



Department of Health

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Executive Deputy Commissioner

March 22nd, 2021

Ms. Andrea Inman
Audit Director
Division of State Government Accountability
NYS Office of the State Comptroller
110 State Street, 11th Floor
Albany, New York 12236

Dear Ms. Inman:

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

Please feel free to contact Michelle Newman, Assistant Commissioner, Office of Governmental and External Affairs at (518) 473-1124 with any questions.

Sincerely,

Theresa Egan
Deputy Commissioner for Administration

Enclosure

cc: Ms. Newman

**Department of Health Comments on the
Office of the State Comptroller's Final 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) Final 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:

The Department does not concur there is a potential to recover payments made 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 U.S. Food and Drug Administration website sometimes contains conflicting information.

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 federal law further is indicative of the Department's position that CMS data is not always accurate, given that it is self-reported by the manufacturers.

Recommendation #2:

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

Response #2:

The Department communicated a reminder to MCOs on 4/17/2020, to strengthen their editing around the drug termination date. Pursuant to the State Fiscal Year 2020-21 enacted budget, the Department will transition the pharmacy benefit from managed care to the fee-for-service (FFS) system, at which point all applicable claims will be subject to the Medicaid FFS editing, which includes the rejection of claims with service dates beyond 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 continues to monitor pharmacy encounters. As previously stated, pursuant to the State Fiscal Year 2020-2021 enacted budget, the Department will transition the pharmacy benefit from managed care to the FFS system. Once the transition occurs, all applicable pharmacy claims will be subject to the Medicaid FFS editing, which includes the rejection of claims with service dates beyond the drug termination date. Concurrently, the Department continues to monitor pharmacy encounters and issue statements of deficiency to managed care organizations, as appropriate.

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. The Department investigated other databases (e.g., the Food and Drug Administration website: <https://www.fda.gov/industry/structured-product-labeling-resources/nsde>) and has determined that the only accurate source of information is the manufacturer. Therefore, the Department will continue to utilize the information provided by CMS as it does today, unless and until another available source of reliable and accurate information is made by available by the federal government or other external parties.

Recommendation #5:

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

Response #5:

The Department generated a report that validates that the control is working. Since the edit was set to deny (on 1/16/20) for paper & tape, the system has rejected 81 claim transactions.

State Comptroller's Comment #1 (Refers to Response #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.

Response to State Comptroller's Comment #1:

The Department upholds its original position, stated above. Furthermore, in concert with the pharmacy benefit transition from managed care to FFS, terminated drugs will be handled consistently utilizing FFS claim edit controls. As stated in our previous response, manufacturers self-report the termination date of their drug to CMS, and this reporting can occur retrospectively and inconsistently. The NYS Education Department has purview over the pharmacy profession with regards to expired drugs. See Rules of the Board of Regents Section 29.7(a)(17). The Department continues to address the termination of drugs as expeditiously as possible, consistent with its receipt of reliable termination information for each drug.