DEPARTMENT OF HEALTH
ADMINISTRATION OF THE MEDICAID DRUG REBATE PROGRAM
2000-S-33
Dear Dr. Novello:

The following is our report on the Department of Health’s practices for administering the Medicaid drug rebate program.

This audit was performed pursuant to the State Comptroller’s authority as set forth in Article V, Section 1 of the State Constitution and Article II, Section 8 of the State Finance Law. Major contributors to this report are listed in Appendix A.

June 27, 2001
EXECUTIVE SUMMARY

DEPARTMENT OF HEALTH
ADMINISTRATION OF THE MEDICAID DRUG REBATE PROGRAM

SCOPE OF AUDIT

The Department of Health (Health), which administers the State’s Medical Assistance Plan (Medicaid), processes and pays Medicaid claims, including claims for pharmacy services. Medicaid paid over $5.0 billion for pharmacy services for the 30-month period ended June 30, 2000.

To reduce the cost of drugs prescribed for Medicaid recipients, the Federal government established the Medicaid Drug Rebate Program (Program), overseen nationally by the Federal Health Care Financing Administration (HCFA) and administered in New York State by Health. Since January 1, 1991, state Medicaid programs have recovered a portion of their prescription drug costs by requesting rebates from drug manufacturers, who review and pay any undisputed amounts. All prescription drugs are eligible for Program rebates, except for those dispensed at certain entities which pay discounted prices for drugs and then pass on the savings to Medicaid. States are responsible for collecting and accounting for rebates owed by manufacturers. Health reports collecting approximately $918 million in Program revenue during the above 30-month period, and about $2 billion since the Program began.

Our audit addressed the following question regarding Health’s administration of the Medicaid drug rebate program for the period January 1, 1998 through June 30, 2000:

- Has Health maximized Program revenues owed to Medicaid?

AUDIT OBSERVATIONS AND CONCLUSIONS

We found that Health has not maximized Program revenues owed to Medicaid. Health does not properly track or pursue rebate revenues, and has essentially relied on drug manufacturers to remit the rebates they owe. As a result, Health did not recoup between $14.1 million and $19.6 million in monies it should have collected during our audit period.
Section 1927 of the Social Security Act requires states to develop a method of ensuring they do not request rebates for already-discounted drugs. However, we found that Health did not request rebates for drugs eligible for discounts without ensuring Medicaid had actually paid discounted prices for these drugs. Depending on whether Health should have requested rebates or paid discounted prices, we estimate that Medicaid should have received additional revenues totaling between $7.2 million and $10.6 million during our audit period. We recommend that Health investigate the payments and determine whether a rebate or discount is owed, and develop a process to coordinate the collection of rebates or discounts. (See pp. 5-8)

If manufacturers disagree with Health’s rebate invoice, they can dispute the amount owed and delay payment of this portion until the dispute is resolved with Health. Timely resolution is important, since receivables become harder to collect with age. Further, Health officials report that HCFA is developing guidelines that will limit the time Health has to collect outstanding disputed amounts. Based on information we received from 26 of the 50 largest drug manufacturers, and our review of Health’s files for the remaining 24 manufacturers, we determined that outstanding disputed balances totaled about $23 million as of June 30, 2000. Health reports it is working to resolve about $2 million of this amount, but estimates it could negotiate with manufacturers the remaining $21 million outstanding for between $6 and $8 million. To maximize recoveries and to lessen the risk of uncollectibility, we recommend that Health devote adequate resources to collecting these outstanding disputed rebates. (See pp. 8-9)

We also concluded that, for all practical purposes, Health does not have a functioning accounting system for the Program. Our review showed that Medicaid was owed more than $900,000 as a result of unbilled rebates, pricing changes and interest due. Since eMedNY, Health’s new medical claims processing system now under design, will not be fully implemented for several years, we recommend Health take immediate steps to recoup all available Program revenues for Medicaid. (See pp. 9-11)

**COMMENTS OF OFFICIALS**

Department of Health officials agreed with the report’s recommendations and indicated the steps they have taken or will take to implement them. A complete copy of the Department’s response is included as Appendix B.
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INTRODUCTION

Background

The New York State Department of Health (Health) administers the State’s Medical Assistance Plan (Medicaid), which was established under Title XIX of the Federal Social Security Act to provide medical assistance to needy people. Health uses the Medicaid Management Information System (MMIS), a computerized payment and information reporting system, to process Medicaid claims and make payments to health care providers for services rendered. These services include pharmacy services, such as dispensing prescription and non-prescription drugs. Medicaid paid over $5 billion for pharmacy services between January 1, 1998 and June 30, 2000.

