



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

Division of State Government Accountability

Improper Payments for Controlled Substances That Exceed Allowed Dispensing Limits

**Medicaid Program
Department of Health**



Executive Summary

Purpose

To determine whether the Department of Health paid pharmacy providers for controlled substances in compliance with the New York State Controlled Substances Act, which limits the quantities of controlled substances that pharmacies can dispense under certain circumstances. The audit covered the period January 1, 2009 through December 31, 2013.

Background

The Department of Health (Department) administers the State's Medicaid program, which provides a wide range of health care services, including prescription drugs, to individuals who are economically disadvantaged and/or have special health care needs. The New York State Controlled Substances Act (Act), which was enacted to combat illegal use of controlled substances, limits the quantities of controlled substances that pharmacies can dispense when prescriptions are ordered via telephone or fax, due to the inherent risk of drugs ordered in this manner being diverted for inappropriate or unauthorized use. The supply limits that the Act imposes vary depending on the classification of the controlled substance. Generally, drugs that are highly prone to abuse are limited to a five-day supply, and others that carry less risk are limited to a 30-day supply.

During the audit period, the Medicaid program paid pharmacy providers through the fee-for-service method and the managed care method. Under fee-for-service, Medicaid pays pharmacy providers directly for drugs dispensed to Medicaid recipients. Under managed care, Medicaid pays managed care organizations (MCOs) a monthly premium for each recipient enrolled in the MCO. The MCO then arranges for the provision of services its members require and reimburses providers directly for services provided to enrollees. Effective October 1, 2011, most pharmacy benefits were covered by managed care.

Key Findings

- Medicaid overpaid pharmacies \$1,183,601 for 13,705 fee-for-service claims, in which quantities of controlled substances exceeded supply limits allowed by the Act. In one instance, a pharmacy filled two telephone orders for alprazolam (a drug used to treat anxiety) on the same day for one recipient. Each order was filled for a 30-day supply even though telephone orders for this drug are limited to a five-day supply that can only be dispensed in emergency situations. We further determined the supporting documentation for the prescriptions did not indicate the orders were authorized for emergency purposes.
- We determined the Department's eMedNY claims processing system does not contain edits to deny claims from pharmacies for controlled substances that exceed supply limits allowed by the Act and thus prevent improper payment.
- We also identified 3,323 managed care claims for controlled substances in which the quantities dispensed exceeded the limits set by the Act. We further identified two MCOs that, similar to the Department, do not have system edits to prevent the payment of pharmacy claims for controlled substances that exceed supply limits allowed by the Act. There is considerable risk that other participating Medicaid MCOs also do not have such controls.

Key Recommendations

- Review the improper pharmacy claims and make recoveries, as appropriate.
- Implement eMedNY edits to prevent the payment of pharmacy claims for quantities of controlled substances that exceed supply limits allowed by the Act.
- Instruct MCOs to implement controls to prevent the payment of pharmacy claims for quantities of controlled substances that exceed supply limits allowed by the Act.
- Formally remind pharmacy providers of the supply limits on controlled substances.

Other Related Audits/Reports of Interest

[Department of Health: Selected Operating and Administrative Practices of the Bureau of Narcotic Enforcement \(2011-S-19\)](#)

[Department of Health: Controls Over eMedNY Edit Changes \(2007-S-139\)](#)

State of New York
Office of the State Comptroller

Division of State Government Accountability

February 6, 2015

Howard A. Zucker, M.D., J.D.
Commissioner
Department of Health
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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 *Improper Payments for Controlled Substances That Exceed Allowed Dispensing Limits*. This audit was performed pursuant to the State Comptroller's authority under 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	8
Pharmacy Claims for Controlled Substances Dispensed in Excess of Supply Limits	8
Recommendations	10
Conflicting Guidance on the Use of Rx Serial Numbers	10
Recommendation	11
Audit Scope and Methodology	11
Authority	12
Reporting Requirements	12
Contributors to This Report	13
Agency Comments	14

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This report is also available on our website at: www.osc.state.ny.us

Background

Medicaid is a federal, state, and local government program that provides a wide range of health care services, including prescription drugs, to those who are economically disadvantaged and/or have special health care needs. The State Department of Health (Department) administers and sets forth the rules and policies of New York's Medicaid program. As of December 2013, New York's Medicaid program had approximately 5.3 million recipients, of whom about 4 million were enrolled in Medicaid managed care.

