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Missouri Did Not Obtain Millions of Dollars in Rebates for Medicaid Physician-Administered and Pharmacy Drugs

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Why OIG Did This Audit

- For a covered outpatient drug to be eligible for Federal reimbursement under the Medicaid program's drug rebate requirements, manufacturers must pay rebates to the States for the drugs.
- States invoice the manufacturers for rebates to reduce the cost of drugs to the program.
- This audit is a followup to a previous OIG audit, which reported that between January 1, 2009, and December 31, 2011, Missouri did not always comply with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs.
- This audit, one of a series of OIG audits of the Medicaid drug rebate program, sought to determine whether Missouri complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered and pharmacy drugs.

What OIG Found

- Between January 1, 2019, and December 31, 2022 (audit period), Missouri did not invoice for, and collect from manufacturers, rebates for $9.7 million (Federal share) for physician-administered drugs and $2.5 million (Federal share) for pharmacy drugs.
- Also, during our audit period, Missouri did not invoice manufacturers for rebates for $165,783 (Federal share) for other physician-administered drugs that could have been eligible for rebates.
- Furthermore, Missouri did not implement our previous audit recommendations.

What OIG Recommends

We make six recommendations to Missouri, including that it refund to the Federal Government $9.7 million (Federal share) for physician-administered drugs and obtain rebates for, and refund to the Federal Government, $2.5 million (Federal share) for pharmacy drugs. We also recommend that Missouri work with CMS to determine the unallowable portion of the $165,783 (Federal share) for claims for other physician-administered drugs that may have been required to be rebated; that it work with CMS to resolve all of our previous audit recommendations; and that it strengthen internal controls. The full recommendations are in the report.

Missouri stated that it would work with CMS to resolve our recommendation regarding the $165,783 (Federal share) for claims for other physician-administered drugs that may have been required to be rebated. Missouri did not indicate concurrence or nonconcurrence with our other recommendations but described corrective actions it had taken and planned to take.

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INTRODUCTION

WHY WE DID THIS AUDIT

For a covered outpatient drug to be eligible for Federal reimbursement under the Medicaid program's drug rebate requirements, manufacturers must pay rebates to the States for the drugs. States generally offset their Federal share of these rebates against their Medicaid expenditures. States invoice the manufacturers for rebates to reduce the cost of drugs to the program. However, previous Office of Inspector General (OIG) audits found that States did not always invoice and collect all rebates due for drugs administered by physicians.[1] For this audit, we reviewed the Missouri Department of Social Services's (State agency's) invoicing for rebates for physician-administered and pharmacy drugs for the period January 1, 2019, through December 31, 2022 (audit period).[2]

This audit is a followup to a previous OIG audit, which reported that between January 1, 2009, and December 31, 2011, the State agency did not always comply with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs.[3] That previous audit recommended, among other things, that the State agency refund to the Federal Government over $34.8 million (Federal share) of drugs that were not eligible for Federal reimbursement.

OBJECTIVE

Our objective was to determine whether the State agency complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered and pharmacy drugs.

BACKGROUND

Medicaid Drug Rebate Program

The Medicaid drug rebate program became effective in 1991 (the Social Security Act (the Act) § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the drug's manufacturer must enter into a rebate agreement that is administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each have specific functions under the program.

[1] Physician-administered drug audit reports issued by the OIG are published on the OIG website.

[2] These data were the most recent data available at the start of the audit.

[3] *Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs* (A-07-14-06051), Apr. 13, 2015.

Manufacturers are required to submit a list to CMS of all covered outpatient drugs and to report each drug's average manufacturer price and, where applicable, best price.[4] On the basis of this information, CMS calculates a unit rebate amount for each drug and provides the information to the States each quarter. Covered outpatient drugs reported by participating drug manufacturers are listed in the CMS Medicaid Drug File, which identifies drugs with such fields as National Drug Code (NDC), unit type, units per package size, and product name.

Section 1903(i)(10) of the Act prohibits Federal reimbursement for States that do not capture the information necessary for invoicing manufacturers for rebates as described in section 1927(a)(7) of the Act.[5] To invoice for rebates, States capture drug utilization data that identifies, by NDC, the number of units of each drug for which the States reimbursed Medicaid providers and report the information to the manufacturers (the Act § 1927(b)(2)(A)). The number of units is multiplied by the unit rebate amount to determine the actual rebate amount due from each manufacturer.

