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December 20, 2024

James V. McDonald, M.D., M.P.H.
Commissioner
Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

Re: Maximizing Drug Rebates Under the Federal Medicaid Drug Rebate Program
Report 2024-F-14

Dear Dr. McDonald:

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 initial audit report, *Medicaid Program: Maximizing Drug Rebates Under the Federal Medicaid Drug Rebate Program* (Report 2021-S-11).

Background, Scope, and Objective

The Department of Health (DOH) administers the Medicaid program. For recipients enrolled in fee-for-service Medicaid, DOH makes payments for services rendered directly to health care providers through its Medicaid claims processing and payment system, eMedNY. For recipients enrolled in managed care, DOH pays managed care organizations (MCOs) a monthly premium for each enrolled recipient, and the MCOs pay health care providers for services rendered. The MCOs are also required to submit post-adjudicated claims (called encounters) through DOH's Original Source Data Submitter (OSDS, which replaced the Encounter Intake System in May 2023) to report to DOH about each medical service provided to recipients. Fee-for-service and encounter claim data is captured in the Medicaid Data Warehouse (MDW).

In 1990, Congress created the Medicaid Drug Rebate Program (MDRP) to reduce state and federal expenditures for Medicaid prescription drugs. The MDRP requires drug manufacturers to enter into a national rebate agreement with the Centers for Medicare & Medicaid Services in exchange for state Medicaid coverage of the manufacturer's drugs. On a quarterly basis, states are required to send rebate invoices to each manufacturer for any rebate-eligible drugs their Medicaid programs paid for.

Since April 2018, DOH's rebate contractor, Magellan Medicaid Administration, Inc. (Magellan), has been responsible for submitting rebate invoices to drug manufacturers and collecting payments. On a weekly basis, DOH extracts fee-for-service and encounter drug

claims from the MDW and provides them to Magellan for rebate invoicing. Magellan, with DOH oversight, then determines which claims will be invoiced to drug manufacturers.

The objective of our initial audit, issued on April 5, 2023, was to determine whether DOH took appropriate steps to collect all available drug rebates under the federal MDRP. The audit covered the period from April 2018 through March 2022 and certain claims back to January 2017. We identified uncollected drug rebates totaling $183.7 million due to errors in DOH's claim extraction procedures, inaccurate or incomplete claim information submitted by MCOs and providers, exclusions of Program of All-Inclusive Care for the Elderly (PACE) managed care claims from the rebate process, and claim processing errors made by DOH and the rebate contractor.

The objective of our follow-up was to assess the extent of implementation, as of November 27, 2024, of the 12 recommendations included in our initial audit report.

Summary Conclusions and Status of Audit Recommendations

DOH made progress in addressing the issues we identified in our initial audit report. Of the $183.7 million in missed rebates identified in the initial audit, $124.2 million (68%) were invoiced to drug manufacturers at the time of our follow-up. In addition, DOH began taking steps to prevent missed rebates in the future. For example, DOH and its rebate contractor implemented a routine lookback process to collect missed rebates from claims containing invalid procedure code and national drug code (NDC) combinations. DOH is also making system enhancements to ensure encounter claims submitted to the OSDS contain certain correct information needed for invoicing, and DOH is taking other corrective steps to help ensure the rebate process captures all claims eligible for rebates. DOH plans to invoice another $20.9 million of the $183.7 million in rebates identified in the initial audit. However, about $38.6 million in missed rebates remained outstanding. Of the initial report's 12 audit recommendations, two were implemented, eight were partially implemented, and two were not implemented.

Follow-Up Observations

Recommendation 1

Review the $119 million in missed rebates and invoice manufacturers, as appropriate.

Status – Implemented

Agency Action – The initial audit found errors in DOH's claim extraction procedures that resulted in $119 million in missed rebates. Of the $119 million, $109.4 million in rebates were missed because the drug claims DOH sent to its rebate contractor incorrectly showed a zero-dollar Medicaid payment. The remaining $9.6 million in rebates were missed because the claims DOH sent to its rebate contractor had incorrect drug units, including zero units.

DOH updated its drug extraction procedures in 2020 to fix these issues and our follow-up found $107.3 million of the $109.4 million (over 98%) in missed rebates were invoiced as of July 2024. Most of these recoveries resulted from an effort taken by DOH to invoice $139 million in rebates as part of a retroactive review.

For the remaining $9.6 million (of the $119 million) in missed rebates, DOH officials stated a data correction file was created to update the incorrect drug units. Magellan

then processed the claims with the updated drug quantities and adjusted invoices to recoup the missed rebates. DOH officials invoiced $16.2 million in rebates as part of this process. We concluded almost all of the $9.6 million in missed rebates were invoiced.

Recommendation 2

Review the $44.5 million in missed rebates and invoice manufacturers, as appropriate. Where rebates cannot be sought due to missing NDCs or invalid procedure code and NDC combinations on physician-administered drug claims paid by MCOs, follow up with MCOs for proper drug information or seek recovery directly from MCOs for the missed rebates.

