

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**HAWAII 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.*



Gloria L. Jarmon
Deputy Inspector General
for Audit Services

September 2017
A-09-16-02029

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: September 2017
Report No. A-09-16-02029

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



Why OIG Did This Review

Previous OIG reviews found that States did not always bill and collect all rebates due for drugs administered by physicians to enrollees of Medicaid managed-care organizations (MCOs).

Our objective was to determine whether Hawaii 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 Hawaii's five MCOs from April 2010 through September 2012.

We identified MCO drug utilization data for drugs that were billed for rebates and tested the rebates billed by selecting 24 National Drug Codes (NDCs) associated with 18 manufacturers and reviewing supporting documentation. We also identified MCO drug utilization data for drugs that were not billed for rebates and determined which drugs were eligible or may have been eligible for rebates. For both pharmacy and physician-administered drugs that were not billed for rebates, we calculated the amount of rebates that Hawaii could have collected if it had billed these drugs for rebates.

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

What OIG Found

When Hawaii billed manufacturers for rebates for pharmacy and physician-administered drugs, it did so correctly. However, Hawaii did not bill for and collect from manufacturers rebates of \$18.8 million (\$9.7 million Federal share). For drugs that were eligible for rebates, Hawaii did not bill for rebates of \$8 million (Federal share) for pharmacy drugs and \$1.6 million (Federal share) for single-source and top-20 multiple-source physician-administered drugs. For drugs that may have been eligible for rebates, Hawaii did not bill for rebates of \$57,783 (Federal share) for non-top-20 multiple-source physician-administered drugs with NDCs. In addition, Hawaii did not bill for rebates for 122,436 claim lines for other physician-administered drugs. Hawaii did not provide us sufficient drug utilization data to determine whether these drugs were eligible for rebates and the amount of any rebates that may have been due.

What OIG Recommends and Hawaii Comments

We recommend that Hawaii (1) bill for and collect from manufacturers rebates for pharmacy drugs and refund \$8 million (Federal share); (2) bill for and collect from manufacturers rebates for single-source and top-20 multiple-source physician-administered drugs and refund \$1.6 million (Federal share); (3) work with the Centers for Medicare & Medicaid Services (CMS) to determine whether the non-top-20 multiple-source physician-administered drugs were eligible for rebates and, if so, upon receipt of the rebates, refund up to \$57,783 (Federal share) of rebates collected; (4) work with CMS to determine whether the other physician-administered drugs were eligible for rebates and, if so, determine the rebates due and upon receipt of the rebates refund the Federal share of rebates collected; (5) determine which physician-administered drugs were not billed for rebates after our audit period, determine the rebates due, and upon receipt of the rebates refund the Federal share of the rebates collected; and (6) improve oversight of the processes for rebate billing and collection to ensure that MCOs submit valid and complete drug utilization data for pharmacy and physician-administered drugs dispensed to MCO enrollees.

Hawaii concurred with the findings related to our first, fifth, and sixth recommendations and partially concurred with the findings related to our second, third, and fourth recommendations. We maintain that all of our recommendations are valid.

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 Drugs Dispensed Through Medicaid Managed-Care Organizations	6
The State Agency Did Not Have Adequate Oversight of the Processes for Rebate Billing and Collection	6
RECOMMENDATIONS	7
STATE AGENCY COMMENTS	7
OFFICE OF INSPECTOR GENERAL RESPONSE	8
APPENDICES	
A: Related Office of Inspector General Reports	9
B: Audit Scope and Methodology	12
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 A lists previous OIG reports related to the Medicaid drug rebate program.¹) For this audit, we reviewed the Hawaii Department of Human Services, Med-QUEST Division's (State agency's), billing of rebates for both pharmacy and physician-administered drugs dispensed to MCO enrollees.

OBJECTIVE

Our objective was to determine whether the State agency complied with Federal Medicaid requirements for billing manufacturers for rebates for drugs dispensed to MCO enrollees.