During the audit period, the Medicaid program paid pharmacy providers through the fee-for-service method and the managed care method. Under the fee-for-service method, Medicaid pays providers directly for Medicaid-eligible services provided to Medicaid recipients. Under the managed care method, Medicaid pays managed care organizations (MCOs) a monthly premium for every Medicaid recipient enrolled in the MCO. The MCO then arranges for the provision of services its members require and reimburses providers directly for services provided to their enrollees.

Effective October 1, 2011, most pharmacy benefits were covered by managed care; thus, fee-for-service Medicaid payments to pharmacy providers for those benefits were no longer allowed for recipients enrolled in managed care. During the five-year period ended December 31, 2013, Medicaid paid pharmacy providers more than \$931 million for over 14.3 million fee-for-service claims for controlled substances, and 57 MCOs processed over 8.7 million managed care claims for controlled substances.

Controlled substances can be effective in the treatment of illness and pain and should be made available to people who medically need them. These drugs, however, can cause addiction, impairment, or injuries if misused or diverted for illegal use. To help combat prescription fraud, effective April 19, 2006, the State Public Health Law was amended to require all prescriptions written in the State to be issued on an official New York State prescription form that contains security features (such as serial numbers) to prevent alterations, forgeries, and counterfeiting of prescriptions.

Further, according to Sections 3334, 3337, and 3338 of the New York State Controlled Substances Act (Act), providers are allowed to call in, fax, and – as of March 27, 2013 – electronically transmit prescriptions for controlled substances to a pharmacy. For prescriptions that are called in or faxed, providers must also deliver the original official State prescription form or electronic prescription within 72 hours. Sections 3334 and 3337 also place restrictions on the amounts of certain controlled drugs, ordered by telephone or fax (i.e., without an official State prescription form), that can be dispensed. The scope of the restriction is based on the type of drug and potential for abuse. Regulations categorize controlled substances into one of five schedules based on the potential for abuse. See Table 1 for the supply restrictions by drug schedule.

Table 1

Schedule	Drug Description	Supply Restriction
I	<ul style="list-style-type: none"> • High potential for abuse • No accepted medical use in treatment in U.S. 	
II	<ul style="list-style-type: none"> • High potential for abuse • Currently accepted medical use • Abuse can lead to severe psychological/physical dependence 	5-day emergency supply
III	<ul style="list-style-type: none"> • Decreasingly lesser potential for abuse • Currently accepted medical use • Abuse can lead to decreasingly lesser psychological/physical dependence 	5-day supply
IV	<ul style="list-style-type: none"> • Decreasingly lesser potential for abuse • Currently accepted medical use • Abuse can lead to decreasingly lesser psychological/physical dependence 	Benzodiazepines (e.g., Valium): 5-day emergency supply All others: lesser of a 30-day supply or 100 dosage units
V	<ul style="list-style-type: none"> • Decreasingly lesser potential for abuse • Currently accepted medical use • Abuse can lead to decreasingly lesser psychological/physical dependence 	5-day supply

The Department issues a pharmacy provider manual that includes billing guidelines, and identifies and describes the various fields of data that are included on a pharmacy claim. Two such fields – Rx Origin Code and Rx Serial Number – can be used to identify how a prescription was submitted to the pharmacy:

- The Rx Origin Code is a single-digit field that identifies the specific means of prescription transmittal: either as an original written form or by telephone, fax, or electronic transmission.
- The Rx Serial Number is the series of eight alphanumeric characters found on the original official State prescription form used for the medication order.

When a pharmacy receives a written prescription or a fax of the prescription, New York State health regulations require the pharmacy to use the Rx Serial Number when submitting claims to Medicaid. An Rx Serial Number is not required for prescriptions that are received by telephone or electronically (which may not have a serial number) or for prescriptions from out-of-state providers, but is otherwise required whenever available. For prescriptions without an Rx Serial Number, the pharmacy is instructed to enter various series of characters in the Rx Serial Number field to indicate how the prescriptions were received (e.g., a series of 9's to indicate a telephone order).

