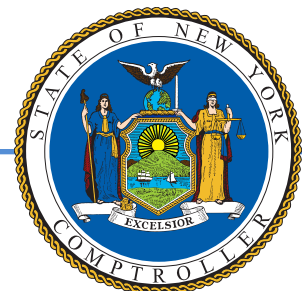


New York State Health Insurance Program

CVS Health: Accuracy of Empire Plan Medicare Rx Drug Rebate Revenue Remitted to the Department of Civil Service

Report 2022-S-1 | June 2023

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



Audit Highlights

Objective

To determine if CVS Health appropriately invoiced drug manufacturers and remitted corresponding rebate revenue to the Department of Civil Service for prescription drugs provided under the Empire Plan Medicare Rx drug benefit. Our audit covered the period January 1, 2014 through December 31, 2019.

About the Program

The New York State Health Insurance Program (NYSHIP), administered by the Department of Civil Service (Civil Service), provides health insurance coverage to over 1.2 million active and retired State, participating local government, and school district employees, and their dependents. The Empire Plan is the primary health benefits plan for NYSHIP, covering nearly 1.1 million members. Individuals who are dual enrolled in the Empire Plan and Medicare have their prescription drug coverage under Empire Plan Medicare Rx, a Medicare Part D Prescription Drug Plan with expanded coverage designed especially for NYSHIP.

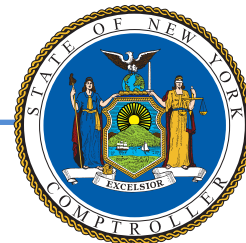
Since 2014, Civil Service has contracted with CVS Health to administer the prescription drug program. Since then, the cost of the prescription drug program averaged \$2.5 billion per year. In accordance with the contracts, CVS Health was required to negotiate agreements with drug manufacturers for rebates, discounts, and other consideration (herein collectively referred to as “rebates”) and remit the rebate revenue to Civil Service. From January 1, 2014 through December 31, 2019, Civil Service received about \$1.2 billion in Empire Plan Medicare Rx rebates.

Key Findings

We reviewed rebate revenue generated by Empire Plan Medicare Rx and found that CVS Health did not always invoice drug manufacturers for rebates, collect rebates from the manufacturers, or remit all rebate revenue to Civil Service. We identified \$10,723,916 in rebates that is due Civil Service from CVS Health.

Key Recommendations

- Remit \$10,723,916 in drug rebate revenue to Civil Service.
- Take corrective steps to ensure all the Empire Plan Medicare Rx rebate-eligible drug utilization is invoiced, collected from drug manufacturers, and remitted in a timely manner to Civil Service.



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

June 21, 2023

Cheryl A. Byron
Division Head, CVS/caremark
CVS Health
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Dear Ms. Byron:

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 entitled *CVS Health: Accuracy of Empire Plan Medicare Rx Drug Rebate Revenue Remitted to the Department of Civil Service*. 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.

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

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Glossary of Terms

Term	Description	Identifier
340B Drug Pricing Program	Federal program that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices	<i>Program</i>
Civil Service	Department of Civil Service	<i>Agency</i>
Contract	Pharmacy Benefit Services Contract between Civil Service and CVS Health to administer the Empire Plan's prescription drug program	<i>Key Term</i>
Empire Plan Medicare Rx	Medicare Part D Prescription Drug Plan with expanded coverage designed especially for NYSHIP	<i>Key Term</i>
FDA	U.S. Food & Drug Administration	<i>Agency</i>
Formulary	A tiered list of prescription drugs approved to be prescribed under the Empire Plan Medicare Rx	<i>Key Term</i>
HRSA	Health Resources & Services Administration	<i>Agency</i>
Manufacturer agreement	Agreement negotiated between CVS Health and a drug manufacturer that sets the terms for the provision of rebates, discounts, and other consideration	<i>Key Term</i>
NYSHIP	New York State Health Insurance Program	<i>Program</i>
Rebates	All revenue negotiated in the manufacturer agreements, including base rates, incremental rebates, market share rebates, price protection, discounts, and administrative fees paid to CVS Health by drug manufacturers	<i>Key Term</i>

Background

The New York State Health Insurance Program (NYSHIP) was established in 1957 under the Civil Service Law. NYSHIP is one of the nation's largest public sector health insurance programs, covering over 1.2 million active and retired State, participating local government, and school district employees, and their dependents. The Department of Civil Service (Civil Service) administers NYSHIP. The Empire Plan is the primary health benefits plan for NYSHIP, providing its nearly 1.1 million members with four types of health insurance coverage: prescription drug, medical/surgical, hospital, and mental health and substance abuse coverage.

