

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

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

*Inquiries about this report may be addressed to the Office of Public Affairs at  
[Public.Affairs@oig.hhs.gov](mailto:Public.Affairs@oig.hhs.gov).*



Gloria L. Jarmon  
Deputy Inspector General  
for Audit Services

February 2018  
A-09-16-02031

# *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 nation-wide 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 Web site.

## **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: February 2018

Report No. A-09-16-02031

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 Arizona 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 Arizona's MCOs from April 2010 through March 2013. We identified MCO drug utilization data for drugs billed for rebates and tested the rebates billed by selecting 27 National Drug Codes (NDCs) associated with 24 manufacturers and reviewing supporting documentation. We also identified these data for physician-administered drugs that were not billed for rebates and determined which drugs were eligible or may have been eligible for rebates. (Pharmacy drugs were properly billed for rebates.) For these physician-administered drugs, we estimated the minimum amount of rebates that Arizona could have collected if it had billed these drugs for rebates.

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

### What OIG Found

When Arizona billed manufacturers for rebates for pharmacy and physician-administered drugs, it did so correctly. However, Arizona did not bill for and collect from manufacturers estimated rebates of \$36.7 million (\$25.6 million Federal share) for physician-administered drugs. For drugs that were eligible for rebates, Arizona did not bill for estimated rebates of \$18.3 million (Federal share) for single-source and top-20 multiple-source physician-administered drugs. For drugs that may have been eligible for rebates, Arizona did not bill for estimated rebates of \$7.3 million (Federal share) for other physician-administered drugs. Arizona did not always bill for and collect from manufacturers rebates because it did not have a system edit to ensure that NDCs or valid NDCs were submitted for physician-administered drugs before October 1, 2012. Even after Arizona implemented the edit on October 1, 2012, this edit did not ensure that NDCs or valid NDCs were captured for all physician-administered drugs.

### What OIG Recommends and Arizona Comments

We recommend that Arizona (1) bill for and collect from manufacturers rebates for single-source and top-20 multiple-source physician-administered drugs and refund the estimated \$18.3 million (Federal share); (2) work with CMS to determine whether the other physician-administered drugs were eligible for rebates and, if so, upon receipt of the rebates, refund up to an estimated \$7.3 million (Federal share) of rebates collected; (3) strengthen the NDC edit to ensure that NDCs are captured and valid for all drug utilization data; and (4) ensure that all physician-administered drugs eligible for rebates are processed for rebates.

Arizona provided information on actions that it planned to take to address our first recommendation and concurred with our third and fourth recommendations. Regarding our second recommendation, the State agency disagreed with our finding that it was required to obtain rebates for other physician-administered drugs. We maintain that our second recommendation is valid. The estimated amount of rebates related to our finding was for drugs that may have been eligible for rebates, not for drugs that were eligible for rebates. Accordingly, we set aside for CMS resolution the estimated \$7.3 million (Federal share) for these drugs.

**TABLE OF CONTENTS**

INTRODUCTION..... 1

    Why We Did This Review ..... 1

    Objective ..... 1

    Background ..... 1

        Pharmacy and Physician-Administered Drugs ..... 1

        Medicaid Drug Rebate Program ..... 1

        Federal Reimbursement to States for Payments to Medicaid Managed-Care  
        Organizations ..... 2

        States’ Collection of Rebates for Pharmacy and Physician-Administered Drugs ... 2

        The State Agency’s Medicaid Drug Rebate Program ..... 3

    How We Conducted This Review ..... 4

FINDING..... 5

    Federal and State Requirements ..... 5

    The State Agency Did Not Bill Manufacturers for Some Rebates for Physician-  
    Administered Drugs Dispensed Through Medicaid Managed-Care Organizations ..... 6

    The State Agency Did Not Have a System Edit To Ensure That National Drug Codes  
    Were Present and Valid in the Drug Utilization Data ..... 6

RECOMMENDATIONS ..... 6

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE ..... 7

    State Agency Comments..... 7

    Office of Inspector General Response ..... 8

APPENDICES

    A: Audit Scope and Methodology ..... 9

    B: Related Office of Inspector General Reports..... 11

    C: Federal and State Requirements Related to Medicaid Drug Rebates..... 14

    D: State Agency Comments ..... 16

## 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.<sup>1</sup>) For this audit, we reviewed the Arizona Health Care Cost Containment System'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.<sup>2</sup> Each HCPCS code may have one or more NDCs.

