

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**COLORADO DID NOT INVOICE
REBATES TO MANUFACTURERS 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: September 2021

Report No. A-07-17-06075

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 Colorado complied with Federal Medicaid 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, 2012, and December 31, 2016.

We removed the physician-administered drug claims that were not eligible for rebate as part of the drug rebate program and worked with Colorado to determine the estimated rebates associated with the remaining drugs.

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

What OIG Found

Colorado did not comply with Federal Medicaid requirements because it did not collect National Drug Codes (NDCs) and invoice manufacturers for rebates for physician-administered drugs dispensed to MCO enrollees. Because the information we received from Colorado lacked NDC-level detail, we identified the physician-administered drugs that would have been eligible for a drug rebate and calculated that Colorado did not invoice for, and collect from manufacturers, an estimated \$2 million (\$1 million Federal share) in rebates that were associated with these physician-administered drugs. We are recommending that Colorado work with the Centers for Medicare & Medicaid Services (CMS) to determine the total amount of claims that were eligible for rebate and the unallowable portion of these claims. Although Colorado contractually required the MCOs to obtain NDCs so that drug rebates could be invoiced, the MCOs did not obtain from the providers NDC-level detail that Colorado needed to invoice for rebates for physician-administered drugs. This occurred because Colorado did not have policies and procedures in place to ensure that the MCOs obtained sufficiently detailed data to properly rebate for physician-administered drugs.

What OIG Recommends and Colorado Comments

We recommend that Colorado work with CMS to determine the total amount of claims that were eligible for rebates as well as the unallowable portion of the physician-administered drug claims, 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. We also recommend that Colorado develop and implement policies and procedures to ensure that all eligible physician-administered drugs, including those dispensed to MCO enrollees, are invoiced for rebate.

Colorado agreed with both of our recommendations and described corrective actions it had taken or planned to take. Colorado said that it would work with CMS to determine the total amount of physician-administered drug encounters that were eligible for rebates but were not invoiced because of missing NDC numbers. Colorado added that it would work with the MCOs to collect the missing NDC numbers, invoice drug manufacturers, and refund the Federal share of rebates collected. For our second recommendation, Colorado stated that it would strengthen its policies and procedures to ensure that physician-administered drugs are appropriately invoiced for rebate.

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INTRODUCTION

WHY WE DID THIS AUDIT

For a covered outpatient drug to be eligible for Federal reimbursement under the Medicaid program's drug rebate requirements, manufacturers must pay rebates to the States for the drugs. States generally offset their Federal share of these rebates against their Medicaid expenditures. States invoice the manufacturers for rebates to reduce the cost of drugs to the program. However, prior Office of Inspector General (OIG) audits found that States did not always invoice and collect all rebates due for drugs administered to Medicaid managed-care organizations' (MCOs') enrollees. (Appendix B lists previous OIG audits and reviews of the Medicaid drug rebate program.¹) Previous OIG audits at Colorado found that the State claimed unallowable Federal Medicaid reimbursement for some fee-for-service (FFS) physician-administered drugs. For this audit, we reviewed the Colorado Department of Health Care Policy and Financing's (State agency's) invoicing for rebates for physician-administered drugs dispensed to MCO enrollees.

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 reviews for rebates due for drugs administered by physicians to fee-for-service (FFS) and MCO enrollees. These reviews are included in this appendix.

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: 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. 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 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 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 billed 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 top 20 multiple-source physician-administered drugs.⁴ For purposes of the Medicaid drug rebate

³ HCPCS codes (sometimes referred to as J-codes) are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

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)).

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)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 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 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 Drug Rebate Analysis and Management System 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. 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 contractor maintains accounts receivable information and works with manufacturers to resolve any unpaid rebates.

HOW WE CONDUCTED THIS AUDIT

We reviewed physician-administered drug claims totaling \$10,176,120 (for which we calculated associated rebates totaling an estimated \$2,049,124) that were paid by the MCOs between January 1, 2012, and December 31, 2016 (audit period).