The Federal government established a national drug rebate program whose objective is to reduce the overall costs of drugs to the Medicaid program. The national Medicaid Drug Rebate Program (Program) was established by Federal legislation in 1990 and became effective January 1, 1991. The Program is overseen by the Federal Health Care Financing Administration (HCFA), which has established a uniform process for states to follow in administering the Program. According to this process, state Medicaid programs first reimburse pharmacies for dispensing prescription drugs to Medicaid recipients and then recover a portion of these expenditures by requesting rebates from the drug manufacturers. Each state is responsible for developing an accounting system capable of properly recording and tracking rebate monies paid or owed to Medicaid by drug manufacturers. According to Health, which administers the Program in New York State, it collected approximately $918 million in rebates during our 30-month audit period, and about $2 billion since the Program’s inception in 1991.

HCFA gives the states data on the rebate per unit sold for all rebate-eligible drugs every calendar quarter to enable states to recover rebates on these drugs. (Some items, such as pharmaceutical supplies, are not rebate-eligible.) HCFA calculates the rebate per unit using drug-pricing information
provided by the manufacturers. Manufacturers often change pricing information, which results in the rebate per unit amount either increasing or decreasing on a quarterly basis. Health uses this rebate per unit data from HCFA, along with MMIS information on paid pharmacy claims, as the basis for determining the amount of its quarterly invoices to drug manufacturers. The manufacturers review the invoices and remit rebates to Health. HCFA requires manufacturers to pay rebates on undisputed amounts within a predetermined timeframe. Otherwise, the manufacturers are obligated to pay interest. If a manufacturer disagrees with an invoice amount, the manufacturer can dispute the questionable portion of the invoice and delay payment of this portion until the dispute is resolved.

Health can request Program rebates on all prescription drugs that are dispensed, except for certain outpatient drugs purchased by specified government-supported facilities (covered entities), such as the outpatient pharmacies of large urban hospitals. These drugs are instead eligible for Federally-mandated discounts. Section 340B of the Public Health Service Act requires that drug manufacturers discount the cost of drugs supplied to these “covered entities,” and that the entities pass on the discounts by billing Medicaid at the discounted prices. According to Federal officials, these discounted prices generally average about 40 percent less than the manufacturers' wholesale price. For the 30 months ended June 30, 2000, the State’s Medicaid program paid $53.1 million in pharmacy claims to covered entities. Drugs that have already been discounted to covered entities are not eligible for Program rebates. In fact, Section 1927 of the Social Security Act states that manufacturers are not to provide duplicate discounts (i.e., a discount and a rebate) on the same drug dispensed. This Section further requires states to develop a method of identifying claims from covered entities to ensure the states do not request rebates for already-discounted drugs.

In April 1999, Health replaced the manual accounting system it had previously used to track rebates with an automated database. This database, which is separate from MMIS, is the accounting system Health uses to collect and account for rebates paid or owed by drug manufacturers. In early 2000, Health began designing a new system, eMedNY, to replace and improve the existing MMIS eligibility and processing systems for all medical service claims, including pharmacy claims. Health
estimates the entire project will take several years to complete. Health officials stated their belief that the redesign of the drug rebate system, which is one small component of the entire eMedNY project, will significantly improve Health’s accounting for the Program.

