NEW YORK STATE | Department of Health

KATHY HOCHUL
Governor

JAMES V. McDONALD, MD, MPH
Commissioner

JOHANNE E. MORNE, MS
Executive Deputy Commissioner

October 16, 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, 2024-S-22 entitled, "Oversight of Clinical Trials."

Thank you for the opportunity to comment.

Sincerely,

Johanne E. Morne

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

Enclosure

cc: Frank Walsh
Amir Bassiri
Jacqueline McGovern
Amber Gentile
Brian Kiernan
Carlie Barella
James Dematteo
James Cataldo
Melissa Fiore
OHIP Audit
DOH Audit

Department of Health Comments on the Office of the State Comptroller's Final Audit Report 2024-S-22 entitled, "Oversight of Clinical Trials"

The following are the Department of Health's (Department) comments in response to the Office of the State Comptroller's (OSC) Final Audit Report 2024-S-22 entitled, "Oversight of Clinical Trials" 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

Remind Medicaid providers to submit the required attestation forms prior to starting clinical trial treatment for Medicaid members.

Response #1

The Department issued a reminder to providers about the required attestation form and process in the May 2026 edition of the NYS Department of Health Medicaid Update (Volume 42-Number 6). The Department also updated the Medicaid Clinical Trials website to clarify the process, provide direct access to the Medicaid clinical trials attestation form and instructions, and document communications about this policy: https://www.health.ny.gov/health_care/medicaid/program/clinical_trials/

Recommendation #2

Review the $23,631 ($113 + $23,518) in improper payments for investigational claims that should have been billed to the sponsor instead of Medicaid, were not covered by the MCO, or lacked prior authorization, and recover as appropriate.

Response #2

Due to Managed Care Organizations coverage of investigational items being determined on a case-by-case basis, and because providers have not been directed to use Q0 and Q1 modifiers to indicate clinical trials in NYS Medicaid, some of the payments identified by OSC as improper, may have been deemed allowable by the Managed Care Organizations.

In collaboration with the Department, OMIG is performing analysis on the OSC-identified claims, as well as the methodology OSC used to calculate the potential overpayments to determine if those payments are subject to recovery. OMIG and the Department are gathering and reviewing additional data to determine an appropriate course of action.

Recommendation #3

Remind providers of the documentation requirements to support Medicaid payments.

Response #3

The Department's Medicaid Update article (May 2026) reminded providers to adhere to Medicaid's documentation requirements when submitting claims to Medicaid. Similar language was added to the Department's Medicaid Clinical Trials website.