



New York State Office of the State Comptroller
Thomas P. DiNapoli

Division of State Government Accountability

Optimizing Medicaid Drug Rebates

Medicaid Program
Department of Health



Report 2015-S-1

January 2016

Executive Summary

Purpose

To determine whether the Department of Health (Department) is maximizing revenues from Medicaid drug rebates. The audit covered the period April 1, 2010 to December 31, 2014.

Background

In 1990, Congress created the Medicaid Drug Rebate Program to reduce state and federal expenditures for Medicaid prescription costs. Since January 1991, the State of New York has been able to recover a portion of the Medicaid prescription drug costs by requesting rebates from drug manufacturers. The Affordable Care Act, enacted in 2010, extended prescription drug rebates to cover medications dispensed to enrollees of Medicaid managed care organizations (MCOs).

Currently, the Department monitors drug dispensing to Medicaid enrollees through claim information that is submitted to the Department's Medicaid claims processing and payment system, eMedNY. Included in this information is a drug's National Drug Code (NDC), which is a unique number that identifies each medication by its drug manufacturer and is the basis for the Department's manufacturer rebate requests. The Department uses NDCs and other information in eMedNY to identify drugs that are eligible for rebates. The Department then calculates quarterly rebates for each drug and submits rebate invoices to the manufacturers. For 2014, the Department invoiced \$2.4 billion in rebates for pharmacy drugs and \$72 million in rebates for physician-administered drugs (drugs administered by a medical professional in an office setting).

Key Findings

- The Department has not maximized revenues from the Drug Rebate Program, and has overlooked multiple sources of rebates that collectively account for an estimated \$95.1 million during our audit period. By the end of the audit fieldwork, the Department had already acted on some of the findings and, as a result, invoiced \$9.3 million of the \$95.1 million in identified rebates.
- The Department implemented exclusionary rebate policies that were dubious when adopted or inadequately monitored thereafter, thus undermining its ability to collect all drug rebate revenue. We found that the Department does not routinely review its internal policy decisions regarding rebate exclusions to reaffirm or reject their validity – which is especially critical given the dynamic nature and complexity of Medicaid claims processing. We found that such policies accounted for \$86.4 million (of the \$95.1 million) in unclaimed rebates.
- The Department did not adequately oversee its rebate invoicing processes to ensure all claims that were eligible for rebate were accurately identified and invoiced to manufacturers. We identified errors in the drug rebate invoicing process that prevented the Department from properly identifying \$8.7 million (of the \$95.1 million) in rebate revenue due. We further found that the Department had not performed sufficient risk assessments of its rebate invoicing processes to ensure key operations functioned correctly and effectively.

Key Recommendations

- Review the rebate policies identified in this report and revise as appropriate to ensure all rebate-eligible drugs are identified for invoicing.

- Review the rebate processing errors identified in this report and take action as appropriate to ensure all rebate-eligible drugs are identified for invoicing.
- Where appropriate, issue retroactive rebate invoices on the drug claims identified.
- Formally document the entire drug rebate process and regularly reassess policy decisions.

Other Related Audits/Reports of Interest

[Department of Health: Medicaid Drug Rebate Program Under Managed Care \(2014-S-41\)](#)

[Department of Health: Rebates and Discounts on Physician-Administered Drugs \(2010-S-72\)](#)

State of New York
Office of the State Comptroller

Division of State Government Accountability

January 7, 2016

Howard A. Zucker, M.D., J.D.
Commissioner
Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

Dear Dr. Zucker:

The Office of the State Comptroller is committed to helping State agencies, public authorities, and local government agencies manage government resources efficiently and effectively and, by so doing, providing accountability for tax dollars spent to support government operations. The Comptroller oversees the fiscal affairs of State agencies, public authorities, and local government agencies, as well as their compliance with relevant statutes and their observance of good business practices. This fiscal oversight is accomplished, in part, through our audits, which identify opportunities for improving operations. Audits can also identify strategies for reducing costs and strengthening controls that are intended to safeguard assets.

Following is a report of our audit of the Medicaid program entitled *Optimizing Medicaid Drug Rebates*. This audit was performed pursuant 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.

This audit's results and recommendations are resources for you to use in effectively managing your operations and in meeting the expectations of taxpayers. If you have any questions about this report, please feel free to contact us.

Respectfully submitted,

Office of the State Comptroller
Division of State Government Accountability

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This report is also available on our website at: www.osc.state.ny.us

Background

Medicaid is a federal, state, and local government program that provides a wide range of health care services to those who are economically disadvantaged and/or have special health care needs. For the State fiscal year ended March 31, 2015, New York's Medicaid program had approximately 7.1 million enrollees and Medicaid claim costs totaled about \$53 billion. The federal government funded about 52.4 percent of New York's Medicaid claim costs, the State funded about 30.2 percent, and the localities (City of New York and counties) funded the remaining 17.4 percent.

