Alan G. Hevesi
COMPTROLLER

OFFICE OF THE
NEW YORK STATE COMPTROLLER

DIVISION OF STATE SERVICES

DEPARTMENT OF HEALTH

MEDICAID PRESCRIPTION DRUG REBATES

Report 2005-S-51

AUDIT OBJECTIVES

One objective of our audit was to determine whether the Department of Health (Department) has taken action to maximize the revenues collected by the State under the federal Medicaid drug rebate program. Another objective was to evaluate the Department's methodology and actions for controlling the cost of prescription drugs dispensed to Medicaid recipients. Our audit covered the period January 1, 2004 through January 18, 2006.

AUDIT RESULTS - SUMMARY

We found the Department had taken action to improve the amount of revenue collected by the State under the federal Medicaid drug rebate program. However, we are unable to conclude that the Department has maximized rebate revenues, as certain major changes have yet to be fully implemented. The Department is in the process of developing and implementing an improved system for billing, tracking and accounting for Medicaid drug rebates owed, including rebates owed for individual drugs over specific time periods. The new system should allow the Department to generate more accurate invoices for manufacturers. Department officials believe this new system, and improved billing accuracy, will enable them to collect rebate revenues more quickly and resolve billing disputes more easily. (Pages 3-5)

The State has reduced the amount it reimburses pharmacies for the drugs they dispense to Medicaid recipients. This change has produced some cost savings on Medicaid prescription drugs.

In addition, the Department has hired a consultant to administer four initiatives intended to reduce costs. Under the contract, the contractor will negotiate additional manufacturer rebates; help develop a preferred drug list; operate a staffed call center to decide approval for drugs not on the preferred list; and establish a State maximum allowable cost program that uses federal formulas to set maximum reimbursement rates for certain drugs. These initiatives seek to limit the use of drugs that are expensive and subject to abuse or overuse. The Department estimated it would save $240 million in 2005-2006 from the above initiatives. However, because of delays in implementing these initiatives, the Department did not achieve its original estimated savings in 2005-2006. We could not fully evaluate the initiatives' impact since they were still being developed and implemented at the time of our audit. (Pages 5-6)

This report contains two recommendations that suggest the Department continue to implement its new accounting system to fully bill and collect all rebates owed, and continue to develop and implement the pharmacy initiatives. Department officials agreed with our recommendations and have taken steps to implement them.

This report, dated September 6, 2006, is available on our website at http://www.osc.state.ny.us. Add or update your mailing list address by contacting us at: (518) 474-3271 or
Office of the State Comptroller
Division of State Services
State Audit Bureau
110 State Street, 11th Floor
Albany, NY 12236

BACKGROUND

The Department administers the Medicaid program in New York State, and uses eMedNY, the State's Medicaid management information and claims processing system, to pay provider claims. In administering the pharmacy benefits portion of Medicaid, Department officials must provide adequate access to prescription drugs to eligible recipients, but do so in a cost efficient manner. Prescription drugs represent about 15 percent of the State's Medicaid spending. The State's Medicaid expenses for prescription drugs in 2004 increased 15 percent from 2003, rising from $4.296 billion in 2003 to $4.944 billion in 2004. The Department has pursued two options available for controlling the costs of Medicaid prescription drugs: rebates from drug manufacturers and reduced reimbursement to dispensing pharmacies.

The federal Center for Medicaid and Medicare Services (CMS) operates a federal Medicaid prescription drug rebate program (CMS rebate program) that entitles states to collect rebates from drug manufacturers. Manufacturers pay rebates to states on a drug-by-drug basis. The rebate amount is based on the number of units of the drug dispensed in the state for a three-month period. Individual states are responsible for calculating the amount of rebate owed; for billing and collecting the rebates; and for resolving disputes with manufacturers about rebate amounts owed. New York State has participated in the CMS rebate program since it was initiated in 1991. For the period January 1, 2004 through October 31, 2005, the Department reported it collected almost $2 billion in CMS program rebates. Recently, the State passed legislation that allows the Department to seek supplemental rebates, in addition to those available through the CMS rebate program.

