Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

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

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Office of Inspector General

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Report in Brief
Date: September 2017
Report No. A-09-16-02028

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

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

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 Washington State 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 Washington's 10 MCOs from April 2010 through December 2013.

We identified MCO drug utilization data for drugs that were billed for rebates and tested the rebates billed by selecting 29 National Drug Codes (NDCs) associated with 19 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 Washington could have collected if it had billed these drugs for rebates.

What OIG Found

When Washington billed manufacturers for rebates for pharmacy and physician-administered drugs, it did so correctly. However, Washington did not bill for and collect from manufacturers rebates of $34.1 million ($17 million Federal share). For drugs that were eligible for rebates, Washington did not bill for rebates of $14.2 million (Federal share) for pharmacy drugs and $2.4 million (Federal share) for single-source and top-20 multiple-source physician-administered drugs. For drugs that may have been eligible for rebates, Washington did not bill for rebates of $395,746 (Federal share) for non-top-20 multiple-source physician-administered drugs with NDCs. In addition, Washington did not bill for rebates for 17,140 claim lines for other physician-administered drugs. Because there was insufficient information to determine the amount of any rebates that may have been due, we set aside these claim lines for resolution by the Centers for Medicare & Medicaid Services (CMS).

What OIG Recommends and Washington Comments

We recommend that Washington (1) bill for and collect from manufacturers rebates for pharmacy drugs and refund $14.2 million (Federal share); (2) bill for and collect from manufacturers rebates for single-source and top-20 multiple-source physician-administered drugs and refund $2.4 million (Federal share); (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 $395,746 (Federal share) of the rebates collected; and (4) work with CMS to determine the amount of any rebates due for the 17,140 claim lines that we set aside and refund the Federal share of rebates collected. We also make a recommendation related to pharmacy and physician-administered drugs that were not billed for rebates after our audit period and a procedural recommendation to improve oversight of the processes for determining drug rebate eligibility.

Washington concurred with all of our recommendations and provided information on actions that it had taken or planned to take to address our recommendations.

TABLE OF CONTENTS

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 Washington State Health Care Authority'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 Washington, the State agency manages its drug rebate program and is responsible for billing and collecting Medicaid drug rebates for both pharmacy and physician-administered drugs.[8] The State agency bills manufacturers by NDC for rebates and collects the payments for every quarter.

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[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. 30, 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.

Before and throughout our audit period, 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 uses the data to bill for drug rebates. From April 1, 2010, through December 31, 2013 (audit period), Washington's 10 MCOs served approximately 789,000 Medicaid beneficiaries.

HOW WE CONDUCTED THIS REVIEW

We reviewed drug utilization data for both pharmacy and physician-administered drugs for Washington's 10 MCOs from April 1, 2010, through December 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 29 NDCs associated with 19 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 17,140 claim lines for physician-administered drugs, there was insufficient information to determine 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.

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.[9] However, the State agency did not bill for and collect from manufacturers rebates of $34,114,767 ($17,057,486 Federal share) for some pharmacy and physician-administered drugs that were eligible or may have been eligible for rebates. In addition, the State agency did not bill for rebates for 17,140 claim lines for other physician-administered drugs. Because there was insufficient information to determine the amount of any rebates that may have been due, we set aside these claim lines for CMS resolution.

[9] These drugs were associated with the 29 NDCs that we selected for review.

The State agency did not always bill manufacturers for rebates because it did not have adequate oversight of the processes for determining rebate eligibility for pharmacy and physician-administered drugs. Specifically, the State agency did not appropriately identify all of the rebate-eligible drugs contained in the utilization data submitted by the MCOs. As a result, the State agency 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)).

The contracts between the State agency and the MCOs require that the MCOs follow State guidance when submitting drug utilization data. Before and throughout our audit period, State agency guidance required MCOs to include NDCs in the drug utilization data for pharmacy drugs. On February 27, 2012, the State agency revised its guidance to require MCOs to include NDCs in the drug utilization data for physician-administered drugs as well.

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 $33,323,284 ($16,661,740 Federal share). This amount consisted of $28,474,277 ($14,237,150 Federal share) for pharmacy drugs and $4,849,007 ($2,424,590 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 $791,483 ($395,746 Federal share). Because these drugs were non-top-20 multiple-source physician-administered drugs with NDCs,[10] the State agency's obligation to bill for rebates is unclear. Accordingly, we set aside for CMS resolution $791,483 ($395,746 Federal share) for these drugs.