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

We requested drug claim details from the State agency for all physician-administered drugs that were paid by the MCOs for our audit period. Although our analysis and overall projections use the information provided by the State agency, we do not make assertions as to the accuracy and completeness of this information. We removed claims for drugs that would not have been eligible for rebates. We worked with the State agency to determine the annual drug rebate percentages (that is, the total drug rebates received as a percentage of the total drug costs) for the State fiscal years ending June 30, 2008, through June 30, 2011.⁸ We used the lowest annual drug rebate percentage to determine the estimated rebate total.

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 scope and methodology.

FINDINGS

During our audit period, the State agency did not comply with Federal Medicaid requirements because it did not collect NDCs and did not attempt to invoice manufacturers for any rebates for physician-administered drugs dispensed to MCO enrollees. Because the information we received from the State agency lacked NDC-level detail, we identified the physician-administered drugs that would have been eligible for a drug rebate and calculated that the State agency did not invoice for, and collect from manufacturers, an estimated \$2,049,124 (\$1,024,562 Federal share) in rebates that were associated with these physician-administered drugs. We are recommending that the State agency work with CMS to determine the total amount of claims that were eligible for rebate and the unallowable portion of these claims, and that the State agency consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable.

Although the State agency contractually required the MCOs to obtain NDCs so that drug rebates could be invoiced, the MCOs did not obtain from the providers NDC-level detail that the State agency needed to invoice for rebates for physician-administered drugs.⁹ This occurred because the State agency did not have policies and procedures in place to ensure that the MCOs obtained sufficiently detailed data to properly rebate for physician-administered drugs.

⁸ This timeframe generally reflected the period before the State agency began to transition to a Medicaid managed-care model.

⁹ Although the contractor manages the State agency's drug rebate program, it is the State agency itself that contracts with the 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)).

The State agency's *Colorado Provider Bulletin*, reference B1000274, dated January 2010, states that claims submitted for single-source or top-20 multiple-source physician-administered drugs "using only HCPCS codes or only NDC numbers will be denied."

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

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES FOR DRUGS DISPENSED THROUGH MEDICAID MANAGED-CARE ORGANIZATIONS

During our audit period, the State agency did not comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs dispensed to MCO enrollees. The State agency did not provide sufficient oversight of the MCOs, which were paid a capitation payment to pay providers for certain medical services for enrollees and which did not obtain from the providers sufficient NDC-level detail that the State agency needed to invoice for rebates for physician-administered drugs. Because the information we received from the State agency lacked this NDC-level detail, we identified (based on the data that we did receive) \$8,010,649 in claims for physician-administered drugs that were dispensed to MCO enrollees and for which the State agency did not invoice manufacturers to collect rebates. (See Appendix A.) Under the Medicaid drug rebate program, these claims could have been eligible for rebates.

Accordingly, we calculated an estimated \$2,049,124 (\$1,024,562 Federal share) for the rebate amounts that were associated with these physician-administered drugs. We are recommending that the State agency work with CMS to determine the total amount of claims that were eligible for rebate and the unallowable portion of these claims, and that the State agency consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable.

LACK OF POLICIES AND PROCEDURES

Although the State agency contractually required the MCOs to obtain NDCs so that drug rebates could be invoiced, the State agency did not have policies and procedures in place to ensure that the MCOs obtained sufficiently detailed drug utilization data, to include NDC-level detail, for physician-administered drugs. Nor did the State agency have policies and procedures in place to ensure that eligible physician-administered drugs, including those dispensed to MCO enrollees, were invoiced for rebate.

Further, State agency officials stated that during our audit, the State agency placed each of the MCOs on a mitigation plan and began to develop policies and procedures to ensure that the drug manufacturers are invoiced for rebates for physician-administered drugs dispensed to MCO enrollees.

RECOMMENDATIONS

We recommend that the Colorado Department of Health Care Policy and Financing:

- work with CMS to determine the total amount of claims that were eligible for rebates as well as the unallowable portion of the physician-administered drug claims, 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
- develop and implement policies and procedures to ensure that all eligible physician-administered drugs, including those dispensed to MCO enrollees, are invoiced for rebate.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency agreed with both of our recommendations and described corrective actions it had taken or planned to take. Specifically, for our first recommendation the State agency said that it would work with CMS to determine the total amount of physician-administered drug encounters that were eligible for rebates but were not invoiced because of missing NDC numbers. The State agency added that it would work with the MCOs to collect the missing NDC numbers, invoice drug manufacturers, and refund the Federal share of rebates collected for the years covered by our audit period and

for years after our audit period. For our second recommendation, the State agency stated that it would strengthen its policies and procedures to ensure that physician-administered drugs are appropriately invoiced for rebate. The State agency said that its MMIS currently has an edit that will deny an FFS physician-administered drug claim that is not submitted with a valid NDC, and added that it is working with the MCOs so that they implement a similar edit. The State agency also said that it is currently invoicing manufacturers for all physician-administered drug claims that include a valid NDC.

