Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MISSISSIPPI DID NOT ALWAYS INVOICE REBATES TO MANUFACTURERS FOR PHYSICIAN-ADMINISTERED DRUGS DISPENSED TO ENROLLEES OF MEDICAID MANAGED-CARE ORGANIZATIONS

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October 2023
A-07-21-06103

Office of Inspector General

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Report in Brief
Date: October 2023
Report No. A-07-21-06103

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

Mississippi Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations

Why OIG Did This Audit

For a covered outpatient drug to be eligible for Federal Medicaid reimbursement under the Medicaid Drug Rebate Program, drug manufacturers must pay rebates to the States for covered drugs. Previous OIG audits found that States did not always invoice and collect all rebates due for drugs administered to Medicaid managed-care organizations' (MCOs') enrollees.

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

How OIG Did This Audit

We reviewed physician-administered drug claims totaling $192.2 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 list.

What OIG Found

Mississippi did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs dispensed to MCO enrollees. Mississippi did not invoice for, and collect from manufacturers, estimated rebates totaling $13.7 million ($10.4 million Federal share) for physician-administered drugs during our audit period. Of this amount, $12.5 million ($9.5 million Federal share) was for single-source and top-20 multiple-source drugs, which were required to be rebated, and $1.2 million ($887,816 Federal share) represented other multiple-source physician-administered drugs that could have been eligible for rebates.

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

What OIG Recommends and Mississippi Comments

We recommend that Mississippi: (1) work with CMS to calculate the rebate amount for claims identified in our findings, invoice drug manufacturers for the calculated rebates, and refund the Federal share of rebates collected for the years covered by our audit period and for years after our audit period; and (2) strengthen internal controls to facilitate the invoicing of all physician-administered drugs for rebate.

Mississippi concurred with both of our recommendations and described actions it had taken or planned to take to address them. Mississippi said that it was working with a new fiscal agent to establish a process to identify claims that are eligible for rebate, and added that it anticipated that it would begin invoicing for these rebates in December 2023. Mississippi also said that it was working with the new fiscal agent to ensure that drug rebate policies and procedures are being followed, and that it was working to strengthen internal controls to ensure that all eligible physician-administered drugs are invoiced, including retrospectively invoicing as needed.

The full report can be found at https://oig.hhs.gov/oas/reports/region7/72106103.asp.

TABLE OF CONTENTS

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 to enrollees of Medicaid managed-care organizations (MCOs). (Appendix B lists previous OIG audits 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 dispensed to MCO enrollees 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 dispensed to MCO enrollees.

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.

[1] OIG performed similar audits for rebates due for drugs administered by physicians to fee-for-service and MCO enrollees. These audits are included in Appendix B.

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

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, 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.

Federal Reimbursement to States for Payments to Medicaid Managed-Care Organizations

States use two primary models to pay for Medicaid services: fee-for-service (FFS) and managed care. In the managed-care model, States contract with MCOs to provide specific services to enrolled Medicaid beneficiaries (enrollees), usually in return for a predetermined periodic payment known as a capitation payment. States pay MCOs for each covered individual regardless of whether the enrollee received services during the relevant time period (42 CFR § 438.2). MCOs use the capitation payments to pay provider claims for these services. Capitation payments may cover outpatient drugs, which include physician-administered drugs.

To claim Federal reimbursement, States report capitation payments made to MCOs as MCO expenditures on the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program (CMS-64 report). These expenditures are not identified by specific type or service (such as physician-administered drugs). When States receive drug rebates from manufacturers, the States must report the rebates as decreasing adjustments on the CMS-64 report. States report drug rebate accounts receivable data to CMS on the Medicaid Drug Rebate Schedule (Form CMS-64.9R), which is part of the CMS-64 report. CMS reimburses States for the Federal share of Medicaid expenditures reported on the CMS-64 report.

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

[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.

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.

