

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**NEW JERSEY DID NOT BILL
MANUFACTURERS FOR TENS OF
MILLIONS OF DOLLARS IN
REBATES FOR 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: August 2019

Report No. A-02-16-01011

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



Why OIG Did This Review

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 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 New Jersey 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 pharmacy and physician-administered drugs for New Jersey's MCOs from January 1, 2014, through December 31, 2016.

We identified MCO drug utilization data for drugs billed for rebates and tested the rebates billed by selecting 29 National Drug Codes (NDCs) associated with 22 manufacturers and reviewed supporting documentation. We also identified these data for pharmacy and physician-administered drugs that were not billed for rebates and determined which drugs were eligible or may have been eligible for rebates. For these drugs, we estimated the amount of rebates that New Jersey could have collected if it had billed these drugs for rebates.

New Jersey Did Not Bill Manufacturers for Tens of Millions of Dollars in Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations

What OIG Found

New Jersey did not fully comply with Federal Medicaid requirements for billing manufacturers for rebates for drugs dispensed to MCO enrollees. Specifically, New Jersey did not bill for and collect from manufacturers estimated rebates of \$75.5 million (Federal share) for pharmacy and physician-administered drugs that were eligible or may have been eligible for rebates for our audit period. For drugs that were eligible for rebates, New Jersey did not bill for estimated rebates of \$28.1 million (Federal share) for single-source and top-20 multiple-source pharmacy and physician-administered drugs. For drugs that may have been eligible for rebates, New Jersey did not bill for estimated rebates of \$47.4 million (Federal share) for other pharmacy and physician-administered drugs. New Jersey did not always bill for and collect from manufacturers rebates because it did not have a system edit to ensure that NDCs were submitted for physician-administered drugs before January 1, 2015. Even after New Jersey implemented the edit on January 1, 2015, this edit did not ensure that NDCs or valid NDCs were captured for all physician-administered drugs.

Additionally, using data for our audit period, we estimated that the State agency did not bill for and collect \$119.6 million (Federal share) in drug rebates from manufacturers for the nearly 4-year period before our audit period.

What OIG Recommends and New Jersey Comments

We recommend that New Jersey (1) bill for and collect from manufacturers rebates for single-source and top-20 multiple-source pharmacy and physician-administered drugs and refund the estimated \$28.1 million (Federal share); and (2) work with CMS to determine whether the other pharmacy and physician-administered drugs were eligible for rebates and, if so, upon receipt of the rebates, refund up to an estimated \$47.4 million (Federal share) for our audit period and \$119.6 million (Federal share) for the nearly 4-year period before our audit period. We also made procedural recommendations.

In written comments on our draft report, New Jersey concurred with our findings, agreed with our recommendations, and described corrective actions it had taken or planned to take to address them.

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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 B lists previous OIG reports related to the Medicaid drug rebate program.)¹ For this audit, we reviewed the New Jersey Department of Human Services' (State agency's) billing of 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.² 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 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 OIG performed similar reviews for rebates due for drugs administered by physicians to fee-for-service enrollees. These reviews are also listed in Appendix B.

² HCPCS codes are used throughout the healthcare industry to standardize coding for medical procedures, services, products, and supplies.

Manufacturers are required to submit a list of all covered outpatient drugs to CMS and to report each drug's average manufacturer price and, where applicable, best price.³ Based on this information, CMS calculates a unit rebate amount for each drug (i.e., each NDC) 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 invoicing manufacturers for rebates as described in section 1927(a)(7) of the Act. To invoice for rebates, States must use drug utilization data that identify, by NDC, the number of units⁴ 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 enrollees receive services during the relevant time (42 CFR § 438.2). MCOs use the capitation payments to pay 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). States must report adjustments to drug expenditures and drug rebates on the Form CMS-64. These expenditures, adjustments, and rebates do not distinguish between amounts related to pharmacy drugs and amounts related to physician-administered drugs.

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

⁴ NDC units are expressed in metric units (e.g., grams or milliliters).

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 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 claim did not contain NDCs. NDCs were more readily available for pharmacy drug claims because providers used NDCs to bill for pharmacy drugs.

