DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

AUG 16 2004

TO: Wynethea Walker
Acting Director, Audit Liaison Staff
Centers for Medicare & Medicaid Services

FROM: Joseph E. Vengrin
Deputy Inspector General for Audit Services

SUBJECT: Medicaid Drug Rebate Program in New York State (A-02-03-01009)

Attached is an advance copy of our final report on the Medicaid drug rebate program in New York State. We will issue this report to the State Medicaid agency within 5 business days.

We suggest that you share this report with the Centers for Medicare & Medicaid Services (CMS) components involved with program integrity, provider issues, and State Medicaid agency oversight, particularly the Center for Medicaid and State Operations.

The Omnibus Budget Reconciliation Act 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 manufacturers offer to other large purchasers. Under this 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 CMS on the Medicaid Drug Rebate Schedule (Form CMS 64.9R).

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

The Health Department produced timely rebate billings and collections in accordance with sections 1927(b)(1) and 1927(b)(2) of the Social Security Act. However, the processes and controls for rebate billings, collections, and dispute resolutions were not always coordinated effectively, did not maximize savings, and did not produce accurate and complete records of rebate activities. Also, the Health Department did not properly account for its rebate activity or correctly report its outstanding rebate amounts to CMS.

In evaluating the impact of these weaknesses, we identified:

- cost savings of approximately $3.3 million a year ($1.65 million Federal share) that could be achieved by seeking rebates from section 340B entities that do not bill the Health Department at discounted prices

- an understatement of the Federal share of reported rebates for drugs used for family planning services amounting to approximately $730,000 a year

- an estimated balance of $350.6 million in outstanding rebates (including $31.6 million in unresolved disputes) as of June 30, 2002 that was not reported to CMS on the Medicaid Drug Rebate Schedule

We believe that the Health Department did not fully consider certain program provisions of the Omnibus Budget Reconciliation Act of 1990, section 1927 of the Social Security Act, 45 CFR §§ 74.21 (b)(1) and (b)(3), 31 CFR § 205.11, CMS instructions and advice in the State Medicaid Manual, and CMS "release" memorandums for the rebate program. In addition, the Health Department's segregation of duties for the rebate program required a coordination of effort that was not always present. Finally, weaknesses in the Health Department's processes and controls for rebate billings and collections, as well as its ineffective accounts receivable system, contributed to the inability to properly report the outstanding rebate balance to CMS.

We recommend that the Health Department:

- 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 section 340B entities that do not bill the Health Department 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

- 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)

- 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

In addition, although the Health Department's new business model and computer system may improve the administration of the rebate program, we believe that the Health Department should carefully consider limitations in the available accounting data and weaknesses in coordination of effort as it plans and implements the new business model.

The Health Department generally concurred with the recommendations in the draft report, but expressed concerns about the use of the term "uncollected rebates" when referring to the total

rebate balance. The Health Department also suggested that a distinction be made between the total rebate balance and the $31 million of that total pertaining to disputed rebates that have not been collected.

We addressed the Health Department's concern about the term "uncollected rebates" by revising the report language. The $350.6 million drug rebate balance as of June 30, 2002 is now referred to as the "total" or "outstanding" drug rebate balance. We also note that both the draft and final reports indicate that only $31.6 million of the total balance had been disputed by the manufacturers and remained uncollected as of June 30, 2002.

Our report summarizes the Health Department's comments and our response and includes the Health Department's comments, in their entirety, as an appendix.

If you have any questions or comments about this report, please do not hesitate to call me or your staff may contact George M. Reeb, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or Timothy J. Horgan, Regional Inspector General for Audit Services, Region II, at (212) 264-4620.

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF INSPECTOR GENERAL

OFFICE OF AUDIT SERVICES
Region II
Jacob K. Javits Federal Building
New York, New York 10278
(212) 264-4620

AUG 18 2004

Report Number: A-02-03-01009

Antonia C. Novello, M.D., M.P.H., Dr. P.H.
Commissioner
State of New York Department of Health
Corning Tower, Empire State Plaza
14th Floor, Room 1408
Albany, New York 12237

Dear Dr. Novello:

Enclosed are two copies of the Department of Health and Human Services (HHS), Office of Inspector General (OIG) final report entitled "Medicaid Drug Rebate Program in New York State." A copy of this report will be forwarded to the action official noted below for review and any action deemed necessary.

Final determination as to actions taken on all matters reported will be made by the HHS action official. 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.

In accordance with the principles of the Freedom of Information Act (5 U.S.C. § 552, as amended by Public Law 104-231, OIG reports issued to the Department's grantees and contractors are made available to members of the press and general public to the extent information contained therein is not subject to exemptions in the Act that the Department chooses to exercise (see 45 CFR part 5).

Please refer to report number A-02-03-01009 in all correspondence.

Sincerely yours,

Timothy J. Horgan
Regional Inspector General
for Audit Services

Enclosures - as stated

Direct Reply to HHS Action Official:
Ms. Sue Kelly
Associate Regional Administrator
Division of Medicaid and Children's Health
Centers for Medicare & Medicaid Services, Region II
26 Federal Plaza, Room 3811
New York, New York 10278

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICAID DRUG REBATE PROGRAM IN NEW YORK STATE

AUGUST 2004
A-02-03-01009

Office of Inspector General

http://oig.hhs.gov

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OAS FINDINGS AND OPINIONS

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

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) on the Medicaid Drug Rebate Schedule.

