

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**FLORIDA DID NOT INVOICE
MANUFACTURERS FOR SOME REBATES
FOR PHYSICIAN-ADMINISTERED DRUGS
DISPENSED TO ENROLLEES OF MEDICAID
MANAGED-CARE ORGANIZATIONS**

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Office of Inspector General

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

Report in Brief

Date: March 2023

Report No. A-04-21-07098

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 Florida complied with requirements for invoicing manufacturers for rebates for physician-administered drugs dispensed to Medicaid managed-care organization (MCO) enrollees.

How OIG Did This Audit

We reviewed claims for physician-administered drugs paid between January 1, 2019, and December 31, 2019.

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

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

What OIG Found

Florida generally complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs dispensed to MCO enrollees. However, the State agency did not invoice for, and collect from manufacturers, an estimated \$57,700 (\$35,126 Federal share) in rebates for single-source physician-administered drugs. Furthermore, we were unable to determine whether, in some cases, Florida was required to invoice for rebates for other multiple-source physician-administered drug claims. Florida did not invoice manufacturers for rebates totaling \$40,635 (\$24,772 Federal share) for these multiple-source drugs.

What OIG Recommends and Florida Comments

We recommend that Florida invoice for, and collect from manufacturers, an estimated \$57,700 (\$35,126 Federal share) in rebates for single-source physician-administered drugs and refund the Federal share of rebates collected. We also recommend that Florida work with CMS to determine whether the other claims for multiple-source physician-administered drugs, totaling \$40,635 (\$24,772 Federal share), were eligible for rebates and, if so, determine the rebates due and refund the Federal share of the rebates collected. In addition, we recommend that Florida ensure that all physician-administered drugs eligible for rebates.

In written comments on our draft report, Florida concurred with our findings and recommendations and described actions that it had taken to address them.

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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 the 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, a prior Office of Inspector General review found that States did not always invoice and collect all rebates due for drugs administered by physicians.¹ (Appendix B lists previous audits of the Medicaid drug rebate program.) For this audit, we reviewed the Florida Agency for Health Care Administration's (State agency's) invoicing for rebates for physician-administered drugs dispensed to Medicaid managed-care organizations' (MCO's) enrollees for the period January 1, 2019, 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 with 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 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 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. Physician-administered drugs may be covered by the capitation payments.

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 drug). 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 For purposes of the

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.

Medicaid drug rebate program, physician-administered drugs are classified as either single-source or multiple-source.⁴

The Deficit Reduction Act of 2005 (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 for the top 20 multiple-source physician-administered drugs.⁵ 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. Before the DRA, many States did not collect rebates on physician-administered drugs if the drug claims did not contain NDCs. NDCs enable States to identify the drugs and their manufacturers and facilitate the collection of rebates for the drugs.

Effective March 23, 2010, the Affordable Care Act (ACA)⁶ required manufacturers to pay rebates on covered outpatient drugs dispensed to MCO enrollees if the MCOs are responsible for coverage of such drugs. Before the enactment of the ACA, drugs dispensed by Medicaid MCOs were excluded from the rebate requirements. States typically require MCOs to submit NDCs to the State agency 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 conveys drug utilization data, which States must include when invoicing manufacturers for rebates.

The State Agency's Medicaid Drug Rebate Program

The State agency, which is responsible for invoicing and collecting Medicaid drug rebates for physician-administered drugs, contracts with a contractor to manage its drug rebate program. As the rebate administrator, the contractor maintains the Medicaid Drug Rebate Operations Program to administer the rebate program.

The State agency receives claims data from MCOs in its Medicaid Management Information System, which contains a data field for NDCs associated with drug utilization. The State agency forwards the drug utilization data to the contractor to invoice the manufacturers quarterly and to maintain a record of rebates accounts receivable due from the manufacturers. Manufacturers pay rebates directly to the State agency; the State agency then forwards the payment information to the contractor, which reconciles the payments to the rebates. The

⁴ See, e.g., the Act § 1927(a)(7). 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 Food and Drug Administration. See, e.g., the Act § 1927(k)(7). Multiple-source drugs stand in contrast to single-source drugs, which do not have therapeutic equivalents.

⁵ 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).

⁶ P.L. No. 111-148 (March 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010, P.L. No. 111-152 (March 30, 2010).

contractor maintains accounts receivable information and coordinates with manufacturers to resolve any unpaid rebates.

