

New York State Office of the State Comptroller Thomas P. DiNapoli

Division of State Government Accountability

Maximizing Drug Rebates for Health and Recovery Plans

Medicaid Program Department of Health



Executive Summary

Purpose

To determine whether the Department of Health took appropriate steps to collect all available drug rebates for Health and Recovery Plans. The audit covered the period October 1, 2015 through December 31, 2017.

Background

In 1990, Congress created the Medicaid Drug Rebate Program to reduce state and federal expenditures for Medicaid prescription drug costs. In January 1991, New York's Medicaid program began requesting rebates from drug manufacturers. On a quarterly basis, the Department of Health (Department) submits rebate invoices to the manufacturers. The Affordable Care Act, enacted in 2010, extended prescription drug rebates to cover medications dispensed to enrollees of Medicaid managed care organizations (MCOs).

As a result of New York State's restructuring of the Medicaid program, the Department created a new type of health plan, Health and Recovery Plans (HARP). These health plans allowed qualified managed care organizations to provide specialized care, including prescription drugs, to Medicaid recipients age 21 or older with serious mental illness and/or substance use disorders. Beginning on October 1, 2015, adult Medicaid recipients with significant behavioral health needs were enrolled into HARP.

Key Findings

- With the inception of HARP and the transition of certain behavioral health services to this new specialized program the Department did not take appropriate steps to ensure that HARP-related drugs were identified and processed for rebate invoicing.
- We determined that the Department erroneously excluded HARP drugs from rebate invoices due to inadequate monitoring of the drug rebate process by Department management. Rebates for HARP drugs were not invoiced and collected from manufacturers until after we informed Department officials of the errors.
- After we notified the Department of the issue, the Department updated its procedures to include HARP drug encounters in its quarterly drug rebate process. Additionally, the Department sent retroactive invoices to manufacturers for previously missed HARP rebates.
- We determined that, due to the Department's corrective actions, \$425.9 million in drug rebates has been sought for the period October 1, 2015 through December 31, 2017. An additional \$1.2 million in rebates could be collected with further efforts by the Department.

Key Recommendations

- Regularly monitor the activities of the rebate contractor to ensure the accuracy of the drug rebate function.
- Take steps to invoice any remaining uncollected drug rebates from HARP encounters.

Other Related Audits/Reports of Interest

Department of Health: Medicaid Drug Rebate Program Under Managed Care (2014-S-41) Department of Health: Optimizing Medicaid Drug Rebates (2015-S-1) Department of Health: Errors in Identification of 340B Providers in the Medicaid Drug Rebate Program (2016-S-6)

State of New York Office of the State Comptroller

Division of State Government Accountability

June 22, 2018

Howard A. Zucker, M.D., J.D. Commissioner Department of Health Corning Tower Empire State Plaza Albany, NY 12237

Dear Dr. Zucker:

The Office of the State Comptroller is committed to helping State agencies, public authorities, and local government agencies manage government resources efficiently and effectively and, by so doing, providing accountability for 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 *Maximizing Drug Rebates for Health and Recovery Plans.* 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,

Office of the State Comptroller Division of State Government Accountability

Table of Contents

Background	5
Audit Findings and Recommendations	6
Errors in Identifying Rebates for Health and Recovery Plans	6
Recommendations	7
Audit Scope, Objective, and Methodology	7
Authority	8
Reporting Requirements	8
Contributors to This Report	10
Agency Comments	11

State Government Accountability Contact Information: Audit Director: Andrea Inman Phone: (518) 474-3271 Email: <u>StateGovernmentAccountability@osc.ny.gov</u> Address: Office of the State Comptroller Division of State Government Accountability 110 State Street, 11th Floor Albany, NY 12236 This report is also available on our website at: <u>www.osc.state.ny.us</u>

Background

The New York State Medicaid program is a federal, state, and locally 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, 2018, New York's Medicaid program had approximately 7.3 million recipients and Medicaid claim costs totaled about \$62.9 billion. The federal government funded about 55.7 percent of New York's Medicaid claim costs; the State funded about 28.4 percent; and the localities (the City of New York and counties) funded the remaining 15.9 percent.