Status – Partially Implemented

Agency Action – In order for DOH to process rebates for physician-administered drug claims, a valid combination of the NDC and the procedure code are needed. The initial audit identified $44.5 million in rebates that were missed primarily due to inaccurate or incomplete NDC and procedure code information on the claims submitted by MCOs and providers. A breakdown of the $44.5 million in missed rebates is as follows.

The initial audit identified $26.1 million in missed rebates because MCOs submitted physician-administered drug encounter claims without NDCs. During our follow-up, DOH provided the invoiced claim data for $317,555 in rebates that resulted from a retroactive collection project; however, we determined only $80,263 consisted of missed rebates identified in our initial audit. In addition, DOH officials stated they reached out to MCOs and required them to retroactively void and resubmit claims with missing NDCs for which they were able to determine the NDC information. DOH also sought recoveries from four MCOs but had settled with only one MCO as of November 2024. DOH officials should promptly act to recover the remaining missed rebates from the $26.1 million.

The initial audit identified $16.7 million in missed rebates on fee-for-service and encounter claims because they contained invalid NDC and procedure code combinations. DOH officials stated Magellan completed a lookback on 7 years of fee-for-service and encounter claims that were previously excluded during the rebate process for invalid combinations of NDCs and procedure codes and invoiced $28 million in rebates. DOH officials provided the claims data for the portion of the $28 million that pertained to the $16.7 million in missed rebates from our initial audit showing it invoiced for $7.3 million (44%) of the $16.7 million. DOH indicated the lookback project will be done annually; however, we encourage DOH to review the remaining claims from the $16.7 million in missed rebates identified in the initial audit and invoice drug manufacturers as appropriate.

The initial audit identified $1.7 million in missed rebates for fee-for-service and encounter claims because they contained drug procedure codes described as “unclassified” and those codes were excluded from invoices. According to DOH officials, a project to address this issue has been completed, and they plan to invoice for the $1.7 million in missed rebates.

Recommendation 3

Ensure the EIS edit is working properly and requires a valid NDC on physician-administered drug encounter claims.

Status – Partially Implemented

Agency Action – As stated in our initial audit report, DOH officials updated an Encounter Intake System (EIS) edit in September 2021 that significantly decreased the amount of physician-administered drug encounter claims with missing NDCs. During our follow-up, DOH provided information that showed the count of encounter claims with missing NDCs decreased from approximately 1.3 million in 2021 to 211,615 in 2023 (83% decrease). We confirmed that the encounter claims without NDCs decreased each year from January 2021 through December 2023 as DOH officials asserted.

In addition, DOH initiated a system change request in July 2024 to include an enhanced edit on encounter data in the new OSDS to ensure all such encounter claims contain a valid NDC. DOH officials indicated that this would include ensuring encounter claims don't have missing NDCs. At the time of our follow-up, DOH did not yet have all approvals in place for this system change and did not have an estimated date of completion. DOH officials stated this project has not been completed because it was delayed due to the implementation of the OSDS, and they are in discussions to determine the requirements to achieve the recommended corrective action. DOH should take timely action to ensure the edit is implemented in the OSDS to avoid additional missed rebates due to missing NDCs on physician-administered drug encounter claims.

Recommendation 4

Add or enhance system edits to ensure all claims include a valid procedure code and NDC combination, where applicable.

Status – Partially Implemented

Agency Action – The July 2024 system change request referenced in Recommendation 3 includes an OSDS system edit on encounter data to ensure all claims include a valid procedure code and NDC combination. DOH did not yet have all approvals in place for this system change and did not have an estimated date of completion. DOH should take timely action to ensure the edit is implemented in the OSDS to avoid additional missed rebates due to invalid procedure code and NDC combinations on encounter claims.

Recommendation 5

Add or enhance system edits to prevent the use of unclassified drug codes on claims when a procedure code has been assigned.

Status – Partially Implemented

Agency Action – The July 2024 system change request referenced in Recommendation 3 includes an OSDS system edit on encounter data to prevent the use of unclassified drug codes on claims when a procedure code has been assigned. DOH did not yet have all approvals in place for this system change and did not have an estimated date of completion. DOH should ensure the edit is implemented in the OSDS timely to avoid additional missed rebates due to improper use of unclassified drug codes on claims.

Recommendation 6

Formally determine whether rebates can be sought on physician-administered drug claims where the procedure code and NDC combination is not yet on the crosswalk or the procedure code is an unclassified drug code, either by invoicing claims in a subsequent quarter or by using NDC information on the claims.

Status – Implemented

Agency Action – DOH determined rebates can be sought on physician-administered drug claims where the procedure code and NDC combination is not yet on the crosswalk or the procedure code is an unclassified drug code. DOH officials stated Magellan has completed a lookback project on 7 years of claims that were excluded due to invalid NDC and procedure code combinations and invoiced $28 million in rebates. As referenced in Recommendation 2, the lookback captured $7.3 million of the $16.7 million in missed rebates identified in our initial audit for claims with this issue. In addition, DOH plans to invoice for the $1.7 million in missed rebates for claims with unclassified drug procedure codes. DOH officials stated the lookback will be done annually, and the next lookback will also include claims with unclassified drug procedure codes.

