Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

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

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Report in Brief
Date: September 2023
Report No. A-04-22-07102

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

Kentucky Did Not Always Invoice Manufacturers for Rebates 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 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 Kentucky complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs dispensed to 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, 2020.

We removed the physician-administered drug claims that were not eligible for rebate as part of the drug rebate program and worked with Kentucky to calculate the amounts of rebates that were associated with the remaining drugs and that were not invoiced.

What OIG Found

Kentucky did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs dispensed to MCO enrollees. Kentucky did not file invoices for and collect from manufacturers, rebates totaling $21.6 million ($15.5 million Federal share) for physician-administered drugs dispensed to MCO enrollees. Of this amount, $15.6 million ($11.2 million Federal share) was for drugs that were required to be rebated. In addition, Kentucky did not invoice for rebates associated with $6.0 million ($4.3 million Federal share) in other multiple-source physician-administered drugs that were eligible for rebates.

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

What OIG Recommends

We recommend that Kentucky: (1) files invoices for and collect from manufacturers rebates totaling $15,611,770 ($11,209,642 Federal share) for single-source and top-20 multiple-source physician-administered drugs and refund the Federal share of rebates collected; (2) work with CMS to determine whether the other claims for multiple-source physician-administered drugs, totaling $5,967,128 ($4,281,678 Federal share), were eligible for rebate and, if so, determine the rebates due and, upon receipt of the rebates, refund the Federal share of the rebates collected; (3) strengthen its internal controls to ensure that all eligible physician-administered drugs are invoiced for rebate; and (4) ensure that all physician-administered drugs eligible for rebates after our audit period are processed for rebates.

In written comments on our draft report, Kentucky 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, 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 audits of the Medicaid drug rebate program.)[1] For this audit, we reviewed the Kentucky Cabinet for Health and Family Services, Department for Medicaid Service's (State agency's) invoicing for rebates for physician-administered drugs dispensed to Medicaid managed-care organizations' (MCOs') enrollees for the period January 1, 2019, through December 31, 2020.

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 to the States 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 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 the drug utilization data containing NDCs for the drugs to the manufacturers. NDCs enable States to identify the drugs and their manufacturers and facilitate the collection of rebates for the drugs. Before the Deficit Reduction Act of 2005 (DRA), many

[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.

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 for 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 for 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)[7] 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, contracted with an outside vendor (the contractor) to administer its drug rebate program during our audit period. The State agency's Medicaid Management Information System (MMIS) operator receives claims data on a weekly basis from the MCOs, which contains a data field for NDCs associated with drug utilization; the MMIS operator then sends rebate files to the contractor. The contractor loads these files into its rebate-processing system to invoice manufacturers for rebates quarterly. Manufacturers pay rebates directly to the State agency; the State agency then forwards the payment information to the contractor,

[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] 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).

which reconciles the payments to the rebates. The 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 $92,993,625 that were paid by the State agency MCOs between January 1, 2019, and December 31, 2020 (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] In addition, 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. For the remaining claims, we worked with the State agency to calculate the amounts of rebates that were not invoiced.

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 file invoices for and collect from manufacturers rebates totaling $21.6 million ($15.5 million Federal share) for physician-administered drugs dispensed to MCO enrollees.[9] Of this amount, $15.6 million ($11.2 million

[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 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)).

[9] Specifically, the State agency did not invoice manufacturers for rebates associated with drug expenditures that totaled $21,578,898 ($15,491,320 Federal share).

Federal share) was for drug payments that were required to be rebated.[10] In addition, the State agency did not invoice for rebates associated with $6.0 million ($4.3 million Federal share) in other multiple-source physician-administered drugs that were eligible for rebates.[11]

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

FEDERAL 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)).

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

[10] Specifically, the State agency did not invoice manufacturers for rebates associated with drug expenditures that totaled $15,611,770 ($11,209,642 Federal share). This amount consisted of $15,303,386 ($10,988,286 Federal share) for single-source drugs and $308,384 ($221,356 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 $5,967,128 ($4,281,678 Federal share) for other multiple-source drugs.

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES FOR PHYSICIAN-ADMINISTERED DRUGS DISPENSED TO ENROLLEES OF MEDICAID MANAGED-CARE ORGANIZATIONS

During our audit period, the State agency did not file invoices for and collect from manufacturers, rebates totaling $21.6 million ($15.5 million Federal share) for physician-administered drugs dispensed to MCO enrollees. Of this amount:

- $15.6 million ($11.2 million Federal share) was for drugs that were required to be rebated. Specifically, $15.3 million ($11.0 million Federal share) was for single-source drugs and $308,384 ($221,356 Federal share) was for top-20 multiple-source drugs.

- $6.0 million ($4.3 million Federal share) was for other multiple-source 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. The State agency generally possessed sufficient information (such as NDCs) to invoice the manufacturers for rebates for these drugs. If the State agency had invoiced these claims for rebate, the drug manufacturers would have been required to pay the rebates. Accordingly, we set aside $6.0 million ($4.3 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.

Although its contracts required the collection of drug utilization data necessary to invoice for rebates on all claims, the State agency's internal controls did not always ensure that the data were used to invoice manufacturers and collect rebates for physician-administered drugs dispensed to enrollees of MCOs. Specifically, the State agency did not forward some physician-administered drug claims to the contractor for rebate processing because a system logic incorrectly rejected claims submitted by certain provider types. In addition, the State agency did not invoice some claims for rebate because providers submitted claims with invalid information in the HCPCS and NDC fields needed for processing rebates.