#### Medicaid Drug Rebate Program

The Medicaid drug rebate program became effective in 1991 (the Social Security Act (the Act) § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the drug manufacturer must enter into a rebate agreement administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. Manufacturer rebates are essentially shared between the States and the Federal Government to offset the cost of prescription drugs. CMS, the States, and drug manufacturers each have specific functions under the program.

---

<sup>1</sup> OIG performed similar reviews for rebates due for drugs administered by physicians to fee-for-service enrollees. These reviews are included in this appendix.

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

Manufacturers are required to submit a list to CMS of all covered outpatient drugs and to report each drug's average manufacturer price and, where applicable, best price.<sup>3</sup> On the basis of this information, CMS calculates a unit rebate amount for each drug (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 billing manufacturers for rebates as described in section 1927(a)(7) of the Act. To bill for rebates, States must use drug utilization data that identify, by NDC, the number of units of each drug for which the States reimbursed Medicaid providers. The States must capture these drug utilization data and report the information to the manufacturers (the Act § 1927(b)(2)(A)). The number of units is multiplied by the unit rebate amount to determine the actual rebate amount due from each manufacturer.

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

### **Federal Reimbursement to States for Payments to Medicaid Managed-Care Organizations**

States use two primary models to pay for Medicaid services: fee-for-service and managed care. In the managed-care model, States contract with MCOs to provide specific services to enrolled Medicaid beneficiaries, usually in return for a predetermined periodic payment, known as a capitation payment. States pay MCOs for each covered individual regardless of whether the enrollee receives services during the relevant time period (42 CFR § 438.2). MCOs use the capitation payments to pay claims for these services. Capitation payments may cover outpatient drugs, which include both 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 drugs or physician-administered drugs). States must report adjustments to drug expenditures and drug rebates on the Form CMS-64. The expenditures, adjustments, and rebates do not distinguish between amounts related to 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

---

<sup>3</sup> The Act § 1927(b) and the Medicaid rebate agreement (§ II).

manufacturers and facilitate the collection of rebates for the drugs. Before the Deficit Reduction Act of 2005, many States did not collect rebates on physician-administered drugs if the drug claims did not contain NDCs. NDCs were more readily available for pharmacy drug claims because providers used NDCs to bill for pharmacy drugs.

The Deficit Reduction Act 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.<sup>4</sup> For purposes of the Medicaid drug rebate program, single-source drugs are those covered outpatient drugs produced or distributed under an original new drug application approved by the Food and Drug Administration (FDA).<sup>5</sup> Multiple-source drugs are defined, in part, as those covered outpatient drugs that have at least one other drug rated as therapeutically equivalent by FDA.<sup>6</sup> Beginning on January 1, 2007, CMS was responsible for publishing annually the list of the top 20 multiple-source drugs by HCPCS codes that had the highest dollar volume dispensed.

Effective March 23, 2010, the Patient Protection and Affordable Care Act (ACA)<sup>7</sup> 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 Arizona, the State agency is responsible for billing and collecting Medicaid drug rebates for both pharmacy and physician-administered drugs.<sup>8</sup> The State agency uses a contractor to

---

<sup>4</sup> The term “top-20 multiple-source drugs” is drawn from a CMS classification and describes these drugs in terms of highest dollar volume of physician-administered drugs in Medicaid (the Act § 1927(a)(7)(B)(i)).

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

<sup>6</sup> Section 1927(k)(7) of the Act. According to the definition of “therapeutic equivalence” in the FDA glossary of terms, a therapeutically equivalent drug product can be substituted with another product to achieve the same clinical effect as the prescribed drug. <http://www.fda.gov/drugs/informationondrugs/ucm079436.htm>. Accessed on March 21, 2017.

<sup>7</sup> P.L. No. 111-148 (Mar. 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010, P.L. No. 111-152 (Mar. 23, 2010).

<sup>8</sup> State agency officials told us that, before October 1, 2012, they billed manufacturers for rebates for only single-source physician-administered drugs. According to the officials, after implementing a claims processing system edit on October 1, 2012, to ensure that valid NDCs were submitted for physician-administered drugs, they began billing manufacturers for rebates for all multiple-source physician-administered drugs.



manage its drug rebate program.<sup>9</sup> The contractor bills manufacturers by NDC for rebates and collects the payments for every quarter.

