

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**NEW MEXICO DID NOT BILL  
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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## Report in Brief

Date: June 2021

Report No. A-06-16-00001

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 Medicaid reimbursement, the manufacturer must enter into a rebate agreement administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. Previous **OIG** audits found that States did not always bill and collect all rebates due for drugs administered by physicians to enrollees of Medicaid managed-care organizations (MCOs).

Our objective was to determine whether New Mexico complied with Federal Medicaid requirements for billing manufacturers for rebates for drugs dispensed to MCO enrollees.

### How **OIG** Did This Audit

We reviewed physician-administered drug claims that were paid by the MCOs from March 23, 2010, through December 31, 2014 (audit period). We identified drugs that had not been billed by New Mexico and worked with New Mexico to calculate the amount of rebates that would have been collected from manufacturers had it billed them for the drugs.

## New Mexico Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations

### What **OIG** Found

New Mexico properly billed manufacturers for all pharmacy rebates and some rebates for physician-administered drugs. However, New Mexico did not bill for and collect from manufacturers rebates for 70,131 claim lines totaling at least \$1.5 million (\$1.1 million Federal share) for physician-administered drugs. In addition, the State agency did not bill for rebates for 183,859 claim lines for other physician-administered drugs that may have been eligible for rebates. These errors occurred because the State agency's internal controls did not always ensure that it billed manufacturers to secure rebates and because the State agency did not always collect the utilization data necessary to bill the manufacturers.

### What **OIG** Recommends and New Mexico Comments

We recommend that New Mexico (1) bill for and collect manufacturers' rebates for the 44,790 claim lines related to single-source and top-20 multiple-source physician-administered drugs that we calculated to be at least \$1.2 million (\$900,971 Federal share) and refund the Federal share of rebates collected; (2) work with CMS to determine whether the 25,341 claim lines related to non-top-20 multiple-source physician-administered drugs that we calculated to be at least \$226,644 (\$164,793 Federal share) were eligible for rebates and, if so, determine the rebates due and, upon receipt of the rebates, refund the Federal share of rebates collected; and (3) work with CMS to determine whether the other physician-administered drugs, associated with 183,859 claim lines and rebates of at least \$170,674 (\$124,097 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. We also made procedural recommendations.

In written comments on our draft report, New Mexico partially concurred with our findings. The State agency said that it has billed manufacturers for rebates totaling \$1.6 million for claims related to our audit. The State agency disagreed that some claim lines could be billed for rebates for various reasons. The State agency additionally outlined steps it would take to address our findings and recommendations. We addressed the State agency's comments in our final report and maintain the validity of our recommendations.

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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 bill 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 bill and collect all rebates due for drugs administered to enrollees of Medicaid managed-care organizations (MCOs). (Appendix B lists previous OIG audits of the Medicaid drug rebate program.<sup>1</sup>) For this audit, we reviewed the New Mexico Human Services Department's (State agency's) billing for rebates for both pharmacy and physician-administered drugs dispensed to MCO enrollees.

### OBJECTIVE

Our objective was to determine whether the State agency complied with Federal Medicaid requirements for billing manufacturers for rebates for drugs dispensed to MCO enrollees.

### BACKGROUND

#### Pharmacy and Physician-Administered Drugs

Drugs may be provided to a beneficiary through a pharmacy or administered by a physician in an office or a hospital. Pharmacy drugs are typically billed to Medicaid using National Drug Codes (NDCs). A valid NDC is a unique identifier that represents a drug's specific manufacturer, product, and package size. Physician-administered drugs are typically billed to the Medicaid program on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes.<sup>2</sup> Each HCPCS code may have more than one NDC.

#### 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.

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<sup>1</sup> 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.

<sup>2</sup> HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

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.<sup>3</sup> 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 NDC, unit type, units per package size, and product name.

Section 1903(i)(10) of the Act prohibits Federal reimbursement for States that do not capture the information necessary for billing manufacturers for rebates as described in section 1927 of the Act. To bill 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, usually in return for a predetermined periodic payment known as a capitation payment. States pay MCOs for each covered individual regardless of whether the enrollee received services during the relevant time period (42 CFR § 438.2). MCOs use the capitation payments to pay provider claims for these services. Capitation payments may cover outpatient drugs, which include both pharmacy and physician-administered drugs.

