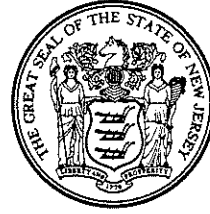


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**New Jersey State Legislature  
Office of Legislative Services  
Office of the State Auditor**

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**Department of Human Services  
Division of Medical Assistance and Health Services  
Drug Rebate Programs**

July 1, 2008 to October 31, 2011

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**Stephen M. Eells  
State Auditor**



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# New Jersey State Legislature

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The Honorable Chris Christie  
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The Honorable Stephen M. Sweeney  
President of the Senate

The Honorable Sheila Y. Oliver  
Speaker of the General Assembly

Mr. Albert Porroni  
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Enclosed is our report on the audit of the Department of Human Services, Division of Medical Assistance and Health Services, Drug Rebate Programs for the period of July 1, 2008 to October 31, 2011. If you would like a personal briefing, please call me at (609) 292-3700.

A handwritten signature in black ink, reading "Stephen M. Eells".

Stephen M. Eells  
State Auditor  
February 13, 2012

## Table of Contents

	Page
Scope .....	1
Objectives .....	1
Methodology.....	1
Background.....	1
Conclusions .....	2
Findings and Recommendations	
Drug Rebate Billings and Collections .....	3
Collection Issues.....	3
System Issues.....	4
Billing Issues .....	5
Dispute Resolutions.....	5
Auditee Response .....	6

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## *Scope*

We have completed an audit of the Department of Human Services, Division of Medical Assistance and Health Services (division), Drug Rebate Programs for the period July 1, 2008 through October 31, 2011. As part of our audit we reviewed the program's billing, collection, and dispute resolution processes at the division. Our review of rebates included drugs dispensed through the Medicaid program, as well as other state prescription programs. These programs include the Pharmaceutical Assistance to the Aged and Disabled Program (PAAD), the Senior Gold Program, the AIDS Drug Distribution Program (ADDP), the General Assistance Program, and Co-insurance which is for PAAD recipients who are also eligible for Medicare Part D. Annual rebates billed for calendar year 2010 amounted to \$448.9 million.

## *Objectives*

The objectives of our audit were to determine if the division had adequate procedures and controls in place for drug rebate billings, collections, and dispute resolutions. We also reviewed the effectiveness of these controls to determine if the division was maximizing their collection efforts.

This audit was conducted pursuant to the State Auditor's responsibilities as set forth in Article VII, Section I, Paragraph 6 of the State Constitution and Title 52 of the New Jersey Statutes.

## *Methodology*

Our audit was conducted in accordance with *Government Auditing Standards*, issued by the Comptroller General of the United States. In preparation of our audit, we studied legislation, the administrative code, and policies of the agency. Provisions that we considered significant were documented and compliance with those requirements was verified by interview, observation, and through our review of the rebate program transactions. We also interviewed agency personnel to obtain an understanding of the program and the internal controls.

A nonstatistical sampling approach was used. Our samples were designed to provide conclusions about the billing, collection, and dispute resolution processes. Drug manufacturer populations were sorted and rebate invoices were judgmentally selected for testing.

## *Background*

The prescription drugs utilized by Medicaid recipients, as well as the prescription drugs provided to qualified recipients under other state prescription drug programs are eligible for drug rebates. The Medicaid Drug Rebate Program was created by the federal Omnibus Budget Reconciliation Act of 1990. The act requires drug manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services for states to receive federal funding for outpatient drugs dispensed to Medicaid recipients. The drug rebate program is administered by the Centers for Medicare and Medicaid Services' Center for Medicaid and State Operations. State Medicaid programs reimburse pharmacies and prescribers

for dispensing prescription drugs to Medicaid recipients and the states recover a portion of these expenditures as rebates by submitting invoices to the drug manufacturers. The program was established to make Medicaid pharmaceutical costs similar to discounted prices that manufacturers offer to other large purchasers. All pricing information is provided by the manufacturers to the Centers for Medicare and Medicaid Services (CMS), which provides the division with quarterly data listing the unit rebate rate for each drug code covered under the program. The division is required to maintain records, by manufacturer, of the number of units of each drug dispensed during each calendar quarter. The division uses the rebate rates from CMS and the state's utilization data to prepare quarterly invoices for rebates due from each manufacturer. These procedures are also used for other state prescription programs identified in the scope section of this report. However, these programs are covered under separate rebate agreements between the New Jersey Department of Health and Senior Services and the drug manufacturers. A manufacturer can consist of several different labelers. A labeler is any firm that manufactures, repacks, or distributes a drug product. The State of New Jersey receives rebate payments from over 400 drug labelers.

