Department of Health

Medicaid Program: Medicaid Payments for Early Refills of Prescription Drugs and Supplies

Report 2024-S-16 | March 2026

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

Audit Highlights

Objective

To determine whether Medicaid made improper payments on pharmacy claims for early refills of prescription drugs and supplies. The audit covered the period from April 2023 through October 2024.

About the Program

The Department of Health (DOH) administers New York's Medicaid program. Beginning April 1, 2023, enrollees in mainstream Medicaid managed care plans, Health and Recovery Plans, and HIV-Special Needs Plans receive pharmacy benefits through NYRx, New York State Medicaid's Pharmacy program. Through NYRx, DOH pays pharmacies directly for medically necessary prescription drugs and supplies provided to Medicaid members. Early refills are refills on prescriptions before the previous supply has been fully used. States set early refill thresholds to prevent misuse, overuse, and diversion, while also ensuring medications are dispensed safely and appropriately. According to the New York Medicaid Pharmacy Manual, a pharmacy claim will be paid when more than 75% of the previously dispensed amount has been used, or up to a 10-day supply of medication is remaining of the cumulative amount that has been dispensed over the previous 90 days (the more stringent rule will apply). To prevent stockpiling and potential misuse of medication, DOH uses system controls known as edits to deny claims for early refills that violate DOH policy.

Key Findings

For the period from April 2023 through October 2024, we identified over 3.6 million claims totaling approximately $585.2 million for drugs and supplies refilled too early. While many claims were filled just a few days earlier than allowed by policy, nearly 43% of our findings had 20 or more excess supply days. For example, we identified one member who received 36 fills (20-day supply each) of the same drug from April 2023 through June 2024, resulting in 280 days' supply on hand at the time of the last fill. These include 31 claims, totaling $622,384, filled earlier than allowed per the New York Medicaid Pharmacy Manual. This example shows that when early refills are continually allowed to bypass edits, the supply on hand can grow excessively high. In response to our findings, DOH officials stated that, in the long run, excess supply from early refills will generally balance out with fewer fills later. However, relying on this overlooks the risks of excessively early refills, such as misuse or diversion, and assumes that future behavior will correct current issues of excessive supply.

We identified multiple weaknesses in DOH's edit logic that allowed these claims to be paid despite meeting DOH's criteria for denial. These included situations where controls incorrectly calculated the member's supply on hand due to historical dispensing patterns or the timing of claim processing. We also identified issues that, without mitigating controls, could allow for additional improper payments. According to DOH officials, DOH does not specifically monitor claims that violate early refill policies, nor has it performed recent risk assessments targeting this area. Due to the sensitive nature of the issues we identified, we disclosed these matters to DOH officials in a preliminary report and, consequently, do not address them in detail in this report.

Key Recommendations

- Conduct a risk-based review of the approximately $585.2 million in payments for drugs and supplies refilled too early and take action, including recoveries, as appropriate.
- Enhance monitoring to identify improper early refill claims, and strengthen eMedNY system controls to address issues related to early refills.

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

March 20, 2026

James V. McDonald, M.D., M.P.H.
Commissioner
Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

Dear Dr. McDonald:

The Office of the State Comptroller is committed to helping State agencies, public authorities, and local government agencies manage their resources efficiently and effectively. By so doing, it provides accountability for the tax dollars spent to support government operations. The Comptroller oversees the fiscal affairs of State agencies, public authorities, and local government agencies, as well as their compliance with relevant statutes and their observance of good business practices. This fiscal oversight is accomplished, in part, through our audits, which identify opportunities for improving operations. Audits can also identify strategies for reducing costs and strengthening controls that are intended to safeguard assets.

Following is a report of our audit of the Medicaid program entitled *Medicaid Payments for Early Refills of Prescription Drugs and Supplies*. 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,

Division of State Government Accountability

Contents

Glossary of Terms

Term	Description	Identifier
DOH	Department of Health	*Auditee*
CMS	Centers for Medicare & Medicaid Services	*Federal Agency*
Early refill	A fill on a prescription before the previous supply has been fully used	*Key Term*
eMedNY	Medicaid claim processing and payment system	*System*
Historical claim	A claim prior to the in-process claim for the same member and drug or supply	*Key Term*
In-Process claim	A claim for a pharmacy service that is actively being processed by eMedNY	*Key Term*
MCO	Managed care organization	*Key Term*
MDW	Medicaid Data Warehouse	*System*
NYRx	New York State Medicaid Pharmacy program	*Key Term*
OMIG	Office of the Medicaid Inspector General	*Agency*

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. During the State fiscal year ended March 31, 2025, New York's Medicaid program had approximately 8.4 million members and Medicaid claim costs totaled about $93 billion. The federal government funded about 55.7% of New York's Medicaid claim costs, and the State and the localities (the City of New York and counties) funded the remaining 44.3%.

