



Department of Health

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February 5, 2025

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

Dear Andrea Inman:

Enclosed are the Department of Health's comments on the Office of the State Comptroller's Follow-Up Audit Report, **2024-F-14** entitled, "Medicaid Program: Maximizing Drug Rebates Under the Federal Medicaid Drug Rebate Program."

Thank you for the opportunity to comment.

Sincerely,

A handwritten signature in blue ink that reads "Johanne E. Morne".

Johanne E. Morne, M.S.
Executive Deputy Commissioner

Enclosure

cc: Frank Walsh
Amir Bassiri
Jacqueline McGovern
Amber Rohan
Brian Kiernan
Timothy Brown
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OHIP Audit
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**Department of Health Comments on the
Office of the State Comptroller's
Follow-Up Audit Report 2024-F-14 entitled,
"Medicaid Program: Maximizing Drug Rebates Under the Federal
Medicaid Drug Rebate Program (Report 2021-S-11)"**

The following are the Department of Health's (Department) comments in response to the Office of the State Comptroller's (OSC) Follow-Up Audit Report 2024-F-14 entitled, "Medicaid Program: Maximizing Drug Rebates Under the Federal Medicaid Drug Rebate Program (Report 2021-S-11)." Included in the Department's response is the Office of the Medicaid Inspector General's (OMIG) replies to applicable recommendations. OMIG conducts and coordinates the investigation, detection, audit, and review of Medicaid providers and recipients to ensure they are complying with the laws and regulations.

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.

Response #1

The Department confirms agreement with the status of this recommendation.

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.

Response #2

The Department reached out to four Managed Care Organization plans in order to collect on the missed rebates related to Managed Care Organizations submitting physician-administered drug encounter claims without National Drug Codes. The Department is currently working on the penalty phase for the three remaining plans.

The Department has processed all the claims associated with the estimated \$16.7 million. As previously shared with OSC on November 27, 2024, the results of reprocessing yielded an actual invoice amount of \$10.8 million. The Department has completed the review of claims, and considers this recommendation as fully implemented.

The Department has also successfully updated its systems to include the processing of eligible miscellaneous J codes into invoicing process. When the next “Look back” project is completed, the claims will be reviewed, and if eligible invoiced.

State Comptroller’s Comment – Our audit recommended DOH invoice manufacturers, as appropriate, for missed rebates totaling \$44.5 million that occurred under three scenarios (\$26.1 million + \$16.7 million + \$1.7 million). As explained in our follow-up report, the audit recommendation had not been fully implemented. Specifically:

- DOH still needed to recover the majority of missed rebates from the \$26.1 million.
- DOH did not provide any explanation for approximately \$9.4 million in missed rebates that still had not been invoiced (\$16.7 million - \$7.3 million). We note that the \$10.8 million referenced by DOH in its Response #2 is the actual invoiced amount that pertains to the \$7.3 million in estimated missed rebates from the initial audit.
- DOH planned to invoice 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.

Response #3

The Department disagrees with the partially implemented status, and considers this recommendation as implemented.

As previously shared with OSC, the Encounter Intake System edit was successfully completed in advance of this Follow-Up Audit. See the published March 2019 Medicaid Update reminder entitled “*Reporting of the National Drug Code is Required for all Fee-for-Service Physician-Administered Drugs*”, which addresses the Original Source Data Submitter recommendation. The article can be found in Volume 35 Number 4:

https://www.health.ny.gov/health_care/medicaid/program/update/2019/2019-03.htm#ndc.

The enhancements from the edit reduced the number of missing National Drug Codes, and the Department will continue to assess the impact of the edit and any potential improvements. The Department disagrees with OSC's comments under Agency Action, regarding the enhanced edit falling under this recommendation status. The enhanced edit is related to the National Drug Code valid combination issue in recommendation #4.

State Comptroller's Comment – The encounter system edit doesn't prevent all encounter claims with missing NDCs. Over 211,000 claims with missing NDCs were accepted by the encounter system in 2023, according to DOH.

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.

Response #4

The Department agrees with this status of recommendation. The enhancement to the Original Source Data Submitter system to verify valid combinations is still in progress.

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.

Response #5

The system edit for the Original Source Data Submitter is still in progress and once completed will help to avoid additional missed rebates due to improper use of unclassified drug codes on claims. As mentioned in Response #4, the Department will consider both recommendation #4 and #5 to be fully implemented once this system edit is completed.

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.

Response #6

The Department confirms agreement with the status of this recommendation.

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.

Response #7

The Department intends to invoice the Program of All-Inclusive Care for the Elderly encounter drug rebates that are determined eligible. The Federal Share of the collected rebates will be refunded to the Centers for Medicare and Medicaid Services. The Department will continue to monitor the progress of the system project to ensure expeditious completion.

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.

Response #8

The Department intends to invoice the Program of All-Inclusive Care for the Elderly encounter drug rebates that are determined eligible. The Federal Share of the collected rebates will be refunded to the Centers for Medicare and Medicaid Services. The Department will continue to monitor the progress of the system project to ensure expeditious completion. The system project includes Program of All-Inclusive Care for the Elderly claims dating back to the beginning of the initial audit scope as well as future 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.

Response #9

The claims related to the estimated \$6.4 million in missed rebates have been supplied to Magellan to be included in the next round of invoicing. Once completed, OSC will be able to confirm results in the Medicaid Data Warehouse.

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.

Response #10

The Department supplied proof of the ongoing weekly reviews during the original audit. The exercise had started prior to the audit and has continued since. Please find attached the

protocol that is used to review rejected claims. The purpose of the review is to mitigate any issues that can be resolved to make sure all eligible claims are invoiced. The Department continues to work through identifying if any rejected claims can be recaptured.

State Comptroller's Comment – Despite our requests, no support for this process was provided to OSC during this follow-up.

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.

Response #11

The Department maintains that the claims related to the estimated \$933,207 were properly excluded. The Department is updating the labeling of the exclusions in the Medicaid Data Warehouse to avoid any future confusion. The invoice process relies on information published by the Centers for Medicare and Medicaid Services in the Medicaid Drug Program which is not shared publicly. The Medicaid Drug Program is the source of truth for the rebate agreement dates. The Department is reviewing the negative unit issue.

State Comptroller's Comment – OSC provided DOH with an example of a manufacturer that signed a rebate agreement according to other valid sources (such as eMedNY, DOH's Medicaid claims processing and payment system), yet certain claims for drugs from this manufacturer

were excluded from invoices, with DOH citing that there was no drug rebate agreement in place. Additionally, DOH invoiced claims for certain service dates both before and after the manufacturer's rebate agreement date that DOH has stated is the true date. DOH officials should further review this issue to ensure eMedNY is accurate and its drug rebate processes function correctly.

We are pleased DOH is further reviewing the negative unit 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.

Response #12

The Department concurs with this status of recommendation. As noted in the Agency Action, the Department has created and sent a project request to Magellan to include appropriate exclusion codes on "ignored" claims. Once the project has been completed, the Department considers this recommendation as fully implemented.