Beginning October 1, 1982, the State agency required its MCOs to submit NDCs in the drug utilization data for pharmacy drugs. Beginning July 1, 2012, the State agency required its MCOs to submit NDCs in the drug utilization data for physician-administered drugs. The MCOs submit these data to the State agency, which sends the data to the contractor; the contractor uses these data to bill for drug rebates.

During calendar years 2010 through 2013, the number of MCOs operating in Arizona ranged from 15 to 21. These MCOs served approximately 1.2 million Medicaid beneficiaries.

## **HOW WE CONDUCTED THIS REVIEW**

We reviewed drug utilization data for both pharmacy and physician-administered drugs for Arizona's MCOs from April 1, 2010, through March 31, 2013 (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 27 NDCs associated with 24 manufacturers and reviewing the supporting documentation. We also identified MCO drug utilization data for physician-administered drugs that were not billed for rebates and determined which drugs were eligible or may have been eligible for rebates. (Pharmacy drugs were properly billed for rebates.) We requested that the State agency estimate the amount of rebates that the State agency could have collected if it had billed these physician-administered drugs for rebates. However, because the State agency did not provide the requested information, we proceeded with our own estimates. Specifically, we estimated the minimum amount of rebates that the State agency could have collected if it had billed these drugs for rebates.

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.

---

<sup>9</sup> Magellan Medicaid Administration was the State agency's contractor during our audit period.

## FINDING

During our audit period, the State agency did not fully comply with Federal Medicaid requirements for billing manufacturers for rebates for drugs dispensed to MCO enrollees. The State agency properly billed manufacturers for rebates for pharmacy drugs and for some rebates for physician-administered drugs.<sup>10</sup> However, the State agency did not bill for and collect from manufacturers estimated rebates of \$36,659,237 (\$25,634,628 Federal share) for physician-administered drugs that were eligible or may have been eligible for rebates.

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 or valid NDCs were submitted for physician-administered drugs before October 1, 2012. Even after the State agency implemented the edit on October 1, 2012, this edit did not ensure that NDCs or valid NDCs were captured for all physician-administered drugs.

### FEDERAL AND STATE REQUIREMENTS

The Deficit Reduction Act 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)).

In an April 6, 2012, memo, the State agency informed its MCOs of the ACA's rebate requirements. To collect drug rebates, the State agency required its MCOs to submit drug utilization data for physician-administered drugs with NDCs with dates of service beginning on July 1, 2012.

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

---

<sup>10</sup> These drugs were associated with the 27 NDCs that we selected for review.

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

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

- For drugs that were eligible for rebates, we estimated that the State agency did not bill for and collect rebates of \$26,400,078 (\$18,326,775 Federal share). This amount consisted of \$25,283,617 (\$17,560,393 Federal share) for single-source physician-administered drugs and \$1,116,461 (\$766,382 Federal share) for top-20 multiple-source physician-administered drugs. Even though these drugs did not have NDCs, we were able to identify single-source and top-20 multiple-source drugs by using the drugs' HCPCS codes.
- For drugs that may have been eligible for rebates, we estimated that the State agency did not bill for and collect rebates of \$10,259,159 (\$7,307,853 Federal share) for other physician-administered drugs without NDCs or valid 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 \$10,259,159 (\$7,307,853 Federal share) for these drugs.

As a result, the State agency did not bill for and collect from manufacturers estimated rebates of \$36,659,237 (\$25,634,628 Federal share) for physician-administered drugs that were eligible or may have been eligible for rebates.

## **THE STATE AGENCY DID NOT HAVE A SYSTEM EDIT TO ENSURE THAT NATIONAL DRUG CODES WERE PRESENT AND VALID 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 2½ years of our audit period to ensure that NDCs were present and valid in the MCO drug utilization data for physician-administered drugs. Although State agency guidance required MCOs to submit drug utilization data for physician-administered drugs with NDCs, the State agency did not implement an NDC edit until October 1, 2012. Even after the State agency implemented the edit, this edit did not ensure that NDCs or valid NDCs were captured for all physician-administered drugs. As a result, the State agency did not collect some rebates for physician-administered drugs dispensed to MCO enrollees.

