



Department of Health

ANDREW M. CUOMO
Governor

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

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

March 16, 2016

Ms. Andrea Inman
Audit Director
New York State Office of the State Comptroller
110 State Street, 11th Floor
Albany, New York 12236

Dear Ms. Inman:

Pursuant to the provisions of Section 170 of New York State Executive Law, I hereby transmit to you a copy of the New York State Department of Health's comments related to the Office of the State Comptroller's final audit report 2015-S-1 entitled, "Optimizing Medicaid Drug Rebates."

Please feel free to contact Amy Nickson, Assistant Commissioner, Office of Governmental and External Affairs at (518) 473-1124 with any questions.

Sincerely,

A handwritten signature in black ink that reads "Howard Zucker M.D.".

Howard A. Zucker, M.D., J.D.
Commissioner of Health

Enclosure

cc: Ms. Nickson

**Department of Health
Comments on the
Office of the State Comptroller's
Final 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) Final 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. With the transition to care management, the Office of the Medicaid Inspector General (OMIG) continues to improve upon our processes and direct our resources to match this changing direction in the Medicaid program. In conjunction with the Department, NYS will continue its focus on achieving improvements to the Medicaid program and aggressively fighting fraud, waste and abuse wherever it exists.

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 1,405,500 fragile and low income New Yorkers. Additionally, Medicaid spending per recipient has decreased to \$7,868 in 2014, 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 as a result of 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 FFS claims data.
- The 2016-17 Executive Budget includes a proposal to expedite the request for proposal and implementation of a contract that will consolidate four separate rebate contracts into one. This consolidation will create greater efficiencies and streamline the process to generate greater savings.

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:

Rebate Policy	Department Response
Physician Administered Drugs Omitted from the Crosswalk Processes	<p>The Department has made improvements in the oversight of the crosswalk table to ensure that all rebate eligible National Drug Codes (NDCs) are invoiced. This includes the utilization of CMS's average sales price chart, which provides J and Q codes and the CMS outpatient code editor, which provides quarterly updates for S and C codes.</p> <p>As of 4Q 2015, the Department is invoicing for applicable Q, S, C and J Code procedures. The Department will continue to closely monitor NDC submission requirements for physician administered drugs.</p>
Ambulatory Payment Group Claims	<p>As a matter of policy, the Department has consistently and will continue to follow all written guidance as issued by CMS. Specific data on the number of units of the drug administered is required on the claims submission by the provider in order to calculate the rebate that will be claimed. APG payment for drugs is a bundled payment (similar to the bundled payment methodology for Epogen in dialysis clinics) and does not vary based on the number of units administered. Since the provider's payment is irrespective of units, the units reported by a provider on their claim cannot be relied upon as being accurate. In all probability, CMS was not advised by OSC of the bundled payment methodology employed in the APG payment structure. Without this information, CMS would not be able to make an accurate assessment of the appropriateness of the bundled APG payment structure.</p>
Inaccurate Claim Information	<p>The OSC is incorrect in stating that the Department does not invoice rebates for drug</p>

	<p>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 corrects 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.</p> <p>The Department is also actively working to improve the accuracy of the claim encounter submissions, so that corrections 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.</p> <p>The Governor's executive budget for SFY 2016 – 2017 includes proposals to sanction MCOs when submitting incomplete/inaccurate encounter data, and contracting with a single vendor to administer the various drug rebate programs.</p>
Program of All-Inclusive Care for the Elderly (PACE)	<p>PACE utilization prior to 2Q 2014 has been compiled and is currently being analyzed for accuracy and completeness. The Department is in the process of identifying encounter utilization eligible for rebates and intends to invoice for PACE utilization in early 2016.</p>
Drug Encounter Claims Reported with No MCO payment.	<p>The Department is re-evaluating this policy and its applicability to MCO claims to ensure appropriate rebate collection. The Department has modified rebate programming to include applicable MCO data/claims where the MCO amount paid is being reported as zero.</p>
Compound Drugs	<p>The Department has addressed compound drugs through the invoicing process by including utilization in the April 2015 retrospective invoice.</p>

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	The Department has modified rebate programming and removed the current minimum quarterly requirements for rebate invoices.
NDCs not Invoiced in Managed Care	The Department has modified the invoicing process to include applicable NDCs.
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 to be generated in early 2016.
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	The Department is evaluating the impact of modifying this policy in order to make a decision regarding manufacturer account adjustments for negative rebates.

Recommendation #3

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

Response #3

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

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

The Department has initiated 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 drug rebate contractor and the systems documentation has been updated. The Department also intends to consolidate the administration of all pharmacy rebate programs into a single procurement, to be released in early 2016, 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:

- For this audit period, quarterly validation reports were sent to the plans and also reviewed by Department staff to ensure accurate, timely and complete submission of encounter claims. Deficient MCOs are contacted by Managed Long Term Care (MLTC) staff. MCOs 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.

A summary report is then produced based on the survey responses from plans. The report summarizes the problems/challenges that plans have with MEDS as well as challenges and issues that vendors might have. During the survey process, the Department and IPRO also conduct conference calls with plans. The final report gets distributed to plans by IPRO with a final recommendation so plans can improve on their encounter submissions.