The New York State Medicaid program, administered by the Department of Health (Department), pays health care providers either directly through fee-for-service arrangements or through monthly premium payments made to managed care organizations (MCOs). Under the fee-for-service method, providers submit Medicaid claims for services rendered to Medicaid-eligible recipients to the Department's eMedNY computer system, which then processes the claims and generates payments to reimburse the providers for their claims.

Under the managed care method, Medicaid pays each MCO a monthly premium for each Medicaid recipient enrolled in the MCO. MCOs are responsible for ensuring enrollees have access to a comprehensive range of services, including pharmacy drug benefits as of October 1, 2011, which previously were covered under the fee-for-service method. MCOs arrange for the provision of services their members require and reimburse providers for services provided to their enrollees. MCOs are required to submit encounter claims to the Department's eMedNY system to inform the Department of each medical service provided to recipients enrolled in the MCO.

In 1990, Congress created the Medicaid Drug Rebate Program to reduce state and federal expenditures for Medicaid prescription drug costs. Since January 1991, New York has been able to recover a portion of Medicaid prescription drug costs by requesting rebates from drug manufacturers. The Affordable Care Act, enacted in 2010, extended prescription drug rebates to cover medications dispensed to enrollees of Medicaid MCOs.

The Department obtains rebates on prescription drugs, including pharmacy-dispensed drugs and drugs administered by a medical professional in an office setting (physician-administered drugs). The Department monitors drug dispensing through claim information submitted to eMedNY, including the drug's National Drug Code (NDC). The NDC is a unique 11-digit, three-segment number that specifically identifies each medication by manufacturer, strength, dosage form and formulation, and packaging, and is the basis for the Department's manufacturer rebate requests.

The Department also uses procedure codes on physician-administered drug claims in the rebate process. Physician-administered drug claims include a five-character procedure code (one letter and four numbers) that is based on the Healthcare Common Procedure Coding System (HCPCS). The HCPCS code set, which is maintained by the U.S. Department of Health and Human Services' Centers for Medicare & Medicaid Services (CMS), establishes a common code for each specific medical procedure (e.g., drug, quantity, method of administration) used in the delivery of health care services. CMS issues updates to the HCPCS code set quarterly.

In order to guide its invoicing of manufacturer rebates for physician-administered drugs, the Department must use a HCPCS to NDC crosswalk, which is a conversion table that translates codes from one system to the other. For instance, the crosswalk lists HCPCS procedure codes along with their corresponding NDCs. The crosswalk also converts HCPCS procedure code units into NDC units. For example, a drug's quantity from the HCPCS procedure code (such as 30 mg) would be converted to the appropriate NDC quantity (e.g., 5 ml) for the rebate process.

The Department uses NDC information to calculate quarterly rebates for each drug and submit rebate invoices to drug manufacturers. In 2014, the Department invoiced managed care encounters and fee-for-service claims that totaled \$2.4 billion in rebates for pharmacy services and \$72 million in rebates for physician-administered drugs.

In February 2015, we issued a report (2014-S-41) entitled *Medicaid Drug Rebate Program Under Managed Care*. In that audit, we concluded that the Department had not taken the appropriate steps to maximize rebates on drugs dispensed to individuals enrolled in managed care. In addition, we recommended that the Department take actions to obtain uncollected rebates and improve related claim and rebate invoicing processes.

Audit Findings and Recommendations

The Department has not maximized revenues from the Drug Rebate Program, and has overlooked multiple sources of rebates that collectively account for an estimated \$95.1 million in additional potential revenue for the period April 1, 2010 to December 31, 2014.

We determined that the Department implemented exclusionary rebate policies that were dubious when adopted or were inadequately monitored thereafter, thus undermining its ability to collect all drug rebate revenue to which the Medicaid program is entitled. We found that the Department does not routinely review internal policy decisions regarding rebate exclusions to reaffirm or reject their validity, which is especially critical given the dynamic nature and complexity of Medicaid claims processing.

We also identified errors in the Department's drug rebate invoicing process that prevented the Department from properly identifying all drug rebate revenue due. We further found that the Department had not performed sufficient preemptive risk assessments of its rebate invoicing processes to ensure all operations were functioning correctly and effectively. The Department also lacks complete documentation of the entire invoicing process.

We recommended that the Department: review the rebate policies identified in this report and revise them as appropriate to ensure all drug rebates are collected; regularly reassess policy decisions to ensure their validity; review and correct the rebate processing errors identified in this report; and, where appropriate, issue retroactive rebate invoices for the drug claims we identified.

By the end of the audit fieldwork, the Department had already acted on some of our findings and, as a result, invoiced \$9.3 million of the \$95.1 million in identified rebates.

Policy Matters

The Department had not adequately developed, implemented, and monitored policies to optimize Medicaid drug rebate revenues. Dubious policies and deficient monitoring undermined the Department's ability to collect certain rebates. Among a range of concerns, there were flaws in policies pertaining to physician-administered drugs, ambulatory patient group claims, basic claim information, and compound drugs. Such problems accounted for \$86.4 million in unclaimed rebates for the period April 1, 2010 to December 31, 2014.

