

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MISSISSIPPI DID NOT ALWAYS
INVOICE REBATES TO
MANUFACTURERS FOR PHYSICIAN-
ADMINISTERED DRUGS**

*Inquiries about this report may be addressed to the Office of Public Affairs at
Public.Affairs@oig.hhs.gov.*



Amy J. Frontz
Deputy Inspector General
for Audit Services

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Office of Inspector General

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Report in Brief

Date: October 2022

Report No. A-07-21-06101

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



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. However, prior OIG audits found that States did not always invoice and collect all rebates due for drugs administered by physicians.

Our objective was to determine whether Mississippi complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs.

How OIG Did This Audit

We reviewed physician-administered drug claims totaling \$88.5 million paid between January 1, 2016, and December 31, 2019 (audit period).

We used the Centers for Medicare & Medicaid Services's (CMS's) Medicare Part B crosswalk and the CMS Medicaid Drug Rebate files to identify single-source and multiple-source drugs. Additionally, we determined whether the Healthcare Common Procedures Coding System codes were published in CMS's top-20 multiple-source drug listing.

Mississippi Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs

What OIG Found

Mississippi did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Mississippi did not invoice for, and collect from manufacturers, rebates associated with \$2.2 million (Federal share) in physician-administered drugs. Of this amount, \$820,732 (Federal share) was for single-source drugs and \$395,621 (Federal share) was for top-20 multiple-source drugs.

Further, we were unable to determine whether Mississippi was required to invoice for rebates associated with claims totaling \$1.0 million (Federal share) for other multiple-source physician-administered drug claims. In addition, Mississippi did not invoice for, and collect from manufacturers, \$35.6 million (Federal share) in rebates for physician-administered drugs invoiced on crossover claims, for which beneficiaries are eligible for both Medicare and Medicaid services. Although its policies required the collection of drug utilization data necessary to invoice for rebates, Mississippi's internal controls did not always ensure that the collected data were used to invoice manufacturers and collect rebates for physician-administered drugs for these claims.

What OIG Recommends and Mississippi Comments

We recommend that Mississippi: (1) refund to the Federal Government \$820,732 (Federal share) for single-source physician-administered drugs and (2) \$395,621 (Federal share) for top-20 multiple-source physician-administered drugs; (3) work with CMS to determine the unallowable portion of \$1.0 million (Federal share) for other multiple-source physician-administered drugs that may have been ineligible for reimbursement, refund that amount, and consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable; (4) strengthen internal controls for non-crossover claims to ensure that all eligible physician-administered drugs are invoiced; and (5) consider revising its payment methodology going forward regarding payments for crossover claims.

Mississippi concurred with our fourth recommendation but did not concur with our other recommendations. Mississippi said that it disputed our findings for single-source and top-20 multiple-source drugs in their entirety. Mississippi added that it was transitioning to a new fiscal agent and a new methodology for paying crossover claims in the future. We removed claims totaling \$12,767 (Federal share) for this final report and adjusted our recommendations; we otherwise maintain that our findings and recommendations remain valid.

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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, prior Office of Inspector General (OIG) audits found that States did not always invoice and collect all rebates due for drugs administered by physicians. (Appendix B lists previous OIG audits and reviews of the Medicaid drug rebate program.¹) For this audit, we reviewed the Mississippi Division of Medicaid's (State agency's) invoicing for rebates for physician-administered drugs for the period January 1, 2016, through December 31, 2019.

OBJECTIVE

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

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.² 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. To invoice for rebates, States capture drug utilization data that identifies,

¹ OIG performed similar audits for rebates due for drugs administered by physicians to fee-for-service and Medicaid managed care organizations' enrollees. These audits are included in Appendix B.

² Section 1927(b) of the Act and section II of the Medicaid rebate agreement.

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.³ 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 multiple-source physician-administered drugs.⁴ 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).⁵ 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.⁶ 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.

³ 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.

⁴ 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)).

⁵ Section 1927(k)(7) of the Act. Single-source drugs are commonly referred to as "brand-name" drugs.

⁶ 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.

The State Agency's Medicaid Drug Rebate Program

The State agency is responsible for invoicing and collecting Medicaid drug rebates for physician-administered drugs. The State agency is required to submit drug utilization data to manufacturers, detailing drug usage by Medicaid beneficiaries, within 60 days of the end of each quarter. During our audit period, the State agency contracted with a fiscal agent to handle the claims data.⁷ The fiscal agent processed, invoiced, and collected Federal rebates through its rebate administration system. The fiscal agent was also responsible for payment tracking and reconciliation as well as resolving disputes related to Federal rebates. The fiscal agent housed historic quarterly rebate data in its rebate management system.

