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June 30, 2017

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

Re: Medicaid Drug Rebate Program
Under Managed Care
Report 2016-F-27

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, *Medicaid Drug Rebate Program Under Managed Care* (Report 2014-S-41).

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. The Department reimburses Medicaid providers either directly through fee-for-service arrangements or through managed care. Under managed care, the Department contracts with managed care organizations (MCOs) to provide services to Medicaid recipients. The Department pays MCOs a monthly premium for each enrolled Medicaid recipient. In turn, MCOs are responsible for ensuring enrollees have access to a comprehensive range of medical services. MCOs reimburse health care providers for services provided to their enrollees, and must submit encounter claims to the Department that detail each medical service provided to enrolled recipients. Prior to September 2015, MCOs submitted encounter claims to the Department's Medicaid claims processing and payment system (eMedNY). Since September 2015, MCOs have been required to submit encounters to the Department's new Encounter Intake System (EIS).

In 1990, Congress created the Medicaid Drug Rebate Program (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 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 MCOs, including both pharmacy and physician-administered drugs (physician-administered drugs are administered to patients by a medical professional in an office setting).

In order to calculate rebates, the Department requires MCOs to record specific drug utilization data and other information on encounter claims. For example, encounter claims must include the identification numbers of the providers who prescribed as well as dispensed the drug. Encounter claims must also have accurate National Drug Codes (NDCs) for all drugs dispensed during a patient encounter. A valid NDC is a unique identifier that represents a drug's specific manufacturer, the drug product, package size, and strength. The Department uses information from the EIS (and formerly eMedNY) to identify drugs that are eligible for rebate. Based on the NDC information submitted on the encounter claim, the Department calculates the rebates owed and submits rebate invoices to the drug manufacturers. The eMedNY claims processing system had edits to reject MCO encounter claims that had invalid or incomplete information, such as a missing NDC. The EIS also contains edits, although the edits are separate and distinct from those that were used in eMedNY. When encounter claims are rejected, MCOs are expected to correct any errors and resubmit revised encounter claims to the Medicaid program.

We issued our initial audit report on February 18, 2015. The audit objective was to determine if the Department had taken appropriate steps to maximize rebate collections on drugs dispensed to individuals enrolled in Medicaid managed care. The audit covered the period October 1, 2011 to June 30, 2014. Our initial audit determined the Department had not taken sufficient steps to maximize rebate collections on drugs dispensed to individuals enrolled in managed care. As a result, the Department did not collect as much as \$119.3 million in available rebates.

In our initial audit, we estimated that approximately 1 million encounter claims rejected by eMedNY were never successfully resubmitted by MCOs, accounting for an estimated \$69 million in potential rebates earned but not collected. The majority of the rejected encounter claims had an invalid provider identification number. We determined the Department did not have proper monitoring controls in place to ensure rejected encounter claims were successfully resubmitted to eMedNY so that rebates could be requested.

We also estimated that \$50.3 million in rebates for physician-administered drugs were never billed to manufacturers under certain circumstances. As previously stated, NDCs identify each medication based on manufacturer, strength, dosage form and formulation, and package form and size. Physician-administered drug encounter claims include both an NDC as well as a procedure code. A physician-administered procedure code represents a specific drug (e.g., a chemotherapy drug). However, some physician-administered procedure codes have more than one corresponding NDC because a drug may come in different strengths and package sizes or from multiple manufacturers. For example, a particular chemotherapy drug may be provided by two manufacturers and, therefore, that chemotherapy procedure code may have two corresponding NDCs; or a chemotherapy drug may be provided by only one manufacturer, but be provided in three different strengths and therefore have three NDCs. Physician-administered drug procedure

codes with more than one corresponding NDC are referred to as “one-to-many” drugs and those with only one NDC are referred to as “one-to-one.”

