



Department of Health

KATHY HOCHUL
Governor

JAMES V. McDONALD, MD, MPH
Commissioner

JOHANNE E. MORNE, MS
Executive Deputy Commissioner

September 10, 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:

Pursuant to the provisions of Section 170 of New York State Executive Law, I hereby transmit to you a copy of the New York State Department of Health's comments related to the Office of the State Comptroller's final audit report 2024-S-16 entitled, "Payments for Early Refills of Prescription Drugs and Supplies."

Please feel free to contact the Office of Governmental and External Affairs at (518) 473-1124 with any questions.

Sincerely,

A handwritten signature in cursive script that reads "Johanne E. Morne".

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

Enclosures

cc: Melissa Fiore
DOH Audit

**Department of Health Comments on the
Office of the State Comptroller's
Final Audit Report 2024-S-16 entitled, "Medicaid Program: Medicaid
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) Final Audit Report 2024-S-16 entitled, "Medicaid Program: Medicaid 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.

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

The Department acknowledges the findings of the recent audit and reiterates a commitment to transparency and continuous improvement. In light of OSC's report, it is important to note that many of the claims identified as an early refill are clinically justified based on a multitude of factors including but not limited to individual patient needs, medication stability, medication titration, eligibility delays, and other specific medical conditions. Additionally, the New York Medicaid Fee-For-Service program employs a comprehensive set of safeguards that reach beyond the two early refill edits referenced within this audit including prior authorization, retrospective reviews, and clinical oversight to prevent misuse and diversion. Private and publicly funded pharmacy benefits both allow early fills to process at an individual level to meet a patient's needs. For this reason, the Department remains committed to health equity for all Medicaid members.

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 or 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 misinterprets 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.

The Centers for Medicare & Medicaid Services (CMS) regulates both Medicare and Medicaid Drug Utilization Review (DUR) Programs. Our program is consistent with [CMS DUR](#) Section 1927(g)(3)(D) of the Social Security Act. This includes early refill editing. Prospective DUR (ProDUR) is one component of the DUR process that is performed prior to dispensing of the prescription to the patient. It requires the electronic monitoring of prescription drug claims to identify problems such as early refill as well as therapeutic duplication, incorrect dosage or duration of treatment, etc. ProDUR functions are performed at the point-of-sale (POS) when the prescription is being processed at the pharmacy.

CMS recognizes that early refill editing is an important utilization management tool used to promote compliance and prevent waste. However, it is equally important that Medicare and Medicaid implement such edits in a manner that does not unreasonably put members at risk of interruptions in drug therapy with potentially serious consequences. There needs to be consideration of differences that some dosage forms, such as ophthalmic preparations, topical antibiotics, injectable insulin, etc. present when establishing early refill edits. Because of this, such edits need to reasonably accommodate waste that can be anticipated given the nature of these products and their self-administration among the patient population. Editing on early refills is required across all state Medicaid and Medicare programs. All programs have a similar edit to our edit 01642 which is currently set at a 75% refill threshold. Additionally, some have an accumulation edit which is similar to our edit 02242, to conduct further lookbacks to prevent

stockpiling. When reviewing the various categories OSC provided such as “Gaps in Dispensing History” and “Unidentified Reason for Bypassing Edit,” OSC’s own report demonstrates edit 01642 to be effective, with 0% and 0.003% of the total claims to be in violation of the edit.

State Comptroller’s Comment – 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). Therefore, claims must meet the criteria of both edit 01642 and edit 02242 or include the appropriate overrides. The majority of the findings we identified in the audit were related to weaknesses in edit 02242, not edit 01642.

The basis of OSC’s report on early refill demonstrates only single instances of claims bypassing edits based on simple calculations, while ignoring the unique member and realistic provider needs considered by the Department. The report does not indicate, nor prove medication supply waste. Early refills cannot infer that the previous supply was not utilized or appropriate on the date of service. The Department conducted an internal review across State Fiscal Year ‘26 and determined long-term overall accumulation to be unremarkable, with only 0.09% of claims exceeding the refill threshold at the conclusion of the fiscal year. This includes scenarios where the early refill was appropriately overridden due to replaced medication supply, or nursing home transitions. In conclusion, the data supports our findings and proves that long-term accumulation is very minimal. There is not demonstrated evidence of improper overutilization of medication indicative of fraud, waste, or abuse.

State Comptroller’s Comment – The internal review referenced in DOH’s response considered claims outside the scope of our audit. DOH’s conclusions are inconsistent with our audit findings. DOH has established overrides to provide flexibility in its early refill policy; however, none of the claims in our findings had the appropriate overrides as indicated by DOH. We provided DOH with multiple opportunities to review our work and share additional information. As noted in the State Comptroller’s Comment above, our audit identified weaknesses in edit 02242 that allowed claims to bypass DOH’s controls inappropriately. If the issues are not addressed, they could result in Medicaid payments for excessive prescription drugs and supplies.