OBJECTIVES

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

SUMMARY OF FINDINGS

The Health Department produced timely rebate billings and collections in accordance with sections 1927(b)(1) and 1927(b)(2) of the Social Security Act. However, the processes and controls for rebate billings, collections, and dispute resolutions were not always coordinated effectively, did not maximize savings, and did not produce accurate and complete records of rebate activities. Also, the Health Department did not properly account for its rebate activity or correctly report its outstanding rebate amounts to CMS.

In evaluating the impact of these weaknesses, we identified:

- cost savings of approximately $3.3 million a year ($1.65 million Federal share) that could be achieved by seeking rebates from section 340B entities that do not bill the Health Department at discounted prices

- an understatement of the Federal share of reported rebates for drugs used for family planning services amounting to approximately $730,000 a year

- an estimated balance of $350.6 million in outstanding rebates (including $31.6 million in unresolved disputes) as of June 30, 2002 that was not reported to CMS on the Medicaid Drug Rebate Schedule

We believe that the Health Department did not fully consider certain program provisions of the rebate program as contained in OBRA of 1990, section 1927 of the Social Security Act,

45 CFR §§ 74.21 (b)(1) and (b)(3), 31 CFR § 205.11, CMS instructions and advice in the State Medicaid Manual, and CMS "release" memorandums for the rebate program. In addition, the Health Department's segregation of duties for the rebate program required a coordination of effort that was not always present. Finally, weaknesses in the Health Department's processes and controls for rebate billings and collections, as well as its ineffective accounts receivable system, contributed to the inability to properly report the outstanding rebate balance to CMS.

RECOMMENDATIONS

We recommend that the Health Department:

- 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 section 340B entities that do not bill the Health Department 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

- 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)

- 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

In addition, although the Health Department's new business model and computer system may improve the administration of the rebate program, we believe that the Health Department should carefully consider limitations in the available accounting data and weaknesses in coordination of effort as it plans and implements the new business model.

AUDITEE COMMENTS

The Health Department generally concurred with the recommendations in the draft report, but expressed concerns about the use of the term "uncollected rebates" when referring to the total rebate balance. The Health Department also suggested that a distinction be made between the total rebate balance and the $31 million of that total pertaining to disputed rebates that have not been collected.

The full text of the Health Department's comments is presented as an appendix.

OFFICE OF INSPECTOR GENERAL RESPONSE

We addressed the Health Department's concern about the term "uncollected rebates" by revising the report language. The $350.6 million outstanding rebate balance as of June 30, 2002 is now referred to as the "total" or "outstanding" drug rebate balance. We also note that both the draft and final reports indicate that only $31.6 million of the total balance had been disputed by the manufacturers and remained uncollected as of June 30, 2002.

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 Social Security Act by enacting OBRA of 1990 which, among other provisions, established the rebate program. 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 rebate 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 rebate 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 rebate program.

- State agencies are required to maintain records, by manufacturer, of the number of units of each drug dispensed each calendar quarter. The State agencies 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.

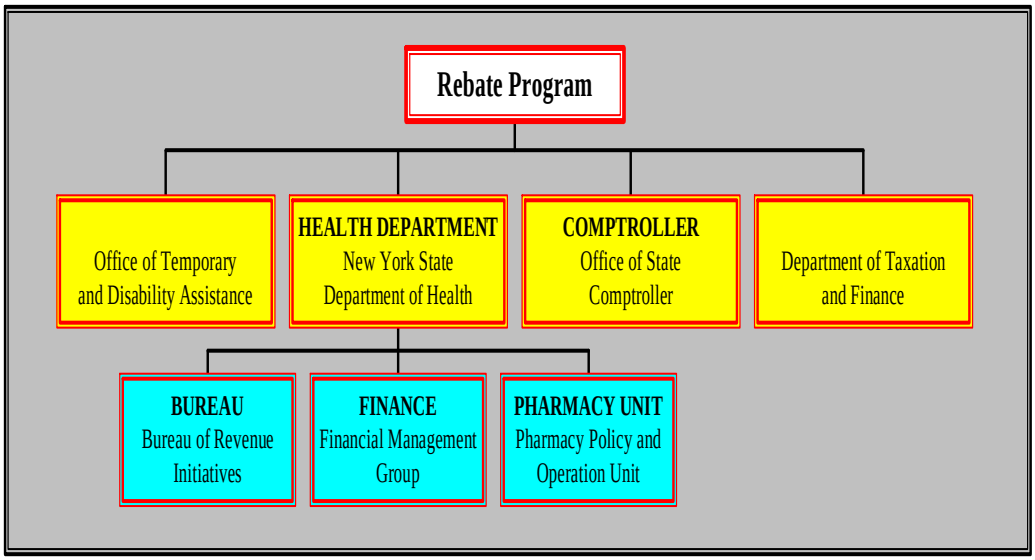
Rebate Processing Time Frame

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 appear to be erroneous. If the State agencies and manufacturers are unable to resolve a discrepancy within 60 days, the State agencies must make a hearing mechanism available in order to resolve the dispute.

New York State Rebate Program

Administration of the New York State rebate program involves four State agencies, including the Health Department and three of its divisions, as discussed below.



