



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

Division of State Government Accountability

Errors in Identification of 340B Providers in the Medicaid Drug Rebate Program

**Medicaid Program
Department of Health**



Executive Summary

Purpose

To determine whether the Department of Health (Department) accurately excluded 340B drugs from the Medicaid Drug Rebate Program and sought appropriate rebates. The audit covered the period April 1, 2010 through June 30, 2015.

Background

Congress created the Medicaid Drug Rebate Program in 1990. The program requires drug manufacturers to pay rebates to state Medicaid programs for prescription drugs dispensed to Medicaid recipients. To collect rebates, states determine the amount of rebates owed to them and send invoices to the manufacturers. Congress also created the 340B Drug Pricing Program in 1992. The 340B program requires drug manufacturers to discount the price of drugs sold to eligible health care providers. The Medicaid program benefits when these providers submit claims reflecting the discounted (lower) drug prices.

Federal law prohibits duplicate discounts, which occur if manufacturers pay Medicaid rebates on drugs sold at the already-discounted 340B price. Consequently, to collect allowable rebates and avoid duplicate discounts, states must accurately exclude 340B drugs from the Medicaid Drug Rebate Program.

The Department developed its own 340B provider list, which contained about 200 Medicaid provider ID numbers. During the audit period, the accuracy of the Department's 340B provider list was crucial to ensuring proper rebates were sought because the Department excluded drugs from the rebate process based on this list. Effective April 1, 2017, the Department will solely rely on 340B drug claim identifiers to exclude 340B drugs from the rebate process. Accordingly, the Department has instructed providers to accurately identify 340B drugs with the required claim identifiers.

Key Findings

- The Department incorrectly identified 13 Medicaid providers as 340B providers. Consequently, the drug claims that these providers submitted were improperly excluded from the Medicaid Drug Rebate Program. These errors, if left undetected, could have resulted in \$10.7 million in uncollected rebates. In response to the audit, the Department took steps to correct some of the errors identified and invoiced \$4.7 million of the drug rebates before the conclusion of the audit fieldwork.
- We identified an additional 26 providers whom the Department identified as 340B providers, but who were not on the official federal Medicaid Exclusion File of 340B providers. Because these providers were identified by the Department as 340B providers, claims from these providers were excluded from the drug rebate process. As a result, we estimated that \$531,650 in potential rebates may have gone uncollected. The Department agreed to review the discrepancies and seek rebates where appropriate.

Key Recommendations

- We made four recommendations to the Department to recover about \$6.5 million (\$6 million + \$531,650) in uncollected drug rebates and to take certain steps to help ensure future rebates are properly collected.

Other Related Audits/Reports of Interest

[Department of Health: Optimizing Medicaid Drug Rebates \(2015-S-1\)](#)

[Department of Health: Medicaid Drug Rebate Program Under Managed Care \(2014-S-41\)](#)

State of New York
Office of the State Comptroller

Division of State Government Accountability

June 30, 2017

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 *Errors in Identification of 340B Providers in the Medicaid Drug Rebate Program*. 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	7
Errors in the Identification of 340B Providers for the Medicaid Drug Rebate Program	7
Recommendations	9
Audit Scope, Objective, and Methodology	10
Authority	10
Reporting Requirements	11
Contributors to This Report	12
Agency Comments	13

State Government Accountability Contact Information:

Audit Director: Andrea Inman

Phone: (518) 474-3271

Email: StateGovernmentAccountability@osc.state.ny.us

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: www.osc.state.ny.us

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 Department of Health (Department). For the fiscal year ended March 31, 2016, New York's Medicaid program had approximately 7.4 million enrollees and Medicaid claim costs totaled about \$56 billion. The federal government funded about 53.2 percent of New York's Medicaid claim costs; the State funded about 30.6 percent; and the localities (the City of New York and counties) funded the remaining 16.2 percent.