Physician-Administered Drugs Omitted From the Crosswalk Process

We determined that the Department did not seek as much as \$35 million in rebates on physician-administered drug claims because of internal decisions to exclude certain HCPCS procedure codes from invoicing and to use a HCPCS to NDC crosswalk that did not contain all necessary information.

Physician-administered drug claims include a five-character procedure code (one letter and

four numbers) that indicates the medical procedure provided. The Department has historically excluded from rebate invoicing physician-administered drug claims with Q, S, C, and certain J procedure codes. One procedure code in particular – Q4081 (“Injection, Epoetin Alfa, 100 Units”) – accounted for an estimated \$13.7 million in potential rebates.

That policy decision as well as the Department’s reliance on incomplete information in its HCPCS to NDC crosswalk resulted in uncollected rebates. The Department’s crosswalk, modeled after another created by a CMS contractor, is a listing of procedure codes along with their corresponding NDCs. The crosswalk also converts procedure code units into NDC units. Procedure codes and the corresponding NDCs must be listed in the crosswalk in order for the Department to include them in its rebate invoicing process.

However, we determined the Department’s crosswalk omitted procedure codes for many of the services provided to Medicaid recipients because it largely mirrored the contractor’s crosswalk, which was not designed for rebate purposes and, therefore, lacked functionality. The Department did not undertake the necessary scrutiny to tailor the crosswalk to meet its specific needs, and this incomplete crosswalk became the Department’s default criterion for the invoicing of physician-administered drugs.

Furthermore, in some cases the Department recorded incorrect NDC information on the crosswalk (such as invalid NDCs). Also, the crosswalk excludes terminated drug NDCs for certain physician-administered drugs that, if included and indicated on the crosswalk as “NDC is terminated/follow-up on accuracy of claim information,” the Department could realize additional rebates. To illustrate, some physician-administered drug procedure codes can have more than one corresponding NDC (e.g., a chemotherapy drug may be provided by two manufacturers and, therefore, that chemotherapy procedure code may have two corresponding NDCs). Sometimes one of the NDCs may be terminated because the manufacturer no longer produces the drug.

However, the termination of one particular NDC does not mean other related NDCs are terminated as well. Therefore, there is considerable risk that providers record the wrong NDCs on claims for certain drugs. By excluding terminated NDCs from the crosswalk for physician-administered drugs that have multiple corresponding NDCs and not taking the necessary steps to determine whether the provider actually administered one of the other valid NDCs, rebate opportunities could be missed.

Based on our findings, the Department has sought guidance from CMS on several of the excluded and missing procedure codes, and has already added eight procedures to its crosswalk, which we estimate accounts for about \$4.7 million (of the \$35 million) in uncollected rebates. Further, Department officials stated they have improved their oversight of the crosswalk, and will now obtain updated crosswalk information directly from CMS’s quarterly files (CMS issues quarterly updates to the HCPCS code set) to ensure all procedure codes that appear on rebate-eligible claims are included.

Department officials agreed there were omissions and invalid NDCs on its crosswalk, and they plan to evaluate all identified claims to determine whether additional rebates should be sought.

Ambulatory Patient Group Claims

Ambulatory Patient Group (APG) claims are submitted for services provided by emergency departments, hospital outpatient departments, and providers in clinical settings. During our audit period, the Department did not seek rebates for physician-administered drugs reported on APG claims, which we estimated to account for about \$14.3 million in uncollected rebates during our audit period.

We questioned the Department about the basis for this policy and the Department cited concerns over bundled APG payments (e.g., when services are consolidated into fewer categories for payment purposes, such as one bundled payment that covers multiple services provided during a single patient visit). We sought further guidance from CMS officials, who stated that the APG method is considered a direct reimbursement method and, therefore, drugs paid through APG claims qualify for rebates.

In response to our audit, the Department stated that effective January 2015 it started invoicing for certain physician-administered drugs that are paid via a separate APG fee schedule that stipulates a specific reimbursement amount for each physician-administered drug. The new January 2015 invoicing, however, does not include physician-administered drugs that are paid by the APG grouping method (i.e., bundling) that is typical of most services reimbursed under APGs. In the grouping method, reimbursement for a drug either is based upon its historical average price or is included in the payment for the medical visit or significant procedure and, therefore, no additional payment is made at the line level for the drug. (A single APG claim can have multiple claim lines indicating each service provided; accordingly, grouped payments can result in an individual claim line showing a zero dollar payment.)

