DEPARTMENT OF HEALTH & HUMAN SERVICES **OFFICE OF INSPECTOR GENERAL**

OFFICE OF AUDIT SERVICES
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October 14, 2004

Report Number: A-02-03-01024

Ms. Gwendolyn L. Harris
Commissioner
State of New Jersey
Department of Human Services
Division of Medical Assistance and Health Services
222 South Warren Street, 6th Floor
Trenton, New Jersey 08625-0700

Dear Ms. Harris:

Enclosed 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 Medicaid Drug Rebate Program in New Jersey." A copy of this report will be forwarded to the action official noted below for his/her review and any action deemed necessary.

Final determination as to actions taken on all matters reported will be made by the HHS action official named below. We request that you respond to the HHS action 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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Any questions or further comments on any aspect of the report are welcome. Please address them to me at (212) 264-4620 or though e-mail at Timothy.Horgan@oig.hhs.gov.

To facilitate identification, please refer to Report Number A-02-03-01024 in all correspondence relating to this report.

Sincerely yours,

Timothy J. Horgan
Regional Inspector General
for Audit Services

Enclosures - as stated

Direct Reply to HHS Action Official:

Ms. Sue Kelly, Regional Administrator
Center for Medicaid
Centers for Medicare & Medicaid Services
26 Federal Plaza, Room 3811
New York, New York 10278

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF THE MEDICAID DRUG REBATE PROGRAM IN NEW JERSEY

OCTOBER 2004
A-02-03-01024

Office of Inspector General

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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.

EXECUTIVE SUMMARY

BACKGROUND

The Omnibus Budget Reconciliation Act (OBRA) of 1990 established the Medicaid drug rebate program (rebate program) to address concerns about the costs that Medicaid was paying for outpatient drugs. The purpose of the rebate program is to make Medicaid costs similar to discounted prices that pharmaceutical manufacturers offer to other large purchasers. Under the program, State Medicaid agencies bill manufacturers for rebates based on the States' records of drugs dispensed during the quarter. At the end of each quarter, the States are required to report their rebate activity and their outstanding rebate amounts to the Centers for Medicare & Medicaid Services (CMS).

OBJECTIVES

Our objectives were to evaluate the State of New Jersey Department of Human Services (State Agency), Division of Medical Assistance & Health's accountability in terms of reporting outstanding rebate balances to CMS and its processes and controls as of June 30, 2002 for drug rebate billings, collections, and dispute resolutions.

FINDINGS

The State Agency produced timely rebate billings and collections in accordance with provisions of sections 1927 (b)(1) and 1927 (b)(2) of the Social Security Act (Act) and successfully avoided billings for duplicate discounts or rebates for drugs covered under section 340B of the Public Health Service Act, as required by section 1927 (a)(5) of the Act. There were, however, opportunities to improve the reporting of program results and accountability to CMS and to strengthen the processes for late and disputed rebates.

Specifically, the audit results indicated that the State Agency:

- understated the June 30, 2002 balance of outstanding drug rebates to CMS by $38,017,771

- could potentially have saved as much as $4,100,740 ($2,050,370 Federal share) in interest on Medicaid funds through more timely consideration of drug rebate collections when determining its needs for drawdowns of Federal funds

- had not implemented a hearing mechanism to resolve disputed rebates within 60 days

- did not have processes to estimate or accrue interest for late or disputed rebates, and

- did not report interest collected on late rebate payments as of June 30, 2002 in the amount of $1,134,372 ($567,186 Federal share) to CMS

We believe that the State Agency had not fully considered or implemented certain provisions of the rebate program as contained in 45 CFR §74.21(b), CMS instructions and advice in Section V of the Medicaid "Rebate Agreement", the State Medicaid Manual, and CMS "release" memorandums for the rebate program. We also noted that the State Agency officials had not fully reconciled the "Medicaid Drug Rebate Schedule" (Form CMS 64.9R) to underlying accounting records and apparently misunderstood instructions from the CMS regional office about the reporting of interest collected from drug manufacturers.

RECOMMENDATIONS

We recommend 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)

AUDITEE COMMENTS

The State Agency indicated that they have recorded adjustments amounting to $1,860,864 for errors identified on their Form CMS 64.9R. They did not, however, feel that it would be appropriate to include an estimate of drug costs incurred during the quarter ($36,156,907) as part of the outstanding rebate balance on the Form CMS 64.9R for the quarter ended June 30, 2002. With respect to reducing drawdowns by the amount of rebates collected, the State Agency asserted that its processes comply with the Cash Management Improvement Act, that the proposed changes to these processes might not be cost effective and that our analysis was inconclusive.[a]T

With respect to its controls for late and disputed rebates, the State Agency commented that it was in the process of implementing the recommended improvements to offer hearings when disputes are not resolved. Regarding the monitoring of interest due on overdue rebates, however, the State Agency reiterated that it does verify interest

[a] Office of Inspector General note: The State Agency subsequently informed us that they recently implemented the recommendation

submitted by manufacturers but that it would not be feasible to invoice manufacturers for interest on overdue rebates. Finally, the State Agency noted that it had both adjusted its procedures and also adjusted $1,134,372 ($567,186 Federal share) on its Form CMS 64 for the quarter ended June 30, 2003 to account for unreported interest collected on rebate amounts.

The text of the State Agency's response is presented at Appendix A.