**Audit Scope, Objective and Methodology**

We audited Health’s process for collecting and accounting for rebate revenues owed to Medicaid for the period January 1, 1998 through June 30, 2000. The objective of our performance audit was to determine whether Health is maximizing Program revenues owed to Medicaid. To accomplish our audit objective, we interviewed Health officials, examined relevant Health records and reviewed applicable drug rebate payment policies and procedures. In addition, we developed computer programs to compare pharmacy claims MMIS paid with invoices Health sent to manufacturers. Further, we reviewed all the rebates collected from the 50 largest drug manufacturers for the period January 1, 1998 through March 31, 2000. (We did not review rebates collected for April 1 through June 30, 2000, the remainder of our audit period, because Health had not yet processed Program-related rebates for these three months.) These drug manufacturers accounted for approximately 85 percent of Medicaid prescription drug expenditures during our entire audit period. The rebates collected from these manufacturers totaled over $784 million, which represents 21.9 percent of the amount Medicaid paid these manufacturers for prescription drugs during this period. We also surveyed ten states and the 50 largest manufacturers to identify best practices that Health could use to improve its operation of the Program.

We conducted our audit in accordance with generally accepted government auditing standards. Such standards require that we plan and perform our audit to adequately assess the Health operations included in our audit scope. Further, these standards require that we understand Health’s internal control structure and its compliance with those laws, rules and regulations that are relevant to the operations included in our audit scope. An audit includes examining, on a test basis, evidence supporting transactions recorded in the accounting and operating records and applying such other auditing procedures as we consider necessary in the circumstances. An audit also includes assessing the estimates, judgments and
decisions made by management. We believe that our audit provides a reasonable basis for our findings, conclusions and recommendations.

We use a risk-based approach when selecting activities to be audited. This approach focuses our audit efforts on those operations that have been identified through a preliminary survey as having the greatest probability for needing improvement. Consequently, by design, finite audit resources are used to identify where and how improvements can be made. Thus, little audit effort is devoted to reviewing operations that may be relatively efficient or effective. As a result, our audit reports are prepared on an “exception basis.” This report, therefore, highlights those areas needing improvement and does not address activities that may be functioning properly.

Response of Health Officials to Audit

Draft copies of this report were provided to Health officials for their review and comment. Their comments have been considered in preparing this report and are included as Appendix B.

In addition to the matters discussed in this report, we have also reported separately to Health officials about a number of other audit issues. While these are matters of lesser significance, officials should implement our recommendations related to these issues to improve the efficiency of the Medicaid drug rebate program.

Within 90 days after final release of this report, as required by Section 170 of the Executive Law, the Commissioner of the Department of Health shall report to the Governor, the State Comptroller and leaders of the Legislature and fiscal committees, advising what steps were taken to implement the recommendations contained herein, and where recommendations were not implemented, the reasons therefor.
DRUG REBATE PRACTICES

The Program exists to help states recoup a substantial part of the cost Medicaid incurs to provide prescription drugs for recipients. However, we found that Health does not administer the Program effectively to maximize the monies Medicaid could realize from the Program. In fact, Health essentially relies on drug manufacturers to remit the rebates they owe; it does not properly track or pursue rebate revenues or timely resolve disputed rebates. Program monies Health does not collect are monies the State does not have available to help support its Medicaid program.

We found that Health has not collected a total of between $14.1 million and $19.6 million owed to Medicaid, as follows:

- between $7.2 million and $10.6 million for claims related to covered entities;
- between $6 million and $8 million in recoveries from outstanding disputed rebates; and
- approximately $900,000 in undisputed rebates and interest due.

Both HCFA and the Office of the State Comptroller have previously audited the Program’s operation and reported on Health’s weak controls over the Program. Our prior audit (Report 94-S-5, issued October 31, 1994) recommended that Health work to maximize Program revenues by developing an automated system to accurately account for rebates requested and received. However, Health has made only minimal improvements to date in accounting for Program rebates. We believe Health could have collected significant additional rebates if it had implemented the recommendations of our prior audit.
Section 1927 of the Social Security Act requires each state to develop a method of identifying claims from covered entities that should receive discounts for the drugs they dispense. As stated earlier, these discounts reduce drug prices by about 40 percent on average. Such discounted drugs are not eligible for rebates under the Program. To coordinate the operation of these two Federally-sponsored programs, Health needs to ensure that Medicaid pays the appropriate discounted prices on claims from covered entities, and that it then excludes these claims from Program rebate requests. However, we found that Health is excluding covered entity claims from rebate eligibility without first ensuring it has received the proper discounts on the claims.