- The **Office of Temporary and Disability Assistance** merges utilization data provided by the Health Department with the rebate amounts provided by CMS to create rebate invoices. These invoices are forwarded to the Health Department, Bureau of Revenue Initiatives (Bureau).

- Within the **New York State Department of Health (Health Department)**, the rebate program processes are principally carried out at three locations in and around Albany by the following divisions:

    - The Bureau maintains billing information, distributes invoices to manufacturers, and tracks rebate collections.

    - The Financial Management Group (Finance) receives rebate payments and prepares the cash receipts log and the quarterly Medicaid Drug Rebate Schedule (Form CMS 64.9R).

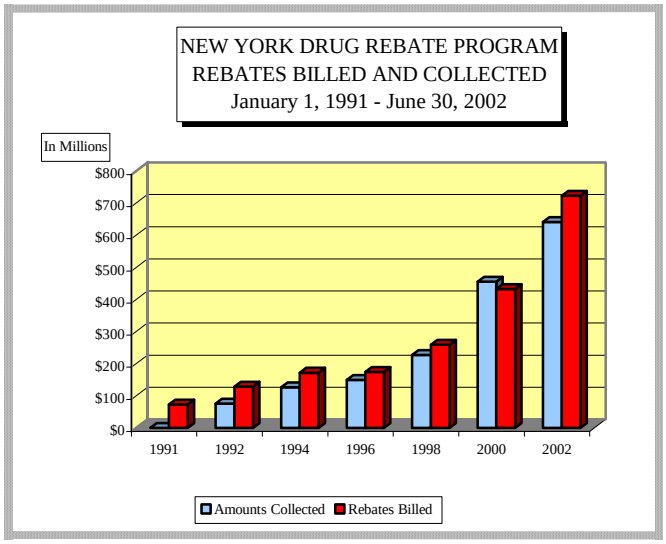
    - The Pharmacy Policy and Operation Unit (Pharmacy Unit) resolves rebate disputes.

- The **Office of State Comptroller (Comptroller)** is responsible for rebate program accounting functions, including the reduction of Federal drawdowns to account for drug rebates.

- The **Department of Taxation and Finance** deposits rebate payments at the banking institution.

Accomplishments of New York's Rebate Program

Between the time when the rebate program began in 1991 and the end of June 2002, the Health Department billed manufacturers approximately $3.7 billion and collected approximately $3 billion in rebates. During that time, billings for drug rebates rose from approximately $72.3 million in 1991 to approximately $722.3 million in 2002. Rebate collections also increased, from approximately $75.6 million in 1992 to approximately $640.4 million in 2002. Furthermore, Health Department officials stated that they now collect 97.8 percent of all rebate amounts they identify. New York's 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 year ended June 30, 2002, the Health Department billed an average of $180.6 million in rebates and collected an average of $160.1 million in rebates per quarter.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

Our objectives were to evaluate the Health Department's processes and controls as of June 30, 2002 for drug rebate billings, collections, and dispute resolutions and its accountability in terms of reporting outstanding rebate balances to CMS.

Scope

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

In order to evaluate the accuracy, timeliness, and completeness of the Health Department'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 the Health Department's Medicaid program. We did, however, consider those control procedures that we believed would be appropriate for effective administration of New York's rebate program.

Methodology

To accomplish the objectives, we:

- reviewed applicable sections of the Medicaid laws, regulations, and guidelines for the rebate program
- reviewed Comptroller and CMS reports and files about New York's rebate program
- held discussions with Health Department, Comptroller, and CMS officials
- reviewed the Health Department's policies, procedures, internal controls, and records for the rebate program

Specifically, we gained an understanding of the Health Department's processes and controls by analyzing the flow of activity from the creation of the rebate invoices through the reporting of the 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 Albany, at the Health Department's offices in Albany and Menands, and at the Comptroller's office in Rensselaer between February and May 2003. The audit was performed in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

The Health Department produced timely rebate billings and collections in accordance with provisions of sections 1927(b)(1) and 1927(b)(2) of the Social Security Act. However, the processes and controls for rebate billings, collections, and dispute resolutions were not always coordinated effectively, did not maximize savings, and did not produce accurate and complete records of rebate activities. We also concluded that the Health Department did not properly account for its rebate activity or correctly report its outstanding rebate amount to CMS.

The audit identified:

- cost savings of approximately $3.3 million a year ($1.65 million Federal share) that could be achieved by seeking rebates from section 340B entities that do not bill the Health Department at discounted prices
- an understatement of the Federal share of rebates for drugs used for family planning services amounting to approximately $730,000 a year

- an estimated balance of $350.6 million in outstanding rebates (including $31.6 million in unresolved disputes) as of June 30, 2002 that was not reported to CMS on the Medicaid Drug Rebate Schedule

We concluded that the Health Department had not effectively coordinated the efforts of its three divisions and the other three agencies involved in administering the rebate program. We also believe that the Health Department must correct weaknesses in the processes, controls, and accountability for the rebate program as it implements the new business model and claims processing system that were under development at the time of the audit.

OVERVIEW OF FEDERAL REQUIREMENTS

The provisions of the rebate program are contained in OBRA of 1990 and in section 1927 of the Social Security Act. CMS supplemented these instructions with guidelines issued in the State Medicaid Manual (Publication 45) and rebate program "releases" (memorandums) to State Medicaid agencies and drug manufacturers.