### *Conclusions*

We found that the division has adequate controls over the billing process; however, controls over the uncollected balances and dispute resolution processes are inadequate. The timeliness of billings, collections, and the recovery of rebate program revenue may be improved by evaluating staffing levels and enhancing the drug rebate accounting system. System improvements should be made to calculate interest owed on late payments and to automate rebate receivable adjustments for retroactive price changes and unit amount changes. In addition, utilizing the dispute resolution services offered by CMS and pharmaceutical organizations will assist the division in finalizing contested rebate issues.

## Drug Rebate Billings and Collections

### *Collection Issues*

**Procedures for reviewing quarterly rebate payments from the drug manufacturers should be improved to maximize collections.**

The division invoices and receives quarterly rebates from over 400 drug labelers. Invoices are electronically entered and receipts are manually inputted into the Drug Rebate System, which is a subsystem of the New Jersey Comprehensive Financial System. The manufacturers remit their rebate checks to the state with a Reconciliation of State Invoice (ROSI) document. The ROSI lists all the drugs invoiced for the quarter, along with any adjustments the manufacturer has made to the drug unit amounts or the invoiced rebate rates. The manufacturer may include prior quarter adjustments in their payment. These adjustments can occur when CMS modifies the rebate rates that affect rebate amounts paid in prior quarters or when a dispute settlement occurs between the manufacturer and the state that affect a prior quarter. Discrepancies between invoiced amounts and receipt amounts are not pursued by the division. Invoices are typically filed away, unless the division is contacted by a manufacturer seeking to resolve disputed rebate information. Resolution of rebate disputes is the responsibility of one employee with the assistance of a pharmacist within the division. Other staff members will assist, if their schedule permits. Our review also found that the division does not track drug rebate collections and consequently does not know if a manufacturer remitted a quarterly payment. Based upon our review of the division's collections for the Medicaid program from 2005 through 2009, we found 472 invoices totaling \$14 million where the manufacturers did not remit a payment. By not placing adequate emphasis on monitoring rebate payments, the division is not maximizing rebate collections.

As of October 2011, the uncollected amount of drug rebates was \$60.7 million for billings through calendar year 2009. Approximately \$48.5 million represents uncollected amounts from 2005 through 2009. The schedule below identifies invoiced amounts and collection activity by prescription program (dollars expressed in millions).

<u>Program</u>	<u>Invoiced Amount</u>	<u>Received Amount</u>	<u>Uncollected</u>	<u>Collection Rate</u>
Medicaid	\$2,325.4	\$2,300.7	\$24.7	98.9%
Pharmaceutical Assistance to the Aged and Disabled (PAAD)	\$976.1	\$971.7	\$4.4	99.6%
AIDS Drug Distribution Program (ADDP)	\$164.5	\$163.5	\$1.0	99.4%
General Assistance	\$103.5	\$81.4	\$22.1	78.7%
Co-Insurance	\$63.5	\$53.8	\$9.7	84.7%
Senior Gold	\$23.6	\$24.8	(\$1.2)	105.2%
Total	\$3,656.6	\$3,595.9	\$60.7	94.5%

A portion of the uncollected balance, totaling \$22.1 million, is attributed to the General Assistance Program (GA). The manufacturers have agreements with the state, but not with the GA program. The division is currently seeking a court ruling. The uncollected balance of \$60.7 million could be reduced, depending upon the ruling. The non-GA related balance, totaling \$38.6 million, may involve disputed amounts, including injectable drugs, and other unpaid quarterly billings.