Effective March 23, 2010, the Affordable Care Act (ACA) required manufacturers to pay rebates on covered outpatient drugs dispensed to MCO enrollees if the MCOs are responsible for coverage of such drugs.[7] Before the enactment of the ACA, drugs dispensed by Medicaid MCOs were excluded from the rebate requirements. States typically require MCOs to submit to the State agency NDCs for covered outpatient drugs dispensed to eligible individuals. MCOs submit to the State agency provider claim information, including claim lines for covered outpatient drugs. This information contains drug utilization data, which States must include when invoicing manufacturers for rebates.

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 people enrolled in Medicaid, 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.[8] 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.

[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.

[7] Section 2501(c) of P.L. No. 111-148 (Mar. 30, 2010), as amended by the Health Care and Education Reconciliation Act of 2010, P.L. No. 111-152 (Mar. 23, 2010).

[8] 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.

HOW WE CONDUCTED THIS AUDIT

We reviewed physician-administered drug claims totaling $192,194,287 that were paid by the MCOs 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.[9] 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.

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 dispensed to MCO enrollees. The State agency did not invoice for, and collect from manufacturers, estimated rebates totaling $13.7 million ($10.4 million Federal share) for

[9] 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.

physician-administered drugs dispensed to MCO enrollees.[10, 11] Of this amount, $12.5 million ($9.5 million Federal share) was for drugs that were required to be rebated.[12] The remaining $1.2 million ($888,000 Federal share) represented other multiple-source physician-administered drugs, which were eligible for rebates.[13]

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 dispensed to enrollees of MCOs.

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 ACA amended section 1927 of the Act, effective March 23, 2010, to specifically require manufacturers to pay rebates on covered outpatient drugs dispensed to MCO enrollees if the MCOs are responsible for coverage of such drugs. To invoice for rebates, States must include information for drugs dispensed to individuals enrolled in MCOs when invoicing manufacturers for rebates (the Act §§ 1927(b)(1)(A) and (b)(2)(A)).

The ACA also amended section 1903 of the Act to specifically address the conditions of Federal reimbursement for covered outpatient drugs dispensed to MCO enrollees. Essentially, States must secure rebates for drugs dispensed through MCOs and require MCOs to submit to the State NDCs for drugs dispensed to eligible individuals (the Act § 1903(m)(2)(A)).

[10] To estimate the amount the State agency could have invoiced manufacturers for physician-administered drugs, we multiplied the net payment amount from the claims data by the percentage of rebates collected by the State, as reported on the CMS-64 report.

[11] Specifically, the State agency did not invoice manufacturers for rebates associated with drug expenditures that we estimated to be $13,707,201 ($10,388,764 Federal share).

[12] Specifically, the State agency did not invoice manufacturers for rebates associated with drug expenditures that we estimated to be $12,532,826 ($9,500,948 Federal share). This amount consisted of $12,268,540 ($9,301,986 Federal share) for single-source drugs and $264,286 ($198,962 Federal share) for top-20 multiple-source drugs.

[13] Specifically, the State agency did not invoice manufacturers for rebates associated with drug expenditures that we estimated to be $1,174,375 ($887,816 Federal share) for other multiple-source drugs.

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 FOR PHYSICIAN-ADMINISTERED DRUGS DISPENSED TO ENROLLEES OF MEDICAID MANAGED-CARE ORGANIZATIONS

The State agency did not invoice for, and collect from manufacturers, estimated rebates totaling $13.7 million ($10.4 million Federal share) for physician-administered drugs dispensed to MCO enrollees. Of this amount:

- $12.5 million ($9.5 million Federal share) was for drugs that were required to be rebated. Specifically, $12.2 million ($9.3 million Federal share) was for single-source drugs and $264,000 ($199,000 Federal share) was for top-20 multiple-source drugs. The State agency was required to rebate for single-source and top-20 multiple-source physician-administered drugs.

- $1.2 million ($888,000 Federal share) was for other multiple-source drugs that could have been eligible for rebates. We were unable to determine whether, in some cases, the State agency was required to invoice for rebates for these other multiple-source drugs. Although the State agency generally possessed sufficient information (such as NDCs) to invoice the manufacturers for rebates for these drugs, the State agency did not invoice the manufacturers for rebates associated with these drugs.