The DRA amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs for all single-source drugs and the top 20 multiple-source drugs.⁵ 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).⁶ Multiple-source drugs are defined, in part, as those covered outpatient drugs that have at least one other drug rated as therapeutically equivalent by FDA.⁷ 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 Patient Protection and Affordable Care Act (ACA)⁸ 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. Pharmacy and physician-administered drugs dispensed to MCO enrollees are recorded in MCO drug utilization data on claim lines.

The State Agency's Medicaid Drug Rebate Program

In New Jersey, the State agency is responsible for billing and collecting Medicaid drug rebates for both pharmacy and physician-administered drugs. According to State agency officials, as of January 1, 2015, the State agency implemented an edit to the computer system (system edit) responsible for capturing claims data. The system edit was designed to ensure that all

⁵ The term "top 20 multiple-source drugs" is drawn from a CMS classification and describes these drugs in terms of highest dollar volume of physician-administered drugs in Medicaid (the Act § 1927(a)(7)(B)(i)).

⁶ Section 1927(k)(7) of the Act. Single-source drugs are commonly referred to as "brand-name" drugs.

⁷ 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. Available online at <http://www.fda.gov/drugs/informationondrugs/ucm079436.htm>. Accessed on June 19, 2018.

⁸ 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).

physician-administered drug claims contained NDCs.⁹ The State agency uses its claim utilization data for physician-administered drugs, which it derives from claims submitted by MCOs, to invoice manufacturers on a quarterly basis. The manufacturers then pay the rebates directly to the State agency. During calendar years 2014 through 2016, New Jersey's five MCOs served approximately 1.6 million Medicaid beneficiaries.

HOW WE CONDUCTED THIS REVIEW

We reviewed drug utilization data for both pharmacy and physician-administered drugs for New Jersey's MCOs from January 1, 2014, through December 31, 2016 (audit period).

We identified MCO drug utilization data for pharmacy and physician-administered drugs that were billed for rebates and tested the rebates billed by selecting 29 NDCs associated with 22 manufacturers and reviewing the supporting documentation. We also identified MCO drug utilization data for pharmacy and physician-administered drugs that were not billed for rebates and determined which drugs were eligible or may have been eligible for rebates. We estimated the amount of rebates that the State agency could have collected if it had billed these drugs for rebates.¹⁰

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 drugs dispensed to MCO enrollees. The State agency properly billed manufacturers for rebates for some pharmacy and physician-administered drugs.¹¹ However, the State agency did not bill for and collect from manufacturers estimated rebates of \$138,347,944 (\$75,530,290 Federal share) for pharmacy and physician-administered drugs that were eligible or may have been eligible for rebates.

⁹ State agency officials stated that, before January 1, 2015, they did not invoice manufacturers for rebates for physician-administered drugs. According to the officials, the MCO claims did not contain reliable data required for invoicing physician-administered drugs (e.g., NDC and metric quantity). The officials also stated that, as of April 30, 2018, invoicing for rebates on some physician-administered drugs was not being submitted.

¹⁰ We calculated the amount of rebate due for each drug's HCPCS code using the median rebate amount and estimated the total amount of rebates that the State agency could have collected.

¹¹ These drugs were associated with the 29 NDCs that we selected for review.

The State agency did not always bill for and collect from manufacturers rebates because it did not have a system edit to ensure that NDCs were submitted for physician-administered drugs before January 1, 2015. However, even after implementing an edit, the State agency did not ensure that NDCs were captured for all physician-administered drugs. Additionally, the State agency did not provide OIG a copy of its written policies for rebating physician-administered drugs. In response to a recent OIG report, the State agency stated that it is working on a manual for the drug rebate program that will include all the necessary policies and procedures. Without this manual, we could not determine the State agency's ability to implement the Federal requirement of inclusion of NDCs on all claims.

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 physician-administered 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)).

New Jersey requires physicians to report the NDC, quantity of the drug administered or dispensed, and a two-digit qualifier identifying the unit of measure for the medication on the claim when requesting Medicaid reimbursement (Title 10 § 54-8.4(d) of the New Jersey Administrative Code). 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 pharmacy and physician-administered drugs dispensed to MCO enrollees:

- For drugs that were eligible for rebates, we estimated that the State agency did not bill for and collect rebates of \$49,694,519 (\$28,103,346 Federal share). This amount consisted of \$48,875,659 (\$27,684,951 Federal share) for single-source drugs and \$818,860 (\$418,394 Federal share) for top-20 multiple-source pharmacy and physician-administered drugs.
- For drugs that may have been eligible for rebates, we estimated that the State agency did not bill for and collect rebates of \$88,653,425 (\$47,426,944 Federal share) for other pharmacy and physician-administered drugs, some of which did not have NDCs. Because the drugs' HCPCS codes could not be used to determine whether the drugs were required to be billed for rebates, we set aside for CMS resolution the estimated \$88,653,425 (\$47,426,944 Federal share) for these drugs.