The Department of Health (DOH) administers the Medicaid program in New York State. DOH uses two methods to pay health care providers for Medicaid services: fee-for-service and managed care. Under the fee-for-service method, Medicaid-enrolled providers submit claims for services delivered to Medicaid members to eMedNY, DOH's claim processing and payment system. Under managed care, DOH pays managed care organizations (MCOs) a monthly premium for each Medicaid member enrolled in one of their plans, and the MCOs are then responsible for ensuring that enrollees have access to services.

Beginning April 1, 2023, enrollees in mainstream Medicaid managed care plans, Health and Recovery Plans, and HIV-Special Needs Plans receive pharmacy benefits through NYRx, the New York State Medicaid Pharmacy program. Through NYRx, a fee-for-service method, DOH pays pharmacies directly for medically necessary prescription drugs and supplies provided to Medicaid members.

Early refills are refills on prescriptions before the previous supply has been fully used. States set early refill thresholds to prevent misuse, overuse, and diversion while also ensuring medications are dispensed safely and appropriately. According to the New York Medicaid Pharmacy Manual, a pharmacy claim will be paid when more than 75% of the previously dispensed amount has been used, or up to a 10-day supply of medication is remaining of the cumulative amount that has been dispensed over the previous 90 days (the more stringent rule will apply).

Controlled substances are defined by New York State law as any drug listed in Public Health Law Section 3306. Per Public Health Law Section 3339, unless authorized by the prescriber, no prescription for a controlled substance may be refilled earlier than 7 days prior to the date the previously dispensed supply would be exhausted if used in conformity with the directions for use.

When Medicaid claims are processed by eMedNY, they are subject to various automated edits. The purpose of the edits is to determine whether the claims are eligible for reimbursement and the amounts claimed for reimbursement are appropriate. In the Centers for Medicare & Medicaid Services' (CMS) 2022 Medicaid Drug Utilization Review Annual Report, all states reported early refill percent utilization thresholds ranging from 75% to 100%. At 75%, New York is in line with other states. In addition, New York was one of 29 states that had an accumulation edit to prevent patients from repeatedly filling prescriptions early, although the lookback period and accumulation amount allowed varied state to state.

eMedNY edits 02242 and 01642 deny claims for early refills that violate DOH policy. When a claim is submitted to eMedNY (referred to as the in-process claim), edit 02242 evaluates 90 days of claims history for the member and drug to determine if the cumulative amount of supply the member has on hand is higher than the allowed amount over that time frame. The amount of supply the member has on hand is determined based on the pharmacy-submitted supply days field, which is the number of days the dispensed quantity of drug or supply should last based on the prescription. This edit denies claims if there is more than 10 remaining days' supply for non-controlled substances or more than 7 for controlled substances. Separately, edit 01642 denies claims if less than 75% of a dispensed amount from a previous (historical) claim has been used. Both edits require the member and drug to be the same between claims and are subject to additional non-public criteria that affects whether a claim is denied or approved for payment. DOH states that the purpose of these edits is to prevent stockpiling and potential misuse of medication.

Audit Findings and Recommendations

For the period from April 2023 through October 2024, we identified over 3.6 million claims totaling about $585.2 million for drugs and supplies refilled too early. These include over $251.5 million in improper claims due to system processing weaknesses and over $341.5 million in other issues; nearly $8 million is in multiple findings categories. While many of these claims were filled only a few days earlier than allowed by policy, nearly 43% of the claims in our findings (about $220 million) had 20 or more excess supply days. Furthermore, of the over 3.6 million claims, 43,991 claims totaling over $6.9 million were for refills for members who—at least 30 times each during our audit period—already had 30 or more days' supply on hand at the time the latest refill was dispensed. We have summarized our findings by category in the following table.