HOW WE CONDUCTED THIS AUDIT

We reviewed physician-administered drug claims totaling \$88,524,026 that were paid by the State between January 1, 2016, and December 31, 2019 (audit period).

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.⁸ 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 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.

⁷ During our audit period, the State agency contracted with Conduent Business Services, LLC, to act as its fiscal agent to support it in meeting the requirements of the Medicaid Drug Rebate Program.

⁸ 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 the State pays to 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 (Jul. 11, 2006)). If the claim did not include the NDC, we used the Part B crosswalk to identify drug classifications for all 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.

FINDINGS

During our audit period, the State agency did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. The State agency did not invoice for, and collect from manufacturers, rebates totaling \$2.9 million (\$2.2 million Federal share) for physician-administered drugs.⁹ Of this amount, \$1.1 million (\$821,000 Federal share) was for single-source drugs and \$525,000 (\$396,000 Federal share) was for top-20 multiple-source drugs.¹⁰ Because the State agency's internal controls did not always ensure that it invoiced manufacturers to secure rebates, the State agency improperly claimed Federal reimbursement for these single-source drugs and top-20 multiple-source drugs.

Further, we were unable to determine whether, in some cases, the State agency was required to invoice for rebates for other multiple-source physician-administered drug claims. Although the State agency generally collected the drug utilization data necessary to invoice manufacturers for rebates associated with these drugs, the State agency did not invoice the manufacturers for rebates associated with the claims totaling \$1.3 million (\$1.0 million Federal share) for these other multiple-source physician-administered drugs.¹¹ Accordingly, we are recommending that the State agency work with CMS to determine the unallowable portion of the \$1.3 million (\$1.0 million Federal share) of claims and consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable.

In addition, the State agency did not invoice for, and collect from manufacturers, \$46.7 million (\$35.6 million Federal share) in rebates for physician-administered drugs invoiced on crossover claims, for which beneficiaries are eligible for both Medicare and Medicaid services.¹²

Although its policies required the collection of drug utilization data necessary to invoice for rebates on all physician-administered drug claims, the State agency's internal controls did not always ensure that the collected data were used to invoice manufacturers and collect rebates for physician-administered drugs for these claims.

⁹ Specifically, the State agency did not invoice manufacturers for rebates associated with drug expenditures that totaled \$2,940,081 (\$2,218,202 Federal share).

¹⁰ This amount consisted of \$1,086,744 (\$820,732 Federal share) for single-source drugs and \$524,561 (\$395,621 Federal share) for top-20 multiple-source drugs.

¹¹ Specifically, the State agency did not invoice manufacturers for rebates associated with drug expenditures that totaled \$1,328,776 (\$1,001,849 Federal share) for other multiple-source drugs.

¹² Specifically, the State agency did not invoice manufacturers for rebates totaling \$46,699,451 (\$35,611,451 Federal share) for physician-administered drugs invoiced on crossover claims.

FEDERAL REQUIREMENTS AND STATE AGENCY 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 also requires providers of Medicaid services to include the NDC on the claim form when submitting invoices to the State for payment (*Mississippi Division of Medicaid, Provider Billing Handbook, 2014 Edition*).

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

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

The State agency improperly claimed Federal reimbursement of \$1.1 million (\$821,000 Federal share) for single-source physician-administered drug claims for which it did not invoice manufacturers for rebates.

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 \$525,000 (\$396,000 Federal share) for top-20 multiple-source physician-administered drug claims for which it did not invoice manufacturers for rebates.

CMS last provided the State agency with an annual listing of top-20 multiple-source HCPCS codes and their respective NDCs in 2011. We relied upon this listing in order to identify top-20 multiple-source physician-administered drugs. However, the State agency did not always submit the utilization data for the drugs on the list 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 SOME OTHER MULTIPLE-SOURCE PHYSICIAN-ADMINISTERED DRUGS

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

Although the State agency generally collected the drug utilization data necessary to invoice manufacturers for rebates associated with these multiple-source physician-administered drugs, the State agency did not invoice the manufacturers for rebates associated with these drugs, which were not identified as top-20 multiple-source drugs. Providers submitted claims totaling \$1.3 million (\$1.0 million Federal share) that were not used to obtain Medicaid drug rebates. Under the Medicaid drug rebate program, these claims could have been eligible for rebates.