In addition to the specific rebate 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 programs such as Medicaid that are sponsored by the Department of Health and Human Services

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

Finally, 31 CFR § 205.11 requires that transfers of Federal funds to a State agency shall be limited to the minimum amount needed to meet actual cash needs.

PROCESSES AND CONTROLS FOR REBATE BILLINGS, COLLECTIONS, AND DISPUTE RESOLUTIONS

While the rebate billings and collections were timely, our review of the processes and controls applicable to rebate billings, collections, and dispute resolutions identified opportunities to achieve additional savings and the need to improve the coordination of effort in the rebate program, especially with respect to the financial data needed to calculate the outstanding rebate balance. In addition, the Health Department did not always resolve disputes on a timely basis.

Invoice Processes Excluded Billings for Rebates Available to the Health Department

There was no assurance that drugs were purchased at discounted prices.

To prepare timely invoices, the Office of Temporary and Disability Assistance matched paid claims data about the quantities of each drug dispensed during the quarter to rebate amounts provided by CMS. The invoice processes, however, categorically excluded billings to entities entitled to discounts under the Public Health Service Act despite the fact that the Health Department had no assurance that these entities had billed the rebate program at discounted prices.

Specifically, rebates are not available if manufacturers offer drugs at a discounted price to certain providers (for example, entities that receive funding for specified HIV or hemophilia services)

under section 340B of the Public Health Service Act. Both section 340B (a)(5) of the Public Health Service Act and section 1927 of the Social Security Act, therefore, require providers and State Medicaid agencies to prevent rebate requests that would duplicate price reductions for claims billed at the section 340B discount amounts. The Health Department, in accordance with CMS guidance in Release Memorandum 101, addressed this concern by providing a listing of all providers entitled to the section 340B discounts to the Office of Temporary and Disability Assistance. Through these means, the Health Department prevented the issuance of rebate invoices for any drugs dispensed by section 340B providers. CMS, however, had also advised State Medicaid agencies that:

> . . . a Notice in the Federal Register on March 15, 2000 . . . pertains to situations where State Medicaid agencies did not request rebates for drugs purchased by covered entities which participate in the 340B drug pricing program (and do not participate in the 340B program for Medicaid). . . . some covered entities have elected to maintain a dual inventory, purchasing Medicaid drugs above the 340B price and billing the State Medicaid agency a non-340B price. For these drugs, the Medicaid agencies are entitled to a rebate. For these latter drugs, you may invoice the manufacturers for the drugs, requesting rebates retroactive to the quarter(s) in which covered entities did not participate in the 340B program for their Medicaid patients. Please contact (CMS) for further information on how to determine which covered entities participated in 340B for which quarters.[1]

Health Department officials did not implement procedures to determine whether section 340B providers had billed Medicaid at the discounted prices. According to Health Department officials, it could be quite difficult, given the frequent price changes and the number of drugs, manufacturers, and providers in the rebate program, to make these determinations without further assistance from CMS.

The invoice processes, therefore, did not achieve all of the savings available under the rebate program. Indeed, our review of historical records showed that the Health Department could be achieving additional savings of approximately $3.3 million a year ($1.65 million Federal share) from section 340B entities that billed the Health Department at non-340B prices.

Billing Processes and Records Were Inadequate

The procedures did not ensure that accurate billing information was available to other agencies or to all divisions within the Health Department.

The Health Department had not coordinated efforts to develop billing records that could effectively meet the needs of all users charged with managing and reporting the results of the rebate program.

The Health Department, however, is required by regulations at 45 CFR § 74.21(b)(1) to report accurate, current, and complete results of the rebate program.

While the Bureau received a tape from the Office of Temporary and Disability Assistance with the invoice information and downloaded the data into Access and Excel files for analysis and monitoring purposes, these billing records were not provided to other agencies or to the divisions

[1] CMS Release Memorandum 98 (April 18, 2000).

within the Health Department responsible for monitoring and reporting the drug rebate balances. Furthermore, the billing information maintained by the Bureau generally reflected the amounts as originally invoiced but was not systematically updated to correct errors in the quantities billed or in the rebate amounts. For example, if the quarterly rebate amount provided by CMS was not accurate, the Bureau contacted the manufacturer to help resolve these matters.

The Bureau's procedures, however, did not ensure that the files were updated once the new information was received; therefore, the billing records did not always include information needed both to create reliable financial records for management of the rebate program and also to report accurate, current, and complete results of the rebate program as required by the regulations at 45 CFR § 74.21(b)(1).

Cash Receipts and Collection Processes Needed Improvement

The Health Department's procedures ensured neither the timely deposit of rebate payments nor the coordination of effort needed to develop adequate records for reporting the results of its rebate program.

The cash receipts processes and controls permitted delays in the recording, endorsement, and deposit of checks and produced incomplete records that lacked information about the invoice date to which a rebate payment should be applied.

To ensure an appropriate segregation of duties among the Bureau's billing functions and the cash receipts and collections functions, the Health Department asked manufacturers to send their payments to Finance's revenue unit. Finance prepared the cash receipts log and forwarded the data to the Comptroller for recording in the account books and for determining the amount to be offset against Federal drawdowns. The funds were then deposited by the Department of Taxation and Finance.

