

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**NEVADA DID NOT BILL
MANUFACTURERS FOR SOME REBATES
FOR 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 2017
Report No. A-09-16-02027

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



Why OIG Did This Review

Previous OIG reviews 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 Nevada complied with Federal Medicaid requirements for billing manufacturers for rebates for drugs dispensed to MCO enrollees.

How OIG Did This Review

We reviewed drug utilization data for both physician-administered and pharmacy drugs for Nevada's two MCOs from April 2010 through June 2011.

We identified MCO drug utilization data for drugs that were billed for rebates and tested the rebates billed by selecting 30 National Drug Codes (NDCs) associated with 22 manufacturers and reviewing copies of rebate invoices submitted to manufacturers to verify the billing of rebates by NDC. We also identified drugs that were not billed for rebates but were eligible for rebates and requested that Nevada's contractor estimate the amount of uncollected rebates. We reviewed these estimates to determine whether they were reasonable. Finally, we identified claim lines for other drugs that may have been eligible for rebates.

Nevada Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations

What OIG Found

When Nevada billed manufacturers for rebates for physician-administered and pharmacy drugs, it did so correctly. However, Nevada estimated that it did not bill for rebates of \$520,137 (\$327,624 Federal share) for physician-administered and pharmacy drugs that were eligible for rebates. In addition, Nevada did not bill for rebates for 19,650 claim lines for other physician-administered and pharmacy drugs that may have been eligible for rebates. Because there was insufficient information to determine the amount of any rebates that may have been due, we set aside these claim lines for resolution by the Centers for Medicare & Medicaid Services (CMS). Nevada's internal controls did not ensure that it billed for and collected rebates for all drugs dispensed to MCO enrollees.

What OIG Recommends and Nevada Comments

We recommend that Nevada (1) bill for and collect from manufacturers rebates for physician-administered and pharmacy drugs that were eligible for rebates and refund to the Federal Government the estimated \$327,624 (Federal share); (2) work with CMS to determine the amount of any rebates due for the 19,650 claim lines that we set aside and refund the Federal share of rebates collected; (3) determine which physician-administered and pharmacy drugs were not billed for rebates after our audit period, determine the rebates due, and upon receipt of the rebates, refund the Federal share of the rebates collected; and (4) strengthen its internal controls to ensure that it bills for and collects from manufacturers rebates for all physician-administered and pharmacy drugs dispensed to MCO enrollees.

Nevada concurred with our first, third, and fourth recommendations and partially concurred with our second recommendation. Specifically, Nevada disagreed with the number of claim lines we set aside for our audit period. However, Nevada stated that it was reviewing all claim lines regardless of whether they were within the audit period to determine whether the utilization was eligible for rebates from manufacturers. After reviewing Nevada's comments, we adjusted the number of set-aside claim lines to reflect our audit period.

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INTRODUCTION

WHY WE DID THIS REVIEW

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. States bill the manufacturers for rebates to reduce the cost of drugs to the program. However, previous Office of Inspector General (OIG) reviews 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). (Appendix A lists previous OIG reports related to the Medicaid drug rebate program.¹) For this audit, we reviewed the Nevada Department of Health and Human Services' (State agency's) billing of rebates for both physician-administered and pharmacy 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

Physician-Administered and Pharmacy Drugs

Drugs may be administered by a physician in an office or a hospital or provided to a beneficiary through a pharmacy. Physician-administered drugs are typically billed to Medicaid on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes.² 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.

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 manufacturer must enter into a rebate agreement administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. Manufacturer rebates are essentially shared between the States and the Federal Government to offset the cost of prescription drugs. CMS, the States, and drug manufacturers each have specific functions under the program.

¹ We performed similar reviews for rebates due for drugs administered by physicians to fee-for-service enrollees. These reviews are included in this appendix.

² 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.³ On the basis of this information, CMS calculates a unit rebate amount for each drug and provides these amounts 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(a)(7) of the Act. To bill for rebates, States must use drug utilization data that identify, by NDC, the number of units of each drug for which the States reimbursed Medicaid providers. The States must capture these drug utilization data 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.

States report drug rebate accounts receivable data to CMS on the Medicaid Drug Rebate Schedule. This schedule is part of the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program report (Form CMS-64), which contains a summary of actual Medicaid expenditures for each quarter and is used by CMS to reimburse States for the Federal share of Medicaid expenditures.

