Department of Health

Medicaid Program: Improper Medicaid Payments for Terminated Drugs

Report 2019-S-45 | September 2020

OFFICE OF THE NEW YORK STATE COMPTROLLER
Thomas P. DiNapoli, State Comptroller

Division of State Government Accountability

Audit Highlights

Objective

To determine whether the Medicaid program made improper payments for drugs dispensed after their drug termination date. The audit covers the period July 1, 2014 through June 30, 2019.

About the Program

The State's Medicaid program is administered by the Department of Health (Department) and is overseen at the federal level by the Centers for Medicare & Medicaid Services (CMS). The Medicaid program covers medically necessary prescription and non-prescription drugs. Drugs may be removed from the market (i.e., terminated) for safety or commercial reasons. To ensure terminated drugs will not be dispensed or paid for, CMS requires state Medicaid programs to reject these claims on the basis of the drug's termination date (defined as either the expiration date of the final batch produced or the date the drug was recalled for health and safety reasons). Pursuant to CMS guidelines, the Department maintains drug termination dates in eMedNY, its claims processing control system.

Key Findings

For the audit period, auditors identified $29 million in improper Medicaid payments for drugs dispensed after their termination date. Specifically:

- Medicaid managed care organizations (MCOs) made improper payments to pharmacies totaling $27.2 million. The improper payments occurred because the Department failed to communicate CMS' "termination date" claim rejection policy to its MCOs.
- The eMedNY system made improper fee-for-service payments to pharmacies totaling $1.8 million. Nearly $1.5 million of the improper payments occurred because the Department had not received the drugs' termination dates from CMS at the time the claims were processed. The remaining improper payments occurred because the Department did not apply its controls to all types of claim submissions (e.g., paper claims).

Key Recommendations

- Review the Medicaid payments made for terminated drugs identified by the audit and determine an appropriate course of action, including recovery where feasible.
- Formally instruct MCOs to reject the payment of claims for terminated drugs.
- Monitor managed care encounters to ensure MCOs are not paying claims for terminated drugs.

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

September 17, 2020

Howard A. Zucker, M.D., J.D.
Commissioner
Department of Health
Corning Tower
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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 the tax dollars spent to support government operations. The Comptroller oversees the fiscal affairs of State agencies, public authorities, and local government agencies, as well as their compliance with relevant statutes and their observance of good business practices. This fiscal oversight is accomplished, in part, through our audits, which identify opportunities for improving operations. Audits can also identify strategies for reducing costs and strengthening controls that are intended to safeguard assets.

Following is a report of our audit of the Medicaid program entitled *Improper Medicaid Payments for Terminated Drugs*. The audit was performed pursuant to the State Comptroller's authority as set forth in Article V, Section 1 of the State Constitution and Article II, Section 8 of the State Finance Law.

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

Respectfully submitted,

Division of State Government Accountability

Contents

Glossary of Terms

Term	Description	Identifier
CMS	Centers for Medicare & Medicaid Services	*Agency*
Department	Department of Health	*Auditee*
DME	Durable medical equipment	*Key Term*
eMedNY	The Department's Medicaid claims processing system	*System*
Encounter	Record of a health care service provided to a recipient	*Key Term*
FDA	U.S. Food and Drug Administration	*Agency*
FFS	Fee-for-service	*Key Term*
MCO	Managed care organization	*Key Term*
MDRP	Medicaid Drug Rebate Program	*Key Term*
PBM	Pharmacy Benefit Manager	*Key Term*
Termination date	As defined by CMS, either (1) the expiration date of the final batch of a drug produced or (2) the date the manufacturer or FDA recalled the drug for health and safety reasons	*Key Term*

Background

The New York State Medicaid program is a federal, state, and local government-funded program that provides a wide range of medical services to those who are economically disadvantaged and/or have special health care needs. For the State fiscal year ended March 31, 2019, New York's Medicaid program had approximately 7.3 million recipients and Medicaid claim costs totaled about $67.4 billion. The federal government funded about 56.5 percent of New York's Medicaid claim costs, and the State and the localities (the City of New York and counties) funded the remaining 43.5 percent. The State's Medicaid program is administered by the Department of Health (Department) and overseen at the federal level by the Centers for Medicare & Medicaid Services (CMS).