BACKGROUND

Pharmacy and Physician-Administered Drugs

Drugs may be provided to a beneficiary through a pharmacy or administered by a physician in an office or a hospital. Pharmacy drugs are typically billed to Medicaid using National Drug Codes (NDCs). A valid NDC is a unique identifier that represents a drug's specific manufacturer, product, and package size. Physician-administered drugs are typically billed to the Medicaid program on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes.²

Medicaid Drug Rebate Program

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

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

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

Manufacturers are required to submit a list to CMS of all covered outpatient drugs and to report each drug's average manufacturer price and, where applicable, best price.³ On the basis of this information, CMS calculates a unit rebate amount for each drug and provides these amounts to the States each quarter. Covered outpatient drugs reported by participating drug manufacturers are listed in the CMS Medicaid Drug File, which identifies drugs with such fields as NDC, unit type, units per package size, and product name.

Section 1903(i)(10) of the Act prohibits Federal reimbursement for States that do not capture the information necessary for billing manufacturers for rebates as described in section 1927(a)(7) of the Act. To bill for rebates, States must use drug utilization data that identify, by NDC, the number of units of each drug for which the States reimbursed Medicaid providers. The States must capture these drug utilization data and report the information to the manufacturers (the Act § 1927(b)(2)(A)). The number of units is multiplied by the unit rebate amount to determine the actual rebate amount due from each manufacturer.

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

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

States use two primary models to pay for Medicaid services: fee-for-service and managed care. In the managed-care model, States contract with MCOs to provide specific services to enrolled Medicaid beneficiaries, usually in return for a predetermined periodic payment, known as a capitation payment. States pay MCOs for each covered individual regardless of whether the enrollee receives services during the relevant time period (42 CFR § 438.2). MCOs use the capitation payments to pay claims for these services. Capitation payments may cover outpatient drugs, which include both 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

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

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

The Deficit Reduction Act 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.⁴ 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).⁵ 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.⁶ 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)⁷ 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 Hawaii, the State agency is responsible for billing and collecting Medicaid drug rebates for both pharmacy and physician-administered drugs.⁸ The State agency uses a contractor to

⁴ 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)).

⁵ Section 1927(k)(7) of the Act. Single-source drugs are commonly referred to as "brand-name" drugs.

⁶ 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.

⁷ 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).

⁸ Although section 1927(a)(7) of the Act specifically addresses rebates for single-source drugs and the top 20 multiple-source drugs, State agency officials told us that they bill manufacturers for rebates on all physician-administered drugs.

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

Beginning June 15, 2011, the State agency required its MCOs to submit drug utilization data for pharmacy and 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. From April 1, 2010, through September 30, 2012, Hawaii's 5 MCOs served approximately 271,000 Medicaid beneficiaries.

HOW WE CONDUCTED THIS REVIEW

We reviewed drug utilization data for both pharmacy and physician-administered drugs for Hawaii's five MCOs from April 1, 2010, through September 30, 2012 (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 24 NDCs associated with 18 manufacturers and reviewing the supporting documentation. We also identified MCO drug utilization data for pharmacy and physician-administered drugs that were not billed for rebates and determined which drugs were eligible or may have been eligible for rebates. For both pharmacy and physician-administered drugs that were not billed for rebates, we calculated the amount of rebates that the State agency could have collected if it had billed these drugs for rebates. However, for 122,436 claim lines for physician-administered drugs, the State agency did not provide us sufficient drug utilization data to determine whether the drugs were eligible for rebates and the amount of any rebates that may have been due.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix B contains the details of our audit scope and methodology.

⁹ Xerox State Healthcare, LLC, was the State agency's contractor during the 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 some rebates for pharmacy and physician-administered drugs.¹⁰ However, the State agency did not bill for and collect from manufacturers rebates of \$18,792,670 (\$9,735,955 Federal share) for pharmacy drugs and some physician-administered drugs that were eligible or may have been eligible for rebates. In addition, the State agency did not bill for rebates for 122,436 claim lines for other physician-administered drugs. The State agency did not provide us sufficient drug utilization data to determine whether these drugs were eligible for rebates and the amount of any rebates that may have been due.