The Department reimburses pharmacies for the prescription drugs they dispense to Medicaid recipients. Federal law requires states to reimburse pharmacies for their costs to obtain these prescription drugs (estimated acquisition cost), but leaves it to states to determine the methodology for defining estimated acquisition cost. In New York State, the methodology to determine reimbursement rates is set by legislation. In the past three years, the State Legislature has twice changed the reimbursement methodology which resulted in reduced reimbursement to pharmacies for Medicaid prescription drugs.

In April 2005, the Legislature authorized the Department to seek additional cost savings through new initiatives, such as a preferred drug program; an enhanced clinical drug review program; and a State maximum cost for certain drugs. The goal of all the above programs is to further lower the State's costs for Medicaid prescription drugs without diminishing recipients' access to necessary medications.

AUDIT FINDINGS AND RECOMMENDATIONS

The Rebate Program

The objective of the CMS rebate program is to enable states to save money on Medicaid prescription drugs by getting rebates from drug manufacturers. Manufacturers report drug pricing information to CMS on a quarterly basis, which CMS uses to calculate a rebate per unit of each drug. CMS then sends the rebate per unit information to the states. The states are to prepare bills for the manufacturers by multiplying the CMS-calculated rebate per unit for a particular drug by the units dispensed in the state.

Our prior audit entitled *Administration of the Medicaid Drug Rebate Program* (Report 2000-S-33, issued June 27, 2001) found the Department had not collected millions of dollars in rebates from drug manufacturers because its rebate collection system was inadequate. A July 2005 audit by the federal Health and Human Services Inspector General entitled, *Multi-state Review of Medicaid Drug Rebate Programs* (Report A-06-03-00048), also cited the Department's rebate collection system as problematic. In response to our prior audit, Department officials indicated they would develop a new system to collect and account for rebate revenues owed the State. To fulfill our objectives for this audit, we examined the Department's progress in implementing the system.

We found the Department is still developing its new accounting system. According to Department officials, the new system will more effectively record, track and account for rebates owed on individual drugs. The Department estimates it will take six to nine months to complete updating the new system with outstanding drug rebate data. Additional time will be required beyond the six to nine months to design statistical reports to assist management in analyzing and evaluating the drug rebate process. Since the Department is still updating the new accounting system with previously existing data, we could not fully evaluate its effectiveness.

Nonetheless, based on our review of the elements of the new system that have been implemented and the Department's results to date in using it, we concluded the system could be capable of providing the accurate and comprehensive data the Department needs to prepare the accurate invoices for drug manufacturers. Features that enhance accuracy include new reference tables that clarify information and help reduce errors. For example:

- A unit conversion table helps convert the quantity of particular drugs used in New York to comparable unit sizes so CMS rebate per unit figures can be accurately applied.

- A drug eligibility table identifies all the drugs eligible for rebates so Department staff can make sure a drug is eligible for a rebate before including it on a manufacturer's invoice.

- A retroactive price table, which is updated quarterly, allows the Department to bill manufacturers for rebates on drugs previously ineligible for rebates, but become eligible after a status adjustment by the manufacturer. Using the retroactive price table and the unit conversion tables, the Department could calculate the rebate amount owed from a prior period. Officials anticipate that analysis of retroactive rebate billings back to the second quarter of 1999 will continue for another six to nine months.

The use of these tables should enable Department staff to prepare accurate invoices, which should result in faster bill payment and easier resolution of billing disputes with manufacturers. As evidence, the Department cites statistics that show it fully collected amounts owed for 125 invoices, billed in August 2005, in three months; by contrast, it took two years for the Department to fully collect amounts owed on 106 invoices billed in November 2003. Department officials also stated the enhanced invoice accuracy has improved their ability to resolve billing disputes with manufacturers. Analysis of Department statistics showed the Department

resolved 48 percent of the total dollars disputed in fiscal year 2003-2004; for the first two quarters of fiscal year 2005-2006, the Department resolved 78 percent of the total dollars in dispute.

