

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**NEW JERSEY CLAIMED
UNALLOWABLE FEDERAL
REIMBURSEMENT FOR SOME
MEDICAID PHYSICIAN-
ADMINISTERED DRUGS**

*Inquiries about this report may be addressed to the Office of Public Affairs at
Public.Affairs@oig.hhs.gov.*



Gloria L. Jarmon
Deputy Inspector General
for Audit Services

May 2019
A-02-16-01012

Office of Inspector General

<https://oig.hhs.gov>

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at <https://oig.hhs.gov>

Section 8M of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG website.

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: May 2019

Report No. A-02-16-01012

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 reimbursement under the Medicaid program's drug rebate requirements, manufacturers must pay rebates to the States for the drugs. However, a prior OIG review found that States did not always invoice and collect all rebates due for drugs administered by physicians.

Our objective was to determine whether New Jersey complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs.

How OIG Did This Review

Our review covered fee-for-service claims for physician-administered drugs paid between January 2014 and December 2016.

We used the Centers for Medicare & Medicaid Services' (CMS's) Medicare Part B crosswalk and the CMS Medicaid Drug File to identify single-source and multiple-source drugs. Additionally, we determined whether the Healthcare Common Procedure Coding System codes were published in CMS's top-20 multiple-source drug listing.

New Jersey Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs

What OIG Found

New Jersey did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Specifically, New Jersey did not invoice manufacturers for rebates associated with \$8.1 million (Federal share) in single-source and top-20 multiple-source physician-administered drugs. Because New Jersey's internal controls did not always ensure that it invoiced manufacturers to secure rebates, New Jersey improperly claimed Federal reimbursement for these single-source drugs and top-20 multiple-source drugs.

Further, New Jersey did not submit the drug utilization data necessary to secure rebates for other physician-administered drugs. These drugs were included in claims totaling \$7,889 (Federal share) that did not have drug codes and in claims totaling \$1.1 million (Federal share) that contained drug codes.

What OIG Recommends and New Jersey's Comments

We recommend that New Jersey refund to the Federal Government \$8.1 million for single-source and top-20 multiple-source physician-administered drugs and work with CMS to determine the unallowable portion of the \$1.1 million for other drug claims in question. We also made procedural recommendations.

In written comments on our draft report, New Jersey partially concurred with our financial disallowance, concurred with our remaining recommendations, and described corrective actions it planned to take.

Regarding our financial disallowance, New Jersey agreed that it should have invoiced manufacturers for rebates for physician-administered drugs but disagreed with the amount of our recommended refund. After reviewing New Jersey's comments, we maintain that our findings and recommendations are valid. New Jersey stated it will work with CMS to determine the amount owed to the Federal Government.

TABLE OF CONTENTS

| | |
|---|----|
| INTRODUCTION..... | 1 |
| Why We Did This Review | 1 |
| Objective | 1 |
| Background | 1 |
| Medicaid Drug Rebate Program | 1 |
| Physician-Administered Drugs | 2 |
| The State Agency’s Medicaid Drug Rebate Program | 2 |
| How We Conducted This Review | 3 |
| FINDINGS..... | 3 |
| Federal and State Requirements | 4 |
| The State Agency Did Not Invoice Manufacturers for Rebates for Some Single-Source Physician-Administered Drugs | 4 |
| The State Agency Did Not Invoice Manufacturers for Rebates for Some Top-20 Multiple-Source Physician-Administered Drugs..... | 4 |
| The State Agency Did Not Invoice Manufacturers for Rebates for Other Physician-Administered Drugs..... | 5 |
| RECOMMENDATIONS | 5 |
| STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE | 6 |
| APPENDICES | |
| A: Audit Scope and Methodology | 7 |
| B: Related Office of Inspector General Reports..... | 9 |
| C: Federal and State Requirements Related to Physician-Administered Drugs..... | 12 |
| D: State Agency Comments | 14 |

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 for the drugs. States generally offset the Federal share of these rebates against their Medicaid expenditures. States invoice the manufacturers for rebates to reduce the cost of drugs to the program. However, a prior Office of Inspector General review found that States did not always invoice and collect all rebates due for drugs administered by physicians.¹ (Appendix B lists previous reviews of the Medicaid drug rebate program.) For this audit, we reviewed the New Jersey Department of Human Services' (State agency's) invoicing for rebates for physician-administered drugs for the period January 1, 2014, through December 31, 2016.

