New York State Comptroller
THOMAS P. DiNAPOLI

# Department of Health

## Medicaid Program – Oversight of Clinical Trials

**June 2026 | Report 2024-S-22**
Prepared by the Division of State Government Accountability

# Contents

**Authority** 3

**Background** 3

**Results of Audit** 4

Attestations 4

Claims With a “Q0” Modifier 5

**Recommendations** 5

**Audit Objective, Scope, and Methodology** 5

**Statutory Requirements** 6

Authority 6

Reporting Requirements 7

**DOH Response** 8

## Authority

Pursuant to the State Comptroller's authority as set forth in Article V, Section 1 of the State Constitution and Article II, Section 8 of the State Finance Law, we have conducted an audit of the Department of Health (DOH) to determine whether it has provided adequate oversight of services for Medicaid members enrolled in clinical trials. The audit covered the period from July 2019 through June 2024.

## Background

The New York State Medicaid program is a federal, state, and local government-funded program that provides a wide range of medical services to those who are economically disadvantaged and/or have special health care needs. DOH administers the Medicaid program. During the State fiscal year ended March 31, 2025, New York's Medicaid program had approximately 7 million members per month and annual Medicaid claim costs totaled about $93 billion (comprising $49.2 billion in fee-for-service health care payments and $43.8 billion in managed care premium payments).The federal government funded about 55.7% of New York's Medicaid claim costs, and the State and the localities (the City of New York and counties) funded the remaining 44.3%.

DOH uses two methods—fee-for-service and managed care—to pay for Medicaid services. Under fee-for-service, DOH, through its Medicaid claim processing and payment system (eMedNY), pays Medicaid-enrolled providers directly for services delivered to Medicaid members. Under managed care, DOH pays managed care organizations (MCOs) monthly premiums, which they use to pay providers for health care services rendered to Medicaid members enrolled in their plans. MCOs then submit records of these claims (referred to as encounter claims) to DOH's Original Source Data Submitter system (formerly the Encounter Intake System) to inform DOH of each service provided to their members.

Clinical trials are research studies that evaluate the safety and effectiveness of medical care. New York's Medicaid program generally does not cover investigational items or services that are the subject of the clinical trial, nor does it cover services provided solely for data collection. However, Medicaid covers the routine costs of items or services that are necessary for clinical trial participants and are typically covered outside of the trial under the state plan or waiver. These include costs related to preventing, diagnosing, monitoring, or treating complications arising from participation in the trial. Routine costs may also include any item or service required only for administering the investigational treatment, such as laboratory tests or medical imaging.

The Social Security Act requires state Medicaid programs to complete a Medicaid coverage determination for members participating in clinical trials within 72 hours of the request. In addition to verifying a member's Medicaid status, a coverage determination must be based on an attestation of the appropriateness of the clinical trial by both the principal investigator and the health care provider responsible for the trial. States must use a streamlined form that captures reference information about the clinical trial for the attestation and coverage determination requirements. In April 2022, DOH began requiring providers to submit a Medical Attestation Form on the Appropriateness of Qualified Clinical Trial (attestation form) for Medicaid members

participating in clinical trials. In July 2022, DOH published a Medicaid Update (DOH's official notification to providers) informing providers that, effective immediately, the attestation form must be submitted for each member enrolled in a clinical trial prior to providing treatment in the trial.

Medicare is the federal health insurance program administered by the Centers for Medicare & Medicaid Services (CMS). CMS billing guidelines require that claims submitted to Medicare for services related to clinical trials contain certain diagnosis and modifier codes. For example, modifier code "Q0" indicates the service is investigational. According to DOH officials, the use of these modifier codes on Medicaid claims for services related to clinical trials is not required. For the period of July 2019 through June 2024, we identified 77,035 Medicaid claims totaling over $279 million where providers billed claims with diagnosis and/or modifier codes indicating the services were related to a clinical trial.

## Results of Audit

We found that DOH did not always receive an attestation form before members participated in a clinical trial, as required. Additionally, we identified a limited number of improper Medicaid payments for services that were the responsibility of the clinical trial sponsor, investigational services not covered by the member's MCO, or services that lacked supporting prior authorization.

### Attestations

For the period from April 2022 through June 2024, we identified 32,578 claims totaling approximately $94 million for 7,447 members who lacked a corresponding attestation form, even though the claims indicated the services were part of a clinical trial. We judgmentally sampled 75 claims, totaling almost $7.7 million, for 38 members and found that 22 of these 38 members participated in a clinical trial, so an attestation form should have been on file. Additionally, we found claims totaling $1,169 for services that should have been billed to the clinical trial sponsors instead of Medicaid. At the end of our audit fieldwork, these claims were corrected, saving Medicaid $1,169.