The State agency did not always bill manufacturers for rebates because it did not have adequate oversight of the processes for rebate billing and collection. Specifically, the State agency did not ensure that the MCOs submitted all drug utilization data. As a result, it did not collect some rebates for drugs dispensed to MCO enrollees.

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 a June 15, 2011, 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 both pharmacy and physician-administered drugs with NDCs with payment dates beginning on March 23, 2010.

¹⁰ These drugs were associated with the 24 NDCs that we selected for review.

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

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

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

- For drugs that were eligible for rebates, the State agency did not bill for and collect rebates of \$18,680,442 (\$9,678,172 Federal share). This amount consisted of \$15,542,262 (\$8,045,840 Federal share) for pharmacy drugs and \$3,138,180 (\$1,632,332 Federal share) for single-source and top-20 multiple-source physician-administered drugs.
- For drugs that may have been eligible for rebates, the State agency did not bill for and collect rebates of \$112,228 (\$57,783 Federal share). Because these drugs were non-top-20 multiple-source physician-administered drugs with NDCs,¹¹ the State agency's obligation to bill for rebates is unclear. Accordingly, we set aside for CMS resolution \$112,228 (\$57,783 Federal share) for these drugs.

In addition, the State agency did not bill for rebates for 122,436 claim lines for other physician-administered drugs that may have been eligible for rebates. The State agency did not provide us sufficient drug utilization data (e.g., no NDCs were available) to determine whether these drugs were eligible for rebates and the amount of any rebates that may have been due. Therefore, we set aside for CMS resolution the claim lines for physician-administered drugs.

THE STATE AGENCY DID NOT HAVE ADEQUATE OVERSIGHT OF THE PROCESSES FOR REBATE BILLING AND COLLECTION

The State agency did not always bill manufacturers for rebates because it did not have adequate oversight of the processes for rebate billing and collection. Although State agency guidance required MCOs to submit drug utilization data, the State agency did not ensure that the MCOs submitted all drug utilization data. During our audit period, the State agency did not receive from all five MCOs some of these data for pharmacy drugs. During and after our audit period, the State agency did not receive from two MCOs any drug utilization data for physician-administered drugs. As a result, the State agency did not collect some rebates for drugs dispensed to MCO enrollees.

¹¹ The NDCs for these multiple-source drugs matched the NDCs in CMS's Medicaid Drug File.

RECOMMENDATIONS

We recommend that the State agency:

- bill for and collect from manufacturers rebates for pharmacy drugs and refund to the Federal Government \$8,045,840 (Federal share);
- bill for and collect from manufacturers rebates for single-source and top-20 multiple-source physician-administered drugs and refund to the Federal Government \$1,632,332 (Federal share);
- work with CMS to determine whether the non-top-20 multiple-source physician-administered drugs were eligible for rebates and, if so, upon receipt of the rebates, refund up to \$57,783 (Federal share) of rebates collected;
- work with CMS to determine whether the other physician-administered drugs, associated with 122,436 claim lines, were eligible for rebates and, if so, determine the rebates due and upon receipt of the rebates refund the Federal share of the rebates collected;
- determine which physician-administered drugs were not billed for rebates after our audit period, determine the rebates due, and upon receipt of the rebates refund the Federal share of the rebates collected; and
- improve oversight of the processes for rebate billing and collection to ensure that MCOs submit valid and complete drug utilization data for pharmacy and physician-administered drugs dispensed to MCO enrollees.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency concurred with the findings related to our first, fifth, and sixth recommendations and partially concurred with the findings related to our second, third, and fourth recommendations:

