

Governor

JAMES V. McDONALD, M.D., M.P.H. Commissioner JOHANNE E. MORNE, M.S. Acting Executive Deputy Commissioner

August 29, 2023

Ms. Andrea Inman Audit Director Division of State Government Accountability NYS Office of the State Comptroller 110 State Street, 11th Floor Albany, New York 12236 ainman@osc.ny.gov

Dear Ms. Inman:

Pursuant to the provisions of Section 170 of New York State Executive Law, I hereby transmit to you a copy of the New York State Department of Health's comments related to the Office of the State Comptroller's final audit report 2021-S-11 entitled, "Medicaid Program: Maximizing Drug Rebates Under the Federal Medicaid Drug Rebate Program."

Please feel free to contact Mischa Sogut, Assistant Commissioner for Governmental Affairs, at (518) 473-1124 or mischa.sogut@health.ny.gov, with any questions.

Sincerely,

Johanne E. Morne

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Acting Executive Deputy Commissioner

Enclosure

cc: Mischa Sogut

Department of Health Comments to Final Audit Report 2021-S-11 entitled, "Medicaid Program: Maximizing Drug Rebates Under the Federal Medicaid Drug Rebate Program" by the Office of the State Comptroller

The following are the responses from the New York State Department of Health (the Department) to Final Audit Report 2021-S-11 entitled, "Medicaid Program: Maximizing Drug Rebates Under the Federal Medicaid Drug Rebate Program" by the Office of the State Comptroller (OSC).

General Comments:

The Department issued invoices totaling \$16.9 billion (gross) during the six-year audit period in its fee-for-service (FFS) and managed care program. This audit identified an additional \$183.7 million (gross) in rebates that should have been invoiced during the audit period, this audit's findings represent one percent over the audit period.

The Department recognizes the OSC audit process as an opportunity to improve and strengthen policies and procedures. In November 2017, the Department secured an independent contractor to assume the invoicing process and has recently renewed the contract to continue the work to administer the pharmacy rebate program. As found by the OSC and discussed below, the Department has already addressed certain issues raised in the audit and has mobilized the contractor to handle all concerns raised in this audit. If claims are found to have been missed, the Department will seek to bill where appropriate.

Recommendation #1:

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

Response #1:

The Department has reviewed the \$119 million and has verified that the issues listed under this recommendation have already been addressed. Proof of this work was supplied to OSC for verification. The Department intends to invoice for the drug rebates referenced and will refund the federal share of the collected rebates to the CMS. The total amount of this finding is all related to the period prior to the prospective query update that the Department put into place in 2021. The retroactive correction was deployed in December 2022 for older claims and is in the queue for processing. The Department will continue to monitor and work with its contractor to ensure the claims are properly 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.

Response #2:

The Department concurs that there was an issue with missing NDCs and invalid NDC procedure code combinations. The Department discovered the findings prior to the audit and implemented steps to resolve.

In 2019 the Department took steps to ensure all claims for covered outpatient physician-administered drugs were invoiced going forward by requiring NDCs on all physician-administered drugs billed on the institutional claim form effective July 1, 2019. The Department published a Medicaid Update reminder in March 2019 entitled Reporting of the National Drug Code is Required for all FFS Physician-Administered Drugs, which addresses the OSC 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 Department would like to note that steps have already been taken to enhance the edit logic in the managed care encounter system. Effective 9/30/2021 the edit was turned to a hard edit to ensure the collection of NDCs on all drug encounters. There was a request for retroactive resubmission of MCO drug claims back to 1/1/2016 to capture missing MCO claims, which was completed on 3/4/2022 and the impact of these changes were made evident long thereafter. However, it has proved challenging for the MCOs to either obtain the missing NDC within their systems or through provider outreach. The Department has seen that the stronger edit is working and the errors of missing NDCs on rebate eligible MCO claims have decreased significantly. As discussed below, these enhancements address Recommendation Nos. 3 and 4 and the edit appears to be working with respect to these Recommendations as well. The Department is committed to continue to improve and strengthen policies and procedures and appreciates OSC confirming that our efforts were timely and appropriate. The following are the Department's next steps:

Missing NDCs

- Actions Planned: The Department is following up with MCOs for proper drug information for the missed rebates related to the \$26.1M and the \$225K.
- Actions Completed: The Department has reviewed and enhanced its edit logic to ensure that physician-administered drug encounter claims include NDCs effective 9/30/2021.

Invalid procedure code and NDC combinations

 Actions Planned: The Department is initiating a project to require valid combinations on MCO claims on intake. However, the project must wait until the new encounter system transition is complete. The Department will follow up with MCOs for proper drug information for the claims related to the audit period.

