NEW YORK STATE OF OPPORTUNITY. Department of Health

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June 9, 2023

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
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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 2020-S-62 entitled, "Improper Medicaid Payments for Brand Name Drugs."

Please feel free to contact Mischa Sogut, Assistant Commissioner for Governmental Affairs, at (518) 473-1124 or mischa.sogut@health.ny.gov, with any questions.

Sincerely,

Megan E. Baldwin
Acting Executive Deputy Commissioner

Enclosure

cc: Mischa Sogut

Department of Health Comments to Final Audit Report 2020-S-62 entitled, "Medicaid Program: Improper Payments for Brand Name Drugs" by the Office of the State Comptroller

The following are the responses from the New York State Department of Health (the Department) to Final Audit Report 2020-S-62 entitled, "Medicaid Program: Improper Payments for Brand Name Drugs" by the Office of the State Comptroller (OSC).

Recommendation #1:

Review the FFS claims identified for brand name drugs that had generics available and recover the $739,446 in overpayments, as appropriate; and, as necessary, take corrective actions to prevent incorrect payments from recurring.

Response #1:

The Department is reviewing the updated claims file received from OSC. OSC provided the Department with a larger data set originally, for which the Department provided comments. Subsequent changes were made by OSC that decreased the total questioned cost. However, the Department needs to review the updated file which did not specify what was removed.

OMIG performed data analysis on the OSC-identified payments not already adjusted or recovered to ensure the data used by OSC was complete and to confirm the accuracy of the claims detail prior to any potential audit activity. Pursuant to State regulations, any identified overpayments OMIG pursues for recovery are subject to the provider's right to due process.

During the Department's review process, which began during the preliminary stages of OSC's audit, OSC adjusted the number of claims and total dollar impact for Recommendation #1. OMIG reviewed the remaining claims, and in collaboration with the Department, identified the following areas of concern with OSC's findings:

- OSC included Tamiflu in their findings but did not consider that there was a shortage of the generic alternative. During the scope of this audit, Tamiflu was moved to the Preferred Drug List, and a prior authorization was not needed, despite being paid at a brand price.

State Comptroller's Comment – The audit identified brand name drug claims that were paid at brand drug prices where approved generic drugs were available and the claim did not indicate that a brand name drug was necessary. As stated by Department officials during the audit, a prior approval requirement or lack thereof does not affect the drug price that is paid on a claim. A "dispense as written" (DAW) code of "8" is available for pharmacies to use on claims when a generic drug is not available in the marketplace. None of the claims for Tamiflu reported in the audit had a DAW code of "8." The Department needs to research the issue identified in the audit – specifically, why eMedNY paid claims for brand name drugs at brand drug prices where approved generic drugs were available and the claims did not indicate that a brand name drug was necessary; otherwise, additional incorrect payments could occur.

- In the OSC criteria both Humalog and Novolog were considered multi-source brand name drugs; however, there were no generic equivalents for these instances of biosimilar drugs or authorized generics.

State Comptroller's Comment – Contrary to the Department's statement, Humalog had authorized generics available during the audit period. These authorized generic drugs were listed in eMedNY as generic drugs and had generic prices on file in eMedNY, as would be expected of generic drugs. Additionally, NovoLog was not part of the audit's findings.

- Within the OSC data, there were instances where brand name drugs were cheaper when generic prices were not loaded timely but post-dated into eMedNY.

State Comptroller's Comment – The Department did not provide this information during the audit. In most instances, the drug pricing information used for the audit was extracted years after the service dates on the claims. Therefore, the instances of post-dated generic drug prices would likely impact only a small portion of the findings; however, the impact is not clear based on the Department's statement.

- Potential for generic drug shortages on the date of service, as shortages cannot be determined by reviewing the formulary file. The dates of viability and regional availability may become erratic, and it is then reasonable for a pharmacist to dispense the brand name drug.

State Comptroller's Comment – A DAW code of "8" is available for pharmacies to use on claims when a generic drug is not available in the marketplace. None of the claims reported in the audit had a DAW code of "8." The Department needs to research the issue identified in the audit – specifically, why eMedNY paid claims for brand name drugs at brand drug prices where approved generic drugs were available and the claims did not indicate that a brand name drug was necessary; otherwise, additional incorrect payments could occur.

Recommendation #2:

Review the Department policy that caused "same label name" drugs to be paid using brand name drug pricing methods and ensure corrective actions are taken where appropriate.

Response #2:

The generic product indicator assignment logic structure, which drives reimbursement, has been in place since at least 2008. The Department is considering a modification to this logic. The Department has reviewed modifications to that component of the reimbursement logic. The savings represents less than a quarter of the amount reported by OSC.

It should be noted, OSC inaccurately identified OxyContin as generically available in this audit's Draft Report. To date, there is no FDA approved abbreviated new drug application (ANDA) product which is AB-rated to OxyContin. OxyContin patent exclusivity remains with Purdue through 2027. Those claims should be removed from recovery.

State Comptroller's Comment – Contrary to the Department's statement that OxyContin was not generically available, there were authorized generics available during the audit period. These authorized generic drugs were listed in eMedNY as generic drugs and had generic prices on file in eMedNY, as would be expected of generic drugs.

Recommendation #3:

Review the 21 Epclusa encounter claims identified and ensure overpayments are recovered, as appropriate.

Response #3:

OMIG performed data analysis on the OSC-identified payments not already adjusted or

recovered to ensure the data used by OSC was complete and to confirm the accuracy of the claims detail prior to any potential audit activity. Pursuant to State regulations, any identified overpayments OMIG pursues for recovery are subject to the provider's right to due process.

OMIG is in the process of following up with the managed care organization to determine an appropriate course of action and ensure overpayments are recovered, as appropriate.