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 dispensed to enrollees of MCOs.

RECOMMENDATIONS

We recommend that the Mississippi Division of Medicaid:

- work with CMS to calculate the rebate amount for claims identified in our findings, invoice drug manufacturers for the calculated rebates, and refund the Federal share of rebates collected for the years covered by our audit period and for years after our audit period; and

- strengthen internal controls to facilitate the invoicing of all physician-administered drugs for rebate.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency concurred with both of our recommendations and described actions it had taken or planned to take to address them. Specifically, the State agency said that it was working with a new fiscal agent "to establish a process to determine the rebate eligible claims identified by the OIG during this audit."[14] The State agency added that it anticipated that it would begin invoicing for these rebates in December 2023. With respect to our second recommendation, the State agency said that it was "diligently working with the new fiscal agent to ensure that up-to-date drug rebate policies and procedures are followed" and that it was "working to strengthen internal controls to ensure that all rebate-eligible drugs are invoiced, including retrospectively invoicing as needed."

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

[14] See footnote 8 for an explanation of the State agency's relationship with a fiscal agent. During our audit, State agency officials told us that the State agency would be transitioning to a new fiscal agent to assist it in invoicing for rebates for physician-administered drugs.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed physician-administered drug claims that were paid by the MCOs between January 1, 2016, and December 31, 2019 (audit period). During our audit period, MCOs paid $192,194,287 associated with physician-administered drugs dispensed to MCO enrollees.

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 2023.

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 the State agency's policies and procedures regarding 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 9), 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 from January 1, 2016, through December 31, 2019. In response to this request, the

[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).

State agency provided data associated with claims totaling $192,194,287. 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 9).

- 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 estimated the dollar amount of rebates not collected by taking 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 the CMS-64 report) for the audit period (footnote 10).

  - We multiplied the percentage of rebates collected for each year of our audit period (calculated as explained just above) by the net payment amount from the claims data.

- We discussed the results of our audit with State agency officials on June 16, 2023.

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
Alabama Did Not Always Invoice Rebates to Manufacturers for Pharmacy and Physician-Administered Drugs	A-04-21-08090	9/21/2023
Kentucky Did Not Always Invoice Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-04-22-07102	9/12/2023
Georgia Did Not Always Invoice Rebates to Manufacturers for Pharmacy and Physician-Administered Drugs	A-04-21-08089	3/13/2023
Florida Did Not Invoice Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-04-21-07098	3/2/2023
North Carolina Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs	A-07-21-07002	2/7/2023
Mississippi Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs	A-07-21-06101	10/27/2022
Tennessee Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-07-21-06096	9/14/2022
South Carolina Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs	A-07-21-07003	8/10/2022
Colorado Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-07-17-06075	9/8/2021
New Mexico Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-06-16-00001	6/2/2021
Massachusetts Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-06-18-04001	10/22/2020
Minnesota Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-05-17-00018	10/21/2020
Vermont Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs	A-07-19-06086	9/18/2020

Report Title	Report Number	Date Issued
Maine Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs	A-07-18-06079	9/14/2020
Michigan Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-05-17-00017	8/25/2020
Alaska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-09-19-02001	7/21/2020
New York Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-02-18-01016	4/7/2020
New York Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-02-18-01011	2/19/2020
New Jersey Did Not Bill Manufacturers for Tens of Millions of Dollars in Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-02-16-01011	8/30/2019
Texas Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-06-17-04001	8/21/2019
Connecticut Claimed Unallowable Federal Reimbursement for Medicaid Physician-Administered Drugs That Were Not Invoiced to Manufacturers for Rebates	A-07-18-06078	8/16/2019
Illinois Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-05-18-00030	6/18/2019
New Jersey Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-02-16-01012	5/9/2019
Indiana Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-05-17-00038	4/5/2019
Arizona Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-09-16-02031	2/16/2018
Arkansas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-06-16-00018	2/12/2018
Nebraska Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-07-13-06046	12/22/2017