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 receives services during the relevant time period (42 CFR § 438.2). MCOs use the capitation payments to pay claims for these services. Capitation payments may cover outpatient drugs, which include both physician-administered and pharmacy 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 physician-administered drugs or pharmacy drugs). States must report adjustments to drug expenditures and drug rebates on the Form CMS-64. The expenditures, adjustments, and rebates do not distinguish between amounts related to physician-administered drugs and amounts related to pharmacy drugs.

States' Collection of Rebates for Physician-Administered and Pharmacy 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

³ The Act § 1927(b) and the Medicaid rebate agreement (§ II).

manufacturers and facilitate the collection of rebates for the drugs. Before the Deficit Reduction Act of 2005, 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.

The Deficit Reduction Act of 2005 amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs. Federal reimbursement for covered outpatient drugs administered by a physician is not available to States that do not comply with Federal requirements for capturing NDCs to bill and collect rebates.

Effective March 23, 2010, the Patient Protection and Affordable Care Act (ACA)⁴ requires manufacturers to pay rebates on covered outpatient drugs dispensed to MCO enrollees if the MCOs are responsible for coverage of such drugs. States typically require MCOs to submit NDCs to the State for covered outpatient drugs dispensed to eligible individuals. States must include the drug utilization data reported by MCOs when billing manufacturers for rebates. Physician-administered and pharmacy drugs dispensed to MCO enrollees are recorded in MCO drug utilization data on claim lines.

The State Agency's Medicaid Drug Rebate Program

In Nevada, the State agency is responsible for billing and collecting Medicaid drug rebates for both physician-administered and pharmacy drugs. The State agency uses a contractor to manage its drug rebate program.⁵ The contractor bills manufacturers by NDC for rebates, and the State agency collects the payments for every quarter.

Beginning September 29, 2011, the State agency required its two MCOs to submit drug utilization data for physician-administered and pharmacy drugs. The MCOs submit these data to the contractor, which uses the data to bill for drug rebates.

HOW WE CONDUCTED THIS REVIEW

We reviewed the Form CMS-64 and determined that the State agency paid MCOs \$405,623,955 (\$253,976,891 Federal share) for the period April 1, 2010, through June 30, 2011 (audit period). This total included expenditures for physician-administered and pharmacy drugs. We reviewed drug utilization data for both physician-administered and pharmacy drugs for Nevada's two MCOs for the audit period.

We identified physician-administered and pharmacy drugs billed for rebates by matching the MCO drug utilization data against the State agency's invoiced drug data. We tested the rebates

⁴ 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. 30, 2010).

⁵ Magellan Health Services Inc. was the State agency's contractor during the audit period.

billed by selecting 30 NDCs associated with 22 manufacturers and reviewing copies of rebate invoices submitted to manufacturers to verify the billing of rebates by NDC.

For the MCO drug utilization data that could not be matched against the invoiced drug data, we (1) identified physician-administered and pharmacy drugs that were not billed for rebates but were eligible for rebates and (2) requested that the State agency's contractor estimate the amount of uncollected rebates. We reviewed these estimates to determine whether they were reasonable. However, for 19,650 claim lines for other physician-administered and pharmacy drugs that may have been eligible for rebates, there was insufficient information to determine the amount of any rebates that may have been due.

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 contains the details of our audit scope and methodology.

FINDING

During our audit period, the State agency did not fully comply with Federal Medicaid requirements for billing manufacturers for rebates for drugs dispensed to MCO enrollees. The State agency properly billed manufacturers for some rebates for physician-administered drugs and pharmacy drugs.⁶ However, the State agency estimated that it did not bill for and collect from manufacturers rebates of \$520,137 (\$327,624 Federal share) for physician-administered and pharmacy drugs that were eligible for rebates. In addition, the State agency did not bill for rebates for 19,650 claim lines for other physician-administered and pharmacy drugs that may have been eligible for rebates. Because there was insufficient information to determine the amount of any rebates that may have been due, we set aside the claim lines for CMS resolution.

The State agency's internal controls did not ensure that the State agency billed for and collected rebates for all physician-administered and pharmacy drugs dispensed to MCO enrollees.

FEDERAL AND STATE REQUIREMENTS

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)).

⁶ These drugs were associated with the 30 NDCs that we selected for review.

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)).

Federal regulations prohibit Federal reimbursement for physician-administered drugs unless the States require the submission of claims containing NDCs (42 CFR § 447.520).

