NEW YORK STATE | Department of Health

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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, 2024-F-9 entitled, "*Improper Payments for Brand Name Drugs* (Report 2020-S-62)."

Thank you for the opportunity to comment.

Sincerely,

Johanne E. Morne

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

Enclosure

cc: Frank Walsh
Amir Bassiri
Jacqueline McGovern
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# Department of Health Comments on the Office of the State Comptroller's Follow-Up Audit Report 2024-F-9 entitled, "Improper Payments for Brand Name Drugs"

The following are the Department of Health's (Department) comments in response to the Office of the State Comptroller's (OSC) Follow-Up Audit Report 2024-F-9 entitled, "Improper Payments for Brand Name Drugs" (Report 2020-S-62). Included in the Department's response are 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.

**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 payment from recurring.*

Status – Not Implemented

Agency Action – Our initial audit identified overpayments totaling $739,446 on brand name drug claims that met conditions where they were expected to be paid based on generic pricing methods in accordance with eMedNY system documents. OMIG investigates and recovers improper Medicaid payments on behalf of DOH. OMIG officials stated that $9,821 (less than 2%) of our initial audit's findings had been recovered. However, the recoveries were unrelated to the issues identified in this audit. The other $729,625 has not been recovered.

DOH and OMIG reviewed a sample of the overpayments as to the appropriateness of the dispensing of the brand name drug but had not looked at the pricing methodology, which was the basis of our initial audit recommendations, and provided no information about further recovery efforts. In addition, DOH did not take any corrective actions to prevent incorrect payments from recurring. We encourage DOH and OMIG to review the identified overpayments for the issue identified in our initial audit and take corrective actions as necessary, particularly now that all Medicaid recipients enrolled in mainstream managed care receive their prescription drugs through the FFS Medicaid program, NYRx.

**Response #1**

The Department strongly disagrees with OSC's recommendation and status. Several factors account for brand name drug usage that OSC flagged as an overpayment. The following categories define the policy/rationale for the brand reimbursement:

New Generic Launches:

> All new drugs to market are subject to clinical and fiscal review by NYRx, the Medicaid Program, for formulary placement and prior authorization requirements. All insurers perform these types of reviews prior to the addition of drugs to their formulary. The review process also evaluates brand products for inclusion in our Brand less than Generic (BLTG) Program. This program generates high rebate savings for the Medicaid Program. While we evaluate for the above, the generic product is not activated. Many of

the generics identified by OSC include newly launched generics during this short review period.

**State Comptroller's Comment** – Recommendation 1 pertains to brand name drug claims that were paid at brand name drug prices where approved generic drugs were available on Medicaid's formulary and the claim did not indicate that a brand name drug was necessary. The initial audit's analysis did not include inactive generic drugs.

Use of a Preferred Brand:

The Department had provided OSC with a listing of drugs included in the BLTG program. Drugs that were part of the BLTG program were still included in the OSC report. Some examples are Humalog, Proventil HFA, Renagel, etc., all of which were in this program for a portion of the audit period. The Department promotes the use of these brands as they are cost effective for the State, net of rebates.

**State Comptroller's Comment** – The initial audit's analysis removed BLTG program drugs. During the initial audit, DOH could not provide us with a comprehensive list of NDCs and time periods for drugs in the BLTG program, so we compiled this information from various BLTG drug notices and Preferred Drug Lists published by DOH.

Drug Shortages:

OSC included in the report brand name drugs that were affected by drug shortages on the date of service. Access to critical care is a vital consideration by the Department. Tamiflu and its generics experienced increased demand and drug shortages during the audit period. It was the Department's decision not to disadvantage pharmacies and patients due to market availability concerns.

**State Comptroller's Comment** – A "dispense as written" (DAW) code of "8" is available for pharmacies to use on claims when a drug is not available in the marketplace. None of the claims reported in the audit had a DAW code of "8."

Interchangeability Between Products:

Not all generically named ingredients are interchangeable to their brand counterpart. One such example is Albuterol Sulfate, which is available in three different formulations: Proair, Proventil, and Ventolin. Brands and their respective generics are not interchangeable due to differences in propulsion mechanisms. OSC inappropriately identified this drug in the 2020-S-62 report, as Proventil's generic, which was not available until May 28, 2021.

**State Comptroller's Comment** – Our methodology is described on page 10 of the initial audit report: "We extracted FFS pharmacy claims for brand name prescription drugs with dates of service from July 2016 to July 2021 where the prescribers did not indicate DAW and the brand name drugs were multi-source, had generic drugs covered by Medicaid, and were not in the BLTG program on the dates of service." The audit's methodology was based on eMedNY's system documentation for pharmacy claim pricing, which defines when generic drug prices should be used on claims rather than brand name drug prices.

**Recommendation #2**

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

Status – Partially Implemented

Agency Action – Our initial audit identified $1,011,990 in potential cost avoidance for claims that were paid using brand name pricing methods because eMedNY referenced the drugs as brand name single-source drugs on the date of service.