In the original audit, we determined the Department did not seek rebates for “one-to-many” drugs under managed care because they erred in their process and failed to extract the NDC information from these encounter claims. We also determined the Department did not seek rebates on drug encounter claims from all categories of Medicaid services, such as clinic-based physician-administered drugs. The audit further concluded the Department did not conduct risk assessments to determine the impact of its policies and processes (*which we found needed significant improvements*) on MCO encounter claims processing and rebate revenue.

We recommended that the Department: review the identified \$119.3 million in uncollected rebates and, where appropriate, seek rebates; develop a process to routinely evaluate rejected encounter claims and their impact on the rebates to the Medicaid program; coordinate with MCOs to resubmit rejected encounters; evaluate and consider expanding the Medicaid service categories included in the Rebate Program; and ensure MCOs are properly trained regarding submission of encounter claims.

The objective of our follow-up was to assess the extent of implementation, as of May 4, 2017, of the 12 recommendations included in our initial audit report.

Summary Conclusions and Status of Audit Recommendations

Department officials made significant progress in addressing the problems we identified in the initial audit report. However, further actions are still needed. Since the initial audit, the Department has invoiced a total of \$159 million in rebates regarding the rejected encounter claims and physician-administered drug issues we reported in the initial audit. We also determined that as much as \$72.4 million in rebates has not been invoiced, but could still be collected with additional efforts by the Department. Given the current fiscal stress on state Medicaid programs, we strongly urge the Department to take the steps necessary to collect these rebates. The Department has also provided training and assistance to MCOs regarding the proper submission of encounter claims and implemented controls to prevent some of the problems we identified from recurring.

Of the initial report’s 12 audit recommendations, seven were implemented and five were partially implemented.

Follow-Up Observations

Recommendation 1

Review the identified \$69 million in uncollected rebates and, where appropriate, seek rebates.

Status – Implemented

Agency Action – In order to process encounter claims – and to identify those that are eligible for

drug rebates – the Department requires that MCOs provide certain information on their encounter claims, including provider ID numbers and NDCs. The eMedNY claims processing system had edits in place to reject MCO encounter claims that were incomplete (e.g., missing an NDC) or incorrect (e.g., invalid provider ID number). In such cases, the MCO would be notified of the rejection and expected to correct any errors and resubmit the encounter claim for reprocessing. Once encounter claims are accepted, the Department uses the NDC to identify rebate-eligible claims, and the Department then calculates the rebates for the drugs and submits invoices to the manufacturers.

In our initial audit we estimated that \$69 million in uncollected drug rebates resulted from rejected encounter claims that were never successfully resubmitted by MCOs. About \$53 million (of the \$69 million) was based on rejected MCO encounter claims for pharmacy-dispensed drugs from August 10, 2012 to June 30, 2014. The remaining \$16 million was estimated for the period October 2011 to July 2012, during which the Department did not retain rejected encounter data.

On October 23, 2014 and December 26, 2014, the Department sent emails to MCOs requesting resubmissions of the rejected encounter claims identified during the original audit (totaling about \$53 million in estimated rebates). As a result of the successfully resubmitted rejected encounters, the Department was able to invoice drug manufacturers for \$61.6 million in rebates. For the rejected encounters that the MCOs were not able to resubmit successfully (approximately \$4.9 million in rebates), the Department is working on a settlement process with MCOs to collect additional monies.

Recommendation 2

Coordinate with MCOs to resubmit all rejected encounter claims, including those denied by Edit 78.

Status – Implemented

Agency Action – In the original audit, we determined that encounter claims accounting for \$42 million out of \$53 million in collectable rebates were rejected by eMedNY's Edit 78 (referring provider ID number invalid). Based on our findings and recommendations in the initial audit, Department officials re-evaluated this edit and, effective October 9, 2014, reprogrammed eMedNY to no longer reject encounter claims that fail the logic of Edit 78. Additionally, as a result of the audit, the Department evaluated two other eMedNY edits that rejected encounters to determine whether their purpose was still appropriate. As a result, the Department modified the edits to accept encounter claims that previously were rejected. The Department then communicated with the MCOs regarding the findings from the original audit and requested resubmissions of previously rejected encounter claims. MCOs were able to successfully resubmit 83 percent of the rejected encounters (representing about \$61.6 million in rebates; referenced in Recommendation 1, Agency Action). For the remaining 17 percent of encounters that were not resubmitted (about \$4.9 million in rebates), the Department determined that MCOs had reached a limit as to

what they could identify and resubmit and, at the time of our follow-up, was working on a settlement process with MCOs to collect additional monies.

