Department of Health

Medicaid Program: Improper Payments for Brand Name Drugs

Report 2020-S-62 | December 2022

OFFICE OF THE NEW YORK STATE COMPTROLLER
Thomas P. DiNapoli, State Comptroller
Division of State Government Accountability

Audit Highlights

Objective

To determine whether Medicaid made improper payments for brand name drugs. The audit covered the period from July 2016 through January 2022.

About the Program

The Department of Health (Department) 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.

Key Findings

We identified $1,102,823 in Medicaid overpayments for brand name prescription drugs where generic drugs were available. Our review found:

- Overpayments of $739,446 on 16,261 fee-for-service (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.
- Overpayments of $363,377 on 21 pharmacy claims paid by one managed care organization for the period 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.

Additionally, we identified $1,011,990 in potential cost avoidance associated with 27,455 Medicaid 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.

Key Recommendations

- Review the improperly paid claims for brand name drugs that had generics available and ensure overpayments are recovered, as appropriate.
- Review the Department policy that caused claims for generic drugs to be paid using brand name drug pricing methods and ensure corrective actions are taken, where appropriate.

Office of the New York State Comptroller
Division of State Government Accountability

December 13, 2022

Mary T. Bassett, M.D., M.P.H.
Commissioner
Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

Dear Dr. Bassett:

The Office of the State Comptroller is committed to helping State agencies, public authorities, and local government agencies manage their resources efficiently and effectively. By doing so, it provides accountability for the tax dollars spent to support government operations. The Comptroller oversees the fiscal affairs of State agencies, public authorities, and local government agencies, as well as their compliance with relevant statutes and their observance of good business practices. This fiscal oversight is accomplished, in part, through our audits, which identify opportunities for improving operations. Audits can also identify strategies for reducing costs and strengthening controls that are intended to safeguard assets.

Following is a report of our audit of the Medicaid program entitled *Improper Payments for Brand Name Drugs*. This audit was performed pursuant to the State Comptroller's authority under Article V, Section 1 of the State Constitution and Article II, Section 8 of the State Finance Law.

This audit's results and recommendations are resources for you to use in effectively managing your operations and in meeting the expectations of taxpayers. If you have any questions about this report, please feel free to contact us.

Respectfully submitted,

Division of State Government Accountability

Contents

Glossary of Terms

Term	Description	Identifier
Department	Department of Health	*Auditee*
ANDA	Abbreviated new drug application	*Key Term*
BLTG	Brand Less Than Generic Program	*Key Term*
DAW	Dispense as written	*Key Term*
eMedNY	Department's Medicaid claims processing and payment system	*System*
FDA	Food and Drug Administration	*Agency*
FDB	First Databank Inc.	*Contractor*
FFS	Fee-for-service	*Key Term*
GDIT	General Dynamics Information Technology	*Contractor*
MCO	Managed care organization	*Key Term*
MDW	Medicaid Data Warehouse	*System*
NDA	New drug application	*Key Term*
NDC	National Drug Code	*Key Term*
OMIG	Office of the Medicaid Inspector General	*Agency*

Background

The New York State Medicaid program is a federal, state, and local government-funded program that provides a wide range of medical services to those who are economically disadvantaged and/or have special health care needs. The Department of Health (Department) administers the Medicaid program in New York. For the State fiscal year ended March 31, 2022, New York's Medicaid program had approximately 7.8 million recipients and Medicaid claim costs totaled about $74.6 billion (comprising $27.5 billion in fee-for-service health care payments and $47.1 billion in managed care premium payments). The federal government funded about 57.1% of New York's Medicaid claim costs, and the State and the localities (the City of New York and counties) funded the remaining 42.9%.

The State's Medicaid program covers medically necessary prescription and non-prescription drugs. However, Medicaid only covers drugs that are included on the Medicaid Pharmacy List of Reimbursable Drugs. The Department 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 the Department's claims processing and payment system (eMedNY) for each drug dispensed to Medicaid recipients, and the Department pays providers directly for each claim. Under the managed care method, the Department pays managed care organizations (MCOs) a monthly premium for each Medicaid recipient enrolled in their plan and the MCOs arrange for the provision of health care services, including pharmacy benefits, and reimburse providers for those services. MCOs, or their contracted Pharmacy Benefit Manager, process drug claims and reimburse pharmacies directly. MCOs are required to submit encounter claim data to the Department detailing each service or drug provided.