OBJECTIVE

Our objective was to determine whether the State agency complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs.

BACKGROUND

Medicaid Drug Rebate Program

The Medicaid drug rebate program became effective in 1991 (the Social Security Act (the Act) section 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the drug's manufacturer must enter into a rebate agreement that is administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each have specific functions under the program.

Manufacturers are required to submit a list of all covered outpatient drugs to CMS and to report each drug's average manufacturer price and, where applicable, best price.² On the basis of this information, CMS calculates a unit rebate amount for each drug and provides the information to the States quarterly. Covered outpatient drugs reported by participating drug manufacturers are listed in the CMS Medicaid Drug File, which identifies drugs with such fields as National Drug Code (NDC), unit type, units per package size, and product name.

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 of the Act. To invoice for rebates, States capture drug utilization data that identifies, by NDC, the number of units of each drug for which the States reimbursed Medicaid providers and

¹ *States' Collection of Medicaid Rebates for Physician-Administered Drugs* (OEI-03-09-00410), issued June 24, 2011.

² Section 1927(b) of the Act and section II of the Medicaid rebate agreement.

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 Form CMS-64, Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program, 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.

Physician-Administered Drugs

Drugs administered by a physician are typically invoiced to the Medicaid program on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes.³ For purposes of the Medicaid drug rebate program, physician-administered drugs are classified as either single-source or multiple-source.⁴

The Deficit Reduction Act of 2005 (DRA) amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs for all single-source and the top 20 multiple-source drugs.⁵ 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. Before the DRA, many States did not collect rebates on physician-administered drugs if the drug claims did not contain NDCs. NDCs enable States to identify the drugs and their manufacturers and to facilitate the collection of rebates for the drugs.

The State Agency's Medicaid Drug Rebate Program

The State agency is responsible for paying Medicaid claims, submitting invoices to manufacturers, and collecting Medicaid drug rebates for physician-administered drugs. The State agency also requires physician-administered drug claims to be submitted with the NDC of the product. The State agency uses its claim utilization data for physician-administered drugs, which it derives from claims submitted by providers, to invoice manufacturers quarterly and to maintain a record of rebate accounts receivable due from the manufacturers. The manufacturers then pay the rebates directly to the State agency.

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

⁴ See, e.g., the Act § 1927(a)(7). In general terms, multiple-source drugs are covered outpatient drugs for which there are two or more drug products that are rated therapeutically equivalent by the Food and Drug Administration. See, e.g., the Act § 1927(k)(7). Multiple-source drugs stand in contrast to single-source drugs, which do not have therapeutic equivalents.

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)).

HOW WE CONDUCTED THIS REVIEW

The State agency claimed \$22,826,292 (\$17,525,848 Federal share) for fee-for-service claims for physician-administered drugs paid between January 1, 2014, and December 31, 2016.

We used CMS's Medicare Part B crosswalk to identify, if possible, the NDCs associated with each HCPCS code listed on claims from providers. We then used the CMS Medicaid Drug File to determine whether the identified NDCs were classified as single-source drugs or multiple-source drugs.⁶ Additionally, we determined whether the HCPCS codes were published in CMS's top-20 multiple-source drug listing.

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

The State agency did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. The State agency did not invoice manufacturers for rebates associated with \$10,351,923 (\$8,139,939 Federal share) in physician-administered drugs. Of this amount, \$9,658,584 (\$7,578,002 Federal share) was for single-source drugs, and \$693,339 (\$561,937 Federal share) was for top-20 multiple-source drugs. Because the State agency's internal controls did not always ensure that it invoiced manufacturers to secure rebates, the State agency improperly claimed Federal reimbursement for these single-source drugs and top-20 multiple-source drugs. Additionally, the State agency did not provide any written policies and procedures for rebating physician-administered drugs.

