# Department of Health

## Medicaid Program: Improper Payments for Drugs Without a Federal Drug Rebate Agreement

Report 2022-S-40 | February 2024

OFFICE OF THE NEW YORK STATE COMPTROLLER
Thomas P. DiNapoli, State Comptroller
Division of State Government Accountability

# Audit Highlights

## Objective

To determine whether Medicaid inappropriately paid for drugs from manufacturers that did not enter into a national drug rebate agreement (NDRA). The audit covered the period from January 2017 through March 2023.

## About the Program

The Department of Health (Department) administers New York's Medicaid program. The Medicaid Drug Rebate Program (MDRP) helps to offset the costs of most covered outpatient drugs dispensed to Medicaid patients. The MDRP requires drug manufacturers to enter into an NDRA with the Department of Health and Human Services in exchange for state Medicaid coverage of most of the manufacturer's drugs. Manufacturers then pay states rebates on those drugs for which Medicaid payments were made.

Covered outpatient drugs include prescription drugs, some over-the-counter (OTC) drugs, certain compound drug ingredients, and physician-administered drugs. Under Medicaid managed care, the Department pays managed care organizations (MCOs) a monthly capitation payment for each Medicaid recipient enrolled in their plans. MCOs then arrange for the provision of health care services, including outpatient drugs, and reimburse providers for those services. MCOs are required to submit encounter claim data to the Department detailing each service or drug provided.

## Key Findings

We found the Department lacked adequate oversight of Medicaid managed care payments for drugs, which led to improper MCO payments for drugs from manufacturers without an NDRA at the time of service. Additionally, we found flaws in the Department's managed care capitation rate adjustment methodology intended to offset improper managed care payments for drugs from manufacturers without an NDRA. These flaws resulted in a significant number of encounter claims not being included in the capitation rate adjustments. Accordingly, we identified nearly $50.3 million in improper MCO payments for drugs from manufacturers without NDRAs at the time of service that were not included in the rate adjustments, as follows:

- 2.5 million encounter claims totaling over $41.7 million for prescription, OTC, and compound drugs were not part of the rate adjustment process due to Department errors in determining which manufacturers and which drugs to include, and
- 84,554 encounter claims for physician-administered drugs totaling nearly $8.6 million were not part of the rate adjustment because the Department erroneously did not include any physician-administered drug claims.

## Key Recommendations

- Review the $50.3 million in managed care encounter claim payments for drugs from manufacturers without an NDRA, and determine the appropriate course of action to maximize recoveries.
- Review the capitation rate adjustment process to ensure all applicable drug encounter claims from manufacturers without an NDRA are incorporated.

**Office of the New York State Comptroller**
**Division of State Government Accountability**

February 23, 2024

James V. McDonald, M.D., M.P.H.
Commissioner
Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

Dear Dr. McDonald:

The Office of the State Comptroller is committed to helping State agencies, public authorities, and local government agencies manage their resources efficiently and effectively. By so doing, it provides accountability for the tax dollars spent to support government operations. The Comptroller oversees the fiscal affairs of State agencies, public authorities, and local government agencies, as well as their compliance with relevant statutes and their observance of good business practices. This fiscal oversight is accomplished, in part, through our audits, which identify opportunities for improving operations. Audits can also identify strategies for reducing costs and strengthening controls that are intended to safeguard assets.

Following is a report of our audit of the Medicaid program entitled *Improper Payments for Drugs Without a Federal Drug Rebate Agreement.* The 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.

This audit's results and recommendations are resources for you to use in effectively managing your operations and in meeting the expectations of taxpayers. If you have any questions about this report, please feel free to contact us.