### **RECOMMENDATIONS**

We recommend that the State agency:

- bill for and collect from manufacturers rebates for single-source and top-20 multiple-source physician-administered drugs and refund to the Federal Government the estimated \$18,326,775 (Federal share);

- work with CMS to determine whether the other physician-administered drugs were eligible for rebates and, if so, upon receipt of the rebates, refund up to an estimated \$7,307,853 (Federal share) of rebates collected;
- strengthen the NDC edit (implemented on October 1, 2012) to ensure that NDCs are captured and valid for all drug utilization data; and
- ensure that all physician-administered drugs eligible for rebates are processed for rebates.

## **STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, the State agency provided information on actions that it planned to take to address our first recommendation and concurred with our third and fourth recommendations. Regarding our second recommendation, the State agency disagreed with our finding that it was required to obtain rebates for other physician-administered drugs. The State agency's comments are included in their entirety as Appendix D.

### **STATE AGENCY COMMENTS**

Regarding our first recommendation, the State agency commented that it will bill and collect rebates for single-source and top-20 multiple-source physician-administered drugs that were eligible for rebates during our audit period and report the applicable Federal share on the Form CMS-64.

Regarding our second recommendation, the State agency commented that it disagreed with our finding that it was required to obtain rebates for the other physician-administered drugs. The State agency commented that it is communicating with CMS to determine whether these other drugs were eligible for rebates. The State agency also commented that it is reviewing the claims to determine whether "the utilization is eligible for rebates," and if so, it will "initiate the billing and collection of rebates for these drugs."

In addition, the State agency provided background information and (1) commented that Arizona operated its Medicaid program throughout the audit period under a comprehensive demonstration approved by the Secretary of Health and Human Services and (2) referenced information from the expenditure authorities under the demonstration. The State agency also referenced sections 1903(i)(10) and 1927(a)(7) of the Act, which relate to the conditions of Federal financial participation for covered outpatient drugs.

The State agency commented that, pursuant to the expenditure authority granted to Arizona, the State agency was not required to collect and report utilization data and coding information for physician-administered drugs during our audit period. It stated: "Because the requirements [of] sections 1903(i)(10) and 1927(a)(7) [of the Act] were specific for the purpose of securing and collecting Medicaid drug rebates on physician-administered drugs, the State agency did not

make any programming or system changes because it was waived from collecting rebates on these drugs.” The State agency also commented: “It is Arizona’s position that there is no basis for an audit of Arizona’s compliance with the provision of the Medicaid Act that, but for the expenditure authority in Arizona’s approved demonstration, would have required the State to bill manufacturers for physician administered drugs.”

The State agency concurred with our third recommendation and stated that it intends to implement a processing table to identify the HCPCS codes that designate physician-administered drugs, as well as the applicable NDCs for each code. The State agency also concurred with our fourth recommendation.

#### **OFFICE OF INSPECTOR GENERAL RESPONSE**

After reviewing the State agency’s comments, we maintain that our second recommendation is valid. The estimated amount of rebates related to our finding was for drugs that may have been eligible for rebates, not for drugs that were eligible for rebates. Accordingly, we set aside for CMS resolution the estimated \$10,259,159 (\$7,307,853 Federal share) for these drugs because their HCPCS codes could not be used to determine whether the drugs were required to be billed for rebates.

We are aware that the State agency operated (and still operates) its Medicaid program under a comprehensive demonstration waiver, and we discussed the waiver and related expenditure authorities with State agency and CMS officials. CMS officials told us that the State agency was not waived from collecting rebates both during and after our audit period for eligible drugs that were required to be billed for rebates under the Medicaid drug rebate program. In addition, the State agency has been billing manufacturers for rebates. As part of our review, we determined that the State agency properly billed manufacturers for rebates for pharmacy drugs and for some rebates for physician-administered drugs. Therefore, we maintain that the State agency should work with CMS to determine whether the other physician-administered drugs were eligible for rebates and, if so, upon receipt of the rebates, refund up to an estimated \$7,307,853 (Federal share) of rebates collected.

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

### **SCOPE**

We reviewed drug utilization data for both pharmacy and physician-administered drugs for Arizona's MCOs from April 1, 2010, through March 31, 2013.