Findings by Category

Findings Category	Number of Claims	Amount Paid
Gaps in Dispensing History	1,086,474	$207,726,207
Historical Claims Processed After In-Process Claims	10,453	2,296,390
Claim Processing Delays	3,799	510,970
Unidentified Reason for Bypassing Controls	204,520	41,080,095
***Total System Processing Weaknesses**	1,304,491	$251,530,542
Other Issues	2,361,334	$341,541,090
***Total**	**3,612,232**	**$585,173,469**

*Number of claims and amount paid do not equal totals, as claims can be in multiple findings categories.

We identified multiple system processing weaknesses in DOH's edit logic that allowed these claims to be paid despite meeting DOH's criteria for denial. According to DOH officials, DOH does not specifically monitor claims that violate early refill policies, nor has it performed risk assessments targeting this area, aside from when the most recent edit was created in 2015. Instead, it indicated the Office of the Medicaid Inspector General (OMIG) identifies patterns of issues. DOH also depends on other general oversight processes like the Drug Utilization Review, which is used to examine if outpatient drugs in Medicaid programs are being used properly. Finally, DOH applies clinical editing via its prior authorization programs when it sees patterns of drug utilization inconsistent with Food and Drug Administration indications and use.

We judgmentally sampled 139 claims, totaling $1,428,259, that appeared to have been refilled too early and requested supporting documentation from the billing pharmacies. We determined 89 of the 139 claims, totaling $1,197,588, were in violation of the early refill policy, and eight claims, totaling $1,066, were improper for other reasons including insufficient supporting documentation or billing errors. The remaining claims were appropriate for reasons such as medical necessity, incorrect information entered into eMedNY for a historical claim, or because the member entered a facility and no longer had access to the previously dispensed prescription fills. We also identified nine historical claims totaling $16,957 that were improperly billed, of which eight were reversed by the pharmacies after we contacted them, saving Medicaid $6,750.

In response to our findings, DOH officials stated that, in the long term, excess supply from early refills will generally balance out with fewer fills later on. However, in relying

on this, DOH is ignoring the risks of excessively early refills, such as misuse or diversion, and relying on possible behavior in the future to correct current issues of excessive supply. For example, one member received 36 fills (20-day supply each) of the same drug from April 2023 through June 2024, leading to 280 days' supply on hand as of the last fill. These include 31 claims, totaling $622,384, filled earlier than allowed per the New York Medicaid Pharmacy Manual. During this period, there were no mitigating gaps in fills that would allow the excess supply on hand to be used up. This shows that when early refills are continually allowed to bypass the edits, the supply on hand can grow excessively high.

DOH officials repeatedly questioned our calculations and gave justifications for excessively early refill claims that did not align with the eMedNY edit logic and DOH's early refill policies. We calculated supply days following the early refill edit logic and confirmed our calculations through multiple tests of claim data and reviewing sample scenarios contained in the original edit creation documentation provided by DOH.

System Processing Weaknesses

Gaps in Dispensing History

We identified 1,086,474 claims totaling about $207.7 million where edit 02242 incorrectly calculated the member's supply on hand at the time of the claim due to gaps in their dispensing history (i.e., prescriptions were not refilled before supply on hand should have run out), which allowed the early refill claims to be paid inappropriately.

When calculating a member's supply on hand, edit 02242 considers the service date of the first historical claim and the service date of the in-process claim, but does not consider when any intermediate claims occurred, assuming that supply is evenly dispensed over the lookback period. When a prescription is refilled after a gap in supply occurs, edit 02242 incorrectly calculates supply as if the member had access to the drug prior to it being filled. Therefore, the edit may fail to appropriately deny claims for members with more than the allowed supply on hand.

For example, we identified a member who, during their 90-day lookback period, had a 13-day gap between when one prescription's supply had run out and when the next prescription was filled for a 90-day supply (presumably, the member would have been without any supply of the prescription for 13 days). After that fill, the member again refilled their prescription, but this time they refilled it 23 days prior to the previous fill running out. Therefore, they had a 23-day supply (of the 90-day supply) on hand at the time of the final refill. However, because the edit does not take actual fill dates of intermediate historical claims into account, the edit allocated the supply from the second fill to the 13-day gap, erroneously calculating a 10-day supply on hand (23 days early for the latest fill minus the 13 days late from the previous refill = 10) on the date of the in-process claim and allowing the claim (for another 90-day supply) to be paid despite being in violation of DOH's early refill policy. The pharmacy acknowledged it was filled 23 days early but was only following the 75%

utilization requirement and did not indicate that it was aware of the additional 10-day accumulation policy that should have been applied. We provided this example to DOH officials for feedback; however, their response was inconsistent with the early refill policy (i.e., referencing an irrelevant data field not used in the edit logic).