During our audit period, Medicaid paid $53.1 million in pharmacy claims to covered entities. We reviewed these claims and determined that the covered entities did not always use the manufacturers’ discounted prices when billing Medicaid. Although Medicaid received some type of discount on approximately $23.5 million of these paid claims, it received no covered entity discount – and no rebates – on the remaining payments of $29.6 million. As covered entities, these providers should have billed Medicaid using the discounted price, generally 40 percent less than the manufacturers’ wholesale price. Instead, these providers billed at the full Medicaid price, which is generally 10 percent less than the manufacturers’ wholesale price. Health should have received an additional 30 percent discount off the manufacturers’ wholesale price for these claims. To estimate the value of discounts Health could have received on this $29.6 million in claim payments, we calculated that the manufacturers’ undiscounted wholesale price would have approximated $32.8 million. If the providers had billed Medicaid at 60 percent of the manufacturers’ wholesale price (wholesale price less 40 percent discount) then the payments on these claims would have been $19.7 million. The $9.9 million difference between what the providers billed ($29.6 million) and the discounted price they should have billed ($19.7 million) represents the potential cost savings to Health.
Alternately, if these claims were not eligible for manufacturers’ discounts, then Health should have requested rebates from the manufacturers. As stated earlier, the Program rebates Health collected from the 50 largest drug manufacturers between January 1, 1998 and March 31, 2000 represented 21.9 percent of the amount Medicaid paid these manufacturers for prescription drugs during this period. If Health had received this average rebate percentage on these claims, it would have collected rebates of at least $6.4 million. Therefore, depending on whether Medicaid should have received rebates or discounts, we estimate Health would have saved between $6.4 million (in rebates) and $9.9 million (in discounts).

Furthermore, even for those cases in which the covered entities billed Medicaid at discounted rates, Medicaid may not have received the proper amount of discount. Of the $23.5 million in pharmacy claims billed at a discount, $3.2 million in claims were at discounts of between 1 and 10 percent. These discounts appear minimal when compared with an average discount of 40 percent. In these cases we question the accuracy of the discount the covered entities provided. If Medicaid had received the full 40 percent discount on these claims, Health could have saved approximately $796,000 in additional discounts.

To establish the total amount of achievable savings, Health must first determine whether the claims we identified are eligible for discounts under the covered entity program, and then wait for the entities to re-bill Medicaid at the discounted rates. Further, since our review of claims was limited to our audit period, it is possible that Health can obtain additional rebates and discounts by examining claims before and after our audit period.

Collection of Disputed Rebates

If manufacturers disagree with an invoice, such as the number of units being invoiced, they can dispute the amount owed associated with the disputed item. This action will delay payment of the disputed portion of the rebate until the dispute is resolved with Health. Timeliness is essential in resolving these disputes. Health officials report that HCFA is developing guidelines that will place a time limit on collecting outstanding disputed amounts from manufacturers. Therefore, it is important that Health resolve disputes promptly to avoid losing
settlement money owed to Medicaid. Further, as is the case with any receivable, the longer it remains outstanding, the greater the likelihood the amount will be uncollectible, regardless of a time limit set for collection.

However, we found that Health is making little progress in resolving and collecting disputed amounts or even in determining the total disputed rebates owed. Health's accounting system was unable to identify the amount of outstanding disputed rebates as of June 30, 2000, either in total or by individual drug manufacturer. In an effort to determine the amounts of outstanding disputed rebates, we contacted the 50 largest drug manufacturers cited earlier in this report to identify their respective outstanding disputed rebate balances. Of the 50 manufacturers, 26 responded indicating they had outstanding disputed rebates, some of which dated to the Program's inception in 1991. We reviewed Health's files for the remaining 24 manufacturers to determine whether Health's records showed any unresolved disputed amounts. Based on the manufacturers' responses and our review of Health's files, we identified about $23 million in outstanding disputes.

We also attempted to determine the age of the outstanding disputed balances. We received the detailed information needed for this analysis from only 11 of the 26 manufacturers who responded to our survey. These manufacturers reported disputed balances totaling $9.25 million as of June 30, 2000. Of this amount, $5.06 million are disputed balances that are no more than two and one-half years old; $4.19 million are disputed balances over two and one-half years old, some of which have existed since 1991. If HCFA does impose a collection time limit, this $4.19 million in disputed rebates is at the greatest risk of being uncollectible.