Medicaid reimburses health care providers through the fee-for-service method and through managed care arrangements. Under the fee-for-service method, providers submit Medicaid claims for services rendered to Medicaid-eligible recipients to the Department's eMedNY computer system, which then processes the claims and generates payments to reimburse the providers for their claims. If a Medicaid recipient is enrolled in a managed care organization (MCO), Medicaid pays the MCO a monthly premium for the enrolled Medicaid recipient and the MCO is responsible for ensuring the enrollee has access to a comprehensive range of services, including prescription drug benefits which, until October 1, 2011, were covered under the fee-for-service method. MCOs arrange for the provision of services their members require and reimburse providers for services provided to their enrollees. MCOs must also submit encounter claims ("encounters") to the Department's claims processing system to inform the Department of each medical service provided to recipients enrolled in a MCO.

Medicaid Drug Rebate Program

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.

The claims that health care providers and MCOs submit to the Department contain information that the Department uses to collect rebates. In particular, pharmacy claims and physician-administered drug claims (drugs administered to patients by a medical professional in an office setting) 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. In 2014, the Department invoiced fee-for-service claims and managed care encounters that totaled \$2.4 billion in rebates for pharmacy services and \$72 million in rebates for physician-administered drugs.

340B Drug Pricing Program

In 1992, Congress created the 340B Drug Pricing Program (340B Program), which requires drug manufacturers to provide outpatient drugs to eligible health care organizations (i.e., covered entities) at significantly reduced prices. The 340B Program enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. Only non-profit health care organizations that have certain federal designations or receive funding from specific federal programs are eligible to purchase discounted drugs through the 340B Program. Covered entities are defined in statute and include Medicare/Medicaid Disproportionate Share Hospitals, Ryan White clinics and State AIDS Drug Assistance programs, children's hospitals, and other safety net providers.

To participate in the 340B Program, covered entities must register and be enrolled with the 340B Program and comply with all program requirements. Covered entities must also recertify their eligibility every year and notify the federal Health Resources and Services Administration (HRSA) whenever there is a change in their eligibility.

Upon enrollment in the 340B Program, covered entities must determine whether they will use 340B drugs for their Medicaid patients (carve-in) or whether they will purchase drugs for their Medicaid patients through other sources (carve-out). Covered entities that decide to use 340B drugs for their Medicaid patients and bill Medicaid for drugs purchased under the 340B Program must list their Medicaid provider ID number or National Provider Identifier (NPI) in the HRSA Medicaid Exclusion File (MEF). It is the responsibility of 340B covered entities to ensure that the information in the MEF is correct. Any changes in billing of 340B drugs to Medicaid (for instance, regarding a covered entity's carve-in or carve-out status) must be reported to HRSA before implementing the billing change.

Drug manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug (i.e., duplicate discount). During our audit period, the Department developed an internal 340B provider list based in part on the MEF to identify 340B drugs from 340B providers that must be removed from the rebate process. Therefore, the accuracy of the 340B provider list was critical to ensure proper rebates were sought. The Department takes additional steps to avoid duplicate discounts, such as instructing Medicaid providers to use claim level identifiers for 340B drugs.

Audit Findings and Recommendations

We identified errors in the Department's 340B provider list which was used to exclude 340B drugs from the Medicaid Drug Rebate Program. These errors, if left undetected, could have resulted in a total of \$10.7 million in uncollected rebates. In response to the audit, the Department took steps to correct some of the errors identified and invoiced \$4.7 million of the drug rebates before the conclusion of the audit fieldwork.

Specifically, we determined the Department's 340B provider list incorrectly identified 11 providers as 340B carve-in providers. We determined that these providers did not administer 340B drugs to Medicaid recipients, and therefore, such providers should not have been on the list. For an additional two providers (that operated facilities at multiple locations) on the Department's list, we determined that only one service location of each provider administered 340B drugs to recipients, yet the Department excluded drugs from the drug rebate process regardless of the service location. The errors occurred primarily because the Department's 340B provider list was developed through informal and undocumented procedures and without proper oversight. Consequently, eligible drug claims and encounters were excluded from drug rebate invoices because of the Department's flawed 340B provider list.