Recommendation 7

Review the $12.8 million in missed rebates and invoice the manufacturers, as appropriate.

Status – Partially Implemented

Agency Action – Our initial audit identified $12.8 million in missed rebates pertaining to PACE managed care claims. DOH reviewed the claims and agreed they fit the criteria for the PACE population of Medicaid recipients and would be eligible for rebates. However, at the time of our follow-up, none of the $12.8 million had been invoiced. DOH developed a methodology to capture the eligible PACE claims (which should include the $12.8 million in missed rebates) and was in the process of implementing a system project to correct the issue going forward. DOH should take expedient action to complete the project and recoup the $12.8 million in missed rebates.

Recommendation 8

Ensure all rebate-eligible PACE encounter claims are included in the rebate process and invoiced appropriately.

Status – Partially Implemented

Agency Action – Since our initial audit, DOH created a methodology for obtaining the population of rebate-eligible PACE claims. In addition, DOH provided a November 2024 internal correspondence regarding an MDW system project that was started to properly include PACE claims in the rebate process. According to DOH officials, the project request includes PACE claims dating back to the beginning of the initial audit scope as well as future claims. We encourage DOH officials to take expedient action to complete the system project and obtain all drug rebates on PACE encounter claims.

Recommendation 9

Review the $6.4 million in missed rebates and invoice the manufacturers, as appropriate.

Status – Not Implemented

Agency Action – Our initial audit identified missed rebates totaling $6.4 million, of which $6.1 million (95%) occurred during the transition of the rebate process to Magellan in the second quarter of 2018. The remaining $276,806 in missed rebates were likely due to Magellan's rebate system incorrectly rejecting claims that were eligible for rebates. To recoup the missed rebates, DOH officials stated they sent the claims for the estimated $6.4 million in rebates to Magellan for invoicing. However, the supporting documentation DOH provided did not specify that the $6.4 million in claims were sent, and the claims had not yet been invoiced.

Recommendation 10

Take corrective actions to ensure rebate-eligible claims are not incorrectly rejected by the rebate contractor's system.

Status – Not Implemented

Agency Action – Our initial audit identified missed rebates likely due to Magellan's rebate system incorrectly rejecting claims that were eligible for rebates. During our follow-up, DOH officials stated DOH analysts conduct an ongoing weekly review of the rejected claims provided by Magellan to determine if any rejected claims can be processed and invoiced for rebates. However, DOH did not provide evidence of a review to support its assertions.

Recommendation 11

Review the $993,207 in missed rebates and invoice the manufacturers, as appropriate.

Status – Partially Implemented

Agency Action – Our initial audit identified $993,207 in missed rebates for drug claims that were processed by Magellan but were not listed as invoiced, voided, or excluded when reported back to DOH. DOH officials provided their claim review and stated the claims were properly excluded from invoices and provided reasons for the exclusions. Although some of the claims appeared to be appropriately excluded based on the reasons provided, we identified other claims with reasons that did not justify their exclusion. For example, DOH excluded certain pharmacy drug claims because the sum of the adjusted drug units (unit adjustments ensure the appropriate rebate amount) on the claims was negative for the given NDC during the quarter the claims were processed by Magellan. However, the sum of the original drug units for the NDC was positive for the quarter, indicating rebates were likely missed. DOH officials agreed to further review this issue.

There were also inconsistencies with the exclusions of claims for drugs where the drug manufacturer did not have a Medicaid drug rebate agreement in place. Rebates can only be collected when manufacturers have signed a drug rebate agreement. We found instances where the MDW and eMedNY indicated a manufacturer did in fact have a drug rebate agreement in place, but DOH indicated there was no drug rebate agreement. For example, according to DOH, the rebate start date for one manufacturer

was in May 2020, but the rebate start date in the MDW and eMedNY was in January 2020. DOH officials stated the rebate agreement start date used by Magellan is from a federal government source. We note that the MDW and eMedNY are systems of record for Medicaid and should be accurate. For one of this manufacturer's drugs, we also identified both invoiced claims and claims excluded from invoices for service dates between January 2020 and May 2020. Accordingly, it is not clear why some claims with the same NDC for the same time frame were invoiced and others were excluded. DOH officials agreed to further review this issue.

Recommendation 12

Periodically review Magellan's data after it processes claims to ensure drug claims eligible for rebates are not ignored during the invoicing process.

Status – Partially Implemented

Agency Action – Following our initial audit, DOH officials stated they created and sent a project request to Magellan to include appropriate exclusion codes on "ignored" claims. At the time of our follow-up, the project had not yet been completed.

Major contributors to this report were Samuel Carnicelli, Mostafa Kamal, and Jamala Benjamin-Hurdle.

DOH officials are requested, but not required, to provide information about any actions planned to address the unresolved issues discussed in this follow-up within 30 days of the report's issuance. We thank the management and staff of DOH for the courtesies and cooperation extended to our auditors during this follow-up.

Sincerely,

Mark Breunig
Audit Manager

cc: Melissa Fiore, Department of Health
Frank T. Walsh, Jr., Office of the Medicaid Inspector General