



Department of Health

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Commissioner

JOHANNE E. MORNE, M.S.
Executive Deputy Commissioner

July 29, 2024

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 Andrea 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 2022-S-40 entitled, "Medicaid Program: Improper Payments for Drugs Without a Federal Drug Rebate Agreement."

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

Sincerely,

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

Enclosure

cc: Mischa Sogut

Department of Health Comments to Final Audit Report 2022-S-40 entitled, “Medicaid Program: Improper Payments for Drugs Without a Federal Drug Rebate Agreement” by the Office of the State Comptroller

The following are the Department of Health’s (Department) comments in response to the Office of the State Comptroller’s (OSC) Final Audit Report 2022-S-40 entitled, “Medicaid Program: Improper Payments for Drugs Without a Federal Drug Rebate Agreement”. Included in the Department’s response are 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.

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.

Response to #1 & #2:

The Department respectfully disagrees with OSC. OSC has grossly overestimated what can be invoiced for rebate. The Department provides coverage and collects rebates for ‘covered outpatient drug(s)’ per the definition found in Social Security Administration (SSA) Section 1927 (k)(2). The Department also provides coverage for nonprescription drugs (also known as over the counter (OTC) as defined in SSA Section 1927(k)(4), when dispensed as a prescribed drug which is authorized by SSA Section 1905(a)(12). Further, the Department provides coverage for prescribed drugs per our State Plan Amendment (SPA). This includes OTC and extemporaneously compounded active pharmaceutical ingredients (API) when the API serves as the active drug component in the compounded formulation per the SPA.

State Comptroller’s Comment – Department officials continue to misunderstand the audit. Drug rebates were not part of the audit findings. The drug encounter claims the audit reported on were for drugs from manufacturers that did not sign a national drug rebate agreement. As such, the Department would not be able to collect federal drug rebates for these drugs.

The audit found managed care organizations should not have made the \$50.3 million in Medicaid drug payments. However, because the improper payments were made, the

Department should have included these improper encounter claims in its managed care capitation rate adjustment methodology to allow for offsets, but it did not.

Further, our audit analysis was appropriately completed using the definition of a “covered outpatient drug” from the Social Security Act, Section 1927. Covered outpatient drugs include prescription drugs, OTC drugs, physician-administered drugs, and certain compound drug ingredients. A drug rebate agreement must be in place for covered outpatient drugs to be paid for under the federal Medicaid statute.

The amount OSC has provided for the compound ingredient amount is grossly overstated due to the above and limitations with their data set that did not allow them to isolate the specific drug they identified as rebate eligible. The amounts represent the total compound cost and is not on the individual drug line level.

State Comptroller’s Comment – The Department maintains the Medicaid encounter claim data set and that data does not contain individual payment amounts for each ingredient in compound drugs.

In collaboration with the Department, OMIG is continuing to perform analysis on the identified encounters to determine an appropriate course of action.

State Comptroller’s Comment – We note that we provided the Department and the Office of the Medicaid Inspector General the physician-administered drug audit findings in July 2023 and the prescription, OTC, and compound drug audit findings in October 2023. Officials should act promptly to maximize recoveries, particularly since officials stated they might not be able to recoup improper payments from all prior years through the capitation rate adjustments because they are not able to adjust rates further than 2 years in the past.

Recommendation #3:

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

Response #3:

The Department will adjust Managed Care capitation rates for physician-administered drugs from manufacturers without an NDRA effective April 1, 2022, based on the most current information available at the time of Managed Care rate development.

Recommendation #4:

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

Response #4:

The Department will continue to adjust Managed Care capitation rates for drugs from manufacturers without an NDRA for all rates prior to when the pharmacy benefit carve-out from Managed Care became effective (April 1, 2023) based on the most current information available at the time of Managed Care rate development.

Responses to State Comptroller's Comments:

State Comptroller's Comment (2nd Comment on page 12):

The State should not pay for 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.

Response:

Per SSA, the Department is allowed to cover drugs without a rebate agreement in certain circumstances. This includes OTC and extemporaneously compounded API when the API serves as the active drug component in the compounded formulation per the SPA. This falls under the prescribed drugs authority.

State Comptroller's Comment – Our audit analysis was appropriately completed using the definition of a “covered outpatient drug” from the Social Security Act, Section 1927. Covered outpatient drugs include prescription drugs, OTC drugs, physician-administered drugs, and certain compound drug ingredients. A drug rebate agreement must be in place for covered outpatient drugs to be paid for under the federal Medicaid statute.

State Comptroller's Comment (1st Comment on page 13):

Compound drugs are \$8 million of the \$50.2 million in audit findings. As stated in the report, the Department's data doesn't contain payment amounts for each ingredient on compound drug encounter claims.

Response:

As explained in the Department's response to recommendations #1 & #2, OSC has grossly overestimated the rebate amounts. The extemporaneously compounded API are allowed to be covered without a rebate agreement.

State Comptroller's Comment – Department officials continue to misunderstand the audit. Drug rebates were not part of the audit findings. The drug encounter claims the audit reported on were for drugs from manufacturers that did not sign a national drug rebate agreement. As such, the Department would not be able to collect federal drug rebates for these drugs.

The audit found managed care organizations should not have made the \$50.3 million in Medicaid drug payments. However, because the improper payments were made, the Department should have included these improper encounter claims in its managed care capitation rate adjustment methodology to allow for offsets, but it did not.

Further, our audit analysis was appropriately completed using the definition of a “covered outpatient drug” from the Social Security Act, Section 1927. Covered outpatient drugs include prescription drugs, OTC drugs, physician-administered drugs, and certain compound drug ingredients. A drug rebate agreement must be in place for covered outpatient drugs to be paid for under the federal Medicaid statute.

State Comptroller’s Comment (2nd Comment on page 13):

Officials should act promptly to maximize recoveries, particularly since officials stated they might not be able to recoup improper payments from all prior years through the capitation rate adjustments because they are not able to adjust rates further than 2 years in the past. We note that we provided the Department and the Office of the Medicaid Inspector General the physician-administered drug audit findings in July 2023 and the prescription, OTC, and compound drug audit findings in October 2023.

Response:

The Department has an existing process to ensure rate adjustments are made for pharmacy drugs covered by the MCOs that did not have a drug rebate agreement. The Department is adjusting rates for physician-administered drugs covered by MCOs without a drug rebate agreement.