



**STATE OF NEW JERSEY**  
**OFFICE OF THE STATE COMPTROLLER**  
**MEDICAID FRAUD DIVISION**

**COMPLIANCE AUDIT**  
**NEW JERSEY DRUG REBATE PROGRAM**

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## *Executive Summary*

As part of its oversight of the Medicaid and New Jersey FamilyCare programs, the Medicaid Fraud Division of the Office of the State Comptroller (OSC) conducted a limited scope audit of the State of New Jersey's (the State) drug rebate program. The Medicaid drug rebate program, which began in 1991, is a partnership between the Centers for Medicare and Medicaid Services (CMS), state Medicaid agencies, and participating drug manufacturers. Its purpose is to help offset both Federal and state costs of outpatient prescription drugs dispensed to Medicaid patients.

All 50 states and the District of Columbia cover prescription drugs under the Medicaid drug rebate program. In New Jersey, the drug rebate program is administered by the Department of Human Services' Division of Medical Assistance and Health Services (DMAHS). DMAHS oversees seven public assistance programs that are eligible to participate in the drug rebate program. Of these seven programs, two specifically relate to the Medicaid program: Medicaid Fee for Service (FFS) and Medicaid Encounter (e.g., managed care).

Currently, DMAHS has dedicated nine full-time/full-time equivalent employees to manage New Jersey's drug rebate program. These employees are responsible for administering all aspects of the drug rebate program including: preparing and sending invoices to the manufacturers; performing account reconciliations; resolving disputes; and updating the program's accounting systems.

For each of the two programs, DMAHS maintains a listing of all balances due from (receivable) or due to (payable) the individual manufacturers. As of January 2013, the total receivable balances for the Medicaid FFS and the Medicaid Encounter drug rebate programs were \$63.4 million and \$95.8 million, respectively. Between 1991 and 2012, DMAHS invoiced to the manufacturers \$3.32 billion and collected \$3.31 billion in drug rebates for the Medicaid FFS and Medicaid Encounter programs, resulting in a collection rate of 99.7%.

During our audit, OSC noted that DMAHS did not always reconcile the individual manufacturers' accounts or resolve disputes on a timely basis. For example, approximately 40% of the \$63.4 million balance due to the Medicaid FFS drug rebate program was greater than one year old. OSC further noted that portions of the receivable balance have been outstanding for more than 20 years as evidenced by the approximately \$3.9 million in currently unresolved disputes between DMAHS and drug manufacturers, which date back to 1991. In addition, the audit identified the need to eliminate bankrupt and terminated manufacturers from the State's listing of drug rebate accounts in accordance with CMS guidance. Finally,

OSC noted DMAHS' internal policies and procedures for the drug rebate program have not been updated in at least 10 years.

### ***Background***

The Medicaid drug rebate program, which began in 1991, is set forth in Section 1927 of the Social Security Act (the Act) and the Omnibus Budget Reconciliation Act of 1990. In 2010, the program was extended to include Medicaid enrollees in Managed Care Organizations (MCOs). The overall purpose of the drug rebate program is to make Medicaid costs for covered outpatient drugs comparable to the best prices in the private sector.

For a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the drug rebate program, the manufacturer must enter into a rebate agreement with CMS and pay quarterly rebates to the states. CMS, the states, and the drug manufacturers each undertake certain functions in connection with the drug rebate program.

Pursuant to Section II of the rebate agreement and Section 1927(b) of the Act, manufacturers are required to submit a list to CMS of all covered outpatient drugs and to report each drug's average manufacturer price and, where applicable, best price. Based on this information, CMS calculates a unit rebate amount for each covered outpatient drug and provides the amounts to the states on a quarterly basis via computer tape.

Section 1927(b)(2)(A) of the Act requires states to maintain drug utilization data that identifies, by National Drug Code (NDC), the number of units of each covered outpatient drug for which the states reimbursed providers. The number of units is then applied to the unit rebate amount obtained from CMS to determine the actual rebate amount due from each manufacturer. The states utilize this information to prepare quarterly invoices for rebates due from each manufacturer.