We identified an additional \$531,650 in potential rebates corresponding to 26 providers in which there were discrepancies between the Department's 340B provider list and the MEF. The providers were on the Department's 340B provider list for at least one quarter (and therefore were not included in the Department's rebate process), but were not listed as 340B carve-in providers on the MEF for the given time period. The Department agreed to review the discrepancies for the providers we identified and to seek rebates where appropriate.

Effective April 1, 2017, the Department will rely solely on the mandated 340B claim level identifiers to exclude 340B drugs from rebates. Accordingly, the Department has instructed providers of the requirement to accurately identify 340B drugs with claim identifiers.

Errors in the Identification of 340B Providers for the Medicaid Drug Rebate Program

HRSA requires 340B covered entities that choose to bill Medicaid for discounted drugs purchased under the 340B Program to list their Medicaid provider ID number or NPI on the MEF. Listing this information on the MEF indicates to states and drug manufacturers which drugs are not subject to Medicaid rebates, and helps ensure the prevention of duplicate discounts, as prohibited by statute.

The Department developed its own 340B provider list, which contained about 200 Medicaid provider numbers. During the audit period (April 1, 2010 through June 30, 2015), the accuracy of this 340B provider list was crucial to ensuring proper rebates were sought because the Department excluded drug claims and encounters from the rebate process based on this list.

Prior to August 2014, the Department did not have a formal process or oversight in place for maintaining and accurately updating its 340B provider list. According to Department officials, the list was initially developed without the use of the MEF. Rather, Department staff reached out to certain providers (that staff believed were 340B providers) to determine their 340B status. During the audit period, staff routinely added providers to its list, but rarely removed providers, which also led to inaccuracies. According to Department officials, starting in 2012, staff used the MEF to add new providers to the Department's 340B provider list, but the MEF was not used to remove providers until 2014.

We compared the Department's 340B provider list with the official MEF to identify Medicaid providers who were likely not 340B carve-in providers (i.e., those who likely did not use 340B drugs, in which case the drugs they billed to the Medicaid program should have been rebated). We judgmentally selected providers whose drug claims and encounters had the highest potential rebates at risk of going uncollected and confirmed their 340B carve-in or carve-out status. We determined the Department's 340B provider list was inaccurate. Specifically, 11 providers were incorrectly classified as 340B carve-in providers, and an additional two providers were classified as carve-in providers, although most of their service locations did not administer 340B drugs to Medicaid recipients. As a result, certain drug claims and encounters were incorrectly excluded from drug rebate invoices. These errors, if left undetected, could have resulted in a total of \$10.7 million in uncollected rebates. The Department took steps to correct some of the errors we identified, which resulted in the invoicing of \$4.7 million in drug rebates for nine providers. Further corrective action by the Department could lead to an additional \$6 million in drug rebate revenue pertaining to the 13 (11 + 2) Medicaid providers for the audit period.

For example, one provider was on the Department's 340B provider list from October 1, 2011 through March 31, 2014, but was not on the MEF at any point during our audit period from April 1, 2010 through June 30, 2015. We contacted this provider and confirmed it was not a 340B carve-in provider. Based on our findings, the Department removed this provider from its 340B list effective April 1, 2014. We estimated that rebates totaling \$3.5 million were not collected as a result of this error for the period October 1, 2011 through March 31, 2014. In response to our audit, the Department retroactively invoiced \$2.1 million of the \$3.5 million in rebates.

In another case, a provider (with multiple service locations) was on the Department's 340B provider list from January 1, 2012 through March 31, 2014. We contacted this provider and determined, however, that only one of its service locations administered 340B drugs to Medicaid recipients. The provider's other locations did not. Therefore, we estimated that \$3.2 million in rebates could be collected based on claims and encounters from this provider, for the period January 1, 2012 through March 31, 2014, for its non-340B locations. As a result of our audit, the Department retroactively invoiced \$796,912 of the \$3.2 million in potential rebates by the time our fieldwork was completed.