States report drug rebate accounts receivable data to CMS on the Medicaid Drug Rebate Schedule. This schedule is part of the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program report (Form CMS-64), which contains a summary of actual Medicaid expenditures for each quarter and is used by CMS to reimburse States for the Federal share of Medicaid expenditures.

States' Collection of Rebates for Physician-Administered Drugs

Drugs administered by a physician are typically invoiced to the Medicaid program on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes.[6] To collect rebates for drugs, States submit to the manufacturers the drug utilization data containing NDCs for the drugs. NDCs enable States to identify the drugs and their manufacturers to facilitate the collection of rebates for the drugs. Before the Deficit Reduction Act of 2005 (DRA), many States did not collect rebates on physician-administered drugs if the drug claims did not contain NDCs.

The DRA amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs for all single-source physician-administered drugs and the top 20

[4] Section 1927(b) of the Act and section II of the Medicaid rebate agreement.

[5] Additionally, CMS issued a final rule on September 26, 2024, that amended 42 CFR § 447.520 to require States to collect NDC information on all covered outpatient single-source and multiple-source physician-administered drugs. Specifically, to receive Federal reimbursement States must invoice for rebates for all covered outpatient physician-administered drugs, including those that are not single-source drugs and are not on CMS's list of top-20 multiple-source drugs (89 Fed. Reg. 79020, 79084-85 (Sept. 26, 2024)).

[6] HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies. The HCPCS codes associated with physician-administered drugs generally begin with a "J" and are referred to as J-Codes. These physician-administered drugs include injectable drugs that ordinarily cannot be self-administered, such as chemotherapy drugs, immunosuppressive drugs, and inhalation solutions.

multiple-source physician-administered drugs.[7] For purposes of the Medicaid drug rebate program, single-source drugs are those covered outpatient drugs produced or distributed under an original new drug application approved by the Food and Drug Administration (FDA).[8] Multiple-source drugs are defined, in part, as those covered outpatient drugs that have at least one other drug rated as therapeutically equivalent by the FDA.[9] Beginning on January 1, 2007, CMS was responsible for publishing annually the list of the top 20 multiple-source drugs by HCPCS codes that had the highest dollar volume dispensed.

The State Agency's Medicaid Drug Rebate Program

The State agency is responsible for invoicing and collecting Medicaid drug rebates for physician-administered and pharmacy drugs.[10] The State agency required health care providers to include NDCs on claims for all physician-administered and pharmacy drugs. According to the State agency's *MO HealthNet Pharmacy Manual*, Section 13.1.B, January 2019 edition, providers must include the NDCs when submitting their claims for all medications administered in a clinic or outpatient hospital setting.[11] The State agency's *MO HealthNet Pharmacy Manual* has been incorporated into the Missouri Code of State Regulations (CSR) (13 CSR 70-3.100(2)).

During our audit period, the State agency contracted with a fiscal agent, which invoiced drug manufacturers for rebates for physician-administered and pharmacy drugs. The State agency handled all other functions related to the Medicaid drug rebate program, such as collecting funds and resolving disputes with drug manufacturers.

HOW WE CONDUCTED THIS AUDIT

We reviewed physician-administered and pharmacy drug claims totaling $6.4 billion that the State agency paid during our audit period. These paid claims consisted of $667 million in physician-administered drugs and $5.7 billion in pharmacy drugs.

[7] The term "top-20 multiple-source drugs" is drawn from a CMS classification and describes these drugs in terms of highest dollar volume of physician-administered drugs in Medicaid (the Act § 1927(a)(7)(B)(i)). CMS published lists of the top 20 multiple-source drugs (with respective HCPCS codes and NDCs) in 2006, 2009, 2010, and 2011 and then not again until 2021.

[8] Section 1927(k)(7) of the Act. Single-source drugs are commonly referred to as "brand-name" drugs.

[9] Section 1927(k)(7) of the Act. According to the definition of "therapeutically equivalent" in the FDA Glossary of Terms, a therapeutically equivalent drug product can be substituted for another product to achieve the same clinical effect as the prescribed drug.

[10] The term "pharmacy drugs" generally refers to prescription drugs dispensed from a retail or other outpatient pharmacy.

[11] Although the manual was updated during our audit period and after the audit period, the relevant language that was summarized here did not substantively change.

