

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**NEW YORK DID NOT BILL
MANUFACTURERS FOR SOME REBATES
FOR DRUGS DISPENSED TO
ENROLLEES OF MEDICAID
MANAGED-CARE ORGANIZATIONS**

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April 2020
A-02-18-01016

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: April 2020

Report No. A-02-18-01016

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 York complied with Federal Medicaid requirements for billing manufacturers for rebates for drugs dispensed to MCO enrollees.

How OIG Did This Audit

We reviewed drug utilization data for both pharmacy and physician-administered drugs dispensed to enrollees of New York Medicaid MCOs from January 2015 through December 2017.

We identified 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 York could have collected if it had billed these drugs for rebates.

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

What OIG Found

New York did not fully comply with Federal Medicaid requirements for billing manufacturers for rebates for drugs dispensed to MCO enrollees. Specifically, New York did not bill for and collect from manufacturers estimated rebates of more than \$10.8 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 York did not bill for estimated rebates of \$7.8 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 York did not bill for estimated rebates of \$3 million (Federal share) for other pharmacy and physician-administered drugs. Although its policies and procedures require the collection of drug utilization data necessary to invoice for rebates on all claims, New York's internal controls did not always ensure that the data were used to invoice manufacturers to secure rebates.

What OIG Recommends and New York Comments

We recommend that New York (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 \$7.8 million (Federal share); (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 \$3 million (Federal share) of rebates collected; and (3) strengthen its internal controls to ensure that all pharmacy and physician-administered drugs eligible for rebates are invoiced.

In written comments on our draft report, New York partially agreed with our recommended refund, agreed with our second and third recommendations, and described corrective actions it has taken or planned to take to address them. New York also provided corrected figures for calculating rebates for several drugs as well as information related to rebates it already collected and for drug claims not eligible for reimbursement. After reviewing New York's comments and the additional data provided, we revised our findings and related recommendations accordingly. We maintain that our findings and recommendations, as revised, are valid.

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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. States bill the manufacturers for rebates to reduce the cost of drugs to the program. However, previous Office of Inspector General (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). (Appendix B lists previous OIG reports related to the Medicaid drug rebate program.)¹ For this audit, we reviewed the New York State Department of Health's (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

¹ OIG performed similar audits for rebates due for drugs administered by physicians to fee-for-service enrollees. These audits 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.

to offset the cost of prescription drugs. CMS, the States, and drug manufacturers each have specific functions under the program.

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 identifies, by the 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,

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).

and rebates do not distinguish between amounts related to pharmacy drugs and amounts related to physician-administered drugs.

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 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 York, the State agency is responsible for billing and collecting Medicaid drug rebates for both pharmacy and physician-administered drugs. The State agency uses its claim utilization

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 October 30, 2019.

⁸ P.L. No. 111-148 (Mar. 23, 2010), as amended by the Healthcare and Education Reconciliation Act of 2010, P.L. No. 111-152 (Mar. 30, 2010).

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 2015 through 2017, New York's MCOs served approximately 4.5 million Medicaid beneficiaries.

HOW WE CONDUCTED THIS AUDIT

We reviewed drug utilization data for both pharmacy and physician-administered drugs for New York's MCOs from January 1, 2015, through December 31, 2017 (audit period).

We 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.⁹

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. However, the State agency did not bill for and collect from manufacturers estimated rebates of \$21.1 million (\$10.8 million Federal share) for pharmacy and physician-administered drugs that were eligible or may have been eligible for rebates. Although the State agency's policies and procedures require the collection of drug utilization data necessary to invoice for rebates, its internal controls did not always ensure that the data were used to invoice manufacturers to secure rebates.

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

⁹ 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.

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 York requires physicians to report the NDC, quantity of the drug administered or dispensed, and the unit of measure for the medication on the claim when requesting Medicaid reimbursement (*New York State Medicaid Update*, October 2008, volume 24, number 11, and August 2013, volume 29, number 9).

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 \$15.2 million (\$7.8 million¹⁰ Federal share). This amount consisted of \$14.7 million (\$7.6 million Federal share) for single-source drugs and \$432,098 (\$223,116 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 \$5.9 million (\$3 million¹¹ 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 \$5.9 million (\$3 million Federal share) for these drugs.

¹⁰ The total was \$7,846,147.

¹¹ The total was \$3,039,473.

As a result, the State agency did not bill for and collect from manufacturers estimated rebates of \$21.1 million (\$10.8 million Federal share) for pharmacy and physician-administered drugs that were eligible or may have been eligible for rebates for our audit period.