The New York State Medicaid program covers medically necessary prescription and non-prescription drugs. The Department uses two methods to pay health care providers for Medicaid services, including pharmacy services: fee-for-service (FFS) and managed care. Under FFS, Medicaid-enrolled pharmacy providers submit claims for drugs dispensed to Medicaid recipients to the Department's claims processing and payment system, called eMedNY. Under managed care, the Department pays managed care organizations (MCOs) a monthly premium for each Medicaid recipient enrolled in one of their plans, and the MCOs are then responsible for ensuring that enrollees have access to pharmacy services. MCOs, or their contracted Pharmacy Benefit Manager (PBM), process drug claims and reimburse pharmacies directly. MCOs are required to submit pharmacy encounter data to the Department detailing each service provided.

In order to have their drugs covered under Medicaid, drug manufacturers must participate in the federal Medicaid Drug Rebate Program (MDRP). When a drug in the MDRP is removed from the market, whether for safety concerns or commercial reasons, manufacturers report critical drug end date information (e.g., termination date, inactive date) to CMS. Under the MDRP agreement, manufacturers are required to report drug termination dates to CMS timely to ensure the drugs will not be dispensed or paid for after their termination date. CMS defines a drug's termination date as either (1) the expiration date of the final batch produced or (2) the date the manufacturer or the U.S. Food and Drug Administration (FDA) recalled the drug for health and safety reasons. CMS disseminates drug termination dates to state Medicaid programs and drug data companies through quarterly reports, and requires Medicaid programs to reject claims for terminated drugs. Pursuant to CMS guidelines, the Department must maintain drug termination dates and deny claims for terminated drugs.

Audit Findings and Recommendations

For the five-year audit period, July 1, 2014 to June 30, 2019, pharmacies received $29 million in improper payments through managed care and FFS for drugs that were dispensed after their termination date. Payments by MCOs accounted for $27.2 million of this amount. The Department does not monitor MCOs' pharmacy encounters to ensure MCOs comply with CMS' guidance regarding terminated drugs, nor has it communicated CMS' "termination date" policy to MCOs. As a result, many MCOs lacked controls to properly identify and reject claims for terminated drugs.

FFS pharmacy claims paid by the Department accounted for the remaining $1.8 million in improper payments. The majority of these payments (nearly $1.5 million) were attributable to timing issues, where the drug claim was processed for payment before the Department received the drug's termination date from one of CMS' quarterly reports. The remaining improper payments occurred because the Department did not apply its eMedNY controls to claims submitted by paper or data tape.

Improper Payments Made by MCOs

MCOs made 2,603,546 improper payments to pharmacies totaling $27,188,357 for terminated drugs. Table 1 shows examples of various paid encounters for drugs that were terminated prior to being dispensed.

Table 1 – Examples of Terminated Drugs From Managed Care Encounter Claims

Drug Name	Common Uses	Termination Date	Dispensed Date	Amount Paid
Epinephrine	Allergic reactions (especially anaphylaxis), bronchospasm	2/15/2017	8/20/2018	$407
First-omeprazole	Gastroesophageal reflux disease (GERD), heartburn, acid reflux	6/7/2016	6/21/2019	$360
Prednisolone	Allergic reactions, various autoimmune disorders, asthma	12/31/2017	1/3/2019	$32
Diltiazem	Angina, cardiac arrhythmias, high blood pressure	9/30/2014	10/30/2018	$25
Levothyroxine	Hypothyroidism	11/30/2017	6/25/2019	$14

As stated, a drug can be terminated because a manufacturer or the FDA recalled the drug for health and safety reasons. Additionally, for other terminated drugs, once a drug's termination date has passed, the drug's efficacy may go down. According to the FDA's website, expired drugs can be less effective or risky due to a decrease in strength or change in chemical make-up, and an FDA official advised not to use expired medicines.

Notably, three MCOs, which use the same PBM to process their pharmacy claims, accounted for 64 percent of the improper payments. We found this PBM's claims processing controls do not use the manufacturer's drug termination date as the

basis for denying claims but rather the PBM's drug obsolete date, which may be well after the termination date. PBM officials stated they use "obsolete" dates to allow pharmacies to exhaust their stock of inactive drugs. The PBM adds two years to the manufacturer's drug "inactive" date to derive the obsolete date (the inactive date is the date when the drug will no longer be available from the manufacturer). Consequently, this can allow payments for terminated drugs when the PBM's obsolete date is after the manufacturer's termination date. When questioned why they do not use the termination date, the MCOs and PBM stated they were unaware they should have done so. Officials from all three MCOs stated that the Department has never communicated CMS' policy to reject drug claims based on termination dates. According to the PBM officials, they have access to CMS' drug termination dates and their controls can be set to use the termination date instead of the obsolete date, but the MCO must choose to do so. They added that a small number of their client MCOs use the termination date, but the majority use the obsolete date.