We identified MCO drug utilization data for pharmacy and physician-administered drugs that were billed for rebates and tested the rebates billed by selecting 27 NDCs associated with 24 manufacturers and reviewing the supporting documentation. We also identified MCO drug utilization data for physician-administered drugs that were not billed for rebates and determined which drugs were eligible or may have been eligible for rebates. (Pharmacy drugs were properly billed for rebates.) We requested that the State agency estimate the amount of rebates that the State agency could have collected if it had billed these physician-administered drugs for rebates. However, because the State agency did not provide the requested information, we proceeded with our own estimates.

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

We conducted our audit from June 2016 to September 2017, which included fieldwork performed at the State agency office in Phoenix, Arizona.

### **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 and contractor 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 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 27 NDCs associated with 24 manufacturers<sup>11</sup> and
  - reviewing copies of rebate invoices submitted to manufacturers to verify the billing of rebates by NDC;
- identified MCO drug utilization data for physician-administered 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<sup>12</sup> and
  - identifying other physician-administered drugs that may have been eligible for rebates;<sup>13</sup>
- estimated the minimum amount of rebates that the State agency could have collected for single-source, top-20 multiple-source, and other physician-administered drugs if it had billed these drugs for rebates;<sup>14</sup> 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.

---

<sup>11</sup> These NDCs represented drugs that had high payment amounts, high units of service, or high payment amounts per unit.

<sup>12</sup> Even though these drugs did not have valid NDCs, we were able to identify single-source and top-20 multiple-source drugs by using the drugs' HCPCS codes.

<sup>13</sup> The drugs' HCPCS codes could not be used to determine whether the drugs were required to be billed for rebates.

<sup>14</sup> For each drug's HCPCS code, we multiplied the number of drug units by the unit rebate amount for each associated NDC to calculate the amounts of rebates due (each HCPCS code may have one or more NDCs). We selected the lowest amount of rebate due for each drug's HCPCS code and estimated the total amount of rebates that the State agency could have collected.

**APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS**

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>Arkansas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-06-16-00018</u></a>	2/12/2018
<i>Nebraska Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-07-13-06046</u></a>	12/22/2017
<i>Texas Did Not Bill Manufacturers for Some Rebates for Pharmacy Drugs of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-06-16-00004</u></a>	12/12/2017
<i>Ohio Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-05-16-00013</u></a>	11/1/2017
<i>Hawaii Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-09-16-02029</u></a>	9/26/2017
<i>Washington State Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-09-16-02028</u></a>	9/26/2017
<i>Nevada Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-09-16-02027</u></a>	9/12/2017
<i>Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-07-16-06065</u></a>	5/5/2017
<i>Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-05-16-00014</u></a>	3/23/2017
<i>Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-14-06050</u></a>	1/5/2017
<i>Delaware Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-03-15-00202</u></a>	12/30/2016



<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>Virginia Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-03-15-00201</u></a>	12/22/2016
<i>California Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Some Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-09-15-02035</u></a>	12/8/2016
<i>Kansas Correctly Invoiced Rebates to Manufacturers for Most Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-07-15-06060</u></a>	8/18/2016
<i>Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-14-06057</u></a>	5/26/2016
<i>Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-15-06063</u></a>	3/31/2016
<i>South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-15-06059</u></a>	2/9/2016
<i>Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-15-06062</u></a>	1/14/2016
<i>North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-15-06058</u></a>	1/13/2016
<i>California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<a href="#"><u>A-09-14-02038</u></a>	1/7/2016
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-14-06056</u></a>	9/18/2015
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-14-06049</u></a>	7/22/2015
<i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-06-12-00060</u></a>	5/4/2015

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-09-13-02037</u></a>	3/4/2015
<i>Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<a href="#"><u>A-06-14-00031</u></a>	2/10/2015
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-03-12-00205</u></a>	8/21/2014
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-13-06040</u></a>	8/7/2014
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-09-12-02079</u></a>	4/30/2014
<i>Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<a href="#"><u>A-09-12-02080</u></a>	4/24/2014
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-03-12-00200</u></a>	11/26/2013
<i>Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<a href="#"><u>A-06-12-00059</u></a>	9/19/2013
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	<a href="#"><u>A-06-10-00011</u></a>	8/12/2011
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	<a href="#"><u>OEI-03-09-00410</u></a>	5/6/2011

## **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 Deficit Reduction Act of 2005 added section 1927(a)(7) to the Act to require that States capture information necessary to secure rebates from manufacturers for certain covered outpatient drugs administered by a physician. In addition, section 6002 of the Deficit Reduction Act amended section 1903(i)(10) of the Act to prohibit a Medicaid Federal share for covered outpatient drugs administered by a physician unless the States submit the utilization and coding data described in section 1927(a)(7) of the Act.