Although the State agency's guidance required MCOs to submit drug utilization data for physician-administered drugs with NDCs, its internal controls did not always ensure that the data contained sufficient information (e.g., claim information) to be used to invoice manufacturers to secure rebates. Specifically, the State agency did not receive sufficient NDC information for all physician-administered drugs; therefore, it did not bill and collect some rebates for some of these drugs dispensed to MCO enrollees.

RECOMMENDATIONS

We recommend that the New York State Department of Health:

- 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 \$7,846,147 (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 the rebates, refund up to an estimated \$3,039,473 (Federal share) of rebates collected; and
- strengthen its internal controls to ensure that all pharmacy and physician-administered drugs eligible for rebates are invoiced.

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the State agency partially agreed with our first recommendation (refund), agreed with our second and third recommendations, and described corrective actions it has taken or planned to take to address them. Such actions included the State agency securing an independent contractor to administer its drug rebate program to ensure that drugs eligible for rebates are invoiced.

Regarding our recommended refund, the State agency asserted that estimated uncollected drug rebates identified in our draft report should be reduced. The State agency provided the following reasons for this reduction: (1) it discovered that the calculation of uncollected rebates included incorrect conversion factors for several single-source drugs, (2) it identified NDCs for which it had previously invoiced manufacturers for rebates, and (3) it identified drug claims for certain plan types that were not eligible for rebate. Under separate cover, the State agency provided additional information to support these assertions. Finally, the State agency indicated that it will invoice for the drug rebates referenced in this audit and refund the Federal share of the collected rebates as appropriate.

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

After reviewing the State agency's comments and the additional information provided, we revised our findings and related recommendations by recalculating rebate amounts for claims with incorrect NDC figures, removing claims that were identified as invoiced, and removing plan types that were ineligible for rebate. We maintain that our findings and recommendations, as revised, are valid.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed drug utilization data for both pharmacy and physician-administered drugs for New York's MCOs from January 1, 2015, through December 31, 2017.

We 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 Albany, New York.

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 Medicaid Data Warehouse the drug utilization data for pharmacy and physician-administered drugs for the audit period;
- excluded from our audit 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 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;¹²
- 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;¹³ 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.

¹² Some of the drugs' HCPCS codes could not be used to determine whether the drugs were required to be billed for rebates.

¹³ 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 using the median rebate amounts for each HCPCS code that were calculated in the previous step.

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>New York Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-02-18-01011</u>	2/19/2020
<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>	<u>A-02-16-01011</u>	8/30/2019
<i>Texas Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-06-17-04001</u>	8/21/2019
<i>Connecticut Claimed Unallowable Federal Reimbursement for Medicaid Physician-Administered Drugs That Were Not Invoiced to Manufacturers for Rebates</i>	<u>A-07-18-06078</u>	8/16/2019
<i>Illinois Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-18-00030</u>	6/18/2019
<i>New Jersey Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-02-16-01012</u>	5/09/2019
<i>Indiana Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-17-00038</u>	4/05/2019
<i>Arizona Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-16-02031</u>	2/16/2018
<i>Arkansas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-06-16-00018</u>	2/12/2018
<i>Nebraska Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-07-13-06046</u>	12/22/2017
<i>Texas Did Not Bill Manufacturers for Some Rebates for Pharmacy Drugs of Medicaid Managed-Care Organizations</i>	<u>A-06-16-00004</u>	12/12/2017
<i>Ohio Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-16-00013</u>	11/01/2017
<i>Washington State Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-16-02028</u>	9/26/2017

Report Title	Report Number	Date Issued
<i>Hawaii Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-09-16-02029	9/26/2017
<i>Nevada Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-09-16-02027	9/12/2017
<i>Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs of Medicaid Managed-Care Organizations</i>	A-07-16-06065	5/05/2017
<i>Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-05-16-00014	3/23/2017
<i>Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-14-06050	1/05/2017
<i>Delaware Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-03-15-00202	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-03-15-00201	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-09-15-02035	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-07-15-06060	8/18/2016
<i>Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-14-06057	5/26/2016
<i>Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-15-06063	3/31/2016
<i>South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-15-06059	2/09/2016
<i>Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	A-07-15-06062	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>	1/07/2016
<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>	5/04/2015
<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>	3/04/2015
<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>	8/07/2014
<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
<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

Report Title	Report Number	Date Issued
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	A-06-10-00011	8/12/2011
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	OEI-03-09-00410	6/24/2011

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).¹⁴

STATE REQUIREMENT

The State agency requires physicians to report the 11-digit NDC, quantity of the drug administered or dispensed, and the unit of measure for the medication on the claim when requesting Medicaid reimbursement. The State agency's guidance further states that reimbursement is limited to drugs for which manufacturers have a signed rebate agreement with CMS (*New York State Medicaid Update*, October 2008, volume 24, number 11, and August 2013, volume 29, number 9).