In response to this issue, DOH officials stated that there may be clinical rationale behind gaps in the dispensing history. They explained that they are trying to maintain a level of control over refilling medications while balancing that with flexibility. We agree that there may be reasons for gaps in a member's dispensing history where a member does not need the medication to be filled immediately. However, the issue is that the edit, which is supposed to deny claims for early refills in violation of DOH's policy, does not take these gaps into consideration when calculating how much supply the member has on hand. It therefore inconsistently applies DOH policy depending on whether there are significant gaps in the member's dispensing history. DOH officials indicated they did not plan to fix the flaws in edit 02242, as the weaknesses were intentional to allow flexibility. However, a weakness that miscalculates the amount of supply on hand reflects a control deficiency, not flexibility, and results in bypassing the purpose of the control that was put into place to prevent it.

Historical Claims Processed After In-Process Claims

We identified 10,453 claims, totaling approximately $2.3 million, where historical and in-process claims were not processed sequentially, preventing the claims from being flagged by the edits.

Due to flexibility in when a claim can be submitted, claims may be submitted for payment in a different order than they actually occurred. This can result in an older drug fill claim being submitted for payment after a more recent one. When processing the later claim, the edits would not consider the unsubmitted historical claim, so the edit would be unable to properly calculate the excess supply available to the member on the service date.

For example, we identified a pharmacy that filled two prescriptions for 30-day supplies of the same medication for the same member, 1 day apart. However, because the claim with the earlier service date was billed 40 minutes after the claim with the later service date, the edits failed to deny the second fill.

Claim Processing Delays

We identified 3,799 claims, totaling $510,970, where the claims were billed well after the service occurred and were paid despite being too early to refill.

Claims submitted for payment and processed by eMedNY a certain period of time after the service date are not subject to early refill edits. DOH officials were unable to adequately explain why a claim submitted near the threshold would be subject to the edits, but these claims are not. DOH officials provided multiple reasons: claims must be submitted timely, pharmacies are allowed to adjust claims several times,

claims may be submitted late due to retroactive coverage determinations, and DOH procedures align with CMS' lookback period for Retrospective Drug Utilization Review. However, these explanations do not justify allowing claims to circumvent the early refill edits solely based on when they are submitted for payment rather than the content of the claims.

For example, we identified a claim that was paid despite the member having a 16-day supply on hand at the time of the fill. The pharmacy submitted this claim for payment to eMedNY well after the drug was filled. Because this claim was submitted late, it was not evaluated by the edit. According to the pharmacy, this claim was adjudicated late because it had rolled out a new system; during this rollout, the pharmacy did not have access to Medicaid billing. If the claim had been submitted a few days earlier with all the same claim information, it would have been denied by the early refill edits.

Unidentified Reason for Bypassing Controls

We identified 204,520 claims, totaling approximately $41.1 million, that appear to have inappropriately bypassed edits 02242 and 01642 for unknown reasons. Nearly all the claims bypassed edit 02242. In every case, the claims met all the edit criteria provided by DOH and did not have any of the other issues identified in this report. We provided DOH officials examples, and they were unable to explain why these claims were not denied by the edits .

For example, we identified a member who, between two different pharmacies, received 90 days' supply of a controlled substance within a 73-day period. At the time of the last claim, the member had 17 days' supply on hand, violating DOH's early refill policy for controlled substances where a refill may be processed only if there are 7 days or less of supply on hand. This claim bypassed the edit despite the claims matching the edits' criteria for denial.

Other Issues

We identified 2,361,334 claims, totaling about $341.5 million, that met the criteria outlined in the New York Medicaid Pharmacy Manual of being too early to refill but were able to bypass the edits due to other issues. Both edit 02242 and edit 01642 can be purposefully bypassed by pharmacies using prior authorizations or override codes. The edits also use additional criteria that allow them to be bypassed based on claim information.

DOH is aware of potential weaknesses in one of the current bypasses. Prior to our audit, DOH started Evolution Project 8016 to address this bypass. According to the project documentation, the current eMedNY system is unable to effectively validate the relationship between certain claim data. Further, DOH acknowledged that pharmacies could circumvent the early refill edits by manipulating this data. The project is currently in the early stages of development, and DOH does not have a timeline for any system changes.