Further, the State agency did not submit the utilization data necessary to secure rebates for all other physician-administered drugs. Although the State agency generally collected the drug utilization data necessary to invoice the manufacturers for rebates associated with these claims, providers submitted claims totaling \$9,610 (\$7,889 Federal share) that did not have NDCs. We were unable to determine whether the State agency was required to invoice for rebates for these claims. Furthermore, under the Medicaid drug rebate program, claims totaling \$1,443,007 (\$1,109,110 Federal share), which contained NDCs, could have been eligible for rebates. Accordingly, we set aside these amounts and are recommending that the State

⁶ The Medicare Part B crosswalk is published quarterly by CMS and is based on published drug and biological pricing data and information submitted to CMS by manufacturers. It contains the payment amounts that will be used to pay for Part B covered drugs as well as the HCPCS codes associated with those drugs. CMS instructed States that they could use the crosswalk as a reference because HCPCS codes and NDCs are standardized codes used across health care programs.

agency work with CMS to determine (1) the unallowable portion of the \$9,610 (\$7,889 Federal share) of claims that were submitted without NDCs and (2) whether the remaining \$1,443,007 (\$1,109,110 Federal share) of claims could have been invoiced to the manufacturers for rebates.

FEDERAL AND STATE REQUIREMENTS

The DRA amended section 1927 of the Act to 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)). To secure rebates, States are required to report certain information to manufacturers within 60 days after the end of each rebate period (the Act § 1927(b)(2)(A)). Federal regulations prohibit Federal reimbursement for physician-administered drugs for which a State has not required the submission of claims containing the NDCs (42 CFR § 447.520).

The State 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 any claims submitted with blank or invalid NDCs are rejected or denied by its system edits.

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

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES FOR SOME SINGLE-SOURCE PHYSICIAN-ADMINISTERED DRUGS

The State agency improperly claimed Federal reimbursement of \$9,658,584 (\$7,578,002 Federal share) for single-source physician-administered drug claims for which it did not invoice manufacturers for rebates.

Because the State agency did not submit utilization data to the manufacturers to secure rebates, the State agency improperly claimed Federal reimbursement for these single-source physician-administered drugs.

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES FOR SOME TOP-20 MULTIPLE-SOURCE PHYSICIAN-ADMINISTERED DRUGS

The State agency improperly claimed Federal reimbursement of \$693,339 (\$561,937 Federal share) for top-20 multiple-source physician-administered drug claims for which it did not invoice manufacturers for rebates.

Because the State agency did not submit utilization data to the manufacturers to secure rebates, the State agency improperly claimed Federal reimbursement for these top-20 multiple-source physician-administered drugs.

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES FOR OTHER PHYSICIAN-ADMINISTERED DRUGS

We were unable to determine whether, in some cases, the State agency was required to invoice for rebates for other physician-administered drug claims.

Although the State agency generally collected the drug utilization data necessary to invoice the manufacturers for rebates associated with other physician-administered drug claims, providers submitted some claims, totaling \$9,610 (\$7,889 Federal share), that did not have NDCs. We were unable to determine whether the State agency properly claimed Federal reimbursement for the physician-administered drugs associated with these claims. Additionally, under the Medicaid drug rebate program, claims totaling \$1,443,007 (\$1,109,110 Federal share), which contained NDCs, could have been eligible for rebates. These claims related to drugs that were non-top-20 multiple-source physician-administered drugs with NDCs. The State agency's obligation to invoice these claims for rebate is unclear.

Accordingly, we set aside these amounts and are recommending that the State agency work with CMS to determine (1) the unallowable portion of the \$9,610 (\$7,889 Federal share) of claims that were submitted without NDCs and (2) whether the remaining \$1,443,007 (\$1,109,110 Federal share) of other physician-administered drug claims should have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims.