Recommendation 3

Ensure MCOs are trained regarding submission of encounter claims to reduce rejection of encounter claims and continue to provide assistance.

Status – Implemented

Agency Action – On September 14, 2015, MCOs began submitting encounter claims to the Department's new Encounter Intake System (EIS). Since then the Department has held weekly webinars for MCOs to assist them with EIS-related issues. For example, during webinars on February 22, 2016 and March 14, 2016, MCOs were informed of a new edit that would deny certain encounters. According to Department officials, MCOs receive invitations and agendas a week prior to each webinar, and details such as the presentation materials and the question and answer sessions are distributed to MCOs after the webinars.

Recommendation 4

Develop a process for routinely evaluating rejected encounter claims (and the corresponding edits) and their impact on the rebates to the Medicaid program.

Status – Partially Implemented

Agency Action – The EIS began accepting Medicaid encounter claims as of September 14, 2015. With the implementation of the EIS, the Department stated that rejected encounters are not stored. However, the system does create weekly summary reports on the statuses (denial/acceptance) of encounter submissions. The Department provides these reports to MCOs. The Department then relies on the MCOs to reconcile rejected encounters and resubmit them timely. However, the aggregated information in the weekly summary reports does not allow for the Department to track whether specific rejected encounters were eventually resubmitted or not. Therefore, the Department cannot accurately evaluate the impact of rejected encounters on the Rebate Program in the EIS system. However, the Department believes that the further strengthening of edits, production of the weekly reports for the MCOs, along with continuous outreach on all facets of encounter data will improve the quality of encounter data submissions.

As stated previously, prior to the implementation of the EIS, MCOs submitted encounter claims to eMedNY. During the follow-up review, we obtained all eMedNY-denied pharmacy encounters for the period after the original audit (July 2014 to August 2015). We analyzed this data similarly to the analysis conducted during the original audit. Using this data, we estimated that \$10.4 million in rebates were invoiced as a result of Department actions to emphasize encounter claim resubmissions. We also identified some denied encounters that have not been resubmitted, which could result in approximately \$807,271 in additional

rebates. The Department is reviewing these remaining encounters to determine if rebates can be invoiced.

Recommendation 5

Review the identified \$50.3 million in uncollected rebates and, where appropriate, seek rebates.

Status – Partially Implemented

Agency Action – In our original audit, we recommended that the Department begin seeking rebates on physician-administered drugs that have multiple corresponding NDCs (i.e., “one-to-many” drugs) and on drugs provided within certain additional “service categories,” such as clinic-based services. As a result, the Department changed its policies and now includes both items in its drug rebate processes and has submitted retroactive rebate invoices to manufacturers. For the initial audit period of October 1, 2011 to June 30, 2014, the Department retroactively invoiced \$32 million in rebates for one-to-many physician-administered drugs and expanded service categories.

We also determined that an additional \$30.1 million in rebates, identified during the original audit, have not been invoiced by the Department. The majority of these rebates are for encounter claims that have a missing or invalid NDC. An NDC uniquely identifies the drug product delivered to a patient and is used as the basis for obtaining drug rebates from manufacturers. In order to obtain the missing NDC information through resubmissions, Department officials discussed the feasibility of allowing MCOs to resubmit old encounter claims through the EIS. This would require lifting the two-year timely filing edit and installing historical Medicaid enrollment data into the EIS. Department officials decided not to proceed with the EIS system changes because they believe the costs and time required of the Department, the MCOs, and the provider community would not be worthwhile. Department officials also doubted the likelihood that these efforts would produce measurable success in collecting the data. About \$29.7 million of the \$30.1 million in rebates could go uncollected because of the Department’s decision. The Department acknowledges that submission of the NDC information was required by Medicaid for certain physician-administered drug encounters. Furthermore, given the significance of the amount of rebates in question, we encourage officials to reconsider their decision or pursue alternate methods of collecting the monies owed.