OFFICE OF INSPECTOR GENERAL RESPONSE

The State Agency's adjustments to Form CMS 64.9R accurately account for the reconciling items that had been improperly reported to CMS. Regarding the concerns raised about including an estimate of current rebate invoices on Form CMS 64.9R, we note that this was based not only on the instructions cited by the State Agency but, more importantly, on discussions with CMS officials responsible for oversight of the Medicaid drug rebate program. We, therefore, encourage the State Agency to dialogue with appropriate CMS officials about this matter. Concerning the timely consideration of rebate collections when requesting Federal funds, we note that drug rebates should have earned interest amounting to at least $125,000 during each quarter of the fiscal year ending on June 30, 2002 and, therefore, the recommended change in procedures would likely be cost effective. We also note that Footnote 4 of both the draft and final reports clearly indicates that the periodic commingling of drug rebate funds with funds from other programs would require a detailed analysis of transactions that would have expanded the scope of this audit to matters unrelated to the rebate program. We, nevertheless, believe that our analysis was sufficient to determine that the recommended procedural change should be given serious consideration. Finally, the fact that the State Agency recently implemented the recommendation would also appear to validate the merit of this finding.

With respect to the controls for late and disputed rebates, the State Agency is implementing the recommendation to offer hearings when disputes are not resolved. We note, however, that the State Agency may have misunderstood our position on the monitoring of interest earned on outstanding rebates. Specifically, we note that the draft report did not indicate that the State Agency should issue invoices to manufacturers for unpaid interest; to minimize the possibility of any further misinterpretation, we have clarified our intent by stating that the State Agency should estimate and/or accrue the interest. Finally, the State Agency furnished us with evidence that they included the unreported interest on late and disputed rebates on Form CMS 64.

TABLE OF CONTENTS

Glossary of Abbreviations and Acronyms

CFR	Code of Federal Regulations
CMS	Centers for Medicare & Medicaid Services
OBRA	Omnibus Budget Reconciliation Act of 1990

INTRODUCTION

BACKGROUND

The Medicaid program was established in 1965 by Title XIX of the Social Security Act. A cooperative venture funded by the Federal and State governments, Medicaid was designed to assist States in furnishing medical assistance to eligible needy persons.

On November 5, 1990, Congress amended the Act by enacting the OBRA of 1990. Enacted out of concern for the costs that Medicaid was paying for outpatient drugs, the rebate program was established to make Medicaid costs similar to discounted prices that pharmaceutical manufacturers offer to other large purchasers.

The drug manufacturer(s), CMS, and the State(s) share responsibility for the program:

- Drug manufacturers that wish to have their products covered under the rebate program must maintain rebate agreements with CMS. Under the terms of these agreements, manufacturers must submit pricing information to CMS for each of their covered outpatient drugs. Approximately 520 pharmaceutical companies and 56,000 National Drug Codes (drug codes) are represented in the program.

- Based on the pricing information supplied by the manufacturers, CMS provides State Medicaid agencies with a quarterly computer tape listing the unit rebate amount for each of the drug codes covered under the program.

- State agencies are required to maintain records, by manufacturer, of the number of units of each drug dispensed during each calendar quarter. The State agencies then use the rebate amounts from CMS and the State agencies' records of utilization for each drug code to prepare quarterly invoices for rebates due from each manufacturer.

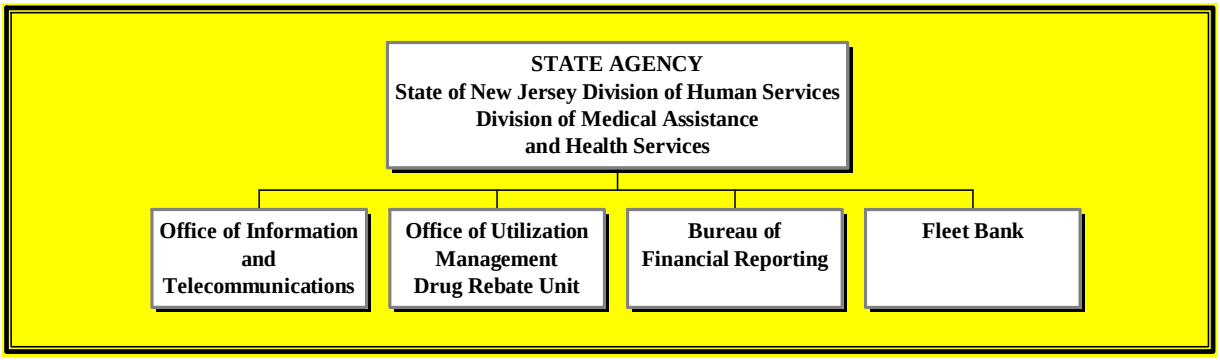
Rebate Processing Time Frame

The rebate process, measured from the time when manufacturers send their pricing information to CMS at the end of a calendar quarter to the time when State agencies send rebate invoices to the manufacturers, typically takes 60 days. Once the State agencies send the invoices, drug manufacturers must pay the rebate within 38 days to avoid interest charges.

Although manufacturers are required to pay rebates by the due date, they have the opportunity to dispute rebates if the State agencies' utilization data appears to be erroneous. If the State agencies and the manufacturers are not able to resolve a discrepancy within 60 days, the State agencies must make a hearing mechanism available in order to resolve the dispute.