We used the quarterly CMS Medicaid Drug Rebate files and the Medicaid Drug Product files to determine whether the NDCs listed on the claims were classified as single-source drugs or multiple-source drugs. For claims submitted without an NDC, we matched the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify the drug classification.[12] Additionally, we determined whether the HCPCS codes were published in CMS's top-20 multiple-source drug list.

We removed claims for drugs that either were not eligible for rebates or were invoiced for rebates.

We also examined the State agency's responses to the recommendations in our previous report (footnote 3) and discussed these responses, and any followup actions that the State agency had undertaken, with State agency and CMS officials.

We conducted this 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 objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains the details of our audit scope and methodology.

FINDINGS

Although the State agency improved its controls over invoicing for rebates for physician-administered drugs, during our audit period the State agency did not comply with Federal Medicaid requirements for invoicing manufacturers for rebates for some physician-administered and pharmacy drugs. Specifically, the State agency did not invoice for, and collect from manufacturers, rebates for $14.8 million ($9.7 million Federal share) for physician-administered drugs.[13] Of this amount, $14.5 million ($9.5 million Federal share) was for single-source drugs and $311,551 ($204,564 Federal share) was for top-20 multiple-source drugs.[14]

[12] The Medicare Part B crosswalk is published quarterly by CMS and is based on drug and biological information submitted to CMS by manufacturers. CMS uses this information, along with pricing data submitted by manufacturers, to calculate a volume-weighted sales price for each HCPCS code, which becomes the basis for the reimbursement rate that States pay to health care providers for the following quarter. CMS instructed States that they could use the crosswalk as a reference because HCPCS codes and NDCs are standardized codes used across health care programs (State Medicaid Director Letter No. 06-016 (July 11, 2006)). If the claim did not include the NDC, we used the Part B crosswalk to identify drug classifications for all of the NDCs that map to the HCPCS code from the claim. Then we used the most conservative drug classification. For example, if a HCPCS code had NDCs with drug classifications of single-source and multiple-source, we categorized the claim as multiple-source.

[13] Specifically, the State agency did not invoice manufacturers for rebates associated with drug expenditures that totaled $14,801,086 ($9,714,869 Federal share).

[14] Specifically, $14,489,535 ($9,510,305 Federal share) was for single-source drugs.

In addition, we were unable to determine whether, in some cases, the State agency was required to invoice for rebates for other physician-administered drug claims. Although the State agency required that physician-administered drug claims be submitted with the NDC, which is necessary to invoice manufacturers for rebates associated with these drugs, the State agency did not always reject payment for claims that did not include an NDC. These claims totaled $253,294 ($165,783 Federal share). Because these claims did not include NDCs, and some did not include procedure codes, we could not always ascertain whether they were single-source drugs or top-20 multiple-source drugs and were thus required to be invoiced for rebate (footnote 12).

We also identified $3.8 million ($2.5 million Federal share) in pharmacy drug claims for which the State agency did not collect rebates from manufacturers.[15]

Because the State agency's internal controls did not always ensure that it invoiced manufacturers to secure rebates and did not always deny claims that were submitted without an NDC, the State agency improperly claimed Federal reimbursement for these drugs.

Furthermore, the State agency did not implement our previous report's recommendations in a timely manner (footnote 3). The State agency began to invoice drug manufacturers for rebates for physician-administered drugs that we identified in our previous audit in November 2022, which was more than 7 years after issuance of our previous audit report.

FEDERAL REQUIREMENTS AND STATE AGENCY REGULATIONS AND GUIDANCE

The DRA amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs. States must capture NDCs for single-source and top-20 multiple-source drugs (the Act § 1927(a)(7)(C)). To secure rebates, States are required to report certain information to manufacturers within 60 days after the end of each rebate period (the Act § 1927(b)(2)(A)). Federal regulations prohibit Federal reimbursement for physician-administered drugs for which a State has not required the submission of claims containing NDCs (42 CFR § 447.520).

The State agency required NDCs for all physician-administered and pharmacy drugs (footnote 10) during our audit period. However, State agency officials stated that their system was not updated until August 30, 2020, to deny all physician-administered and pharmacy drug claims (except crossover claims) that were submitted without an NDC.[16]

Appendix B contains Federal requirements and State agency guidance related to physician-administered drugs.

[15] Specifically, the State agency did not collect rebates associated with drug expenditures that totaled $3,773,346 ($2,478,099 Federal share) for pharmacy drugs.

[16] The term "crossover claims" refers to Medicaid claims for Federal reimbursement that involve enrollees who are eligible for both Medicare and Medicaid services (also known as "dual-eligible" enrollees).