- Regarding our first recommendation, the State agency commented that collection of the rebate amount for pharmacy drugs will be completed by the end of 2017.
- Regarding our second, third, and fourth recommendations, the State agency acknowledged that it did not invoice for some MCO physician-administered drugs; however, it disagreed with the amounts we identified until it can complete further analysis. The State agency commented that it believed some of these drugs were not

eligible for rebates but were 340B drugs that were not properly identified.¹² Regarding our second recommendation, the State agency also disagreed with the methodology that we used to calculate the rebate amounts. The State agency requested that we provide it the detailed encounter data we used and our methodology for calculating the rebate amounts so that it could attempt to collect any missing rebates for single-source, top-20 multiple-source, non-top-20 multiple-source, and other physician-administered drugs. The State agency commented that it estimated the date of completion to be 9 months following receipt of the detailed encounter data and our methodology.

- Regarding our fifth and sixth recommendations, the State agency provided information on processes that it had developed and implemented to address these recommendations.

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

OFFICE OF INSPECTOR GENERAL RESPONSE

Regarding our second, third, and fourth recommendations, as part of our methodology, we excluded certain drugs not eligible for rebates (e.g., 340B drugs). To calculate the amount of rebates due for a drug, we multiplied the number of drug units by the unit rebate amount for the NDC. This is the methodology that States use for the Medicaid drug rebate program and is based on CMS guidance. On August 25, 2017, we provided to the State agency the detailed encounter data and information on our methodology. We maintain that our recommendations are valid.

Although the State agency provided information on processes that it had developed and implemented to address our fifth recommendation, the State agency did not specifically address whether it had already determined which physician-administered drugs were not billed for rebates after our audit period. We maintain that our recommendation is valid.

¹² 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. 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)).

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

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

Report Title	Report Number	Date Issued
<i>North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06058</u>	1/13/2016
<i>California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<u>A-09-14-02038</u>	1/7/2016
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06056</u>	9/18/2015
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06049</u>	7/22/2015
<i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-06-12-00060</u>	5/4/2015
<i>Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06051</u>	4/13/2015
<i>Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-13-02037</u>	3/4/2015
<i>Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<u>A-06-14-00031</u>	2/10/2015
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00205</u>	8/21/2014
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-13-06040</u>	8/7/2014
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	<u>A-09-12-02079</u>	4/30/2014
<i>Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<u>A-09-12-02080</u>	4/24/2014

Report Title	Report Number	Date Issued
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00200</u>	11/26/2013
<i>Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<u>A-06-12-00059</u>	9/19/2013
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	<u>A-06-10-00011</u>	8/12/2011
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	<u>OEI-03-09-00410</u>	5/6/2011

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed drug utilization data for both pharmacy and physician-administered drugs for Hawaii's five MCOs from April 1, 2010, through September 30, 2012.

We identified MCO drug utilization data for pharmacy and physician-administered drugs that were billed for rebates and tested the rebates billed by selecting 24 NDCs associated with 18 manufacturers and reviewing the supporting documentation. We also identified MCO drug utilization data for pharmacy and physician-administered drugs that were not billed for rebates and determined which drugs were eligible or may have been eligible for rebates.

Our audit objective did not require an understanding or assessment of the complete internal 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 April 2016 to February 2017, which included fieldwork performed at the State agency office in Kapolei, Hawaii.

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 MCO personnel to gain an understanding of the MCOs' roles and responsibilities for submitting drug utilization data to the State agency;
- interviewed State agency and contractor personnel to gain an understanding of the administration of and controls over the Medicaid billing and rebate process for pharmacy and physician-administered drugs;
- obtained from the 5 MCOs 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 24 NDCs associated with 18 manufacturers¹³ and
 - reviewing copies of rebate invoices submitted to manufacturers to verify the billing of rebates by NDC;
- identified MCO drug utilization data for pharmacy and physician-administered drugs not billed for rebates and identified the drugs that were eligible or may have been eligible for rebates by:
 - identifying pharmacy drugs and single-source and top-20 multiple-source physician-administered drugs that were eligible for rebates,
 - identifying non-top-20 multiple-source physician-administered drugs that may have been eligible for rebates, and
 - identifying 122,436 claim lines for other physician-administered drugs that may have been eligible for rebates;¹⁴
- calculated the amount of rebates that the State agency could have collected for pharmacy drugs and single-source, top-20 multiple-source, and non-top-20 multiple-source physician-administered drugs if it had billed these drugs for rebates;¹⁵ 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.