The cash receipts records prepared by Finance, however, were incomplete and deposits of rebate funds were not always timely. For example, although Finance recorded payments in a computerized check register that automatically listed the date the check was posted to the system, it kept no record of the date the payments were received. In addition, the Health Department did not endorse checks as soon as they were received. Finally, we noted that checks were not always recorded or deposited timely. For example, a payment for $6.9 million dated March 18, 2002 was not recorded in the check register until April 10, 2002 and was not prepared for deposit until April 15, 2002, by which time $130 million in undeposited payments had accumulated; this amount included several other checks that were not deposited timely.

Once the checks were deposited, Finance forwarded cash receipts data and supporting documents to the Bureau. The Bureau used this information to develop computer files to track the status of rebate collections. These files, however, generally lacked information on dates when rebates were invoiced and only recorded activity from the time when the billing and collection functions were taken over by the Bureau in mid-1999.[2]

Regulations at 45 CFR § 74.21 (b)(1) and CMS instructions on the preparation of the Medicaid Drug Rebate Schedule require that States maintain accurate records for the rebate program and effective control over rebate funds. In addition, 31 CFR § 205 and CMS guidelines in

[2] For rebates pertaining to quarters prior to 1999, the Bureau forwarded the documents to the Pharmacy Unit where hard copy files for older unpaid rebates were maintained.

section 2500.6 of the State Medicaid Manual require that States implement cash management procedures that require the timely deposit of funds and the recognition of interest income attributable to the Federal Government.

The Health Department could not fully comply with these requirements because it failed to:

- record the invoice date for the rebate when rebate payments were received
- record the date when rebate payments were received
- endorse rebate checks until after they were posted in Finance's revenue unit, transferred to Finance's accounting unit for review, and returned to Finance's revenue unit for further processing
- deposit checks until all of these processes were complete
- coordinate the effort needed for efficient reporting of the rebate program results

These weaknesses:

- affected the Health Department's ability to properly age its receivables
- subjected unendorsed checks to the risk of misuse
- resulted in the loss of interest income that could have been earned if funds were deposited timely
- resulted in records that did not include information needed to create reliable financial records for managing and reporting the results of the rebate program

Better Records Are Needed to Monitor and Resolve Disputed Rebates

The Health Department did not have an efficient system to monitor and resolve outstanding disputes.

The Health Department had no comprehensive listing of disputed rebates to help track the outstanding rebates and to facilitate dispute resolutions.

To determine if unpaid items were likely to result in disputes, Bureau staff monitored collection activity. If the amount collected was lower than the amount invoiced, the staff first determined whether the matter could be resolved without referral to a pharmacist. When the Bureau concluded that a pharmacist was needed to review the drug code billed or the quantity of the drug per package, the documentation was forwarded to the Pharmacy Unit to initiate the dispute resolution process.

The Health Department was only able to provide a complete listing of disputed amounts resolved or outstanding from the middle of 1999 through the end of our audit period, but analysis of files maintained by the Comptroller and the Health Department showed a balance of at least

$31.6 million in unresolved disputes as of June 30, 2002, of which $27.4 million had been outstanding for 90 days or more.

In this regard, section VII-10 of the CMS "Best Practices for Dispute Resolution" recommends that State agencies prioritize the resolution of rebates from the oldest outstanding quarters.

The inability to provide a complete listing of disputed amounts and to resolve certain disputed items apparently arose from weaknesses in the Health Department's coordination of effort for monitoring and resolving disputes.

The balance of unresolved disputes from periods prior to July 2000 amounted to $19.2 million. While the Health Department received $2.4 million from two manufacturers in April 2002 for dispute resolutions pertaining to quarters from 1991 to 2001, we believe that considerable efforts may be needed to resolve the remaining disputes for periods prior to July 2000.

Interest on Late, Disputed, and/or Unpaid Rebates Was Not Verified

The Health Department had no controls to determine if interest for late or disputed rebates was correct.

The Health Department accepted and recorded interest received for late, disputed, and/or unpaid rebates without any further verification.

According to the rebate agreements between the manufacturers and CMS, manufacturers are required to both calculate and pay interest on late, disputed, or unpaid rebates. CMS, however, also recommends that States reach an agreement with manufacturers as to the amount of interest due. To this end, CMS publishes the relevant interest rates in its periodic rebate program release memorandums.

The Health Department, though, did not implement procedures to accrue or verify interest on drug rebates and, therefore, had no assurance that interest received represented the amounts actually due.

The Federal Share of Rebate Payments Was Not Properly Reported

The Health Department understated the Federal share of rebate collections.

Although the Health Department generally credited the Federal Government with the appropriate share of rebate payments, it did not credit the appropriate share of rebate collections on drugs used for family planning services.

The Federal and State governments each paid 50 percent of the costs for most drugs, but section 1903(a)(5) of the Social Security Act and CMS guidelines at section 4270.A of the State Medicaid Manual provide that the Federal share of pharmaceuticals used for family planning services is 90 percent.

Finance, however, informed us that the Health Department had not implemented procedures to link the Federal share of drug costs to the Federal share of drug rebates; therefore, rebates on all drugs were credited to the Federal Government at the 50 percent rate.