New Jersey's Drug Rebate Program

Administration of New Jersey's rebate program involves three offices within the Department of Human Services, and an external banking institution, as discussed below:



- The **Office of Information and Telecommunications** merges the State Agency's drug utilization data with the rebate amounts provided by CMS to create the rebate invoices. This office also uploads the rebate deposit information provided by the bank into the computer system.

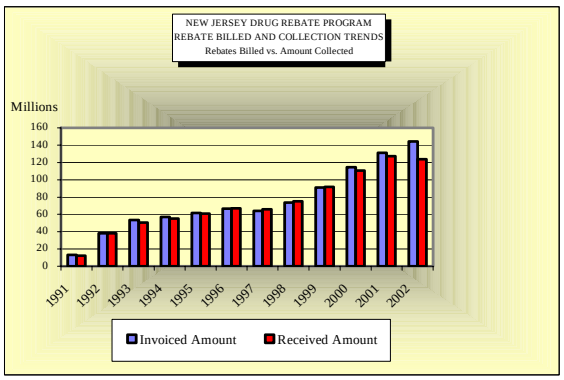
- The **Office of Utilization Management**'s rebate unit is responsible for program functions, including:
  - mailing of invoices to drug manufacturers
  - reconciliation of rebate payments received at the Fleet Bank lockbox and deposit of rebate payments received at the rebate unit
  - record keeping functions for the program
  - preparation of reports used by the Bureau of Financial Reporting for reporting of program results to CMS, and
  - dispute resolutions with drug manufacturers

- The **Bureau of Financial Reporting** prepares the "Quarterly Statement of Medicaid Expenditures" (Form CMS 64).

- **Fleet Bank** provides the Office of Information and Telecommunications with reports of rebate payments received at its lock box and deposits made by the drug rebate unit.

Accomplishments of New Jersey's Drug Rebate Program

Between the time when the rebate program began in 1991 and the end of June 2002, the State Agency billed manufacturers approximately $908 million and collected approximately $878 million in rebates. During that time, billings for drug rebates rose from approximately $13 million in 1991 to approximately $144 million in 2002. Rebate collections also increased, from approximately $12 million in 1991 to approximately $124 million in 2002. Furthermore, State Agency officials stated



that they now collect approximately 98 percent of all rebate amounts they identify. New Jersey's drug rebate program, as measured by the increase in billings and collections over time, is illustrated in the bar chart.

Quarterly Reporting of Rebate Activity

In order to facilitate periodic monitoring of disputed rebates by CMS, States are required to report their quarterly rebate invoices and collections on Form CMS 64.9R. Proper reporting of rebate activity requires an effective accounts receivable system to identify and track the cumulative balance of outstanding rebates. Form CMS 64.9R is part of the Quarterly Statement of Medicaid Expenditures (Form CMS 64), which is used by CMS to reimburse the Federal share of Medicaid expenditures to the States.

For the fiscal year ended June 30, 2002, the State Agency billed an average of $36 million in rebates and collected an average of $31 million in rebates per quarter.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

Our objectives were to evaluate the State of New Jersey Department of Human Services (State Agency), Division of Medical Assistance & Health's accountability in terms of reporting outstanding rebate balances to CMS and its processes and controls as of June 30, 2002 for drug rebate billings, collections, and dispute resolutions.

Scope

The audit included a review of rebate activity from the inception of the program in 1991 through June 30, 2002. Although we concentrated on the State Agency's policies, procedures and controls as of June 30, 2002, we also interviewed State officials to gain an understanding of how the program has operated since 1991.

In order to evaluate the accuracy, timeliness and completeness of the State Agency's reporting of rebate program activity, we examined the processes and controls used to develop the rebate data. We did not review the overall internal control structure of New Jersey's Medicaid program. We did, however, consider those control procedures that we believed would be appropriate for effective administration of New Jersey's drug rebate program.

Methodology

To accomplish the objectives, we:

- reviewed applicable sections of the Medicaid laws, regulations and guidelines for the drug rebate program
- reviewed CMS reports about New Jersey's drug rebate program
- held discussions with State Agency and CMS officials

- reviewed the State Agency's policies, procedures, internal controls and records related to the rebate program

Specifically, we gained an understanding of the State Agency's processes and controls by analyzing the flow of activity from the creation of the rebate invoices through the reporting of rebate program results to CMS. We then obtained historical records of rebate billings, payments, and disputes and reviewed rebate activity reported to CMS as of June 30, 2002.

We performed fieldwork at CMS regional and field offices in New York City and Trenton, New Jersey and at the State Agency's offices in Trenton, New Jersey between May and October 2003. The audit was performed in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

The State Agency produced timely rebate billings and collections in accordance with provisions of sections 1927 (b)(1) and 1927 (b)(2) of the Social Security Act (Act) and successfully avoided billings for duplicate discounts or rebates for drugs covered under section 340B of the Public Health Service Act, as required by section 1927 (a)(5) of the Act. There were, however, opportunities to improve the reporting of program results and accountability to CMS and to strengthen the processes for late and disputed rebates.