Due to the sensitive nature of these other issues, we provided additional details to DOH officials in a preliminary report. In response, DOH officials disagreed with our findings, stating that early refill edits that are too restrictive can risk delays in therapy and potential escalation in disease requiring emergency care. While DOH officials state that the intent of these system bypasses is to introduce flexibility into the edits to ensure members receive necessary medication and to support timely therapy continuation and billing, without additional mitigating controls such as those that would be introduced by Evolution Project 8016 or focused monitoring, these bypasses could lead to members receiving unintended excess supplies of medication. This contradicts the purpose of the early refill guidelines and potentially allows abuse by bad actors.

Recommendations

1. Conduct a risk-based review of the approximately $585.2 million in payments for drugs and supplies refilled too early, such as by starting with the over $6.9 million in claims for members who received early refills at least 30 times during our audit period when they already had 30 or more days' supply on hand, and take action, including recoveries, as appropriate.
2. Formally remind pharmacy providers of early refill policies and their responsibility to timely and accurately report claim information, including supply days.
3. Enhance monitoring to identify improper early refill claims, and strengthen eMedNY system controls, including implementing the system changes described in Evolution Project 8016, to address issues related to:
    - gaps in dispensing history;
    - historical claims processed after in-process claims;
    - claim processing delays; and
    - other reasons (sensitive in nature).
4. Review claims that bypassed early refill claim edits for unknown reasons to identify the cause and take corrective actions as needed.

Audit Objective, Scope, and Methodology

The objective of our audit was to determine whether Medicaid made improper payments on pharmacy claims for early refills of prescription drugs and supplies. The audit covered the period from April 2023 through October 2024.

To accomplish our objective and assess relevant internal controls, we interviewed DOH officials and reviewed relevant DOH policies and procedures, eMedNY system documentation, and applicable State laws, rules, and regulations. We used DOH's Medicaid Data Warehouse (MDW) to identify fee-for-service pharmacy claims that were refilled too early but that were not denied by edits 02242 or 01642. We removed claims with valid overrides per the edit logic, claims with 7 or fewer supply days, claims submitted by tape and paper, and claims that appeared to be pharmacies combining packaging sizes to meet prescribed dosages.

We used a non-statistical sampling approach to provide conclusions on our audit objective. We selected a judgmental sample. However, because we used a non-statistical sampling approach, we cannot project the results to the population. Our sample, which is discussed in detail in the body of our report, includes:

- A judgmental sample of 139 in-process claims totaling $1,428,259 from an audit population of 3,612,274 claims totaling $585,403,074, based on risk factors such as being high-dollar claims, claims occurring when the member appears to have had a high amount of excess supply on hand, and to test all the different issues identified in our analysis (such as gaps in dispensing history and claim processing delays). As part of our sample review, we also reviewed related historical claims to assess whether the 139 sampled claims were findings.

We relied on data from eMedNY and the MDW, that, based on work performed by OSC, is sufficiently reliable for the purposes of this audit.

Statutory Requirements

Authority

The audit was performed pursuant to the State Comptroller's authority as set forth in Article V, Section 1 of the State Constitution and Article II, Section 8 of the State Finance Law.

We conducted our performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

In addition to being the State Auditor, the Comptroller performs certain other constitutionally and statutorily mandated duties as the chief fiscal officer of New York State. These include operating the State's accounting system; preparing the State's financial statements; and approving State contracts, refunds, and other payments. These duties could be considered management functions for the purposes of evaluating organizational independence under generally accepted government auditing standards. In our professional judgment, these duties do not affect our ability to conduct this independent performance audit of DOH's oversight and administration of Medicaid payments for early refills of prescription drugs and supplies.

Reporting Requirements

We provided a draft copy of this report to DOH officials for their review and formal comment. We considered DOH's comments in preparing this report and have included them in their entirety at the end of the report. In their response, DOH officials agreed with some of the audit recommendations and indicated that certain actions have been and will be taken to address them. Our responses to certain DOH remarks are included in the report's State Comptroller's Comments, which are embedded in DOH's response.