The Department pays health care providers either directly through fee-for-service arrangements (for instance, the Department makes payments directly to pharmacies for drugs dispensed to Medicaid recipients) or through monthly premium payments to managed care organizations (MCOs). Under managed care, an MCO receives a monthly premium for each Medicaid recipient enrolled in the plan and the MCO is responsible for ensuring the enrollees have access to a comprehensive range of medical services, including pharmacy benefits. MCOs are responsible for reimbursing providers for services provided to their enrollees.

As part of New York State's 2011 initiative to reduce Medicaid costs and improve the delivery of health care services, Medicaid behavioral health services were transitioned from a primarily fee-for-service environment to Medicaid managed care. As of October 1, 2015, adult Medicaid recipients with significant behavioral health needs began to be enrolled into Health and Recovery Plans (HARPs) – a type of managed care program that provides specialized care, including prescription drugs, to Medicaid recipients age 21 or older with serious mental illness and/or substance use disorders. Approximately 118,207 Medicaid recipients were enrolled in a HARP during 2017.

In 1990, Congress created the Medicaid Drug Rebate Program to reduce state and federal expenditures for Medicaid prescription drug costs. Since January 1991, New York has been able to recover a portion of Medicaid prescription drug costs by requesting rebates from drug manufacturers. The Affordable Care Act, enacted in 2010, extended prescription drug rebates to cover medications dispensed to enrollees of Medicaid MCOs, including pharmacy-dispensed drugs and physician-administered drugs (administered by a medical professional in an office setting).

MCOs are contractually required to submit encounter claims to the Department, which provide information about each prescription drug or medical service provided to their enrollees. As of September 2015, MCOs are required to submit encounter claims to the Department's new Encounter Intake System (EIS). In the drug rebate process, the Department uses certain encounter information submitted to the EIS to obtain rebates. In particular, pharmacy encounter claims and physician-administered drug encounter claims contain a drug's National Drug Code (NDC). The NDC is a unique number that serves as a universal product identifier for each medication and is the basis for the Department's manufacturer rebate requests. The Department uses the NDC information to calculate quarterly rebates for each drug and submit rebate invoices to drug manufacturers.

Audit Findings and Recommendations

With the inception of HARP – and the transition of certain behavioral health services to this new specialized program – the Department did not take appropriate steps to ensure that HARP-related drugs were identified and processed for rebate invoicing. We determined that the Department erroneously excluded HARP drugs from rebate invoices due to inadequate monitoring of the drug rebate process by Department management. Rebates for HARP drugs were not invoiced and collected from manufacturers until after we informed Department officials of their errors in identifying and requesting available rebates for HARP drugs. Furthermore, subsequent to the launch of HARP, despite noticing a decrease in the total rebate amounts from previous quarters, the Department did not sufficiently investigate the anomaly to identify or rule out any possible errors.

Especially given the dynamic nature and complexity of the Medicaid program, it is critical that Department policies and procedures keep pace with new and evolving drug rebate scenarios to ensure that all eligible sources of rebate revenue are being tapped. Toward this end, the Department's management must be actively involved in overseeing the rebate process to ensure the completeness and accuracy of drug rebate invoicing.

After we notified officials of the issue, the Department promptly updated its procedures to include HARP drug encounters in its quarterly drug rebate invoicing process, and retroactively invoiced manufacturers for previously missed HARP rebates. As a result of the Department's corrective actions, \$425.9 million in drug rebates has been invoiced for the period October 1, 2015 to December 31, 2017. Additionally, another \$1.2 million in rebates could be collected with further efforts.