Department officials stated they do not believe they can collect rebates on APG drugs that are not paid via the separate fee schedule. They believe that providers do not submit accurate units in these cases because the payment is unaffected by the number of drug units reported on the claim. We note that the APG manual instructs providers to report the number of units provided on claims. Furthermore, as mentioned, CMS officials stated that APG drugs are eligible for rebates regardless of bundling. Also, CMS officials stated that APG claim lines that indicate a zero payment at the line level also qualify for rebates. We recommend that the Department consult with CMS for greater guidance to ensure its policy accurately captures the rules for APG claim rebates.

Inaccurate Claim Information

Accurate drug claim data is essential for proper rebate processing, and in certain instances, the Department corrected inaccurate claim data to prepare invoices for rebates. However, we also concluded that officials frequently did not invoice rebates for drug claims when they concluded that the reported claim information could potentially be inaccurate. The Department evaluates the quantity of the drug dispensed, reported payment amounts, and the potential rebate amount to reach its conclusion about the accuracy of a claim. However, if the Department took the additional steps to investigate many more potentially inaccurate claims and ensured that providers corrected them, we estimate that about \$13.7 million in rebates could have been collected.

For example, one encounter claim submitted for an injectable drug that blocks the effects of opioid medication reported a quantity of 38,000 units rather than the typical amount of 380 units. The Department's rebate system calculated a potential rebate of over \$500,000 based on the inaccurate reported quantity. When the system compared the calculated rebate amount with the reported payment of less than \$1,100, the claim was excluded from the rebate process. However, if the Department researched this claim and found that the claim should have been submitted for only 380 units, then the Department could have collected a rebate of over \$500.

Accurate claim information is essential to calculating an accurate rebate amount, and according to Department officials, inaccurate claim information can result in excessive rebates which could then cause a dispute from the manufacturers. We recognize the Department's commitment to appropriate invoicing; however, taking no further action to investigate these claims can allow valid rebates to go uncollected. We determined the Department does not have a comprehensive process in place for validating the accuracy of the information listed on these claims and resolving any claim errors so that rebates can be recalculated and invoiced.

In response to our findings, the Department stated it will re-assess this policy, evaluate claim details to determine whether rebates should be sought, and develop a process with providers to resolve data/claim issues that could result in manufacturer disputes.

Program of All-Inclusive Care for the Elderly

Historically, the Department has not collected rebates for drug encounter claims related to a managed care program known as the Program of All-Inclusive Care for the Elderly (PACE). PACE plans provide a comprehensive range of health care services, including prescription drugs, for certain Medicaid recipients age 55 and older. Upon further questioning during our audit about the Department's exclusion of these claims, in July 2014 Department officials informed us there was no supporting documentation for this practice. Subsequently, the Department decided to begin invoicing PACE encounters as of the second quarter of 2014.

We estimate that for the period April 1, 2010 to December 31, 2014 this rebate-eligible source accounted for \$11.6 million in rebates. This included nearly \$500,000 in rebates sought by the Department on invoices submitted to drug manufacturers since the second quarter of 2014. Additionally, \$6.8 million is an estimate attributable to one MCO that we determined did not submit any pharmacy encounters from August 1, 2012 to December 31, 2014. When presented with this finding, the Department took action to contact the MCO about the missing encounters, and the MCO has begun submitting them. The remaining \$4.3 million in rebates is for encounters reported prior to the second quarter of 2014. The Department is currently developing a process to collect these rebates.

Drug Encounter Claims Reported With No MCO Payment

The Department does not currently seek rebates for physician-administered drug encounter claims that an MCO reports with a zero dollar payment – a source that we estimate accounted for \$8.7 million in potential rebates for our audit period. Such claims are likely eligible for rebates

because, according to the Affordable Care Act, manufacturers are required to pay rebates for drugs dispensed to individuals enrolled in an MCO if the organization is responsible for coverage of such drugs. Furthermore, CMS Release No. 84, issued July 19, 2012, states, “While section 1927(b)(1)(A) of the Act references payments made under the state plan, the amended statutory language does not limit the provision of additional manufacturer rebates to only drugs for which the MCO incurred a cost.”

We provided three MCOs with judgmental samples of high-cost physician-administered drug encounter claims with a zero payment to verify that the recipients actually received the drug reported on the encounter. The MCOs reported that the majority of the drugs (approximately 85 percent) were provided to recipients as part of approved claims, making them eligible for rebate.

In response to our findings, the Department stated it would re-evaluate its zero payment policy and its applicability to MCO claims, and will develop a process with the MCOs to resolve data/claim issues.

Compound Drugs

Compound drugs are custom-prepared prescriptions in which individual ingredients are mixed together in the exact strength and dosage form required by the patient. Historically, the Department did not collect rebates for compound drugs. However, in July 2014, we questioned the basis for this decision, and as a result of our inquiry, the Department evaluated the issue and began invoicing compound drugs as of the first quarter of 2015. Additionally, the Department submitted retroactive invoices in April 2015 for \$3.1 million in rebates for the period October 1, 2011 to December 31, 2014.