Civil Service entered into a Pharmacy Benefit Services Contract (Contract) with CVS Health to administer the Empire Plan's prescription drug program for the period January 1, 2014 through December 31, 2018 and subsequently a second contract, with similar terms and conditions, effective January 1, 2019 through December 31, 2023. During the audit period, January 1, 2014 to December 31, 2019, CVS Health processed and paid over 100 million claims totaling \$14.9 billion.

Medicare is the federal health insurance program for people aged 65 and older and for those under age 65 with certain disabilities. Medicare-primary enrollees and dependents enrolled in the Empire Plan have their prescription drug coverage under Empire Plan Medicare Rx, a Medicare Part D Prescription Drug Plan with expanded coverage designed especially for NYSHIP. Empire Plan Medicare Rx is administered by SilverScript, an affiliate of CVS Health.

In accordance with the Contract, CVS Health must utilize the Empire Plan's significant enrollment to maximize savings to the prescription drug program by negotiating agreements with drug manufacturers (manufacturer agreements) for rebates, discounts, and other consideration, and pass 100% of the value of those agreements on to Civil Service. Accordingly, CVS Health must credit the prescription drug program for all such rebates, discounts, and other considerations that are attributable to the Empire Plan's prescription drug utilization, including that of Empire Plan Medicare Rx. For this report, the term "rebates" is used to refer collectively to all revenue negotiated in the manufacturer agreements relating to drug utilization of the Empire Plan Medicare Rx. CVS Health is further required to calculate and distribute rebate revenue to Civil Service in a fully transparent and verifiable manner.

During the audit period, January 1, 2014 through December 31, 2019, Civil Service was credited about \$1.2 billion in Empire Plan Medicare Rx rebates derived from manufacturer agreements.

Audit Findings and Recommendations

In accordance with the Contract, CVS Health is required to maximize revenue and pass 100% of rebates to Civil Service. We reviewed claims and relevant rebate information to identify rebates that were uncollected or never invoiced to manufacturers. We identified a total of \$10,723,916 in rebates that CVS Health should have, but did not, invoice or collect – and did not remit to Civil Service. CVS Health officials were unable to adequately support why these rebates were not collected and remitted to Civil Service. Accordingly, we recommend that CVS Health remit the \$10,723,916 to Civil Service.

We considered a rebate to be owed to Civil Service when:

- Rebates had been requested from the manufacturer but had not been received, or the amounts received were less than the amount originally requested, and CVS Health did not provide sufficient information to substantiate why the full amount was not collected.
- Empire Plan Medicare Rx drug utilization (based on claim information) was not included in the invoice requests to manufacturers and CVS Health did not provide sufficient information to substantiate the absence of that drug utilization.

Rebates Not Invoiced, Collected, and Remitted

Manufacturer Disputes

CVS Health did not collect \$4,222,741 in rebates due to manufacturer disputes (i.e., when a drug manufacturer disagrees with the original rebate amount invoiced by CVS Health).

For one drug with \$3,469,753 in rebates owed, CVS Health officials originally stated the incorrect rate was used to calculate rebates. Rates are determined by the formulary status of a drug, which dictates prescription preference by placing those drugs into tiers. They later stated that the rebates were correctly invoiced, but the manufacturer had disputed the rebates and subsequently CVS Health was unable to collect them. We reviewed the formulary for the applicable periods, along with the manufacturer agreement, and confirmed that the rebates were calculated correctly. Therefore, CVS Health should have paid Civil Service for the disputed rebates, even though it failed to collect them.

CVS Health also failed to provide detailed documentation to support that the remaining \$752,988 in rebates were not collected due to valid manufacturer disputes. According to CVS Health officials, they consider dispute settlements proprietary and thus would not make such documentation available to auditors.

Aberrant Quantity

CVS Health officials stated drug quantities that exceed limits imposed by the U.S. Food & Drug Administration (FDA) – known as aberrant quantities – are not eligible for rebate. We determined CVS Health invoiced but subsequently did not collect

\$1,680,856 in rebates for claims that officials incorrectly indicated contained aberrant quantities.