As a result, the State agency did not bill for and collect from manufacturers estimated rebates of \$138,347,944 (\$75,530,290 Federal share) for pharmacy and physician-administered drugs that were eligible or may have been eligible for rebates for our audit period.

Using data for our audit period, we estimated that the State agency did not bill for and collect \$266,059,265 (\$119,561,574 Federal share) in drug rebates from manufacturers for the nearly 4-year period prior to our audit period.¹²

THE STATE AGENCY DID NOT HAVE A SYSTEM EDIT TO ENSURE THAT NATIONAL DRUG CODES WERE PRESENT IN THE DRUG UTILIZATION DATA

The State agency did not always bill manufacturers for rebates because it did not have a system edit for the first year of our audit period to ensure that NDCs were present in the MCO drug utilization data for physician-administered drugs. Although the State agency required MCOs to submit drug utilization data for physician-administered drugs with NDCs, the State agency stated that it did not implement an NDC edit until January 1, 2015. Even after the State agency implemented the edit, this edit did not ensure that NDCs were captured for all physician-administered drugs. In addition, the State agency did not provide any written policies or procedures for rebating physician-administered drugs. Therefore, we could not determine its ability to implement the Federal requirement of inclusion of NDCs on all claims. As a result, the State agency did not collect some rebates for physician-administered drugs dispensed to MCO enrollees.

¹² Specifically, we estimated uncollected rebates for the period April 1, 2010, through December 31, 2013, because the requirement for manufacturers to pay rebates became effective March 23, 2010.

RECOMMENDATIONS

We recommend that the State agency:

- bill for and collect from manufacturers rebates for single-source and top-20 multiple-source pharmacy and physician-administered drugs and refund to the Federal Government the estimated \$28,103,346 (Federal share);
- work with CMS to determine whether the other pharmacy and physician-administered drugs were eligible for rebates and, if so, upon receipt of rebates collected, refund up to an estimated \$47,426,944 (Federal share) for our audit period and \$119,561,574 (Federal share) for the nearly 4-year period before our audit period;
- strengthen its NDC edit (implemented on January 1, 2015), to ensure that NDCs are captured for all drug utilization data;
- develop and implement written policies and procedures for its drug rebate program; and
- ensure that all pharmacy and physician-administered drugs eligible for rebates after our audit period are processed for rebates.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency concurred with our findings, agreed with our recommendations, and described corrective actions it had taken or planned to take to address them.

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

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed drug utilization data for both pharmacy and physician-administered drugs for New Jersey's MCOs from January 1, 2014, through December 31, 2016.

We identified MCO drug utilization data for pharmacy and physician-administered drugs that were billed for rebates and tested the rebates billed by selecting 29 NDCS associated with 22 manufacturers and reviewing the supporting documentation. We also identified MCO drug utilization data for pharmacy and physician-administered drugs that were not billed for rebates and determined which drugs were eligible or may have been eligible for rebates.

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 and collection of Medicaid rebates for pharmacy and physician-administered drugs.

We conducted our fieldwork at the State agency's offices in Trenton, New Jersey.

METHODOLOGY

To accomplish our objective, we:

- reviewed Federal laws, regulations, and guidance related to the Medicaid drug rebate program for both pharmacy and physician-administered drugs;
- reviewed State guidance to MCOs, including billing instructions for pharmacy and physician-administered drugs;
- interviewed State agency personnel to gain an understanding of the MCOs' roles and responsibilities for submitting drug utilization data to the State agency;
- interviewed State agency personnel to gain an understanding of the administration of and controls over the Medicaid billing and rebate process for pharmacy and physician-administered drugs;
- obtained from the State agency the Medicaid drug utilization data for pharmacy and physician-administered drugs for the audit period;
- excluded from our review certain MCO drug utilization data for pharmacy and physician-administered drugs not eligible for rebates;