Recommendation

1. Continue to implement the new accounting system used for rebate billing and collection.

Reimbursement Reduction

Federal law allows states to reimburse pharmacies for Medicaid prescription drugs at the lower of a pharmacy's estimated acquisition cost plus a dispensing fee, or the pharmacy's usual and customary charge to the public. The objective of the federal law is to require states to keep reimbursement rates at reasonable levels. States are left to individually determine acquisition cost and the reimbursement methodology used. In New York State, the methodology for determining the reimbursement rates is set in the Social Services Law (Law).

Recent changes in the Law have enabled the State to save significant amounts by reducing this reimbursement rate. Until 2003, State reimbursement was established as the drug's average wholesale price (AWP), less 10 percent for all Medicaid prescription drugs, plus a dispensing fee to help offset pharmacies' overhead. In 2003-2004, the Law was amended to reduce reimbursement for all drugs to AWP less 12 percent, plus dispensing fees. In fiscal year 2004-2005, the Law was amended again to set different reimbursement rates for brand name and generic drugs. The Law now states that acquisition cost equals the AWP less 12.75 percent for brand name drugs, and the AWP less 16.5 percent for generic drugs, plus dispensing fees. Dispensing fees per prescription are $4.50 for generic drugs and $3.50 for brand name drugs. We estimate that this change saved the State approximately $15 million in the fourth quarter of 2004.

Department officials acknowledge there may be opportunities to reduce reimbursement rates. However, Department officials caution that reducing the reimbursement rate too much could cause pharmacies to decline to participate in the Medicaid program. This result would limit access to prescription drugs to some recipients, particularly in rural areas of the State.

Other Cost Savings Measures

The Department has also contracted with a consultant to administer four initiatives intended to reduce costs. In the spring of 2005, the Public Health Law was amended to authorize the creation of three of the initiatives. According to the contract, the consultant will:

- Negotiate additional manufacturer rebates. These supplemental rebates are to be negotiated on the basis of the State's participation in a multi-state purchasing pool. These additional rebates are to be factored into the drug's net cost (the cost of the drug less all rebates paid).

- Assist in developing a preferred drug list. The list will include drugs considered "preferred." Prior approval will be required to prescribe drugs that are not on this list. The list is to be developed by a committee of experts from the medical and pharmaceutical community.

- Operate a staffed call center. The consultant will operate a call center to

answer questions from providers seeking approval to use drugs not on the preferred list. Previously, the process for overriding mandatory generic drug usage involved an automated system that routinely granted approval for brand name drugs. With this new clinical drug review function in place, the caller must speak to a staff and provide justification for their request to use a drug that is considered high cost or subject to abuse or overuse.

The fourth initiative included in the contract requires the consultant to identify a State maximum allowable cost as authorized by State Social Services Law. For certain drugs, the federal government calculates a maximum reimbursement rate, which limits the cost of these drugs for states. Since the federal rate setting process is often lengthy, states are authorized to follow this formula to calculate a "state" maximum rate that anticipates the federal maximum rate. States can then use this rate to reimburse pharmacies for affected drugs. The consultant is to calculate maximum rates so the Department can save money on related reimbursements.

The Department had estimated that, based on the savings experienced by other states that have implemented similar programs, New York State would save about $240 million in fiscal year 2005-2006 ($161 million from the preferred drug list, and $79 million from the clinical drug review program) as a result of these initiatives. Because of delays in implementing these initiatives, the Department's actual savings for 2005-2006 will not reach these expectations.

Recommendation

2. Work to implement the cost savings measures discussed in this report without further delay.

AUDIT SCOPE AND METHODOLOGY

We did our audit according to generally accepted government auditing standards. To accomplish our objectives, we met with Department officials as well as officials from the Department's pharmacy unit to discuss the CMS rebate program. We walked through the rebate accounting process and observed the new accounting system. We reviewed laws governing the CMS rebate program.