Our review of historical records indicates that this practice understated the Federal share of rebates by approximately $730,000 a year.

ACCOUNTABILITY FOR THE REBATE PROGRAM

The Health Department did not implement an effective accounts receivable system to identify and track the cumulative rebate balance, including the balance of outstanding rebates. In addition to the rebate balance, CMS requests information as to the "age" of the receivables; that is, the length of time that an invoice has remained unpaid. Weaknesses in the processes and controls for rebate billings and collections contributed to the Health Department's inability to create accurate accounts receivable records and undermined its ability to effectively monitor and report the rebate program results. Although the Health Department was not able to provide the outstanding rebate amount as of June 30, 2002, we estimated this amount at $350.6 million.

The Accounts Receivable System Was Ineffective

The Health Department was unable to provide the outstanding rebate amount as of June 30, 2002.

The Health Department did not maintain an effective accounts receivable system for the rebate program; therefore, we used the results of our review of the Health Department's processes and controls to determine means to estimate the outstanding rebate balance.

The Bureau's databases represented the most complete record of rebate program activity but only included invoice and collection information from the middle of 1999 through the end of our audit period. While these databases appeared to be adequate for the Bureau's billing and collection functions, they were not intended to capture accounts receivable data and were unable to provide all of the information required by CMS on the Medicaid Drug Rebate Schedule, Form CMS 64.9R. For instance, these databases:

- included unadjusted invoice information that was not updated to reflect corrections reported by CMS or manufacturers
- lacked information as to when payments were received and, therefore, prevented the Health Department from using those data to determine the balance of outstanding rebates as of any particular date
- did not generally indicate the quarter when the rebates were invoiced and, therefore, precluded the "aging" of the receivables

As a result, these databases did not represent an accurate accounts receivable system that could satisfy rebate program requirements at 45 CFR § 74.21(b)(3).

For these reasons, we concluded that neither the Health Department nor the Comptroller had an effective accounts receivable system for the rebate program, could perform a proper reconciliation to the general ledger accounts, or could provide outstanding rebates data for financial reporting purposes.

Since neither the Health Department nor the Comptroller could provide a cumulative accounts receivable total representing the outstanding rebates, we used Health Department records along with historical records from the Comptroller and CMS to calculate the balance as of June 30, 2002. The resulting estimate was, nevertheless, subject to limitations inherent in the underlying data, including the following:

- The invoices were generally recorded at the amounts originally billed and were not adjusted to reflect subsequent corrections in either the rebate amounts or the utilization data.

- The amount of the rebates received included interest as well as principal; however, there was no consistent, feasible means to identify the principal or interest components separately.

Despite the limitations of the available data, we were able to use information from other sources, such as CMS and Comptroller reports, to adjust the billed amount to take into account the effect of improper rebate amounts on the original CMS tapes. We also accounted for errors detected through the Health Department's dispute resolution processes. Through these efforts, we estimated an outstanding rebate balance of $350.6 million as of June 30, 2002, as detailed below:

Estimate of Outstanding Rebates as of June 30, 2002

		$ in millions
Rebates Billed January 1, 1991 to June 30, 2002		$3,670.8
Less:		
Improper Rebate Amounts on CMS Tapes	$313.0	
Corrections Resulting From Dispute Resolutions	2.9	(315.9)
Subtotal		$3,354.9
Cash Receipts (Principal and Interest)		(3,004.3)
Total - Estimated Outstanding Rebate Balance		$350.6

The Medicaid Drug Rebate Schedule Was Improperly Prepared

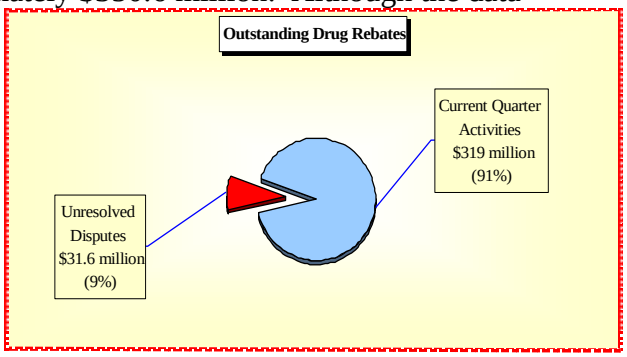
The Health Department's Form CMS 64.9R improperly showed that there were no outstanding rebates.

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. Errors in Form CMS 64.9R deprived CMS of information it would need to monitor the rebate program results. For example, the Health Department provided no information on outstanding rebates and, therefore, did not meet rebate program requirements.

Accordingly, the Health Department did not comply with requirements at 45 CFR § 74.21 (b)(1) or CMS instructions on the preparation of Form CMS 64.9R.

Finance prepared Form CMS 64.9R based on cash receipts records prepared in its revenue and accounting units. As previously noted, however, Finance did not receive information on the rebates billed to manufacturers; therefore, Finance's staff could not properly account for the outstanding rebates. For example, lacking information on the rebates billed to the manufacturers, Finance's staff reported the rebates collected as both the amount invoiced and the amount collected in that quarter.