According to the federal Food and Drug Administration (FDA), brand name drugs are sold under a specific proprietary name and are protected by a patent. Typically, generic drugs are identified by the active ingredient, which is the same active ingredient as a brand name drug, meaning they are pharmaceutically and therapeutically equivalent to a brand name drug. Drug manufacturers submit a new drug application (NDA) to request that the FDA approve a new drug for sale and marketing while an abbreviated new drug application (ANDA) is submitted to the FDA for the approval of a generic drug. Generic drugs may have certain minor differences from brand name drugs, such as different inactive ingredients, colors, or flavorings; but they do not affect the performance, safety, or effectiveness of the generic drug. Usually, brand name drugs are more expensive than generic drugs.

State law requires pharmacies to substitute prescribed drugs with less expensive drugs containing the same active ingredients, dosage form, and strength. Usually, this means a brand name drug will be substituted with a generic drug that is equivalent to the brand name drug. Prescribers can indicate that the brand name drug is necessary by directing pharmacies to "dispense as written" (DAW) on prescriptions either in writing or electronically; otherwise, a generic drug should be dispensed.

Drugs may be single-source or multi-source. The Medicaid Pharmacy Policy Manual states single-source drugs are produced or distributed under an original NDA

approved by the FDA, but are not generic or available as a generic. Multi-source drugs are defined as marketed or sold by two or more manufacturers or sold by the same manufacturer under two or more brand names. Multi-source drugs can be either generic or brand name.

The Department has several programs that promote the use of lower-cost drugs to FFS Medicaid recipients. Among them, the Brand Less Than Generic (BLTG) program ensures the use of multi-source brand name drugs when the cost to the State for the brand name drug is less than the cost of the generic equivalent.

In Medicaid FFS, eMedNY generally pays brand name drugs at the lower of various brand name pricing methods, and pays generic drugs using the lower of various generic pricing methods. According to eMedNY system documents, if a brand name drug claim indicates DAW, eMedNY should use brand name pricing methods. However, when a brand name drug claim does not indicate DAW, eMedNY should use generic pricing methods, as long as the prescribed drug is “multi-source” and has an FDA-approved generic drug covered by Medicaid.

Audit Findings and Recommendations

We identified overpayments for brand name prescription drugs totaling $739,446 on 16,261 FFS claims with service dates between July 2016 and July 2021. These claims did not indicate the brand name drug was necessary, and generic drugs were available. Additionally, we identified potential cost avoidance totaling $1,011,990 on 27,455 Medicaid FFS claims for service dates between April 2017 and January 2022. These claims were paid using brand name drug pricing methods, but the drugs appear to be FDA-approved generic drugs. Generic drugs are typically paid using generic pricing methods. Lastly, we identified overpayments totaling $363,377 on 21 claims at one MCO with service dates between October 2019 to December 2020. These 21 claims were improper because a brand name drug was dispensed and paid instead of a generic drug due to a pharmacy claims processing system malfunction when the claims were processed and paid.

Deficiencies in Fee-for-Service Payment Processes

Improper Brand Name Drug Claim Payments

For service dates between July 2016 and July 2021, we identified overpayments totaling $739,446 on 16,261 FFS brand name drug claims that were improperly paid using brand name pricing methods despite the requirement that the brand drug be substituted with a generic drug. These claims met the following conditions and were therefore expected to be paid based on generic pricing methods in accordance with eMedNY system documents:

- DAW was not indicated,
- The brand drug was multi-source,
- The brand drug had a generic drug covered by Medicaid, and
- The brand drug was not in the BLTG program on the date of service.

The Department paid $3,367,602 for these claims. However, if generic pricing methods were used to pay these claims, the Department would have paid $739,446 less than it did.