HOW WE CONDUCTED THIS AUDIT

We reviewed physician-administered drug claims totaling \$152,982,288 that were paid by the State agency MCOs between January 1, 2019, and December 31, 2019.

We obtained drug claim details from the State agency for all physician-administered drugs that were paid by the MCOs during our audit period. We used the CMS Medicaid Drug File 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.⁷ In addition, we determined whether the HCPCS codes were published in CMS's top-20 multiple-source drug listing.

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 generally complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs dispensed to MCO enrollees. However, the State agency did not invoice for, and collect from manufacturers, an estimated \$57,700 (\$35,126 Federal share) in rebates for single-source physician-administered drugs. These errors occurred because the State agency's internal controls did not always ensure that it invoiced manufacturers to secure rebates.

Furthermore, 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

⁷ 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 States pay 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)).

manufacturers for rebates totaling \$40,635 (\$24,772 Federal share) for these multiple-source drugs. Accordingly, we are recommending that the State agency work with CMS to determine whether these claims were eligible for rebates and, if so, determine the rebates due and, upon receipt of the rebates, refund the Federal share of the rebates collected.

FEDERAL AND STATE REQUIREMENTS

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)). 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 the 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)).

The State agency's Provider Notice, dated June 7, 2010, states that that effective July 1, 2010, Florida Medicaid will deny claims billed without the corresponding NDC for physician-administered drugs billed with HCPCS codes. In addition, the State agency's Prescribed Drugs Services Coverage Policy, dated December 2017, specifies that Florida Medicaid managed-care plans must comply with the services coverage requirements outlined in the policy. The policy requires that providers to include the 11-digit NDC code when billing for physician-administered drugs.

The State agency also stated that its system edit rejects any claims submitted with missing or invalid NDCs.

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

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

During our audit period, the State agency did not invoice for and collect from manufacturers some rebates for physician-administered drugs dispensed to MCO enrollees that were eligible

for rebates. Specifically, the State agency did not invoice for and collect an estimated \$57,700 (\$35,126 Federal share) in rebates for single-source physician-administered drugs. These errors occurred because the State agency's internal controls did not always ensure that it invoiced manufacturers to secure rebates.

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON 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 drug 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. CMS last provided the State agency with an annual listing of top-20 multiple-source HCPCS codes and their respective NDCs during 2011. We relied upon this listing to identify the top-20 multiple-source physician-administered drugs.

The MCOs paid providers \$40,635 (\$24,772 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 \$40,635 (\$24,772 Federal share) for the remaining multiple-source drug claims and are recommending that the State agency work with CMS to determine whether these claims were eligible for rebates and, if so, determine the rebates due and, upon receipt of the rebates, refund the Federal share of the rebates collected.

RECOMMENDATIONS

We recommend that the Florida Agency for Health Care Administration:

- invoice for, and collect from manufacturers, an estimated \$57,700 (\$35,126 Federal share) in rebates for single-source physician-administered drugs and refund the Federal share of rebates collected;
- work with CMS to determine whether the other claims for multiple-source physician-administered drugs, totaling \$40,635 (\$24,772 Federal share), were eligible for rebates and, if so, determine the rebates due and, upon receipt of the rebates, refund the Federal share of the rebates collected; and
- ensure that all physician-administered drugs eligible for rebates after our audit period are processed for rebates.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency concurred with our findings and recommendations and described actions that it had taken to address them. Specifically, the State agency said that if it updates the claims extract logic to include these claims, assuming they would not otherwise be excluded from the extract for other reasons, they could be processed through its usual invoicing business process. The State agency's comments appear as Appendix D.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed physician-administered drug claims that were paid by the MCOs between January 1, 2019, and December 31, 2019. Our audit covered the State agency's MCO payments and MCO drug utilization data with an amount paid total of \$152,982,288 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 processes for and controls over invoicing for Medicaid rebates for physician-administered drugs.

We conducted our audit work, which included contacting the State agency in Tallahassee, Florida, from June 2021 to September 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 requirements and guidance to providers, including invoicing instructions for 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 invoicing and rebate process for physician-administered drugs.
- We obtained listings of the CMS top-20 multiple-source physician-administered drugs, the Medicare Part B crosswalk, and the CMS Medicaid Drug File for our audit period.
- We obtained claim details from the State agency for all physician-administered drugs for the period January 1, 2019, through December 31, 2019.