We also identified 588 claims totaling over $4 million for 115 members where the claim's service date was prior to the date the member's attestation form was signed. We judgmentally sampled 82 claims totaling over $2.4 million for 20 members. We found 26 claims totaling $12,123 that should have been billed to the clinical trial sponsors. At the end of our audit fieldwork, one provider corrected 14 claims, saving Medicaid $12,010. The remaining 12 claims totaling $113 still need to be adjusted.

All seven providers we sampled for the 157 claims (75 + 82) stated that they reviewed claims for members in clinical trials. They did this by either using specific software or by manually reviewing claims against clinical trial documents. For example, one provider stated that claims for approved research studies are reviewed against negotiated clinical trial billing grids. These grids are documents used for clinical trials to identify and differentiate routine costs that may be billed to the participant's insurance (e.g., Medicaid) from research procedures and services billable to the sponsor. In response to our findings, DOH officials stated they will issue a reminder to providers

about the requirement and process for obtaining clinical trial attestation forms. They will also consider developing a schedule for these reminders.

### Claims With a "Q0" Modifier

For the period from July 2019 through June 2024, we identified 4,813 claims totaling nearly $4 million that contained the "Q0" modifier, indicating the services were related to an investigational clinical trial. Of this amount, over $3.5 million was for encounter claims. According to the Managed Care Model Contract, MCOs may cover experimental and investigational treatments on a case-by-case basis with prior approval. Of the seven MCOs we contacted, four stated that they have provided guidance to their network providers for billing clinical trial claims, and three stated that their claim processing systems include edits related to clinical trials. Specifically, one MCO stated claims billed with the "Q0" modifier are denied payment, another stated that claims with investigational procedure codes are flagged for additional review, and a third stated that processing for clinical trial claims depends on prior authorization and clinical trial modifiers. However, none of the MCOs had performed any risk assessment of clinical trial claims, and they were not aware of how providers track costs billable to Medicaid versus the clinical trial sponsor.

We judgmentally sampled 134 claims totaling $736,909 from seven providers. We identified $23,518 in improper Medicaid payments because the provider or MCO could not provide supporting prior authorization for the claim, or the MCO stated it did not cover the investigational service that was billed. For example, one MCO acknowledged that one claim totaling $4,200 was paid incorrectly due to a clerical error; the claim should not have been paid because the prior authorizations for the services were either voided or denied by the MCO. In response to our findings, DOH officials agreed to issue a reminder to providers that proper documentation is required when submitting Medicaid claims.

## Recommendations

1. Remind Medicaid providers to submit the required attestation forms prior to starting clinical trial treatment for Medicaid members.
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.
3. Remind providers of the documentation requirements to support Medicaid payments.

## Audit Objective, Scope, and Methodology

The objective of our audit was to determine whether DOH has provided adequate oversight to ensure payments for services provided to Medicaid members enrolled in clinical trials were appropriate. The audit covered the period from July 2019 through June 2024.

To accomplish our objective and assess related internal controls, we interviewed officials and gathered information from DOH, MCOs, and providers. We examined the relevant DOH policies

and procedures as well as applicable federal and State laws, rules, and regulations. We used the Medicaid Data Warehouse to identify claims indicating the member was involved in a clinical trial. We reviewed supporting claim documentation from MCOs and providers as well as clinical attestation forms and logs from DOH.

We used a non-statistical sampling approach to provide conclusions on our audit objective and to test internal controls and compliance. We selected judgmental samples. However, because we used a non-statistical sampling approach for our tests, we cannot project the results to the respective populations. Our samples, which are discussed in detail in the body of our report, include:

- A judgmental sample of 75 of 32,578 claims with no attestation form on file for the member. The sample focused on recent claims based on high dollar amount by providers, members, and procedure codes to test the appropriateness of the claims and to confirm member participation in a clinical trial.
- A judgmental sample of 82 of 588 claims where the service date was prior to the date the attestation was signed. The sample focused on recent claims based on high dollar amount by providers, members, and procedure codes to test the appropriateness of the claims and to confirm member participation in a clinical trial.
- A judgmental sample of 134 of 4,813 claims based on high dollar amount by providers, members, and procedure codes to test the appropriateness of claims indicating payment for an investigational item or service and to confirm member participation in a clinical trial.