For example, we identified 1,024 claims that paid a total of $552,577 for various strengths of brand name Oxycontin ER tablets from July 2016 through March 2017. These claims did not indicate DAW. Additionally, on the claim service dates, Oxycontin ER was multi-source, was not in the BLTG program, and had a generic drug covered by Medicaid. These Oxycontin ER claims were processed using brand name pricing methods instead of generic pricing methods, resulting in an overpayment totaling $54,602.

Potential Cost Avoidance in Pricing Generic Drugs

An FDA-approved ANDA certifies a drug as a generic drug, meaning it is bioequivalent (considered equal) and can be an alternative to the brand name drug.

Similarly, an FDA-approved NDA with an "authorized generic" designation certifies that a drug is the exact same product as the brand name drug, but the drug is marketed as a generic drug. Essentially, both ANDA generic and NDA authorized generic drugs are what an average consumer would recognize in a retail pharmacy as generic 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. We identified drugs in eMedNY where the drug label (proprietary) name matched its generic name (based on the first six characters of each name). We refer to this condition as "same label name." For example, the drug label name "Diflorasone 0.05% cream" was matched to its generic name (the active ingredient), "Diflorasone Diacetate."

We identified 27,455 Medicaid FFS drug claims with the "same label name" condition for service dates between April 2017 and January 2022 that were paid using brand name pricing methods. These claims were paid using brand name pricing methods because eMedNY referenced the drugs as brand name single-source drugs on the date of service. Medicaid paid $7,163,804 for these drug claims. If the Department used generic pricing methods to pay these drug claims, it would have paid $1,011,990 less than it did.

We reviewed FDA approval information for five drugs with high total claim paid amounts. The FDA identifies drugs using a unique numeric identifier called the National Drug Code (NDC). We determined two NDCs for Doxepin were NDA authorized generics, and three NDCs, for Diflorasone, Famotidine, and Oxymorphone, were ANDA approved generics. Since the FDA approved these drugs as generic drugs or authorized generic drugs, these five NDCs were expected to be generic drugs in eMedNY and priced using generic pricing methods. However, eMedNY referenced them as brand name drugs and paid them using the more expensive brand name pricing methods.

Department officials stated that claims will be paid according to the drug data loaded in eMedNY. The eMedNY fiscal agent, General Dynamics Information Technology (GDIT), contracts with First Databank Inc. (FDB) to obtain drug data for eMedNY. GDIT loads the data from FDB files into eMedNY. If FDB files list a drug as a brand name or as a single-source drug, regardless of the NDA or ANDA status, then that is how the information is loaded into eMedNY.

Recommendations

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.

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.

Improper Managed Care Payments for a Brand Name Drug

We determined one MCO improperly paid a total of 21 encounter claims for service dates between October 2019 and December 2020 for the brand name drug Epclusa. The MCO confirmed these brand name drugs should have been substituted with a generic drug. The MCO paid a total of $529,238 for these 21 claims. However, we determined the generic drug would have paid $165,861, resulting in an overpayment of $363,377.

According to MCO officials, their Pharmacy Services Team identified a system malfunction in February 2020 that allowed these brand name drug claims to be processed in cases where the generic drug should have been substituted. The MCO reported the system configuration issue to its Pharmacy Benefit Manager, which investigated and confirmed the system error. The MCO implemented a manual review process on March 9, 2020 to prevent further improper payments of Epclusa drug claims by the system. However, nine of the 21 improperly paid claims occurred after they began their manual review because a claim reviewer did not follow the new process. MCOs should report the details of such cases of potential waste to the Office of the Medicaid Inspector General (OMIG) to ensure recoveries are made, as appropriate.

Recommendation

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

Audit Scope, Objective, and Methodology

The objective of our audit was to determine whether Medicaid made improper payments for brand name drugs. The audit findings have different audit periods, as noted throughout the report. Overall, the audit covered the period from July 2016 through January 2022.

To accomplish our objective and assess related internal controls, we used the Medicaid Data Warehouse (MDW) to identify brand name drug pharmacy claims. We interviewed officials from MCOs, the Department, and their contractors, and examined the Department's relevant Medicaid policies and procedures, eMedNY system documentation, and applicable federal and State laws, rules, and regulations.