In a contract amendment dated September 29, 2011, the State agency required its MCOs to submit drug utilization data for both physician-administered and pharmacy drugs with NDCs with dates of service effective April 1, 2010.

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 and pharmacy drugs dispensed to MCO enrollees:

- The State agency estimated that it did not bill for and collect rebates of \$520,137 (\$327,624 Federal share) for physician-administered and pharmacy drugs that were eligible for rebates. We determined this estimate to be reasonable.
- The State agency did not bill for rebates for 19,650 claim lines for other physician-administered and pharmacy drugs that may have been eligible for rebates. Because there was insufficient information to determine the amount of any rebates that may have been due, we set aside these claim lines for CMS resolution.

The State agency's internal controls did not ensure that it billed for and collected rebates for all physician-administered and pharmacy drugs dispensed to MCO enrollees. The State agency did not bill for some claims with valid NDCs during the audit period but could not explain to us why it did not.

RECOMMENDATIONS

We recommend that the State agency:

- bill for and collect from manufacturers rebates for physician-administered and pharmacy drugs that were eligible for rebates and refund to the Federal Government the estimated \$327,624 (Federal share);

- work with CMS to determine the amount of any rebates due for the 19,650 claim lines that we set aside and refund the Federal share of rebates collected;
- determine which physician-administered and pharmacy drugs were not billed for rebates after our audit period, determine the rebates due, and upon receipt of the rebates, refund the Federal share of the rebates collected; and
- strengthen its internal controls to ensure that it bills for and collects from manufacturers rebates for all physician-administered and pharmacy drugs dispensed to MCO enrollees.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency concurred with our first, third, and fourth recommendations and partially concurred with our second recommendation:

- Regarding our first recommendation, the State agency commented that it had initiated the billing and collection of rebates for physician-administered and pharmacy drugs that were eligible for rebates. The State agency also commented that this effort is ongoing and that it will refund the Federal share of the manufacturers' rebates for these invoiced claims once the rebates have been received.
- Regarding our second recommendation, the State agency commented that only 19,650 of the 36,757 claim lines that we set aside in our draft report were from the audit period. The State agency also commented that, regardless of whether the claim lines were within the audit period, the State agency was reviewing them to determine whether the utilization was eligible for rebates. The State agency said that, to date, it has determined that 29,238 of the 36,757 claim lines were not eligible for rebates. Further, the State agency said that the remaining 7,519 claim lines are still under review. The State agency also said that any claims eligible for rebates will be invoiced to the manufacturers and that it will refund the Federal share of the rebates.
- Regarding our third recommendation, the State agency commented that it is reviewing claims outside of the audit period and that all claims identified as eligible for rebates will be invoiced to the manufacturers. The State agency also commented that it will refund the Federal share of the manufacturers' rebates for these invoiced claims once the rebates have been received.
- Regarding our fourth recommendation, the State agency commented that it is currently implementing a new Medicaid Management Information System, which, when fully implemented, will ensure that all claims that the MCOs report to the State agency are passed on to the rebate vendor.

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

OFFICE OF INSPECTOR GENERAL RESPONSE

Regarding our second recommendation, we agree with the State agency that only 19,650 claim lines were within our audit period. Therefore, we adjusted the number of set-aside claim lines to reflect our audit period.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs of Medicaid Managed-Care Organizations</i>	<u>A-07-16-06065</u>	5/5/2017
<i>Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-16-00014</u>	3/23/2017
<i>Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06050</u>	1/5/2017
<i>Delaware Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-03-15-00202</u>	12/30/2016
<i>Virginia Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-03-15-00201</u>	12/22/2016
<i>California Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Some Medicaid Managed-Care Organizations</i>	<u>A-09-15-02035</u>	12/8/2016
<i>Kansas Correctly Invoiced Rebates to Manufacturers for Most Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-07-15-06060</u>	8/18/2016
<i>Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06057</u>	5/26/2016
<i>Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06063</u>	3/31/2016
<i>South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06059</u>	2/9/2016
<i>Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06062</u>	1/14/2016

Report Title	Report Number	Date Issued
<i>North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06058</u>	1/13/2016
<i>California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<u>A-09-14-02038</u>	1/7/2016
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06056</u>	9/18/2015
<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
<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

Report Title	Report Number	Date Issued
<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>	5/6/2011

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed the Form CMS-64 and determined that the State agency paid MCOs \$405,623,955 (\$253,976,891 Federal share) for the period April 1, 2010, through June 30, 2011. We reviewed drug utilization data for both physician-administered and pharmacy drugs for Nevada's two MCOs for that period.