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 the state agencies send rebate invoices to the manufacturers, typically takes 60 days. The manufacturer submits to DMAHS, by NDC, a "Reconciliation of State Invoice" (ROSI) that details the current quarter's payment. A manufacturer can dispute utilization data that it believes is erroneous, but the manufacturer is required to pay the undisputed portion by the due date. Adjustments that are made by the

manufacturer in a subsequent quarter are reported to DMAHS via a “Prior Quarter Adjustment Statement” (PQAS).

If the manufacturer and DMAHS cannot resolve the discrepancy, the manufacturer must provide written notification to the state agency by the invoice due date. If DMAHS and the manufacturer are not able to resolve the discrepancy within 60 days, DMAHS must give the manufacturer the option to have a hearing in order to resolve the dispute.

### ***Objective***

The objective of the audit is to determine the accuracy, validity, and collectability of the amounts due to or due from the State of New Jersey and the individual drug manufacturers under the Medicaid FFS and Medicaid Encounter drug rebate programs.

### ***Scope***

The scope of the drug rebate audit entailed a review of the policies and procedures as well as the accounting for and processing of drug rebates. The scope was limited to analyses of the Medicaid FFS receivable balance, the Medicaid Encounter receivable balance, and bankrupt and terminated manufacturers. The initial audit period was July 1, 2010 through June 30, 2012. However, based on testing during our fieldwork, the audit period was revised to include the commencement date of the drug rebate program (January 1, 1991). This revision was made so that OSC could better determine the overall impact of unresolved and/or uncollectable items on the receivable balances for the Medicaid FFS and Medicaid Encounter programs. The audit was conducted under the authority of the *Medicaid Program Integrity and Protection Act* (N.J.S.A. 30:4D-53 *et seq.*) and the Office of the State Comptroller (N.J.S.A. 52:15C-1 *et seq.*).

## *Audit Findings*

### **1. Policies and Procedures**

CMS periodically issues newsletters and other guidance on the drug rebate program. Through discussions with DMAHS personnel, OSC noted that although DMAHS follows the current guidelines issued by CMS, the Division has not updated its formal written policies and procedures for the drug rebate program in at least ten years.

#### **Recommendation:**

DMAHS should update its formal written policies and procedures for the drug rebate program. This update should incorporate all policies, procedures, and guidance issued by CMS. The Division should also address critical provisions of the drug rebate program that have occurred since DMAHS' last policy update such as physician-administered drugs and the extension of the program to include Medicaid recipients who are enrolled in MCOs.

### **2. Receivable Balances**

#### **2A. Analysis of the Receivable Balance for Medicaid FFS:**

OSC obtained DMAHS' listing of all accounts for the Medicaid FFS drug rebate program dated January 17, 2013. This report summarizes, by manufacturer, the net amounts due to or due from the State for drug rebates invoiced by the State and payments made on these invoices by the manufacturers.

OSC also obtained DMAHS' analysis of invoices and payments. This report summarizes, by quarter, the aggregate dollar amounts billed to the manufacturers and the aggregate dollar amounts paid by the manufacturers under the Medicaid FFS drug rebate program. This report is updated periodically and included information from 1991 through the second quarter of 2012.

OSC noted that the account balances for each manufacturer can fluctuate on a day-to-day basis due to the timing of the billing and collection cycles. OSC further noted that account balances may occasionally change from amounts due to the State to amounts due from the State. These changes may

be attributed to factors such as adjustments of unit rebate amounts by CMS, overpayments by the manufacturers, and billing revisions by the State.