Processing Errors

We identified errors in the Department’s drug rebate invoicing process that prevented the Department from properly identifying rebate-eligible claims and invoicing all drug rebate revenue due. Among a range of concerns, there were: problems related to rebates below the quarterly minimum requirement, omissions of certain NDCs from invoices for managed care drugs, drugs improperly classified as terminated or ineligible for rebates, and improper adjustments resulting in “negative rebates.” For each of these issues, the Department did not routinely assess risk to help ensure that rebate operations functioned correctly and effectively. We estimate that errors made during the processing of drug rebate invoices accounted for about \$8.7 million in uncollected rebates for the period April 1, 2010 to December 31, 2014.

Manufacturer Rebates Below the Quarterly Minimum Requirement

The Department does not invoice a drug manufacturer if, for a given quarter, the total rebates for a drug are less than \$50 or the total reimbursement amount for a drug is less than \$250. All such claims for the manufacturer for the quarter are “labeled” by the Department to indicate they are not to be invoiced. For our audit period, we identified \$4.5 million in uncollected rebates pertaining to MCO drug encounter claims that were incorrectly labeled and excluded from invoicing.

When presented with our finding, Department officials acknowledged that this error originated in the beginning of the fourth quarter of 2011 when managed care encounters became part of the invoicing process. (As stated previously, effective October 1, 2011 pharmacy drug benefits were covered by managed care and, therefore, fee-for-service payments to pharmacy providers for these benefits were no longer allowed for recipients enrolled in managed care.) At that time the Department began producing two invoices for each manufacturer (one for fee-for-service drugs and one for managed care drugs). The Department erroneously excluded some claims from both the fee-for-service and managed care invoice when it should have only excluded the claims from the fee-for-service invoice. The Department reviewed the issue and invoiced manufacturers \$4.5 million in rebates in October 2015.

NDCs Not Invoiced in Managed Care

We identified NDCs that were not included on the Department's managed care invoices despite meeting the Department's rebate eligibility criteria and not being on the Department's list of ineligible drugs. We estimate as much as \$1.7 million in rebates could be collected for these drugs. For example:

- \$204,705 in rebates were not invoiced for Valsartan, a drug used to treat high blood pressure. The drug's utilization amount was invoiced in the third quarter of 2014, but its next-quarter utilization was not included on the fourth-quarter invoice; and
- \$45,976 in rebates were not invoiced for another drug, Rizatriptan, which is used to treat migraine headaches. CMS first published the rebate amount per unit for this NDC in the second quarter of 2013, which was retroactive to the first quarter of 2013. The Department started invoicing for this drug in the second quarter, but did not invoice retroactively for the first-quarter utilization.

The Department is currently researching this issue; however, Department officials stated that these errors are due to occasional delays in CMS's publishing of a drug's per unit rebate amount. Unit rebate amounts are published quarterly by CMS and are necessary in order to calculate the rebate amount for each drug in the Drug Rebate Program. When these delays occurred, the Department did not then go back and ensure all rebates were collected.

Drugs Improperly Classified as Terminated

We determined that, for our audit period, rebates totaling \$1.2 million were not collected because the Department misclassified drugs as "terminated" (i.e., no longer produced by the manufacturer). Every quarter, drug manufacturers provide the federal government with updates to their drug inventory (e.g., NDCs added or terminated), and the Department includes this information in its invoicing process. When a manufacturer indicates an NDC has been terminated, the Department labels claims for that NDC to indicate they are not to be invoiced. We determined that while the Department has a process in place for excluding claims with terminated NDCs, its rebate process does not recognize NDCs that have been reactivated by the manufacturer, which led to uncollected rebates.

For example, one drug – Premarin, which is used to treat symptoms of menopause – was set to terminate on October 31, 2011; however, it was reactivated before this date. Nonetheless, between 2011 and 2014, the Department did not submit invoices for rebates totaling \$184,716 although the drug remained in active status and was eligible for a rebate. The Department is currently researching this issue.

Ineligible Drug List

Certain drugs are not eligible for rebates, and the Department maintains a list of these drugs to guide its rebate invoicing. However, we found that the Department’s list included some NDCs that CMS established as rebate-eligible, and as a result these drugs were improperly excluded from invoices. When presented with our findings, the Department reviewed its ineligible drug list, identified errors, and invoiced manufacturers approximately \$750,000. The Department also invoiced an additional \$450,000 in October 2015, for a total of about \$1.2 million.

Adjusted (Negative) Rebates

Medicaid reimburses providers based on the claim information they submit to eMedNY. Providers can later choose to correct this reported information by submitting a new, adjusted claim – a routine occurrence in the Medicaid claims processing system. The Department’s rebate invoicing system follows a similar approach, and evaluates the original claim as well as any additional “adjustment” claim submitted subsequently. The following example illustrates the typical process and how the rebate system works. A provider submits a claim to eMedNY, which pays \$100 for the claim, and the rebate system determines the appropriate rebate to be \$35. If the provider later submits a claim voiding the original claim, the rebate system then calculates a negative rebate (i.e., -\$35). When the information from both claims is combined, no rebate is paid.