It was noted rebate disputes can result from physician administered injectable drugs. Beginning in June 2008, injectable drugs administered by a physician were included in the rebate billings and collections. Discrepancies in the conversion of units of measure for these injectable drugs have caused the rebate invoices to be overstated. Manufacturers are aware of this problem and often dispute unit amounts and withhold rebates. We reviewed six calendar year 2009 invoices that had a total disputed amount of \$841,000 and determined that 40 percent of the amounts disputed related to injectable drugs. In applying this rate to rebate quarters subsequent to June 2008, we estimate that \$5.9 million of the uncollected balance relates to injectables, a portion of which may be collectible. The division is aware of this issue and has implemented a system edit which will minimize these types of drug rebate disputes in the future.

Based on the conditions stated above, the uncollected balance could possibly be reduced to \$32.7 million. Because the division does not review uncollected balances and reviews disputed amounts only when contacted by a manufacturer, the division cannot determine how much of this amount is collectible. Based upon our review of ten current dispute resolutions, which totaled \$2.4 million and included some disputes dating back to 1991, we noted that 47 percent of the disputed amount was collected. The division should take a more active role in addressing uncollected balances so that outstanding amounts can be resolved timely.

### *System Issues*

#### **The division needs a more effective system to accurately account for drug rebates.**

The quarterly rebate checks from the manufacturer may include prior quarter adjustments. A division employee enters payments into the applicable quarters on the Drug Rebate System. However, this system can only accommodate 11 entries per rebate check. If more than 11 entries are needed, the employee has to consolidate the entries in an incorrect quarter. Prior quarter rebate activity should be allocated to quarters in which the transaction originated.

We tested 22 payments and found that three had more than 11 entries which resulted in incorrect postings. Negative adjustments can also occur for a prior period if there is a rate or unit reduction, or as a result of a dispute settlement. However, because negative amounts cannot be posted to the system, the negative quarterly adjustment is netted against a quarter showing a positive amount. Because checks are received that include Medicaid program drug rebates and other state prescription drug rebates, negative amounts may be applied to positive balances in different programs. This process may create misstatements in the accounting of individual rebate programs or for specific quarters within a program.



## ***Billing Issues***

### **The division does not estimate or accrue interest for late or disputed rebates.**

According to federal regulations, interest begins accruing on disputed or unpaid amounts 38 calendar days from the date the state mails the invoice. Federal regulations allow interest to be calculated based on a 365-day year with simple interest applied to the average of the yield of the weekly 90-day Treasury bill auction rates. We found that the division does not calculate interest on any unpaid or disputed amounts, and therefore, is unaware of the amount of interest due on its unpaid balances. The division relies on the drug manufacturers to calculate and remit interest. The division has no system for verifying the accuracy of the interest payments. If the 47 percent dispute resolution rate holds true, we estimate that \$1.1 million in interest is collectible on the balances outstanding as of the end of calendar year 2009.

Federal regulations also require that the state invoice manufacturers for drug rebates within 60 days after the end of a quarter. We found that the division was consistently late in mailing the invoices to the manufacturers. On average, the invoices were mailed 43 days late. We estimate that the state lost \$4 million in interest between 2002 and 2009 because of late invoicing.

### **Recommendation**

We recommend the division evaluate staffing levels to ensure timely invoicing and review of quarterly rebate payments from the drug manufacturers. Appropriate procedures should be implemented for all outstanding unpaid balances. The division should also seek an alternative accounting system which would have the capacity to accurately reflect rebate payments and adjustments. The system should also be able to automatically calculate interest owed on late payments.



## **Dispute Resolutions**

### **The division needs to utilize existing external dispute resolution processes to clear disputes promptly.**

The Center for Medicaid and Medicare Services (CMS) and other pharmaceutical organizations have offered dispute resolution conferences in which state Medicaid agencies and manufacturers meet to discuss and resolve disputed rebate amounts. Due to budgetary issues, the division has not always taken advantage of these opportunities. It is in the division's best interest to resolve disputes promptly as a means of settling outstanding issues.

### **Recommendation**

We recommend that the division utilize the dispute resolution services of CMS and other organizations in an effort to finalize outstanding cases.







## State of New Jersey

DEPARTMENT OF HUMAN SERVICES

DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES

PO Box 712

TRENTON, NJ 08625-0712

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*Governor*

KIM GUADAGNO  
*Lt. Governor*

JENNIFER VELEZ  
*Commissioner*

VALERIE HARR  
*Director*

February 9, 2012

John J. Termyna, Assistant State Auditor  
Office of Legislative Services  
Office of the State Auditor  
125 South Warren Street  
P O Box 067  
Trenton, NJ 08625-0067

Dear Mr. Termyna:

This is in response to your letter of January 4, 2012 to Commissioner Jennifer Velez concerning the Office of Legislative Services (OLS) draft audit report entitled "**Department of Human Services, Division of Medical Assistance and Health Services, Drug Rebate Programs**". Your letter provides an opportunity to comment on the draft audit report.