RECOMMENDATIONS

We recommend that the Kentucky Cabinet for Health and Family Services, Department for Medicaid Services:

- file invoices for and collect from manufacturers rebates totaling $15,611,770 ($11,209,642 Federal share) for single-source and top-20 multiple-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 $5,967,128 ($4,281,678 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;

- strengthen its internal controls to ensure that all eligible physician-administered drugs are invoiced for rebate; 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. 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, 2020 (audit period). During our audit period, MCOs paid $92,993,625 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 Frankfort, Kentucky, from April 2022 to February 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 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.[12]

[12] 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)).

- We obtained from the State agency a detailed list of physician-administered drug claims paid between January 1, 2019, through December 31, 2020. In response to this request, the State agency provided data associated with claims totaling $92,993,625. With this information, we then 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 necessary, 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 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.

    - We identified other multiple-source drugs eligible for rebate that were not single-source or top-20 multiple-source drugs.

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

- We worked with the State agency to determine the dollar amount of rebates not collected.

- We discussed the results of our audit with State agency officials on February 13, 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
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	3/3/2023
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
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

Report Title	Report Number	Date Issued
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
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

Report Title	Report Number	Date Issued
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
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

Report Title	Report Number	Date Issued
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
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

Report Title	Report Number	Date Issued
States' Collection of Medicaid Rebates for Physician-Administered Drugs	OEI-03-09-00410	6/24/2011

APPENDIX C: FEDERAL 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.[13] 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

[13] 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. 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 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 AGENCY GUIDANCE

The State agency stated that it required in its contracts that MCOs report timely drug utilization data that is necessary to bill manufacturers for rebates in accordance with section 1927(b)(1)(A) of the Social Security Act—or the conditions of any supplemental rebate program that the State agency has entered into with the manufacturers—no later than 45 days after the end of each quarterly rebate period (or however many days required by the agency). The MCO shall transmit a file according to agency's specifications and shall fully cooperate with the agency and its contractors to ensure file transmissions are complete, accurate and delivered by the specified deadlines.

In addition, claims for drug products obtained and/or administered in an office/clinic or other non-institutional setting and processed through the MCO's medical benefit shall contain a valid eleven-digit NDC and other necessary information, such as a HCPCS codes and appropriate billable units for the actual drug and quantity administered. The State agency required that its MCOs reject any claims with missing or invalid NDCs.

Andy Beshear
GOVERNOR

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August 1, 2023

Report Number: A-04-22-07102
Lori S. Pilcher
Regional Inspector General for Audit Services
Office of Audit Services, Region IV
61 Forsyth Street, SW
Suite 3T41
Atlanta, GA 30303

Dear Ms. Pilcher:

The Kentucky Department for Medicaid Services (the Department or DMS) has reviewed the Office of Inspector General (OIG) draft report entitled *Kentucky Did Not Always Invoice Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations.* The Department appreciates the opportunity to respond to the recommendations in the audit.

OIG Recommendation:
File invoices for and collect from manufacturers rebates totaling $15,611,770 ($11,209,642 Federal share) for single-source and top-20 multiple-source physician-administered drugs and refund the Federal share of rebates collected;

The Department concurs with this recommendation.

As a result of this review, a large volume of claims (~254,000) have been identified as part of this analysis which were never sent from MMIS to the rebate vendor for rebate invoicing. This is due to limited provider types being present in the rebate extract logic; additional provider types were added to the extract logic in March, 2020 upon discovery of the issue.

OIG Recommendation:
Work with CMS to determine whether the other claims for multiple-source physician-administered drugs, totaling $5,967,128 ($4,281,678 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;

The Department will work with CMS to determine which claims, if any, are appropriately eligible for rebates. DMS notes, however, that having a Medicaid-specific crosswalk which is provided

by CMS would be very beneficial in assisting the Department in accurately submitting these and future claims for rebate.

The Department has taken steps to ensure that Managed Care Organizations (MCOs) collect NDCS on these products, to identify these multi-source drugs within encounter claims, and to submit these claims accordingly.

Finally, DMS collects NDC information on all claims for physician-administered drugs. The Department has submitted ***all*** claims for physician-administered drugs for rebates.

OIG Recommendation:
Strengthen its internal controls to ensure that all eligible physician-administered drugs are invoiced for rebate;

The Department agrees with this recommendation. DMS has established a process with the current PBM vendor to identify and report the rejected medical encounters from the rebate system due to Invalid NDC or Invalid HCPCS NDC combination and to work with the MCOs to correct and resubmit the encounters. DMS has recently procured a new PBM and rebate vendor and is working with this vendor to identify opportunities to streamline the process and significantly reduce the number of rejected encounters.

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

The Department agrees with this recommendation. DMS has

- Updated logic to submit additional eligible encounters for rebate processing, and
- Reviewed processes with the current and new PBMs to improve rebate billing

Please contact KY Pharmacy Director, Fatima Ali, at Fatima.ali@ky.gov, if we may answer any questions or provide additional information on our responses.

Sincerely,

Lisa Lee, Commissioner

cc: Fatima Ali, Medicaid Pharmacy Director