To claim Federal reimbursement, States report capitation payments made to MCOs as MCO expenditures on the Form CMS-64. These expenditures are not identified by specific type of service (such as pharmacy or 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 Pharmacy and Physician-Administered Drugs**

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 and 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. NDCs were more readily available for pharmacy drug claims because providers used NDCs to bill for pharmacy drugs.

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<sup>3</sup> Section 1927(b) of the Act and section II of the Medicaid rebate agreement.

The DRA amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs for all single-source and top-20 multiple-source drugs.<sup>4</sup> 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).<sup>5</sup> 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.<sup>6</sup> 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)<sup>7</sup> 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 includes drug utilization data, which States must include when billing manufacturers for rebates.

### **The State Agency's Medicaid Drug Rebate Program**

The State agency, which is responsible for billing and collecting Medicaid drug rebates for both pharmacy and physician-administered drugs, contracted with Conduent State Healthcare, LLC (the contractor), during our audit period to manage its drug rebate program. However, during most of our audit period, the State agency conducted most of those duties. Officials at the State agency utilized a drug rebate application system (Drug Rebate Analysis and Management System) to calculate rebate amounts. State agency officials prepared invoices, collected rebate payments, maintained accounts receivable, and resolved disputes with manufacturers. The contractor was responsible for operating and maintaining the drug rebate system and mailing invoices to manufacturers. The State agency did not start billing manufacturers for rebates related to physician-administered drugs until 2013, at which time they began retroactively billing for claims back to 2010. According to State agency officials, during 2014 the State agency transitioned some of these duties to the contractor. At that time, the contractor

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<sup>4</sup> 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)).

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

<sup>6</sup> Section 1927(k)(7) of the Act. According to the definition of "therapeutic equivalence" in the FDA glossary of terms, a therapeutically equivalent drug product can be substituted with another product to achieve the same clinical effect as the prescribed drug.

<sup>7</sup> 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).



assumed responsibility for calculating rebate amounts, issuing invoices to the manufacturers, and working with manufacturers to resolve any unpaid rebates. The State agency continued to maintain the accounts receivable information and collect the rebate payments.

## **HOW WE CONDUCTED THIS AUDIT**

We reviewed pharmacy and physician-administered drug claims that were paid by the MCOs between March 23, 2010, through December 31, 2014 (audit period). We limited our audit of physician-administered drugs to HCPCS codes listed on CMS's Medicare Part B Crosswalk.<sup>8</sup> We used the crosswalk to identify the NDCs associated with each HCPCS code and used the CMS Medicaid Drug File to determine whether the NDCs were classified as single-source or multiple-source drugs. Additionally, we determined whether the HCPCS codes were published in CMS's top-20 multiple-source drug listing. We identified drugs that had not been billed by the State agency and worked with the State agency to calculate the amount of rebates that would have been collected from manufacturers had it billed them for the drugs.

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 fully comply with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs dispensed to MCO enrollees. The State agency properly billed manufacturers for all pharmacy rebates and some rebates for physician-administered drugs; however, the State agency did not bill for and collect from manufacturers rebates for 70,131 claim lines totaling at least \$1,465,773 (\$1,065,764 Federal share). In addition, the State agency did not bill for rebates for 183,859 claim lines totaling at least \$170,674 (\$124,097 Federal share) for other physician-administered drugs that may have been eligible for rebates. These errors occurred because the State agency's internal controls did not always ensure that it billed manufacturers to secure rebates and because the State agency did not always collect the utilization data necessary to bill the manufacturers.

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<sup>8</sup> The Medicare Part B Crosswalk is published quarterly by CMS and is based on published drug and biological pricing data and information submitted to CMS by manufacturers. It contains the payment amounts that will be used to pay for Part B covered drugs as well as the HCPCS codes associated with those drugs. 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.

## **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)(C)). Federal regulations prohibit Federal reimbursement for such drugs unless the States require 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 bill for rebates, States must include information for drugs dispensed to individuals enrolled in MCOs when billing 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 requires its MCOs to meet all Federal and State requirements related to pharmacy rebates and submit all necessary information as directed by the State agency. The State agency stated that its system edit rejects any claims submitted with blank NDCs.