In addition, the State agency did not bill for rebates for 17,140 claim lines for other physician-administered drugs. Because there was insufficient information to determine the amount of any rebates that may have been due, we set aside these claim lines for CMS resolution.[11]

THE STATE AGENCY DID NOT HAVE ADEQUATE OVERSIGHT OF THE PROCESSES FOR DETERMINING DRUG REBATE ELIGIBILITY

The State agency did not always bill manufacturers for rebates because it did not have adequate oversight of the processes for determining rebate eligibility for pharmacy and physician-administered drugs. Although the MCOs submitted drug utilization data, the State agency did not appropriately identify all of the rebate-eligible pharmacy and physician-administered drugs contained in the utilization data submitted by the MCOs. For example, during and after our audit period, the State agency incorrectly excluded all drug utilization data submitted by one MCO plan when the State agency billed manufacturers for rebates. As a result, the State agency did not collect some rebates for drugs dispensed to MCO enrollees.

RECOMMENDATIONS

We recommend that the State agency:

- bill for and collect from manufacturers rebates for pharmacy drugs and refund to the Federal Government $14,237,150 (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 $2,424,590 (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 $395,746 (Federal share) of the rebates collected;

- work with CMS to determine the amount of any rebates due for the 17,140 claim lines that we set aside and refund the Federal share of rebates collected;

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

[11] These claim lines contained HCPCS codes that did not have the unit conversion factors needed to calculate the rebate amounts.

- determine which pharmacy and 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 determining drug rebate eligibility to ensure that all rebate-eligible pharmacy and physician-administered drugs contained in the drug utilization data submitted by the MCOs are identified and billed for rebates.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency concurred with all of our recommendations and provided information on actions that it had taken or planned to take to address our recommendations. The State agency's comments are included in their entirety as Appendix D.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
Nevada Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-09-16-02027	9/12/2017
Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs of Medicaid Managed-Care Organizations	A-07-16-06065	5/5/2017
Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-05-16-00014	3/23/2017
Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-14-06050	1/5/2017
Delaware Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-03-15-00202	12/30/2016
Virginia Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-03-15-00201	12/22/2016
California Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Some Medicaid Managed-Care Organizations	A-09-15-02035	12/8/2016
Kansas Correctly Invoiced Rebates to Manufacturers for Most Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-07-15-06060	8/18/2016
Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-14-06057	5/26/2016
Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-15-06063	3/31/2016
South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-15-06059	2/9/2016

Report Title	Report Number	Date Issued
Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs	A-07-15-06062	1/14/2016
North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs	A-07-15-06058	1/13/2016
California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs	A-09-14-02038	1/7/2016
Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs	A-07-14-06056	9/18/2015
Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-14-06049	7/22/2015
Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-06-12-00060	5/4/2015
Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-14-06051	4/13/2015
Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-09-13-02037	3/4/2015
Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs	A-06-14-00031	2/10/2015
The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-03-12-00205	8/21/2014
Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-13-06040	8/7/2014
Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs	A-09-12-02079	4/30/2014

Report Title	Report Number	Date Issued
Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs	A-09-12-02080	4/24/2014
Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-03-12-00200	11/26/2013
Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs	A-06-12-00059	9/19/2013
Nationwide Rollup Report for Medicaid Drug Rebate Collections	A-06-10-00011	8/12/2011
States' Collection of Medicaid Rebates for Physician-Administered Drugs	OEI-03-09-00410	5/6/2011

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed drug utilization data for both pharmacy and physician-administered drugs for Washington's 10 MCOs from April 1, 2010, through December 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 29 NDCs associated with 19 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 May 2016 to May 2017, which included fieldwork performed at the State agency office in Olympia, Washington.

METHODOLOGY

To accomplish our objective, we:

- reviewed Federal laws, regulations, and guidance related to the Medicaid drug rebate program for both pharmacy and physician-administered drugs;

- reviewed State guidance to MCOs, including billing instructions for pharmacy and physician-administered drugs;

- interviewed State agency personnel to gain an understanding of the MCOs' roles and responsibilities for submitting drug utilization data to the State agency;

- interviewed State agency personnel to gain an understanding of the administration of and controls over the Medicaid billing and rebate process for pharmacy and physician-administered drugs;

- obtained from the State agency the drug utilization data for pharmacy and physician-administered drugs for the audit period;

- excluded from our review certain MCO drug utilization data for pharmacy and physician-administered drugs not eligible for rebates;

- identified MCO drug utilization data for pharmacy and physician-administered drugs billed for rebates and tested the rebates billed by:

    - selecting 29 NDCs associated with 19 manufacturers[12] 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 17,140 claim lines for other physician-administered drugs for which there was insufficient information to determine the amount of any rebates that may have been due;

- 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;[13] 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.