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

Agency Comments and State Comptroller's Comments

NEW YORK STATE | Department of Health

KATHY HOCHUL
Governor

JAMES V. McDONALD, MD, MPH
Commissioner

JOHANNE E. MORNE, MS
Executive Deputy Commissioner

January 9, 2026

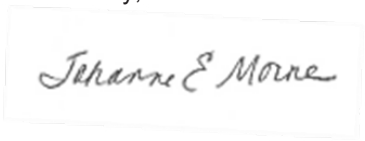
Christopher Morris, Audit Director
Office of the State Comptroller
Division of State Government Accountability
110 State Street – 11th Floor
Albany, NY 12236-0001

Dear Christopher Morris:

Enclosed are the Department of Health's comments on the Office of the State Comptroller's Draft Audit Report 2024-S-16 entitled, "Medicaid Program: Payments for Early Refills of Prescription Drugs and Supplies."

Thank you for the opportunity to comment.

Sincerely,



Johanne E. Morne, M.S.
Executive Deputy Commissioner

Enclosure

cc: Melissa Fiore
Amir Bassiri
Jacqueline McGovern
Jennifer Danz
James Dematteo
James Cataldo
Brian Kiernan
Timothy Brown
Amber Gentile
Michael Lewandowski
OHIP Audit
DOH Audit

Department of Health Comments on the Office of the State Comptroller's Draft Audit Report 2024-S-16 entitled, "Medicaid Program: Payments for Early Refills of Prescription Drugs and Supplies"

The following are the Department of Health's (Department) comments in response to the Office of the State Comptroller's (OSC) Draft Audit 2024-S-16 entitled, "Medicaid Program: Payments for Early Refills of Prescription Drugs and Supplies." Included in the Department's response is the Office of the Medicaid Inspector General's (OMIG) replies to applicable recommendations. OMIG conducts and coordinates the investigation, detection, audit, and review of Medicaid providers and recipients to ensure they are complying with the laws and regulations.

Executive Summary

The Department will continue to work diligently to ensure that all Medicaid benefits, including pharmacy services, are delivered in a responsible manner. However, the Department respectfully believes that the recommendations as presented are based on an incomplete understanding of clinical practice, administrative processes, and the nuances of medication management and dispensing. Early refill edits are not intended to be analyzed in a vacuum; they are one tool in a suite of protections the Department utilizes to detect and combat fraud, waste and abuse in the prescription drug program. Early refill edits are purposely deferential to clinical judgment as a matter of patient safety. Additionally, calculations presented by OSC overestimate days on hand for a singular instance and do not account for the patient's profile for that medication over time.

State Comptroller's Comment – DOH's response fails to adequately address the concerns raised in our audit findings. Our audit has clearly identified significant weaknesses in DOH's early refill edits, which pose a risk of excessive medication fills in the Medicaid program. While DOH has mechanisms like prior authorizations to override these edits for changing medication needs, our findings were missing these critical authorizations.

Moreover, DOH's claim that OSC overestimated days on hand directly contradicts the logic of its own eMedNY system.

Lastly, while we acknowledge that some claims were filled only a few days early, it is important to emphasize that nearly 43% of the claims in our findings—approximately $220 million—exhibited 20 or more excess supply days on hand. We strongly urge DOH to take action to rectify the control deficiencies we have identified, including necessary edits and enhanced monitoring practices.

The Department supplements this summary with the following points:

- The Department's policy and logic for refill is aligned with all other state Medicaid programs as well as commercial payers. It allows patients the flexibility to obtain their prescriptions reasonably in advance of running out of medication. It is important that patients have enough medication therapy on hand. This does not always align with the exact date that the refill is due, giving patients the ability to call the pharmacy ahead to

prepare their medications. This is crucial as it ensures continuity of therapy and prevents gaps in treatment.

- The Department utilizes refill edits and other methods, such as retrospective drug utilization review and therapeutic duplication, to assess each patient's medication history. The Department also applies clinical editing via prior authorization programs when patterns of drug utilization are inconsistent with FDA indications and use. In leveraging prior authorization along with claim edits, there is robust drug utilization review.

  State Comptroller's Comment – The audit removed all claims that included overrides, such as prior authorization, and identified weaknesses in DOH's eMedNY edits. If left unaddressed, these weaknesses could lead to Medicaid payments for excessive prescription drugs and supplies.

- The Department has highlighted that many of the discrepancies noted are due to the limitations of the "days on hand" calculations used by OSC, which added an extra day to each lookback period and also added extra days by not accounting for the actual time the claim adjudicated. The analysis also does not account for numerous clinical realities such as dosing adjustments, medication stability, titrations, accidents, hospital stays, or the timing of late refills. Relying solely on such calculations without clinical input or context can result in inaccurate assessments and lead to unjustified conclusions.