Recommendation 6

Evaluate the feasibility of retroactively recovering additional rebates that were earned but not collected prior to the scope of this audit.

Status – Implemented

Agency Action – The Department took action to recover additional rebates that were earned but not collected prior to the scope of the initial audit (October 1, 2011 through June

30, 2014). The Department retroactively invoiced for additional service categories of physician-administered drug encounters since April 1, 2010. As a result, \$4.3 million in rebates were invoiced for the period prior to October 1, 2011.

We identified an additional \$9.8 million in rebates that could be collected for the period April 1, 2010 to September 30, 2011. However, according to Department officials, the main reasons for not including these encounters were missing NDCs for one-to-many physician-administered drug encounters and the fact that the encounters were more than two years old. As stated previously (see Recommendation 5, Agency Action), Department officials discussed the feasibility of allowing MCOs to submit NDCs for old encounter claims through the EIS. This would require lifting the two-year timely filing edit and installing historical Medicaid enrollment data into the EIS. Department officials decided not to proceed with the EIS system changes because they believe the costs and time required of the Department, the MCOs, and the provider community would not be worthwhile. However, as stated, about \$9.8 million in rebates could go uncollected because of the Department's decision. The Department acknowledges that submission of the NDC information was required by Medicaid for certain physician-administered drug encounters. Furthermore, given the significance of the amount of rebates in question, we encourage officials to reconsider their decision or pursue alternate methods of collecting the monies owed.

Recommendation 7

Coordinate with MCOs to resubmit all encounter claims that lack the required NDC information.

Status – Partially Implemented

Agency Action – As explained in Recommendations 5 and 6, Department officials decided not to seek NDCs from MCOs for encounters prior to 2015, citing concerns over the time and costs required to do so. For the period between January 1, 2015 and December 31, 2016, the Department identified some of the encounter claims that did not contain NDCs. MCOs were contacted on January 25, 2017 to advise them to resubmit the encounters. We note that not all of the expanded service categories were included in the Department's reports, so additional actions by the Department will be necessary to collect all rebates for this time period.

Recommendation 8

Evaluate the existing service categories included in the Rebate Program, and consider expanding to include all others with rebate potential. Modify the relevant eMedNY edits to reject physician-administered drug encounter claims with an invalid or a missing NDC in the expanded service categories.

Status – Partially Implemented

Agency Action – During the original audit, the Department maintained a list of service categories that it would accept for rebate and did not seek rebates on drug encounter claims from categories of service not on the list, even when the claims contained the required information for rebate. Most notably, this list excluded clinic-based services. The Department evaluated this issue and decided to expand the service categories it includes in the Rebate Program, as recommended.

Beginning on September 14, 2015, MCOs submitted encounter claims to the EIS instead of eMedNY. The Department is in the process of fixing the EIS edit that would reject institutional physician-administered drug encounter claims (such as those from a hospital or free-standing clinic) without an NDC. During the time when this edit is not working, the Department will continue running reports and contacting the MCOs on the resubmission of certain service categories of physician-administered drug encounters without a valid NDC. We note that not all of the expanded service categories were included in the Department's reports, so additional actions by the Department to include the missing service categories in the reports will be necessary to collect all rebates.

Recommendation 9

Evaluate and, as appropriate, modify the relevant eMedNY edits to reject adjustment physician-administered drug encounter claims with an invalid or a missing NDC.

Status – Implemented

Agency Action – During our original audit, we identified many physician-administered drug encounter claims that were submitted to eMedNY with an invalid or a missing NDC, making it impossible for the Department to collect rebates. To address the problem the Department implemented two eMedNY edits in April 2013. However, the edits allowed adjustments to prior claims to bypass these edits and the adjusted claims were accepted by the system even if the NDC error had not been corrected.