Based on the incomplete information available to Finance, Form CMS 64.9R for the quarter ended June 30, 2002 improperly showed an outstanding rebate balance of $0.00; as noted above, however, the total as of that date was approximately $350.6 million. Although the data limitations discussed above prevented a detailed aging of the rebate balance, our analysis showed that only $31.6 million of this amount represented unresolved disputes.[3] As noted in the chart, the remaining $319 million in outstanding rebates related to the most recent quarters and was likely to be collected on a timely basis.



CONCLUSION

The audit identified weaknesses in processes and controls for rebate billings, collections, and dispute resolutions. These weaknesses resulted in the potential loss of rebates from section 340B entities, inaccurate and incomplete records of rebate activities needed for the financial management of the rebate program, understatement of amounts owed the Federal Government for drugs used for family planning, and difficulties and delays in resolving disputes.

The audit also noted deficiencies in the Health Department's accountability for the rebate program, which contributed to the inability to determine the actual accounts receivable amount and incorrect totals on Form CMS 64.9R.

We concluded that the Health Department had not effectively coordinated the efforts of its three divisions and the other three agencies involved in administering the rebate program. We also believe that the Health Department must devote attention to the rebate program requirements as it corrects weaknesses in its processes, controls, and accountability for the rebate program.

Some necessary changes may be on the horizon. For example, the Health Department's Bureau plans to migrate from a series of Excel and Access files that rely heavily on data entry to a more automated system that should facilitate better management of the rebate program. In addition, the Health Department has started to design a new business model with enhanced eligibility and processing systems for all medical claims, including pharmacy claims. Health Department officials anticipate that the redesign of the drug rebate system should significantly improve their accounting for the rebate program; help track and identify outstanding rebates; and help in verifying the amount of interest due on late, disputed, or unpaid rebates.

[3] The unresolved disputes consisted of $27.4 million that had been outstanding for at least 90 days as of June 30, 2002 and $4.2 million in disputes, pertaining to the most recent quarters, which had not been outstanding for 90 days.

RECOMMENDATIONS

We recommend that the Health Department coordinate and modify its processes and controls in order to strengthen both the rebate program and fiscal accountability to CMS. Specifically, the Health Department should:

- 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 section 340B entities that do not bill the Health Department 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

- 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)

- 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

In addition, although the Health Department's new business model and computer system may improve the administration of the rebate program, we believe that the Health Department should carefully consider limitations in the available accounting data and weaknesses in coordination of effort as it plans and implements the new business model.

AUDITEE COMMENTS

The Health Department generally concurred with the recommendations in the draft report, but expressed concerns about the use of the term "uncollected rebates" when referring to the total rebate balance that should have been reported on the Medicaid Drug Rebate Schedule as of June 30, 2002. In this regard, the Health Department noted that the total rebate balance of $350.6 million as of June 30, 2002 includes rebates applicable to the current quarter's drug payments[4] and that manufacturers were not obligated to pay these rebates at the date the Medicaid Drug Rebate Schedule was filed. The Health Department, therefore, suggested that a distinction be made between the total rebate balance and the $31 million of that total pertaining to disputed rebates that have not been collected.

The full text of the Health Department's response is presented as an appendix to this report.

[4] Office of Inspector General note: Rebates for the quarter ended June 30, 2002 amounted to $204.6 million of the $350.6 million total. In addition, manufacturers were not obligated to remit rebates for the quarter ended March 31, 2002, amounting to $184.1 million at the time this Medicaid Drug Rebate Schedule was filed.

OFFICE OF INSPECTOR GENERAL RESPONSE

We addressed the Health Department's concern about the term "uncollected rebates" by revising the report language. The $350.6 million rebate balance as of June 30, 2002 is now referred to as the "total" or "outstanding" drug rebate balance. We also note that both the draft and final reports indicate that only $31.6 million of the total balance had been disputed by the manufacturers and remained uncollected as of June 30, 2002.

APPENDIX

STATE OF NEW YORK
DEPARTMENT OF HEALTH
Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Antonia C. Novello, M.D., M.P.H., Dr.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

November 18, 2003

Timothy J. Horgan
Regional Inspector General for
Audit Services
DHHS OIG Office of Audit Services
26 Federal Plaza
Room 3900A
New York, New York 10278

Dear Mr. Horgan:

Enclosed are the Department of Health's (DOH) comments in response to the Department of Health and Human Services (DHHS), Office of Inspector General (OIG) draft audit report (A-02-03-01009) entitled "Review of the Medicaid Drug Rebate Program in New York State."

Thank you for the opportunity to comment.

Sincerely,

Dennis P. Whalen
Executive Deputy Commissioner

Enclosure

Department of Health
Comments on the
Department of Health and Human Services
Office of Inspector General
Draft Audit Report
A-02-03-01009 Entitled
"Review of the Medicaid Drug Rebate Program in New York State"

The following are the Department of Health's (DOH) comments in response to the Department of Health and Human Services (DHHS), Office of Inspector General (OIG) draft audit report (A-02-03-01009) entitled "Review of the Medicaid Drug Rebate Program in New York State."

The following section contains the Department's comments on specific OIG statements throughout the audit.

Comment:

Disputes are not always resolved on a timely basis.

Response:

Additional resources have been allocated to investigate and collect disputed rebates. Proactive rebate invoice reviews are completed with many drug manufacturers to resolve potential disputes. However, until there are specific time limits placed on the ability of manufacturers to continue to amend pricing data, the rebate resolution process will continue to be a difficult task, requiring extensive resources in each state.

