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December 20, 2017

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

Re: Optimizing Medicaid Drug Rebates
Report 2017-F-9

Dear Dr. Zucker:

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, we have followed up on the actions taken by officials of the Department of Health to implement the recommendations contained in our audit report, *Optimizing Medicaid Drug Rebates* (Report 2015-S-1).

Background, Scope, and Objective

The Department of Health (Department) administers the State's Medicaid program, which provides a wide range of health care services to individuals who are economically disadvantaged and/or have special health care needs. In 1990, Congress created the Medicaid Drug Rebate Program to reduce state and federal Medicaid expenditures for prescription drugs. Since January 1991, the State of New York has been able to recover a portion of Medicaid prescription drug costs on fee-for-service claims 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), including both pharmacy and physician-administered drugs (i.e., drugs administered to patients by a medical professional in an office setting).

The Department reimburses Medicaid providers for prescription drugs either directly through fee-for-service arrangements, based on claims submitted to the Department's eMedNY claims processing and payment system, or through monthly premium payments to MCOs, which in turn reimburse health care providers for services rendered to their enrollees. MCOs are required to submit encounter claims to the Department detailing each medical service provided. Prior to September 2015, MCOs submitted encounter claims to eMedNY. Since September 2015, MCOs have been required to submit encounter claims to the Department's Encounter Intake System (EIS).

In the drug rebate process, the Department uses certain claim information submitted to eMedNY and the EIS to obtain rebates, such as a drug's National Drug Code (NDC), which is a unique number that 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 Healthcare Common Procedure Coding System (HCPCS) procedure codes from physician-administered drug claims. The HCPCS code set establishes a common code for each medical procedure used in the delivery of health care services. To guide its invoicing (billing) of manufacturer rebates for physician-administered drugs, the Department uses a HCPCS to NDC crosswalk to translate HCPCS information to the corresponding NDC information.

We issued our initial audit report on January 7, 2016. The audit objective was to determine whether the Department was maximizing revenues from drug rebates. The audit covered the period April 1, 2010 to December 31, 2014. Our initial audit determined the Department had overlooked multiple sources of drug rebate revenue. As a result, the Department did not collect an estimated $95.1 million in available rebates during our audit period.

We determined that some of the Department's rebate policies undermined its ability to collect all drug rebate revenue to which the Medicaid program was entitled. Furthermore, the Department did not routinely review their policy decisions regarding rebate exclusions to reaffirm or reject their validity. We also identified errors in the drug rebate invoicing process that prevented the Department from properly identifying all drug rebate revenue due.

We recommended that the Department: review the rebate policies identified in the 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.

The objective of our follow-up was to assess the extent of implementation, as of November 30, 2017, of the five recommendations included in our initial audit report.

Summary Conclusions and Status of Audit Recommendations

Department officials made progress in addressing the problems we identified in the initial audit report; however, further actions are still needed. Corrective actions by the Department to rectify policy and processing problems have resulted in the invoicing of $47.6 million in rebates for the period April 1, 2010 to March 31, 2017. However, we also determined that as much as $118.6 million in additional rebates could still be collected for this period with further efforts by the Department. Given the current fiscal stress on state Medicaid programs, we strongly urge the Department to promptly take the steps necessary to collect these rebates.

The Department awarded a new contract for drug rebate administration and management services. The Department and the new contractor are discussing all of the issues identified in the initial audit and in this follow-up, and will be working to address them. The contractor will begin processing drug rebates in the first quarter of 2018.

All five of the initial report's audit recommendations were partially implemented.

Follow-Up Observations

Recommendation 1

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

Status – Partially Implemented

Agency Action – In our initial audit, we identified six areas where the Department's policies prevented it from identifying all drugs that were eligible for rebates. While the Department has been responsive to our findings, it has not completed all of its planned corrective actions to ensure that the Medicaid program will receive all of the rebate revenue to which it is entitled. We reviewed drug rebate data provided by the Department for a period after the initial audit from January 1, 2015 to March 31, 2017. We determined that rebates totaling $22.6 million were invoiced as a result of changes to rebate policies by the Department and $46.7 million in additional rebates could still be collected with further efforts by the Department, as detailed below.

