

Dear Mr. Edert:

This is in response to your correspondence of April 2, 2008 concerning the Department of Health and Human Services, Office of the Inspector General's (OIG) draft audit report entitled "Follow-Up Audit of the Medicaid Drug Rebate Program in New Jersey." Your letter provides an opportunity to comment on the draft audit report.

The draft report correctly indicates the State agency implemented the recommendations from the prior audit that related to drawing down Federal funds, offering a hearing mechanism for resolving disputes and reporting interest on late rebate payments on its Form CMS-64. Additionally, the State agency established controls over collecting rebates on single source drugs administered by physicians. However, this draft report includes two findings and recommendations. The auditor's findings indicate the State does not correctly report drug rebate activity on Form CMS-64R and the State could not assure that all interest due on overdue rebates was paid.

In summary, the recommendations contained in the report and our responses are provided below:

1. New Jersey should revise its reporting procedures to ensure that its Form CMS-64.9R is accurate.

New Jersey will make the necessary revisions to comply with the requirements of Form CMS-64.9R to ensure its accuracy.

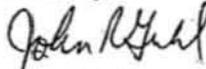
James P. Edert
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2. New Jersey should improve its procedures to ensure the entire amount of interest due from manufacturers on late or disputed claims is collected.

New Jersey will examine interest payments more closely to ensure interest calculations are in accordance with guidelines and regulations established by CMS. Procedures will be reviewed to ensure interest collections are accurate, efficient and effective.

The opportunity to review and comment on this draft report is greatly appreciated. If you have any questions or require additional information, please contact me or David Lowenthal at 609-588-7933.

Sincerely,



John R. Guhl
Director

JRG: L

c: Jennifer Velez
David Lowenthal
Patricia Dix
Rebecca Joslin