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON SOME SINGLE-SOURCE PHYSICIAN-ADMINISTERED DRUGS

The State agency improperly claimed Federal reimbursement of $14.5 million ($9.5 million Federal share) for single-source physician-administered drug claims for which it did not invoice manufacturers for rebates (footnote 14).

Because the State agency did not invoice manufacturers for rebates for these single-source drugs, these claims were not eligible for Federal reimbursement.

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON SOME TOP-20 MULTIPLE-SOURCE PHYSICIAN-ADMINISTERED DRUGS

The State agency improperly claimed Federal reimbursement of $311,551 ($204,564 Federal share) for top-20 multiple-source physician-administered drug claims for which it did not invoice manufacturers for rebates.

Between 2012 and June 2021, CMS did not provide State Medicaid agencies with an annual list of the top-20 multiple-source HCPCS codes and their respective NDCs. We therefore relied on the 2011 list to identify top-20 multiple-source physician-administered drugs from the start of our audit period (January 1, 2019) until the publication of the updated list in June 2021. We then used the June 2021 list to identify top-20 multiple-source physician-administered drugs from that point to the end of our audit period (December 31, 2022).

We determined that for our audit period, the State agency did not always submit the utilization data for the top 20 multiple-source physician-administered drugs (on either the 2011 or 2021 lists) to the drug manufacturers for rebate purposes.

Because the State agency did not invoice manufacturers for rebates for these top-20 multiple-source drugs, these claims were not eligible for Federal reimbursement.

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON OTHER PHYSICIAN-ADMINISTERED DRUGS

We were unable to determine whether, in some cases, the State agency was required to invoice for rebates for other physician-administered drug claims.

Although the State agency required that physician-administered drug claims be submitted with the NDCs, which is necessary to invoice manufacturers for rebates associated with these drugs, the State agency did not always reject payment for claims that did not include an NDC. These claims totaled $253,294 ($165,783 Federal share). Because these claims did not include NDCs, and some did not include procedure codes, we could not always ascertain whether they were single-source or top-20 multiple-source drugs and were thus required to be invoiced for rebate (footnote 12).

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON SOME PHARMACY DRUGS

The State agency did not collect rebates from manufacturers for claims totaling $3.8 million ($2.5 Federal share) for pharmacy drugs (footnotes 10 and 15).

The State agency requires health care providers to include NDCs on claims for all physician-administered and pharmacy drugs. According to the State agency's *MO HealthNet Pharmacy Manual*, Section 13.1.B, January 2019 edition, providers must include the NDCs when submitting their claims for all medications administered in a clinic or outpatient hospital setting. Although the State agency required NDCs, its system was not fully updated to deny all physician-administered and pharmacy drug claims (except crossover claims; footnote 16) that were submitted without an NDC until August 30, 2020.

Because the State agency did not always deny claims that were submitted without an NDC, some claims did not have the NDC; therefore, the State agency did not always have the information necessary to invoice all rebates for physician-administered and pharmacy drugs.

THE STATE AGENCY DID NOT IMPLEMENT PREVIOUS AUDIT RECOMMENDATIONS

Although the State agency has improved its controls over invoicing for rebates for physician-administered drugs, during our audit period the State agency did not fully implement our previous report's recommendations, including refunding for claims for all physician-administered drugs. This contributed to the continuing deficiencies we identified in this audit.

Specifically, our current audit is a followup to a previous OIG audit (footnote 3), which reported that between January 1, 2009, and December 31, 2011, the State agency did not always comply with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs. That previous audit recommended that the State agency refund to the Federal Government $34.2 million (Federal share) for single-source, and $656,000 (Federal share) for top-20 multiple-source, physician-administered drugs. Our previous audit also recommended that the State agency work with CMS to determine the unallowable portion of $13.2 million (Federal share) in other physician-administered drugs and refund that amount.

Furthermore, we recommended in that previous report that the State agency work with CMS to determine and refund the unallowable Federal reimbursement for physician-administered drugs claimed without NDCs and not billed for rebates after December 31, 2011; and that the State agency update its system edits to reject claims for all physician-administered drugs that do not include NDCs.