- *Physician-Administered Drugs Omitted From the Crosswalk Process:* Our initial audit determined the Department had missed rebates on physician-administered drug claims because of internal decisions to exclude certain HCPCS procedure codes from the HCPCS to NDC crosswalk and to use a crosswalk that did not contain complete, accurate NDC information. Department officials agreed there were omissions and invalid information on its crosswalk, and stated they have improved their oversight of the crosswalk to ensure all procedure codes and NDCs that appear on rebate-eligible claims are included. For the period January 1, 2015 to March 31, 2017, we found the Department invoiced $18.5 million in drug rebates for procedure codes that were excluded from the drug rebate process during our initial audit. However, we also identified some rebate-eligible drugs that were not listed on the crosswalk for part of this time period, accounting for an additional $1.9 million in uncollected rebates. Department officials agreed to review these claims and seek rebates as appropriate.

- *Ambulatory Payment Group (APG) Claims:* Previously, the Department did not seek rebates for physician-administered drugs reported on APG claims (i.e., fee-for-service claims for services provided by emergency departments, hospital outpatient departments, and providers in clinical settings). In response to our initial 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. Furthermore, in the May 2015 *Medicaid Update*, the Department informed providers that the billing system would begin enforcing the payment policy that

requires providers to report the NDC for the drugs listed in the APG fee schedule beginning July 1, 2015. Department officials stated that about 90 percent of drug payments made for APG claims are now part of the rebate process.

We determined, however, that the Department's changes to the invoicing process for APGs in January 2015 did not include all APG drugs that are eligible for rebates. Specifically, physician-administered drugs that are reimbursed based on the APG procedure grouping method, and not the separate fee schedule, continue to be excluded from the rebate process, even if a Medicaid payment was made for the drug. In the grouping method, reimbursement for a drug is based on a historical average price. Officials stated one reason for the continued exclusion of these claims is the concern that the NDC and unit quantity may not be reported accurately because the payment to providers is not affected by such information.

In addition to the Department's decision to exclude all grouped procedures paid within APGs, we determined that the Department's extraction of APG claim lines was flawed and, as a result, many APG claim lines were not even considered for rebates. Furthermore, we determined the Department has been extracting the APG procedure unit quantity from the incorrect data field to calculate rebates.

The Department has invoiced $400,794 in rebates for APG claims via retroactive rebates and quarterly rebate activity for the period January 1, 2015 through March 31, 2017. However, we estimate that with further corrective actions, the Department could collect as much as $9.3 million more in rebates for APG drug claims for this time period, as follows.

About $6.8 million (of the $9.3 million) in rebates could be collected for drugs that are listed on the separate APG fee schedule if the Department corrects the APG claim line extraction method; an estimated $1.2 million could be collected if the Department uses the correct unit quantity field for the APG claims already invoiced; and the remaining $1.3 million in rebates is related to other issues such as grouped procedures and missing NDCs. The Department agreed that the extraction of APG claim lines was flawed and will review potential solutions with the new rebate contractor. Department officials also acknowledged the unit quantity error, and plan to take steps to correct it, including seeking retroactive rebates with the correct unit quantities.

- *Inaccurate Claim Information:* If the Department identifies fee-for-service claims or encounter claims that have potentially incorrect information that the Department cannot correct, the Department excludes them from the invoices to avoid disputes with the manufacturers over excessive rebate amounts. A comprehensive process to review claim-level data accuracy issues for encounter claims is planned, but not yet implemented by the Department. Until then, the Department will continue excluding encounter claims with potentially inaccurate information, missing out on rebates. We estimate that $10.3 million in rebates could have been invoiced if

steps were taken to obtain corrected information (from providers, for instance) on certain fee-for-service claims and encounter claims processed during the period January 1, 2015 to March 31, 2017. The Department has stated it will address this issue with the new rebate contractor.

- *Program of All-Inclusive Care for the Elderly (PACE):* In the initial audit, we determined the Department had been excluding drug encounter claims reported by PACE managed care plans from the rebate process. The Department agreed this was an oversight, and began invoicing PACE encounter claims as of the second quarter of 2014. However, the invoicing was stopped in 2015 out of concern over the accuracy of encounter claim reporting by PACE plans, specifically whether it was Medicaid or Medicare that actually had a liability for the drugs.