[12] These NDCs represented drugs that were in the top 100 NDCs that appeared most frequently in the drug utilization data.

[13] 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).[14]

STATE GUIDANCE

The contracts between the State agency and the MCOs require that the MCOs follow State guidance when submitting drug utilization data. Before and throughout our audit period, State agency guidance required MCOs to include NDCs in the drug utilization data for pharmacy drugs. On February 27, 2012, the State agency revised its guidance to require MCOs to include NDCs in the drug utilization data for physician-administered drugs as well.

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

APPENDIX D: STATE AGENCY COMMENTS

STATE OF WASHINGTON
HEALTH CARE AUTHORITY
626 8th Avenue, SE • P.O. Box 45502 • Olympia, Washington 98504-5502

August 29, 2017

Lori A. Ahlstrand
Regional Inspector General for Audit Services
Office of Audit Services, region X
Office of Inspector General
U.S. Department of Health and Human Services
90 7th Street, Suite 3-650
San Francisco, CA 94103

Dear Ms. Ahlstrand:

SUBJECT: Report Number: A-09-16-02028

The Washington State Health Care Authority (HCA) welcomes the opportunity to provide comments on the recommendations contained in draft report A-09-16-02028 entitled *Washington State Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations.*

As requested in your letter dated August 9, 2017, HCA is providing a statement of concurrence or non-concurrence for each of the recommendations contained in the draft report.

Recommendation 1: *Bill for and collect from manufacturers rebates for pharmacy drugs and refund $14.2 million (Federal share).*

Recommendation 2: *Bill for and collect from manufacturers rebates for single-source and top-20 multiple-source physician-administered drugs and refund $2.4 million (Federal Share).*

Recommendation 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 $359,746 (Federal share) of the rebates collected.*

Response: HCA concurs with recommendations 1, 2 and 3 and has worked persistently with system vendors to determine the root causes and corrective action for each identified issue, and also to categorize the affected claims. We are systematically applying corrective actions, and have started the retroactive invoicing for the missed rebates. This process began with the 3Q2016 invoicing quarter and is anticipated to be complete with the SQ2017 invoicing quarter.

Regarding recommendations 2 and 3, it should be noted that HCA does not limit rebate collections for physician-administered drugs to the top 20. The corrective actions described in these responses apply to claims for all rebate-eligible physician-administered drugs, as well as pharmacy drugs.

Recommendation 4: *Work with CMS to determine the amount of any rebates due for the 17,140 physician-administered drug claim lines that we set aside and refund the Federal share of rebates collected.*

HCA concurs with the recommendation and has filed a system change request with the vendor to add additional fields to facilitate physician-administered drug claims adjudication. These fields will enable the system to perform the more complex drug code conversions, and effectively calculate the resulting rebates. We estimate this system update will be implemented April 2018. HCA will retroactively invoice for the missed rebates.

Recommendation 5*: Determine which pharmacy and 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.*

HCA concurs with the recommendation. All corrective actions apply not only retroactively, but also prospectively to all claims after the audit period.

Recommendation 6: *Improve oversight of the processes for determining drug rebate eligibility to ensure that all rebate-eligible pharmacy and physician-administered drugs contained in the drug utilization data submitted by the MCOs are identified and billed for rebates.*

HCA concurs and has taken the following steps to address the findings and future oversight of the processes:

- HCA engaged in daily meetings to collaborate solutions with vendors and internal system staff until all findings/oversights were addressed.

- HCA performed an internal audit of existing system configuration, received updated training from the vendor on manual processes, and made immediate, real-time corrections where possible.

- HCA has strengthened other manual processes by preparing checklists of steps and dependencies to insure all claims are coded correctly for rebate eligibility.

- HCA has developed internal quarterly monitoring reports designed to proactively validate the completeness and accuracy of future rebate cycles. Vendors are developing new, similar reports for comparison.

Should you have any questions or concerns, please contact Kathy E. Smith, Audit and Accountability Manager, by telephone at 360-725-0937 or via email at kathy.smith2@hca.wa.gov.

Sincerely,

/Lou McDermott/	/MaryAnne Lindeblad/
Lou McDermott Acting Director	MaryAnne Lindeblad, BSN, MPH Medicaid Director

By certified mail

By email

cc: Kathy E. Smith, Audit and Accountability Manager, HCA