Specifically, the audit results indicated that the State Agency:

- understated the June 30, 2002 balance of outstanding drug rebates to CMS by $38,017,771

- could potentially have saved as much as $4,100,740 ($2,050,370 Federal share) in interest on Medicaid funds through more timely consideration of drug rebate collections when determining its needs for drawdowns of Federal funds

- had not resolved $3,738,193 ($1,869,097 Federal share) in disputed rebates within 60 days or implemented a mechanism for dispute resolutions

- did not have processes to estimate or accrue interest for late or disputed rebates, and

- did not report interest collected on late rebate payments as of June 30, 2002 in the amount of $1,134,372 ($567,186 Federal share) to CMS

OVERVIEW OF FEDERAL REQUIREMENTS

The provisions of the rebate program are contained in OBRA and in section 1927 of the Social Security Act. CMS supplemented these instructions with guidelines issued in the State Medicaid Manual (Publication 45), provisions contained in the Medicaid drug program "Rebate Agreement", and rebate program "releases" (memorandums) to State Medicaid agencies and drug manufacturers.

In addition to the specific program laws, regulations and guidelines noted above, 45 CFR §§74.21 (b)(1) and (b)(3) require that financial management systems provide for:

- accurate and complete disclosure of the financial results of Department of Health and Human Services sponsored programs such as Medicaid, and

- effective controls and accountability for all funds, property, and other assets

Furthermore, the Cash Management Improvement Act of 1990 and the related regulations at 31 CFR §205 set standards regarding the management of Federal funds used for the rebate program.

Finally, State responsibilities with respect to the reporting of interest collected on late or disputed rebate payments are discussed in section 1903(d)(5) of the Social Security Act.

ACCOUNTABILTY FOR THE REBATE PROGRAM

The State Agency had not reconciled Form CMS 64.9R to its accounting records and did not provide an estimate of the current quarter's rebate invoices to CMS, thereby reducing the accuracy of information CMS needed to monitor the rebate program results. In addition, the State Agency's failure to coordinate withdrawals of Federal funds with rebate collections overstated the immediate cash needs and reduced the interest income for the rebate program.

The Medicaid Drug Rebate Schedule Was Improperly Prepared

The outstanding rebate amount reported by the State Agency contained reporting errors and understated the outstanding rebate balance.

CMS considers periodic review of Form CMS 64.9R by its regional offices a useful means of identifying unresolved disputes that may require further attention. The State Agency, however, had not fully reconciled the "Medicaid Drug Rebate Schedule" to underlying accounting records and did not report the most recently invoiced rebates. As a result, the outstanding rebate "Total" on Form CMS 64.9R for the quarter ended June 30, 2002 was understated as described below.[1]

Description	Amount
Reconciling Items Improperly Reported:	
Rebate Collections for periods prior to the inception of the Medicaid Drug Rebate Program[1]	$896,654
Interest deducted twice	1,088,048
State Agency programming errors	-123,838
Reconciling Items - Subtotal	$1,860,864
Rebates Invoiced in The Current Quarter	$36,156,907
Total Understatement	$38,017,771

[1] Rebates for this period were subject to inclusion on the Form CMS 64.9R as per §1927(a)(4) of the Act.

The reconciling items, which were identified by State Agency officials as the audit began, related to rebate activity in 2001 that should have been, but was not, included in Form CMS 64.9R as of June 30, 2002. In addition to the reconciling items, the State Agency did not provide a reasonable estimate of current quarter activity as required by CMS instructions and State Agency procedures. According to State Agency records, rebates for the quarter ended June 30, 2002 amounted to $36,156,907. Exclusion of these rebates potentially increased the total understatement on Form CMS 64.9R to $38,0177,771.

We, therefore, believe that the State Agency did not fully consider program regulations at 45 CFR §74.21 (b)(1) with respect to accurate and complete disclosure of the financial results of its rebate program and CMS instructions on the preparation of the "Medicaid Drug Rebate Schedule".

Drawdowns of Federal Funds Were Not Coordinated with Rebate Collections

The State Agency did not minimize drawdowns of Federal funds through timely consideration of drug rebate collections.

The State Agency did not offset rebate collections against Federal expenditures on a timely basis. Instead of using rebates from drug manufacturers to reduce the next request for Federal funds as required by CMS guidelines, the State Agency delayed the comparison of rebate collections to drug expenditures until the end of each quarter. More timely consideration of rebate income could have increased the interest applied to the rebate program by as much as $4,100,740 ($2,050,370 Federal share) for the six years ended June 30, 2002.

According to the Cash Management Improvement Act of 1990 (Public Law 101-453) as amended, and associated regulations at 31 CFR §205, States must "… minimize the time elapsing between the transfer of funds from the United States Treasury and the State's payout of funds." CMS guidelines in §2500.6 of the State Medicaid Manual address these concerns by noting that to wait until the end of a quarter to calculate the Federal share of collections assures proper reporting but does not assure proper cash management. Accordingly, CMS instruct States to reduce cash drawdowns to reflect any recoveries and to limit the Federal funds drawn to the amount needed to meet net disbursement requirements.

The review showed that the State Agency collected 72 to 90 percent of its rebates in the first month of each quarter. For example, $27.2 million (86 percent) of the $31.7 million in rebates collected during the quarter ended June 30, 2002 was deposited in April 2002. State Agency officials also confirmed that most rebates are collected at the start of each quarter. Therefore, the State Agency's delayed offset of rebates against Medicaid drug expenditures until the end of a quarter did not conform to the prescribed cash management practices cited above. In this respect, we also note that 31 CFR §205.15(b)(1) states that:

> A State incurs interest liability on refunds of Federal funds from the day the refund is credited to a State account to the day the refund is either paid out for Federal assistance programs or credited to the Federal government.[2]

[2] According to 31 CFR §205.2, rebates from third parties are considered to be refunds.