Under the fee-for-service reimbursement method, pharmacies submit their claims to the Department's Medicaid claims processing and payment system, eMedNY, and Medicaid reimburses pharmacy providers directly for the provision of services to Medicaid recipients. The eMedNY system has various automated edits to determine whether a claim is eligible for reimbursement and the amount claimed is appropriate. The Department has several processes to evaluate current edits and assess the need for new ones. For example, the Department has a pharmacy hotline that it uses to track concerns raised by prescribers, pharmacies, and Medicaid recipients. In addition, the Department has a formal process for requesting edits. Edits to be implemented are prioritized based on the cost to implement, potential cost savings, and the impact on pharmacy benefits.

Audit Findings and Recommendations

The eMedNY system does not have edits in place to enforce the Act's limits on the amounts of controlled substances that can be dispensed (by phone or fax orders) without official State prescription forms. As a result, Medicaid overpaid 13,705 fee-for-service pharmacy claims by about \$1.2 million for quantities of controlled substances that exceeded the limits allowed by the Act. We also determined that some MCOs do not have edit controls to prevent the payment of pharmacy claims for controlled substances that exceed supply limits allowed by the Act. Consequently, we identified 3,323 managed care claims for controlled substances that exceeded the dispensing limits set by the Act. Further, the Department's instruction manual for submitting pharmacy claims conflicts with New York Codes, Rules and Regulations as well as with guidelines issued by the Department's Bureau of Narcotic Enforcement. To help ensure pharmacy providers properly indicate how prescriptions are submitted, and that medications are dispensed in accordance with the Act, pharmacies must be given appropriate and consistent guidance.

Pharmacy Claims for Controlled Substances Dispensed in Excess of Supply Limits

For the period January 1, 2009 through December 31, 2013, we reviewed pharmacy claims to determine whether controlled substances were dispensed – and pharmacies were reimbursed – in accordance with the Act's supply restrictions. We examined fee-for-service pharmacy claims where the Rx Origin Code and the Rx Serial Number indicated the prescription was transmitted by telephone or fax, and identified 13,705 pharmacy claims totaling more than \$1.4 million for controlled substances where the quantities dispensed exceeded the limit set by the Act. Consequently, Medicaid overpaid providers \$1,183,601 for the excessive amounts dispensed.

Due to the potential for abuse or diversion, when controlled substances are dispensed in excess of the limits, there is less assurance they are being prescribed, handled, and dispensed appropriately, as the Act intended. We analyzed the top ten drugs comprising these claims, and found they accounted for more than 640,000 pills dispensed in excess of the limits set by the Act (see Table 2).

Table 2

Generic Name	Brand Name	Excess Pill Count	Claim Count
Clonazepam	Klonopin	139,137	2,518
Pregabalin	Lyrica	92,570	1,588
Alprazolam	Xanax	78,255	1,320
Lorazepam	Ativan	70,299	1,295
Hydrocodone/acetaminophen	Vicodin	70,019	1,264
Oxycodone HCL	OxyContin	64,926	844
Oxycodone HCL/acetaminophen	Percocet	46,636	833
Diazepam	Valium	28,374	688
Methylphenidate HCL	Ritalin	28,234	749
Diphenoxylate HCL/atropine	Lomotil	21,555	292
Totals		640,005	11,391

The Act's supply limitations placed on drug dispensing are designed to meet patients' legitimate need for medication while reducing the potential for inappropriate use. However, for example, a pharmacy filled two telephone orders for alprazolam (a schedule II medication for anxiety) on the same day for one recipient. Each order was filled for a 30-day supply although telephone orders for this drug are limited to a five-day supply that can only be dispensed in emergency situations. In reviewing the supporting documentation for these prescriptions, there was nothing to indicate the orders were authorized for emergency dispensing purposes.

We determined the 13,705 pharmacy claims were overpaid because the eMedNY system does not have edits that would automatically deny pharmacy claims for controlled substances that exceed supply limits allowed by the Act and thus prevent overpayment. This lack of controls combined with the inherent risk related to the authenticity of prescriptions for controlled substances transmitted by telephone and fax significantly increases the risk that controlled substances will be inappropriately prescribed and dispensed in excess of supply limits set by the Act.

In addition, we reviewed managed care claims for controlled substances and identified 3,323 claims in which the quantities dispensed exceeded the limits set by the Act. We also reviewed the payment controls in place at two MCOs and found that neither had edit controls in place to prevent the dispensing of controlled substances in excess of supply limits set by the Act. Based on our review, we believe there is considerable risk that other MCOs similarly do not have the necessary edits to enforce the Act's supply limits.