OSC reviewed these reports and noted the following items:

- The total gross receivable balance due to the State from the manufacturers was \$63.4 million. A total of 955 manufacturer accounts were being maintained by DMAHS for the Medicaid FFS program. The individual balances in these accounts ranged from a due to the State (receivable) amount of \$4.2 million to a due from the State (payable) amount of \$1.5 million.
- The total gross payable balance due from the State to the manufacturers was \$12.7 million.
- The resulting net receivable balance due to the State from the manufacturers was \$50.7 million.
- Of the \$63.4 million due to the State, approximately \$25.1 million (40%) was not current (e.g., greater than one year old). The \$25.1 million amount is net of payments received by the State and adjustments made by the State on its billings to the manufacturers. OSC noted that prior to 2010, these payments and adjustments were recorded in the year they were made rather than being allocated to the year in which they originally occurred. This method of recording payments and adjustments resulted in the net receivable balance fluctuating to a negative (payable) amount between 1998 and 2005.
- It appears that portions of the non-current balance related to transactions that occurred more than 20 years ago. For example, there was approximately \$3.9 million in outstanding (unresolved) items for the years 1991 through 1993.
- DMAHS has not written off (e.g., eliminated) from its accounts any unresolved or uncollectable balances since the inception of the Medicaid FFS drug rebate program in 1991. Consequently, portions of the \$63.4 million receivable balance may be overstated due to the inclusion of uncollectable amounts. Due to the volume of transactions, OSC was unable to determine the exact amount of any overstatement.

## **Recommendations:**

- i. DMAHS should research the \$25.1 million (non-current) balance and establish procedures to resolve the older items. Once these issues are resolved, DMAHS should implement procedures to help prevent a recurrence of this finding. These procedures should include an ongoing reconciliation of individual invoices to receipts for each manufacturer, a periodic reconciliation of all manufacturer accounts, and the timely resolution of any disputed items.
- ii. DMAHS should research and resolve any outstanding disputes. Amounts that are deemed uncollectable should be written off in accordance with CMS guidelines.
- iii. DMAHS should determine the necessity of maintaining all 955 accounts. As part of this determination, DMAHS should consider closing any inactive accounts as allowed by CMS.

### **2B. Analysis of the Receivable Balance for Medicaid Encounter:**

OSC obtained DMAHS' listing of all accounts for the Medicaid Encounter drug rebate program dated January 25, 2013. This report summarizes, by manufacturer, the net amounts due to or due from the State for drug rebates invoiced by the State and payments made on these invoices by the manufacturers.

OSC also obtained DMAHS' analysis of invoices and payments. This report summarizes, by quarter, the aggregate dollar amounts billed to the manufacturers and the aggregate dollar amounts paid by the manufacturers under the Medicaid Encounter drug rebate program. This report is updated periodically and included information from 2010 through the second quarter of 2012.

OSC noted that the account balances for each manufacturer can fluctuate on a day-to-day basis due to the timing of the billing and collection cycles. OSC further noted that account balances may occasionally change from amounts due to the State to amounts due from the State. These changes may be attributed to factors such as adjustments of unit rebate amounts by CMS, overpayments by the manufacturers, and billing revisions by the State.

OSC reviewed these reports and noted the following items:

- The total gross receivable balance due to the State from the manufacturers was \$95.8 million. A total of 548 manufacturer accounts were being maintained by DMAHS for the Medicaid Encounter program. The individual balances in these accounts ranged from a due to the State (receivable) amount of \$14.2 million to a due from the State (payable) amount of \$200,000.
- The total gross payable balance due from the State to the manufacturers was \$216,000.
- The resulting net receivable balance due to the State from the manufacturers was \$95.6 million.
- Of the \$95.6 million due to the State, approximately \$2.2 million (2.3%) was not current (e.g., greater than one year old).
- It appears that the bulk of the \$2.2 million (about \$1.7 million of the non-current amount) was incurred in 2010 which was the year that the Medicaid Encounter drug rebate program began.
- DMAHS has not written off any unresolved or uncollectable balances since the inception of the Medicaid Encounter drug rebate program in 2010. Consequently, portions of the \$95.8 million receivable balance may be overstated due to the inclusion of uncollectable amounts. Due to the volume of transactions, OSC was unable to determine the exact amount of any overstatement.