  State Comptroller's Comment – DOH's response is incorrect. As stated on page 9 of the report, we calculated supply days using the early refill edit logic and confirmed our calculations through multiple tests of claim data and by reviewing sample scenarios in the original edit creation documentation provided by DOH.

  Additionally, as previously noted, we removed claims with allowable override exceptions from our findings, such as those with prior authorizations, which are intended to address the clinical realities referenced by DOH.

- Upon an expanded review of this audit's scope, such as reviewing refill patterns over the course of a calendar year, the Department has determined that the overall accumulation of drug on hand is minimal. Most often there are late refills that negate the early refill(s) obtained throughout the year. Rigidly editing these claims without considering clinical context creates a risk of delay to necessary treatment and undermines provider discretion.

  State Comptroller's Comment – DOH has edit override mechanisms in place to address clinically justified early refills. Relying on future behavior to correct current issues of excessive supply ignores the risk of early refills.

Audit Recommendation Responses:

Recommendation #1

Conduct a risk-based review of the approximately $585.2 million in payments for drugs and supplies refilled too early, such as by starting with the over $6.9 million in claims for members

who received early refills at least 30 times during our audit period when they already had 30 or more days' supply on hand, and take action, including recoveries, as appropriate.

Response #1

In collaboration with the Department, OMIG continues to perform analysis of the OSC-identified overpayments to determine an appropriate course of action, which may include recovery of any payment determined to be inappropriate. Pursuant to State regulations, any identified overpayments OMIG pursues for recovery are subject to the provider's right to due process. The Department will also evaluate what, if any, additional measures are appropriate.

The recommendation to conduct a risk-based review targeting over $6.9 million in claims—specifically those with at least 30 early refills while patients already had 30 or more days' supply—fails to consider the clinical justifications underlying such refill patterns. Additionally, it should be noted these 30 instances are not limited to one drug item, but the patient's entire medication profile within the audit period. Many of these cases involve legitimate clinical scenarios such as dose titrations, medication adjustments for acute conditions, or institutional discharges, which are clinically justified.

- For example: OSC identified one member who received 36 fills (20-day supply each) of the same drug from April 2023 through June 2024, resulting in 280 days' supply on hand at the time of the last fill. These include 31 claims totaling $622,384, filled earlier than allowed per the NY Medicaid Pharmacy Manual.

    - The medication was for Buphenyl powder, which is used for urea cycle disorder involving elevated plasma ammonia glutamine levels. The powder is weight based & given three to six times a day with meals. It needs to be mixed with food or liquid for immediate use and once mixed is only stable for up to one week at room temperature or refrigerated. Due to the nature of the disease, preparation, administration, dosing and stability of the drug, the amount of drug and frequency that it is mixed/prepared for consumption could vary, impacting the length of stability and quantity which remains for additional use. This is due to the unpredictability of how long the product will ultimately last for the child based on the various factors noted above. This child has been on this lifesaving medication since birth. This drug is not a risk for fraud/abuse.

    - Also, while the cost of medication appears to be $622,384 for 31 claims totaling $20,077 per claim, this drug is a preferred product under New York Medicaid Pharmacy Program. When considering supplemental rebates, the net cost of the drug is negligible.

      State Comptroller's Comment – DOH continues to misinterpret our audit findings. The audit did not assess whether the prescribed medications were medically necessary; rather, its purpose was to identify weaknesses in DOH's controls that could lead to excessive medication fills and waste within the Medicaid program.

      In response to the example cited, DOH suggested factors that may have influenced the available supply. However, we did not find that these factors caused the excessive supply we calculated. Our review revealed numerous

instances over a short period in which two pharmacies filled a 20-day medication supply just days apart, including one instance on consecutive days. We also contacted both pharmacies and obtained documentation for the prescriptions. We observed that the members' dosages were the same and remained consistent throughout the observation period, indicating stable medication requirements.

Auditors acknowledge that specific situations, such as dose titrations or medication adjustments for acute conditions, may be clinically justified. However, DOH has established overrides to address these scenarios. We urge DOH to review our audit findings and take corrective action.

Recommendation #2

Formally remind pharmacy providers of early refill policies and their responsibility to timely and accurately report claim information, including supply days.