We also identified errors regarding one 340B covered entity that had multiple Medicaid provider ID numbers. The Department's 340B provider list included three provider numbers for this entity for the period April 1, 2010 through September 30, 2013. The three Medicaid provider numbers were listed on the MEF from April 1, 2010 through June 30, 2013. We contacted officials at the

entity and determined, however, that during our audit period only one of its service locations, corresponding to one of the provider numbers, was a carved-in provider location. Therefore, the entity's other locations and provider ID numbers were listed incorrectly on the MEF. (Note: The entity has since corrected the errors on the MEF.) We estimated that \$972,733 in rebates could be collected, based on claim and encounter data for the entity's non-340B locations, for the period April 1, 2010 through September 30, 2013.

In addition to the 13 providers who we determined were incorrectly classified as 340B providers (representing \$10.7 million in uncollected rebates), we identified an additional 26 providers who were on the Department's 340B provider list for at least one quarter, but were not listed as 340B carve-in providers on the MEF for the given time period. Because these providers were on the Department's list, claims and encounters from these providers were excluded from drug rebate invoices. As a result, we estimated that \$531,650 in potential rebates may have gone uncollected. The Department agreed to research the discrepancies between the MEF and the Department's list for the 26 providers and will seek rebates where appropriate.

After we notified Department officials of our findings, they reviewed their 340B provider list and confirmed that errors were made, and therefore some rebates went unclaimed and uncollected. Officials planned to conduct a comprehensive analysis of potential missed rebates in order to validate all claims and encounters for 340B status retroactive to April 1, 2010. The Department also published two official communications to Medicaid providers reminding them of the importance of the MEF and the need to keep it updated accurately. Furthermore, effective April 1, 2017, the Department will rely solely on the mandated 340B claim level identifiers to exclude 340B drugs from rebate invoices. The Department has issued formal communications to providers instructing them of the requirement to accurately identify 340B drugs with claim identifiers.

Recommendations

1. Review the remaining \$6 million in drug rebates identified for the 13 providers and seek retroactive rebates where appropriate.
2. Determine whether the \$531,650 in drug rebates can be collected for the 26 providers who were not on the MEF and seek retroactive rebates where appropriate.
3. Ensure that rebates from July 1, 2015 and thereafter are appropriately claimed and collected for the providers we identified, including the two providers with service locations that did not administer 340B drugs to Medicaid recipients.
4. Monitor providers' use of 340B claim level identifiers to ensure they properly identify 340B drugs. If errors are detected (i.e., providers inaccurately identified 340B drugs on claims and encounters), ensure providers correct their submissions of such information and retroactively invoice manufacturers for the corresponding rebates.

Audit Scope, Objective, and Methodology

The objective of our audit was to determine whether the Department accurately excluded 340B drugs from the Medicaid Drug Rebate Program and sought appropriate rebates. The audit covered the period April 1, 2010 through June 30, 2015.

To accomplish our audit objective and assess internal controls, we interviewed Department officials and Drug Rebate Unit staff. We reviewed the Department's policies, procedures, historical invoiced claim data, and supporting documentation relating to the Medicaid Drug Rebate Program as well as federal regulations. We compared the Department's 340B provider list with the official MEF to identify Medicaid providers who were likely not 340B carve-in providers (i.e., those who likely did not administer 340B drugs, in which case the drugs they billed to the Medicaid program should have been rebated). We then judgmentally selected providers with high potential rebates to determine if they administered 340B drugs to Medicaid recipients. We requested archived MEF information from HRSA officials. We also utilized the Medicaid Data Warehouse.