In April 2014, the Department issued a retroactive invoice to manufacturers for physician-administered drug encounters dating back to the second quarter of 2010. The invoice, however, included nearly \$100,000 in incorrectly calculated negative rebates for which there were no corresponding positive rebates to offset. This resulted in a rebate shortfall of nearly \$100,000. In response to our findings, Department officials stated they will research and evaluate the claims to determine a plan of action.

Recommendations

1. Review the rebate policies identified in this report and revise as appropriate to ensure all rebate-eligible drugs are identified for invoicing.
2. Review the rebate processing errors identified in this report and take action as appropriate to ensure all rebate-eligible drugs are identified for invoicing.
3. Where appropriate, issue retroactive rebate invoices for the fee-for-service and encounter claims identified in this audit.

4. Regularly reassess policy decisions, and maintain supporting documentation of the entire invoicing process, including but not limited to:
 - Criteria guiding the selection of fee-for-service claims and encounter claims for rebate;
 - Criteria guiding the exclusion of fee-for-service claims and encounter claims for rebate;
 - Sign-offs by appropriate levels of management; and
 - Resolution of data/claim errors with providers.
5. Ensure that PACE MCOs submit pharmacy encounters timely, accurately, and completely.

Audit Scope and Methodology

The objective of our audit was to determine whether the Department is maximizing revenues from drug rebates. Our audit covered the period April 1, 2010 to December 31, 2014.

To accomplish our audit objective and assess internal controls, we interviewed Department officials and Drug Rebate Unit staff and consulted with CMS officials. We reviewed the Department's policies, procedures, historical invoiced claim data, and supporting documentation relating to the Medicaid Drug Rebate Program for the period April 1, 2010 to December 31, 2014, as well as federal regulations. We requested information from MCOs regarding encounters for high-cost physician-administered drugs with a reported payment of zero. We also utilized the Medicaid Data Warehouse. We designed and executed computer programs to quantify the amount of rebates that went untapped by the Department's current process. Our analyses to determine the financial impact associated with uncollected rebates involved various methodologies, including (but not limited to) using the Department's actual rebate amount per NDC and applying the Department's average rebate amount (generally 35 percent of the cost of rebate-eligible drugs) where an NDC did not exist. We shared our methodologies with the Department, and officials agreed to the audit approach used.

We conducted our performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

In addition to being the State Auditor, the Comptroller performs certain other constitutionally and statutorily mandated duties as the chief fiscal officer of New York State. These include operating the State's accounting system; preparing the State's financial statements; and approving 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, these functions do not affect our ability to conduct independent audits of program performance.

Authority

The 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.

Reporting Requirements

We provided a draft copy of this report to Department officials for their review and formal comment. We considered the Department's comments in preparing this report and have included them in their entirety at the end of it. In their response, Department officials generally concurred with our recommendations and indicated that certain actions have been and will be taken to address them. Our rejoinders to particular Department comments are included in the report's State Comptroller's Comments.

Within 90 days of the final release of this report, as required by Section 170 of the Executive Law, the Commissioner of Health shall report to the Governor, the State Comptroller, and the 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 why.

Contributors to This Report

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Vision

A team of accountability experts respected for providing information that decision makers value.

Mission

To improve government operations by conducting independent audits, reviews and evaluations of New York State and New York City taxpayer financed programs.

Agency Comments



ANDREW M. CUOMO
Governor

Department of Health

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

November 30, 2015

Ms. Andrea Inman, Audit Director
Office of the State Comptroller
Division of State Government Accountability
110 State Street – 11th Floor
Albany, NY 12236-0001

Dear Ms. Inman:

Enclosed are the Department of Health's comments on the Office of the State Comptroller's Draft Audit Report 2015-S-1 entitled, "Optimizing Medicaid Drug Rebates."

Thank you for the opportunity to comment.

Sincerely,

A handwritten signature in black ink, appearing to read "Sally Dreslin".

Sally Dreslin, M.S., R.N.
Executive Deputy Commissioner

Enclosure

cc: Michael J. Nazarko
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**Department of Health
Comments on the
Office of the State Comptroller's
Draft Audit Report 2015-S-1 entitled,
"Optimizing Medicaid Drug Rebates"**

The following are the Department of Health's (Department) comments in response to the Office of the State Comptroller's (OSC) Draft Audit Report 2015-S-1 entitled, "Optimizing Medicaid Drug Rebates."

Background

New York State is a national leader in its oversight of the Medicaid Program. Through the efforts of the Department and the Office of the Medicaid Inspector General (OMIG), for 2009 through 2013, New York State alone accounted for 54.9 percent of the national total of fraud, waste, and abuse recoveries. These results reflect a trend of increased productivity and enforcement. For 2011 through 2013, the administration's Medicaid enforcement efforts recovered over \$1.73 billion, a 34 percent increase over the prior three-year period.

