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OFFICE OF THE STATE COMPTROLLER

July 3, 2024

James V. McDonald, M.D., M.P.H.
Commissioner
Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

Re: Improper Payments for Brand Name Drugs
Report 2024-F-9

Dear Dr. McDonald:

Pursuant to the State Comptroller's authority as set forth in Article V, Section 1 of the State Constitution and Article II, Section 8 of the State Finance Law, we have followed up on the actions taken by officials of the Department of Health (DOH) to implement the recommendations contained in our initial audit report, *Improper Payments for Brand Name Drugs* (Report 2020-S-62).

Background, Scope, and Objective

DOH administers New York's Medicaid program. The Medicaid program covers medically necessary prescription and non-prescription drugs. State law directs pharmacies to substitute prescribed drugs with less expensive drugs containing the same active ingredients, dosage form, and strength. Generally, this means a brand name drug will be substituted with a generic drug that is equivalent to the brand name drug. Prescribers of drugs can indicate that a brand name drug is necessary by directing pharmacies to "dispense as written" either in writing or electronically; otherwise, a generic drug should be dispensed. Usually, brand name drugs are more expensive than generic drugs.

DOH uses two methods to pay for Medicaid pharmacy services: fee-for-service (FFS) and managed care. Under the FFS method, Medicaid-enrolled pharmacy providers submit claims through DOH's claims processing and payment system (eMedNY) for each drug dispensed to Medicaid recipients, and DOH pays providers directly for each claim. Under the managed care method, DOH pays managed care organizations a monthly premium for each Medicaid recipient enrolled in their plans and the managed care organizations arrange for the provision of health care services, including pharmacy benefits, and reimburse providers for those services. As of April 1, 2023, all Medicaid recipients enrolled in mainstream managed care received their prescription drugs through NYRx, the Medicaid Pharmacy Program, which is FFS.

The objective of our initial audit, issued on December 13, 2022, was to determine whether Medicaid made improper payments for brand name drugs. The audit found $1,102,823 in Medicaid overpayments for brand name prescription drugs where generic drugs were available. This included overpayments of $739,446 for FFS pharmacy claims for the period

July 2016 through July 2021. These overpayments were for brand name drug claims where prescriptions allowed for generic substitutions and there was a generic drug available. The remaining overpayments of $363,377 came from 21 pharmacy claims paid by one managed care organization from October 2019 through December 2020 where a brand name drug was incorrectly dispensed and paid instead of a generic drug due to a system malfunction when the claims were processed and paid. The audit also identified an additional $1,011,990 in potential cost avoidance associated with FFS claims for drugs that appear to be generic drugs but were paid using brand name pricing methods for the period April 2017 through January 2022.

The objective of our follow-up was to assess the extent of implementation, as of May 16, 2024, of the three recommendations included in our initial audit report.

Summary Conclusions and Status of Audit Recommendations

DOH officials made some progress in addressing the problems we identified in our initial audit report. For example, they instituted a system enhancement that identified certain drugs as generic, which more accurately reflects their approval status by the federal Food and Drug Administration (FDA). However, our follow-up found that the system enhancement did not apply to all FDA-approved generics, and since our initial audit, Medicaid has paid an additional $6.3 million for drugs that appear to be generic drugs but were paid using brand name drug pricing methods. In addition, the Office of the Medicaid Inspector General (OMIG) has made minimal progress in reviewing and recovering any improper payments identified in the initial report. Of the initial report's three audit recommendations, two were not implemented and one was partially implemented.

Follow-Up Observations

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.

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's recommendation, 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 issues 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.

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 proprietary 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 marketed 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 at 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 numeric identifier used to identify drugs) for authorized generic or unbranded biologic drugs were identified as brand name drugs (the remaining 1,236 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 those claims being for unbranded biologic insulins (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.

Recommendation 3

Review the 21 Epclusa encounter claims identified and ensure overpayments 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 drug 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 and recover overpayments identified in our initial audit as appropriate.

Major contributors to this report were Daniel Rossi, Justine Maloy, and Kevin Ainsworth.

DOH officials are requested, but not required, to provide information about any actions planned to address the unresolved issues discussed in this follow-up within 30 days of the report's issuance. We thank the management and staff of DOH for the courtesy and cooperation extended to our auditors during this follow-up.

Sincerely,

Mark Breunig
Audit Manager

cc: Melissa Fiore, Department of Health
Frank T. Walsh, Jr., Office of the Medicaid Inspector General