Our review of a sample of 71 encounters for terminated drugs paid by the three MCOs included in our review found that, for all 71, the obsolete date occurred after the termination date or there was no obsolete date. For encounters where obsolete dates were available (52 of 71), most were one or more years after the termination date (47 of 52), and several obsolete dates were over five years after the termination date (8 of 47).

Improper FFS Payments

The Department paid 240,884 FFS pharmacy claims totaling $1,834,134 for terminated drugs. Of these, 192,672 claims (80 percent), totaling $1,470,301, were paid because the Department had not received the drugs' termination dates from CMS at the time the claims were processed. For the remaining 48,212 claims, totaling $363,833, the Department did not apply its controls to all claims regardless of submission format.

Timing of CMS' Termination Date Notification

The Department's eMedNY system uses drug termination dates received from CMS in its claims processing controls to reject claims for terminated drugs. However, CMS only sends drug termination dates on a quarterly basis. With the potential lag of up to three months – or longer depending on the timeliness of manufacturers' reporting to CMS – there is an inherent risk that eMedNY will process and pay claims for terminated drugs dispensed during that period. To illustrate, the drug Zonegran was terminated on July 31, 2018 – in the third quarter of the year. However, CMS did not report the drug's termination date until December 11, 2018, when it issued its fourth-quarter report. In the meantime, a pharmacy had dispensed Zonegran to an enrolled recipient and billed Medicaid $2,226 for the cost of the drug. Because eMedNY was not yet updated with the drug's termination date, the pharmacy claim was processed and paid.

The Department has not established a procedure to routinely reconcile past pharmacy claims based on CMS' current quarterly report of drug termination dates

and recover improper payments. For the audit period, the Department made 192,672 improper payments, totaling $1,470,301, due to this timing issue.

Paper and Tape Claims

While the Department has established a "termination date" control within eMedNY to reject terminated drug claims, the control only applies to electronically submitted claims and does not apply to claims submitted by paper and data tape. For the audit period, the Department paid 48,212 such claims, totaling $363,833, for terminated drugs that were not properly identified and rejected. Table 2 shows paid paper and tape claims for terminated drugs that the processing control would have stopped if set properly.

Table 2 – Examples of Paid Paper and Tape FFS Claims for Terminated Drugs

Drug Name	Common Uses	Termination Date	Dispensed Date	Adjudication Date	Amount Paid
Avonex Pen	Multiple sclerosis	6/30/2016	5/12/2017	2/2/2019	$6,050
Epinephrine	Allergic reactions (especially anaphylaxis), bronchospasm	2/15/2017	5/8/2017	2/2/2019	$349
Prednisolone	Allergic reactions, various autoimmune disorders, asthma	6/30/2016	4/19/2017	1/26/2019	$46
Gabapentin	Anti-seizure, nerve pain	2/17/2017	8/11/2017	5/18/2019	$14
Topiramate	Anti-seizure, migraine prophylaxis	2/17/2017	12/13/2017	6/22/2019	$13

For example, a pharmacy dispensed Avonex on May 12, 2017 and subsequently submitted the $6,050 claim in tape format. According to the CMS quarterly file, the drug's termination date was June 30, 2016. Despite the drug's termination date being available in eMedNY, the Department did not set this control to apply to claims submitted in tape format, and eMedNY did not reject the claim when it processed and adjudicated the claim on February 2, 2019.

According to Department officials, they did not apply the control to paper or tape claims because there is a delay between when pharmacies dispense drugs and when eMedNY receives paper and tape claims for processing. Furthermore, they stated paper and tape claims make up a small percentage of all claims eMedNY processes. Despite this, it is still improper for the Department to pay for such claims. We note, however, that, in response to our finding, effective January 16, 2020, the Department applied the control to claims submitted by paper and tape.

Recommendations

1. Review the Medicaid payments made for terminated drugs identified by the audit and determine an appropriate course of action, including recovery where feasible.
2. Formally instruct MCOs on CMS guidance to ensure they, or their PBMs, reject claims for drugs based on termination date.
3. Monitor pharmacy encounters and take steps to ensure MCOs are not paying for terminated drugs.
4. Monitor FFS payments for terminated drugs that were a result of the timing issue and investigate options to mitigate this problem.
5. Ensure proper functioning of the new drug termination date control for paper and tape claim submission types.

Audit Scope, Objective, and Methodology

The objective of the audit was to determine whether Medicaid made improper payments for drugs dispensed after their drug termination date. The audit covered the period July 1, 2014 through June 30, 2019.

To accomplish our objective and assess related internal controls, we interviewed officials from the Department, Office of the Medicaid Inspector General, CSRA (the Department's Medicaid fiscal agent), and selected MCOs. We examined the Department's relevant Medicaid policies and procedures as well as applicable federal and State laws, rules, and regulations.