Errors in Identifying Rebates for Health and Recovery Plans

Our analysis of the Department's drug rebate invoicing data revealed that, despite HARP drug encounters being eligible for rebate, the Department failed to invoice and collect rebates since the program's inception. We determined HARP drug encounters were erroneously omitted from the rebate invoice process because the Department's list of MCO plan types, which it uses to extract Medicaid drug encounter data in the drug rebate process, had never been updated to include HARP, a new plan type. Consequently, HARP drug encounters were not identified for rebate processing. For the audit period, these drugs accounted for a total of \$427.1 million in rebates.

Department officials confirmed that drugs administered by HARPs are eligible for rebates, but up until June 2017, when we shared our audit findings, they were unaware that manufacturers were not being invoiced for these drugs. Furthermore, the Department's drug rebate unit was not informed of the new plan type, and thus was not able to identify the error while performing its duties. During its review to verify invoices, for instance, the drug rebate unit had noticed a decrease in the total rebate amount from previous quarters but, without knowledge of the new plan in effect, assumed the decrease was a result of variability in the reporting of encounters to the new EIS system. After we informed the Department of the oversight, the Department promptly modified the plan type list – a correction that captured HARP encounters as of the second quarter of 2017. As a result of our audit, the Department invoiced \$221.8 million (of the \$427.1 million) via the regular quarterly rebate process for the period April 1, 2017 to December 31, 2017. In January 2018, the Department retroactively invoiced manufacturers for drug encounters submitted from October 1, 2015 to March 31, 2017, the time period that HARP drugs were excluded from the rebate process, totaling \$204.1 million in rebates.

The remaining \$1.2 million in estimated rebates pertains to certain physician-administered drug encounter claims that the Department excluded from the rebate process for the period October 1, 2015 to September 30, 2017, such as encounters that reported a zero dollar payment, encounters with no NDC, and other encounter claims excluded for unknown reasons. According to Department officials, these encounters are under review and rebates will be sought as appropriate.

Department officials stated that a process has been established to ensure that the drug rebate unit will be informed if any new MCO plan types are created going forward. Department officials also informed us that a new drug rebate administration and management services contractor will begin processing drug rebates in the second quarter of 2018, and the Department is working with the new contractor to improve the quality of the drug rebate process and formalize procedures.

The Department has also initiated an independent comprehensive risk assessment of the rebate invoicing/collections protocols, and views this as an opportunity to identify errors (e.g., claims overlooked for invoicing or inappropriately invoiced) and take corrective measures.

Recommendations

- 1. Regularly monitor the activities of the new rebate contractor to ensure the accuracy of the drug rebate function, including:
 - Ensuring all appropriate HARP drug encounters are included in the rebate process;
 - Ensuring all new programs eligible for rebates are included in the rebate process; and
 - Independently verifying the accuracy of the final rebate invoices.
- 2. Take appropriate steps, including working with the new contractor, to invoice any remaining uncollected drug rebates from HARP encounters, including the \$1.2 million in physician-administered drug rebates identified.

Audit Scope, Objective, and Methodology

The objective of our audit was to determine whether the Department took appropriate steps to collect all available drug rebates for HARP. The audit covered the period October 1, 2015 through December 31, 2017.

To accomplish our audit objective and assess relevant internal controls, we interviewed officials

from the Department and examined the Department's relevant Medicaid policies and procedures as well as reviewed applicable federal and State laws, rules, and regulations. We reviewed historical invoiced claim data and identified HARP plans using the Medicaid Data Warehouse (MDW). We also utilized encounter data stored in the MDW.

In addition, we designed and executed computer programs to quantify the amount of rebates that should have been invoiced in our audit scope. Our analyses to determine the financial impact associated with uncollected rebates involved various methodologies, including (but not limited to) using the Department's actual rebate amount per NDC and applying the Department's historical average rebate amount where an NDC did not exist. We shared our methodologies with Department officials, and they agreed with the audit approach used.

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. In addition, the Comptroller appoints members to certain boards, commissions, and public authorities, some of whom have minority voting rights. These duties may be considered management functions for purposes of evaluating organizational independence under generally accepted government auditing standards. In our opinion, these functions do not affect our ability to conduct independent audits of program performance.