The Department maintains that balancing medication access with safety is essential; the current policies and controls are effective in safeguarding public resources while ensuring patient care. The Department remains dedicated to refining processes and prioritizing opportunities to uphold the integrity of the Medicaid program.

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.

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](#)
- March 2026: [Clarification and Reminder: Pharmacy Providers Servicing Requirements for NYRx Members](#)

Pharmacy Provider Direct Communications:

- January 22, 2015: [Tighten_Early_Fill_Edit_Effective_1-22-15.pdf](#)
- March 14, 2023: [Clarification for Long-Term Care Pharmacies New Patient and Leave of Absence](#)
- November 1, 2023: [UPDATE: Long-Term Care Pharmacies New Patient and Leave of Absence](#)
- May 8, 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

The Department continuously evaluates the pharmacy program, including claims processing functionality for pharmacy claims edits, and can consider enhancements to these edits. The Department wants to ensure any changes made allow for the flexibility described above while maintaining control. For edit 02242, the Department will focus on consecutive claims that have a break in therapy within the 90-day lookback, since thematically this was a bigger subset of claims reviewed by OSC.

The failure to properly balance early fill edits with clinically justified administrative policy overrides can result in inconsistencies within the audit findings. For example, the OSC report references an example for two claims billed 1-day apart. Upon the Department's review of the claim, it was determined to be related to a nursing home transition and critical drug therapy for hepatic encephalopathy. At the time of the claim, administrative overrides allowed for early fill bypass per policy. The Department reviewed numerous claims within this grouping where the patient was transitioned to a skilled nursing facility, requiring new

supplies of existing prescriptions. This clinically justified administrative override was not considered within the audit findings.

State Comptroller's Comment – DOH's explanation of these claims is misleading. The claim for the second fill of medication did not bypass the edit because of an administrative override; rather, it was processed before the claim for the first fill. Simply, the claims bypassed the edit because they were billed out of order. In fact, the claim for the second fill had no administrative overrides at all. We reached out to the pharmacy that billed both claims and requested supporting documentation. We found that both claims were for a 30-day supply of the same drug with the same dosing instructions, delivered to the same floor of the same facility, 2 days in a row.

Our audit removed all claims from our findings that had appropriate overrides as indicated by DOH's edit logic. We provided DOH with multiple opportunities to review our work and provide us with additional information. At no point did they indicate that there were additional administrative overrides we had not considered.

The Department's examination of the claims included in this audit accounts for utilization of the members' claims in the previous 90 days, including credit for older prescription fills that fall into the 90-day lookback period. Any claim submitted after 90 days is out of scope of this edit, and therefore, this audit. The Department also acknowledges standard practices of all enrolled providers servicing members and that a claim may be delayed for many reasons, including but not limited to the following:

1. Retroactive Prior Authorization (PA): A drug may have been denied initially because a Prior Authorization was missing. The prescriber subsequently obtained a "retroactive PA," allowing the pharmacy to resubmit the older claim.
2. Correcting Rejected or Denied Claims: If an earlier claim was rejected due to errors, the pharmacy may take time to correct and re-submit it, while newer claims are processed timely.
3. Transferring Pharmacies: If a prescription was filled at one pharmacy, then transferred to another, the first pharmacy might reverse its claim late, requiring a new submission by the new pharmacy.
4. Administrative Delays: The pharmacy may have faced internal bottlenecks, such as new billing software implementation, staffing shortages, or a high volume of claims, leading to a backlog where older claims are processed last. Additionally, member eligibility delays should also be considered.

State Comptroller's Comment – Our audit objective was not limited to a single edit; therefore, DOH's assertions that these claims were outside the audit scope are incorrect. We also acknowledge that there are multiple reasons a claim may be billed late. However, as the example in the State Comptroller's Comment above demonstrates, DOH must enhance its monitoring of claims that bypass the edits, such as those in which older claims are processed last. The claims in our audit violated DOH's public early-refill policy and lacked allowable overrides.

All claims reviewed in this category fall under administrative review. Additionally, these claims contained allowable bypass indicators or prior authorization codes that allowed them to be paid.

The Department also notes the inclusion of claims within the findings for which Medicaid coverage was not primary. Claims where Medicaid, as the payer of last resort, is covering the remaining balance (such as deductibles, copayments, or coinsurance) up to the Medicaid fee limit, after the primary insurer performs their claim logic, approves and reimburses on the claim, are not subject to Medicaid's early fill 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

The Department reviewed the claims and all claims bypassed edits per the program policy. Please see response to recommendation #3.