To calculate the potential effect of the delayed offset of rebate collections against the drug expenditures for the six years ended June 30, 2002, we:

- discussed the State Agency's procedures for Federal funds drawdowns with State and Federal officials involved in implementing and monitoring the Federal cash management regulations

- analyzed rebate deposits for each quarter from April 1, 1996 through June 30, 2002

- obtained the applicable interest rates, as determined by the U.S. Department of the Treasury, for drawdowns in excess of cash needs

- used a conservative assumption that all collections were deposited on the last day of the month to estimate the additional interest that could have been applied to the rebate program, and

- applied a conservative assumption that the Federal share of all rebates is 50 percent[3]

Through these means, we estimated that more timely consideration of rebate collections and the interest earned on the rebates could potentially have reduced Medicaid drug expenditures by as much as $4,100,740 ($ 2,050,370 Federal share) between April 1996 and June 2002[4].

In our opinion, the State Agency had not fully considered certain program provisions contained in CMS guidelines at §2500.6 E of the State Medicaid Manual, the underlying Federal provisions of the Cash Management Improvement Act of 1990 as amended, and the related regulations at 31 CFR §205.

CONTROLS FOR LATE AND DISPUTED REBATES

The State Agency's controls produced timely rebate invoices and collections. When manufacturers disputed the State Agency's rebate invoices, however, the disputes were not always resolved on a timely basis and might have benefited from the hearings available under CMS guidelines. In addition, the State Agency did not estimate the interest due on late or disputed rebates. Improvements to the controls for disputed rebates, therefore, might have increased collections of rebates and interest. We also noted that the State Agency had not reported certain interest collected on late or disputed payments to CMS.

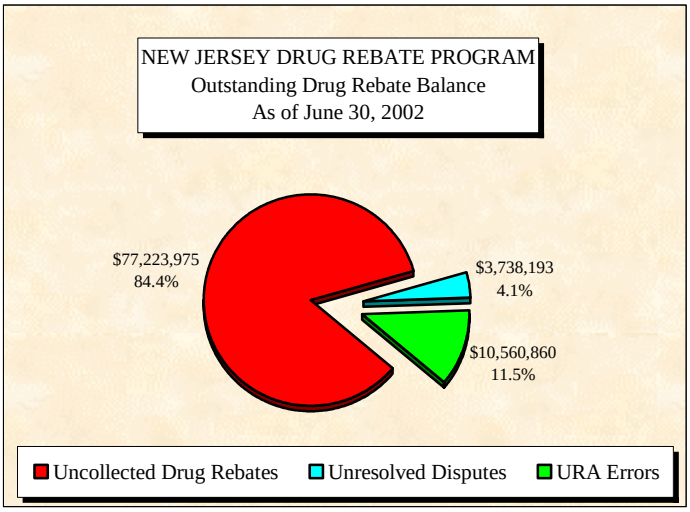
[3] The Federal share of certain Medicaid drug expenditures is higher than 50 percent. We also note that the State Agency properly applies the appropriate Federal share of its drug expenditures to the rebates received.

[4] Drug rebate collections were periodically transferred to a statewide bank account where they were commingled with funds from other programs and "lost their identity" as drug rebates. The impact of the delayed offset of rebate income against drug expenditures on the Medicaid drug rebate program was estimated because a comprehensive analysis of the cash flows through the statewide account was considered to be beyond the scope of this audit.

Disputes Were Not Always Resolved Timely

Disputes were not always resolved within 60 days.

As noted in the chart, over 84% of the outstanding rebate balance as of June 30, 2002 related to the most recent quarters and, based on the State Agency's experience, was likely to be collected on a timely basis. Information on Form CMS 64.9R reported the balance outstanding for 90 days or more as of June 30, 2002 as $12,438,189. The State Agency, however, did not identify errors that should have increased that balance to $14,299,053[5] ($10,560,860 related to incorrect unit rebate amounts provided by CMS,[6] and $3,738,193 in unresolved disputes).



In general, the State Agency had properly implemented dispute resolution procedures when a rebate payment was not the same as the amount invoiced. For example, the State Agency's written procedures on dispute resolutions generally conformed to, and in some instances exceeded, CMS requirements. The State Agency was also proactive in developing procedures to monitor and resolve the disputes from its largest suppliers. The State Agency's controls, however, did not ensure that all disputes would be resolved in 60 days.

Section V of the drug rebate agreement requires that states and manufacturers use their best efforts to resolve disputes within 60 days of notification of a discrepancy. As noted in the chart, however, $3,738,193 (4.1%) in disputes as of June 30, 2002 was not resolved within 60 days. CMS Release Memorandum 105 states that, in the event that a State and a manufacturer cannot resolve a dispute within 60 days, the State must make a hearing mechanism available to the manufacturer. Although the State Agency's policies contemplated a hearing mechanism for the dispute resolution process, it has never been implemented.

Interest on Late or Disputed Rebates Was Not Estimated

The State Agency did not estimate or accrue interest for late or disputed rebates.

Although it is the manufacturers' responsibility to both calculate and pay the interest due and the State's responsibility to collect the interest, CMS recommends that States reach an agreement with the manufacturers as to the amount of interest due.