We identified MCO drug utilization data for physician-administered and pharmacy drugs that were billed for rebates and tested the rebates billed by selecting 30 NDCs associated with 22 manufacturers and reviewing copies of rebate invoices submitted to manufacturers to verify the billing of rebates by NDC. We also identified MCO drug utilization data for physician-administered and pharmacy drugs that were not billed for rebates but were eligible for rebates and requested that the State agency's contractor estimate the amount of uncollected rebates. We reviewed these estimates to determine whether they were reasonable. Finally, we identified claim lines for other physician-administered and pharmacy drugs that may have been eligible for rebates.

Our audit objective did not require an understanding or assessment of the complete internal 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 and collection of Medicaid rebates for physician-administered and pharmacy drugs.

We conducted our audit from April to November 2016, which included fieldwork performed at the State agency office in Carson City, Nevada.

METHODOLOGY

To accomplish our objective, we:

- reviewed Federal laws, regulations, and guidance related to the Medicaid drug rebate program for both physician-administered and pharmacy drugs;
- reviewed State guidance to providers and MCOs, including billing instructions for physician-administered and pharmacy drugs;
- reviewed State agency policies and procedures related to rebates for physician-administered and pharmacy drugs;
- interviewed MCO personnel to gain an understanding of the MCOs' roles and responsibilities for submitting drug utilization data to the State agency;

- interviewed State agency and contractor personnel to gain an understanding of the administration of and controls over the Medicaid billing and rebate process for physician-administered and pharmacy drugs;
- reviewed drug expenditures reported on the State agency's Form CMS-64 for the audit period;
- obtained from the 2 MCOs the drug utilization data for physician-administered and pharmacy drugs for the audit period;
- excluded from our review certain MCO drug utilization data for physician-administered and pharmacy drugs not eligible for rebates;
- identified MCO drug utilization data for physician-administered and pharmacy drugs billed for rebates and tested the rebates billed by:
 - selecting 30 NDCs associated with 22 manufacturers⁷ and
 - reviewing copies of rebate invoices submitted to manufacturers to verify the billing of rebates by NDC;
- identified MCO drug utilization data for physician-administered and pharmacy drugs not billed for rebates and identified drugs that were eligible for rebates;
- obtained from the State agency's contractor an estimate of the uncollected rebate for each drug eligible for a rebate and determined the total estimated amount of uncollected rebates;
- reviewed the methodology that the State agency's contractor used to calculate the estimate and determined whether the estimate and methodology were reasonable;
- identified 19,650 claim lines for other physician-administered and pharmacy drugs that may have been eligible for rebates;⁸ and
- discussed the results of our review with State agency officials.

⁷ To select the 30 NDCs, we sorted the claim data by date of service and selected NDCs from the first 2 claim lines of each month for 15 months.

⁸ For these claim lines, there was insufficient information to determine the amount of any rebates that may have been due.

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 C: FEDERAL AND STATE REQUIREMENTS RELATED TO MEDICAID DRUG REBATES

FEDERAL LAWS

Under the Medicaid program, States may provide coverage for outpatient drugs as an optional service (the Act § 1905(a)(12)). The Act provides for Federal financial participation (Federal share) in State expenditures for these drugs (§ 1903(a)).

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)). Manufacturer rebates are essentially shared between the States and the Federal Government to offset the cost of prescription drugs (the Act § 1927(b)(1)(B)). Responsibility for the drug rebate program is shared among the drug manufacturers, CMS, and the States.

Section 6002 of the Deficit Reduction Act of 2005 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 Deficit Reduction Act amended section 1903(i)(10) of the Act to prohibit a Medicaid Federal share for covered outpatient drugs administered by a physician unless the States submit the utilization and coding data described in section 1927(a)(7) of the Act.

States must collect utilization and coding data necessary to secure rebates for certain physician-administered drugs (the Act § 1927(a)(7)). Effective January 1, 2007, the utilization data must be submitted using NDCs (the Act § 1927(a)(7)(C)). To bill for 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. 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, payment is prohibited unless the MCO contracts provide that the Medicaid rebate obligations apply to drugs dispensed through MCOs and require the MCOs to submit to the State the drug utilization by NDCs for drugs dispensed to eligible individuals.