The State agency did not concur with any of our previous report's recommendations. The State agency's written comments on our previous report stated, in part, that the requirements for the collection of rebates on physician-administered drugs, implemented as part of the DRA, created "significant administrative and financial" difficulties for hospitals in Missouri. The State

agency added that CMS had previously granted the State agency a "hardship exemption" to give the State agency additional time to comply with the NDC reporting requirements. In our response to the State agency's written comments on our previous report, we noted that this exemption expired on June 30, 2008, which was 6 months before the beginning of the audit period for that previous audit. Our response also noted that the hardship exemption had expired over 6 years before issuance of that audit's final report. In the interim, the State agency had not taken the steps necessary to ensure that providers submit NDCs with physician-administered drug claims in keeping with the requirements of the DRA.

In November 2022, more than 7 years after the issuance of our previous audit report, the State agency reported to CMS that it had begun to invoice drug manufacturers for the rebates we had identified in our previous audit. In response to a query from us, CMS stated that as of July 2025, the State agency had not invoiced drug manufacturers for all of the physician-administered drug claims included in our previous audit's recommendations. CMS added that invoicing efforts were still ongoing.

RECOMMENDATIONS

We recommend that the Missouri Department of Social Services:

- refund to the Federal Government $9,510,305 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;

- refund to the Federal Government $204,564 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement;

- work with CMS to determine the unallowable portion of $165,783 (Federal share) for claims for other physician-administered drugs that may have been required to be invoiced, and invoice drug manufacturers for rebates for those drugs;

- obtain rebates for the pharmacy drugs totaling $2,478,099 (Federal share), which had not previously been invoiced for rebate, and refund the Federal share;

- work with CMS to resolve all of the recommendations made in our previous audit report; and

- strengthen internal controls to ensure that all pharmacy and physician-administered drugs eligible for rebates are invoiced.

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the State agency stated that it would work with CMS to resolve our third recommendation. The State agency did not specifically indicate concurrence or nonconcurrence with our other recommendations, but it did describe corrective actions that it had taken or planned to take. The State agency also said that the rebates we identified related to "a small subset of the overall claims" that it had reimbursed, "accounting for 0.29% of total reimbursement during the audit period."

The State agency's comments appear in their entirety as Appendix C.

After reviewing the State agency's comments, we maintain that all of our recommendations remain valid.

STATE AGENCY COMMENTS

For our first, second, and fourth recommendations, for which we identified claims that the State agency should have invoiced drug manufacturers for rebate but did not, the State agency said that in November 2024 and February 2025, it invoiced drug manufacturers for a total of $18.1 million (of the $18.6 million comprising the total amount of the associated findings). The State agency said that during our audit, it had "identified the system error that prevented the claims from being brought into the rebate system and invoiced manufacturers for rebates for much of the audit findings."

The State agency also stated that "we believe $11,863,720.72 of the recommended disallowance is no longer supported" based on its invoicing efforts.[17] The State agency added that "the Federal share of the rebates was returned to CMS on March 2025 and June 2025." The State agency agreed with a disallowance of $329,248.24 "for the claims [that the State agency] is unable to invoice manufacturers."[18]

For our third recommendation, the State agency said that it would work with CMS to determine whether there is an unallowable portion of the $165,783 (Federal share) for claims for other physician-administered drugs that we identified and would invoice drug manufacturers for rebates for those drugs.

The State agency's written comments did not address our fifth recommendation, but in a separate email communication to us after it had submitted those comments, the State agency said that it would continue to work with CMS to resolve all of the recommendations we made in our previous audit report (footnote 3).

[17] Office of Inspector General note—This amount represents the Federal share of the $18.1 million that the State agency said that it invoiced in November 2024 and February 2025.

[18] Office of Inspector General note—This amount represents the Federal share of the remaining claims in our findings for which the State agency said that it was unable to invoice manufacturers.

For our sixth recommendation, regarding the strengthening of internal controls to provide for the invoicing of all eligible pharmacy and physician-administered drugs, the State agency provided details regarding its efforts over time to prevent claims from being paid if they did not include NDCs. The State agency stated that as of August 2020, "[s]ystem updates were completed that [allow] for the denial of all drug HCPCS and CPT code claims (excluding crossover claims) that lack NDCs" and that, as of June 2024, "[s]ystem work was finalized to deny all drug HCPCS and CPT codes billed on crossover claims when no corresponding NDC is present."

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing the State agency's comments on our draft report, we maintain that all of our recommendations remain valid.