In addition, we reviewed laws adjusting reimbursement rates as well as laws authorizing the Department's new initiatives such as the preferred drug list, clinical drug review program and the state maximum cost. We also obtained all pharmacy claims data for the fourth quarter of 2004. We re-priced the claims in the quarter using different methodologies for comparative purposes. Using data analysis software, we took price data for each National Drug Code and adjusted the price data to reflect different pricing strategies and what the State would have paid under different reimbursement rates. We reviewed prior State Comptroller and federal Health and Human Services Inspector General reports relating to the CMS rebate program as well as prescription drug prices. We obtained and reviewed documentation relating to the Department's billing and collection of rebate payments as well as resolution of disputed invoices.

In addition to being the State Auditor, the Comptroller performs certain other duties as the chief fiscal officer of New York State that have been mandated by statute and the State Constitution. The Division of State Services is responsible for several of these, including operation of the State's accounting system; preparation of the State's financial statements; and approval of State contracts, refunds, and other payments. In addition, the Comptroller appoints members some of whom have minority voting rights to certain boards, commissions, and public authorities. These duties may be considered management functions for purposes of evaluating organizational independence under generally accepted government auditing standards. In our opinion, they do not affect our ability to conduct independent audits of program performance.

AUTHORITY

The audit was performed according to the State Comptroller's authority under Article V, Section 1, of the State Constitution; and Article II, Section 8, of the State Finance Law.

REPORTING REQUIREMENTS

We provided a draft copy of this report to Department officials for their review and comment. Department officials agreed with our recommendations and indicated actions planned and taken to implement them. A complete copy of the Department's response is included as Appendix A.

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 the leaders of the Legislature and fiscal committees, advising of the steps that were taken to implement the recommendations it contained, and/or the reasons certain recommendations were not implemented.

CONTRIBUTORS TO THE REPORT

Major contributors to this report include David Hancox, Sheila Emminger, Don Paupini, Brian Krawiecki, Paul Alois, John Karwacki, Nicole VanHoesen and Nancy Varley.

APPENDIX A - AUDITEE RESPONSE

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

July 25, 2006

Steven E. Sossei
Audit Director
Office of the State Comptroller
110 State Street
Albany, New York 12236

Dear Mr. Sossei:

Enclosed are the Department of Health's comments on the Office of the State Comptroller's (OSC) draft audit report (2005-S-51) on "Medicaid Prescription Drug Rebates."

Thank you for the opportunity to comment.

Sincerely,

Dennis P. Whalen
Executive Deputy Commissioner

Enclosure

cc: Mr. Charbonneau
Mr. Griffin
Mr. Howe
Ms. Napoli
Ms. O'Connor
Mr. Reed
Mr. Seward
Mr. Wing

Department of Health
Comments on the
Office of the State Comptroller's
Draft Audit Report 2005-S-51 on
"Medicaid Prescription Drug Rebates"

The following is the Department of Health's response to the Office of the State Comptroller's (OSC) Draft Audit Report 2005-S-51 on "Medicaid Prescription Drug Rebates."

Recommendation #1:

Continue to implement the new accounting system used for rebate billing and collection.

Response #1:

Staff will continue to improve and implement the drug rebate accounting system to ensure maximum collection of rebates owed.

Recommendation #2:

Work to implement the cost savings measures discussed in this report without further delay.

Response #2:

Significant progress has already been made toward implementing the cost savings measures discussed in this report.

- New York participates in the National Medicaid Pooling Initiative (NMPI) and is eligible to receive additional manufacturer rebates retroactive to March 30, 2006 on Medicaid preferred drugs once the Centers for Medicare and Medicaid Services (CMS) approves the State Plan Amendment that was submitted to CMS in March 2006.

- The Medicaid Preferred Drug Program (PDP) was implemented June 28, 2006. Prior authorization is required for non-preferred drugs within drug classes that are subject to the PDP.

- The call center became operational on May 24, 2006 and call center staff are responding to PDP questions and prior authorization requests for drugs not on the preferred drug list. The Mandatory Generic Program will continue to use the existing automated voice response system as a cost effective means to conduct these prior authorization activities. The live call center is being used for the PDP and will be used for the Clinical Drug Review Program this fall.

- The State maximum allowable cost will be implemented September 5, 2006.