The State agency's comments appear in their entirety 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, 2012, and December 31, 2016 (audit period). Our audit covered the State agency's MCO payments and MCO drug utilization data with an amount paid total of \$10,176,471 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 Denver, Colorado.

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 interviewed CMS officials about the Federal requirements and guidance governing physician-administered drugs under the Medicaid drug rebate program.
- We reviewed the State agency's policies and procedures regarding rebates for physician-administered drugs and its contract with the MCOs.
- We reviewed State agency regulations and guidance to providers, including invoicing instructions 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 asked the State agency to provide a detailed listing of all physician-administered drugs dispensed to MCO enrollees for the period January 1, 2012, through December 31, 2016. In response to this request, the State agency provided claims totaling \$10,176,120.

- We obtained the listing of 340B entities from the State agency.¹⁰
- We removed \$2,165,471 of physician-administered drug claims that were not eligible for rebate as part of the drug rebate program (including the drug claims submitted by 340B entities).
- We reviewed the remaining \$8,010,649 of claims to determine whether the State agency complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs.
- Specifically, we identified the physician-administered drugs that would have been eligible for a drug rebate and worked with the State agency to determine the estimated rebates associated with these drugs. Accordingly, for the remaining \$8,010,649 of drug claims, we took the following steps:
 - We obtained from the State agency its annual drug rebate percentages (that is, the total drug rebates received as a percentage of the total drugs' cost) for the State fiscal years ending June 30, 2008, through June 30, 2011 (footnote 8). Based on the information that the State agency provided, we used the lowest annual drug rebate percentage for that timeframe, which was 25.58 percent.
 - We multiplied the \$8,010,649 in physician-administered drug claims by the State agency's lowest annual drug rebate percentage (25.58 percent) to arrive at an estimated amount of drug rebates that could have been obtained (\$2,049,124 (\$1,024,562 Federal share)).
- We discussed the results of our audit with State agency officials on June 2, 2021.

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.

¹⁰ 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).

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<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

Report Title	Report Number	Date Issued
<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>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>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>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
<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

Report Title	Report Number	Date Issued
<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

Report Title	Report Number	Date Issued
<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
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06049</u>	7/22/2015
<i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-06-12-00060</u>	5/4/2015
<i>Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06051</u>	4/13/2015
<i>Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-13-02037</u>	3/4/2015
<i>Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<u>A-06-14-00031</u>	2/10/2015
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00205</u>	8/21/2014
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-13-06040</u>	8/7/2014
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	<u>A-09-12-02079</u>	4/30/2014

Report Title	Report Number	Date Issued
<i>Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<u>A-09-12-02080</u>	4/24/2014
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00200</u>	11/26/2013
<i>Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<u>A-06-12-00059</u>	9/19/2013
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	<u>A-06-10-00011</u>	8/12/2011
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	<u>OEI-03-09-00410</u>	6/24/2011

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

FEDERAL LAWS

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

Section 6002 of the DRA added section 1927(a)(7) to the Act to require that States capture information necessary to secure rebates from manufacturers for certain covered outpatient drugs administered by a physician. In addition, section 6002 of the DRA amended section 1903(i)(10) of the Act to prohibit 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, 2008.¹¹ 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

¹¹ 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., 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 section 1927(a)(7)(B)(i).

must require that Medicaid rebates apply to drugs dispensed through the MCO. Section 2501 prohibits payment unless the MCO contracts require MCOs to submit to the State NDC drug utilization data for drugs dispensed to eligible individuals.