Appendix C contains Federal and State requirements related to Medicaid drug rebates.

## **THE STATE AGENCY DID NOT BILL MANUFACTURERS FOR SOME REBATES FOR DRUGS DISPENSED THROUGH MEDICAID MANAGED-CARE ORGANIZATIONS**

The State agency did not bill for and collect from manufacturers some rebates for physician-administered drugs dispensed to MCO enrollees:

- For drugs that were eligible for rebates, the State agency did not bill for and collect rebates for 44,790 claim lines, amounting to at least \$1,239,129 (\$900,971 Federal share) for single-source and top-20 multiple-source physician-administered drugs. The claim lines associated with these drugs contained sufficient drug utilization data to determine the specific drug administered, but we did not have all of the information needed to calculate the rebate amount. The State agency provided the rebate amounts related to 40,831 of these claim lines.
- For drugs that may have been eligible for rebates, the State agency did not bill for and collect rebates totaling at least \$226,644 (\$164,793 Federal share). We identified 25,341 claim lines for non-top-20 multiple-source physician-administered drugs with NDCs. The State agency provided the rebate amounts related to 19,129 of these claim lines. The State agency has sufficient information (such as NDCs) to bill the

manufacturers for rebates for these drugs and, had the State agency billed these claims for rebate, the drug manufacturers would have been required to pay the rebates. However, since these drugs were non-top-20 multiple-source physician-administered drugs with NDCs, the State agency's obligation to bill for rebates for such drugs is unclear. There is no Federal requirement to bill these claims for rebate. Accordingly, we set aside for CMS resolution \$226,644 (\$164,793 Federal share) for these drugs.

In addition, the State agency did not bill for rebates for 183,859 claim lines totaling at least \$170,674 (\$124,097 Federal share) for other physician-administered drugs that may have been eligible for rebates. We determined that the HCPCS codes for these claim lines were HCPCS codes that corresponded with only single-source or top-20 multiple-source physician-administered drugs. The State agency provided rebate information for 11,896 of these claims. However, the State agency did not provide us sufficient drug utilization data (e.g., no NDCs were available) to determine the specific drug administered and the amount of rebates due for the remaining claims. Therefore, we set aside for CMS resolution the claim lines for these physician-administered drugs.

## **RECOMMENDATIONS**

We recommend that the New Mexico Human Services Department:

- bill for and collect manufacturers' rebates for the 44,790 claim lines related to single-source and top-20 multiple-source physician-administered drugs that we calculated to be at least \$1,239,130 (\$900,971 Federal share) and refund the Federal share of rebates collected;
- work with CMS to determine whether the 25,341 claim lines related to non-top-20 multiple-source physician-administered drugs that we calculated to be at least \$226,644 (\$164,793 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;
- work with CMS to determine whether the other physician-administered drugs, associated with 183,859 claim lines and rebates of at least \$170,674 (\$124,097 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 internal controls to ensure that all eligible physician-administered drugs are billed for rebate; and
- ensure that all pharmacy and physician-administered drugs eligible for rebates after our audit period are processed for rebates.

## STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

### STATE AGENCY COMMENTS

In written comments on our draft report, the State agency partially concurred with our findings. In its partial concurrence with our findings, the State agency indirectly addressed our first three recommendations; it did not address whether it concurred with the last two recommendations.

The State agency said that it has billed manufacturers for rebates totaling \$1,465,773 for single-source and multiple-source physician-administered drug claims and \$170,671 for other physician-administered drugs that may have been eligible for rebates. The State agency said that it would return the Federal share of the rebates as they are collected.

The State agency disagreed that some claim lines could be billed for rebates for various reasons. The State agency said that (1) the manufacturer did not have a rebate agreement with CMS to participate in the Medicaid drug rebate program on the paid date of the claim; (2) the manufacturer no longer had a rebate agreement with CMS to participate in the Medicaid drug rebate program; (3) the CMS Drug Inclusion code was set to "Never," and the drug was not on the current quarter tape received from CMS, which identifies manufacturer product and pricing information; (4) the provider listed on the claim was identified on the Ineligible Provider list<sup>9</sup> on the service date of the claim; and (5) the Medicaid paid amount on the claim was zero dollars.