- We obtained the listing of 340B entities from the State agency.⁸
- We removed drug claims totaling \$152,866,287 that either were not eligible for a drug rebate (including the drug claims submitted by 340B entities) or were invoiced for rebate.
- We reviewed the remaining drug claims totaling \$116,001 to determine whether the State agency complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs.
 - We identified single-source drugs based on the classification of the drugs in the CMS Medicaid Drug File. If necessary, we matched the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify the NDCs associated with each HCPCS code listed on claims from providers.
 - 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 listing.⁹
 - We identified the remaining drugs as other outpatient physician-administered drugs. These drugs were not identified as single-source or as top-20 multiple-source drugs.
- We discussed the results of our audit with State agency officials on September 7, 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.

⁸ 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 uninsured patients, and State Acquired Immune Deficiency Syndrome 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)).

⁹ 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.

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>North Carolina Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs</i>	<u>A-07-21-07002</u>	2/7/2023
<i>Mississippi Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs</i>	<u>A-07-21-06101</u>	10/27/2022
<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

Report Title	Report Number	Date Issued
<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
<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
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06056</u>	9/18/2015

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

APPENDIX C: FEDERAL AND STATE REQUIREMENTS 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 U.S. Secretary of Health and Human Services (HHS) 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, 2008.¹⁰ 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 1927(a)(7)(D) of the Act allowed HHS to delay any of the above requirements to prevent hardship to States that required additional time to implement the physician-administered drug reporting requirements.

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

¹⁰ 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)).

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 prohibits payment unless the MCO contract 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 REQUIREMENTS

The State agency's Provider Notice, dated June 7, 2010, states:

Medicaid is implementing the HCPCS to NDC crosswalk, which contains NDC numbers matched up to HCPCS codes. The crosswalk is published and updated quarterly by the Centers for Medicare and Medicaid Services. Effective July 1, 2010, Medicaid will process HCPCS J-code drug claims in accordance with the crosswalk drug information. Use of the crosswalk to adjudicate drug claims will ensure that physician-administered drugs furnished in physician offices or other outpatient settings are not reimbursed unless they are for drugs for which there is a rebate.

Physician-administered drugs billed with HCPCS codes, such as the J-codes, must always be accompanied by the corresponding NDC number on the CMS-1500 claim form. This requirement also applies to Medicare and Medicaid crossover claims. The NDC must reflect the correct amount and dosage provided to the Medicaid recipient. Therefore, for claims received on or after July 1, 2010, Medicaid will deny claims billed without the correct corresponding NDC number.

In addition, the State agency's *Prescribed Drugs Services Coverage Policy*, dated December 2017, describes Florida Medicaid's coverage of outpatient prescription drugs, and specifies that Florida Medicaid MCO plans must comply with the services coverage requirements outlined in the policy. The policy requires that providers include the 11-digit NDC code when billing for physician-administered drugs.

The State agency also stated that its system edit rejects any claims submitted with missing or invalid NDCs.

APPENDIX D: STATE AGENCY COMMENTS



RON DESANTIS
GOVERNOR

SIMONE MARSTILLER
SECRETARY

December 21, 2022

Ms. Lori S. Pilcher
Regional Inspector General for Audit Services
Department of Health & Human Services
Office of Inspector General
Office of Audit Services, Region IV
61 Forsyth Street, SW, Suite 3T41
Atlanta, GA 30303

Dear Ms. Pilcher:

Thank you for your letter of November 21, 2022, requesting us to provide comments on the draft report number A-04-21-07098 entitled *Florida Did Not Invoice Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations*. In accordance with your request, we have sent you an electronic copy of our comments.

If you have any questions regarding our response, please contact Karen Preacher, Audit Director, at 850-412-3968.

Sincerely,

A handwritten signature in blue ink that reads "Simone Marsteller". The signature is fluid and cursive.

Simone Marsteller
Secretary

SM/sgb

Enclosure: Response to Draft Report No. A-04-21-07098

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Agency for Health Care Administration
Florida Did Not Invoice Manufacturers for Some Rebates for
Physician-Administered Drugs Dispensed to Enrollees of
Medicaid Managed-Care Organizations
Response to HHS/OIG Draft Report A-04-21-07098 dated November 21, 2022

Summary of Findings

Florida generally complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs dispensed to MCO enrollees. However, the State agency did not invoice for, and collect from manufacturers, an estimated \$57,700 (\$35,126 Federal share) in rebates for single-source physician-administered drugs. Furthermore, we were unable to determine whether, in some cases, Florida was required to invoice for rebates for other multiple-source physician-administered drug claims. Florida did not invoice manufacturers for rebates totaling \$40,635 (\$24,772 Federal share) for these multiple-source drugs.