Respectfully submitted,

*Division of State Government Accountability*

# Contents

# Glossary of Terms

| Term | Description | Identifier |
|---|---|---|
| Department | Department of Health | *Auditee* |
| | | |
| eMedNY | The Department's Medicaid claims processing and payment system | *System* |
| FFS | Fee-for-service | *Key Term* |
| MCO | Managed care organization | *Key Term* |
| MDRP | Medicaid Drug Rebate Program | *Program* |
| MDW | Medicaid Data Warehouse | *System* |
| NDC | National Drug Code | *Key Term* |
| NDRA | National drug rebate agreement | *Key Term* |
| OTC | Over-the-counter drug | *Key Term* |

# 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. The Medicaid program is administered by the State's Department of Health (Department). For the State fiscal year ended March 31, 2023, New York's Medicaid program had approximately 8.4 million recipients, and Medicaid claim costs totaled about $80.2 billion. The federal government funded about 56.9% of New York's Medicaid claim costs, and the State and the localities (the City of New York and counties) funded the remaining 43.1%.

The Department uses two methods to pay for drugs dispensed to Medicaid recipients: fee-for-service (FFS) and managed care. Under the FFS method, Medicaid-enrolled providers submit drug claims through the Department's claims processing and payment system (eMedNY) and the Department pays providers directly. Under the managed care method, the Department pays managed care organizations (MCOs) a monthly capitation payment for each Medicaid recipient enrolled in their plans. MCOs then arrange for the provision of health care services, including drugs, and reimburse providers for those services. MCOs are required to submit encounter claim data to the Department detailing each service or drug provided.

The Medicaid Drug Rebate Program (MDRP) helps to offset the costs of most covered outpatient drugs dispensed to Medicaid patients. The MDRP requires drug manufacturers to enter into a national drug rebate agreement (NDRA) with the Department of Health and Human Services in exchange for state Medicaid coverage of most of the manufacturer's drugs. Manufacturers then pay states rebates on those drugs for which Medicaid payments were made.

Section 1927(k)(2)(A) of the Social Security Act defines covered outpatient drugs as drugs that may be dispensed only upon prescription, including some over-the-counter (OTC) drugs and physician-administered drugs that are not billed as part of a bundled service within certain settings, such as a hospital stay. Physician-administered drugs are usually injectable or intravenous drugs and are typically administered by a medical professional in a physician's office or other outpatient clinical setting. Compound drugs are those in which two or more ingredients are mixed by the dispensing pharmacist. Compound drugs do not meet the definition of covered outpatient drugs as defined by Section 1927(k)(2)(A) of the Social Security Act. However, the ingredients of a compound drug may be eligible for rebate if they satisfy the definition of a covered outpatient drug. All drugs are identified using a National Drug Code (NDC), a universal product identifier for human drugs.

The State fiscal year 2021-22 New York State budget established that, beginning on April 1, 2023, all Medicaid mainstream managed care plan, Health and Recovery plan, and HIV-Special Needs plan members are required to receive prescription drugs, OTC drugs, and compound drugs through FFS. Prior to this, managed care recipients received their prescription drug benefit through managed care. This change does not apply to physician-administered drugs, which continue to be paid through MCOs for managed care enrollees.

# Audit Findings and Recommendations

We found the Department lacked adequate oversight of Medicaid managed care payments for drugs, which led to improper payments for drugs from manufacturers without an NDRA at the time of service. In State fiscal year 2019-20, the Department began adjusting the managed care capitation rates to offset improper managed care payments for drugs from manufacturers without an NDRA. However, we identified several flaws in the methodology used to calculate the rate adjustments. As a result of these flaws, we identified nearly $50.3 million in encounter claim payments for drugs from manufacturers without NDRAs that were not included in the rate adjustments. This included over $41.7 million in payments for prescription drugs, OTC drugs, and compound drugs with service dates between January 2017 and December 2021 and nearly $8.6 million in payments for physician-administered drugs with service dates between January 2017 and March 2023. Specifically, the Department's rate adjustments did not include physician-administered drugs and only included OTC drugs for the first 2 years of the adjustments. In addition, although the rate adjustment methodology included a process to identify NDCs from manufacturers without an active NDRA, this process was limited to only include NDCs from a specific Medicaid Data Warehouse (MDW) table and with a rebate participation indicator status signifying there was no active agreement. However, we found many NDCs from manufacturers without an active NDRA that were not on that MDW table.