Accordingly, we set aside \$1.3 million (\$1.0 million Federal share) for the remaining multiple-source drug claims and are recommending that the State agency work with CMS to determine the unallowable portion of these claims and consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable.

Although its policies require the collection of drug utilization data necessary to invoice for rebates on all physician-administered drug claims, the State agency's internal controls did not always ensure that the collected data were used to invoice manufacturers and collect rebates for physician-administered drugs.

THE STATE AGENCY HAS AN OPPORTUNITY TO IMPROVE ITS PAYMENT METHODOLOGY FOR CROSSOVER CLAIMS TO OBTAIN REBATES FOR PHYSICIAN-ADMINISTERED DRUGS

The State agency did not invoice for, and collect from manufacturers, \$46.7 million (\$35.6 million Federal share) in rebates for physician-administered drugs invoiced on crossover claims. The term "crossover claims" refers to Medicaid claims for Federal reimbursement that involve beneficiaries who are eligible for both Medicare and Medicaid services (also known as "dual-eligible" beneficiaries). For crossover claims, health care providers invoice Medicare, which calculates its payment first and then submits an invoice containing any applicable coinsurance or deductible amounts to the State agency. As part of the invoice process, Medicare submits two sets of data for these services: (1) the line-item level, which shows each individual service, such as physician-administered drugs, and (2) the header level, which consolidates the services to show a combined total amount for all the services on the claim. The State agency's payment methodology specifies that the State agency pays a claim's coinsurance and deductible amounts, as reported by Medicare, at the header level.

For example, an Infliximab injection, along with other services, was administered to a dual-eligible beneficiary on November 7, 2018.¹³ For this claim, the provider submitted a claim to

¹³ Infliximab is a monoclonal antibody that works to enhance and improve the immune system. It is used to reduce the symptoms of moderate-to-severely active Crohn's disease and ulcerative colitis.

Medicare for reimbursement. Medicare paid \$3,362 for the claim and then submitted the claim to the State agency for \$858. In conformance to its payment methodology for crossover claims, the State agency paid the coinsurance of \$858 at the header level. If the State agency had paid at the line-item level, the State agency could have collected an estimated \$2,295 (\$1,753 Federal share) for this claim.

Because the State agency made these payments only at the header level, the crossover claims paid during our audit period were not eligible for rebate. We acknowledge that the State agency is not required to break out its payments on a line-item level; however, we believe that the State agency has an opportunity to improve its administration of the Medicaid drug rebate program insofar as crossover claims are concerned. If it had put in place a revised payment methodology that allowed the State agency to pay on the line-item level, we estimate that the State agency could have invoiced for additional rebates totaling \$46.7 million (\$35.6 million Federal share) during our audit period.¹⁴

RECOMMENDATIONS

We recommend that the Mississippi Division of Medicaid:

- refund to the Federal Government \$820,732 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;
- refund to the Federal Government \$395,621 (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 \$1,001,849 (Federal share) for other claims for multiple-source physician-administered drugs that may have been ineligible for Federal reimbursement, refund that amount, and consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable;
- strengthen internal controls for non-crossover claims to ensure that all eligible physician-administered drugs are invoiced; and
- consider revising its payment methodology going forward regarding payments for crossover claims, thereby to allow collection of manufacturers' rebates for associated physician-administered drugs.

¹⁴ To estimate the amount the State agency could have invoiced manufacturers for physician-administered drugs as reported on crossover claims, we multiplied the allowed amount from the claims data by the percentage of rebates collected by the State, as reported on the Form CMS-64.

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency concurred with our fourth recommendation but did not concur with our other recommendations. For our first two recommendations, the State agency said that it had “identified 1,164 claims that should not have been rebated and therefore, should not have been included in the refund calculation. Further, because of the number of claims incorrectly identified by the OIG as rebate eligible, [the State agency] disputes this entire finding and believes, if time and manpower permitted for further analysis, no refund would be necessary.”

For our third recommendation, the State agency said that it was not sure which multiple-source drugs were referred to in the associated finding, “which makes it difficult for [the State agency] to properly respond.” The State agency also described its process for requiring health care providers to include NDCs on physician-administered drug claims and for matching the claimed NDCs with the NDCs on the quarterly CMS Medicaid Drug Rebate File to initiate rebate invoicing.