RECOMMENDATIONS

We recommend that the State agency:

- refund to the Federal Government \$7,578,002 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;
- refund to the Federal Government \$561,937 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement;
- work with CMS to determine:
 - the unallowable portion of \$7,889 (Federal share) for other claims for covered outpatient physician-administered drugs that were submitted without NDCs and that may have been ineligible for Federal reimbursement and refund that amount, and
 - whether the remaining \$1,109,110 (Federal share) of other physician-administered drug claims could have been invoiced to the manufacturers to

receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims;

- work with CMS to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not invoiced for rebates after December 31, 2016;
- develop and implement written policies and procedures for its drug rebate program; and
- strengthen its internal controls to ensure that all 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 concurred with our first two recommendations (financial disallowance), concurred with our remaining recommendations, and described corrective actions it planned to take. Specifically, the State agency indicated that it plans to work with CMS to identify claims eligible for rebates, invoice the claims to manufacturers, and return to the Federal Government its share of these rebates. The State agency further stated that it would review its current internal controls, processes, and procedures to identify any needed improvements to ensure that eligible drugs are invoiced for rebates and will consider additional provider outreach regarding the drug rebate program.

Regarding our recommended financial disallowance, the State agency agreed that it should have invoiced manufacturers for rebates for physician-administered drugs but disagreed with the amount of our recommended refund. The State agency pointed out that it identified claims for certain discounted drugs (known as 340B claims) in our findings that would not be eligible for rebates, thereby reducing the amount it should refund.⁷ As part of our methodology, we utilized Health Resources and Services Administration data to identify 340B-covered entities and removed all claims associated for these entities from our review. The State agency stated it will identify and remove any additional 340B claims and work with CMS to determine the amount it should refund to the Federal Government for claims eligible for rebate.

After reviewing the State agency's comments, we maintain that our findings and recommendations are valid. The State agency's comments are included in their entirety as Appendix D.

⁷ Manufacturers frequently do not pay Medicaid drugs rebates for 340B-covered entities and contract pharmacies since they are already providing a discount on the purchase of the drug.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

The State agency claimed \$22,826,292 (\$17,525,848 Federal share) for fee-for-service claims for physician-administered drugs paid between January 1, 2014, and December 31, 2016.

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 reimbursing physician-administered drug claims and its process for claiming and obtaining Medicaid drug rebates for physician-administered drugs.

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

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance pertaining to the Medicaid drug rebate program and physician-administered drugs;
- reviewed State requirements, including invoicing instructions for physician-administered drugs;
- interviewed State agency personnel to gain an understanding of the administration of and controls over the Medicaid invoicing and rebate process for physician-administered drugs;
- obtained listings of the CMS top-20 multiple-source physician-administered drugs, the Medicare Part B crosswalk, and the CMS Medicaid Drug File for our audit period;
- obtained claim details from the State agency's Medicaid Management Information System for all physician-administered drugs for the period January 1, 2014, through December 31, 2016;
- obtained the listing of 340B entities using the Health Resources and Services Administration's Office of Pharmacy Affairs Medicaid Exclusion File;⁸

⁸ Under the 340B drug-pricing program set forth in 42 U.S.C. § 256b, a 340B entity may purchase reduced-price covered outpatient drugs from manufacturers. Examples of 340B entities are Medicare/Medicaid disproportionate share hospitals, which generally serve large numbers of low-income and/or uninsured patients, and State AIDS drug-assistance programs. Drugs subject to discounts under the 340B drug-pricing program are not subject to rebates under the Medicaid drug rebate program (the Act § 1927(j) and 42 U.S.C. § 256b(a)(5)(A)).