  Upon consulting with the Department officials responsible for overseeing PACE plans, we were told the plans should be able to determine the split between Medicare and Medicaid payments when a recipient is enrolled in both programs. Furthermore, according to Department officials, the plans are required to report the encounter claims completely and accurately, and the EIS has the capability to receive third-party insurance information. The Department plans to take steps to obtain accurate third-party insurance information on PACE encounter claims. When the data accuracy issues are resolved, Department officials stated that PACE encounter claims will be included in the drug rebate process. Furthermore, regarding past encounter transactions, officials stated they are discussing whether it will be feasible for MCOs to resubmit past encounter claims or whether recouping the rebates through a settlement process with plans will be necessary.

  As a result of the encounter data issues and the subsequent decision to temporarily exclude PACE encounter claims from the drug rebate process, we estimate that $4 million in rebates went uncollected between January 1, 2015 and March 31, 2017 for recipients who did not have Medicare prescription drug coverage (and so there was no Medicare liability for the drugs). We note that, in the first two quarters of 2015, the Department invoiced $288,062 in rebates for such recipients.

- *Drug Encounter Claims Reported With No MCO payment:* In the initial audit, we determined the Department was not seeking rebates for physician-administered drug encounter claims when an MCO reported zero payment. However, these claims are eligible for rebates. In response to our recommendation, the Department claimed it had modified its rebate programming to include applicable encounter claims where the MCO amount paid was reported as zero. Upon our evaluation, however, we identified 1.4 million such encounter claims that were not processed by the Department between January 1, 2015 and March 31, 2017, which we estimate could account for as much as $21.2 million in rebates. Department officials stated this issue will be reviewed and addressed with the new rebate contractor.

- *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, as a result of the initial audit, the Department reevaluated the issue and began invoicing compound drugs as of the first quarter of 2015. Between January 1, 2015 and March 31, 2017, the Department invoiced $3.4 million in rebates for compound drugs.

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.

Status – Partially Implemented

Agency Action – In our initial audit, we identified several errors in the Department's invoicing process that prevented it from properly identifying rebate-eligible claims and invoicing all drug rebate revenue due. The Department has taken steps to correct most of them; however, more needs to be done. We reviewed drug rebate data provided by the Department for a period after the initial audit from January 1, 2015 to March 31, 2017. We determined $1.9 million in rebates were invoiced by the Department as a result of improvements to the rebate processes and $1.2 million in additional potential rebates could still be collected with further efforts by the Department, as detailed below.

- *Manufacturer Rebates Below the Quarterly Minimum Requirement:* Previously, we found the Department did not invoice a drug manufacturer if, for a given quarter, the total rebates were less than $50. Department officials acknowledged that an error occurred beginning with the fourth quarter of 2011, when managed care encounter claims became part of the invoicing process. At that time, the Department began producing two invoices for each manufacturer: one for fee-for-service drugs and one for managed care drugs. It was determined that the Department erroneously excluded certain drug claims from both the fee-for-service invoice and the managed care invoice due to the minimum rebate requirement when it should have only excluded the claims from the fee-for-service invoice. The Department has since corrected this issue.

- *NDCs Not Invoiced in Managed Care:* We previously identified NDCs that were not included on the Department's managed care rebate invoices despite meeting rebate eligibility criteria. In response to the initial audit, the Department stated it had modified the invoicing process to include the applicable NDCs, but did not provide details as to the specific changes that were made. During this follow-up review, we identified the same issue for several NDCs from one manufacturer between January 1, 2015 and March 31, 2015. However, this was remedied soon after when the manufacturer informed the Department of the missing invoice. In September 2015, the Department invoiced the manufacturer for the previously missed rebates.

Additional steps may be needed by the Department to prevent this type of omission from recurring. Department officials stated this issue will be discussed with the new contractor and addressed if necessary.

- *Drugs Improperly Classified as Terminated:* Due to a flaw in the Department's process, drugs were misclassified as "terminated" (i.e., no longer produced by the manufacturer) and thus not invoiced for rebate. In response to the initial audit, the Department stated it had corrected the issue beginning with the first quarter 2015 invoices. We determined that, as a result of its corrective actions, the Department invoiced $1.4 million in rebates between January 1, 2015 and March 31, 2017 for the drugs identified in the initial audit.

- *Ineligible Drug List:* Certain drugs are not eligible for rebates, and the Department maintains a list of these drugs to guide its rebate invoicing. In the initial audit, however, we found that the Department's list of rebate-ineligible drugs included some NDCs that were, in fact, eligible; as a result, these drugs were improperly excluded from invoices. During the initial audit, the Department reviewed and corrected its list of ineligible drugs in order to collect appropriate rebates. As a result of its corrective actions, the Department invoiced $507,614 in rebates from January 1, 2015 to March 31, 2017 for the NDCs identified in the initial audit.