The State agency concurred with our fourth recommendation and stated that it was in the process of transitioning to a new fiscal agent and was “diligently working with this agent to ensure that up-to-date drug rebate policies and procedures are followed.” The State agency added that it would “work to strengthen internal controls to ensure that all rebate-eligible drugs are invoiced, including retrospectively invoicing as needed.”

The State agency did not concur with our fifth recommendation, noting that under section 1902(n)(2) of the Act, it is not required to break out its payments for crossover claims at the line-item level. The State agency added, however, that it would require the new fiscal agent to devise a methodology for invoicing for rebate-eligible crossover claims, which would involve paying these claims at the line-item level.

The State agency’s comments appear in their entirety as Appendix D.

OFFICE OF INSPECTOR GENERAL RESPONSE

During the audit fieldwork, we asked the State agency to review the claims data for the physician-administered drugs that, according to our analysis, should have been rebated. In response, the State agency identified 1,164 claims, totaling \$346,559 (\$262,909 Federal share), that it did not believe were eligible for rebate. Of these 1,164 claims, we removed 987 claims, totaling \$329,652 (\$250,142 Federal share), from our findings prior to issuance of the draft report. A majority of these 987 claims had been processed and were then subsequently reversed or were claims for 340B entities. Thus, in its comments on our draft report, the State agency based its nonconcurrences with our first three recommendations on a number of

claims, almost 85 percent of which (987 divided by 1,164) we had removed from our findings before we issued our draft report.

After reviewing the State agency's comments on our draft report, we removed the remaining 177 claims (of the 1,164 to which the State agency referred) and revised our findings, and the dollar amounts in our first three recommendations, by a total of \$16,907 (\$12,767 Federal share) for this final report.

The audit process that we used gave the State agency multiple opportunities to identify specific claims that were not eligible for rebates. As discussed above, we worked with the State agency to identify claims that were not eligible for drug rebate. Accordingly, we maintain that our remaining findings, as conveyed in this final report, are valid.

Nothing else in the State agency's comments caused us to revise our findings and recommendations. With respect to the State agency's comments on our third recommendation, we acknowledge that the State agency requires providers to include NDCs when invoicing for physician-administered drugs. Regarding its comment about being unsure which claims were referenced in our third recommendation, we note that, as part of our exit conference, we gave the State agency detailed data on the other multiple-source drug claims that we are setting aside for CMS adjudication.

For our fifth recommendation, we agree with the State agency that—as our report acknowledges—the State agency is not required to break out its payments for crossover claims on a line-item level. We acknowledge as well that because the State agency did not make a payment on these claims at the line-item level, the claims were not eligible for rebate. Contrary to the State agency's nonconcurrency with this recommendation, we believe that the new fiscal agent and new payment methodology that the State agency described in its comments on both our fourth and fifth recommendations offer the State agency the opportunity to improve its administration of the Medicaid drug rebate program in much the same way as our report has suggested.

We maintain that with the exception of the revisions that we discuss above, all of our findings and recommendations remain valid.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed physician-administered drug claims that were paid by the State agency between January 1, 2016, and December 31, 2019 (audit period). During our audit period, the State agency paid \$88,524,026 associated with physician-administered drugs.

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 Jackson, Mississippi, from May 2021 to August 2022.

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 drugs.
- We reviewed State agency policies and procedures for rebates for physician-administered 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 drugs.
- We obtained lists of the CMS top-20 multiple-source physician-administered drugs, the Medicare Part B crosswalk (footnote 8), the CMS Medicaid Drug Rebate File, and the CMS Medicaid Drug Product File for our audit period.
- We obtained a list of 340B entities from the State agency.¹⁵
- We obtained from the State agency a detailed list of physician-administered drug claims paid between January 1, 2016, through December 31, 2019. In response to this request,

¹⁵ 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).

the State agency provided data associated with claims totaling \$88,524,026. Specifically, we took the following steps:

- We identified single-source drugs based on the classification of the drugs in the quarterly CMS Medicaid Drug Rebate File and the CMS Medicaid Drug Product File. 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 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 (footnote 8).
- 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 multiple-source drugs eligible for rebate that were not single-source or top-20 multiple-source drugs.
- We followed up with State agency officials for an explanation of eligible claims that had not been invoiced for rebate.
- We identified the physician-administered drugs invoiced on crossover claims that would have been eligible for a drug rebate if the State agency had made payments on the line-item level and, to estimate the finding amount, we took the following steps:
 - We calculated the State agency's percentage of rebates collected (that is, the total drug rebates received as a percentage of the total drug costs, as reported on Form CMS-64) for the audit period (footnote 14).
 - We multiplied the percentage of rebates collected for each year of our audit period (calculated as explained in the subbullet just above) by the allowed amount from the claims data.
- We discussed the results of our audit with State agency officials on June 16, 2022.