States must provide for the collection and submission of utilization and coding data necessary 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 (the Act § 1927(a)(7)). Effective January 1, 2007, the utilization data must be submitted using NDCs (the Act § 1927(a)(7)(C)). To bill for rebates, States are required to report certain information to manufacturers within 60 days after the end of each rebate period (the Act § 1927(b)(2)(A)).

Section 2501 of the ACA amended section 1927(b)(1)(A) of the Act to require that manufacturers pay rebates for covered outpatient drugs dispensed to individuals enrolled in an MCO if the MCO is responsible for coverage of such drugs. Section 2501 of the ACA also amended section 1927(b)(2)(A) to require that States submit information necessary to secure rebates from manufacturers for covered outpatient drugs dispensed through MCOs. In addition, section 2501 amended section 1903(m)(2)(A) to essentially extend the Medicaid rebate obligations to drugs dispensed through MCOs. Under this provision, payment is prohibited unless the MCO contracts provide that the Medicaid rebate obligations apply to drugs dispensed through MCOs and require the MCOs to submit to the State the drug utilization by NDCs for drugs dispensed to eligible individuals.

## **FEDERAL REGULATIONS**

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

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).<sup>15</sup>

## **STATE GUIDANCE**

In an April 6, 2012, memo, the State agency informed its MCOs of the ACA's rebate requirements. To collect drug rebates, the State agency required its MCOs to submit drug utilization data for physician-administered drugs with NDCs with dates of service beginning on July 1, 2012.

---

<sup>15</sup> 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



Douglas A. Ducey, Governor  
Thomas J. Betlach, Director

December 8, 2017

Report Number: A-09-16-02031

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

Dear Ms. Ahlstrand:

The Arizona Health Care Cost Containment System (AHCCCS) appreciates the opportunity to respond to the draft report and provide additional comments to be included in the final report. AHCCCS is committed to working with the Centers for Medicare & Medicaid (CMS) to resolve the issues identified in this audit.

During the audit period of April 2010 to March 2013, Arizona collected over \$651 million in Total Fund drug rebates. The Office of the Inspector General (OIG) draft report recommendations identified \$36.7 million in Total Fund, potentially representing 5.6% of the overall grand total of potential drug rebates for that period.

AHCCCS has reviewed the OIG draft report entitled *Arizona Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations*. Below is each recommendation and AHCCCS' statement of concurrence.

*We recommend that Arizona:*

- 1) *"Bill for and collect from manufacturers rebates for single source and top-20 multiple-source physician administered drugs and refund the estimated \$18.3 million (Federal Share);"*

AHCCCS will bill and collect rebates for single source and top-20 multiple source physician-administered drugs that were eligible for rebates during the audit period. AHCCCS will thoroughly review the disputed utilization records with our contracted rebate vendor, and will bill the appropriate amount and report the applicable federal share on the Federal Form CMS 64.

- 2) *"Work with the Centers for Medicare & Medicaid Services to determine whether the other physician-administered drugs were eligible for rebates and, if so, upon receipt of the rebates, refund up to an estimated \$7.3 million (Federal share) of the rebates collected;"*

AHCCCS disagrees with this OIG finding that Arizona was required to obtain rebates for physician administered drugs during the audit period and is communicating with the Centers for Medicare & Medicaid Services to determine whether the other physician-administered drugs were eligible for rebates. AHCCCS is reviewing these claims to determine if the utilization is eligible for

rebates. If they are eligible for rebates, AHCCCS will initiate the billing and collection of rebates for these drugs.