We relied on data from eMedNY and the Medicaid Data Warehouse that, based on our work, we determined was sufficiently reliable for the purposes of this audit.

## Statutory Requirements

### Authority

This audit was performed pursuant to the State Comptroller's authority as set forth in Article V, Section 1 of the State Constitution and Article II, Section 8 of the State Finance Law.

We conducted our performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

In addition to being the State Auditor, the Comptroller performs certain other constitutionally and statutorily mandated duties as the chief fiscal officer of New York State. These include operating the State's accounting system; preparing the State's financial statements; and approving State contracts, refunds, and other payments. These duties could be considered management functions for purposes of evaluating organizational independence under generally accepted government auditing standards. In our professional judgment, these duties do not affect our

ability to conduct this independent performance audit of DOH's oversight and administration of payments for clinical trial claims.

## Reporting Requirements

We provided a draft copy of this report to DOH officials for their review and formal comment. We considered DOH's comments in preparing this report and have included them in their entirety at the end of the report. In their response, DOH officials generally agreed with the audit recommendations and indicated that certain actions have been and will be taken to address them.

Within 180 days after the final release of this report, as required by Section 170 of the Executive Law, the Commissioner of the Department of Health shall report to the Governor, the State Comptroller, and the leaders of the Legislature and fiscal committees advising what steps were taken to implement the recommendations contained herein, and where the recommendations were not implemented, the reasons why.

## DOH Response

KATHY HOCHUL
Governor
JAMES V. McDONALD, MD, MPH
Commissioner
JOHANNE E. MORNE, MS
Executive Deputy Commissioner

May 28, 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 Draft Audit Report 2024-S-22 entitled, "Oversight of Services for Medicaid Members Enrolled in Clinical Trials."

Thank you for the opportunity to comment.

Sincerely,

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

Enclosure

cc: Melissa Fiore
Amir Bassiri
Jacqueline McGovern
Jennifer Danz
James Dematteo
James Cataldo
Brian Kiernan
Timothy Brown
Amber Gentile
Michael Lewandowski
OHIP Audit
DOH Audit

# Department of Health Comments on the Office of the State Comptroller's Draft Audit Report 2024-S-22 entitled, "Oversight of Services for Medicaid Members Enrolled in Clinical Trials."

The following are the Department of Health's (Department) comments in response to the Office of the State Comptroller's (OSC) Draft Audit Report 2024-S-22 entitled, "Oversight of Services for Medicaid Members Enrolled in 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.

**General Comments:**

The Department partially agrees with this audit report and offers the following context and background related to clinical trials coverage. The Department updated clinical trial coverage policies and implemented a clinical trials attestation form in 2022. This action was taken in response to a federal requirement, outlined in a Center for Medicare and Medicaid Services letter to State Medicaid Directors, SMD # 21-005, establishing routine costs associated with clinical trials as a mandatory benefit. Prior to this, the Department had already covered routine costs but implemented a structured attestation process to meet federal requirements.

The Department has never issued guidance about or required the use of Q0 or Q1 modifiers to identify claims as investigational. New York's Medicaid managed care plans are required to consider coverage of experimental or investigational items (whether included in a clinical trial or not) on a case-by-case basis. Under New York Medicaid's clinical trials policy and coverage of routine costs, thousands of Medicaid members have benefited from participation in clinical trials over the course of this audit period.

The Department agrees with OSC's recommendation that the Department issue reminders to providers about the required clinical trials attestation form and process, as well as a reminder to providers about documentation requirements more generally.

**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 will remind providers of the required attestation form and process.

**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 MCOs. 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.

**Recommendation #3**

Remind providers of the documentation requirements to support Medicaid payments.

**Response #3**

The Department will remind providers of Medicaid's documentation requirements when submitting claims to Medicaid.

## Contact

Office of the New York State Comptroller
110 State Street
Albany, New York 12236

(518) 474-4044

www.osc.ny.gov

Prepared by the Division of State Government Accountability

June 4, 2026

### Executive Team

Andrea C. Miller – Executive Deputy Comptroller
Tina Kim – Deputy Comptroller
Stephen C. Lynch – Assistant Comptroller

### Audit Team

Christopher Morris – Audit Director
Thomas Sunkel, CPA – Audit Manager
Rebecca Chromey – Audit Supervisor
Nareen Jarrett – Examiner-in-Charge
Fiorella Seminario – Senior Examiner
Anna Williams – Staff Examiner
Suzanne Loudis, RN – Registered Nurse Supervisor 1