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.

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 concurred with the audit recommendations and indicated that certain actions have been and will be taken to address them.

Within 90 days of the final release of this report, as required by Section 170 of the Executive Law, the Commissioner 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.

Contributors to This Report

Andrea Inman, Audit Director Warren Fitzgerald, Audit Manager Mark Breunig, Audit Supervisor Yanfei Chen, Examiner-in-Charge Mary McCoy, Supervising Editor

Division of State Government Accountability

Andrew A. SanFilippo, Executive Deputy Comptroller 518-474-4593, <u>asanfilippo@osc.ny.gov</u>

> Tina Kim, Deputy Comptroller 518-473-3596, <u>tkim@osc.ny.gov</u>

Ken Shulman, Assistant Comptroller 518-473-0334, <u>kshulman@osc.ny.gov</u>

Vision

A team of accountability experts respected for providing information that decision makers value.

Mission

To improve government operations by conducting independent audits, reviews, and evaluations of New York State and New York City taxpayer-financed programs.

Agency Comments



ANDREW M. CUOMO Governor HOWARD A. ZUCKER, M.D., J.D. Commissioner SALLY DRESLIN, M.S., R.N. Executive Deputy Commissioner

May 24, 2018

Ms. 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 Ms. Inman:

Enclosed are the Department of Health's comments on the Office of the State Comptroller's Draft Audit Report 2017-S-61 entitled, "Medicaid: Maximizing Drug Rebates for Health and Recovery Plans."

Thank you for the opportunity to comment.

Sincerely,

Sally Dreslin, M.S., R.N. Executive Deputy Commissioner

Enclosure

Marybeth Hefner cc: Donna Frescatore Dennis Rosen Erin Ives Brian Kiernan **Timothy Brown** Elizabeth Misa Geza Hrazdina Jeffrey Hammond **Jill Montag** James Dematteo James Cataldo **Diane Christensen** Lori Conway OHIP Audit SM

Department of Health Comments on the Office of the State Comptroller's Draft Audit Report 2017-S-61 entitled, Medicaid: Maximizing Drug Rebates for Health and Recovery Plans

The following are the Department of Health's (Department) comments in response to the Office of the State Comptroller's (OSC) Draft Audit Report 2017-S-61 entitled, "Medicaid: Maximizing Drug Rebates for Health and Recovery Plans."

Background

New York State (NYS) is a national leader in its oversight of the Medicaid Program. The Office of the Medicaid Inspector General (OMIG) conducts on-going audits of the Medicaid program and managed care plans. The Department and OMIG will continue to focus on achieving improvements to the Medicaid program and aggressively fighting fraud, waste and abuse.

Under Governor Cuomo's leadership, the Medicaid Redesign Team (MRT) was created in 2011 to lower health care costs and improve quality of care for its Medicaid members. Since 2011, Medicaid spending has remained under the Global Spending Cap, while at the same time providing health care coverage to an additional 1,276,304 fragile and low income New Yorkers. Additionally, Medicaid spending per recipient decreased to \$8,609 in 2016, consistent with levels from a decade ago.

Recommendation #1

Regularly monitor the activities of the new rebate contractor to ensure the accuracy of the drug rebate function, including:

- · Ensuring all appropriate HARP drug encounters are included in the rebate process;
- Ensuring all new programs eligible for rebates are included in the rebate process; and
- Independently verifying the accuracy of the final rebate invoices.

Response #1

The Department has reviewed the audit findings with the new rebate contractor and is developing quality checks to ensure that the system is regularly updated to ensure accuracy of the drug rebate function.

Recommendation #2

Take appropriate steps, including working with the new contractor, to invoice any remaining uncollected drug rebates from HARP encounters, including the \$1.2 million in physician-administered drug rebates identified.

Response #2

As mentioned in the audit report, the Department has completed the task of invoicing for the uncollected Health and Recovery Plan (HARP) drug rebates and will continue to review the process with the new vendor to capture all collectable rebates.