NEW YORK STATE | Department of Health

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Executive Deputy Commissioner

April 8, 2026

Christopher Morris, Audit Director
Office of the State Comptroller
Division of State Government Accountability
110 State Street – 11th Floor
Albany, NY 12236-0001

Dear Christopher Morris:

Enclosed are the Department of Health's comments on the Office of the State Comptroller's Follow-Up Audit Report, 2025-F-20 entitled, "Medicaid Program – Improper Payments for Drugs Without a Federal Drug Rebate Agreement."

Thank you for the opportunity to comment.

Sincerely,

Johanne E Morne

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

Enclosure

cc: Frank Walsh
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Department of Health Comments on the Office of the State Comptroller's Follow-Up Audit Report 2025-F-20 entitled, "Medicaid Program – Improper Payments for Drugs Without a Federal Drug Rebate Agreement"

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 2025-F-20 entitled, "*Medicaid Program – Improper Payments for Drugs Without a Federal Drug Rebate Agreement."* 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.

Audit Recommendation Responses:

Recommendation #1

Review the $50.3 million in managed care encounter claims for prescription drugs, OTC drugs, physician-administered drugs, and compound drug ingredients from manufacturers without an NDRA, and determine the appropriate course of action to maximize recoveries.

Status – Partially Implemented

Agency Action – DOH included physician-administered drugs in rate adjustments for the 2023–24 and 2024–25 State fiscal years, which could account for nearly $3.3 million in improper payments for physician-administered drugs we identified. Additionally, Office of the Medicaid Inspector General (OMIG) officials stated that the NYS Attorney General's Medicaid Fraud Control Unit recovered over $9 million in overpayments for drugs that were not subject to a National Drug Rebate Agreement (NDRA) as of the service date (April 2018 through March 2023).

However, because the review was completed by another agency, OMIG officials did not have the supporting documentation to substantiate the recovery. Additionally, less than 1% of the $50.3 million had actually been recovered through provider voids or was considered unrecoverable because it was identified in other OMIG audits. We note OMIG may have already lost the opportunity to recover over $36 million of the payments due to regulatory lookback provisions. We encourage DOH and OMIG to take prompt action on the payments we identified to prevent further loss of recoveries.

Response #1

The Department will break down the various categories that OSC has identified for this audit and our rationale, which highlights OSC's misunderstanding of Medicaid drug coverage and rebate requirements under CMS regulations.

a. Over-the-Counter (OTC) medications that were covered by Managed Care Plans are covered per the State Plan Amendment (SPA), regardless of rebate agreement status with the manufacturer. Our SPA includes coverage of OTCs as prescribed drugs and permits coverage in-line with federal requirements. If they are prescribed by a practitioner, such a drug shall be regarded as a covered outpatient drug. They are reviewed by the Department for fiscal impact, net-of-all rebates, regardless of the manufacturer of the drug participation with the federal rebate program. Notably, certain

formulations of non-rebateable Over-the-Counter drugs may have a lower net-cost to the state compared to a rebate-eligible product.

- New York 3 Attachment 3.1 A Supplemental and Attachment 3.1 B Supplement – Drugs for which Medical Assistance reimbursement is available are limited to the following: (1) those non-prescription drugs contained in a list established by the New York State Commissioner of Health. (2) covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under Sections 1902(a)(54) and 1927(a) of the Act which are prescribed for a medically accepted indication. (As provided by Section 1927(d)(2) of the Act certain outpatient drugs may be excluded from coverage).

b. Compound active pharmaceutical ingredients that were covered by Managed Care Plans are covered by the State Plan Amendment (SPA) regardless of rebate agreement status with the manufacturer. A compounded prescription is one in which two or more ingredients are mixed together by the dispensing pharmacist. All Medicaid Pharmacy Providers must comply with all Federal and State requirements for compounding prescriptions. Compounded medications are necessary to ensure that certain formulations can be made available to patients, if commercial formulations are not available in the marketplace. It was also previously noted by the Department that the compilation of these claims was overstated because OSC used the total cost of the compound. Drugs within a compound that the Department can claim rebates on were invoiced.

   - New York 2(c.1) Attachment 3.1 B Supplement 1905(a)(12) Prescribed Drugs, Dentures, and Prosthetic Devices; and Eyeglasses – 8. The State will cover APIs that are included in extemporaneously compounded prescriptions when the API serves as the active drug component in the compounded formulation. A current list of covered APIs can be found at https://www.emedny.org/info/formfile.aspx

c. Prescription drugs that were covered by the Managed Care Plans without a Federal Rebate Agreement were shared with the Department's rate setting group to make necessary adjustments. Rate setting removes those encounters from the annual Managed Care base data (as a rate adjustment) used for rate development. The Department also worked with the Managed Care Plans on a regular basis to align coverage with the CMS Managed Care Final Rule prior to the Pharmacy Benefit Transition. All of this was occurring before the original audit on this topic was issued by OSC. Separate from the DOH analysis, the New York State Attorney General's Medicaid Fraud Control Unit independently recovered $9.29 million dollars in overpayments from 13 mainstream Managed Care Plans that caused payments to be made for National Drug Codes, that, as of the time of service, between April 1, 2018 – March 31, 2023, were not subject to a National Drug Rebate Agreement or a NYS rebate agreement with the manufacturer, and/or were not on the NYS Medicaid Pharmacy List of Reimbursable Drugs. Utilization of these National Drug Codes was not otherwise permissible unless due to enrollee specific exceptions, such as medical necessity and maintaining documentation thereof. There are no further reviews being performed.