Report Title	Report Number	Date Issued
Texas Did Not Bill Manufacturers for Some Rebates for Pharmacy Drugs of Medicaid Managed-Care Organizations	A-06-16-00004	12/12/2017
Ohio Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-05-16-00013	11/1/2017
Washington State Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-09-16-02028	9/26/2017
Hawaii Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-09-16-02029	9/26/2017
Nevada Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-09-16-02027	9/12/2017
Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs of Medicaid Managed-Care Organizations	A-07-16-06065	5/5/2017
Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-05-16-00014	3/23/2017
Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-14-06050	1/5/2017
Delaware Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-03-15-00202	12/30/2016
Virginia Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-03-15-00201	12/22/2016
California Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Some Medicaid Managed-Care Organizations	A-09-15-02035	12/8/2016
Kansas Correctly Invoiced Rebates to Manufacturers for Most Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-07-15-06060	8/18/2016
Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-14-06057	5/26/2016
Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-15-06063	3/31/2016

Report Title	Report Number	Date Issued
South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-15-06059	2/9/2016
Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs	A-07-15-06062	1/14/2016
North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs	A-07-15-06058	1/13/2016
California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs	A-09-14-02038	1/7/2016
Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs	A-07-14-06056	9/18/2015
Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-14-06049	7/22/2015
Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-06-12-00060	5/4/2015
Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-14-06051	4/13/2015
Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-09-13-02037	3/4/2015
Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs	A-06-14-00031	2/10/2015
The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-03-12-00205	8/21/2014
Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-13-06040	8/7/2014
Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs	A-09-12-02079	4/30/2014
Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs	A-09-12-02080	4/24/2014

Report Title	Report Number	Date Issued
Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-03-12-00200	11/26/2013
Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs	A-06-12-00059	9/19/2013
Nationwide Rollup Report for Medicaid Drug Rebate Collections	A-06-10-00011	8/12/2011
States' Collection of Medicaid Rebates for Physician-Administered Drugs	OEI-03-09-00410	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)).

Section 2501 of the ACA amended section 1927(b)(1)(A) of the Act to require that manufacturers pay rebates on covered outpatient drugs dispensed to individuals enrolled in an MCO if the MCO is responsible for coverage of such drugs. Section 2501 of the ACA also amended section 1927(b)(2)(A) to require that States submit information necessary to secure rebates from manufacturers for covered outpatient drugs dispensed through MCOs. In addition, section 2501 amended section 1903(m)(2)(A) to essentially extend the Medicaid rebate obligations to drugs dispensed through MCOs. Under this provision, each MCO contract must require that Medicaid rebates apply to drugs dispensed through the MCO. Section 2501

[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)).

prohibits payment unless the MCO contracts require MCOs to submit to the State NDC drug utilization data for drugs dispensed to eligible individuals.

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).

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.

OFFICE OF THE GOVERNOR
Walter Sillers Building I 550 High Street, Suite 1000 I Jackson, Mississippi 39201

MISSISSIPPI DIVISION OF
MEDICAID

September 15, 2023

Report Number A-07-21-06103

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 Dispensed to Enrollees of Medicaid Managed-Care Organizations

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 Dispensed to Enrollees of Medicaid Managed-Care Organizations.* As requested, DOM's response is attached.

Sincerely,

Drew Snyder
Executive Director
Mississippi Division of Medicaid

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Responsibly providing access to quality health coverage for vulnerable Mississippians

Recommendation 1: Work with CMS to calculate the rebate amount for claims identified in our findings, invoice drug manufacturers for the calculated rebates, and refund the Federal share of rebates collected for the years covered by our audit period and for years after our audit period.

DOM Response: *DOM concurs.* DOM is working with the new fiscal agent to establish a process to determine the rebate eligible claims identified by the OIG during this audit. DOM anticipates that the requisite invoicing will occur during the December 2023 invoice cycle. The federal share of any rebates will be returned to the federal government after collection.

Recommendation 2: Strengthen internal controls to facilitate the invoicing of all physician-administered drugs for rebate.

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