¹³ These NDCs represented drugs that had high payment amounts, high units of service, or high payment amounts per unit.

¹⁴ The State agency did not provide us sufficient drug utilization data to determine whether these drugs were eligible for rebates and the amount of any rebates that may have been due.

¹⁵ To calculate the amount of rebates due for a drug, we multiplied the number of drug units by the unit rebate amount for the NDC.

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).¹⁶

STATE GUIDANCE

In a June 15, 2011, 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 both pharmacy and physician-administered drugs with NDCs with payment dates beginning on March 23, 2010.

¹⁶ 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

DAVID Y. IGE
GOVERNOR



PANKAJ BHANDT
DIRECTOR

BRIDGET HOLTHUIS
DEPUTY DIRECTOR

STATE OF HAWAII
DEPARTMENT OF HUMAN SERVICES

Med-QUEST Division
Health Care Services Branch
P. O. Box 700190
Kapolei, Hawaii 96709-0190

August 4, 2017

Ms. Lori A. Ahlstrand, Regional Inspector General for Audit Services
Department of Health and Human Services
Office of Inspector General
Office of Audit Services, Region IX
90-7th Street, Suite 3-650
San Francisco, California 94103

Dear Ms. Ahlstrand:

Thank you for sharing the draft report entitled *Hawaii Did Not Bill manufactures for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations (A-09-16-02029)*. Please see below for the Med-QUEST Division (MQD) responses to your recommendations.

1. *Bill for and collect from manufacturers rebates for pharmacy drugs and refund to the Federal Government \$8,045,840 (Federal share).*

MQD concurs with the OIG findings.

Post-audit review of missing Pharmacy claims suggested that within the 2010-2012 time period one whole quarter's submission for one or more MCOs was not received for invoicing by rebate contractor. The apparent reason for this was all the 2010-2012 claims were submitted over a period of 2 invoicing quarters, resulting in confusion within the MCOs and MQD, thus the missing quarter.

MQD has already submitted the encounter data to the MCOs with a request to submit these as a standard drug rebate file. The majority of these have already been submitted for rebate, and the collections will be completed by the end of 2017.

AN EQUAL OPPORTUNITY AGENCY

2. *Bill for and collect from manufacturers rebates for single-source and top-20 multiple-source physician-administered drugs and refund to the Federal Government \$1,632,332 (Federal share).*

MQD partially concurs with the OIG findings.

While MQD acknowledges the State did not invoice for some of the MCO physician-administered drug utilization during the audit period, MQD disagrees with the amounts identified until further analysis can be completed. MQD believes some of the utilization identified is not eligible for rebates, but rather are 340b drugs that have not been properly identified as such. MQD also disagrees with the methodology used to calculate the collectable rebate amounts. MQD requests that the OIG share the detail encounter data used as well as the line-by-line methodology used to calculate the collectable rebate amounts. We will review this data set and attempt to collect any missing rebates for both single-source and top-20 multiple source drugs by requiring MCOs to resubmit corrected encounter data containing NDCs that accurately reflect utilization.

Due to the uncertainty of when we will obtain the OIG data set, the significant amount of time involved in the analysis of the OIG detail encounter data set, the resubmission of corrected encounter data and the subsequent rebate invoicing to manufacturers, the estimated date of completion is estimated at nine months following the receipt of the OIG data set.