**Recommendations:**

- i. DMAHS should research the \$2.2 million (non-current) balance and establish procedures to resolve the older items. Once these issues are resolved, DMAHS should implement procedures to help prevent a recurrence of this finding. These procedures should include an ongoing reconciliation of individual invoices to receipts for each manufacturer, a periodic reconciliation of all manufacturer accounts, and the timely resolution of any disputed items.

- ii. DMAHS should research and resolve any outstanding disputes. Amounts that are deemed uncollectable should be written off in accordance with CMS guidelines.

**3. Bankrupt and Terminated Manufacturers:**

On a periodic basis, CMS provides guidance to the states on administering their drug rebate programs. This guidance is supplied in the form of “program releases” which are available on the CMS website. The CMS program releases also identify manufacturers that have filed for bankruptcy or that have been terminated from the drug rebate program.

CMS Program Release #19 (issued in May 1992) provides guidance to the states on writing off disputed amounts. Specifically, a state is permitted to write off disputed amounts if these amounts are under \$1,000 per drug per quarter. A maximum amount of \$10,000 per manufacturer may be written off in each quarter. States are prohibited from arbitrarily writing off or adjusting rebate balances.

OSC noted that DMAHS has never written off any disputed items or account balances even if these amounts were deemed uncollectable through the bankruptcy of the manufacturer and/or its termination from the drug rebate program. Consequently, uncollectable balances were included in the total gross receivable balances for both the Medicaid FFS and the Medicaid Encounter programs.

- For the Medicaid FFS program, OSC identified 18 bankrupt manufacturers as follows:

*Table 1: Bankrupt Manufacturers (Medicaid FFS)*

	# of Accounts	Amount Due To (From) State of New Jersey
	13	\$ 159,400
	5	(11,561)
<b>Totals</b>	<b>18</b>	<b>\$147,839</b>

- For the Medicaid FFS program, OSC identified 301 terminated manufacturers as follows:

*Table 2: Terminated Manufacturers (Medicaid FFS)*

	# of Accounts	Amount Due To (From) State of New Jersey
	160	\$ 3,000,000
	141	(6,200,000)
<b>Totals</b>	<b>301</b>	<b>\$(3,200,000)</b>

- For the Medicaid Encounter program, OSC identified 4 bankrupt manufacturers as follows:

*Table 3: Bankrupt Manufacturers (Medicaid Encounter)*

	# of Accounts	Amount Due To (From) State of New Jersey
	2	\$ 4,165
	2	(40)
<b>Totals</b>	<b>4</b>	<b>\$4,125</b>

- For the Medicaid Encounter program, OSC identified 21 terminated manufacturers as follows:

*Table 4: Terminated Manufacturers (Medicaid Encounter)*

	# of Accounts	Amount Due To (From) State of New Jersey
	8	\$ 48,000
	13	(389)
<b>Totals</b>	<b>21</b>	<b>\$47,611</b>

OSC noted that the bankruptcies and terminations spanned the period from the inception of the program (e.g., 1991 for Medicaid FFS and 2010 for Medicaid Encounter) through 2012.

## **Recommendation:**

DMAHS should review all terminated and bankrupt manufacturers for both the Medicaid FFS and the Medicaid Encounter programs. As part of this review, DMAHS should research, resolve, and collect any outstanding balances on these accounts. Additionally, DMAHS should close any accounts where the manufacturer has ceased its participation in the drug rebate program.