Implementing eMedNY edits and instructing MCOs to implement controls that would prevent the dispensing of controlled substances in excess of supply limits set by the Act would help ensure appropriate use of controlled substances. In response to our findings, Department officials initiated a project to develop an edit that will prevent the payment of claims for certain controlled substances dispensed in excess of the five-day supply limit allowed for telephone prescriptions.

The edit will help ensure Medicaid payments for controlled substances are in compliance with the Act.

Recommendations

1. Review the 13,705 fee-for-service pharmacy claims totaling \$1,183,601 in improper payments and make recoveries, as appropriate.
2. Instruct MCOs to review the 3,323 improper managed care claims and take corrective actions, as necessary.
3. Implement eMedNY edits to prevent the payment of fee-for-service pharmacy claims for quantities of controlled substances that exceed supply limits allowed by the Act.
4. Instruct MCOs to implement similar edit controls to prevent the payment of pharmacy claims for quantities of controlled substances that exceed supply limits allowed by the Act.
5. Formally remind pharmacies of the supply limits on controlled substances.

Conflicting Guidance on the Use of Rx Serial Numbers

We determined the Department provides conflicting guidelines on how the Rx Serial Numbers for prescriptions for controlled substances should be used. For example, the Department's pharmacy provider manual instructs pharmacies to enter certain characters (a series of E's) in lieu of the Rx Serial Number for faxed prescriptions. However, these guidelines conflict with the New York Codes, Rules and Regulations, Section 505.3(b)(7), which requires (with certain exceptions) that claims for faxed prescriptions contain the Rx Serial Number from the official New York State prescription form.

In addition, in their respective guidelines, the Department's Office of Health Insurance Programs and Bureau of Narcotic Enforcement each direct providers to enter a different value in the Rx Serial Number field to indicate a faxed prescription when a serial number is not available at that time. The Office of Health Insurance Programs requires pharmacy providers to enter a series of E's for the Rx Serial Number. In contrast, the Bureau of Narcotic Enforcement instructs pharmacy providers to enter a series of 9's for the Rx Serial Number.

To ensure that pharmacy providers adhere to State health regulations and properly indicate how prescriptions are transmitted, the Department should ensure that pharmacies are given appropriate and consistent guidance. Further, by helping to ensure that pharmacies report information regarding prescriptions for controlled substances more accurately, State oversight authorities will be better able to monitor pharmacies' compliance with the applicable State laws and regulations, including the Act.

Recommendation

6. Establish consistent guidelines regarding the use of Rx Serial Numbers on pharmacy claims.

Audit Scope and Methodology

The objective of our audit was to determine whether the Department of Health paid pharmacy providers for controlled substances in compliance with the New York State Controlled Substances Act. Our audit period was from January 1, 2009 through December 31, 2013.

To accomplish our objective and assess internal controls related to our objective, we interviewed Department officials, reviewed applicable sections of federal and State laws and regulations, and examined relevant Medicaid policies and procedures. To identify improper claims, we analyzed data from the Medicaid Data Warehouse and identified instances where dispensed quantities of controlled substances exceeded the allowable days' supply limit. Specifically, we examined pharmacy claims where either the Rx Origin Code or the Rx Serial Number indicated the prescription was transmitted by telephone or fax. Of the 1,083,875 claims we identified, more than 600,000 appeared to involve controlled substances dispensed in excess of the supply limit allowed by the Act.

Based on our review of records at selected pharmacies, we determined that using both the Rx Origin Code and the Rx Serial Number was a more reliable method to accurately identify how prescriptions were transmitted. We, therefore, used both fields to identify prescriptions transmitted by telephone or fax and identified pharmacy claims for controlled substances where quantities dispensed exceeded the supply limit set by the Act. We also visited four selected pharmacies and two MCOs and reviewed supporting documentation for certain claims. We shared the detailed results of our findings with Department officials.