The claims were paid using brand name pricing methods where the proprietary drug label name matched its generic name (“same label name” drugs). According to the FDA, generally brand name drugs are identified by their propriety name on a drug label and generic drugs are identified by their active ingredient name on a drug label. The drugs on these claims included drugs approved under an Abbreviated New Drug Application (ANDA-approved drugs), meaning the FDA had certified the drug to be bioequivalent (considered equal) and an alternative to the brand name drug, as well as FDA-approved “authorized generics” and “unbranded biologics” where the drug is the exact same product as the brand name drug, but the drug is marked as a generic drug.

In response to our initial audit, DOH instituted a system change in September 2023 where all ANDA-approved drugs would be identified as generic drugs. This change, however, only applied to drugs newly added to the eMedNY system. We reviewed the drugs in eMedNY and the time of our follow-up and found that all ANDA-approved drugs added after the system change were listed as generics. However, because this change was not applied to drugs that were already in eMedNY at the time of the change, as of May 16, 2024, eMedNY still identified 338 ANDA-approved generic drugs as brand name drugs. As a result, some ANDA-approved generics were paid for using brand name drug pricing methods instead of generic drug pricing methods after the system change was implemented.

Additionally, DOH designed the system change to exclude identifying all authorized generic drugs as generics. Consequently, as of May 16 2024, we determined that 68 of 1,304 NDCs (National Drug Code, the unique identified used to identify drugs) for authorized generic or unbranded biologic drugs were identified as brand name drugs (the remaining 1,26 were identified as generic drugs).

To determine the effectiveness of DOH’s actions, we analyzed FFS pharmacy claims from the end of our initial audit, February 2022 through April 2024 We identified additional potential cost avoidance of approximately $6.3 million for pharmacy claims that were priced as brand name drugs despite meeting the “same label name” condition. This increase from what was found in our initial audit corresponds with the transition to NYRx. Of the $6.3 million, $5.3 million was for authorized generic or unbranded biologic drugs, with most of the claims being for unbranded biologic insulin (over $3.7 million). Essentially all of the remaining $1 million identified was for ANDA-approved drugs that were added to eMedNY before the September 2023 system change and therefore were still identified as brand name drugs instead of generic drugs (of the $1 million, about $450,000 was paid after the September 2023 system change).

Given the increase in FFS pharmacy claims, potential cost avoidance will likely continue to grow without further action from DOH. We encourage DOH to review whether additional corrective actions are warranted for outstanding claims.

**Response #2**

The Department has reviewed OSC’s estimated savings based on their proposed modification and it is grossly overstated. The Department will continue research in this area and implement necessary changes once finalized. It should be noted, the Department identified discrepancies within the audit dataset. It appears the authorized generic indicator was used as the basis of determining generic availability. This is inaccurate. Authorized generics are not approved under the ANDA pathway. These are not true multi-source products. OSC inaccurately identified

OxyContin as generically available in the 2020-S-62 Draft Report and Final Report. To date, there is no FDA approved ANDA product that is AB-rated to OxyContin. OxyContin patent exclusivity remains with Purdue through 2027.

**State Comptroller's Comment** – As described on page 8 of the initial audit report, we identified drugs in eMedNY where the drug label (proprietary) name matched its generic name (we did not use the authorized generic indicator as the basis of determining generic availability). We refer to this condition as "same label name." For the claims identified, the drug is likely not a brand name drug, yet payments were made at the brand name drug price. Additionally, $1 million of the $6.3 million in potential cost avoidance identified in our follow-up was for ANDA-approved generic drugs that were still identified in eMedNY as brand name drugs instead of generic drugs.

Furthermore, the OxyContin audit findings do not pertain to this recommendation; they actually pertain to Recommendation 1. Regardless, OxyContin had authorized generics available that were listed in eMedNY as generic drugs, and have generic prices on file in eMedNY, as would be expected of generic drugs.

It is unclear why DOH has not implemented policies to avoid paying claims at the higher brand name drug prices.

The Department is reviewing the generic product indicator assignment logic structure, which also drives pharmacy reimbursement. The Department is also working on leveraging additional drug indicators from the First Databank, to better define authorized generics ANDA, NDA, and other market intricacies. This will assist with precise and complicated drug approvals, for which the landscape has changed over time.

The Department will continue to explore additional indicators to provide more precise information to potentially utilize in our reimbursement methodology for more complicated drug approvals.

**Recommendation #3**

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

Status – Not Implemented

Agency Action – Our initial audit determined that one managed care organization improperly paid 21 claims for service dates between October 2019 and December 2020 for the brand name Epclusa. The managed care organization confirmed and agreed with our findings that these brand name drugs should have been substituted with a generic drug, resulting in an overpayment of $363,377. OMIG stated it has not yet reviewed the claims but that it was in the process of developing a notification letter to the managed care organization. We encourage DOH and OMIG to review the claims identified to recover overpayments identified in our initial audit as appropriate.

**Response #3**

OMIG performed data analysis on the OSC-identified payments not already adjusted or recovered. OMIG is in the process of following up with the Plan to determine an appropriate course of action. Pursuant to State regulations, any identified overpayments OMIG pursues for recovery are subject to the provider's right to due process.