Recommendation #3:

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

Response #3:

The edit logic was enhanced in the EIS to ensure NDC collection on all drug encounters effective 9/30/21. There was also a retroactive resubmission of MCO drug claims back to 1/1/2016, which was completed on 3/4/2022. The Department will continue to monitor and work with its contractor to ensure the edit continues to work properly.

Recommendation #4

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

Response #4:

The Department has enhanced system edits and will continue to monitor and work with its contractor to ensure the enhancements continue to work properly.

Action Completed: The Department initiated a system edit on the FFS side that requires valid procedure code and NDC combinations.

Action Planned: The Department is working with its MCO encounter intake vendor to include an enhanced edit to ensure all claims include a valid procedure code and NDC combination.

Estimated Completion date: December 2024

Recommendation #5:

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

Response #5:

The unclassified drug codes are assigned by CMS to new drugs and the Department is dependent on the federal government's timing and updates related to the unclassified drugs. The Department initiated discussions related to this issue prior to the OSC audit and included the unclassified drugs in its pharmacy rebate request for proposal (RFP) as a required task.

The RFP was posted in 2021. The final contract effective December 2022 includes this as a topic to handle in the near future. The Department is working with its contractor towards a solution.

Action Planned: Unclassified drug codes are legitimate in some cases, but the Department will address incorrect combinations once the edit (mentioned in response #4) related to the valid procedure code and NDC combination is completed.

Estimated Completion date: December 2024

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.

Response #6:

The Department has discussed this finding with its contractor and is working with its contractor towards a solution.

Action Planned: In partnership with the Department's vendor, a periodic system review is being developed to invoice for combinations that were unknown at the time of invoicing.

Estimated Completion date: Testing scheduled for Q2 2023 invoicing.

Recommendation #7:

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

Recommendation #8:

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

Response #7 and #8:

The Department intends to invoice for the PACE encounter drug rebates that are determined eligible. The federal share of the collected rebates will be refunded to CMS. The Department will continue to work with its contractor to ensure all appropriate drugs are invoiced.

Estimated Completion date: Fall 2024

Recommendation #9:

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

Recommendation #10:

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

Response #9 and #10:

The Department will invoice for the drug rebates referenced above, as appropriate, and will refund the federal share of the collected rebates to CMS. The Department will continue to work with its contractor to ensure all appropriate drugs are invoiced.

Recommendation #11:

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

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.

Response #11 and #12:

The findings in recommendations 11 and 12 should be clarified, as the claims were not ignored but put through the invoicing process and were excluded because they did not fit the rebate logic. For example, there are claims included in the OSC findings where the labeler was not active when invoicing so it was properly excluded. The Department will continue to work with its contractor to ensure all appropriate drugs are invoiced and create an additional exclusion category for this group of claims so that the reason of exclusion is clear in the future.

The following are responses to the State Comptroller's Comments in the final report.

State Comptroller's Comment 1 (Page 15):

The audit identified \$183.7 million in Medicaid drug rebates that were not invoiced. The \$119 million pertains only to a portion of the audit findings.

Response to State Comptroller's Comment 1:

The Department agrees and has revised the General Comments section to reflect the \$183.7 million.

State Comptroller's Comment 2 (Page 16):

Despite the Department's efforts, tens of millions of dollars in rebates went uncollected due to missing NDCs and invalid NDC and procedure code combinations. If the Department does not act on this recommendation, tens of millions of dollars in rebates will remain uncollected, including the \$26.1 million in rebates that went uncollected because MCOs submitted physician-administered drug encounter claims without an NDC. We urge Department officials to fully implement our recommendation.

Also, only \$5.1 million of the \$16.7 million we identified in missed rebates due to invalid procedure code and NDC combinations was due to a lag in receipt of CMS data. The majority, about \$11.6 million, was due to claims submitted by providers that contained errors. These claims were paid despite including an invalid procedure code and NDC combination. We encourage the Department to take steps to ensure claims contain valid procedure code and NDC combinations; otherwise, missed rebates will continue. Furthermore, as discussed on page 9 of our report, some rebate-eligible MCO drug encounter claims continue to be accepted by the Department when submitted without an NDC. Specifically, we found missed rebates totaling \$225,695 in the 4th quarter of 2021 and 1st quarter of 2022 – after the Department's encounter intake system update was implemented.

Response to State Comptroller's Comment 2:

See **Response #2**.

State Comptroller's Comment 3 (Page 19):

The audit identified missed rebates totaling \$993,207 on 4,102 drug claims for the period April 2018 through March 2022. All of the NDCs listed on these claims were part of the drug rebate

invoices for the corresponding quarters. Therefore, the claims appear to have been incorrectly ignored during the invoicing process because the claims were not listed as invoiced, excluded, or voided when the rebate contractor reported the results of its processes to the Department.

Response to State Comptroller's Comment 3:

The Department believes that the claims in this recommendation were properly excluded. The Department will work with its vendor to assign an appropriate designation for the exclusion of these types of drug claims.