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 (some of whom have minority voting rights) to certain boards, commissions, and public authorities. 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 it. In their response, Department officials concurred with our 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

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Vision

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

Agency Comments

Howard A. Zucker, M.D., J.D.
Acting Commissioner of Health

NEW YORK
state department of
HEALTH

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

January 7, 2015

Ms. Andrea Inman, Audit Director
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Division of State Government Accountability
110 State Street – 11th Floor
Albany, NY 12236-0001

Dear Ms. Inman:

Enclosed are the Department of Health's comments on the Office of the State Comptroller's Draft Audit Report 2013-S59 entitled, "Improper Payments for Controlled Substances That Exceed Allowed Dispensing Limits."

Thank you for the opportunity to comment.

Sincerely,



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

Enclosure

cc: Michael J. Nazarko
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**Department of Health
Comments on the
Office of the State Comptroller's
Draft Audit Report 2013-S-59 entitled,
Improper Payments for Controlled Substances That Exceed
Allowed Dispensing Limits**

The following are the Department of Health's (Department) comments in response to the Office of the State Comptroller's (OSC) Draft Audit Report 2013-S-59 entitled, "Improper Payments for Controlled Substances That Exceed Allowed Dispensing Limits."

Background

New York State is a national leader in its oversight of the Medicaid Program. Through the efforts of the Department and the Office of the Medicaid Inspector General (OMIG), over the last five years, New York State alone accounted for 54.9 percent of the national total of fraud, waste, and abuse recoveries. These results reflect a trend of increased productivity and enforcement. Over the last three calendar years, the administration's Medicaid enforcement efforts have recovered over \$1.73 billion, a 34 percent increase over the prior three-year period.

Under Governor Cuomo's leadership, the Medicaid Redesign Team (MRT) was created in 2011 to lower health care costs and improve quality 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 840,000 fragile and low income New Yorkers. Additionally, Medicaid spending per recipient has decreased to \$7,929 in 2013, consistent with levels from a decade ago.

Recommendation #1

Review the 13,705 fee-for-service pharmacy claims totaling \$1,183,601 in improper payments and make recoveries, as appropriate.

Response #1

The OMIG will review the prescription documentation for the claims, and then pursue recoveries where appropriate.

Recommendation #2

Instruct MCOs to review the 3,323 improper managed care claims and take corrective actions, as necessary.

Response #2

The Department reached out to the managed care plans (plans) on October 28, 2014 and instructed them to respond to the issues discovered during the audit. As a result of plan responses, the Department has also requested and received data from OSC auditors that will provide back-up to the 3,323 plan claims identified by OSC as improper payments. The Department will send this data back to the plans in January 2015 and will follow up on each plan's response.

Recommendation #3

Implement eMedNY edits to prevent the payment of fee-for-service pharmacy claims for quantities of controlled substances that exceed supply limits allowed by the Act.

Response #3

As noted in OSC's audit report, the Department has initiated and formally prioritized fee-for-service (FFS) evolution project (EP) 1963 that will systematically enforce compliance with the supply limits allowed by the New York State Controlled Substances Act. Subsequent to the implementation of EP 1963, claims paid in the interim will be reviewed by the OMIG and any overpayments will be recovered, as appropriate, and as staffing permits.

Recommendation #4

Instruct MCOs to implement similar edit controls to prevent the payment of pharmacy claims for quantities of controlled substances that exceed supply limits allowed by the Act.

Response #4

The Department shared a copy of the OSC's Preliminary Audit Report with the plans as well as a summary of next steps for Medicaid FFS (Medicaid Update and the initiation of an EP by the Department). Also, as described above in response #2, the Department will send each plan their individual data with a directive to review the claims for improper payment and an instruction to take corrective action (which could include additional editing), if deemed necessary.

Recommendation #5

Formally remind pharmacies of the supply limits on controlled substances.

Response #5

The Department's Division of Program Development and Management, with input from the Bureau of Narcotic Enforcement (BNE), formally reminded pharmacies of supply limits on controlled substances via the August, 2014 Medicaid Update.

Recommendation #6

Establish consistent guidelines regarding the use of Rx Serial Numbers on pharmacy claims.

Response #6

The Department has collaborated with BNE to establish consistent guidelines regarding the use of the Rx serial number. The August, 2014 Medicaid Update contains two articles surrounding these

guidelines; “Transmission of the Official Serialized Number is required for all NYS FFS Medicaid Claims” and “Information Regarding Prescriptions for Controlled Substances.” The link to the August, 2014 Medicaid Update is as follows:

http://www.health.ny.gov/health_care/medicaid/program/update/2014/aug14_mu.pdf