Beginning on September 14, 2015, MCOs submitted encounter claims to the EIS instead of eMedNY. The Department implemented an EIS edit in March 2016, which requires NDCs for the physician-administered drug encounter submissions. According to Department officials, the EIS edit does not contain separate logic that allows adjusted claims to bypass it. Both original and adjusted encounters are processed in the same manner.

Recommendation 10

Consider establishing a process to require MCOs to report NDC information on all physician-administered drug encounters.

Status – Implemented

Agency Action – The Department considered such a process and, as a result, implemented an

EIS edit to ensure that physician-administered drug encounter claims will have NDC information. MCOs were made aware of this edit during weekly webinars in February and March of 2016. The edit rejects professional physician-administered drug encounters with an invalid NDC, but it does not reject institutional encounters with an invalid NDC. The Department needs to correct the edit's logic before it can be set to reject institutional encounters.

The Department identified some of the encounter claims without NDCs for the period between January 1, 2015 and December 31, 2016. MCOs were contacted on January 25, 2017 to advise them to resubmit the encounters. During the time when the edit is not rejecting institutional physician-administered drug encounters, the Department will continue running reports and contacting MCOs about the specific encounters in question. We note that not all of the expanded service categories are included in the Department's reports, so additional actions by the Department will be necessary to collect all rebates.

Recommendation 11

Provide training and assistance to MCOs regarding the proper submission of encounters, including reporting of NDC information.

Status – Implemented

Agency Action – The Department holds weekly webinars to provide training and assistance to MCOs on encounter claim submission issues. Details of the webinars such as the presentation materials and the question and answer sessions are distributed to MCOs after the webinars. In the February, March, and December 2016 webinars, the Department explained the edit that would reject physician-administered drug encounters without a valid NDC. Specific instructions for reporting NDCs with physician-administered drug encounters were provided.

Recommendation 12

Prospectively collect drug rebates for all eligible physician-administered drugs paid for by MCOs.

Status – Partially Implemented

Agency Action – In our original audit, we recommended that the Department begin seeking rebates on physician-administered drugs that have multiple corresponding NDCs (i.e., "one-to-many" drugs) and on drugs provided under additional "service categories," such as clinic-based services. The Department has included both issues in its drug rebate processes and has submitted retroactive rebate invoices to manufacturers. As a result, since our initial audit, the Department has already invoiced \$50.6 million in rebates from July 1, 2014 to September 30, 2016 for physician-administered drugs encounters that were previously excluded.

We estimated that an additional \$26.8 million in rebates could be collected on physician-administered drug encounters from July 1, 2014 to September 30, 2016. We determined that these encounters were not included in the Department's retroactive or regular manufacturer invoices at the time of our follow-up. The main reasons the Department has not processed rebates for these encounters are missing NDC information and EIS system issues which allow some duplicate transactions to be submitted.

The Department has taken steps to identify some of the encounters without NDCs for the period between January 1, 2015 and December 31, 2016. MCOs were contacted on January 25, 2017 to advise them to resubmit the encounters. We estimated that \$3.5 million (of the \$26.8 million) in rebates could be collected after the MCOs finish resubmitting the encounters as requested by the Department.

As discussed in Recommendation 5 (see Agency Action), in order to obtain all of the missing NDC information through resubmissions, Department officials discussed the feasibility of allowing MCOs to resubmit old encounter claims through the EIS. This would require lifting the two-year timely filing edit and installing historical Medicaid enrollment data into the EIS. Department officials decided not to proceed with the EIS system changes because they believe the costs and time required of the Department, the MCOs, and the provider community will not be worthwhile. Department officials also doubted the likelihood that these efforts would produce measurable success in collecting the data. As much as \$5.8 million of the \$26.8 million in rebates could go uncollected because of the Department's decision. The Department acknowledges that submission of the NDC information was required by Medicaid for certain physician-administered drug encounters. We encourage officials to reconsider their decision or pursue alternate methods of collecting the monies owed.

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

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