The objective of the audit was to determine if the Division of Medical Assistance and Health Services (DMAHS) had adequate procedures and controls in place for drug rebate billings, collections, and dispute resolutions. In addition, the auditors reviewed the effectiveness of these controls to determine if DMAHS was maximizing their collection efforts.

The draft audit report concluded that DMAHS has adequate controls over the billing process; however, controls over the uncollected balances and dispute resolution processes are inadequate. The timeliness of billings, collections, and the recovery of rebate program revenues may be improved by evaluating staffing levels and enhancing the systems.

### **Collection Issues:**

### **Recommendation:**

*Procedures for reviewing quarterly rebate payments from the drug manufacturers should be improved to maximize collections.*

### **Response:**

DMAHS agrees that procedures for reviewing quarterly rebate payments from drug manufacturers could be improved and has implemented a new accounting system which will significantly improve our ability to manage this program. It should be pointed out that the program has collected 98.9% of invoiced amounts of non-General Assistance related balances which are subject to a pending court ruling. Furthermore, the collection rate is even higher when issues concerning injectable drugs are considered.

John J. Termyna, Assistant State Auditor

February 9, 2012

Page 2

### **System Issues:**

#### **Recommendation:**

*The Division needs a more effective system to accurately account for drug rebates.*

#### **Response:**

The Affordable Care Act raised the rates to the manufacturers for rebates but the additional funds must be paid to the federal government. The states must calculate the additional money owed to the federal government based on NDC level paid units. This new requirement resulted in the development of a new accounting system based on individual unit payments for each drug in each quarter. The new accounting system will be used to determine the federal offset and to help with the dispute resolution process.

As of October 2011, the Division has developed, tested and implemented the new accounting system, which requires a significant amount of data input (60,000 records per quarter). The Division is presently analyzing staffing levels to address these new requirements.

The next set of modifications to the new accounting system will include enhanced edits that will improve the reconciliation of documents that are received from the drug companies. The final enhancements to the system will produce reports that will be utilized by the analysts to assist in dispute resolution. The reports will be used to identify missing payments, unit of measure issues, rate changes by the manufacturer, and data input or math errors by the manufacturer.

A long term solution to the data input problem is the exchange of the data electronically thus eliminating the data input requirement. The state is a member of the "Medicaid Drug Rebate Program Collaborative Working Group" and one of its future goals is electronic exchange of data.

### **Billing Issues:**

#### **Recommendation:**

*We recommend the division evaluate staffing levels to ensure timely invoicing and review of quarterly rebate payments from the drug manufacturers. Appropriate procedures should be implemented for all outstanding unpaid balances. The division should also seek an alternative accounting system which would have the capacity to accurately reflect rebate payments and adjustments. The system should also be able to automatically calculate interest owed on late payments.*

#### **Response:**

The Centers for Medicare and Medicaid Services (CMS) now provides the Division with an electronic file with the data needed to create the quarterly invoices. The electronic file is received three weeks earlier than the previous cart file and does not require an outside vendor to prepare the file for invoicing. The third quarter 2011 invoice was sent out within the required 60 days.

John J. Termyna, Assistant State Auditor

February 9, 2012

Page 3

DMAHS believes the timely billing issue has been resolved and that the new accounting system discussed above addresses this audit recommendation.

**Dispute Resolutions:**

**Recommendation:**

*We recommend that the division utilize the dispute resolution services of CMS and other organizations in an effort to finalize outstanding cases.*

**Response:**

DMAHS agrees with this recommendation.

If you have any questions or require additional information, please contact me or Richard Hurd at 609-588-2550.

Sincerely,

A handwritten signature in black ink, appearing to read "Valerie Harr". The signature is fluid and cursive, with the first name "Valerie" written in a larger, more prominent script than the last name "Harr".

Valerie Harr  
Director

VH:H

c: Jennifer Velez  
Richard Hurd