Comment:

Bureau of Revenue Initiatives (BRI) files contain information from 1999 forward. Earlier rebates received are forwarded to the Pharmacy Unit where hard copy files of older unpaid rebates were maintained.

Response:

The Department can reference the older paper files when needed, but is working to make selected older data available electronically.

Comment:

The pre-1999 system did not contain information needed for reliable financial records for managing and reporting program results.

Response:

All required information for managing and reporting program results are available for review.

Comment:

Our analysis of files maintained by the Office of the State Comptroller (OSC) and the Department showed a balance of at least $31.6 million in unresolved disputes as of June 30, 2002.

Response:

Additional resources have been allocated to investigate and collect disputes, and staff has participated in CMS drug rebate meetings.

Comment:

We believe that considerable efforts may be needed to resolve the $19.2 million in unresolved disputes for the periods prior to July 2000.

Response:

Staff actively investigates unresolved disputes going back to 1991.

Comment:

The lack of information as to when payments were received prevents the Department from using the BRI data to determine the balance of uncollected rebates as of any particular date.

Response:

The Department has improved its current tracking system and is working closely with its eMedNY contractor to develop and implement an electronic tracking system.

Comment:

Limitations in the accounting data presently available to the Department and weaknesses in the current coordination of effort need to be carefully considered as the new business model is planned and implemented.

Response:

A number of improvements have been proposed for the rebate tracking system. The Department is currently working closely with the eMedNY contractor to develop and implement an electronic tracking system.

The following are the Department's responses to OIG's specific recommendations:[1]

Recommendation #1:

Use the estimate of $350.6 million in uncollected rebates ($175.7 million Federal share) as of June 30, 2002 as a starting point for a viable accounts receivable system for the program.

Response #1:

In principle, the Department agrees that it must identify a starting point for a viable accounts receivable system. However, the implication that there is "$350.6 million in uncollected rebates" cited in this recommendation is misleading. At the time of the audit, the estimated dispute balance of uncollected rebates was $31 million. This is the total amount outstanding since the inception of the program in 1991. This 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 invoice and remit the rebate and, therefore, is not "uncollected."

Since June 2002, the Department collected over $4.4 million in rebates through the rebate resolution process. Nearly $3.9 million was part of the estimated uncollected rebates as of June 2002. This significantly reduces the uncollected rebate amount due. For the period April 1998-March 2003, the Department collected $2.55 billion in drug rebates with ongoing dispute resolution amounts of approximately $30-50 million over the sme period. The Department currently collects 97.8 percent (as noted in an audit by the New York State Office of the State Comptroller) of all rebate amounts billed before the resolution process and, from the statistics above, virtually all of the amounts invoiced over time.

Recommendation #2:

Properly report the uncollected rebate amount to CMS on the "Medicaid Drug Rebate Schedule."

Response #2:

The Department will properly report the uncollected rebate amount on the Medicaid Drug Rebate schedule.

[1] **OFFICE OF INSPECTOR GENERAL NOTE:** For the sake of clarity and consistency, the order of the recommendations has been revised since the draft report. Recommendation # 1 in the draft report is now the fifth recommendation and Recommendation # 3 in the draft report is now the first recommendation.

Response #2 (continued):

The Department has allocated additional resources to investigate and collect disputed rebates. Proactive rebate invoice reviews are completed with many drug manufacturers to resolve potential disputes. However, until there are specific time limits placed on the ability of manufacturers to continue to amend pricing data, the rebate resolution process will continue to be a difficult task, requiring extensive resources in each state.

Recommendation #3:

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 340B entities that billed New York at non-340B prices.

Response #3:

The Department agrees that it should be working with CMS to achieve appropriate savings for 340B discounts; however, the collection of rebates due from improper billing by 340B entities is a universal concern for all states and requires that CMS take the lead in this effort.

Recommendation #4:
Assure that the Federal Government receives the appropriate share of rebates for drugs for family planning services (approximately $730,000 Federal share of additional rebates a year).

Response #4:

The Department will investigate its ability to discretely identify appropriate rebate amounts (Federal share) for family planning drugs.

Recommendation #5:

Establish adequate procedures and controls for the Medicaid program to assure timely endorsement and deposit of all rebate funds and the tracking and verification of interest due on rebate payments.

Response #6:

The Department agrees that it should assure timely endorsement and deposit of all rebate funds. The Department has improved its cash management procedures by endorsing all rebate checks immediately upon receipt and by reducing the time between receipt and

deposit of the checks. In addition, when implemented, the new eMedNY drug rebate system will be capable of tracking and verifying any interest due. However, the responsibility for calculation of interest remains with the drug manufacturers.

Recommendation #6:

Although New York's new business model and computer system may improve administration of the program, we believe that limitations in the accounting data presently available to New York and weaknesses in the current coordination of effort need to be carefully considered as the new business model is planned and implemented.

Response #6:

The Department will ensure that limitations in data, as well as overall coordination of effort, will be considered as the eMedNY electronic drug rebate tracking system is developed.

ACKNOWLEDGMENTS

This report was prepared under the direction of Timothy J. Horgan, Regional Inspector General for Audit Services, Region II. Other principal Office of Audit Services staff who contributed include:

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