



**Department
of Health**

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Acting Executive Deputy Commissioner

October 17, 2022

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 Andrea Inman:

Enclosed are the Department of Health's comments on the Office of the State Comptroller's Follow-Up Audit Report, 2022-F-7 entitled, "Medicaid Program: Improper Medicaid Payments for Terminated Drugs."

Thank you for the opportunity to comment.

Sincerely,

Kristin M. Proud
Acting Executive Deputy Commissioner

Enclosure

cc: Diane Christensen
Amir Bassiri
Geza Hrazdina
Andrea Martin
James Dematteo
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**Department of Health Comments on the
Office of the State Comptroller's
Follow-Up Audit Report 2022-F-7 entitled, "Improper Medicaid
Payments for Terminated Drugs" (Report 2019-S-45)**

The following are the responses from the New York State Department of Health (Department) to Follow-Up Audit Report 2022-F-7 entitled, "Improper Medicaid Payments for Terminated Drugs (Report 2019-S-45)" by the Office of the State Comptroller (OSC).

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.

Status – Not Implemented

Agency Action – The Office of the Medicaid Inspector General (OMIG) did not take any action because the Department did not provide regulatory support for recoveries. Department officials disagreed that recoveries of payments for terminated drugs can be made, stating the termination dates provided by the Centers for Medicare and Medicaid (CMS) are often updated retrospectively and there is often conflicting information in the marketplace regarding drug dates.

However, this is contradictory to other Department action. Specifically, to comply with CMS requirements, the Department implemented an eMedNY edit to deny Fee-for-Service (FFS) payments of pharmacy claims for terminated drugs based on drug termination dates provided by CMS. Therefore, it is unclear why there is reluctance to use this data for recovery purposed when the Department uses it to deny claim payments.

Furthermore, retroactive updates of termination dates by CMS are relatively infrequent. Our analysis of the initial audit's findings showed that for 13,689 (97%) of the National Drug Codes (NDC), the drug termination date was not subsequently updated.

Response #1:

As previously stated, the Medicaid FFS Program has editing that utilizes quarterly termination dates provided by CMS. These dates are self-reported by manufacturers participating in the Federal Drug Rebate Program for this purpose. CMS recognizes that there are limitations to the accuracy and timing of the data contained in this file. Specific details can be found in the following State Release: <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-091.pdf>. The Department also receives notifications between the quarterly file updates which contains additions and subtractions with retroactive and future dates, on drugs. Additionally, there are other data files that exist with different information regarding termination dates, for example, NDC SPL Data Elements File (NSDE) <https://www.fda.gov/industry/structured-product-labeling-resources/nsde>.

The Department periodically receives inquiries on termination dates from pharmacies that contradict information from the CMS file. Pharmacies stated that certain NDC's not termed were in stock to dispense to patients, even though the CMS filed had reported them as termed. It was also mentioned that pharmacies may incorrectly submit an old/terminated NDC when billing, but actually dispensed another NDC for that drug, which was not terminated, to the patient. While

this is not correct and problematic for multiple reasons, the drug was ultimately dispensed to the patient and therefore cannot be recovered from payment.

The Encounter Intake System (EIS) does not edit against the CMS termination date like the Medicaid FFS logic. The EIS system is changing over to the Original Source Data Submitter (OSDS) system to process encounters. There is a moratorium on changes in the EIS until the OSDS is fully operational.

Lastly, in collaboration with the Department, OMIG will determine which scenarios may require additional review and action. Pursuant to State regulations, any identified overpayments OMIG pursues for recovery are subject to the provider's right to due process.

Recommendation #2:

Formally instruct Managed Care Organizations (MCOs) on CMS guidance to ensure they, or their Pharmacy Benefit Managers, reject claims for drugs based on termination date.

Status – Implemented

Agency Action – The Department instructed MCOs in April 2020 to deny pharmacy claims if the drug was dispensed after the reported drug termination date.

Response #2:

The Department confirms agreement with this recommendation.

Recommendation #3:

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

Status – Not Implemented

Agency Action – Department officials stated they evaluate pharmacy encounters and issue statements of deficiency to MCOs based on those reviews, if appropriate. However, the Department does not review or monitor MCOs' pharmacy encounters to ensure the MCOs are not paying for terminated drugs.

To determine whether MCOs were still paying claims for terminated drugs, we analyzed pharmacy encounters for the period July 2019 to March 2022 and identified over \$10.5 million in managed care claim payments for terminated drugs made since the initial audit. Furthermore, the top three MCOs that paid for terminated drugs during the original audit are still the top three MCOs, having paid nearly \$6 million (of the \$10.5 million) in claims for terminated drugs. Additionally, some of these terminated drugs were recalled by the U.S. Food and Drug Administration for safety reasons. Medicaid paid for at least 108 such claims totaling \$1,298.

Department officials believe that once managed care pharmacy benefits are carved out of managed care and paid by the Medicaid FFS program (scheduled for April 2023), such improper payments will be reduced. However, this expected carve-out was already postponed from when it was originally scheduled to take effect in April 2021 and there is no certainty that it will be implemented timely. Since the original April 2021 carve-out date, over \$3 million was

paid inappropriately and more will likely continue to be paid while no corrective action is taken by the Department.

Response #3:

As stated previously, the Department will be transitioning the Pharmacy Benefit effective April 1, 2023. It was also reported that Medicaid FFS has the appropriate editing in place, that utilizes the CMS data file of terminated NDCs as reported by the manufacturers. In preparation for the Pharmacy transition, the Department has been reviewing encounter data submitted by the MCOs and has communicated with the MCOs on this specific topic. The MCOs were issued Statements of Findings (SOF) on termed drugs on 2/18/2022. This required the MCOs to provide plans of correction for improper submission of terminated NDCs.

Recommendation #4:

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

Status – Not Implemented

Agency Action – In order to reject FFS claims for terminated drugs, the eMedNY system uses drug termination dates from CMS that are reported to the Department on a quarterly basis. This leaves the potential to process and pay claims for terminated drugs before termination dates are updated. Our original audit identified 192,672 improper payments, totaling \$1,470,301 due to this lag in timing. Since the initial audit, the Department did not take any action to monitor FFS payments for terminated drugs and, as a result, improper payments continue to be made. To determine the extent to which FFS claims were still being paid for terminated drugs, we analyzed FFS pharmacy claims for the period July 2019 to March 2022, and identified \$676,174 in improperly paid FFS pharmacy claims due to the timing issue.

Response #4:

As previously stated, the Medicaid FFS Program has editing that utilizes quarterly termination dates provided by CMS. These dates are self-reported by manufacturers participating in the Federal Drug Rebate Program for this purpose. CMS recognizes that there are limitations to the accuracy and timing of the data contained in this file. Specific details can be found in the following State Release: <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-091.pdf>. The Department also receives notifications between the quarterly file updates which contains additions and subtractions with retroactive and future dates, on drugs. Additionally, there are other data files that exist with different information regarding termination dates, for example, NSDE <https://www.fda.gov/industry/structured-product-labeling-resources/nsde>.

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The Encounter Intake System (EIS) does not edit against the CMS termination date like the Medicaid FFS logic. The EIS system is changing over to the Original Source Data Submitter (OSDS) system to process encounters. There is a moratorium on changes in the EIS until the OSDS is fully operational.

Recommendation #5:

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

Status – Implemented

Agency Action – During our review, we confirmed that an edit was configured to deny FFS paper and tape claims when a drug termination date is on file.

Response #5:

The Department confirms agreement with this recommendation.