We acknowledge the efforts taken by the State agency to invoice drug manufacturers for the findings associated with our first four recommendations, and we commend the State agency's recent efforts to obtain millions of dollars in additional rebates associated with physician-administered drugs that were not initially invoiced. Although the State agency said that it had invoiced a substantial amount of these claims, the invoicing occurred in November 2024 and February 2025, which was after the July 2023 commencement of our audit work. Therefore, we have retained all of these claims in our findings and recommendations. We will close the recommendations as having been implemented when all of the funds we identified have been refunded.

Additionally, we acknowledge the State's efforts to update its payment system edits to help ensure that all claims (including crossover claims; footnote 16) submitted without NDCs are denied for reimbursement.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed physician-administered and pharmacy drug claims totaling $6.4 billion that the State agency paid during our audit period. These paid claims consisted of $667 million in physician-administered drugs and $5.7 billion in pharmacy drugs (footnote 10).

Our audit objective did not require an understanding or assessment of the complete internal control structure of the State agency. We limited our internal control review to obtaining an understanding of the State agency's procedures for and controls over invoicing for Medicaid rebates for physician-administered drugs.

We conducted our audit work, which included contacting the State agency in Jefferson City, Missouri, from July 2023 to August 2025.

METHODOLOGY

To accomplish our objective, we took the following steps:

- We reviewed applicable Federal laws, regulations, and guidance pertaining to the Medicaid drug rebate program and physician-administered and pharmacy drugs.

- We reviewed State agency regulations, guidance, policies, and procedures for rebates for physician-administered and pharmacy drugs.

- We interviewed State agency personnel to gain an understanding of the administration of and controls over the Medicaid rebate invoicing process for physician-administered and pharmacy drugs.

- We obtained lists of the CMS top-20 multiple-source physician-administered drugs, the Medicare Part B crosswalk (footnote 12), the CMS Medicaid Drug Rebate File, and the CMS Medicaid Drug Product File for our audit period.

- We removed claims for 340B entities.[19]

- We obtained from the State agency a detailed list of physician-administered and pharmacy drug claims paid between January 1, 2019, and December 31, 2022. In

[19] Under the 340B drug pricing program (set forth in 42 U.S.C. § 256b), a 340B entity may purchase reduced-price covered outpatient drugs from manufacturers; examples of 340B entities are disproportionate share hospitals, which generally serve large numbers of low-income and/or uninsured patients, and State AIDS drug assistance programs. Drugs subject to discounts under the 340B drug pricing program are not subject to rebates under the Medicaid drug rebate program. Section 1927(j) of the Act and 42 U.S.C. § 256(a)(5)(A).

response to this request, the State agency provided data associated with claims totaling $6.4 billion, consisting of $667 million in physician-administered drugs and $5.7 billion in pharmacy drugs. To analyze these claims data, we took the following steps:

  - We identified single-source drugs based on the classification of the drugs in the quarterly CMS Medicaid Drug Rebate files and the CMS Medicaid Drug Product files. If the claims data did not include an NDC, we matched the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk (footnote 12) to identify all of the NDCs associated with each HCPCS code. Because in each of these cases the NDC was unknown, we used the most conservative drug classification for the NDCs associated with the HCPCS code.

  - We identified the top 20 multiple-source drugs by matching the HCPCS code on the drug claim to the HCPCS code on CMS's top-20 multiple-source drug list.

  - We identified other drugs that were eligible for rebate, but for which we were not able to identify whether the drug was single-source or top-20 multiple-source.

- We removed claims for drugs that either were not eligible for rebates or were invoiced for rebates.

- We followed up with State agency officials for an explanation of eligible claims that had not been invoiced for rebate.

- We examined the State agency's responses to the recommendations in our previous report (footnote 3) and discussed these responses, and any followup actions that the State agency had undertaken, with State agency and CMS officials.

- We discussed the results of our audit with State agency officials.

We conducted this 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 objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: FEDERAL REQUIREMENTS AND STATE AGENCY REGULATIONS AND GUIDANCE RELATED TO PHYSICIAN-ADMINISTERED AND PHARMACY DRUGS

FEDERAL REQUIREMENTS

Under the Medicaid program, States may provide coverage for outpatient drugs as an optional service (the Act § 1905(a)(12)). Section 1903(a) of the Act provides for Federal financial participation (Federal share) in State expenditures for these drugs. The Medicaid drug rebate program, created by the Omnibus Budget Reconciliation Act of 1990 that added section 1927 to the Act, became effective on January 1, 1991. Manufacturers must enter into a rebate agreement with the Secretary of Health and Human Services and pay rebates for States to receive Federal funding for the manufacturer's covered outpatient drugs dispensed to Medicaid patients (the Act § 1927(a)). Responsibility for the drug rebate program is shared among the drug manufacturers, CMS, and the States.