Under Governor Cuomo's leadership, the Medicaid Redesign Team (MRT) was created in 2011 to lower health care costs and improve quality of care for its Medicaid members. Since 2011, Medicaid spending has remained under the Global Spending Cap, while at the same time providing health care coverage to an additional 1,330,000 fragile and low income New Yorkers. Additionally, Medicaid spending per recipient has decreased to \$7,929 in 2013, consistent with levels from a decade ago.

General Comments:

- During the last three years, the Department has collected more than \$5.5 billion in pharmacy rebates.
- During the same time period, the Department saved more than \$400 million from transitioning pharmacy benefits from fee-for-service (FFS) to managed care.
- Where appropriate, the Department will collect all outstanding rebates identified by this audit.
- OSC's statement that "the Department implemented exclusionary rebate policies that were dubious when adopted..." is not accurate. The Department's policies, when adopted were sound, as they were based on several factors including, but not limited to, guidance from the Centers for Medicare and Medicaid Services (CMS) and historical analysis and interpretation of FFS claims data.

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Recommendation #1

Review the rebate policies identified in this report and revise as appropriate to ensure all rebate-eligible drugs are identified for invoicing.

Response #1

The Department's response to recommendation #1 is provided in the chart below:

* See State Comptroller's Comments on Page 24.

Rebate Policy	Department Response
Physician Administered Drugs Omitted from the Crosswalk Processes	The Department will begin invoicing for all applicable Q, S, C and J Code procedures by the 4Q 2015. The Department has already made improvements in the oversight of the crosswalk table to ensure that all rebate eligible National Drug Codes (NDCs) are included. This includes the utilization of CMS's Average Sales Price chart, which reflects the latest J & Q codes and the CMS Outpatient Code Editor, which provides quarterly updates for S & C codes.
Ambulatory Payment Group Claims	As noted in the audit, effective January 2015, a number of drugs reimbursed in Ambulatory Patient Groups (APGs) were moved from APG groups into a separate APG fee schedule. This requires providers to accurately report units administered and provides the information necessary for the Department to request manufacturer rebates. It's important to note that more than 90% of the drugs reimbursed through APGs are now subject to manufacturer rebates. The vast majority of the remaining drugs in APGs for which rebates are not collected group to APG Pharmacotherapy Level 1. APG payment for these drugs is "bundled" into the APG payment to the facility. A line item payment is not made for these drugs. Rebates cannot be collected for drugs where a line item payment is not made. This policy is based, in part, on written guidance issued by CMS prohibiting states from requesting manufacturer rebates for drugs reimbursed by Medicare where the drug is bundled into the Medicare payment and a line item payment for the drug is not made (CMS Medicaid Drug Rebate Program Notice, Release No. 161). The OSC states in their audit that CMS has advised them that "APG claim lines that indicate a zero payment at the line level also qualify for rebates." This statement clearly conflicts with written guidance issued by CMS. We request that OSC provide the Department with the specific written guidance they have received from CMS

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	stating that rebates may be collected for drugs that are bundled in the facility payment resulting in a zero line item payment to the facility.
Inaccurate Claim Information	The OSC is incorrect in stating that the Department does not invoice rebates for drug claims when the information could potentially be inaccurate. In situations where the information reported by managed care plans is inaccurate, but can be corrected, the Department has often corrected the information so that affected encounters are included in the invoicing process. The Department will conduct further analyses to determine what claim encounters may not have been appropriately identified, recalculated and invoiced. The Department is also actively working to improve the accuracy of the claim encounter submissions, so that re-calculation for the purpose of invoicing is not necessary. To ensure that each managed care organization (MCO) is providing accurate pharmacy encounter reporting, the Department intends to develop specific benchmarks against which plans will be measured. Failure to comply will subject the MCO to a remediation plan or financial penalty.
Program of All-Inclusive Care for the Elderly (PACE)	PACE utilization prior to 2Q 2014 has been compiled and is currently being analyzed for accuracy and completeness. The Department intends to invoice for PACE utilization by the end of State Fiscal Year 2015/2016.
Drug Encounter Claims Reported with No MCO payment.	By January 2016, the Department will re-evaluate this policy and its applicability to MCO claims, and will develop a process with the MCOs to resolve data/claim issues that could result in manufacturer disputes due to the amount paid being reported as zero.
Compound Drugs	The Department has addressed compound drugs through the invoicing process by including utilization in the April 2015 retrospective invoice.

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Recommendation #2

Review the rebate processing errors identified in this report and take action as appropriate to ensure all rebate-eligible drugs are identified for invoicing.