To identify the audit population, we used the MDW to extract FFS claims and MCO encounter claims that met certain conditions. 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 drugs were multi-source, had generic drugs covered by Medicaid, and were not in the BLTG program on the dates of service. We identified one MCO's high-risk managed care encounter claims in the MDW for the brand name drug Epclusa with service dates between October 2019 and December 2020. The encounter claims did not indicate DAW and had a generic drug covered by Medicaid on the date of service. We selected these claims based on MCO responses received during our audit survey.

We separately extracted additional FFS pharmacy claims with dates of service from April 2017 through January 2022 where the drug label (proprietary) name matched its generic name (based on the first six characters of each name), the drug was referenced as a brand name drug in eMedNY, and the claim did not indicate DAW. We reviewed FDA approval information for five judgmentally selected drugs with high total claim paid amounts. Because the sample was judgmentally selected, the results cannot be projected to this population as a whole.

Lastly, we calculated what the claims would have paid had generic pricing methods been used. Based on our audit work, we believe the data obtained from the MDW and eMedNY was sufficiently reliable for the purposes of this audit.

We shared our methodology and our findings, including the calculation of overpayments, with officials from the Department and OMIG for their review.

Statutory Requirements

Authority

The audit was performed 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 conducted our performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

In addition to being the State Auditor, the Comptroller performs other constitutionally and statutorily mandated duties as the chief fiscal officer of New York State. They include operating the State's accounting system; preparing the State's financial statements; and approving State contracts, refunds, and other payments. These duties could be considered management functions for purposes of evaluating organizational independence under generally accepted government auditing standards. In our professional judgment, these duties do not affect our ability to conduct this independent audit of the Department's oversight and administration of Medicaid payments for brand name drugs.

Reporting Requirements

We provided a draft copy of this report to Department officials for their review and formal comment. We considered the Department's comments in preparing this report and have included them in their entirety at the end of the report. In their response, Department officials agreed with two audit recommendations and disagreed with one audit recommendation. We addressed the Department's disagreement in our State Comptroller's Comment, which is embedded within the Department's response. Separately from this report, we provided the Department information about findings related to communicating BLTG program drug changes.

Within 180 days after final release of this report, as required by Section 170 of the Executive Law, the Commissioner of Health shall report to the Governor, the State Comptroller, and the leaders of the Legislature and fiscal committees, advising what steps were taken to implement the recommendations contained herein, and where recommendations were not implemented, the reasons why.

Agency Comments and State Comptroller's Comment

NEW YORK STATE OF OPPORTUNITY. | Department of Health

KATHY HOCHUL
Governor

MARY T. BASSETT, M.D., M.P.H.
Commissioner

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

December 2, 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 Draft Audit Report **2020-S-62** entitled, "Improper Medicaid Payments for Brand Name Drugs."

Thank you for the opportunity to comment.

Sincerely,

Kristin M. Proud

Kristin M. Proud
Acting Executive Deputy Commissioner

Enclosure

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Department of Health Comments to Draft Audit Report 2020-S-62 entitled, "Improper Medicaid 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 Draft Audit Report 2020-S-62 entitled, "Improper Medicaid 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.

In collaboration with the Department, the Office of the Medicaid Inspector General (OMIG) is currently performing analysis on the updated OSC data and methodology provided to determine an appropriate course of action.

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:

Abbreviated new drug applications (ANDA) and new drug applications (NDA) evaluated by the Food and Drug Administration (FDA) that are deemed single source products, reimburse at the brand reimbursement logic. These claims are inaccurately identified as being overpaid by OSC (brand reimbursement logic) in the claims reviewed by the Department.

State Comptroller's Comment – As stated in the report, the Department made the choice to pay certain generic drugs at the higher brand name drug reimbursement based on data loaded to eMedNY from a contractor. The Department did not provide a State or federal regulation requiring them to do so; therefore, we encourage the Department to review their internal policy that led to the reimbursement of generic drugs as if they were brand name drugs.

Recommendation #3:

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

Response #3:

In collaboration with the Department, OMIG is currently performing analysis on the OSC data and methodology provided to determine an appropriate course of action.

Contributors to Report

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