State Comptroller's Comment – During our follow-up, we found that fewer than 2% of the unique National Drug Codes identified in the original audit findings were included in DOH's October 2025 Medicaid Pharmacy List of Reimbursable Drugs. The remaining

audit findings, over 98%, pertained to covered outpatient drugs (including prescription drugs, OTC drugs, physician-administered drugs, and certain compound drug ingredients) from manufacturers that have not signed a national drug rebate agreement. DOH's response acknowledges that this was the basis for recoveries made by the New York State Attorney General's Fraud Control Unit. However, as we noted in our report, OMIG was unable to provide evidence of these recoveries.

Additionally, DOH maintains the Medicaid encounter claim data, which does not contain individual payment amounts for each ingredient in compound drugs; therefore, we reported the full cost of the compound drugs.

d. Practitioner administered drugs that are covered by the Managed Care Plans without a federal agreement have also been shared with the Department's rate setting group to make necessary adjustments, effective State Fiscal Year 2023-24. Practitioner administered drugs reimbursed as part of a bundled service provided within certain settings (e.g., a clinic visit, or hospital stay) do not meet the federal definition of a covered outpatient drug [Social Security Act §1927(k)] and are therefore not eligible for rebate.

It is important to note that the pharmacy benefit was transitioned to Medicaid Fee For Service (FFS) effective April 1, 2023. The Department continues to work with the Managed Care Plans regarding drug rebate agreement status/policy, as it pertains to practitioner administered outpatient drugs. Furthermore, claims from manufacturers without a rebate agreement are not inherently invalid or recoverable, as coverage and reimbursement are governed by Federal and State Regulations, contractual agreements, and formulary policies. Current compliance framework includes drug utilization reviews, prior authorization procedures, and reporting obligations.

Recommendation #2

Review the capitation rate adjustment process to ensure all applicable encounter claims for prescription drugs, OTC drugs, and compound drug ingredients from manufacturers without an NDRA are incorporated.

Status – Not Implemented

Agency Action – In State fiscal year 2019–20, DOH began adjusting the managed care capitation rates to offset improper encounter claim payments for prescription drugs, OTC drugs, and compound drug ingredients from manufacturers without a National Drug Rebate Agreement (NDRA). However, the initial audit identified flaws in the methodology used to select encounters for the rate adjustment. At the time of our follow-up, DOH had not made any changes to its capitation rate adjustment process to correct these flaws.

Response #2

The Department previously provided Medicaid Managed Care Information Sharing Reports for State Fiscal Year 2021-22 and 2022-23 to support the methodology utilized to adjust Medicaid Managed Care premiums for pharmacy expenditures not associated with a National Drug Rebate Agreement. The Department reviewed payments identified by OSC in Recommendation

#2 and determined no adjustment to the premium methodology was warranted as the OTC medications and Compound active pharmaceutical ingredients were covered benefits per the State Plan Amendment regardless of rebate agreement status with the manufacturer. Practitioner administered drugs were implemented as part of Recommendation #3.

State Comptroller's Comment – As noted above, the State should not pay for covered outpatient drugs, including OTC drugs and certain compound drug ingredients, from manufacturers that have not signed a national drug rebate agreement. Therefore, DOH should have included these improper encounter claims in its managed care capitation rate adjustment to allow for offsets.

Recommendation #3

Include physician-administered drug encounter claims for drugs from manufacturers without an NDRA in the capitation rate adjustments.

Status – Implemented

Agency Action – Since our initial audit, DOH added a capitation rate adjustment for physician-administered drugs from manufacturers without a National Drug Rebate Agreement (NDRA) for the 2023–24 and 2024–25 State fiscal years.

Response #3

The Department confirms agreement with this recommendation status.

Recommendation #4

Continue adjusting capitation rates for encounter claims for drugs from manufacturers without NDRAs for all service dates prior to the effective date of the requirement for Medicaid recipients to receive prescription drugs through FFS (April 1, 2023).

Status – Not Implemented

Agency Action – According to DOH officials, DOH did not include adjustments to the managed care capitation rate for encounter claims for drugs from manufacturers without a National Drug Rebate Agreement (NDRA) for the 2023–24 and 2024–25 State fiscal years due to the transition of pharmacy coverage from managed care to FFS. However, the managed care rate calculations are based on encounter claim data from 2 years earlier (e.g., State fiscal year 2023–24 rates were completed using encounter claims data from 2021). As a result, improper payments for drugs from manufacturers without NDRAs with service dates in 2021 and 2022 have not been recovered through the rate adjustment process.

Response #4

Federal CMS regulations do not allow the Department to adjust Managed Care premiums for a benefit which is no longer provided by Medicaid Managed Care. Effective April 1, 2023, the retail pharmacy benefit was transitioned out of Medicaid Managed Care to Medicaid FFS and therefore the National Drug Rebate Agreement premium adjustment associated with retail pharmacy expenditures was removed. The Department will continue to adjust for Physician

Administered Drugs which remain included in the Medicaid Managed Care benefit package per Recommendation #3.