In addition, we designed and executed computer programs to quantify the amount of rebates that went uncollected. 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 average rebate amount (generally 35 percent of the cost of rebate-eligible drugs) 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 final report and have included them in their entirety at the end of the report. In their response, Department officials agreed with the audit recommendations and indicated the actions that 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
Paul Alois, Audit Supervisor
Mark Breunig, Audit Supervisor
Yanfei Chen, Examiner-in-Charge
Natesha Salmon, Senior Examiner

Division of State Government Accountability

Andrew A. SanFilippo, Executive Deputy Comptroller
518-474-4593, asanfilippo@osc.state.ny.us

Tina Kim, Deputy Comptroller
518-473-3596, tkim@osc.state.ny.us

Brian Mason, Assistant Comptroller
518-473-0334, bmason@osc.state.ny.us

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



Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

April 11, 2017

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 2016-S-6 entitled, "Errors in Identification of 340B Providers in the Medicaid Drug Rebate Program."

Thank you for the opportunity to comment.

Sincerely,

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

Enclosure

cc: Marybeth Hefner
Jason A. Helgeson
Dennis Rosen
Erin Ives
Brian Kiernan
JoAnn Veith
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 2016-S-6 entitled,
Errors in Identification of 340B Providers in the Medicaid
Drug Rebate Program**

The following are the Department of Health's (Department) comments in response to the Office of the State Comptroller's (OSC) Draft Audit Report 2016-S-6 entitled, "Errors in Identification of 340B Providers in the Medicaid Drug Rebate Program."

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 1,475,319 fragile and low income New Yorkers. Additionally, Medicaid spending per recipient decreased to \$8,305 in 2015, consistent with levels from a decade ago.

Recommendation #1

Review the remaining \$6 million in drug rebates identified for the 13 providers and seek retroactive rebates where appropriate.

Response #1

The Department agrees with OSC's recommendation and has researched the claims (per attachment submitted by OSC) against the Medicaid Exclusion File (MEF) to validate if invoicing was needed. The Department is conducting a more comprehensive analysis of potential missed rebate invoicing for the entire audit period of April 1, 2010 through June 30, 2016 in order to validate all claims for 340B status. The federal MEF has been utilized for periods July 1, 2016 and forward. Invoicing for this will be issued by June 30, 2017. The Department will seek and collect all retroactive rebates, where appropriate.

Recommendation #2

Determine whether the \$531,650 in drug rebates can be collected for the 26 providers who were not on the MEF and seek retroactive rebates where appropriate.

Response #2

The Department agrees with OSC and has researched the claims against the MEF to validate if invoicing was needed. The Department has conducted a more comprehensive analysis of potential missed rebate invoicing for the entire audit period of April 1, 2010 through June 30, 2016, in order to validate all claims for 340B status. The federal MEF has been utilized for periods July

1, 2016 and forward. Invoicing for this will be issued by June 30, 2017. The Department will seek and collect all retroactive rebates, where appropriate.

Recommendation #3

Ensure that rebates from July 1, 2015 and thereafter are appropriately claimed and collected for the providers we identified, including the two providers with service locations that did not administer 340B drugs to Medicaid recipients.

Response #3

The Department agrees with OSC and is conducting a more comprehensive analysis of potential missed rebate invoicing for the entire audit period of April 1, 2010 through June 30, 2016 in order to validate all claims for 340B status. The federal MEF has been utilized for periods July 1, 2016 and forward. Invoicing for this will be issued by June 30, 2017.

Recommendation #4

Monitor providers' use of 340B claim level identifiers to ensure they properly identify 340B drugs. If errors are detected (i.e., providers inaccurately identified 340B drugs on claims and encounters), ensure providers correct their submissions of such information and retroactively invoice manufacturers for the corresponding rebates.

Response #4

The Department agrees with OSC, and effective April 1, 2017, Medicaid providers will be mandated to identify claims for 340B drugs by including claim submission level identifiers; only claims with the claim submission level identifiers will be removed from the rebate system. If a rebate is received by the Department for a drug obtained via the 340B program due to incorrect claim level identifiers, the 340B covered entity will be responsible to reimburse the manufacturer the 340B discount.