FEDERAL REGULATIONS

Federal regulations set conditions for States to obtain a Federal share for covered outpatient drugs administered by a physician and specifically state that no Federal share is available for physician-administered drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to bill a manufacturer for rebates (42 CFR § 447.520).

STATE GUIDANCE

In a contract amendment dated September 29, 2011, the State agency required its MCOs to submit drug utilization data for both physician-administered and pharmacy drugs with NDCs with dates of service effective April 1, 2010.

APPENDIX D: STATE AGENCY COMMENTS

BRIAN SANDOVAL
Governor



RICHARD WHITLEY, MS
Director

MARTA JENSEN
Administrator

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August 22, 2017

Report Number: A-09-16-02027

Ms. Lori A. Ahlstrand
Regional Inspector General
Office of Audit Services, Region IX
San Francisco, CA 94103

Dear Ms. Ahlstrand:

The Department of Health and Human Services (DHHS), Division of Health Care Financing and Policy (DHCFP) has reviewed the Office of Inspector General (OIG) report entitled *Nevada Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations*. Below is each recommendation and the Division's statement of concurrence.

We recommend that the State agency:

- 1) *Bill for and collect from manufacturers rebates for physician-administered and pharmacy drugs that were eligible for rebates and refund to the Federal Government the estimated \$327,624 (Federal share);*

The State concurs and initiated the billing and collection of rebates for physician-administered and pharmacy drugs that were eligible for rebates while the audit was ongoing. To date the State's rebate vendor has invoiced \$ 163,796 (estimated Federal share is \$103,171) of the \$520,139 (\$327,624 estimated Federal share). This effort is ongoing and the State will refund the Federal share of the manufacturers' rebates for these invoiced claims once the rebates are received from the manufacturers.

- 2) *Work with Centers for Medicare & Medicaid Services (CMS) to determine the amount of any rebates due for the 36,757 claim lines that we set aside and refund the Federal share of rebates collected;*

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The State partially concurs. The State agrees there are 36,757 claims that were set aside, however it appears only 19,650 are from the audit period. Regardless if the claims are within the audit period or not, the State is reviewing to determine if the utilization was eligible for rebates from the manufacturers. To date it has been determined 29,238 of the 36,757 contain a National Drug Code (NDC) not on the CMS Unit Rebate Amount (URA) file for the quarter the claim is assigned. A sample of the 29,238 claims reviewed revealed they were for products such as diabetic testing supplies, bulk powders used for compounded drugs, Over the Counter (OTC) items, etc. While these products may not be eligible for rebates, they are items typically covered by Managed Care Organizations (MCOs). The remaining 7,519 claims are under review and any claims eligible for rebate will be invoiced to the manufacturers and the State will refund the Federal share of the manufacturers' rebates for these invoiced claims once the rebates are received from the manufacturers.

- 3) *Determine which physician-administered and pharmacy drugs were not billed for rebates after our audit period, determine the rebates due, and upon receipt of the rebates, refund the Federal share of the rebates collected;*

The State concurs, issues identified during the OIG audit impact claims outside of the audit period and as such the rebate vendor is reviewing claims potentially impacted and all claims identified as eligible for rebate will be invoiced to the manufacturers and the State will refund the Federal share of the manufacturers' rebates for these invoiced claims once the rebates are received from the manufacturers.

- 4) *Strengthen its internal controls to ensure that it bills for and collects from manufacturers rebates for all physician-administered and pharmacy drugs dispensed to MCO enrollees.*

The State concurs, as noted in the audit, the State requires MCOs to include the NDC when submitting drug utilization data for both physician-administered and pharmacy drugs. The State is currently in the process of implementing a new Medicaid Management Information System (MMIS). Once the new MMIS system is fully implemented, MCO utilization used for invoicing rebates will be sent to the rebate vendor from the MMIS instead of directly from the MCOs. This change provides the State with direct control over the utilization used in rebate invoicing and ensures all claims reported to the State by the MCO are passed on to the rebate vendor.

If you have any questions or comments regarding the responses to this report, please do not hesitate to contact me or DuAne Young, Chief of Behavioral Health and Pharmacy Services, at (775) 687-8413 or through email at d.young@dncfp.nv.gov.

Sincerely,



Marta Jensen
Administrator

Cc: Richard Whitley, Director DHHS
Shannon Sprout, Deputy Administrator DHCFP
DuAne Young, Chief, Behavioral Health and Pharmacy Services, DHCFP

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