- removed drug claims totaling \$11,021,752 (\$8,268,910 Federal share) that either were not eligible for a drug rebate or contained an NDC and were invoiced for rebate;
- reviewed the remaining drug claims totaling \$11,804,540 (\$9,256,938 Federal share) to determine whether the State agency complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Specifically, we:
 - identified single-source drugs by matching the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify, if possible, the NDCs associated with each HCPCS code listed on claims from providers. We used the CMS Medicaid Drug File to determine whether these NDCs were classified as single-source drugs;
 - identified the top 20 multiple-source drugs by matching the HCPCS code on the drug claim to the HCPCS code on CMS's top-20 multiple-source drug listing; and
 - identified the remaining drugs (those not identified as single-source or as top-20 multiple-source drugs) as other outpatient physician-administered drugs; and
- 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>Indiana Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i> | <u>A-05-17-00038</u> | 4/5/2019 |
| <i>Arizona Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i> | <u>A-09-16-02031</u> | 2/16/2018 |
| <i>Arkansas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i> | <u>A-06-16-00018</u> | 2/12/2018 |
| <i>Nebraska Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i> | <u>A-07-13-06046</u> | 12/22/2017 |
| <i>Texas Did Not Bill Manufacturers for Some Rebates for Pharmacy Drugs of Medicaid Managed-Care Organizations</i> | <u>A-06-16-00004</u> | 12/12/2017 |
| <i>Ohio Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i> | <u>A-05-16-00013</u> | 11/1/2017 |
| <i>Washington State Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i> | <u>A-09-16-02028</u> | 9/26/2017 |
| <i>Hawaii Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i> | <u>A-09-16-02029</u> | 9/26/2017 |
| <i>Nevada Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i> | <u>A-09-16-02027</u> | 9/12/2017 |
| <i>Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs of Medicaid Managed-Care Organizations</i> | <u>A-07-16-06065</u> | 5/5/2017 |
| <i>Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i> | <u>A-05-16-00014</u> | 3/23/2017 |
| <i>Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i> | <u>A-07-14-06050</u> | 1/5/2017 |
| <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 |

| Report Title | Report Number | Date Issued |
|---|-------------------------------|--------------------|
| <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 | 2/9/2016 |
| <i>Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i> | A-07-15-06062 | 1/14/2016 |
| <i>North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i> | A-07-15-06058 | 1/13/2016 |
| <i>California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i> | A-09-14-02038 | 1/7/2016 |
| <i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i> | A-07-14-06056 | 9/18/2015 |
| <i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i> | A-07-14-06049 | 7/22/2015 |
| <i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i> | A-06-12-00060 | 5/4/2015 |
| <i>Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i> | A-07-14-06051 | 4/13/2015 |
| <i>Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i> | A-09-13-02037 | 3/4/2015 |

| Report Title | Report Number | Date Issued |
|---|--|--------------------|
| <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 |
| <i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i> | <u>A-03-12-00200</u> | 11/26/2013 |
| <i>Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i> | <u>A-06-12-00059</u> | 9/19/2013 |
| <i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i> | <u>A-06-10-00011</u> | 8/12/2011 |
| <i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i> | <u>OEI-03-09-00410</u> | 6/24/2011 |

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

FEDERAL LAWS

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

Section 6002 of the DRA added section 1927(a)(7) to the Act to require that States capture information necessary to secure rebates from manufacturers for certain covered outpatient drugs administered by a physician. In addition, section 6002 of the DRA amended section 1903(i)(10) of the Act to prohibit Medicaid Federal share for covered outpatient drugs administered by a physician unless the States collect the utilization and coding data described in section 1927(a)(7) of the Act.

Section 1927(a)(7) of the Act requires States to provide for the collection and submission of such utilization data and coding (such as J-codes and NDCs) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates for all single-source physician-administered drugs effective January 1, 2006, and for the top 20 multiple-source drugs effective January 1, 2008. Section 1927(a)(7)(C) of the Act stated that, effective January 1, 2007, the utilization data must be submitted using the NDC. To secure rebates, States are required to report certain information to manufacturers within 60 days after the end of each rebate period (the Act § 1927(b)(2)(A)).

Section 1927(a)(7)(D) of the Act allowed HHS to delay any of the above requirements to prevent hardship to States that required additional time to implement the physician-administered drug reporting requirements.