Section 6002 of the DRA added section 1927(a)(7) to the Act to require that States capture information necessary to secure rebates from manufacturers for certain covered outpatient drugs administered by a physician. In addition, section 6002 of the DRA amended section 1903(i)(10) of the Act to prohibit a Medicaid Federal share for covered outpatient drugs administered by a physician unless the States collect the utilization and coding data described in section 1927(a)(7) of the Act.

Section 1927(a)(7) of the Act requires that States shall provide for the collection and submission of such utilization data and coding for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates for all single-source physician-administered drugs effective January 1, 2006, and for the top 20 multiple-source drugs effective January 1, 2008.[20] Section 1927(a)(7)(C) of the Act stated that, effective January 1, 2007, the utilization data must be submitted using the NDC. To secure rebates, States are required to report certain information to manufacturers within 60 days after the end of each rebate period (the Act § 1927(b)(2)(A)).

Federal regulations set conditions for States to obtain a Federal share for covered outpatient drugs administered by a physician and specifically state that no Federal share is available for physician-administered drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to bill a manufacturer for rebates (42 CFR § 447.520).

[20] In general terms, multiple-source drugs are covered outpatient drugs for which there are two or more drug products that are rated therapeutically equivalent by the FDA. See, e.g., section 1927(k)(7) of the Act. Multiple-source drugs stand in contrast to single-source drugs, which do not have therapeutic equivalents. Further, the term "top-20 multiple-source drugs" is drawn from a CMS classification and describes these drugs in terms of highest dollar volume of physician-administered drugs in Medicaid (the Act § 1927(a)(7)(B)(i)).

STATE AGENCY REGULATIONS AND GUIDANCE

The State agency is responsible for invoicing and collecting Medicaid drug rebates for physician-administered and pharmacy drugs (footnote 10). The State agency requires health care providers to include NDCs on claims for all physician-administered and pharmacy drugs. According to the State agency's *MO HealthNet Pharmacy Manual*, Section 13.1.B, January 2019 edition, providers must include the NDCs when submitting their claims for all medications administered in a clinic or outpatient hospital setting (footnote 11). The State agency's *MO HealthNet Pharmacy Manual* has been incorporated into the Missouri CSR (13 CSR 70-3.100(2)).

State agency officials stated that their system was updated, as of August 30, 2020, to deny all physician-administered and pharmacy drug claims (except crossover claims; footnote 16) that were submitted without an NDC.

Missouri Department of Social Services

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Jessica Bax
Director

Mike Kehoe
Governor

September 25, 2025

James I. Korn
Regional Inspector General for Audit Services
Office of Inspector General
Office of Audit Services, Region VII
1201 Walnut Street, Suite 1309
Kansas City, MO 64106

Report Number: A-07-23-06113

Dear Mr. Korn:

The Missouri Department of Social Services (DSS) is writing in response to OIG Report Number A-07-23-06113, which was provided to us by letter dated August 21, 2025. The subject matter of the report is Medicaid reimbursement for physician-administered drugs. For the audit period January 1, 2019, through December 31, 2022, the report concludes that the Department of Social Services, MO HealthNet Division (MHD) "Did Not Obtain Millions of Dollars in Rebates for Medicaid Physician-Administered and Pharmacy Drugs."

The audit report recommends that MHD refund the federal government $9.7 million (federal share) for physician-administered drugs required to be rebated. In addition, the audit found that DSS should refund the federal government $2.5 million (Federal share) for pharmacy drugs.

The audit report also recommends that MHD work with CMS to determine the unallowable portion of the $165,783 (Federal share) for claims for other physician-administered drugs that may have been required to be rebated; that it work with CMS to resolve all previous OIG audit recommendations; and that MHD strengthen internal controls.

The issue of rebates identified in the OIG report relates to a small subset of the overall claims reimbursed by MHD, accounting for 0.29% of total reimbursement during the audit period ($18.6 million/$6.4 billion).

During the ongoing audit, MHD identified the system error that prevented the claims from being brought into the rebate system and invoiced manufacturers for rebates for much of the audit findings. On November 18, 2024 and February 13, 2025, MHD invoiced manufacturers for rebates related to the claims in this audit.