Response #2

The Department regularly reminds providers about refill allowances as part of our routine program reminders via Medicaid Update Articles. We will continue to provide program reminders about refill allowances. The Department also emphasizes that current policies promote appropriate reporting and clinical discretion and are designed to balance patient access with utilization control.

Early Fill Guidance

Medicaid Updates:

- January 2015: New Medicaid FFS Pharmacy Early Fill Edit
- March 2015: Update on Policy for Medicaid Fee-for-Service (FFS) Pharmacy Early Fill Edit
- January 2018: Medicaid FFS Pharmacy Change in Early Fill Edit for Controlled Substances
- December 2020: Reminder: Fee-for-Service Early Refill Guidance to Pharmacies During the Continued Disaster Emergency for COVID-19
- August 2021: Clarification and Reminder: Pharmacy Providers Servicing Medicaid Fee-for-Service Members and Medicaid Managed Care Enrollees
- February 2023: Clarification for Long-Term Care Pharmacies New Patient and Leave of Absence
- November 2023: Update to Long-Term Care Pharmacies New Patient and Leave of Absence
- March 2024: NYRx Out-of-State Traveling

Pharmacy Provider Direct Communications:

- January 22nd. 2015: Tighten_Early_Fill_Edit_Effective_1-22-15.pdf
- March 14th, 2023: Clarification for Long-Term Care Pharmacies New Patient and Leave of Absence

- November 1st, 2023: UPDATE: Long-Term Care Pharmacies New Patient and Leave of Absence
- May 8th, 2024: Top Edit Resource

Recommendation #3

Enhance monitoring to identify improper early refill claims, and strengthen eMedNY system controls, including implementing the system changes described in Evolution Project 8016, to address issues related to:

- gaps in dispensing history;
- historical claims processed after in-process claims;
- claim processing delays; and
- other reasons (sensitive in nature).

Response #3

Project 8016 is in the queue of pharmacy program projects and has not yet been initiated by Division of Systems (DOS). The project focuses on utilizing days' supply logic within eMedNY that will complement some of the components of prior authorization.

The current claims processing system has two early fill edits in place. Edit 02242 determines the cumulative amount of supply over a 90-day time frame, and edit 01642 determines whether less than 75% of a dispensed amount from a previous claim has been used. The more stringent rule applies. These edits are working as designed and as expected. In addition, there are therapeutic duplication warnings sent to the pharmacist for their consideration. The program also has prior authorization criteria applied across numerous drugs/drug classes to help ensure appropriate use. Careful clinical consideration is required for each patient's individual profile and include dose titration/adjustments, medication stability, variable dosing, institutionalizations, and hospitalizations, among others. This editing and approach aligns with other State Medicaid programs and commercial payers. Changes to the established edits should be considered cautiously so as not to inadvertently cause medication delays for unique prescribing requirements, limiting professional discretion by Medicaid-enrolled providers.

The Department continuously evaluates the pharmacy program to implement innovative solutions and program efficiencies. We will continue to review the various buckets listed above in an effort to potentially identify additional opportunities to enhance the current claims processing functionality for pharmacy claims edits.

Recommendation #4

Review claims that bypassed early refill claim edits for unknown reasons to identify the cause and take corrective actions as needed.

Response #4

Bypasses are built within claim editing based on policy and systems development input. Bypasses represent an exercise of clinical judgment and do not independently provide a reasonable suspicion of abuse or misuse. Claims bypassed are often the result of necessary

administrative adjustments, including but not limited to institutional discharges, point-of-service edits, or legitimate timing variations.

We will continue to review claims which bypassed the early refill claim edits in an effort to potentially identify additional opportunities to enhance the current claims processing functionality for pharmacy claims edits.

In summary, early refill edits are an important utilization management tool used to promote compliance and prevent waste. However, it is important that such edits do not get applied in a manner that unreasonably places members at risk of serious consequences from interruptions in drug therapy. Medicaid, as well as Medicare and commercial insurers, utilize a myriad of utilization management tools, including claim edit warnings, letters and notifications regarding medication utilization, prior authorization or manual review, preferred drug lists, step therapy, frequency, duration and quantity limits, and referral to the Office of Medicaid Inspector General. By utilizing all of these tools the Department works to ensure that prescriptions for outpatient drugs are appropriate, medically necessary, and not likely to result in adverse medical consequences. DUR programs and claims system editing use professional medical protocols, computer technology and data processing to assist in the management the dispensing of prescriptions over periods of time.

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