While the State Agency verified the manufacturers' interest computations, there was no systematic effort to estimate or accrue the interest due on late or disputed rebates. Federal regulations at 45 CFR §74.21(b)(3) require that financial management systems provide for

[5] The errors in the reported balance of rebates outstanding for 90 days or more amounted to $1,860,864 and fully account for the reconciling items on the Medicaid Drug Rebate Schedule, as previously discussed.
[6] As noted in CMS Release 019, matters relating to the unit rebate amount are not considered to be disputes between a manufacturer and a State.

effective accountability for assets such as interest due from manufacturers. To this end, CMS publishes the relevant interest rates in its periodic program release memorandums.

We believe that the procedures for verifying interest recieved were generally sound, but that the State Agency's procedures did not fully implement program provisions about tracking the interest due on late rebate payments.

Interest Collected on Late or Disputed Rebates Was Not Reported to CMS

The State Agency did not report interest collected for late or disputed rebate collections to CMS.

The State Agency collected interest on late or disputed rebates totaling $1,134,372 ($567,186 Federal share) that was not reported to CMS on the "Quarterly Statement of Medicaid Expenditures" (Form CMS 64) as of June 30, 2002.

According to program provisions at section 1903(d)(5) of the Social Security Act and CMS Release 15, States must pay or credit the Federal government for interest earned on late, disputed, or unpaid rebates. With particular respect to the amounts reported to CMS, sections 2500.1 B and 2500.6 F of the State Medicaid Manual state that the Federal share of interest received or earned on Medicaid recoveries must be included on Line 3.A of Form CMS 64. In addition, according to CMS Release Memorandum 65, it is the State's responsibility to track and report the collection of interest to CMS.

The State Agency did not report the interest income to CMS because State officials misunderstood instructions from the CMS regional office about the reporting of interest on Form CMS 64.

CONCLUSION

The State Agency produced timely rebate billings and collections and avoided billings for duplicate discounts or rebates for drugs covered under section 340B of the Public Health Service Act. The audit, however, identified certain weaknesses in the processes and controls related to:

- accurate reporting of outstanding drug rebate balances
- timely consideration of drug rebate collections when requesting drawdowns of Federal funds
- timely resolution of disputed rebates
- tracking of interest due on late or disputed rebates, and
- the reporting of interest collected on late or disputed rebates to CMS

RECOMMENDATIONS

We recommend 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."

AUDITEE COMMENTS

The State Agency indicated that they have recorded adjustments amounting to $1,860,864 for errors identified on their Form CMS 64.9R. They did not, however, feel that it would be appropriate to include an estimate of drug costs incurred during the quarter ($36,156,907) as part of the outstanding rebate balance on the Form CMS 64.9R for the quarter ended June 30, 2002. With respect to reducing drawdowns by the amount of rebates collected, the State Agency asserted that its processes comply with the Cash Management Improvement Act, that the proposed changes to these processes might not be cost effective and that our analysis was inconclusive.[7]

With respect to its controls for late and disputed rebates, the State Agency commented that it was in the process of implementing the recommended improvements to offer hearings when disputes are not resolved. Regarding the monitoring of interest due on overdue rebates, however, the State Agency reiterated that it does verify interest submitted by manufacturers but that it would not be feasible to invoice manufacturers for interest on overdue rebates. Finally, the State Agency noted that it had both adjusted its procedures and also adjusted $1,134,372 ($567,186 Federal share) on its Form CMS 64 for the quarter ended June 30, 2003 to account for unreported interest collected on rebate amounts.

The text of the State Agency's response is presented at Appendix A.

OFFICE OF INSPECTOR GENERAL RESPONSE

The State Agency's adjustments to Form CMS 64.9R accurately account for the reconciling items that had been improperly reported to CMS. Regarding the concerns raised about including an estimate of current rebate invoices on Form CMS 64.9R, we note that this recommendation was based not only on the instructions cited by the State Agency but, more

[7] The State Agency subsequently notified the Office of Inspector General that procedures to consider the amount of the rebates collected when requesting drawdowns of Federal funds were implemented after the draft report was issued.

importantly, on discussions with CMS officials responsible for oversight of the Medicaid drug rebate program. We, therefore, encourage the State Agency to dialogue with appropriate CMS officials about this matter. Concerning the timely consideration of rebate collections when requesting Federal funds, we note that drug rebates should have earned interest amounting to at least $125,000 during each quarter of the fiscal year ending on June 30, 2002 and, therefore, the recommended change in procedures would likely be cost effective. We also note that Footnote 4 of both the draft and final reports clearly indicates that the periodic commingling of drug rebate funds with funds from other programs would require a detailed analysis of transactions that would have expanded the scope of this audit to matters unrelated to the rebate program. We, nevertheless, believe that our analysis was sufficient to determine that the recommended procedural change should be given serious consideration. Finally, the fact that the State Agency recently implemented the recommendation would also appear to validate the merit of this finding.

With respect to the controls for late and disputed rebates, the State Agency is implementing the recommendation to offer hearings when disputes are not resolved. We note, however, that the State Agency may have misunderstood our position on the monitoring of interest earned on outstanding rebates. Specifically, we note that the draft report did not indicate that the State Agency should issue invoices to manufacturers for unpaid interest; to minimize the possibility of any further misinterpretation, we have clarified our intent by stating that the State Agency should estimate and/or accrue the interest. Finally, the State Agency furnished us with evidence that they included the unreported interest on late and disputed rebates on Form CMS 64.