STATE AGENCY GUIDANCE

The State agency, *Colorado Provider Bulletin*, reference B1000274, dated January 2010, states (pages 4-5):

All physician, outpatient hospital, EPSDT [Early Periodic Screening, Diagnosis, and Treatment], and Medicare Part B crossover claims for physician-administered single-source and the 20 multiple-source drugs (as identified by the Centers for Medicare and Medicaid Services) must be submitted using both Healthcare Common Procedure Coding System (HCPCS) codes and National Drug Code (NDC) numbers. . . . Claims submitted for these drugs using only HCPCS codes or only NDC numbers will be denied. Claims submitted with NDC numbers that do not correspond to the correct HCPCS codes will also be denied.¹²

The State agency posts a list of the single-source and top 20 multiple-source drugs, and their corresponding NDCs and HCPCS, in the Billing Manuals section of its website.

¹² The term “crossover claims” applies to claims for certain beneficiaries who are eligible for both Medicare and Medicaid. CMS guidance states that State Medicaid programs are obligated to reimburse providers for Medicare cost-sharing amounts due for Qualified Medicare Beneficiaries (QMBs) according to the States’ CMS-approved cost-sharing payment methodology. QMBs are persons who are entitled to Medicare Part A and are eligible for Medicare Part B, have incomes below 100 percent of the Federal Poverty Level, and have been determined to be eligible for QMB status by their State Medicaid agencies. See CMCS [Center for Medicaid and CHIP [Children’s Health Insurance Program] Services]–MMCO [Medicare-Medicaid Coordination Office]–CM [Center for Medicare], Informational Bulletin dated Jun. 7, 2013, subject: *Payment of Medicare Cost Sharing for Qualified Medicare Beneficiaries (QMBs) (June 7, 2013 Informational Bulletin)*; and MMCO – CMCS Informational Bulletin dated Jan. 6, 2012, subject: *Billing for Services Provided to Qualified Medicare Beneficiaries (QMBs)*.



COLORADO
 Department of Health Care
 Policy & Financing

1570 Grant Street
 Denver, CO 80203

August 20, 2021

Report Number A-07-17-06075

Patrick J. Cogley
 Regional Inspector General for Audit Services
 HHS - OIG - Office of Audit Services, Region VII
 601 East 12th Street, Room 0429
 Kansas City, MO 64106

*RE: Colorado Did Not Invoice Rebates to Manufacturers for Physician-Administered
 Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations*

Dear Mr. Cogley,

The Colorado Department of Health Care Policy and Financing (Department) has reviewed the Office of Inspector General (OIG) draft report entitled *Colorado Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations*. As requested in your cover letter dated July 7, 2021, the Department is providing a response for each recommendation. Please see below for each OIG recommendation and the Department's statement of concurrence.

OIG Recommendation 1: *Work with CMS to determine the total amount of claims that were eligible for rebates as well as the unallowable portion of the physician-administered drug claims, 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.*

Department response:

The Department agrees to work with CMS to determine the total amount of physician-administered drug encounters which were eligible for rebates but not invoiced due missing NDC numbers. The Department will work with the MCOs to collect the missing NDC numbers, invoice drug manufacturers for the calculated rebates, and refund the Federal share of rebates collected for the years covered by the audit period and for any years after the audit period. The Department will also work with CMS to determine the unallowable portion of physician-administered drug encounters which were eligible for rebates but cannot be invoiced because the NDC numbers are not available.



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OIG Recommendation 2: *Develop and implement policies and procedures to ensure that all eligible physician-administered drugs, including those dispensed to MCO enrollees, are invoiced for rebate.*

Department response:

The Department agrees to strengthen our policies and procedures to ensure physician-administered drug encounters are appropriately invoiced for rebate. The Department's MMIS requires that all fee-for-service physician-administered drug claims include valid and rebate-eligible NDC numbers, otherwise the claim line is denied. The Department is working with the MCOs to implement a similar edit in their respective claim systems. The MCOs are already contractually required to include valid NDC numbers on physician-administered drug encounters so they can be invoiced for rebate. The Department will strengthen our oversight of that contract requirement through improved reporting on the MCO encounters. The Department would like to note that all encounters with valid NDC numbers are currently being appropriately invoiced for rebate.

If you have any questions, please contact External Audits at ExternalAudits@state.co.us.

From,

Christine
Bickers

Christine Bickers

External Audits Coordinator

Digitally signed by
Christine Bickers
Date: 2021.08.23
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