The State agency neither concurred nor denied that additional claims/lines contained sufficient information to bill manufacturers for drug rebates. The State agency said that it will continue to review the claims to determine whether there is sufficient information for it to bill manufacturers for rebates accordingly.

Additionally, the State agency said that it will issue a letter of direction to its contracted MCOs outlining requirements to ensure that drug claims contain a valid NDC.

We have included the State agency's comments in their entirety in Appendix D.

### OFFICE OF INSPECTOR GENERAL RESPONSE

Regarding the State agency's response that the manufacturer did not have a rebate agreement with CMS on the paid date of the claim or that the manufacturer no longer has a rebate agreement with CMS, a manufacturer in the Medicaid drug rebate program must enter into a rebate agreement and pay rebates for States to receive Federal funding for drugs dispensed to Medicaid patients (the Act § 1927(a)). If the manufacturer participated in the drug rebate program when the drug was purchased, the manufacturer is obligated to pay a rebate.

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<sup>9</sup> The Ineligible Provider list is the list the State agency compiles in order to exclude certain providers from the rebate process.

Therefore, we maintain the validity of our recommendation that the State agency work with CMS to determine whether these claims are eligible for rebates.

Regarding the State agency's response that the CMS Drug Inclusion code is set to "Never" and the drug is not on the current quarter tape received from CMS, we agree that these claims should be excluded from rebate.

Regarding the State agency's response that it could not bill manufacturers for rebates because providers were on the Ineligible Provider list, we acknowledge that claims billed by ineligible providers should be exempt from the rebate process. However, based on conversations with State officials during our audit, we have concerns there may be providers inappropriately included on the State's Ineligible Provider list. Therefore, the State agency should ensure that their Ineligible Provider list only includes entities that should be exempt. The State agency should then verify that the claims it exempted from the rebate process were from ineligible providers and invoice rebates for any of the claims that were not from ineligible providers.

Regarding the State agency's response that the Medicaid paid amount for the claim was zero dollars, we had multiple conversations with the State agency to identify and remove zero-dollar claims. However, we agree that zero-dollar claims should be excluded from rebate.

Regarding the State agency's comment that it will continue to review the claims to determine whether there is sufficient information to bill the rebates, we remind the State agency of the requirement to collect the necessary information to bill manufacturers for rebates (the Act § 1927(a)(7)). Not having the required information does not exempt the State agency from the obligation to return the Federal share for rebates owed. We maintain the validity of our recommendation to work with CMS to resolve these issues.

The State agency did not address our last two recommendations, and we reiterate that the State agency should implement those recommendations.

## **APPENDIX A: AUDIT SCOPE AND METHODOLOGY**

### **SCOPE**

We reviewed drug utilization data for both pharmacy and physician-administered drug claims that were paid by the MCOs between March 23, 2010, and December 31, 2014.

We determined which drugs were eligible or may have been eligible for rebates and submitted the claims that we identified as requiring a rebate but were not billed to the State agency. The State agency provided the drug utilization data needed to calculate rebate amounts for some of the claims we submitted. We used this information to determine the amount that the State agency would have collected from manufacturers had it billed them for the drugs.

Our audit objective did not require an understanding or assessment of the complete internal control structure of the State agency. We limited our internal control review to obtaining an understanding of the State agency's processes for and controls over billing for Medicaid rebates for pharmacy and physician-administered drugs.

We conducted our audit work, which included contacting the State agency in Santa Fe, New Mexico, from October 2015 through November 2020. The audit experienced significant delays because of the time it took for the State agency and the State contractor to provide documentation and address questions.