#### Background Information

In February of 2016, the Department of Health and Human Services, Office of the Inspector General initiated an audit “to determine whether the Arizona Health Care Cost Containment System complied with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs and pharmacy drugs dispensed to enrollees of managed care organizations.” The audit period is from April 1, 2010 through March 31, 2013. Throughout the audit period, Arizona operated (and still operates) its Medicaid program under a comprehensive demonstration approved by the Secretary. The approval documents consist of a list of waived provisions, a list of expenditure authorities, and special terms and conditions.

Demonstrations numbers 11-W-00032/09 and 21-W-00009/9 can be found at [https://azahcccs.gov/Resources/Downloads/1115Waiver/AZ\\_1115Waiver.pdf](https://azahcccs.gov/Resources/Downloads/1115Waiver/AZ_1115Waiver.pdf) and cover the period beginning October 27, 2006 through September 30, 2011. Paragraph 3 of the Expenditure Authorities states that the costs that may be regarded as matchable expenditures includes “Expenditures for outpatient drugs which are not otherwise allowable under section 1903(i)(10)” which is the same language as in the waiver documents referenced in the next paragraph.

Section 2 of the list of “Medicaid Costs Not Otherwise Matchable” for the demonstration period October 22, 2011 through September 30, 2016, 11-WW 00275/09 and 21-W 00064/9, permitted the following expenditures to be regarded as medical expenditures under the State’s Medicaid plan: “expenditures for outpatient drugs which are not otherwise allowable under section 1903(i)(10) of the Act.” While renumbered in revisions and renewal of the demonstration, identical language was included in the approved demonstration throughout the audit period.

Section 1903(i)(10) of the Social Security Act – 42 USC § 1396b(i)(10) - provides that federal financial participation is not available “with respect to covered outpatient drugs described in section 1927(a)(7), unless information respecting utilization data and coding on such drugs that is required to be submitted under such section is submitted in accordance with such section.”

Section 1927, codified as 42 USC § 1396r-8, makes it a condition of federal financial participation (FFP) for covered outpatient drugs that the manufacturer has entered into a rebate agreement with the Secretary of the Department of Health and Human Services. In general, States may not claim FFP for drugs manufactured by companies that do not have a federal rebate agreement on file with CMS. More specifically, section 1927(a)(7) requires that, as a condition of a State’s claim for FFP for physician administered drugs administered after January 1, 2006, the State must collect utilization data and coding information (J-codes and NDC numbers) “for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates.” No later than January 1, 2007, that subsection requires that the States submit the information to the Secretary using NDC numbers “unless the Secretary specifies that an alternative coding system should be used.”

Ms. Lori A. Ahlstead  
December 8, 2017  
Page 3

Pursuant to the expenditure authority granted to Arizona by the Secretary, Arizona was not required to collect and report utilization data and coding information for physician administered drugs during the audit period. Because the requirements sections 1903(i)(10) and 1927(a)(7) were specific for the purpose of securing and collecting Medicaid drug rebates on physician administered drugs, AHCCCS did not make any programming or system changes because we were waived from collecting the federal rebate on these drugs.

It is Arizona's position that there is no basis for an audit of Arizona's compliance with the provision of the Medicaid Act that, but for the expenditure authority in Arizona's approved demonstration, would have required the State to bill manufacturers for physician administered drugs.

3) *Strengthen the NDC edit to ensure that NDCs are captured and valid for all drug utilization data;*

AHCCCS concurs and currently requires MCOs to include the NDC when submitting drug utilization data for both physician-administered and pharmacy point-of-sale dispensed drugs. It is AHCCCS intent to implement a processing table that identifies those physician HCPCS/CPT codes which designate physician-administered drugs as well as applicable NDC's for each. Implementation of this processing table will ensure that related editing is in place to validate that NDC's are appropriately submitted when applicable.

4) *"Ensure that all physician-administered drugs eligible for rebates are processed for rebates."*

AHCCCS concurs.

If you have any questions or comments regarding the responses to the draft report, please contact me at your convenience at 602-417-4726 or through email at [Suzanne.Berman@azahcccs.gov](mailto:Suzanne.Berman@azahcccs.gov).

Sincerely,



Suzanne Berman, RPh  
Director of Pharmacy

C: Tom Betlach, AHCCCS  
Sara Salek, AHCCCS  
Dan Lippert, AHCCCS  
Lori Petre, AHCCCS  
John Moorman, AHCCCS  
Jeff Tegen, AHCCCS