APPENDIX

State of New Jersey
DEPARTMENT OF HUMAN SERVICES
PO Box 700
TRENTON NJ 08625-0700

JAMES E. McGREEVEY
Governor

JAMES M. DAVY
Acting Commissioner

March 31, 2004

Timothy J. Horgan
Regional Inspector General
for Audit Services
Office of the Inspector General
Office of Audit Services
Region II
Jacob K. Javits Federal Building
26 Federal Plaza
New York, NY 10278

Re: Report Number A-02-03-01024

Dear Mr. Horgan:

This is in response to your correspondence of February 4, 2004 concerning the draft audit report titled "Review of the Medicaid Drug Rebate Program in New Jersey." Your correspondence provides an opportunity to comment on the draft audit report.

The draft report contains five findings and recommendations. These findings, recommendations and the State's response are provided below. Specifically, the audit results indicated that the State Agency:

1. Understated the June 30, 2002 balance of outstanding drug rebates to the Center for Medicare and Medicaid Services (CMS) by $38,017,771 and recommended the State revise its reporting procedures to ensure that Form CMS 64.9R is accurate and complete and that the form properly accounts for the types of items that resulted in the $38,017,771 understatement of the outstanding rebate balance as of June 30, 2002.

The amount referenced in the finding includes $1,860,864 for items identified by State staff that had been omitted from previous CMS reports. Once identified, the amounts that had inadvertently been omitted from previous CMS reports were immediately included on the CMS 64 for the quarter ended June 30, 2003. The State will closely monitor the preparation of future reports to preclude similar omissions.

It appears that some confusion exists regarding the remaining $36,156,907 of this finding. This amount represents drug rebates invoiced to manufacturers after the audit period for service utilization in the quarter ended June 30, 2002. While the draft report indicates that New Jersey understated the amount of drug rebates outstanding, the amount reported by the State included all drug rebate amounts invoiced to drug manufacturers as of the due date of the Quarterly Medicaid Statement of Expenditures, Form CMS 64.

The Form CMS 64.9R reports prepared by New Jersey consistently reflect invoiced drug rebate amounts in the calendar quarter of the underlying service utilization. Specifically, drug rebates invoiced during the quarter ended June 30, 2002, reflecting service utilization in the quarter ended March 31, 2002, are included on the quarter ended June 30, 2002 Form CMS 64.9R [redacted]. It appears the instructions for preparation of the Form CMS 64.9R report indicate that these amounts should be reported in the quarter invoiced and not the quarter of service utilization. Consequently, New Jersey will revise the procedures for preparation of the Form CMS 64.9R and report rebate invoiced amounts in the quarter that the manufacturers' invoices are distributed.

Please note that all drug rebates invoiced as of the due date of the Form CMS 64 for the quarter ended June 30, 2002 are included on the Form CMS 64.9R for that period. The audit report should be corrected to indicate that the State understated the amount of drug rebates outstanding at June 30, 2002 by $1,860,864. [redacted]

2. Could potentially have saved as much as $4,100,740 ($2,050,370 Federal share) in interest on Medicaid funds through more timely consideration of drug rebate collections when determining its needs for draw downs of federal funds and recommended the State reduce its draw downs of federal funds through timely consideration of the drug rebates it has collected.

The report correctly concludes that New Jersey did not specifically recognize actual drug rebate deposits in the calculation of the recurring draw of federal funds. However, it appears inappropriate to conclude that any interest or Medicaid funds could be saved in this regard.

The draw down of federal Medicaid funds is accommodated by complicated procedures governed by an agreement between the State and the Federal Department of the Treasury. This agreement is in accordance with the Cash Management Improvement Act and is intended to specify acceptable procedures that will minimize the time elapsing for the transfer of funds between the parties. The procedures encompassed

[8] **OFFICE OF INSPECTOR GENERAL NOTE:** This item is not applicable because the issue referred to by the auditee is not included in this report.

by the agreement are not intended to provide an exhaustive accounting of program expenditures or funding requirements. Rather, the process provides for a current approximation of funding needs and its effectiveness is measured by the total variance between allowable expenditures and funds drawn by the State. The inclusion or exclusion of any specific item in the endorsed draw down process is not indicative of a variance between expenditures and funds drawn. Therefore, the exclusion of collected drug rebates from the draw down calculation process does not indicate the State has drawn excessive federal funds or that any program savings are available.

Absent a specific determination that New Jersey drew down more funds than required, it is inappropriate to surmise that any savings could accrue through the recommended procedural change. It is equally likely that the recommended change could increase costs through added effort and administrative costs. Consequently, this finding and recommendation should be removed from the report or supported through appropriate review and analysis.[9]

3. Had not resolved $3,738,193 ($1,869,097 Federal share) in disputed rebates within 60 days or implemented a mechanism for dispute resolutions and recommended the State establish procedures and controls for adjudicating disputed rebates within the 60 day time frame suggested by CMS and implement procedures to offer a hearing mechanism when dispute resolution procedures are not successful within 60 days.

New Jersey performs dispute resolutions on a regular basis. The established dispute resolution process follows guidelines presented in the CMS Medicaid Dispute Resolution Manual. In an effort to address disputes within the 60 day time frame, procedures are currently being developed for implementation.