### **4. Receivable Balances**

#### **4A. Test of Transactions – Balances Due to the State:**

In order to validate an account with a balance due to the State from a manufacturer, OSC selected for review one manufacturer (Bedford Laboratories) with amounts due to the State for both the Medicaid FFS and the Medicaid Encounter programs. OSC reviewed all invoices sent to the manufacturer and all checks, Reconciliations of State Invoices (ROSIs), and Prior Quarter Adjustment Statements (PQASs) received from the manufacturer in order to validate the outstanding balances. The following items were noted:

- The total amount due to the State from Bedford Laboratories for Medicaid FFS was \$48,074.
- Of the \$48,074, approximately 75% (\$36,096) consisted of two items: an unresolved dispute for one drug which totaled \$32,938 and an unpaid, past due invoice from the fourth quarter of 2007 which totaled \$3,158.

OSC investigated the unresolved dispute for \$32,938. OSC determined that this amount was caused by the manufacturer disputing the number of units invoiced by DMAHS for the drug Polymixin. OSC noted that the dispute involved 15 invoices and spanned the period from the second quarter of 2000 through the fourth quarter of 2003.

As a result of OSC's inquiries, drug rebate management investigated the dispute and determined that the manufacturer was overbilled for 59,322 units of Polymixin. The subsequent correction to the number of units resulted in a \$31,000 reduction to the disputed amount. Consequently, the correct amount

for this dispute is approximately \$1,900, not \$32,938. DMAHS agreed with OSC's findings and is in the process of making the recommended adjustments to this account.

- The remaining 25% of the receivable balance (\$11,978) consisted of \$8,857 in unresolved disputes between DMAHS and the manufacturer and \$3,052 for two current invoices.

The \$8,857 in unresolved disputes pertained to unit amounts that were invoiced by DMAHS but not paid by the manufacturer. The disputes involved several different drugs and, in some cases, dated back 18 years to 1995.

- The total amount due to the State from Bedford Laboratories for Medicaid Encounter was \$1,038.
- Approximately 72% of the receivable balance (\$746) consisted of one current invoice. The remaining 28% of the receivable balance (\$292) consisted of one unpaid past due invoice from the second quarter of 2010 for \$145 and an unresolved dispute for \$147.

OSC investigated the unresolved dispute for \$147. OSC determined that this amount was due to the manufacturer disputing the number of units invoiced by DMAHS for the drug Enalaprilat. OSC noted that the dispute involved one invoice for the second quarter of 2012.

As a result of OSC's inquiries, drug rebate management investigated the dispute and determined that the State overbilled the manufacturer for 403 units of Enalaprilat. DMAHS agreed with OSC's findings and has already made the recommended adjustments to this account.

#### **4B. Test of Transactions – Balances Due from the State:**

In order to validate an account with a balance due from the State to the manufacturer, OSC selected for review one manufacturer (Stiefel Laboratories, Inc.) with an amount due from the State of \$70,799. OSC reviewed all invoices sent to the manufacturer and all checks, ROSIs, and PQASs received from the manufacturer in order to validate the outstanding balance.

OSC determined that the due from balance occurred during January 2011 when the manufacturer made eighteen additional payments and two payment adjustments totaling \$88,426. OSC noted that these transactions were retroactive to the second quarter of 2009 and pertained to two drugs.

OSC noted that the payments represented rate adjustments made by the manufacturer for the per unit amount of each drug. These rate adjustments were made in anticipation of CMS processing the corresponding rate adjustments to its records. To date, CMS has not processed the corresponding rate adjustments to its records. OSC noted that the State cannot make any rate adjustments on its records until these adjustments have been processed by CMS. Consequently, the State owes \$88,426 to the manufacturer unless CMS adjusts its records.

As of the end of our audit, drug rebate management was still working to resolve this dispute with both the manufacturer and CMS.

OSC reviewed a sample of quarterly transactions for the period from January 1991 through December 1996. A total of 24 transactions were reviewed. The following items were noted:

- The total amount invoiced by the State during this period was \$13,949. The total amount paid by the manufacturer was \$11,412. The difference of \$2,537 represented amounts due to the State from the manufacturer.
- Of the \$2,537 amount, \$1,911 was due to an unresolved dispute on the number of units that were invoiced for one drug. The remaining balance of \$626 consists of minor differences on the number of units invoiced by the State versus the number of units paid by the manufacturer.