## Improper Payments for Prescription, OTC, and Compound Drugs

For the period January 2017 through December 2021, we identified improper payments on almost 2.5 million encounter claims totaling over $41.7 million for prescription drugs, OTC drugs, and compound drugs with ingredients from manufacturers without an NDRA at the time of service. This included:

- 101,780 encounter claims totaling over $19.3 million for prescription drugs,
- 2,286,931 encounter claims totaling over $14.4 million for OTC drugs, and
- 104,346 encounter claims totaling almost $8 million for compound drugs.

In State fiscal year 2019-20, the Department began adjusting the managed care capitation rates to offset the improper encounter claim payments for prescription drugs, OTC drugs, and compound drug ingredients from manufacturers that did not participate in the MDRP. The Department identified these encounter claims using the "drug rebate participation indicator" in the MDW Drug Rebate table. However, this table does not include all NDCs that appear on managed care encounter claims. For example, of the more than $19.3 million in prescription drug encounter claims we identified from manufacturers without an NDRA, we found over $19.1 million (99%) in claims were for drugs that were not on the MDW Drug Rebate table at the time of service. As a result, these encounter claims were not included in the Department's capitation rate adjustments. Furthermore, when we reviewed the NDCs used by the Department to adjust the capitation rates, we determined that OTC drugs were only included in the capitation rate adjustment for the first 2 years.

In addition, Department officials were unaware of any specific edits used by MCOs to prevent payments for drugs from manufacturers without an NDRA. They stated they occasionally review managed care encounter claims to determine if payments for drugs from manufacturers without an NDRA have occurred and provide feedback to MCOs. However, we did not receive substantive documentation supporting this process.

Our analysis excluded encounter claims with service dates from January 2022 through March 2023 because the Department had not yet completed the rate adjustment process that would incorporate these years. The Department should revise the rate adjustment process to address the issues identified in this report; otherwise, subsequent capitation rate adjustments could be inaccurate.

In response to our audit, Department officials stated they might not be able to recoup improper payments from all prior years because they are not able to adjust rates further than 2 years in the past and are not able to recover from providers on claims more than 6 years old due to federal lookback period restrictions. The Department should promptly determine a course of action that will allow them to recoup these improper payments. If the Department does not take action in a timely manner, it could lose the opportunity to recoup millions of dollars in improper payments.

## Improper Payments for Physician-Administered Drugs

For the period January 2017 through March 2023, we identified improper payments on 84,554 managed care encounter claims totaling nearly $8.6 million for physician-administered drugs from manufacturers without an NDRA.

In State fiscal year 2019-20, the Department began adjusting managed care capitation rates to offset improper payments for drugs from manufacturers without an NDRA at the time of service. However, physician-administered drugs were not included in these adjustments. As a result, the Department's capitation rate adjustments were inaccurate, as they did not incorporate all improper payments for drugs from manufacturers without an NDRA.

In response to our audit, Department officials indicated that the rate setting process now includes an adjustment for physician-administered drugs from manufacturers without an NDRA. However, officials also stated they might not be able to recoup improper payments from all prior years because they are not able to adjust rates further than 2 years in the past and are not able to recover from providers on claims more than 6 years old due to federal lookback period restrictions. The Department should promptly determine a course of action that will allow them to recoup these improper payments. If the Department does not take action in a timely manner, it could lose the opportunity to recoup millions of dollars in improper payments.

## Recommendations

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

# Audit Scope, Objective, and Methodology

The objective of our audit was to determine whether Medicaid inappropriately paid for drugs from manufacturers that did not enter into an NDRA. The audit covered the period from January 2017 through March 2023.

To accomplish our objective and assess related internal controls, we interviewed Department and Centers for Medicare & Medicaid Services officials and examined applicable federal laws, Department policies and procedures, and eMedNY system documentation.