### **METHODOLOGY**

To accomplish our objective, we:

- reviewed Federal laws, regulations, and guidance pertaining to the Medicaid drug rebate program for both pharmacy and physician-administered drugs;
- reviewed State agency policies and procedures for rebates for pharmacy and physician-administered drugs and the State agency managed-care contract;
- interviewed State agency personnel to gain an understanding of the administration of and controls over the Medicaid rebate billing process for pharmacy and physician-administered drugs;
- obtained lists of the CMS top-20 multiple-source physician-administered drugs, the Medicare Part B crosswalks, and the CMS Medicaid Drug Files for our audit period;
- identified and removed pharmacy and physician-administered drug claims not eligible for rebate as part of the drug rebate program;
- identified MCO drug utilization data for physician-administered drugs not billed for

rebates and identified the drugs that were eligible or may have been eligible for rebates by identifying:

- single-source and top-20 multiple-source physician-administered drugs that were eligible for rebates,
- non-top-20 multiple-source physician-administered drugs that may have been eligible for rebates, and
- 183,859 claim lines for other physician-administered drugs that may have been eligible for rebates;
- followed up with State officials for explanation of eligible claims that were not billed for rebate;
- worked with the State to determine the amount of rebates not collected; and
- discussed the results of our audit with State agency officials.

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**

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>Massachusetts Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-06-18-04001</u></a>	10/22/2020
<i>Minnesota Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-05-17-00018</u></a>	10/21/2020
<i>Vermont Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs</i>	<a href="#"><u>A-07-19-06086</u></a>	9/18/2020
<i>Maine Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs</i>	<a href="#"><u>A-07-18-06079</u></a>	9/14/2020
<i>Michigan Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-05-17-00017</u></a>	8/25/2020
<i>Alaska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-09-19-02001</u></a>	7/21/2020
<i>New York Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-02-18-01016</u></a>	4/7/2020
<i>New Jersey Did Not Bill Manufacturers for Tens of Millions of Dollars in Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-02-16-01011</u></a>	8/30/2019
<i>New York Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-02-18-01011</u></a>	2/19/2020
<i>Texas Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-06-17-04001</u></a>	8/21/2019
<i>Connecticut Claimed Unallowable Federal Reimbursement for Medicaid Physician-Administered Drugs That Were Not Invoiced to Manufacturers for Rebates</i>	<a href="#"><u>A-07-18-06078</u></a>	8/16/2019
<i>Illinois Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-05-18-00030</u></a>	6/18/2019
<i>New Jersey Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-02-16-01012</u></a>	5/09/2019
<i>Indiana Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-05-17-00038</u></a>	4/05/2019
<i>Arizona Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-09-16-02031</u></a>	2/16/2018
<i>Arkansas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-06-16-00018</u></a>	2/12/2018



<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>Nebraska Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#">A-07-13-06046</a>	12/22/2017
<i>Texas Did Not Bill Manufacturers for Some Rebates for Pharmacy Drugs of Medicaid Managed-Care Organizations</i>	<a href="#">A-06-16-00004</a>	12/12/2017
<i>Ohio Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-05-16-00013</a>	11/1/2017
<i>Washington State Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care</i>	<a href="#">A-09-16-02028</a>	9/26/2017
<i>Hawaii Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#">A-09-16-02029</a>	9/26/2017
<i>Nevada Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#">A-09-16-02027</a>	9/12/2017
<i>Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs of Medicaid Managed-Care Organizations</i>	<a href="#">A-07-16-06065</a>	5/5/2017
<i>Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-05-16-00014</a>	3/23/2017
<i>Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-07-14-06050</a>	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>	<a href="#">A-03-15-00202</a>	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>	<a href="#">A-03-15-00201</a>	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>	<a href="#">A-09-15-02035</a>	12/8/2016
<i>Kansas Correctly Invoiced Rebates to Manufacturers for Most Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#">A-07-15-06060</a>	8/18/2016
<i>Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-07-14-06057</a>	5/26/2016
<i>Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician- Administered Drugs</i>	<a href="#">A-07-15-06063</a>	3/31/2016
<i>South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-07-15-06059</a>	2/09/2016