**Recommendations:**

- i. DMAHS continue to work with both the manufacturer and CMS to resolve the \$88,426 discrepancy.
- ii. DMAHS research and resolve all outstanding disputes for this account. Amounts that are deemed uncollectable should be written off in accordance with CMS guidelines.

*Appendix A - Auditee Response*

AUG 1 2014



## State of New Jersey

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July 28, 2014

Ms. Patricia E. Pyckowski, Auditor  
Office of the State Comptroller  
Medicaid Fraud Division  
P.L. Box 025  
Trenton, NJ 08625-0025

**Re: Draft Audit Report – NJ Drug Rebate Program**

Dear Ms. Pyckowski:

This letter provides the Division of Medical Assistance & Health Services' (DMAHS) response to your draft audit report entitled *New Jersey Drug Rebate Program*. The audit covered the period from January 1, 2009 through June 30, 2012. During this audit period, DMAHS's drug rebate unit invoiced drug manufacturers \$3.31B and collected \$3.31B in drug rebates, resulting in a collection rate of 99.7%.

The following is in response to your recommendations:

**1. Formal Policies and Procedures Not Updated:**

DMAHS' Drug Rebate Unit is required to follow the policies and procedures of the Federal Center for Medicare & Medicaid Services (CMS). The Drug Rebate Unit follows all policies and procedures that CMS periodically issues and maintains a file of all CMS releases, but agrees that the formal policy and procedures have not been updated in several years.

**2. FFS Receivable Balances:**

DMAHS agrees with these findings at the time of the audit.

Since the end of the audit, the gross receivable amount owed to the State for FFS invoices has been reduced to \$16M from the \$63.4M noted in the draft audit report. This significant reduction in receivables was the result of actual collections and the resolution of J-Code claims (usually injectable drugs prescribed by physicians). The Division has also retained an outside consultant who is paid on a contingency basis to research and resolve outstanding disputes. The Drug Rebate Unit continues to review and adjust receivables as required and allowed by CMS.

**3. Medicaid Encounter Receivable Balances:**

DMAHS agrees with these findings at the time of the audit.

Since the completion of the audit, the gross receivable amount owed to the State for encounter invoices has been reduced to an actual positive balance of \$4M (monies owed by the State to manufacturers). The Drug Rebate Unit acts as a middleman between the Managed Care Organizations (MCO) and the manufacturers. Although DMAHS works with

the MCOs to resolve their disputes with the manufacturers, the ultimate resolution of these disputes rests with the MCOs. The Drug Rebate Unit is also working with the MCOs to streamline the rebate encounter claim process which began in 2010 with the assumption of pharmacy claims by the MCOs. Our current MCO contracts include a provision (Article 4, Section 4.2.4 -Prescribed Drugs and Pharmacy Services) that holds the MCOs accountable for the quality and timeliness of their encounter claim submissions into the rebate program.

4. **Bankrupt and Terminated Manufacturers:**

DMAHS's Drug Rebate Unit, in an ongoing basis, reviews FFS and Encounter claims that relate to bankrupt and terminated manufacturers and has written-off uncollectible rebates as per the CMS guidelines. The Drug Rebate Unit is currently working with OIT to enhance its rebate system to more efficiently address terminated manufacturers and the write-off of uncollectible rebates.

**Test of Transactions – Due to/from the State:**

DMAHS agrees with these findings and has made the recommended adjustment to the amounts due to the State. The Drug Rebate Unit continues to work with the manufacturer and CMS to resolve the dispute.

Thank you for the opportunity to comment. If you should have any questions, please contact me at (609) 288-2550 or by e-mail at Richard.H.Hurd@dhs.state.nj.us.

Sincerely,



Richard H. Hurd  
Chief of Staff

c. V. Harr  
M. Moskovitz