3. *Work with CMS to determine whether the non-top-20 multiple-source physician-administered drugs were eligible for rebates and, if so, upon receipt of the rebates, refund up to \$57,783 (Federal share) of rebates collected.*

MQD partially concurs with the OIG findings.

While MQD acknowledges the State did not invoice for some of the MCO physician-administered drug utilization during the audit period, MQD disagrees with the amounts identified until further analysis can be completed. MQD believes some of the utilization identified is not eligible for rebates, but rather are 340b drugs that have not been properly identified as such. MQD requests that the OIG share the detail encounter data used as well as the line-by-line methodology used to calculate the collectable rebate amounts. We will review this data set and attempt to collect MCO rebates for the other physician-administered drugs by requiring MCOs to resubmit corrected encounter data containing NDCs that accurately reflect utilization.

Due to the uncertainty of when we will obtain the OIG data set, the significant amount of time involved in the analysis of the OIG detail encounter data set, the resubmission of corrected encounter data and the subsequent rebate invoicing to manufacturers, the estimated date of completion is estimated at nine months following the receipt of the OIG data set.

AN EQUAL OPPORTUNITY AGENCY

Ms. Lori Ahlstrand, Regional Inspector General for Audit Services

August 4, 2017

Page 3

4. *Work with CMS to determine whether the other physician-administered drugs, associated with 122,436 claim lines, were eligible for rebates and, if so, determine the rebates due and upon receipt of the rebates refund the Federal share of the rebates collected.*

MQD partially concurs with the OIG findings.

While MQD acknowledges the State did not invoice for some of the MCO physician-administered drug utilization during the audit period, MQD disagrees with the counts identified until further analysis can be completed. MQD believes some of the utilization identified is not eligible for rebates, but rather are 340b drugs that have not been properly identified as such. MQD requests that the OIG share the detail encounter data used as well as the line-by-line methodology used to calculate the collectable rebate amounts. We will review this data set and attempt to collect MCO rebates for the other physician-administered drugs by requiring MCOs to resubmit corrected encounter data containing NDCs that accurately reflect utilization.

Due to the uncertainty of when we will obtain the OIG data set, the significant amount of time involved in the analysis of the OIG detail encounter data set, the resubmission of corrected encounter data and the subsequent rebate invoicing to manufacturers, the estimated date of completion is estimated at nine months following the receipt of the OIG data set.

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

MQD concurs with the OIG findings.

As a result of this audit, the MQD and its contractor have developed the following best practices: 1) Applied trend analysis on MCO claim files that goes back several quarters to ensure reasonableness, and 2) Provide volume counts for claim and encounter back to the MCO for reconciliation purposes. The following had been implemented earlier, however not during the audit period: 1) Verifying quarterly that each MCO has sent all usable monthly files before creating manufacturer invoices.

These processes have been implemented.

6. *Improve oversight of the processes for rebate billing and collection to ensure that MCOs submit valid and complete drug utilization data for pharmacy and physician-administered drugs dispensed to MCO enrollees.*

MQD concurs with the OIG findings.

AN EQUAL OPPORTUNITY AGENCY

Ms. Lori Ahlstrand, Regional Inspector General for Audit Services

August 4, 2017

Page 4

As a result of this audit, the MQD and its contractor have developed the following best practices: 1) Applied trend analysis on MCO claim files that goes back several quarters to ensure reasonableness, and 2) Provide volume counts for claim and encounter back to the MCO for reconciliation purposes. The following had been implemented earlier, however not during the audit period: 1) Verifying quarterly that each MCO has sent all usable monthly files before creating manufacturer invoices.

These processes have been implemented.

The MQD appreciates the opportunity to comment on the recommendations made and the collaborative efforts made by the OIG audit staff while conducting this review. You may contact Jon Fujii, Health Care Services Branch Administrator, at 808-692-8083 if you have any questions.

Sincerely,



Judy Mohr Peterson, PhD
Med-QUEST Division Administrator

AN EQUAL OPPORTUNITY AGENCY