- *Adjusted Negative Rebates:* Medicaid reimburses fee-for-service providers based on the claim information they submit to the Department. Providers can later choose to correct this reported information by submitting a new, adjusted claim – a routine occurrence in the eMedNY claims processing system. The Department's rebate invoicing process 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 calculations work. A provider submits a drug 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 the initial audit, we identified incorrectly calculated negative rebates for which there were no corresponding positive rebates to offset, resulting in a rebate shortfall. In response, the Department stated it would research and evaluate the claims to determine a plan of action. As part of our follow-up review, we evaluated the Department's quarterly and retroactive invoices processed from January 1, 2015 to March 31, 2017, and identified fee-for-service claims and encounter claims with negative rebates which resulted in a $1.2 million rebate shortfall. Department officials agreed to review these claims and seek rebates as appropriate, and will be discussing this issue with the new rebate contractor.

Recommendation 3

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

Status – Partially Implemented

Agency Action – The Department has submitted retroactive invoices to manufacturers for rebates totaling $23 million for the fee-for-service and encounter claims we identified for the period April 1, 2010 to December 31, 2014.

However, this amount accounts for only a portion of the rebate revenue available from the claims identified, and we believe additional rebates totaling as much as $70.7 million could also be realized. These uncollected rebates stem primarily from claims with inaccurate or incomplete data, such as missing NDCs for one-to-many physician-administered drug encounter claims as well as missing or inaccurate PACE pharmacy encounter claims. Department officials stated they are discussing the feasibility of having MCOs resubmit past encounter claims with corrected information or whether recouping the rebates through a settlement process with MCOs will be necessary.

Additionally, some rebates were not invoiced due to Department errors (e.g., improper extraction of APG claim lines) or the Department's decision to exclude them (e.g., APG drugs paid via the grouping method). In other cases, such as certain MCO encounter claims with a reported zero payment and certain claims with potentially inaccurate information, the Department has not yet updated its policies to either include the claims in the rebate process or investigate and resolve possible data errors.

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.*

Status – Partially Implemented

Agency Action – The Department provided a draft of its procedures, which outlines the selection of fee-for-service claims and encounter claims for rebate. The draft also briefly describes other steps in the rebate process, such as the review for inaccurate fee-for-service and encounter drug claims. However, it does not contain details describing all of the exclusions of claims made during the processing of drug rebate invoices, nor does it contain a sign-off process regarding which levels of management should be involved in changes to the

procedures, or a process to resolve data/claim errors with MCOs and providers.

The Department is undergoing the transfer of drug rebate processing to the new drug rebate administration and management services contractor. Department officials stated that the contractor will have a role in ensuring the data accuracy of rebate-eligible fee-for-service claims and encounter claims. Furthermore, according to Department officials, there have been, and will continue to be, discussions with the contractor about formalizing and updating the drug rebate procedures, the frequency of procedure updates, appropriate management sign-offs, and the resolution of data/claim errors with providers, although no final decisions had been made at the time of this follow-up review.

Recommendation 5

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

Status – Partially Implemented

Agency Action – According to Department officials, encounter data quality reports are provided to all managed long-term care (MLTC) plans, including PACE plans. These reports measure MCO encounter submissions based on timeliness, data format accuracy, and volume benchmarks. As part of the enacted 2016-17 Budget, if a plan fails to meet the Department's benchmarks for any of these measurements, a penalty can be issued.

The encounter data quality reports used by the Department do not yet include issues with claim-level data accuracy (as stated in Recommendation 1, Agency Action, a process to review claim-level data accuracy issues for encounter claims is planned). Furthermore, as previously mentioned, PACE encounter claims do not currently contain the proper information identifying whether the drug claim was paid by Medicare or Medicaid, or by both with Medicaid as the secondary insurer. The Department plans to take additional steps to obtain accurate third-party insurance information on PACE encounter claims.

Major contributors to this report were Mark Breunig and Yanfei Chen.

We would appreciate your response to this report within 30 days, indicating any actions planned to address the unresolved issues discussed in this report. We thank the management and staff of the Department for the courtesies and cooperation extended to our auditors during this review.

Very truly yours,

Warren Fitzgerald
Audit Manager

cc: Ms. Diane Christensen, Department of Health
Mr. Dennis Rosen, Medicaid Inspector General