- identified MCO drug utilization data for pharmacy and physician-administered drugs billed for rebates and tested the rebates billed by:
 - selecting 29 NDCs associated with 22 manufacturers¹³ and
 - reviewing copies of rebate invoices submitted to manufacturers to verify the billing of rebates by NDC;
- identified MCO drug utilization data for pharmacy and 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 and
 - identifying other pharmacy and physician-administered drugs that may have been eligible for rebates;¹⁴
- estimated the amount of rebates in the audit period that the State agency could have potentially collected for single-source, top-20 multiple-source, and other pharmacy and physician-administered drugs if it had billed these drugs for rebates;¹⁵
- estimated the amount of potentially uncollected rebates for the nearly 4-year period before our audit period;^{16, 17} and

¹³ These NDCs represented drugs that had high payment amounts.

¹⁴ Some of the drugs' HCPCS codes could not be used to determine whether the drugs were required to be billed for rebates.

¹⁵ For utilization data where the NDC was available, we calculated the potential amount of uncollected rebates by multiplying the number of drug units reported in the utilization data by the unit rebate amount for each associated NDC. We also used this portion of the utilization data to calculate the median rebate amount associated with each HCPCS code. For the utilization data where the NDC was not available, we estimated the potential amount of uncollected rebates by using the median rebate amounts for each HCPCS code that were calculated in the previous step.

¹⁶ See footnote 12.

¹⁷ We estimated the potentially uncollected rebate amount for each quarter of the prior period by adjusting the quarterly average that we calculated using the first three quarters of 2014 by the annual growth in Medicaid spending on prescriptions. Our source for the annual growth in Medicaid spending on prescriptions was a Kaiser Family Foundation analysis of CMS National Health Expenditure Accounts. (Available online at <https://www.kff.org/medicaid/issue-brief/snapshots-of-recent-state-initiatives-in-medicaid-prescription-drug-cost-control/>. Accessed on February 20, 2019.)

- discussed the results of our review 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

Report Title	Report Number	Date Issued
<i>Illinois Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-18-00030</u>	6/18/19
<i>New Jersey Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-02-16-01012</u>	5/09/19
<i>Indiana Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-17-00038</u>	4/05/19
<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>	2/16/18
<i>Arkansas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-06-16-00018</u>	2/12/18
<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>	12/22/17
<i>Texas Did Not Bill Manufacturers for Some Rebates for Pharmacy Drugs of Medicaid Managed-Care Organizations</i>	<u>A-06-16-00004</u>	12/12/17
<i>Ohio Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-16-00013</u>	11/01/17
<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>	9/26/17
<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>	9/26/17
<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>	9/12/17
<i>Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs of Medicaid Managed-Care Organizations</i>	<u>A-07-16-06065</u>	5/05/17
<i>Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-16-00014</u>	3/23/17

Report Title	Report Number	Date Issued
<i>Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06050</u>	1/05/17
<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>	12/30/16
<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>	12/22/16
<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>	12/8/16
<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>	8/18/16
<i>Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06057</u>	5/26/16
<i>Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06063</u>	3/31/16
<i>South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06059</u>	2/09/16
<i>Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06062</u>	1/14/16
<i>North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06058</u>	1/13/16
<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>	1/07/16
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06056</u>	9/18/15
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06049</u>	7/22/15
<i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-06-12-00060</u>	5/04/15

Report Title	Report Number	Date Issued
<i>Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06051</u>	4/13/15
<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>	3/04/15
<i>Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<u>A-06-14-00031</u>	2/10/15
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00205</u>	8/21/14
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-13-06040</u>	8/07/14
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	<u>A-09-12-02079</u>	4/30/14
<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>	4/24/14
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00200</u>	11/26/13
<i>Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<u>A-06-12-00059</u>	9/19/13
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	<u>A-06-10-00011</u>	8/12/11
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	<u>OEI-03-09-00410</u>	6/24/11

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 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 States to provide for the collection and submission of such utilization data and coding (such as HCPCS and NDCs) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug 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. Section 1927(a)(7)(C) of the Act stated that, effective January 1, 2007, the utilization data must be submitted using NDCs. 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. 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).

Federal regulations in effect during most of our audit period defined a brand-name drug as a single-source or innovator multiple-source drug and, in a relevant part, a multiple-source drug as a covered outpatient drug for which there is at least one other drug product that is rated as therapeutically equivalent (42 CFR § 447.502).¹⁸

STATE REQUIREMENT

Title 10 § 54-8.4(d) of the New Jersey Administrative Code requires physicians to report the 11-digit NDC, quantity of the drug administered or dispensed, and a 2-digit qualifier identifying the unit of measure for the medication on the claim when requesting Medicaid reimbursement. The regulation further states that the labeler and drug product codes of the actual product dispensed must be reported on the claim form.