Although Health officials estimate staff are working on approximately $2 million of these outstanding disputed rebates, the officials have devoted minimal resources to the collection efforts. Health has assigned two pharmacists to dispute resolution, but due to other priorities, these two staff spend only about 20 percent of their time actually resolving disputes. They spend about 80 percent of their time on non-Program duties. In addition to whatever revenue may be realized from resolving the $2 million in disputed rebates above, Health officials estimate that they would collect between $6 million and $8 million in rebate revenue if they were to resolve the remaining $21 million
in outstanding rebates. These amounts represent money the State was not able to use for Medicaid purposes because Health did not resolve disputed rebates promptly. We urge Health officials to commit the necessary resources to resolve and collect these disputed amounts, both to reduce the risk of these amounts becoming uncollectible and to realize Program revenue, to the extent possible, in the period the rebates were due.

**Accounting for Rebates**

As stated earlier, Health replaced the manual accounting system it had previously used to account for and track rebate money owed to Medicaid with an automated database separate from MMIS in April 1999. To evaluate Health’s controls over money owed, we reviewed both the database and the manual records. We determined Health’s database did not properly record all transactions. For example, we compared the information in the database with Health’s manual files and determined that the database contained numerous data entry errors. Health officials are investigating and correcting these errors.

We also determined that the database system could not properly account for rebates billed, amounts outstanding and disputed rebates. Health does not know how much individual drug manufacturers owe Medicaid, or how much is owed to Medicaid in total. We reviewed the manual files for the 50 largest manufacturers cited earlier for the period January 1, 1998 to March 31, 2000. We identified an additional $360,000 in undisputed Program rebates that manufacturers owed to Medicaid. Although Health had requested these rebates, the manufacturers had not paid them and Health had no way to identify or monitor these outstanding balances. From our review of the manual files, we also found that manufacturers owed approximately $105,000 in interest because they had paid their rebates late. According to Federal regulations, the total undisputed amount of the invoice is to be paid by the manufacturer within 38 days. Health officials had not collected these outstanding rebates or interest because the officials were unaware they were owed to Medicaid.

Another deficiency in Health’s accounting system is that Health does not monitor revisions to the rebate per unit data used to calculate rebates owed. As noted earlier, manufacturers can
increase or decrease each drug's pricing information on a quarterly basis. HCFA then sends states corresponding rebate per unit revisions so that states can ensure they receive correct rebate amounts. However, Health’s system does not apply HCFA price revisions retroactively. Therefore, Health has no assurance that manufacturers pay the rebates they actually owe. To determine the impact of Health’s not using this pricing data, we judgmentally selected 75 drug rebate payments made during our audit period. These payments comprised a cross-section of Health’s invoices to drug manufacturers (that is, invoices which showed Health had billed rebate per unit amounts that were either equal to, greater than or less than what HCFA had reported). We then compared the rebates paid by the manufacturers to HCFA’s records. We found that 20 out of the 75 payments differed from what HCFA indicated the payment should be: 15 of these payments were underpaid by about $575,000 and 5 payments were overpaid by $108,000. Therefore, Health could have collected an additional $467,000 in rebates if its system had the capability of adjusting rebate per unit amounts with HCFA data on revised prices.

Given the system’s serious limitations, we conclude that, for all practical purposes, Health does not have a functioning accounting system for the Program. We believe the reason Health has not acted to establish control over the Program is that Health officials have not assigned a high priority to actively managing a Program that generates revenue, even without much attention from management. Health reports the Program collected about $2 billion in rebates since 1991. However, Health has relied primarily on manufacturers submitting the correct rebate payments.

We believe there is a potential for significantly more rebate revenue if Health can develop and use a system to reliably account for, track and pursue all available rebates from drug manufacturers. Such a system should include, at a minimum, the ability to calculate rebates receivable, monitor rebates outstanding, calculate and collect interest owed on late payments, monitor and collect rebate per unit data, and monitor and resolve disputes with manufacturers. Health officials maintain that eMedNY will provide the Program with the necessary accounting system. Since the present system is ineffective, and since eMedNY will likely not be fully implemented for several years, Health should take immediate measures to maximize the Program revenues for Medicaid.
Recommendations

1. Investigate pharmacy claims for covered entities where Medicaid did not receive either a full discount or a rebate, and recover the appropriate rebate or discount.