For these rebates, our comparison of the Empire Plan Medicare Rx paid claims data to FDA limits did not support that they were for aberrant quantities. We requested evidence from CVS Health to support that the uncollected rebates were for aberrant quantities; however, the evidence was either incomplete or insufficient. For example, one drug accounted for \$907,835 in rebates not collected due to aberrant quantity. Because the supporting claims amount would typically be greater than the rebate amount, in this case we expected to see claims that exceeded \$907,835. However, CVS Health officials provided only \$22,944 in claims that they believed were for aberrant quantities and were otherwise unable to support their assertion that these claims were for aberrant quantities.

Invoice Error

CVS Health did not collect \$2,238,242 in rebates after, according to officials, it was determined the rebates were invoiced in error due to a miscalculation (e.g., based on the wrong formulary status) or because they represented duplicate claims. However, evidence provided by CVS Health to support that the rebates were invoiced in error was either incomplete or insufficient.

Ineligible Pharmacy Type

For \$876,753 in rebates, CVS Health officials stated they either did not invoice claims or did not collect the rebates due to pharmacy-related ineligibility, such as pharmacies that qualify for reduced drug pricing from drug manufacturers (e.g., 340B Drug Pricing Program pharmacies, long-term care pharmacies, Indian Health Service pharmacies, government pharmacies).

For example, the 340B Drug Pricing Program, administered by the U.S. Health Resources & Services Administration (HRSA), requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices. Because drugs dispensed through the 340B Drug Pricing Program are purchased at a discount, manufacturers do not pay rebates on them. Using the database of 340B pharmacies available through HRSA, we verified that none of the pharmacies relating to these claims were actively enrolled in the 340B Drug Pricing Program at the time the drugs were dispensed. While CVS Health officials indicated they maintain a list of 340B pharmacies, they do not verify this information through HRSA.

We evaluated the claims for all disallowed pharmacy types and noted that none of the claims relating to the \$876,753 were dispensed by a disallowed pharmacy.

Ineligible for Rebate

CVS Health did not collect \$700,107 in invoiced rebates that, according to CVS Health officials, were deemed ineligible for various reasons, such as: the drug did not meet pre-authorization requirements per the manufacturer agreements; the drug had expired (the drug's National Drug Code was not actively certified by the FDA); or the drug was removed from the Empire Plan Medicare Rx formulary. We reviewed information contained in manufacturer agreements, the Empire Plan Medicare Rx formulary, as well as information available from the FDA, and concluded that the \$700,107 was, in fact, eligible for rebates and should have been collected and remitted to Civil Service.

Other

For \$972,117 in rebates that we determined were due Civil Service, CVS Health did not provide evidence to support why the rebates were not invoiced or collected. Additionally, for \$33,100 in rebates, CVS Health agreed and acknowledged Civil Service was due additional rebates.

Recommendations

1. Remit \$10,723,916 to Civil Service for the rebate revenue identified by our audit.
2. Take corrective steps to ensure all of the Empire Plan Medicare Rx rebate-eligible drug utilization is invoiced, collected from the manufacturers, and remitted in a timely manner to Civil Service.

Audit Scope, Objective, and Methodology

The objective of our audit was to determine if CVS Health appropriately invoiced drug manufacturers and remitted corresponding rebate revenue to Civil Service for prescription drugs provided under the Empire Plan Medicare Rx drug benefit. Our audit covered the period January 1, 2014 through December 31, 2019.

To accomplish our objective and assess internal controls related to our objective, we interviewed Civil Service and CVS Health officials. We also reviewed the Contracts between Civil Service and CVS Health. Using CVS Health's Rebate Payment Detail Reports, we selected a judgmental sample of 10 manufacturers to test for non-invoiced claims. We also used thresholds of 10% (if at least 10% of the invoiced rebates were uncollected, per drug) and \$10,000 (if at least \$10,000 of the invoiced rebates were uncollected, per drug) to select our judgmental sample of rebates to review as uncollected. We determined the data used to be sufficiently reliable for the purposes of our audit. Because we selected judgmental samples, our results cannot be projected to the population as a whole.

Statutory Requirements

Authority

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.

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 may 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 prescription drug rebate revenues remitted by CVS Health to Civil Service.

Reporting Requirements

We provided preliminary reports of our audit observations to CVS Health officials for their review and comment. Their comments were considered in preparing this final report.

Within 180 days after the final release of this report, we request that CVS Health officials report to the State Comptroller, advising what steps were taken to implement the recommendations contained in this report, and where recommendations were not implemented, the reasons why.

Contributors to Report

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