¹⁸ On November 15, 2010, CMS amended 42 CFR § 447.502 to remove the definition of “multiple-source drug” (75 Fed. Reg. 69591, 69592).

APPENDIX D: STATE AGENCY COMMENTS



State of New Jersey

DEPARTMENT OF HUMAN SERVICES
PO Box 700
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PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

CAROLE JOHNSON
Commissioner

July 8, 2019

Brenda M. Tierney
Regional Inspector General for Audit Services
Office of Inspector General
U.S. Department of Health and Human Services
Office of Audit Services, Region II
Jacob K. Javits Federal Building
26 Federal Plaza, Room 3900
New York, NY 10278

Dear Ms. Tierney:

The New Jersey Department of Human Services (Department) is in receipt of the draft audit report issued by the U.S. Department of Health and Human Services' Office of Inspector General (OIG) entitled "*New Jersey Did Not Bill Manufacturers for Tens of Millions of Dollars in Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations*" for the period of January 1, 2014 through December 31, 2016. Thank you for the opportunity to respond to the draft report.

Please accept the following responses to OIG's recommendations:

OIG Recommendation

Bill for and collect from manufacturers rebates for single-source and top-20 multiple-source pharmacy and physician-administered drugs and refund to the Federal Government the estimated \$28.1 million (federal share).

Response

As you may know, administrative leadership of the Department changed in 2018. The Department concurs with OIG's finding that for the audit period January 1, 2014 through December 31, 2016, the Department should have invoiced manufacturers for rebates for certain single-source and top-20 multiple-source pharmacy and physician-administered drugs. The Department will process and collect the rebates for the claims identified by OIG.

The Department is obtaining the necessary information from the managed care organizations (MCOs) to invoice manufacturers for drug rebates for eligible claims identified in the audit. The

Department will work with the Centers for Medicare and Medicaid Services (CMS) to identify claims eligible for rebate, invoice the claims to manufacturers, and remit the federal share of rebates to CMS.

OIG Recommendation

Work with CMS to determine whether the other pharmacy and physician-administered drugs were eligible for rebates and, if so, upon receipt of rebates collected, refund up to an estimated \$47.4 million (federal share) for our audit period and \$119.6 million (federal share) for the nearly 4-year period before our audit period.

Response

As noted above, administrative leadership of the Department changed in 2018. The Department concurs with OIG's finding that for the audit period January 1, 2014 through December 31, 2016, the Department should determine whether other pharmacy and physician-administered drugs were eligible for rebates and refund any federal share upon collection.

The Department also will review the other pharmacy and physician-administered drug claims from the four-year period prior to the audit period, meaning 2010 to 2014, to determine if they are eligible for rebates and if so, invoice and collect the drug rebates receipts and refund the federal share in the next fiscal year.

OIG Recommendation

Strengthen its NDC edit (implemented on January 1, 2015), to ensure that NDCs are captured for all drug utilization data.

Response

The Department and its fiscal agent instituted an edit in early 2017 to deny encounter claims that did not include an NDC. The Department will work with our fiscal agent to review the current logic in the NJMMIS claims processing system to ensure that NDCs for all eligible pharmacy and physician-administered drug claims are captured for drug utilization data and invoiced for rebates. We are working with the MCOs to reinforce what is required for the drug rebate program.

OIG Recommendation

Develop and implement written policies and procedures for its drug rebate program.

Response

The Department concurs with this recommendation. The Department is working on a manual for the drug rebate program that will include all necessary policies and procedures for both pharmacy and physician-administered drug rebates.

OIG Recommendation


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

Response

The Department concurs with OIG's recommendation. All eligible pharmacy and physician-administered drugs for claims after the audit period will be processed for rebates.

Thank you again for the opportunity to review and respond to the OIG's draft audit report.

Sincerely,



Carole Johnson
Commissioner

c: Sarah Adelman, Deputy Commissioner
Carol Grant, Acting Director, Division of Medical Assistance and Health Services
Richard Hurd, Chief of Staff, Division of Medical Assistance and Health Services