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: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Tennessee Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-07-21-06096</u>	9/14/2022
<i>South Carolina Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs</i>	<u>A-07-21-07003</u>	8/10/2022
<i>Colorado Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-07-17-06075</u>	9/8/2021
<i>New Mexico Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-06-16-00001</u>	6/2/2021
<i>Massachusetts Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-06-18-04001</u>	10/22/2020
<i>Minnesota Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-05-17-00018</u>	10/21/2020
<i>Vermont Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs</i>	<u>A-07-19-06086</u>	9/18/2020
<i>Maine Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs</i>	<u>A-07-18-06079</u>	9/14/2020
<i>Michigan Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-05-17-00017</u>	8/25/2020
<i>Alaska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-09-19-02001</u>	7/21/2020
<i>New York Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-02-18-01016</u>	4/7/2020
<i>New York Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-02-18-01011</u>	2/19/2020
<i>New Jersey Did Not Bill Manufacturers for Tens of Millions of Dollars in Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-02-16-01011</u>	8/30/2019

Report Title	Report Number	Date Issued
<i>Texas Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-06-17-04001</u>	8/21/2019
<i>Connecticut Claimed Unallowable Federal Reimbursement for Medicaid Physician-Administered Drugs That Were Not Invoiced to Manufacturers for Rebates</i>	<u>A-07-18-06078</u>	8/16/2019
<i>Illinois Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-18-00030</u>	6/18/2019
<i>New Jersey Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-02-16-01012</u>	5/9/2019
<i>Indiana Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-17-00038</u>	4/5/2019
<i>Arizona Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-16-02031</u>	2/16/2018
<i>Arkansas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-06-16-00018</u>	2/12/2018
<i>Nebraska Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-07-13-06046</u>	12/22/2017
<i>Texas Did Not Bill Manufacturers for Some Rebates for Pharmacy Drugs of Medicaid Managed-Care Organizations</i>	<u>A-06-16-00004</u>	12/12/2017
<i>Ohio Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-16-00013</u>	11/1/2017
<i>Washington State Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-16-02028</u>	9/26/2017
<i>Hawaii Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-16-02029</u>	9/26/2017
<i>Nevada Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-16-02027</u>	9/12/2017

Report Title	Report Number	Date Issued
<i>Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs of Medicaid Managed-Care Organizations</i>	<u>A-07-16-06065</u>	5/5/2017
<i>Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-16-00014</u>	3/23/2017
<i>Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06050</u>	1/5/2017
<i>Delaware Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-03-15-00202</u>	12/30/2016
<i>Virginia Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-03-15-00201</u>	12/22/2016
<i>California Did Not Bill Manufacturers for Rebates For Physician-Administered Drugs Dispensed to Enrollees of Some Medicaid Managed-Care Organizations</i>	<u>A-09-15-02035</u>	12/8/2016
<i>Kansas Correctly Invoiced Rebates to Manufacturers for Most Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-07-15-06060</u>	8/18/2016
<i>Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06057</u>	5/26/2016
<i>Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06063</u>	3/31/2016
<i>South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06059</u>	2/9/2016
<i>Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06062</u>	1/14/2016
<i>North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06058</u>	1/13/2016
<i>California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<u>A-09-14-02038</u>	1/7/2016

Report Title	Report Number	Date Issued
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06056</u>	9/18/2015
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06049</u>	7/22/2015
<i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-06-12-00060</u>	5/4/2015
<i>Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06051</u>	4/13/2015
<i>Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-13-02037</u>	3/4/2015
<i>Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<u>A-06-14-00031</u>	2/10/2015
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00205</u>	8/21/2014
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-13-06040</u>	8/7/2014
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	<u>A-09-12-02079</u>	4/30/2014
<i>Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<u>A-09-12-02080</u>	4/24/2014
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00200</u>	11/26/2013
<i>Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<u>A-06-12-00059</u>	9/19/2013
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	<u>A-06-10-00011</u>	8/12/2011
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	<u>OEI-03-09-00410</u>	6/24/2011

APPENDIX C: FEDERAL REQUIREMENTS AND STATE AGENCY GUIDANCE RELATED TO PHYSICIAN-ADMINISTERED DRUGS

FEDERAL LAWS

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, 2008.¹⁶ 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

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).