2. Evaluate the potential of identifying and recovering additional rebates or discounts before and after the audit period addressed in this report.

3. Develop a process to identify whether covered entities appropriately billed Medicaid at the discount rate and identify claims that should be included in the rebate process.

4. Devote adequate resources to ensure the proper and timely resolution of all outstanding disputes with manufacturers.

5. Routinely follow up with manufacturers with disputed rebate amount balances.

6. Allocate sufficient resources to ensure that, at a minimum, existing and planned systems provide Health with the ability to:
   - compute interest on unpaid balances;
   - research disputed rebates;
   - properly track pricing and rebate per unit changes;
   - reconcile current quarter activity with prior quarters; and
   - record, track and age rebates owed by drug manufacturers.

7. Investigate and recover identified rebates owed.
Major contributors to this report

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June 15, 2001

Kevin M. McClune  
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Albany, New York  12236

Dear Mr. McClune:

Enclosed are the Department of Health’s revised comments on the Office of the State Comptroller’s draft audit report 2000-S-33, entitled “Administration of Medicaid Drug Rebate Program”.

Thank you for the opportunity to comment.

Sincerely,

Dennis P. Whalen  
Executive Deputy Commissioner
The following are the Department of Health's (DOH) revised comments in response to the Office of the State Comptroller's (OSC) Draft Audit Report 2000-S-33 entitled "Administration of the Medicaid Drug Rebate Program".

**Recommendation #1:**

Investigate pharmacy claims for covered entities where Medicaid did not receive either a full discount or a rebate, and recover the appropriate rebate or discount.

**Response #1:**

The Department is investigating the claims in question to determine if the Department was entitled to either a full discount or a rebate and will recover the appropriate rebate or discount.

**Recommendation #2:**

Evaluate the potential of identifying and recovering additional rebates of discounts before and after the audit period addressed in this report.

**Response #2:**

The Department is investigating, identifying and recovering additional rebates or discounts, as appropriate, before and after the audit period addressed in the report. When implemented, the eMedNY computer system will electronically track and identify outstanding rebates due.

**Recommendation #3:**

Develop a process to identify whether covered entities appropriately billed Medicaid at the discount rate and identify claims that should be included in the rebate process.
Response #3:

In response to the findings, the Department has initiated a process to verify the covered entities that participate in the disproportionate share buying program. This process includes the identification by HCFA of all covered entities eligible for disproportionate share buying. Since all eligible entities do not participate in the program, the Department now verifies which entities are participating in the disproportionate share buying program and puts an indicator on the system. In addition, the Department is investigating a suitable plan to monitor appropriate billings from disproportionate share entities.

Recommendation #4:

Devote adequate resources to ensure the proper and timely resolution of all outstanding disputes with manufacturers.

Response #4:

The Department has allocated additional resources for the collection of disputed rebates. This staff will investigate, review and collect appropriate rebates. In the future, eMedNY will provide an enhanced tracking system and identify outstanding rebates due that will result in proper rebate resolution.

Recommendation #5:

 Routinely follow up with manufacturers with disputed rebate amount balances.

Response #5:

Staff will continue to follow up with manufacturers on disputed rebate amount balances. When implemented, the eMedNY computer system will have subsystems in place to assist in the timely identification and tracking of disputed rebate amount balances.

Recommendation #6:

Allocate sufficient resources to ensure that, at a minimum, existing and planned systems provide Health with the ability to:

- compute interest on unpaid balances;
- research disputed rebates;
- properly track pricing and rebate per unit changes;
- reconcile current quarter activity with prior quarters; and,
- record, track and age rebates owed by drug manufacturers.
Response #6:

Staff has been actively involved in the development and review process of the new computer system to ensure that eMedNY has the following capabilities:

- compute interest on unpaid balances;
- research disputed rebates;
- properly track pricing and rebate per unit changes;
- reconcile current quarter activity with prior quarters; and,
- record, track and age rebates owed by drug manufacturers.

Recommendation #7:

Investigate and recover identified rebates owed.

Response #7:

The Department will investigate and recover identifiable rebates owed.