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<a href="#">A-07-15-06062</a>	1/14/2016
<i>North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<a href="#">A-07-15-06058</a>	1/13/2016
<i>California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<a href="#">A-09-14-02038</a>	1/07/2016
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<a href="#">A-07-14-06056</a>	9/18/2015
<i>States' Collection of Rebates for Drugs Paid Through Medicaid Managed Care Organizations Has Improved</i>	<a href="#">OEI-05-14-00431</a>	9/16/2015
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-07-14-06049</a>	7/22/2015
<i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-06-12-00060</a>	5/04/2015
<i>Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-07-14-06051</a>	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 href="#">A-09-13-02037</a>	3/04/2015
<i>Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<a href="#">A-06-14-00031</a>	2/10/2015
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-03-12-00205</a>	8/21/2014
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-07-13-06040</a>	8/07/2014
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-09-12-02079</a>	4/30/2014
<i>Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<a href="#">A-09-12-02080</a>	4/24/2014
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-03-12-00200</a>	11/26/2013
<i>Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<a href="#">A-06-12-00059</a>	9/19/2013

Report Title	Report Number	Date Issued
<i>States' Collection of Rebates for Drugs Paid Through Medicaid Managed Care Organizations</i>	<a href="#">OEI-03-11-00480</a>	9/07/2012
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	<a href="#">OEI-03-09-00410</a>	6/24/2011

## APPENDIX C: FEDERAL AND STATE REQUIREMENTS RELATED TO PHARMACY AND PHYSICIAN-ADMINISTERED DRUGS

### FEDERAL REQUIREMENTS

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 the Federal share in State expenditures for these drugs.

The Medicaid drug rebate program, created by the Omnibus Budget Reconciliation Act of 1990 (which added section 1927 to the Act), became effective on January 1, 1991. A manufacturer 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 (such as J-codes and NDCs) 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.<sup>10</sup> Section 1927(a)(7)(C) of the Act states 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 for 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.

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<sup>10</sup> 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)).

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

#### **STATE REQUIREMENT**

Section 4.10.2.10.8 of the State agency's contract with MCOs states that the contractor shall meet all Federal and State requirements related to pharmacy rebates and submit all necessary information as directed by the State agency.

## APPENDIX D: STATE AGENCY COMMENTS



March 5, 2021

Meagan Summers  
Office of Inspector General, Office of Audit Services, Region VI  
U.S. Department of Health and Human Services  
1100 Commerce Street, Room 632  
Dallas, TX 75242

Re: A-06-16-00001 Drug Rebate Audit

Dear Ms. Summers:

This letter is in response to the U.S. Department of Health and Human Services (DHHS), Office of Inspector General (OIG), Office of Audit Services (OAS) preliminary findings of the Drug Rebate Audit A-06-00001.

As of the date of this response, the New Mexico Human Services Department, Medical Assistance Division (collectively referred to as “the State”) has billed manufacturers for rebates totaling \$1,465,773.44 for single-source and multiple-source physician administered drug claims reviewed by the DHHS/OIG/OAG. Additionally, of the 183,859 claims/lines for which a Healthcare Common Procedure Coding System (HCPCS) code may result in identification of a valid National Drug Code (NDC), the State has billed manufacturers for rebates totaling \$170,670.73. The State has determined the source resulting in delayed billing for rebates to be due to missing or invalid NDC(s) on claims paid by Managed Care Organizations (MCOs). The State will issue a letter of direction to its contracted MCOs outlining requirements to ensure drug claims contain a valid NDC. The State addresses each finding in further detail below.

**“For drugs that were eligible for rebates, the State agency did not bill for and collect rebates for 44,790 claim lines, amounting to at least \$1,239,129 (\$900,971 Federal share) for single-source and top-20 multiple-source physician-administered drugs.”**

The State, in part, concurs with this finding. At the end of the second quarter of calendar year 2019, the State invoiced manufacturers for 40,831 claim lines of single source and top-20 multiple-source physician administered drugs equating to a rebate value of \$1,239,129.79. Since that time, the state has invoiced for an additional 15 claim lines. As rebates are collected, the State will return to CMS the federal share.

Of the remaining 3,944 claim lines, the State does concur that a valid NDC existed on 843 of the claim lines to bill for rebates, however, the State disagrees that these claim lines could be properly billed for rebates due to one of the following reasons:

- 20 claim lines - Manufacturer did not have a contract with CMS to participate in the Medicaid Drug Rebate Program (MDRP) on the paid date of the claim;
- 60 claim lines - Manufacturer no longer has a contract with CMS to participate in the MDRP;
- 65 claim lines - The CMS Drug Inclusion code is set to “Never” and the drug is not on the current quarter tape received from CMS which identifies manufacturer product and pricing information;
- 525 claim lines - The provider listed on the claim was identified on the Ineligible Provider list on the service date of the claim; and
- 173 claim lines - The Medicaid paid amount on the claim was zero dollars.