Response #2

The Department's response to recommendation #2 is provided in the chart below:

Rebate Processing Errors	Department Response
Manufacturer Rebates Below the Quarterly Minimum Requirement	By January 2016, the Department will evaluate the impact of this processing step in order to make a decision regarding its applicability to managed care claim encounters.
NDCs not Invoiced in Managed Care	The Department has modified the invoicing process to include applicable NDCs and will include utilization in the next special invoice that is generated (date: To Be Determined (TBD)).
Drugs Improperly Classified as Terminated	The Department corrected this issue effective with 1Q 2015 invoices and will invoice for retroactive utilization in the next special invoice that is generated (date: TBD).
Ineligible Drug List	The Department completed a comprehensive review of the ineligible drug list, has made corrections and incorporated them into the April 2015 and October 2015 retrospective invoices.
Adjusted Negative Rebates	By January 2016, the Department will complete its research and evaluation of claims detail and determine a plan of action.

Recommendation #3

Where appropriate, issue retroactive rebate invoices for the fee-for-service and encounter claims identified in this audit.

Response #3

The Department has processed two retrospective rebate invoices associated with the OSC audit findings and is in the process of compiling data for a third retrospective invoice. All applicable outstanding rebates will be collected.

Recommendation #4

Regularly reassess policy decisions, and maintain supporting documentation of the entire invoicing process, including but not limited to:

- Criteria guiding the selection of fee-for-service claims and encounter claims for rebate;
- Criteria guiding the exclusion of fee-for-service claims and encounter claims for rebate;
- Sign-offs by appropriate levels of management; and
- Resolution of data/claim errors with providers.

Response #4

Staff will initiate a project to consolidate existing documentation into a more formal policy manual as well as develop protocols to reassess policy decisions and update documentation, as appropriate. Additionally, the Department is working with our contractor, Medicaid Administrative Services, to update systems documentation. And, the Department intends to consolidate the administration of all pharmacy rebate programs into a single procurement, establishing focused resources to continually update and assess rebate policy and supporting documentation.

Recommendation #5

Ensure that PACE MCOs submit pharmacy encounters timely, accurately and completely.

Response #5

The Department has implemented the following processes to ensure accurate and timely claim encounter submission by PACE MCOs:

- Quarterly validation reports are sent to the plans and also reviewed by State staff to ensure accurate, timely and complete submission of encounter claims. Deficient plans are contacted by Managed Long Term Care (MLTC) staff. Plans that are determined to be non-responsive are issued a Statement of Deficiencies.
- The Department, in conjunction with the Island Peer Review Organization (IPRO), developed a readiness review project focused on specific MLTC plans for all lines of business (MLTC, PACE, and Medicaid Advantage Plus (MAP)). These plans were either formed within the past year or were experiencing problems with encounter submissions.

The surveys included the following topics:

- 1) Plan knowledge of and prioritization of reporting requirements of encounter data;
- 2) Claims/encounter data processing;

- 3) Medicaid Encounter Data System (MEDS) reporting process; and
- 4) MEDS Data Capture, etc.

State Comptroller's Comments

1. We maintain that the exclusionary rebate policies in question were dubious. Our report highlights multiple cases where the Department's original decisions were not sound. For example, the Department did not collect rebates for drug encounter claims related to a managed care program known as the Program of All-Inclusive Care for the Elderly (PACE). During our audit period, PACE accounted for \$11.6 million in rebates. When we asked Department officials for information and documentation supporting the decision to exclude these claims from the rebate process, they could not provide any. Moreover, in response to our audit, the Department has already taken steps to change certain policies and collect rebates on many of the drug claims we identified.
2. The Department's assertion is not accurate. Department officials indicated that their policy is based, in part, on CMS Medicaid Drug Rebate Program Notice, Release No. 161. However, this CMS guidance pertains specifically to bundled payments for drugs used in end stage renal disease for individuals who are enrolled in both Medicare and Medicaid. It does not pertain to other drugs. (Note: We were aware of Release No. 161 and, consequently, excluded all claims meeting this criteria from our analysis.) When we asked the Department to provide guidance that pertained to all APG bundled claims, the Department could not provide any such guidance. Therefore, we contacted CMS directly, and CMS officials stated that it was appropriate to claim rebates for APG claim lines that indicate a zero payment at the line level. Additionally, although the Department's comment focuses on drugs where a line item payment is not made, the vast majority of claims we identified did in fact have line level payments.
3. We disagree that the CMS guidance is conflicting. As previously noted, Release No. 161 is specific to a unique type of Medicare service (drugs used in end stage renal disease), while the written guidance we received from CMS pertains to Medicaid APG claims. Further, we provided the Department's Office of Health Insurance Programs with the guidance we received from CMS, including the specific CMS official who provided it to us, on June 29, 2015. We will re-send this guidance to the Department.
4. As stated on page 9 of the report, the Department did not always correct inaccurate drug claim data, and we estimate that about \$13.7 million in rebates could have been collected if the Department took the necessary additional steps to investigate and correct all inaccurate claims. In addition, we modified our report to acknowledge that the Department corrects certain inaccurate drug claim data.