We used the MDW to identify managed care encounter claims containing NDCs for prescription drugs, OTC drugs, physician-administered drugs, and compound drug ingredients from manufacturers without an active NDRA at the time of service. We removed encounter claims for drugs used by the Department to adjust the managed care capitation rate, drugs that were granted an exception to NDRA requirements by the Department, and items that are not rebate eligible. We note that the MDW doesn't contain the managed care payment amount for each ingredient of a compound drug claim; therefore, this report reflects the total payment amount for each compound drug claim. Additionally, we excluded encounter claims for prescription drugs, OTC drugs, and compound drug ingredients with service dates from January 2022 through March 2023 because the Department had not yet completed the rate adjustment process that would incorporate these years.

We relied on data from the MDW and eMedNY that, based on work performed by OSC, is sufficiently reliable for the purposes of this audit. In addition, we obtained encounter data from the MDW and assessed the reliability of that data by reviewing existing information and matching to and from independent data. We determined that the data from these systems was sufficiently reliable for the purposes of this report.

We shared our methodology and findings with Department and Office of the Medicaid Inspector General officials during the audit for their review. We took their comments into consideration and adjusted our analyses as appropriate.

# Statutory Requirements

## Authority

The audit was performed pursuant to the State Comptroller's authority as set forth in Article V, Section I 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 the Department's oversight of Medicaid payments for drugs without an NDRA.

## Reporting Requirements

We provided a draft copy of this report to Department officials for their review and formal comment. We considered the Department's comments in preparing this report and have included them in their entirety at the end of the report. In their response, Department officials generally concurred with the audit recommendations and indicated certain actions have been and will be taken to address them. We address certain Department remarks in our State Comptroller's Comments, which are embedded in the Department's response.

Within 180 days of 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 recommendations were not implemented, the reasons why.

NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

JAMES V. McDONALD, M.D., M.P.H.
Commissioner

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

January 31, 2024

Andrea Inman, Audit Director
Office of the State Comptroller
Division of State Government Accountability
110 State Street – 11th Floor
Albany, New York 12236-0001

Dear Andrea Inman:

Enclosed are the Department of Health's comments on the Office of the State Comptroller's Draft Audit Report 2022-S-40 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: Melissa Fiore
Amir Bassiri
Jacqueline McGovern
Andrea Martin
James Dematteo
James Cataldo
Brian Kiernan
Timothy Brown
Amber Rohan
Michael Atwood
OHIP Audit
DOH Audit

Empire State Plaza, Corning Tower, Albany, NY 12237 | health.ny.gov

## Department of Health Comments to Draft 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 responses from the New York State Department of Health (the Department) to Draft 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 (OSC).

**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.

**Response #1:**

The Department respectfully disagrees with OSC. OSC has overestimated what can be invoiced for rebate.

**State Comptroller's Comment** – Department officials misunderstand the audit findings. Drug rebates are not part of this audit's findings. Rather, the drug encounter claims we reported on are 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. We determined MCOs should not have made Medicaid payments for these drugs; however, because the improper payments were made, the Department should have included these errant encounter claims in its managed care capitation rate adjustment methodology to allow for offsets, but it did not.

The Department provides coverage and collects rebates for 'covered outpatient drug(s)' per 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 dispenses 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** – 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.

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** – Compound drugs are $8 million of the $50.3 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.

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

**State Comptroller's Comment** – 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.

**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 #2:**

Please see the Department's response to Recommendation #1.

**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 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).

**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.

# Contributors to Report

## Executive Team

**Andrea C. Miller** - *Executive Deputy Comptroller*

**Tina Kim** - *Deputy Comptroller*

**Stephen C. Lynch** - *Assistant Comptroller*

## Audit Team

**Andrea Inman** - *Audit Director*

**Mark Breunig** - *Audit Manager*

**Vicki Wilkins**, CIA - *Audit Supervisor*

**Jonathan Brzozowski** - *Examiner-in-Charge*

**Emily Schwartz** - *Senior Examiner*

**Andrea Majot** - *Senior Editor*

**Contact Information**
(518) 474-3271
StateGovernmentAccountability@osc.ny.gov
Office of the New York State Comptroller
Division of State Government Accountability
110 State Street, 11th Floor
Albany, NY 12236

For more audits or information, please visit: www.osc.state.ny.us/state-agencies/audits