Finding#1

The State Agency did not invoice manufacturers for rebates on some single-source physician-administered drugs.

Finding#2

The State Agency did not invoice manufacturers for rebates on other multiple-source physician-administered drugs.

Recommendation #1

Invoice for, and collect from manufacturers, an estimated \$57,700 (\$35,126 Federal share) in rebates for single-source physician-administered drugs and refund the Federal share of rebates collected.

Agency Response and Corrective Action Plan:

We are in concurrence. If the claims extract logic is updated to include these claims, assuming they would not otherwise be excluded from the extract for other reasons, they could be processed through our usual invoicing business process.

As noted previously, until complete claims data is received on the claims extract, we will not be able to confirm that these claims are invoiceable or would otherwise be excluded during invoicing. In addition, the majority of the estimated rebate amount (355 claims with an estimated rebate amount of \$31,526.13) were submitted with dump codes that are non-dosage specific (J3535 and J8499). As a result, drug manufacturers will likely dispute them, and any utilization invoiced may be removed during the dispute resolution process.

Anticipated Completion Date:

A change request has been opened to modify the MMIS to include physician-administered drugs as part of the monthly drug rebate extract process. Once completed, physician-administered drugs will be part of the quarterly invoicing process. At the latest, this modification is estimated to be completed by December 31, 2024, with the Agency's new Florida Health Care Connection (FX) System.

Agency Contact:

*Elizabeth Wade
(850) 412-3692*

Recommendation #2

Work with CMS to determine whether the other claims for multiple-source physician-administered drugs, totaling \$40,635 (\$24,772 Federal share), were eligible for rebates and, if so, determine the rebates due and, upon receipt of the rebates, refund the Federal share of the rebates collected.

Agency for Health Care Administration
Florida Did Not Invoice Manufacturers for Some Rebates for
Physician-Administered Drugs Dispensed to Enrollees of
Medicaid Managed-Care Organizations
Response to HHS/OIG Draft Report A-04-21-07098 dated November 21, 2022

Agency Response and Corrective Action Plan:

We are in concurrence. If the claims extract logic is updated to include these claims, assuming they would not otherwise be excluded from the extract for other reasons, they could be processed through our usual invoicing business process.

As noted previously, until complete claims data is received on the claims extract, we will not be able to confirm that these claims are invoiceable or would otherwise be excluded during invoicing. In addition, the majority of these claims (3,919 claims with an associated reimbursement amount of \$37,259.02) were submitted with dump codes that are non-dosage specific (J3535 and J8499). As a result, drug manufacturers will likely dispute them, and any utilization invoiced may be removed during the dispute resolution process.

Anticipated Completion Date:

A change request has been opened to modify the MMIS to include physician-administered drugs as part of the monthly drug rebate extract process. Once completed, physician-administered drugs will be part of the quarterly invoicing process. At the latest, this modification is estimated to be completed by December 31, 2024, with the Agency's new Florida Health Care Connection (FX) System.

Agency Contact:

*Elizabeth Wade
(850) 412-3692*

Recommendation #3

Ensure that all physician-administered drugs eligible for rebates after our audit period are processed for rebates.

Agency Response and Corrective Action Plan:

We are in concurrence. If the claims extract logic is updated to include these claims, assuming they would not otherwise be excluded from the extract for other reasons, then they would be invoiced through our usual business process moving forward. Since most of these claims were submitted with dump codes that are non-dosage specific, drug manufacturers would likely dispute them, and the utilization may be removed during the dispute resolution process, adding extra workload for operations staff.

Anticipated Completion Date:

A change request has been opened to modify the MMIS to include physician-administered drugs as part of the monthly drug rebate extract process. Once completed, physician-administered drugs will be part of the quarterly invoicing process. At the latest, this modification is estimated to be completed by December 31, 2024, with the Agency's new Florida Health Care Connection (FX) System.

Agency Contact:

*Elizabeth Wade
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