¹⁶ 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 GUIDANCE

According to the State agency's *Mississippi Division of Medicaid, Provider Billing Handbook, 2014 edition*, providers are required to include the NDC when invoicing the State agency for physician-administered drugs.

APPENDIX D: STATE AGENCY COMMENTS

OFFICE OF THE GOVERNOR

Walter Sillers Building | 550 High Street, Suite 1000 | Jackson, Mississippi 39201



MISSISSIPPI DIVISION OF
MEDICAID

September 15, 2022

Report Number A-07-21-06101

Dan Bittner
Assistant Regional Inspector General for Audit Services
HHS – OIG – Office of Audit Services
210 Walnut Street
Neal Smith Federal Building, Room 575
Des Moines, IA 50309

RE: Mississippi Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs

Dear Mr. Bittner,

The Mississippi Division of Medicaid (DOM) has reviewed the Office of the Inspector General draft report entitled *Mississippi Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs*. As requested, DOM's response is attached.

Sincerely,

A handwritten signature in blue ink, appearing to read "Drew Snyder".

Drew Snyder
Executive Director
Mississippi Division of Medicaid

Recommendation 1: Refund to the Federal Government \$821,268 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement

DOM Response: *DOM does not concur.* DOM performed a review of almost 3% of the 44,705 claims used as a basis for this finding and that were included in the calculation of the amount to be repaid to CMS. As a result, DOM identified 1,164 claims that should not have been rebated and therefore, should not have been included in the refund calculation. Further, because of the number of claims incorrectly identified by the OIG as rebate eligible, DOM disputes this entire finding and believes, if time and manpower permitted for further analysis, no refund would be necessary.

Recommendation 2: Refund to the Federal Government \$407,461 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement

DOM Response: *DOM does not concur.* As stated above, DOM performed a review of approximately 3% of the claims used as a basis for this finding. Because of the number of claims incorrectly identified by the OIG as rebate eligible, DOM disputes this entire finding and believes, if time and manpower permitted for further analysis, no refund would be necessary.

Recommendation 3: Work with CMS to determine the unallowable portion of \$1,002,240 (Federal share) for other claims for multiple-source physician-administered drugs that may have been ineligible for Federal reimbursement, refund that amount, and consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable.

DOM Response: *DOM does not concur.* DOM is unsure which multiple-source drugs are referenced in this finding, which makes it difficult for DOM to properly respond. However, DOM submits the following:

- Pursuant to state policy, providers are required to submit NDCs on claims containing physician administered drugs including those billed with a J, Q, and S code.
- Providers billing these HCPCS are required to bill the corresponding NDC with the HCPCS code; otherwise, the claim will deny at the line level.
- The paid claim is then transferred to the rebate system whereby the NDC billed is compared to the most recent CMS quarterly drug file containing rebated NDCs. If the NDC matches the NDC on the file, the NDC is submitted for rebate.
- The state invoices for the top 20 multisource drugs, and, in fact, invoices for any billed NDC billed by a provider matching the rebate file.

Recommendation 4: Strengthen internal controls for non-crossover claims to ensure that all eligible physician-administered drugs are invoiced.

DOM Response: *DOM concurs.* The state is moving to a new fiscal agent and is diligently working with this agent to ensure that up-to-date drug rebate policies and procedures are followed. In addition, during this transition, DOM will work to strengthen internal controls to ensure that all rebate-eligible drugs are invoiced, including retrospectively invoicing as needed.

Recommendation 5: Consider revising its payment methodology going forward regarding payments for crossover claims, thereby to allow collection of manufacturers' rebates for associated physician-administered drugs.

DOM Response: *DOM does not concur.* The term "crossover claims" refers to Medicaid claims for Federal reimbursement that involve beneficiaries who are eligible for both Medicare and Medicaid services (also known as "dual-eligible" beneficiaries). For crossover claims, health care providers bill Medicare, which calculates its payment first and then submits an invoice containing any applicable coinsurance or deductible amounts to the State agency. Although state agencies have the option to pay at the line level, according to the Social Security Act, section 1902(n)(2), this is **not a requirement**. As a result, DOM only pays for the coinsurance/copayment amounts and does not pay a line level amount for each drug. Therefore, crossover claims were not rebated during the time period reviewed.

However, DOM is requiring the new fiscal agent to devise a methodology for invoicing rebate-eligible crossover claims. These crossover claims will be paid at the line level versus the previous method where header level payments were made.