FEDERAL REGULATIONS

Federal regulations set conditions for States to obtain a Federal share for covered outpatient drugs administered by a physician and specify 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 invoice a manufacturer for rebates (42 CFR § 447.520).

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.

APPENDIX D: STATE AGENCY COMMENTS



State of New Jersey Department of Human Services

P.O. BOX 700
TRENTON NJ 08625-0700

PHILIP D. MURPHY
Governor

Carole Johnson
Commissioner

Sheila Y. Oliver
Lt. Governor

April 4, 2019

Brenda M. Tierney
Regional Inspector General for Audit Services
Office of Inspector General
Office of Audit Services, Region II
Jacob K. Javitis Federal Building
26 Federal Plaza, Room 3900
New York, NY 10278

Dear Ms. Tierney:

The Department of Human Services (the Department) is in receipt of the draft audit report issued by the Office of Inspector General (OIG) entitled "*New Jersey Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs*" 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

Refund to the Federal Government \$7,578,002 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement.

Response

The Department concurs with OIG's finding that it should have invoiced manufacturers for rebates for certain single-source physician-administered drugs. However, the Department does not concur with the refund amount of \$7,578,002.

The Department is researching and reviewing the claims identified by OIG. We have determined that the identified claims include 340B claims, which would not be eligible for rebates pursuant to 42 U.S.C. § 256b(a)(5)(A). Removing these claims will reduce the amount of any refund owed by the State.

The Department is also obtaining the necessary information 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. We will also work with CMS to determine any amount owed to the Federal Government.

OIG Recommendation

Refund to the Federal Government \$561,937 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement.

Response

The Department concurs with OIG's finding that it should have invoiced manufacturers for rebates for certain top-20 multiple-source physician-administered drugs. However, the Department does not concur with the refund amount of \$561,937.

As stated above, the Department has identified 340B claims not eligible for rebate, and is invoicing manufacturers for outstanding rebates. Following these efforts, the Department will work with CMS to determine any amount owed to the Federal Government.

OIG Recommendation

Work with CMS to determine: (1) the unallowable portion of \$7,889 (Federal share) for other claims for covered outpatient physician-administered drugs that were submitted without NDCs and that may have been ineligible for Federal reimbursement and refund that amount; and (2) whether the remaining \$1,109,110 (Federal share) of other physician-administered drug claims could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims.

Response

The Department concurs with the recommendation that it determine the unallowable portion of \$7,889 in claims submitted by providers without National Drug Codes (NDCs). The Department will identify the NDCs so that eligible claims can be invoiced for rebates from the manufacturers, and remit the Federal share to CMS. The Department will refund the Federal Government for any unallowable claims.

The Department also concurs with the recommendation that it work with CMS to determine if the remaining \$1,109,110 (Federal share) of other non-top-20 physician-administered drug claims were eligible for rebates. The Department will invoice any eligible claims to manufacturers for rebates and remit any Federal share to CMS.

OIG Recommendation

Work with CMS to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not invoiced for rebates after December 31, 2016.

Response

The Department will invoice manufacturers for rebates for eligible claims after December 31, 2016. The Department will remit the Federal share of these rebates and work with CMS to determine any unallowable amounts.

OIG Recommendation

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

Response

The Department concurs with this recommendation. We are working on a manual for the drug rebate program that will include all necessary policies and procedures.

OIG Recommendation

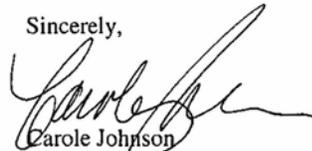
Strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

Response

The Department concurs with this recommendation. We are reviewing the current internal controls, processes and procedures to identify any needed improvements to ensure that eligible physician-administered drug claims are invoiced for rebates. The Department will also consider additional provider outreach regarding the drug rebate program.

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

Sincerely,



Carole Johnson
Commissioner

c: Meghan Davey, Director
Daniel Prupis