With regards to the remaining 3,101 claim lines, the State neither concurs nor denies that these claims lines contained sufficient information to bill manufacturers for drug rebates. The State continues to review these claim lines to determine, whether sufficient information exists and it can bill manufacturers for rebates accordingly.

**“For drugs that may have been eligible for rebates, the State agency did not bill for and collect rebates totaling at least \$226,644 (\$164,793 Federal share). We identified 25,341 claim lines for non-top-20 multiple-source physician-administered drugs with NDCs.”**

The State, in part, concurs with this finding. At the end of the second quarter of calendar year 2019, the State invoiced for 19,129 claim/lines for non-top 20 multiple-source physician administered drugs with NDCs for a total rebate value of \$ 226,643.65. Since that time, the state has invoiced for an additional 52 claims lines. As rebates are collected, the State will return to CMS the federal share.

Of the remaining 6,160 claim lines the State does concur that sufficient information existed to invoice for drug rebates on 1,156 claim lines, however, the State disagrees that these claim lines could be properly billed for rebates due to one of the following reasons:

- 13 claim lines - Manufacturer did not have a contract with CMS to participate in the MDRP on the paid date of the claim;
- 40 claim lines - Labeler no longer has a contract with CMS to participate in the MDRP;
- 395 claim lines - The CMS Drug Inclusion code is set to “Never” and the drug is not on the current quarter tape received from CMS;
- 676 claim lines - The provider listed on the claim was identified on the Ineligible Provider list on the service date of the claim; and
- 32 claim lines - The Medicaid paid amount on the claim was zero dollars.

With regards to the remaining 5,004 claim/lines, the State neither concurs nor denies that these claims/lines contained sufficient information to bill manufacturers for drug rebates. The State continues to review the claims to determine, whether sufficient information exists and it can bill manufacturers for rebates accordingly.

**“In addition, the State agency did not bill for rebates for 183,859 claim lines totaling at least \$170,674 (\$124,097 Federal share) for other physician-administered drugs that may have been eligible for rebates. We determined that the HCPCS codes for these claim lines were HCPCS codes**

that corresponded with only single-source or top-20 multiple-source physician administered drugs. The State agency provided rebate information for 11,896 of these claims. However, the State agency did not provide us sufficient drug utilization data (e.g., no NDCs were available) to determine the specific drug administered and the amount of rebates due for the remaining claims. Therefore, we set aside for CMS resolution the claim lines for these physician-administered drugs.”

As indicated in the report, the State invoiced and billed for 11,896 claim lines at the end of the second quarter in calendar year 2019. The rebate value totaled \$170,673.73. While the State concurs that an additional and separate review of the remaining claim lines can be conducted to determine whether the associated HCPCS codes for these claim lines corresponds with a valid NDC, at this time the State is discussing the level of effort necessary to undertake such a review. The State will continue further discussions and plan accordingly.

We appreciate the work completed by DHHS/OIG/OAS and the open lines of communication with New Mexico staff throughout this audit. If you have any questions or comments about our response to the audit, please contact Julie Lovato, Compliance Officer, at (505) 795-1661 or through email at [julie.lovato@state.nm.us](mailto:julie.lovato@state.nm.us).

Sincerely,



Nicole Comeaux, JD, MPH  
Medicaid Director

cc: David Scrase, Cabinet Secretary, Human Services Department  
Kari Armijo, Deputy Cabinet Secretary, Human Services Department  
Angela Medrano, Deputy Cabinet Secretary, Human Services Department  
Danny Sandoval, Chief Financial Officer, Human Services Department  
Megan Pfeffer, Deputy Director, Medical Assistance Division  
Lorelei Kellogg, Deputy Director, Medical Assistance Division  
Linda Gonzales, Deputy Director, Medical Assistance Division  
Elisa Walker-Moran, Deputy Director, Medical Assistance Division  
Julie Lovato, Compliance Officer, Medical Assistance Division