In total, Missouri invoiced manufacturers for rebates related to $18,071,072.04 (reimbursed amount) in drug claims of the total $18,574,431.67 (reimbursed amount) that the OIG concluded should have been invoiced for rebate. Missouri agrees to refund the federal share for the remaining drugs that should have been rebated, the federal share is $329,248.24. With that refund, the audit should be closed.

Single-Source Physician-Administered Drugs Finding

OIG recommends that MHD refund the Federal Government $9,510,305 (Federal Share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement.

The reimbursement amount to providers for this finding is $14,489,534.81. On November 18, 2024, and February 13, 2025, MHD invoiced manufacturers for rebates related to $14,277,388.15 in claims reimbursement.

Top-20 Multiple Source Physician Administered Drugs Finding

OIG recommends that MHD refund to the federal government $204,564 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for federal reimbursement.

The reimbursement amount to providers for this finding is $311,551.38. MHD invoiced manufacturers for rebates related to $240,692.31 in claims reimbursement on November 18, 2024, and February 13, 2025.

Other Physician-Administered Drugs Finding

OIG recommends that MHD work with CMS to determine the unallowable portion of $165,783 (Federal share) for claims for other physician-administered drugs that may have been required to be invoiced and invoice drug manufacturers for rebates for those drugs.

MHD will work with CMS to determine if there is an unallowable portion of $165,783 (Federal share) for claims for other physician-administered drugs that may have been required to be invoiced and invoice drug manufacturers for rebates for those drugs.

Rebates on Some Pharmacy Drugs Finding

OIG recommends that MHD obtain rebates for the pharmacy drugs totaling $2,478,099 (Federal share), which had not previously been invoiced for rebate, and refund the federal share.

The reimbursement amount to providers for this finding is $3,773,345.48. MHD invoiced manufacturers for rebates related to $3,552,991.58 in claims reimbursement on November 18, 2024, and February 13, 2025.

Strengthen Internal Controls

OIG recommends that MHD strengthen internal controls to ensure that all pharmacy and physician-administered drugs eligible for rebates are invoiced.

As of February 1, 2008, MO HealthNet's guidance to providers requires NDCs for all drugs administered to MO HealthNet Participants. However, our system has not been able to deny medical, outpatient, or crossover claims lacking an NDC for all drug HCPCS or CPT codes.
The following outlines the evolution of system changes designed to deny claims without NDCs since 2008:

- February 1, 2008: Guidance was issued stating that NDCs were required for all medical and outpatient claims. At this time, the system only denied claims submitted with J-codes when there was no corresponding NDC. Hospitals reported issues, including their software providers being unable to send NDCs for payment, which adversely affected their cash flow and resulted in fewer claims being submitted. To address this, it was decided that the system would only require NDCs for

the top 20 J-codes for hospital providers to alleviate their difficulties while remaining compliant with the Deficit Reduction Act (DRA). Medical claims continued to be denied if an NDC was not present with the J-code.

- April 1, 2008: System updates allowed the submission of NDCs for all drug HCPCS/CPT codes, including but not limited to C-codes, G-codes, Q-codes, and S-codes, in addition to J-codes. Despite this update, the system could only deny claims lacking NDCs for J-codes.
- May 22, 2015: The system was updated to deny hospital claims for all J-codes submitted without corresponding NDCs rather than just the top 20.
- April 9, 2019: 340B providers were mandated to submit NDCs for J-code drug claims.
- August 30, 2020: System updates were completed that allows for the denial of all drug HCPCS or CPT code claims (excluding crossover claims) that lack NDCs. Denials now extend beyond just J-codes.
- June 16, 2024: System work was finalized to deny all drug HCPCS and CPT codes billed on crossover claims when no corresponding NDC is present.

We believe $11,863,720.72 of the recommended disallowance is no longer supported based on MHD invoicing manufacturers. The federal share of the rebates was returned to CMS on March 2025 and June 2025.

DDS/MHD agrees with a disallowance of $329,248.24 for the claims MHD is unable to invoice manufacturers. MHD strives to ensure NDCs are submitted for every claim and all rebate-eligible claims are invoiced to manufacturers. MHD continues to make systematic improvements to further improve the 0.29% error rate identified by this audit.

Thank you for the opportunity to comment on the OIG Audit.

Sincerely,

/s/

Jessica Bax
Director

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