The outstanding disputed amount presented in the audit represents 7% of the total uncollected balance as indicated on New Jersey's original submission for June 30, 2002 ($55,861,962). Additionally, the outstanding disputed amount was further reduced by $785,254 with CMS rate adjustments on the invoice for third quarter 2002.

Unit of measure issues are attributed to the remainder of outstanding disputes. During the last year, much of the unit of measure discrepancies were addressed with "off-line" adjustments. The value of unit of measure adjustments posted on the third quarter 2002 invoice cycle was $797,883. Another $338,887 for unit of measure adjustments were posted on the fourth quarter 2002 invoice. New Jersey continues to examine these types of errors on a regular basis.

Experience tells us that the minimal amount remaining $1,814,169 ($907,084 Federal share) is uncollectible. There are various other reasons for dispute balances many of

[9] **OFFICE OF INSPECTOR GENERAL NOTE:** The State Agency has informed us that they subsequently modified their procedures to consider the rebates collected when requesting drawdowns of Federal funds.

which result in New Jersey reducing outstanding amounts due because of erroneous units and/or unit rebate amounts.

While New Jersey has never required a "hearing" to assist in resolving disputes, the same Fair Hearing mechanism currently available for the State PAAD Drug Rebate Program will be used for the Medicaid Drug Rebate Program. The State hearing mechanism is available under N.J.S.A. 52:14B-1 et seq., implementation of the process is forthcoming.

4. Did not have controls to accrue interest for late or disputed rebates and recommended the State estimate and accrue interest on overdue rebate balances.

In accordance with CMS' Best Practices Guide published and distributed in 1999 (Section XI-4 copy enclosed), New Jersey demands that manufacturers calculate and pay interest on outstanding balances due.

New Jersey does track and collect interest. As indicated in the report, interest totaled over one million dollars. Staff examines interest payments made for accuracy and records interest as such in the "Drug Rebate Program" database.

Because the rebate regulation allows manufacturers to "re-price" products back to the inception of the rebate program, invoicing interest is quite intricate and complex. It is not practical to invoice interest one quarter, and then continuously review the same invoice because of rate adjustments or changes in units[10]. CMS Medicaid Director Releases Number 88 and 98 clearly indicate the problems associated with the invoicing of interest.

5. Did not report interest collected on late rebate payments as of June 30, 2002 in the amount of $1,134,372 ($567,186 Federal share) to CMS and recommended the State 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 total amount of interest collected on late rebate payments has been included on the submitted Quarterly Statement of Medicaid Expenditures, Form CMS 64 for the quarter ended June 30, 2003. The State's reporting procedures have been updated to include all interest collected on late rebate payments on the Quarterly State of Medicaid Expenditures.

[10] **OFFICE OF INSPECTOR GENERAL NOTE:** Rules issued in January 2004 limit rebate adjustment requests to three years rather than to the inception of the rebate program.

The opportunity to review and comment on this draft audit report is greatly appreciated. If you have any questions or require additional information, please contact me or Ann Clemency Kohler, Director, Division of Medicaid Assistance and Health Services, at 609-588-2600.

Sincerely,

James M. Davy
Acting Commissioner

JMD:2
Enclosure
c: Ann Clemency Kohler

bc: David C. Heins
Kaye S. Morrow
Edward Vaccaro
Rebecca Joslin
John Guhl
David Lowenthal
Madhu Ahuja
Daniel Upright
John Kresge
Suzanne Bauerle

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FREQUENTLY ASKED QUESTIONS

of Medicaid reimbursement may be found in violation of the rebate agreement and risk termination from the program

Q: ***Do States have to submit invoices for interest due in order to receive payment?***

For more detailed information on interest please refer to Section I of the *Medicaid Drug Rebate Operational Training Guide.*

For all rebates not paid within 38 calendar days after the postmark date of the State's invoice, interest accrues on the unpaid rebates until the date the Manufacturer mails the check to the State. The obligation for calculating interest due to the States on late rebate payments rests with the Manufacturer. It is the State's responsibility to track the collection of interest due, and report those amounts to HCFA. However, whether or not a State invoices for interest has no bearing on the Manufacturers' responsibilities to calculate and pay the amount (s) of interest due.

Q: ***On occasion, the quarterly rebate amount due to a State is a "negative" dollar amount. How should a labeler handle a "negative" rebate amount?***

There is no hard and fast rule regarding this situation. When a "negative" rebate dollar amount is calculated, the labeler and State together should decide which method of payment is better. Some States may prefer to remit a check to the labeler for the balance due, but typically States prefer that the labeler apply a credit to its next quarterly rebate payment. Either method is acceptable to HCFA.

QUESTIONS FREQUENTLY ASKED BY STATES

Q: ***Why can't I terminate a Manufacturer from the rebate program?***

The law requiring the rebate program limits termination authority to HCFA and to Manufacturers. For non-Medicaid, State-only funded drug programs, however, termination authority rests with the State or as provided in the contract or agreement.

Q: ***Is HCFA pursuing changing the administrative funding match for States to attend DRP meetings?***

Yes. We have proposed that States would be able to claim 100% matching funds for approved travel expenses to attend DRP meetings. Currently, the match is 50 percent. We will announce through a release to all States if and when the proposed increase is approved and effective. We do not expect a decision until fiscal year 2000.

OIG NOTE: The Health Care Financing Administration (HCFA) is now known as the Centers for Medicare and Medicaid Services (CMS).