¹⁴ 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



**Department
of Health**

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

January 13, 2020

Ms. Brenda Tierney
Regional Inspector General for Audit Services
Department of Health and Human Services - Region II
Jacob Javits Federal Building
26 Federal Plaza
New York, New York 10278

Ref. No: **A-02-18-01016**

Dear Ms. Tierney:

Enclosed are the New York State Department of Health's comments on the United States Department of Health and Human Services, Office of Inspector General's Draft Audit Report **A-02-18-01016** entitled, "New York Did Not Bill Manufacturers for Over \$24 Million in Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations."

Thank you for the opportunity to comment.

Sincerely,

Sally Dreslin, M.S., R.N.
Executive Deputy Commissioner

Enclosure

cc: Marybeth Hefner
Diane Christensen
Elizabeth Misa
Geza Hrazdina
Dan Duffy
Erin Ives
Timothy Brown
Amber Rowan
Brian Kiernan
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**New York State Department of Health
Comments on the Department of Health and Human Services
Office of Inspector General Draft Audit Report A-02-18-01016 entitled,
“New York Did Not Bill Manufacturers for Over \$24 Million in Rebates
for Drugs Dispensed to Enrollees of Medicaid Managed-Care
Organizations”**

The following are the New York State Department of Health’s (Department) comments in response to the Department of Health and Human Services, Office of Inspector General (OIG) Draft Audit Report A-02-18-01016 entitled, “New York Did Not Bill Manufacturers for Over \$24 Million in Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations.”

General Comments:

The Department recognizes the OIG audit process as an opportunity to improve and strengthen policies and procedures. In November 2017, the Department secured an independent contractor to administer the pharmacy rebate program. The contractor has the expertise and systems to handle all concerns raised in this audit and if claims are found to have been missed, the Department will seek to bill where appropriate.

It should be noted that the Department issued invoices totaling \$8.4 billion (gross) during the three-year period covered by this audit for the managed care program. The additional amount that the OIG believes should have been invoiced for during the three-year audit period amounts to roughly one-half of one-percent of invoices issued.

Recommendation #1:

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 \$24,207,285 (Federal share).

Response #1:

The Department will invoice the claims, as appropriate, and upon receipt of the rebates, refund the Federal share of the manufacturers’ rebates for those claims. However, the Department estimated the amount of the single-source and top-20 multiple-source pharmacy and physician-administered drugs refund amount has been overstated and should be reduced by approximately \$16.5 million (Federal share). See the Department’s findings below:

- The Department discovered the physician-administrated drugs single-source calculation of \$7.7 million (Federal share) included incorrect conversion factors for Jcodes J0401, J1267 and J9355. Once updated, the Federal share amount will decrease by \$2.3 million. Please see Attachment A for the “updated conversion factor” spreadsheet with the corrected Jcode/National Drug Code (NDC) combinations. (Attachments contain PHI that will be sent to OIG via a secure link).
- The Department also discovered that pharmacy single-source with NDCs findings, which totals \$16.3 million (Federal share), included claims that we believe should be excluded, decreasing the Federal share amount by \$14.2 million:
 - Our records show several claims included in the OIG findings have already been invoiced and would decrease the Federal share amount by \$7.8 million. Please see

Attachment B for samples of invoices that were sent to manufacturers related to the NDCs and quarters in question. (Attachments contain PHI that will be sent to OIG via a secure link). The Department will review this newly discovered information with The Centers for Medicare and Medicaid Services (CMS).

- Additionally, several other claims included in the single-source with NDC findings are categorized under certain plan types that have traditionally been excluded from the NYS rebate stream because they are dual integrated products, with Medicare covering the pharmacy costs. However, upon further review, only the non-dual Program of All-Inclusive Care for the Elderly enrollee drug claims are eligible for invoicing. Based on this information, this correction decreases the Federal share amount by an additional \$6.4 million. See Attachment C for details. (Attachments contain PHI that will be sent to OIG via a secure link).

Recommendation #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 \$3,039,473 (Federal share) of rebates collected.

Response #2:

The Department will work with CMS to determine whether the other pharmacy and physician administered drugs are eligible for rebates and upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims.

Recommendation #3:

Strengthen its internal controls to ensure that all pharmacy and physician-administered drugs eligible for rebates are invoiced.

Response #3:

The Department has already taken steps to strengthen internal controls and will continue to employ its vendor's expertise and systems to handle all concerns raised in this audit to ensure that drugs eligible for rebates are invoiced.