We used the Medicaid Data Warehouse to identify FFS and encounter payments where the service date (drug dispense date) was later than the drug's termination date (pharmacy claims related to durable medical equipment [DME] were not included in the findings). We judgmentally selected three MCOs with the highest payment totals for terminated drugs. We randomly selected 25 encounters from each MCO (75 total) to verify the claim information submitted to eMedNY. During our review of these encounters, we learned 4 of the 75 encounters were for DME and we excluded them from our analysis. This occurred because we sent the encounters to the MCOs prior to removing DME encounters from our findings. Because the samples were judgmentally selected, the 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. 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.

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 it. In their response, Department officials agreed with many of the audit recommendations and indicated that certain actions have been and will be taken to address them. Our response to Department comments pertaining to our recommendation for recoveries is included in the report's State Comptroller's Comment.

Within 180 days after final release of this report, as required by Section 170 of the Executive Law, the Commissioner of the Department 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.

Agency Comments

NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

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

LISA J. PINO, M.A., J.D.
Executive Deputy Commissioner

August 21, 2020

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 2019-S-45 entitled, "Medicaid Program: Improper Medicaid Payments for Terminated Drugs".

Thank you for the opportunity to comment.

Sincerely,

Lisa J. Pino, M.A., J.D.
Executive Deputy Commissioner

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Department of Health Comments on the Office of the State Comptroller's Draft Audit Report 2019-S-45 entitled, "Medicaid Program: Improper Medicaid Payments for Terminated Drugs"

The following are the Department of Health's (Department) comments in response to the Office of the State Comptroller's (OSC) Draft Audit Report 2019-S-45 entitled, "Medicaid Program: Improper Medicaid Payments for Terminated Drugs."

Recommendation #1:

Review the Medicaid payments made for terminated drugs identified by the audit and determine an appropriate course of action, including recovery where feasible.

Response #1:

Comment 1

The Department does not concur there is recovery for terminated drugs based on information provided by the Centers for Medicare & Medicaid Services (CMS). The Department utilized information provided by CMS (quarterly and on an ad hoc basis) regarding the termination date once received. This data is reported by manufacturers to CMS for purposes of the drug rebate program. This data is often updated retrospectively. Furthermore, there is often conflicting information in the marketplace regarding the products' expiration dates. For example, pharmacies have reported they have product on hand and manufacturers have verbally provided information that conflicts with the CMS information. Furthermore, the Food and Drug Administration website may also contain conflicting information: https://www.fda.gov/industry/structured-product-labeling-resources/nsde

On April 18, 2019, the President signed into law the Medicaid Services Investment and Accountability Act of 2019, to allow for additional penalty and compliance authorities needed to address the misclassification and misreporting of drug pricing and drug product information by drug manufacturers for purposes of the Medicaid Drug Rebate Program. This further strengthens the Departments position that CMS data is not always accurate, since it is self-reported by the manufacturers.

Recommendation #2:

Formally instruct MCOs on CMS guidance to ensure they, or their PBMs, reject claims for drugs based on termination date.

Response #2:

The Department communicated a reminder to the Managed Care Organizations on 4/17/2020, to strengthen their editing around the drug termination date.

Recommendation #3:

Monitor pharmacy encounters and take steps to ensure MCOs are not paying for terminated drugs.

Response #3:

The Department will continue to monitor pharmacy encounters.

Recommendation #4:

Monitor FFS payments for terminated drugs that were a result of the timing issue and investigate options to mitigate this problem.

Response #4:

The Department utilizes information provided by CMS (quarterly and on an ad hoc basis) regarding the termination date once received.

Recommendation #5:

Ensure proper functioning of the new drug termination date control for paper and tape claim submission types.

Response #5:

The Department will ensure the new drug termination date control is functioning properly.

State Comptroller's Comment

1. As noted in our report, CMS instructs state Medicaid programs to deny claims for terminated drugs. The majority of our findings occurred because the MCOs did not use the termination date as a control to properly process and pay claims. The Department disputes the reliability of CMS' termination dates, but yet uses those dates as a control to prevent FFS payments for terminated drugs. We also note that, in response to our Recommendation 2, the Department has instructed MCOs to strengthen their controls around termination dates. (The Department states, in part, the data that manufacturers report to CMS is often updated retrospectively; however, we note there are many aspects of the Medicaid program and corresponding data/information that are updated retrospectively that do not prevent the Department from making recoveries.) We strongly urge the Department to review our findings and determine an appropriate course of action, which may include recovery of claims.

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